Zacks Small-Cap Research

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Sorrento Therapeutics (SRNE-NASDAQ)

SRNE: Initial positive PK data reported, exited 2Q14 with a strong balance sheet--- Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	12/10/2013
Current Price (10/14/14)	$3.21
Twelve- Month Target Price	**15.00**

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. Both G-MAB® and ADCs have 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	**$3.21**
One-Year Return (%)	**-61.09**
Beta	**1.37**
Average Daily Volume (sh)	**93,427**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$92**
Short Interest Ratio (days)	**4.92**
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	0.98 A	0.78 A	0.08 E	0.08 E	1.91 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	-$0.44 A	-$0.33 A	-$0.34 E	-$0.38 E	-$1.49 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 reports positive initial PK data for TIBECA study, modifies protocol to accelerate approval of Cynviloq;**
- **Out-license Anti-PD-1 antibody to China Oncology Focus;**
- **Balance sheet remains strong;**
- **Valuation is attractive;**

Sorrento Reports Positive Initial PK Data From TRIBECA Study

Earlier today (Oct. 14, 2014), Sorrento Therapeutics (SRNE) announced positive results from recently analyzed pharmacokinetic (PK) data from the first eight (8) patients enrolled in its ongoing **pivotal** TRIBECA™ registrational trial.

The Original Design of Pivotal Trial of Cynviloq

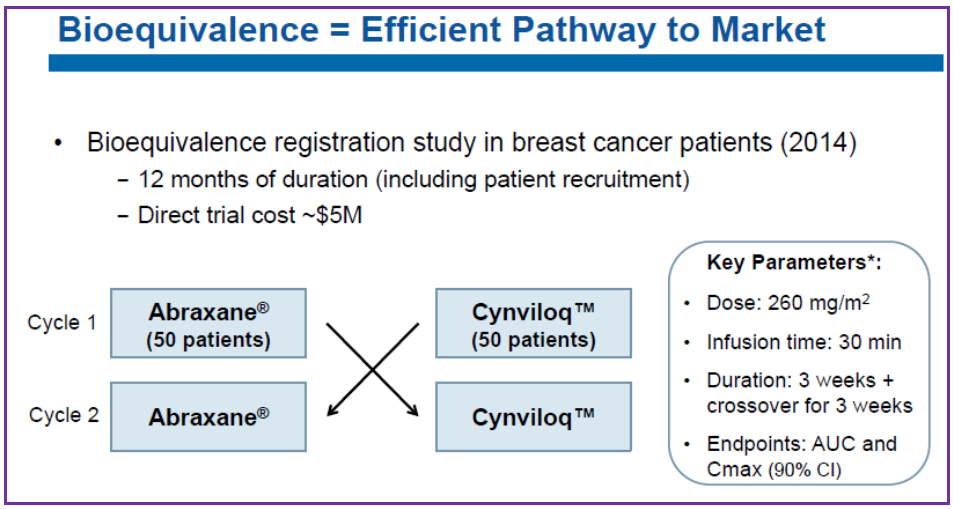
In March, 2014, Sorrento initiated the **pivotal clinical trial** of **Cynviloq** for the treatment of metastatic breast cancer and non-small cell lung cancer.

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.

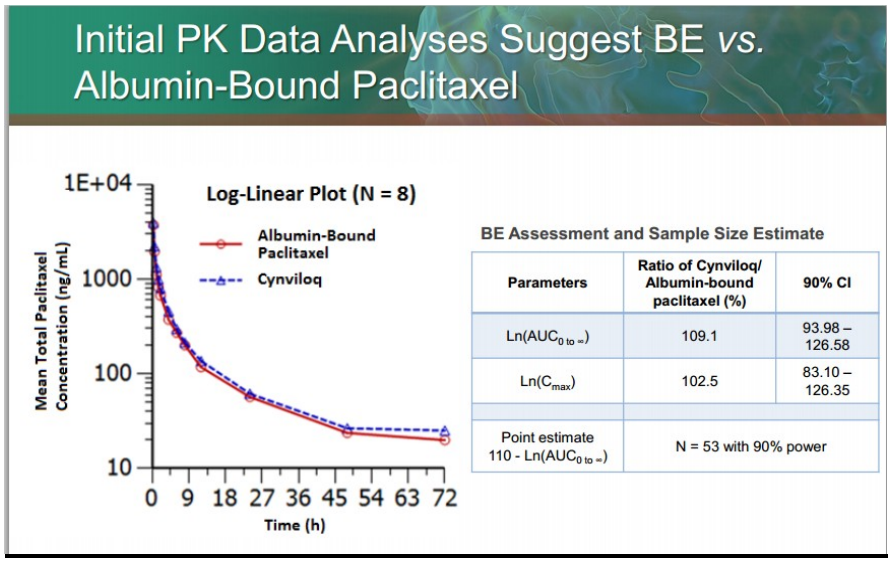


Source: company presentation

The Positive Initial PK Data

The following chart illustrates the initial data from the first 8 patients. The almost coincidental curve between Cynviloq and Abraxane indicates that Cynviloq and Abraxane have similar pharmacokinetics in the patients.

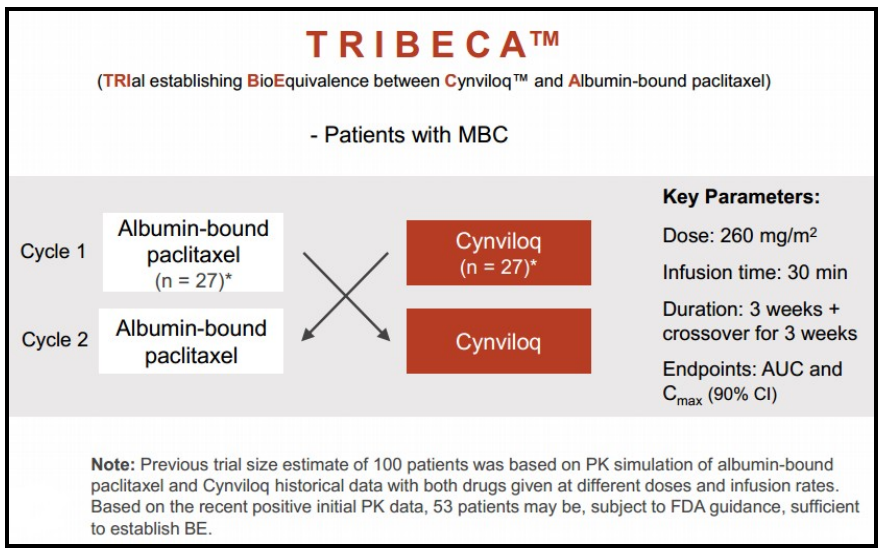
These data support earlier completion of the study.



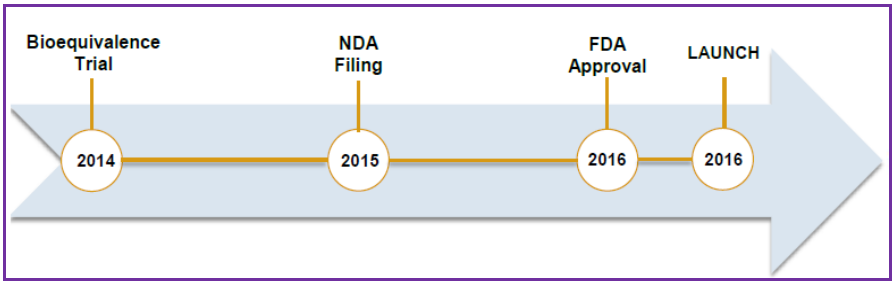
The Modified Trial Protocol

Sorrento amended the current BE cross-over design protocol of the TRIBECA study to un-blind the first 8 patients to reassess the sample size of 100 patients estimated from simulation of historical PK data. The Company does not plan to un-blind additional patient data. Current sample size point estimates suggest that the enrollment target for the current study can be reduced to nearly **half of the original target**.

Based on the initial positive data, Sorrento plans to reduce the TRIBECA patient sample size to **53 patients** to accelerate filing for FDA approval of Cynviloq.



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.



Sorrento Out-licenses Anti-PD-L1 antibody to China Oncology Focus

On Oct. 3, 2014, Sorrento Therapeutics (SRNE) announced that China Oncology Focus Limited has licensed Sorrento's fully human immune-oncology anti-PD-L1 monoclonal antibody (mAb) STI-A1014.

China Oncology Focus is an Affiliate of Lee's Pharmaceutical Holdings Limited, a public biopharmaceutical company based in Hong Kong with operations in China.

As part of the deal, Lee's Pharma will have exclusive rights to develop and commercialize the antibody for the greater Chinese market, including Mainland China, Hong Kong, Macau, and Taiwan.

In turn, Sorrento will receive an up-front payment, potential future milestone payments and high single digit to double digit royalties on future net sales up to $46 million. In addition, Lee's Pharma will invest $3.6 million by purchasing common stock in Sorrento at a substantial premium to the current market price.

STI-A1014 was discovered using Sorrento's proprietary G-MAB® library platform, which has the potential to generate a variety of unique antibodies for internal development or for partnerships. Lee's Pharma plans to start a **Phase I** clinical trial of the anti-PD-L1 antibody in China in 2015.

Despite the rapid growth of mAbs, there are still considerable unmet medical needs. One area is the development of antibodies targeting **immune checkpoints** — immunotherapies for cancer and other indications. Both CTLA-4 and PD-1/PDL-1 inhibitors have shown impressive results in clinical care and in ongoing clinical studies. Recent approval of **Yervoy** (CTLA-4 antibody from BMS) and **Keytruda** (PD-1 antibody from Merck) demonstrated the importance of immune checkpoint inhibitors in the treatment of cancer. We think the cancer immunotherapy by immune checkpoint inhibitors will enter widespread clinical use and will command a large market share of the cancer care market within the next decade.

We welcome this partnership and think it's positive to the Sorrento. The partnership not only boosts the Company's balance sheet in a non-dilutive way, but also validates its antibody technology.

Strong Balance Sheet

As of June 30, 2014, Sorrento had $50.2 million in cash and cash equivalents.

In May, 2014, Sorrento closed an underwritten public offering of 4,765,000 shares of common stock at a public offering price of $5.25 per share. The underwriters also exercised in full their option to purchase an additional 714,750 shares of common stock from the Company at $5.25 per share to cover over-allotments, bringing total gross proceeds from this offering to approximately $28.8 million before deducting underwriting discounts and commissions and other offering expenses.

This financing not only boosted the Company's balance sheet, but also validates Sorrento's technology and clinical programs.

We estimate current cash balance can last into the end of 2015.

Valuation is Attractive

We maintain our Outperform rating on Sorrento shares. Our 12-month price target is $15.00. 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 the end of 2015 according to our financial model.

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.

Current share price of $3.5 values the company at $102 million in market cap based on 29 million outstanding shares. This is 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. 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 $1.26 based on total revenue of $176.8 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 $1.26, we arrive at our price target of $15.o0 per share using 30% discount rate. Our target price values Sorrento at $435 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:** Market fluctuation will also impact our price target though it's independent from the company's fundamentals.

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	$0.10	$0.08	$0.08	$0.08	$0.34	$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/Service revenue	$0.00	$0.00	$0.00	$0.01	$0.01	$0.88	$0.69	$0.00	$0.00	$1.57	$0.00	$5.00	$85.00	$175.00
Total Revenues	**$0.13**	**$0.14**	**$0.08**	**$0.10**	**$0.46**	**$0.98**	**$0.78**	**$0.08**	**$0.08**	**$1.91**	**$1.80**	**$6.80**	**$86.80**	**$176.80**
YOY Growth	19.7%	-35.7%	-38.4%	-18.8%	-21.2%	628.0%	447.3%	-4.5%	-20.6%	315.3%	-5.8%	277.8%	1176.5%	103.7%
CoGS	0.00	0.00	0.00	0.00	0.00	0.56	0.51	0.00	0.00	1.07	0.00	1.02	13.02	26.52
Gross Income	**$0.13**	**$0.14**	**$0.08**	**$0.10**	**$0.46**	**$0.41**	**$0.27**	**$0.08**	**$0.08**	**$0.84**	**$1.80**	**$5.78**	**$73.78**	**$150.28**
Gross Margin	100.0%	100.0%	100.0%	95.6%	99.0%	42.3%	34.2%	100.0%	100.0%	43.9%	100.0%	85.0%	85.0%	85.0%
R&D	$1.40	$3.35	$2.08	$8.17	$15.00	$6.32	$5.31	$6.50	$7.50	$25.63	$32.50	$35.50	$32.00	$30.00
% R&D	1043.3%	2366.6%	2485.1%	8113.7%	3260.3%	647.1%	685.0%	8125.0%	9375.0%	1340.9%	1805.6%	522.1%	36.9%	17.0%
SG&A	$1.25	$1.51	$1.11	$2.45	$6.32	$3.39	$2.36	$2.50	$2.50	$10.75	$13.50	$30.00	$50.00	$60.00
%SG&A	932%	1065%	1330%	2428%	1373%	347%	305%	3125%	3125%	562%	750%	441%	58%	34%
Amortization	$0.00	$0.00	$0.19	$0.61	$0.80	$0.59	$0.59	$0.60	$0.60	$2.37	$2.90	$2.90	$2.90	$2.90
Operating Income	**($2.5)**	**($4.7)**	**($3.3)**	**($11.1)**	**($21.7)**	**($9.9)**	**($8.0)**	**($9.5)**	**($10.5)**	**($37.9)**	**($47.1)**	**($62.6)**	**($11.1)**	**$57.4**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	32.45%
Other Net	($0.0)	($0.0)	($0.0)	($0.2)	($0.2)	($0.2)	($0.5)	($0.1)	($0.1)	($0.9)	($0.1)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($2.5)**	**($4.7)**	**($3.4)**	**($11.3)**	**($21.9)**	**($10.1)**	**($8.5)**	**($9.6)**	**($10.6)**	**($38.8)**	**($47.2)**	**($62.7)**	**($11.2)**	**$57.3**
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)**	**($10.1)**	**($8.5)**	**($9.6)**	**($10.6)**	**($38.8)**	**($47.2)**	**($62.7)**	**($11.2)**	**$56.8**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-608.2%
Net Margin	-	-	-	-	-	-	-	-	-	-	-			
Diluted Shares Out	12.3	13.4	14.1	20.3	15.0	23.1	25.3	28.0	28.0	26.1	30.0	35.0	40.0	45.0
Reported EPS	**($0.20)**	**($0.35)**	**($0.24)**	**($0.56)**	**($1.46)**	**($0.44)**	**($0.33)**	**($0.34)**	**($0.38)**	**($1.49)**	**($1.57)**	**($1.79)**	**($0.28)**	**$1.26**
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)**	**($10.1)**	**($8.5)**	**($9.6)**	**($10.6)**	**($38.8)**	**($47.2)**	**($62.7)**	**($11.2)**	**$56.8**
Non GAAP EPS	**($0.20)**	**($0.35)**	**($0.24)**	**($0.56)**	**($1.46)**	**($0.44)**	**($0.33)**	**($0.34)**	**($0.38)**	**($1.49)**	**($1.57)**	**($1.79)**	**($0.28)**	**$1.26**

Source: Company filings and Zacks estimates

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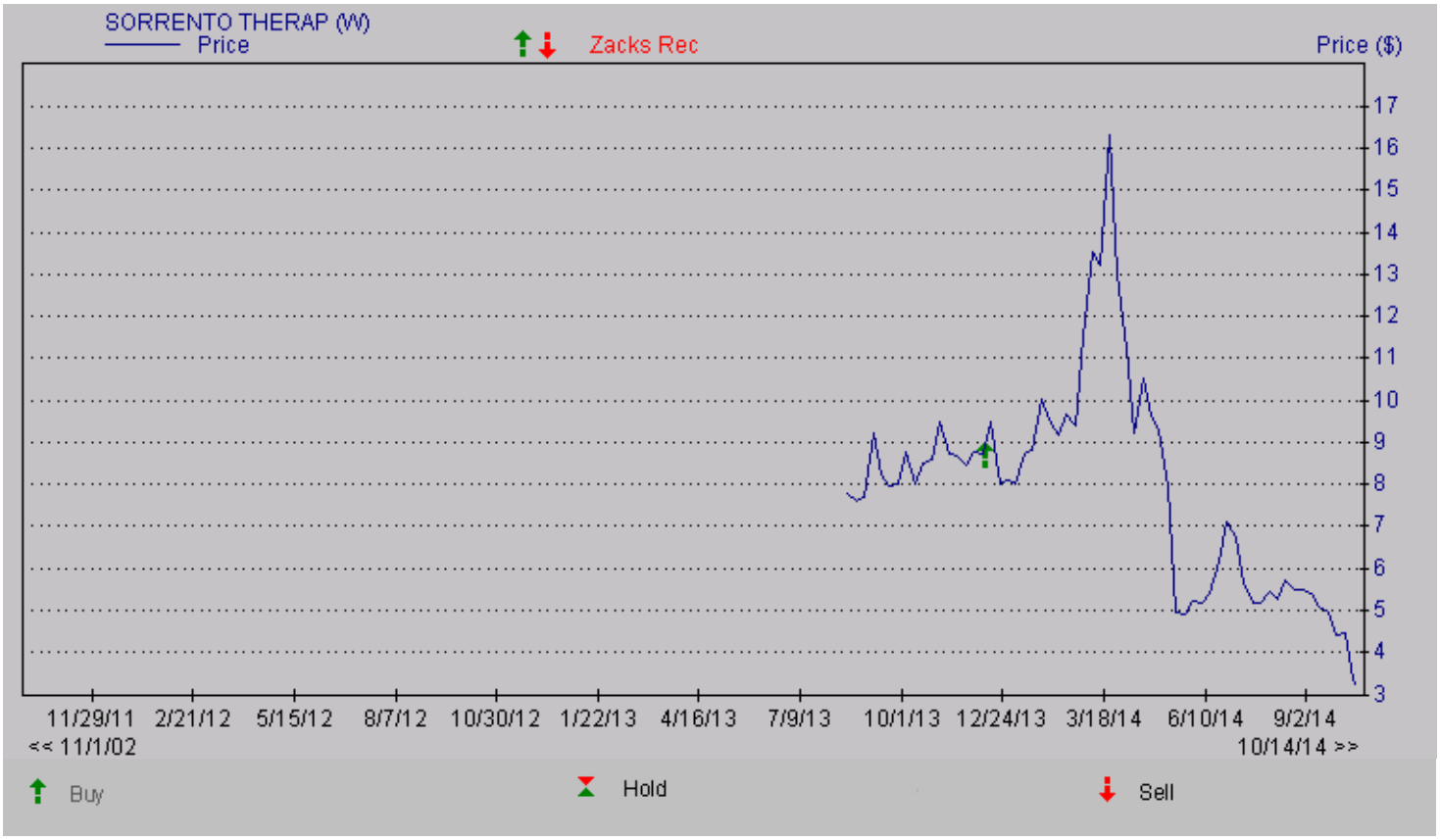

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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