Zacks Small-Cap Research

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Sorrento Therapeutics (SRNE-NASDAQ)

SRNE: Pivotal trial initiated for Cynviloq, new subsidiary will further expand RTX use, balance sheet remains strong--- Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	12/10/2013
Current Price (04/02/14)	$13.07
Twelve- Month Target Price	**22.50**

OUTLOOK

Sorrento is a biopharmaceutical company focused on cancer. Its lead candidate Cynviloq, a competitor to Abraxane®, has advanced to the pivotal trial using 505(b)(2) pathway. The second lead program Resiniferatoxin (RTX) is in mid-stage development for cancer pain. Sorrento also owns two drug development platforms: G-MAB® and antibody drug conjugates (ADCs), which target the therapeutic antibody market. Though in early stages, both G-MAB® and ADCs will expand the company's pipeline dramatically, which has great potential for partnerships that could provide near term revenue for the company.

We are optimistic about the prospect of Sorrento and rate its shares Outperform.

SUMMARY DATA

52-Week High	**$16.33**
52-Week Low	**$7.60**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**191,847**
Shares Outstanding (mil)	**23**
Market Capitalization ($mil)	**$296**
Short Interest Ratio (days)	**0.35**
Institutional Ownership (%)	**40**
Insider Ownership (%)	**30**
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 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**N/A**
Industry	**Med Products**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0.13 A	0.14 A	0.08 A	0.10 A	0.46 A
2014	0.08 E	0.08 E	0.08 E	0.08 E	0.32 E
2015					1.80 E
2016					6.80 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.20 A	-$0.35 A	-$0.24 A	-$0.56 A	-$1.46 A
2014	-$0.34 E	-$0.38 E	-$0.42 E	-$0.46 E	-$1.61 E
2015					-$1.57 E
2016					-$1.79 E

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

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WHAT'S NEW

Sorrento Initiates Pivotal Trial of Cynviloq

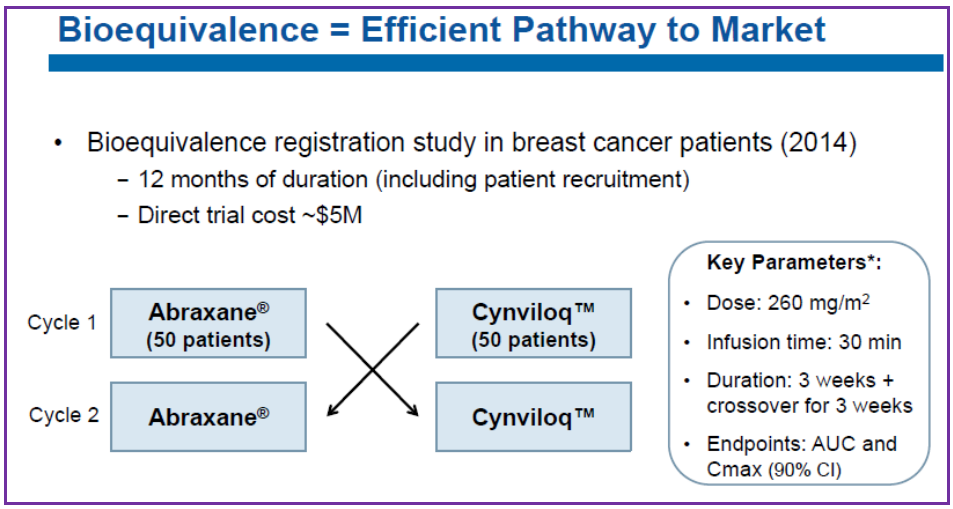
On March 31, 2014, Sorrento Therapeutics (SRNE) announced that the first patient has been dosed in the **pivotal clinical trial** of **Cynviloq** for the treatment of metastatic breast cancer and non-small cell lung cancer.

The registration trial is referred to as **TRIBECA™** (TRIal designed to evaluate BioEquivalence between Cynviloq™ and Abraxane®), which is an open-label, randomized, multi-center, single-dose, crossover registration study being conducted at clinical sites across the U.S., EU, and Singapore.

Based on the **End-of-Phase II** meeting with the FDA in July 2013, this trial was designed to gain marketing approval for Cynviloq under the **505(b)(2) regulatory pathway** in the U.S. using Abraxane as the reference drug.

The 505(b)(2) BE trial design will enroll **100 patients** with MBC and include a crossover 2 cycle design. The first cycle of the trial will involve 50 patients in the Abraxane® arm and 50 patients in the Cynviloq arm. The second cycle of the trial will crossover the patients into the opposite treatment groups. Dosage for both drugs will be 260 mg/m^2 with 30 minutes infusion. The endpoints will be AUC and Cmax (90% CI).

The BE trial will take about 12 months to complete, which will consume roughly $5 million in direct cost.



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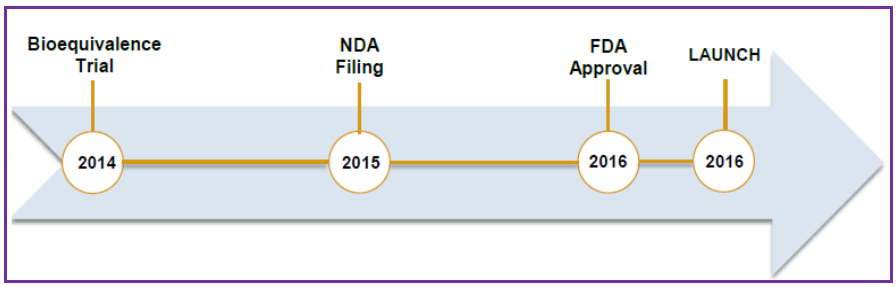
Sorrento expects to file a New Drug Application with the FDA in the first half of 2015. According to this schedule, we expect the FDA approval and launch of Cynviloq in 2H2016.



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We think the initiation of the TRIBECA trial represents a very important milestone for Sorrento. Cynviloq is initially under development for the treatment of **MBC** and **NSCLC** in the US. Beyond MBC and NSCLC, Sorrento plans to expand label of Cynviloq into other cancer indications such as ovarian, pancreatic, bladder cancer and melanoma.

Sorrento Forms Subsidiary to Develop Animal Health Applications

Recently, Sorrento formed a wholly-owned subsidiary, **Ark Animal Therapeutics**. This subsidiary will be devoted to developing **resiniferatoxin (RTX)** for multiple veterinary health applications and vaccines against recurrent staphylococcal infections.

In studies of dogs with advanced bone cancer, treatment with RTX led to sustained reduction in levels of pain throughout a 14-week observation period. Investigators noted that pain control remained evident throughout the dogs' remaining life, which was up to nine months in one case.

Ark's initial development programs will focus on animal health applications for RTX. RTX targets TRPV-1, a receptor expressed on afferent nerves that has been shown to become hyper-activated in diseases associated with chronic inflammation and the resulting severe pain. RTX is highly specific for afferent nerves and does not bind to the myelinated nerves that are responsible for transmitting normal pain sensations, controlling muscle function, nor impacting cognition.

The **lead application** for RTX will be the treatment of **pain associated with osteosarcoma** in companion dogs. Additional development programs will be focused on the treatment of osteoarthritis in dogs, idiopathic cystitis in cats, as well as ocular pain and caudal heel pain in horses.

Ark will utilize existing data generated in dogs with osteosarcoma to file for conditional marketing approval with the Center for Veterinary Medicine (CVM) division of the FDA under the MUMS act, a legislation which is similar to an Orphan Product Designation for human medicines. Under a MUMS designation, drugs with a reasonable expectation of efficacy in a minor use, such as osteosarcomas, can be marketed immediately. The sponsor company then has four years, while it is marketing the product, to complete the registration trial and any additional work required by CVM for full approval.

The veterinary market for IT RTX presents a low cost and low risk opportunity to quickly develop a product for a manageable and profitable market. The market can easily be accessed by 2-3 sales representatives, since there are less than 100 centers in the U.S. treating cancer pain in dogs. The company is actively seeking a commercial partner in the veterinary field to commercialize RTX in the US and the rest of the world.

Ark Animal can secure the financial resources, through an initial public offering, private placement or strategic partnership, and assemble a seasoned leadership team with the expertise needed to maximize the significant opportunity in animal health. Sorrento will remain focused on developing its human therapeutic opportunities.

Ark Animal Therapeutics will also evaluate potential opportunities to develop active **vaccines** against acute and recurring staphylococcal infections in dogs with chronic atopic dermatitis and dairy cows with mastitis.

Balance Sheet Remains Strong

There has been no meaningful revenue for Sorrento since its inception.

As of December 31, 2013, Sorrento held cash and cash equivalents of $31.7 million.

On October 30, 2013, the company closed an underwritten public offering of 4,150,000 shares of common stock, at $7.25 per share, and closed the full exercise of the over-allotment option granted to the

representative of the underwriters to purchase an additional 622,500 shares of its common stock, with total gross proceeds of $34.6 million, before underwriting discounts and commissions and other offering expenses payable by the Company.

Concurrent with the offering, the Company agreed to issue and sell to the underwriters a warrant for the purchase of an aggregate of 182,600 shares of Common Stock, representing 4.4% of the underwritten shares issued. The underwriters warrant agreement is exercisable, in whole or in part, commencing on a date which is one year after the effective date of the Registration Statement and expiring on the five-year anniversary of the effective date of the Registration Statement at an initial exercise price per share of Common Stock of $9.0625, which is equal to 125% of the public offering price of the underwritten shares.

Current cash balance can last into 2015.

Valuation Still Attractive

We maintain our Outperform rating on Sorrento shares and reiterate our 12-month price target of $22.50. Our call is based on the strong fundaments of the company.

Sorrento is a late stage development biopharmaceutical company with diversified pipeline. The company's lead candidate **Cynviloq** has advanced to **pivotal clinical** trial and the company will use 505(b)(2) regulatory pathway to file for approval. This approach will shorten the development time of Cynviloq dramatically and reduce the development risks accordingly. We estimate Cynviloq will reach the market in 2016. Cynviloq targets the multibillion dollar cancer therapeutics market.

The company's second lead clinical program **RTX** targets the huge **cancer pain market**. Its unique mechanism of action and potency will help RTX command a niche of the cancer pain market if approved. RTX is currently in an investigator-sponsored Phase I/II clinical trial and Sorrento plans to initiate additional Phase I/II clinical trial for cancer pain in 2014. Recent formation of a subsidiary Ark Animal Therapeutics further expands the use of RTX in animal health.

In addition to the two lead clinical programs Cynviloq and RTX, Sorrento also owns proprietary **G-MAB® antibody library** and **ADC technology**. Therapeutic antibodies and ADCs represent the biggest market in the current pharmaceutical industry with multibillion dollar sales. Sorrento's G-MAB® is one of the most diverse fully human antibody library in the industry and its ADC technology holds key advantages over currently used competitor ADC technologies. The combination of these two platforms will not only expand its pipeline, but also provide partnership opportunities for the company to generate near term revenues.

Sorrento's balance sheet remains strong. Current cash balance can last into 2015.

Sorrento has all the makings of a successful biotech company. In terms of valuation, we think Sorrento's shares are undervalued at current market price. Since we initiated coverage of Sorrento in early January of 2014, share price of Sorrento has appreciated from $8.20 to current $13.07, an increase of 59%. But we think there is still enough room for further price appreciation in the next 12 months.

Current share price of $13 values the company at $300 million in market cap based on 23 million outstanding shares. This is still a discount compared to its peers. Sorrento is a late stage development company with diversified pipeline. Its lead candidate Cynviloq, which targets the multibillion dollar cancer market, will be approved as early as in 2016 according to our estimate. The company's second lead product RTX, which targets the huge cancer pain market, will also reach the market in 2017 according to our estimate. Sorrento's G-MAB® and ADC platforms have great potential to target a variety of indications and provide partnership opportunities.

According to our model, Sorrento will become profitable in 2018 with an EPS of $1.83 based on total revenue of $206.7 million. We think Sorrento should be valued at a P/E multiple of 35x which is the biotech industry average P/E ratio. Based on our 2018 EPS of $1.83, we arrive at our price target of

$22.50 per share using 30% discount rate. Our target price values Sorrento at $518 million in market cap, which is still conservative in our view.

Risks Related To Our Price Target Include:

- **Development/Regulatory Risk:** Although Sorrento's lead program Cynviloq is in late stage development using the 505(b)(2) pathway, there are still some development and regulatory risks. The company's RTX program is still in mid-stage development and development/regulatory risk is higher than Cynviloq. The G-MAB® and ADC programs are in preclinical development and will have a long way to go to reach the market. Both clinical and regulatory hurdles are significant at this point for these two programs.

- **Market Risk:** The US stock market has enjoyed a significant run in 2013. This may not be repeated in 2014. Market fluctuation will also impact our price target though it's independent from the company's fundamentals.

OVERVIEW

Sorrento Therapeutics (SRNE) is a development stage biopharmaceutical company focused on the discovery, acquisition, development and commercialization of proprietary drug therapeutics for addressing significant unmet medical needs. The Company's primary therapeutic focus is **oncology**, including the treatment of chronic cancer pain, but is also developing therapeutic products for other indications, including inflammation, metabolic disorders, and infectious diseases.

Sorrento's pipeline consists of lead oncology product candidate **Cynviloq™**, a polymeric micellar nanoparticle paclitaxel formulation, **resiniferatoxin (RTX),** a non-opiate, ultra potent and selective agonist of the TRPV-1 receptor for cancer pain, as well as fully human therapeutic antibodies derived from its proprietary **G-MAB®** library platform and antibody drug conjugates **(ADCs**).

Sorrento's **lead clinical candidate** is Cynviloq, a third generation nanoparticle formulation of paclitaxel. Cynviloq is currently approved and marketed in several countries as Genexol-PM®. It has completed **Phase I and/or II** trials in metastatic breast cancer (MBC), non-small cell lung cancer (NSCLC), pancreatic cancer (PC), ovarian cancer (OC) and bladder cancer (BC) in the US and/or ex-US territories. In addition, interim results from an ongoing Phase III study versus Taxol® in MBC in South Korea confirmed its activity with results comparable to those seen in the pivotal, registrational Abraxane® MBC study. As a formulation of paclitaxel, Cynviloq is eligible for approval via FDA's **505(b)(2) bioequivalence** regulatory pathway versus albumin-bound paclitaxel (Abraxane®) in its currently approved MBC and NSCLC indications.

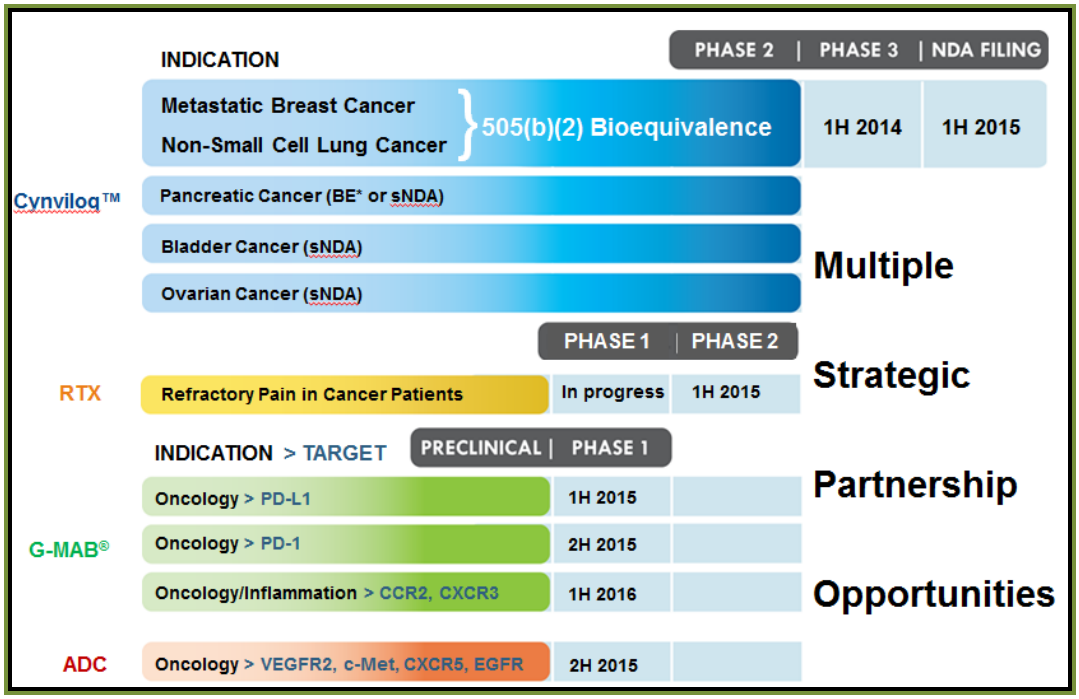
Sorrento's **second clinical lead program** is **Resiniferatoxin (RTX),** which is a non-opiate, ultra potent and selective agonist of the TRPV-1 receptor. Resiniferatoxin is currently in an investigator-sponsored **Phase I/II** clinical trial at the National Institutes of Health (NIH) under a company sponsored Collaborative Research and Development Agreement (CRADA). Sorrento plans to initiate additional clinical studies to rapidly advance the drug.

Sorrento also holds two unique powerful early stage platform technologies: G-MAB® and ADC.

G-MAB® library is one of the industry's most diverse fully **human antibody libraries**. The potential theoretical library diversity has been calculated to be more than10^{16} unique antibodies, making it one of the largest fully human antibody libraries available to pharmaceutical and biotechnology companies for drug discovery and development partnerships.

Sorrento's goal is to advance at least one novel monoclonal antibody (mAb) candidate from the G-MAB® library per year into clinical development, commencing in 2015. The company is also actively pursuing potential **strategic partnerships** for various mAb candidates.

The acquisition of Concortis Biosystems Corp. provides Sorrento with a comprehensive technology platform for the creation of new generation of **antibody drug conjugates (ADCs)** with precise site-specific toxin conjugation and consistent drug-antibody ratios (DARs). Sorrento will utilize the antibodies identified from its G-MAB® library along with Concortis' proprietary conjugation technologies and novel toxins to create a new generation of ADCs.



Source: company presentation

Sorrento's growth strategy is to retain ownership and control of some product candidates, and at the same time, consider partnerships with pharmaceutical or biopharmaceutical organizations to generate revenue through license fees, milestone payments and royalties from marketed products.

Sorrento is headquartered in San Diego, California. Its common shares are listed on the NASDAQ Capital Market under the symbol "SRNE".

INVESTMENT THESIS

Cynviloq, Next Generation of Abraxane®

Cynviloq is Sorrento's lead cancer drug candidate. Sorrento acquired Cynviloq™ in 2013 when the company acquired **IgDraSol**, a privately-held company focused on the development of oncologic agents.

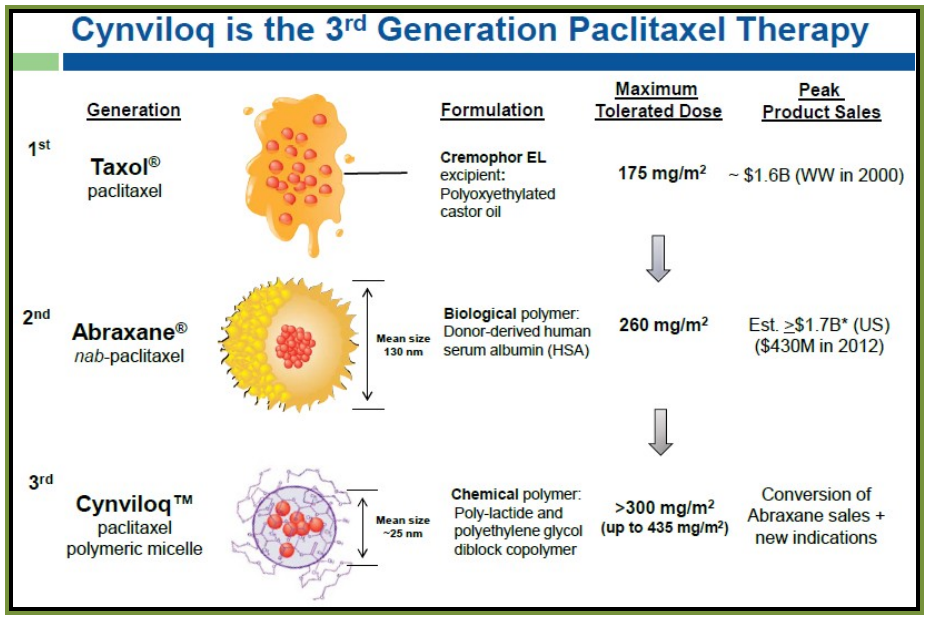
Cynviloq™ is a next-generation **nanoparticle formulation of paclitaxel** for the potential treatment of metastatic breast cancer (MBC), non-small cell lung cancer (NSCLC), pancreatic cancer (PC), ovarian

cancer (OC), bladder cancer (BC) and other solid tumors. This formulation creates an easy-to-administer injectable for effective delivery of drug into tumor tissues.

Cynviloq is currently approved and marketed in several countries, including **South Korea**, MBC, NSCLC and OC under the trade name **Genexol-PM®** by Samyang Inc., a South Korean corporation. Sorrento has the exclusive US and EU rights to Cynviloq.

Cynviloq is a high value proposition for Sorrento, which serves as both near term and long term value drivers. Cynviloq's efficacy and safety have been demonstrated in clinical trials in over 1,260 patients worldwide. Sorrento plans to file a NDA via 505(b)(2) pathway, which will shorten the development time and reduce cost and the risks dramatically. The market potential for Cynviloq is significant. Worldwide sales of Taxol® were about $1.6 billion in 2000 when generic paclitaxel entered into the market. Albumin-bound paclitaxel, Abraxane® (Celgene), an improved formulation over Taxol® was launched by Abraxis Oncology in 2005 in MBC. Sales of Abraxane® were $448 million for the nine months of 2013. With a 2 month survival benefit in combination in gemcitabine in pancreatic cancer and recent approval in NSCLC and pancreatic cancer, Abraxane® sales are projected to reach at least $1.5 billion in the US. Celgene acquired Abraxis for over $2.9 billion in 2010.

Cynviloq holds advantages over either Taxol® or Abraxane®. We believe Cynviloq will take meaningful market share from Abraxane® when it's approved for the indication of MBC and NSCLC. Sales growth will also come from new indications, which Sorrento intends to develop as part of the product life cycle management strategy once it signs up a co-development and commercial partner.



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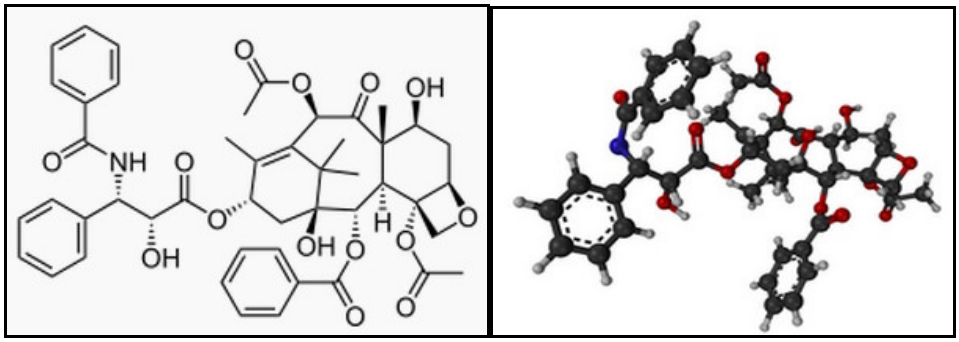
Cynviloq Holds Advantages vs Abraxane® and Taxol®

Taxol® is the first generation of paclitaxel. Since paclitaxel does not dissolve in water, Taxol® is dissolved in Cremophor and ethanol, as a delivery agent. Much of the clinical toxicity of Taxol® is associated with the solvent Cremophor.

Taxol® was developed by Bristol-Myers Squibb (BMS) for a variety of cancer indications including lung, ovarian, breast, head and neck cancer, and advanced forms of Kaposi's sarcoma.

Paclitaxel Molecular Structure



Abraxane® is the **second generation** formulation of paclitaxel approved for MBC, NSCLC and first line metastatic pancreatic cancer. Unlike Taxol® which utilizes Cremophor to solubilize paclitaxel, Abraxane® is an **albumin-bound** paclitaxel formulation. Abraxane's formulation is composed of serum albumin from human donors (HAS). Upon reconstitution of the vial with saline solution, Abraxane® exists as albumin nanoparticles with an approximate size of **130 nanometers**. Free, amorphous paclitaxel molecules are packed inside the albumin nanoparticles. Once Abraxane® is administered into the blood stream, the albumin nanoparticle disintegrates very rapidly to release its cargo and generate free-floating paclitaxel. The free paclitaxel utilizes the natural albumin that is abundant in human body to reversibly bind paclitaxel, transport it across the endothelial cell and concentrate it in areas of tumor.

This albumin formulation eliminates the usage of solvent cremophor, therefore increases the maximum tolerated dose to 260 mg/m^2 for Abraxane® from 175 mg/m^2 for Taxol®. Advantages of Abraxane® vs Taxol® include:

- more effective at treating tumors because a higher dosage can be delivered;
- decrease in side effects from solvent related hypersensitivity reactions;
- decreased use of medications to combat the solvent related hypersensitivity reactions;
- decreased time of administration;

Abraxane® was launched by Abraxis Bioscience in 2005 for the treatment of MBC and was purchased in 2010 by Celgene for more than $2.9 billion in cash and stock. The Abraxane® label has been expanded to include patients with NSCLC as first-line treatment in combination with carboplatin (2010), and in combination with gemcitabine with locally advanced or metastatic pancreatic cancer (2013). Total revenue from the sales of Abraxane® for 2012 was $427 million. For the nine months of 2013, Abraxane sales were $448 million and are projected to reach $1.5B in annual sales.

Cynviloq ™ is the **third generation** of paclitaxel formulation, which is a branded, polymeric nanoparticle. Unlike Abraxane®, Cynviloq's nanoparticle formulation does not contain HSA. Both drugs behave similarly once administered into the blood stream. The Cynviloq nanoparticle disintegrates rapidly to release its cargo of paclitaxel into the blood stream. Free paclitaxel then binds reversibly into the patient's albumin in the circulation to be transported across the tumor endothelial cells and concentrate in the tumor tissues. The particle size of Cynviloq is even smaller than that of Abraxane® (25 nm vs 130 nm). This formulation increase the maximum tolerated dose of Cynviloq to greater than 300 mg/m^2 from 175 mg/m^2 for Taxol® and 260 mg/m^2 for Abraxane®. The higher maximum tolerated doses (MTD) could potentially confer efficacy and/or safety advantages.

Because Cynviloq is HSA-free, we believe it is a superior formulation to Abraxane®. The absence of a biologic protein has advantages such as easier preparation (minimal foaming inside the vial upon reconstitution) and storage (reduced risk for microbial contamination). In addition, it eliminates potential risk of viral/prion transmission from human blood products.

Cynviloq Advantages over Abraxane® and Taxol

	Cynviloq™	Abraxane®	Taxol®	Cynviloq Advantage
Maximum Tolerated Dose (mg/m^2)	>300	260	175	Potential for higher efficacy
Rapid reconstitution: no foaming concerns	●		●	Convenience for busy practices and pharmacies
No donor-derived human serum albumin (HSA)	●		●	No viral / prion concerns
Convenient storage conditions	●		●	No requirement for controlled temp storage
No microbial growth	●		●	Chemical polymer
Cremophor-free	●	●		Reduced side effects
Dosing	q3w	q3w* & weekly**	q3w & weekly	Exploits PK advantage @ higher dose

Source: company presentation

Cynviloq, Shortened Regulatory Pathway Leads To Quick Approval and Commercialization

Cynviloq™ has completed Phase I and/or II trials in MBC, NSCLC, pancreatic cancer, ovarian cancer and bladder cancer in the U.S. and/or non-U.S.

In July, 2013, Sorrento held an End-of-Phase II meeting for Cynviloq with the US FDA, which agreed that the data available are sufficient to support a **505(b)(2)** bioequivalence regulatory pathway for approval, using Abraxane® and Taxol® as the Reference Listed Drugs.

The 505(b)(2) application is one of **three types of NDAs** that can be submitted to the FDA. A **full NDA** is "an application that contains full reports of investigations of safety and effectiveness," according to Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act. Data found in a full NDA must be from studies conducted by or for the sponsor, or must be obtained through a "right of reference." An abbreviated NDA (**ANDA**) is for a proposed drug that is identical to a reference listed drug and must demonstrate its bioequivalence. Generic drugs utilize the ANDA pathway to get into the market without having to do a full complement of studies, pre-clinical and clinical, to demonstrate its safety or efficacy. In a sense, the **505(b)(2)** was intended to be a hybrid of the full NDA and an ANDA: it proposes a limited change to a previously approved product, but demonstrates the required safety and efficacy of the change by referencing the data of the previously approved drug on which it is based on.

505(b)(2) regulatory pathway avoids lengthy, costly and, in many cases, repetitive preclinical and clinical trials. In addition, the 505(b)(2) route may have a more clearly defined timeline than other types of submissions. With proper understanding of the compound, the development cycle and the marketplace, a company can identify which studies to conduct and costs can be more accurately predicted.

There are commercial benefits to a 505(b)(2) approval as well. It can afford the sponsor **three or five years** of market exclusivity, depending on the extent of change to the previously approved drug. This is an apparent advantage when compared to ANDA approval, where exclusivity can be held for only 180 days. With a 505(b)(2) approval, companies have more time to develop a strong marketing strategy, resulting in a brand consumers recognize and may prefer. Companies may also find themselves in a potentially wide-open market with a unique 505(b)(2) approved drug, thus allowing for greater flexibility in pricing.

With Cynviloq, Sorrento will be referencing the safety and efficacy data from Abraxane® and Taxol® as reference drugs. In addition, Sorrento is required to demonstrate that Cynviloq is bioequivalent to Abraxane® at the approved Abraxane® paclitaxel dose of 260 mg/m^2 infused over 30 minutes in patients with metastatic breast cancer.

The 505(b)(2) pathway of Cynviloq is supported by a number of animal studies and human clinical trials. Its clinical efficacy and safety have been demonstrated in a number of clinical studies.

Clinical efficacy and safety of Cynviloq

Total number of patients across all trials: 1,260

Phase 1: Trials established higher MTD in US - Dana Farber Cancer Inst, Russia, & S. Korea (total n=80)

- >300 mg/m^2 (q3w) vs. 175 mg/m^2 (Taxol; weekly) and 275 mg/m^2 (Abraxane; q3w)

Phase 2: Completed trials in MBC, NSCLC, PC, OC, BC; in US - Yale Cancer Center, Russia, S. Korea (total n=259)

- Data suggestive of efficacy comparable to historic data for Abraxane and superior to historic Taxol data or Standard-of-Care
- Possible Phase 3 sNDA programs in these tumor types

Phase 3: Ongoing trial for MBC in S. Korea (total n=209; Cynviloq n=105)

- GPMBC301. An Open-label, Randomized, Parallel, Phase 3 Trial to Evaluate the Efficacy and Safety of Cynviloq compared to Genexol® (Paclitaxel with Cremophor EL) in Subjects with Recurrent or Metastatic Breast Cancer)
- Interim analysis suggests ORR superior to Taxol and comparable to historic Abraxane efficacy
- Efficacy and safety data supportive of 505(b)(2) BE submission

PM-Safety: Completed for MBC and NSCLC (total n=502)

- Efficacy and safety data supportive of 505(b)(2) BE submission

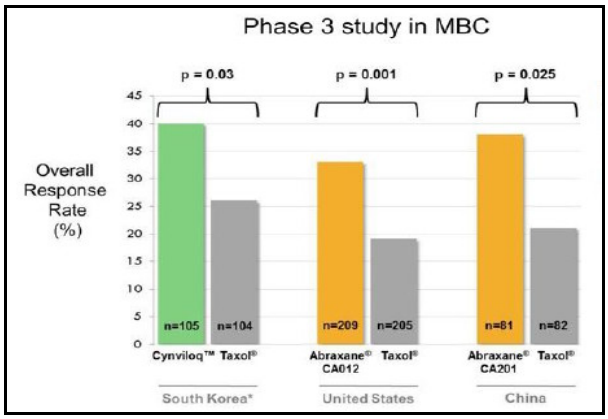
Phase 2b (IIS): Chemo-naïve Stage IIIb/IV NSCLC vs Taxol in S. Korea (total n=276; Cynviloq n=140)

- 230 mg/m^2 + cis (q3w) vs. Taxol 175 mg/m^2 + cis; non-inferiority established

Phase 2 (IIS): 1st line treatment of OC vs Taxol in S. Korea (total n=100; Cynviloq n=50)

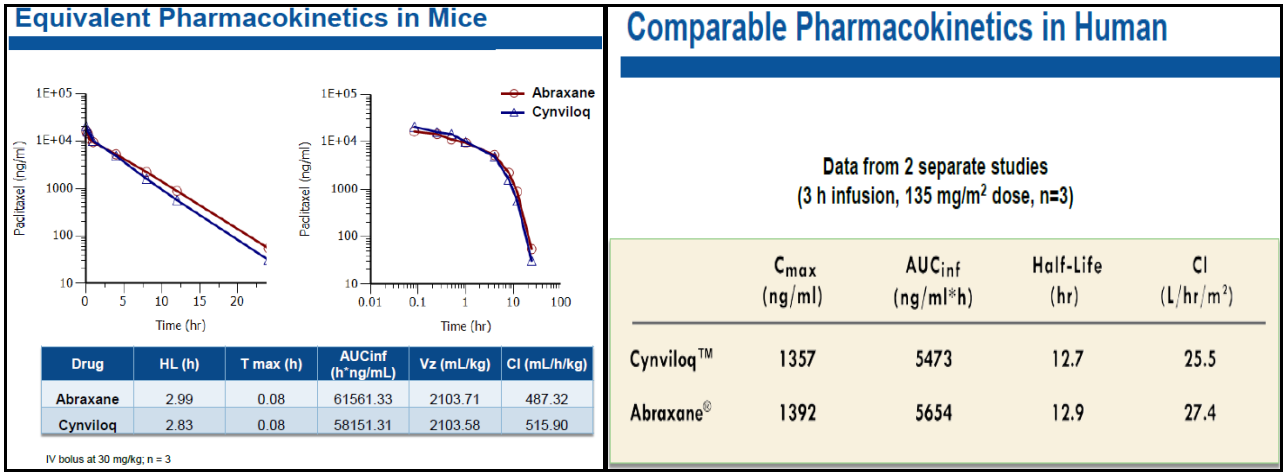
- 260 mg/m^2 + carbo (q3w) vs. Taxol 175 mg/m^2 + carbo; non-inferiority established

In a **Phase III** trial conducted in MBC patients in South Korea, Cynviloq showed significant improvement in overall response rate when directly compared to Taxol®, similar to that of Abraxane® vs. Taxol® in separate pivotal clinical trials in the US and China, respectively.



Source: company presentation

Comparable pharmacokinetics data of Cynviloq and Abraxane® from both animals and humans support the bioequivalence approach of Cynviloq.



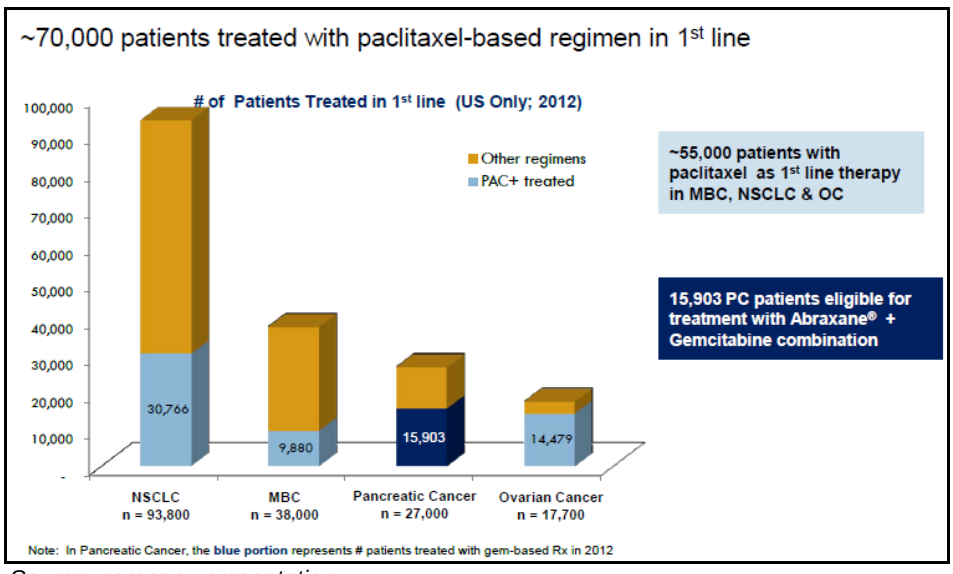
Source: company presentation

The Market For Cynviloq Is Sizable

Paclitaxel-based regimen is widely used for the treatment of various cancers including, but not limited to lung cancer, breast cancer, pancreatic cancer, and ovarian cancer.

In the US, we estimate over 50,000 patients were treated with paclitaxel-based regime in 1st line for MBC, NSCLC and ovarian cancer in 2012. In addition, over 15,000 patients with pancreatic cancer were treated with a gemcitabine-based therapy. Taxanes are also widely used in other cancer types such as hormone refractory prostate cancer and head and neck cancer. It is also used in the adjuvant setting as well as in 2nd line settings.

We think there is still room for further expansion of paclitaxel based regimen market. Due to the side effects of paclitaxel, new formulations, such as Abraxane® and Cynviloq, will assume a major role for the paclitaxel regimen expansion.



Source: company presentation

Abraxane® should serve as the reference for Cynviloq success in our view. Abraxane® was a huge success for Abraxis Bioscience (acquired by Celgene in 2010 for over $2.9 billion) since its approval for MBC. Currently Abraxane® is approved for the treatment of MBC, NSCLC, and pancreatic cancer. Sales of Abraxane® in 2012 were $427 million. For the first nine months of 2013, Abraxane® sales were $448 million. Sales of Abraxane® are expected to reach $1 billion in 2015. When Celgene continues to expand

Abraxane® labels, sales of Abraxane® could grow further and become a multibillion dollar product in a few years.

Cynviloq has advantages over Taxol® and Abraxane®. When approved, it has the potential to take significant market shares from both generic paclitaxel and Abraxane®. The initial indications for Cynviloq are MBC and NSCLC, and has the potential for expansion into other indications.

We believe the high visibility of Taxol® and Abraxane® will help Cynviloq achieve blockbuster potential for Sorrento.

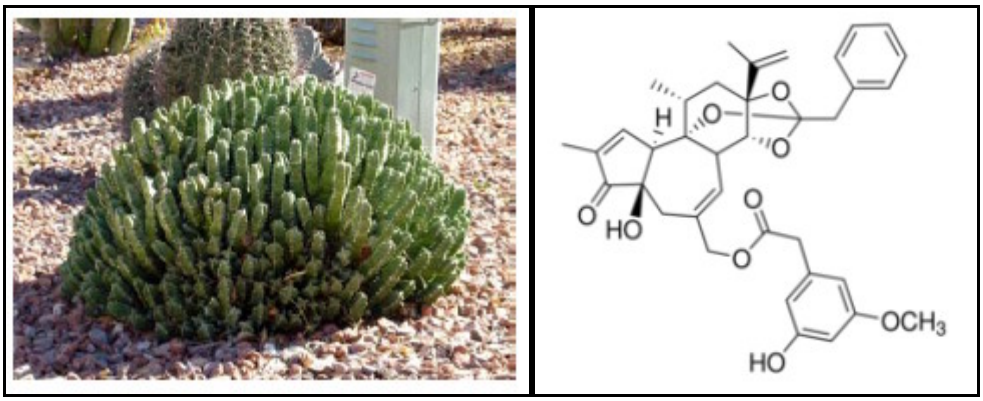
RTX: Unique Mechanism Of Action For Cancer Pain

Sorrento's second lead drug candidate is **Resiniferatoxin (RTX)** for the treatment of chronic pain in end-stage cancer patients and other severe pain indications.

Sorrento acquired RTX through the acquisition of Sherrington Pharmaceuticals, Inc., a privately-held company based in New York. RTX is a non-opiate, ultra potent and selective **agonist** of the **TRPV-1 receptor,** the same receptor for **capsaicin**, the active ingredient in chili pepper. A single injection of the compound is expected to permanently block the transmission of pain signals without impairing the mental or physical faculties of the patient, common side effects of **opiate treatment**. RTX was recently highlighted in the July 2013 issue of Scientific American.

RTX is a naturally occurring chemical found in various euphorbia species such as Euphorbia resinifera, a cactus-like plant commonly found in Morocco.

RTX Chemical Structure



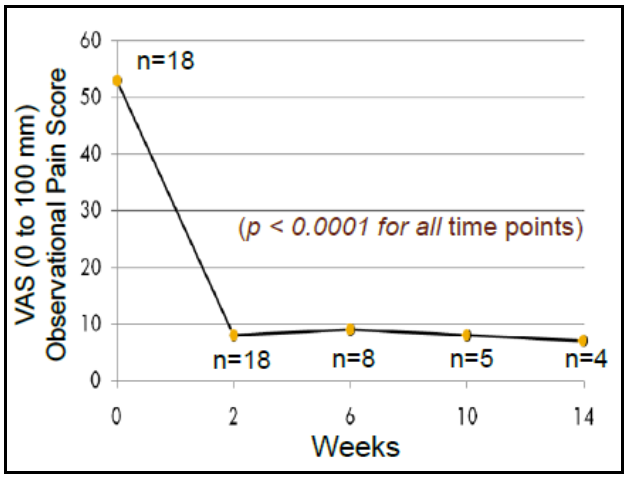
RTX activates the **vanilloid receptor** in a subpopulation of primary afferent sensory neurons involved in nociception (the transmission of physiological pain). RTX causes an ion channel in the plasma membrane of sensory neurons — the transient receptor potential vanilloid 1(TRPV-1) — to become permeable to cations. This causes a massive influx of calcium cations into the TRPV-1 neurons causing apoptosis of the nerve cells leading to desensitization and analgesia.

Like capsaicin, RTX has the same mechanism of action, but it is more potent and highly selective for TRPV-1 neurons only. This increased potency confers both quantitative and qualitative advantages in terms of drug action on the TRPV-1 containing nerve terminal, which result in an increased efficacy and a long duration of action. RTX can be delivered through a variety of route including **central route via intrathecal injection** and **peripherally via intraganglionic injection**. While the central route of administration can be used as a treatment of cancer pain, the peripheral delivery offers the possibility to treat a wide diversity of pain problems by bringing the treatment to the site of the pain. The unique mechanism of action and convenient delivery of RTX makes it a potential candidate for **personalized pain medicine.**

In preclinical cell line and animal studies, RTX has demonstrated the ability to induce accumulation of calcium and **death of TRPV-1 expressing afferent nerves**, but has no effect on normal sensation, acute pain perception or muscle function.

In an 18-dog cancer pain study, single intrathecal injection of RTX led to permanent ablation of nerves. In this animal study, RTX demonstrated attractive therapeutic effect:

- All 18 subjects responded;
- Personality and mood of animals visibly improved;
- No opioid-associated side effects were observed;



Source: Brown et al, 2004

Resiniferatoxin is currently in an investigator-sponsored **Phase I/II clinical trial** at the National Institutes of Health (NIH) under a company sponsored Collaborative Research and Development Agreement (CRADA).

This is a single-site, non-randomized, open-label, dose-escalation study, which will examine the safety and efficacy of **RTX** to treat severe pain in patients with advanced cancer. People 18 years of age with severe pain from advanced cancer that cannot be controlled with standard treatments are eligible for this study. RTX is injected in the operating room under general anesthesia through a catheter placed in the patient's spine. The catheter is also used to obtain samples of cerebrospinal fluid (CSF) to assess drug effects and side effects, chemical changes in the content of the CSF associated with RTX, and how RTX is handled by the body.

The **primary** study outcome is the ED100, the MTD, whichever is achieved first during dose escalation. **Secondary** outcome measures will be other surveys of pain, including an assessment of worst daily pain by the visual analog scale, and assessments of function and quality of life.

Up to 45 patients will be enrolled in this study and data are expected to be available **by the end of 2014**.

Sorrento plans to initiate additional clinical studies to rapidly advance the drug. Initially, Sorrento intends to develop RTX as a leading cancer pain agent for a dual pathway: **intrathecal** injection **Phase I/II** trial for intractable cancer pain in about 40 patients, and **intraganglionic** injection **Phase I/II** trial for osteosarcoma pain in about 15 patients. RTX has been granted an orphan drug designation for patients with intractable pain associated with end stage disease.

Longer term, RTX could be expanded into larger **general interventional markets** such as post herpetic neuralgia (PHN), diabetic neuropathy and other pain conditions.

Cancer Pain: Another Huge Market For Sorrento

With the addition of RTX, Sorrento now has two candidates in middle to late stage of development. Both Cynviloq and RTX target the cancer market with Cynviloq as a **cancer therapeutics** and RTX as the complementary **cancer pain management**.

Cancer is one of the leading causes of death in the US and other countries. According to the American Cancer Society, cancer associated death in the US was 575,313 in 2011, close to the death number associated with heart disease (596,339).

As a result of the increased market size for cancer treatment, the **cancer pain management** market is expected to be the fastest growing segment within the global pain management therapeutics market according to new analysis from business intelligence firm GBI Research. They estimate that the cancer pain management market will increase at a compound annual growth rate (CAGR) of 9.1% from 2012 to 2019, achieving sales of $7 billion by 2019.

The growth of the cancer pain management will be driven by the increasing global prevalence of cancer. Cancer pain market will become the second largest segment of the overall pain management market, claiming 15%, while the neuropathic pain management market will continue to hold the largest share of 16% by 2019.

According to GBI Research, in 2012, 11.8 million people across the top seven markets were suffering from cancer pain, and this number is only continuing to rise. However, just 58% of the diseased population and 78% of the diagnosed population are prescribed medication, as the focus is usually on treating the cancer rather than the pain. This presents a current unmet need in the market which pain management therapeutics will be required to fill over the coming years.

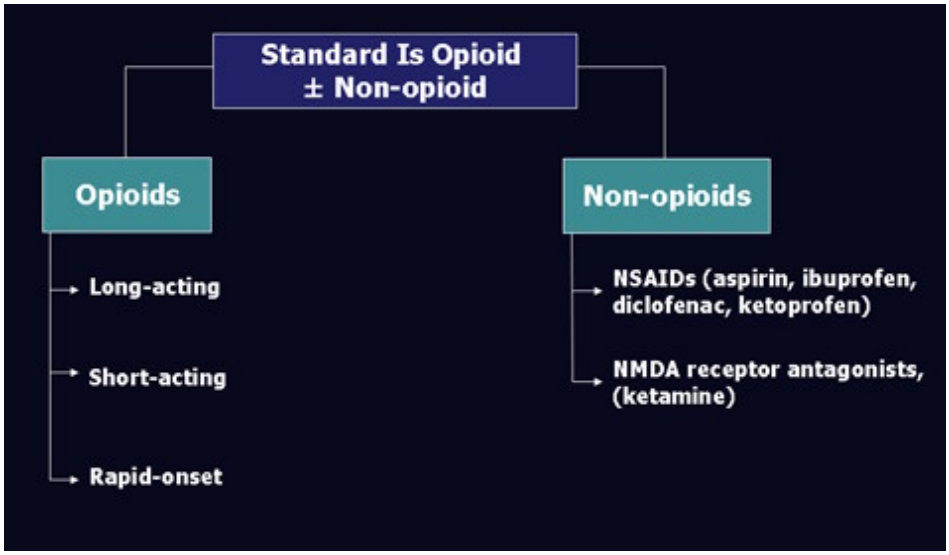
The significant growth of this treatment area will help boost the growth of the overall pain management market, which GBI Research estimates will rise from $36 billion in 2012 to $49 billion in 2019, representing a CAGR of 4.6%.

Cancer patients are afflicted by both chronic and acute pain, with pain estimated to be 50-70% among patients undergoing cancer therapy and 70-80% among patients with advanced cancer. Without treatment, cancer pain can harm a person’s sense of wellbeing, interfere with daily activities, and interrupt disease-related treatment schedules.

Cancer incidence drives the patient population with cancer pain. Cancer stage and location are highly predictive of the frequency and duration of pain. End-stage cancer pain is a high unmet medical need with a huge market.

Current standard of care for cancer pain is opioid analgesics with drugs such as **Nucynta** and **Remoxy** leading the market.

In most patients with advanced cancer, breakthrough cancer pain, defined as a “transient exacerbation of pain occurring in a patient with otherwise stable, baseline persistent pain”, is a significant problem and is treated with drugs like **Actiq** and **Fentora,** or through the use of round-the clock opiate infusion. Datamonitor estimates that there were 2.6 million cancer patients experiencing breakthrough pain in the seven major markets in 2011. Approximately 40% (or 1.03 million) of these were in the US where a large population of cancer patients is diagnosed every year.



Despite the use of opioid analgesics, **5–10%** of cancer-pain patients do not achieve satisfactory pain control or have unacceptable side effects related to pain therapies. For these refractory cancer pain patients, intrathecal therapy (ITT) is an established and superior alternative to conventional opioid use. The Centers for Medicaid and Medicare Services (CMS) data shows that IT pump therapy, which includes surgical implantation, pre-testing, maintenance, programming and the drug itself, results in annual expenditures ranging between $36,000-$60,000 with 47%-90% of the costs being incurred in the first month of treatment (Reference: Miguel R. Interventional Treatment of Cancer Pain Cancer Control 2000; 7: 149-157). This does not include the costs of treating complications such as catheter site infections and otherwise. Additionally, pumps require frequent physician visits and careful monitoring. Therefore, management of cancer pain is a significant economic burden to the payers.

RTX has a unique mechanism of action and strong potency. The early data with Resiniferatoxin are very encouraging. A single intrathecal injection of RTX has the potential to permanently ablate cancer pain associated neurons, resulting in significantly improved patient quality of life, mobility & activity; and reduction of opiate use. If approved, RTX could command a niche of the cancer pain market and will make a significant contribution to Sorrento's top line growth. We estimate peak sales of RTX could reach over **$750 million** in 3 years following launch.

The G-MAB®: Library of Therapeutic Antibodies

Sorrento's **G-MAB®** library is one of the industry's most diverse **fully human** antibody libraries. The potential theoretical library diversity has been calculated to be 10^{16} unique Abs, making it one of the largest fully human antibody libraries available to pharmaceutical and biotechnology companies for drug discovery and development.

The G-MAB® library construction technology was invented by **Dr. Henry Ji,** Sorrento's co-founder, President and Chief Executive Officer. A US patent covering the G-MAB® Technology was issued in July 2008 and additional patent application families for the generation, display and screening of antibody libraries are pending. The company recently filed a group of patent applications covering significant improvements to Sorrento's initial technology relating to its ability to achieve greater library diversity and single-class libraries.

Sorrento's G-MAB® library was constructed using naturally evolved antibody sequences whereas many other libraries contain artificially engineered antibodies to increase antibody diversity. G-MAB® technology also enables fast and cost-effective in vitro screening against a large number of antigens without dependence on a host immune response against these antigens.

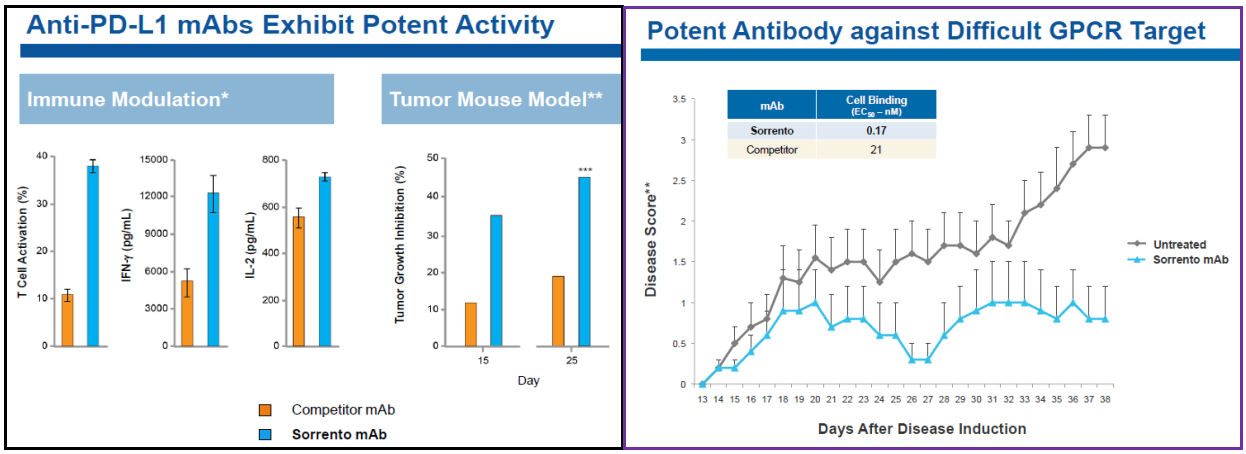
G-MAB® library consists of fully human antibodies, constructed from approximately 600 individual donors ensuring a high degree of diversity.

Sorrento's proprietary technology for the construction of human antibody libraries maximizes diversity by applying patented and proprietary processes, including ribonucleic acid **(RNA) amplification** of the variable regions of the heavy and light chains of human immunoglobulin genes obtained from human blood samples, followed by cloning and expression in a display system. The library technology has been designed to include the full spectrum of human immunoglobulin gene recombination. Sorrento is the only company that used the RNA amplification technology to generate an Ab library, while most other libraries are constructed using **DNA amplification** technology.

The vast diversity of G-MAB® library has been validated with a **successful hit rate**, even against difficult targets, including G protein coupled receptors **(GPCRs).** To date, Sorrento has generated mAbs against more than 40 clinically-relevant targets, including the therapeutic areas of oncology, inflammation, and infectious diseases. The library's diversity has also enabled accelerated hit mAb discovery in less than 2 months and selection of lead antibodies for advanced development within 12 months.

Utilizing the G-MAB® library, Sorrento is able to pursue targets in virtually any therapeutic area. In oncology, the company's lead targets include **PD-L1** and **PD-1**. In inflammation Sorrento is targeting **GPCRs**. And in infectious diseases, the company's NIH/NIAID-sponsored programs are focused on methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* (Cdiff) – both significant threats to hospital patients today.

In animal model, both Sorrento's anti-PD-L1 antibody and GPCR antibody are potent and have demonstrated superiority over competitors.



Source: company presentation

Sorrento's goal is to advance at least one novel monoclonal antibody (mAb) candidate from the G-MAB® library per year into clinical development, commencing in 2015. The company is also actively pursuing potential strategic **partnerships** for various other mAb candidates.

Market for monoclonal antibody therapeutics is the largest in the pharmaceutical industry. In the United States there are over twenty five FDA-approved antibody-based drugs on the market. In 2012, the top-selling antibody-based drugs had aggregate sales exceeding $44 billion.

Antibody	Company	WW Sales ($B)
Humira	Abbott Laboratories/Eisai	$9.48
Enbrel	Amgen/Pfizer/Takeda	$8.37
Remicade	Johnson & Johnson/Merck/Mitsubishi Tanabe	$7.67
Rituxan	Roche	$6.94
Herceptin	Roche	$6.08
Avastin	Roche	$5.98

Source: Zacks Small Cap Research

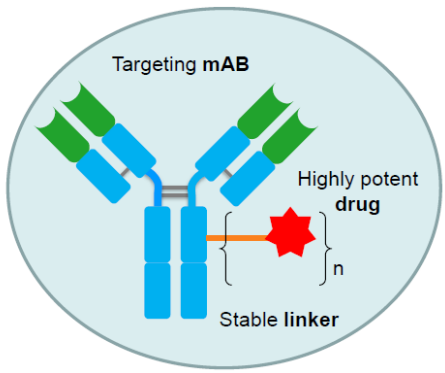
We believe Sorrento's G-MAB® based antibody platform has the potential to become a key player in the antibody therapeutics market. **The strategy** to pursue both internal development and partnership at the same time will mitigate the development risks for Sorrento.

Sorrento Holds New Generation ADC Platform Technology

In December of 2013, Sorrento acquired San Diego-based private company **Concortis Biosystems**. This acquisition provides Sorrento with a comprehensive technology platform for next generation of **antibody drug conjugates (ADC)**.

This deal will enable Sorrento to utilize the antibodies identified from its **G-MAB® library** along with Concortis' **conjugation technologies and novel toxins** to create a new generation of ADCs.

ADC is composed of four parts: targeting monoclonal antibody, highly potent small molecule drug, selective conjugation chemistry, and stable linker which connect the antibody and drug.



Source: company presentation

ADC represents a new class of biotherapeutics with increased selectivity, potency and reduced toxicity. However, there are two key challenges in current ADC technologies. **First**, there are limited choices of linkers and conjugate methods, which may lead to premature drug release or insufficient drug release. **Second**, current ADC technologies lack site-specific conjugation chemistries, therefore producing heterogeneous ADC products.

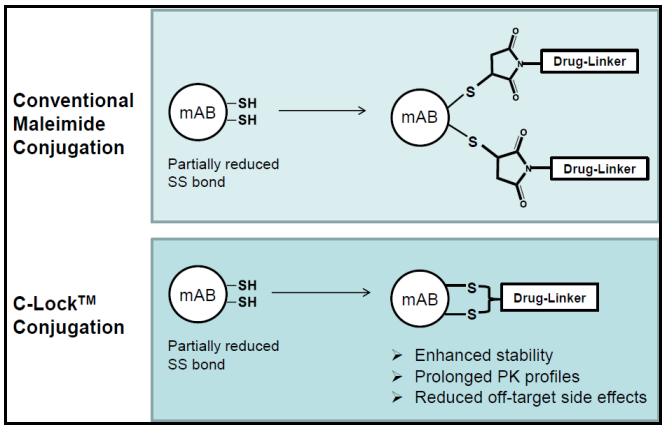
Concortis' proprietary C-lock™ and K-lock™ **conjugation chemistries** enable site-specific conjugation of toxins to the antibody, which will produce **homogenous ADCs** with well-defined drug antibody ratios **(DAR).** In contrast, approved ADCs are a heterogeneous mixture with different DARs. Concortis' conjugation technologies could potentially lead to better ADC stability and pharmacokinetics while reducing off-target effects compared to existing ADCs and therefore, improved therapeutic efficacy and treatment safety.

Linker is the key element to link targeted mAb and payloads effectively. Typical criteria for a suitable linker include:

- Stable in blood stream;
- Cleavable on demand;
- Compatible with antibody and drug in use;
- Controllable and precise conjugate process.

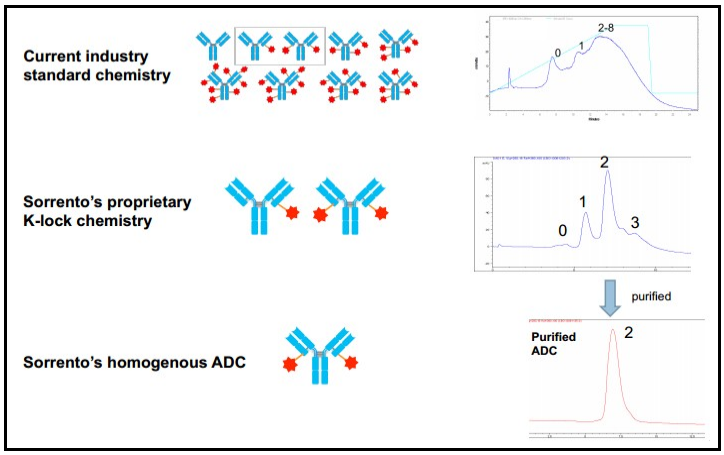
Concortis' linkers and conjugation process fulfill the above requirements, therefore becoming an ideal choice of conjugation technology. Over the years, Concortis has developed proprietary **C-lock™** and **K-lock™ conjugation methods.**

C-lock™ conjugation method enhances ADC stability leading to prolonged PK profile, and reduced off target side effects.



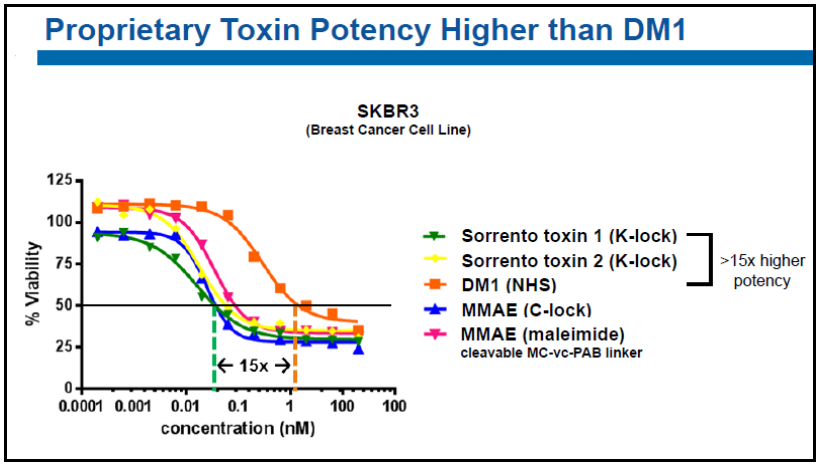
Source: company presentation

While the traditional **NHS-based** conjugation method might involve up to 80-90 NH_2-containing sites to be randomly targeted in drug conjugation, **K-lock™** conjugation methodology only targets 1-2 NH_2 sites for conjugation, which enables homogeneous ADCs and leads to fewer positional isomers and better control of DAR.



Source: company presentation

In addition to its unique antibody library and conjugation technology, Sorrento's proprietary toxins are also more potent than some of the currently used toxins.



Source: company presentation

The US FDA recently approved two ADC drugs: **ADCETRIS**® (brentuximab vedotin) from Seattle Genetics and **Kadcyla**® from Roche/Immunogen.

ADCETRIS obtained accelerated approval for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates; and for the treatment of patients with systemic anaplastic large cell lymphoma (ALCL) after failure of at least one prior multi-agent chemotherapy regimen.

KADCYLA is a HER2-targeted antibody and microtubule inhibitor conjugate indicated, as a single agent, for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.

Although in early development stages, Sorrento's combination of antibody library, conjugation technology and highly potent toxins will enable the company to become a key player in the ADC market place in our view. The ADC space has become a fertile area for partnerships or acquisitions. With its unique ADC platform, it should not be difficult for Sorrento to find partners. With increased mergers and acquisitions (M&A) in the pharmaceutical industry, Sorrento could be a M&A target for a big pharma or biotech company seeking to expand its pipeline.

PROJECTED INCOME STATEMENT

	2013 (Dec)					2014E (Dec)					2015E (Dec)	2016E (Dec)	2017E (Dec)	2018E (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYE	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Grant revenue	$0.13	$0.14	$0.08	$0.09	$0.45	$0.08	$0.08	$0.08	$0.08	$0.32	$0.30	$0.30	$0.30	$0.30
Collaboration revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$1.50	$1.50	$1.50	$1.50
Product revenue	$0.00	$0.00	$0.00	$0.01	$0.01	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00	$85.00	$205.00
Total Revenues	**$0.13**	**$0.14**	**$0.08**	**$0.10**	**$0.46**	**$0.08**	**$0.08**	**$0.08**	**$0.08**	**$0.32**	**$1.80**	**$6.80**	**$86.80**	**$206.80**
YOY Growth	19.7%	-35.7%	-38.4%	-18.8%	-21.2%	-40.3%	-43.5%	-4.5%	-20.6%	-30.5%	462.5%	277.8%	1176.5%	138.2%
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.02	13.02	31.02
Gross Income	**$0.13**	**$0.14**	**$0.08**	**$0.10**	**$0.46**	**$0.08**	**$0.08**	**$0.08**	**$0.08**	**$0.32**	**$1.80**	**$5.78**	**$73.78**	**$175.78**
Gross Margin	100.0%	100.0%	100.0%	95.6%	99.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	85.0%	85.0%	85.0%
R&D	$1.40	$3.35	$2.08	$8.17	$15.00	$5.50	$6.50	$7.50	$8.50	$28.00	$32.50	$35.50	$32.00	$30.00
% R&D	1043.3%	2366.6%	2485.1%	8113.7%	3260.3%	6875.0%	8125.0%	9375.0%	10625.0%	8750.0%	1805.6%	522.1%	36.9%	14.5%
SG&A	$1.25	$1.51	$1.11	$2.45	$6.32	$1.75	$2.00	$2.25	$2.50	$8.50	$13.50	$30.00	$50.00	$60.00
%SG&A	932%	1065%	1330%	2428%	1373%	2188%	2500%	2813%	3125%	2656%	750%	441%	58%	29%
Amortization	$0.00	$0.00	$0.19	$0.61	$0.80	$0.60	$0.60	$0.60	$0.60	$2.40	$2.90	$2.90	$2.90	$2.90
Operating Income	**($2.5)**	**($4.7)**	**($3.3)**	**($11.1)**	**($21.7)**	**($7.8)**	**($9.0)**	**($10.3)**	**($11.5)**	**($38.6)**	**($47.1)**	**($62.6)**	**($11.1)**	**$82.9**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	40.08%
Other Net	($0.0)	($0.0)	($0.0)	($0.2)	($0.2)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.1)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($2.5)**	**($4.7)**	**($3.4)**	**($11.3)**	**($21.9)**	**($7.9)**	**($9.1)**	**($10.4)**	**($11.6)**	**($39.0)**	**($47.2)**	**($62.7)**	**($11.2)**	**$82.8**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.5
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($2.5)**	**($4.7)**	**($3.4)**	**($11.3)**	**($21.9)**	**($7.9)**	**($9.1)**	**($10.4)**	**($11.6)**	**($39.0)**	**($47.2)**	**($62.7)**	**($11.2)**	**$82.3**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-836.3%
Net Margin	-	-	-	-	-	-	-	-	-	-	-			
Diluted Shares Out	12.3	13.4	14.1	20.3	15.0	23.2	24.0	24.5	25.0	24.2	30.0	35.0	40.0	45.0
Reported EPS	**($0.20)**	**($0.35)**	**($0.24)**	**($0.56)**	**($1.46)**	**($0.34)**	**($0.38)**	**($0.42)**	**($0.46)**	**($1.61)**	**($1.57)**	**($1.79)**	**($0.28)**	**$1.83**
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($2.5)**	**($4.7)**	**($3.4)**	**($11.3)**	**($21.9)**	**($7.9)**	**($9.1)**	**($10.4)**	**($11.6)**	**($39.0)**	**($47.2)**	**($62.7)**	**($11.2)**	**$82.3**
Non GAAP EPS	**($0.20)**	**($0.35)**	**($0.24)**	**($0.56)**	**($1.46)**	**($0.34)**	**($0.38)**	**($0.42)**	**($0.46)**	**($1.61)**	**($1.57)**	**($1.79)**	**($0.28)**	**$1.83**

Source: Company filings and Zacks estimates

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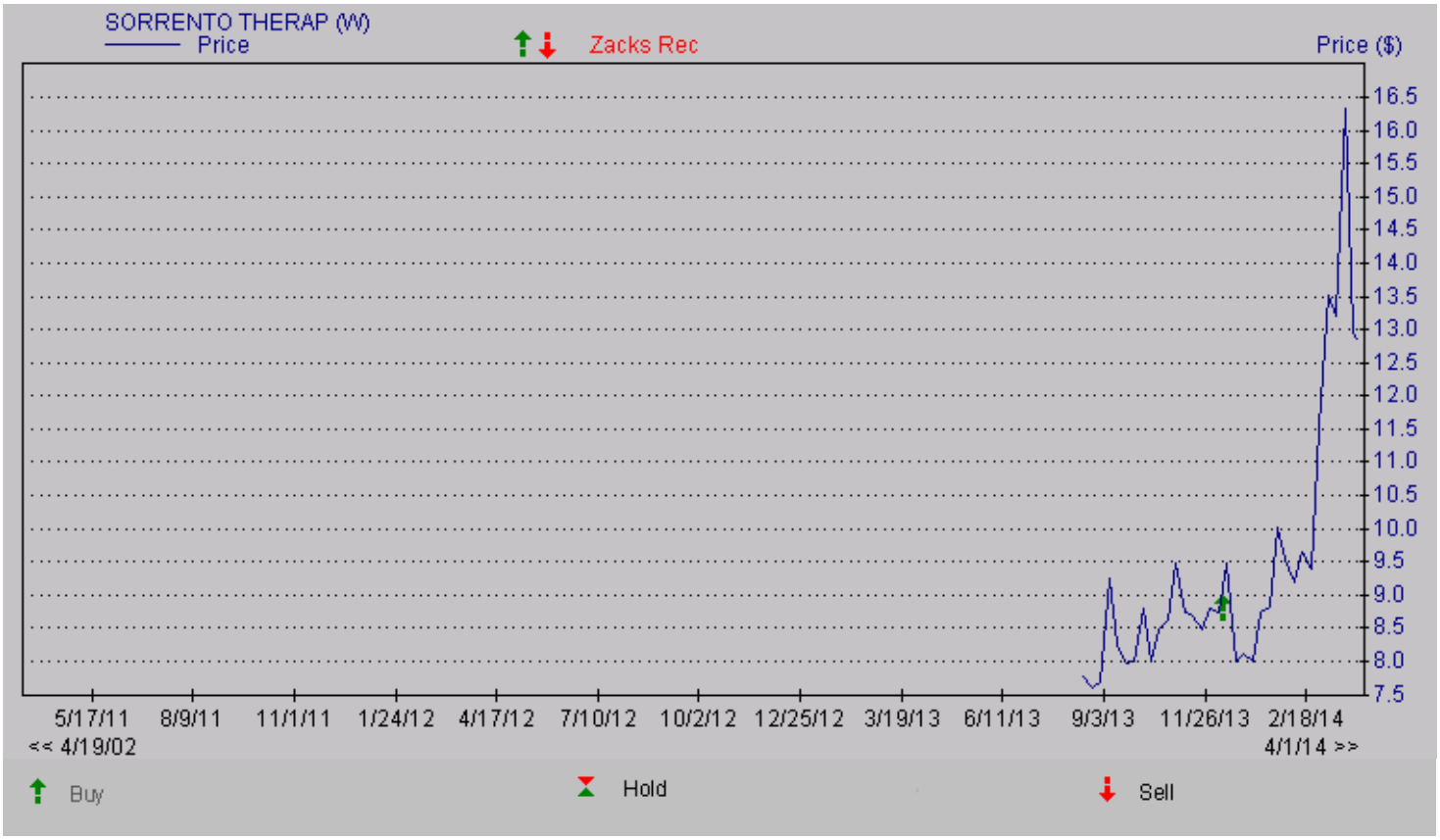
HISTORICAL ZACKS RECOMMENDATIONS



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