Zacks Small-Cap Research

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Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

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

Sorrento Therapeutics (SRNE-NASDAQ)

SRNE: Enrollment completed for TRIBECA trial, Alliance with Nantworks not only boosts balance sheet but also validates Sorrento's antibody technology--- Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	12/10/2013
Current Price (03/13/15)	$13.20
Twelve- Month Target Price	**$20.00**

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	**$3.21**
One-Year Return (%)	**-23.00**
Beta	**1.24**
Average Daily Volume (sh)	**147,400**
Shares Outstanding (mil)	**36**
Market Capitalization ($mil)	**$475**
Short Interest Ratio (days)	**1.26**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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)
2014	0.98 A	0.78 A	1.28 A	0.80 A	3.83 A
2015	0.90 E	1.00 E	1.10 E	1.20 E	4.20 E
2016					6.80 E
2017					

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.44 A	-$0.33 A	-$0.27 A	-$0.29 A	-$1.30 A
2015	-$0.31 E	-$0.33 E	-$0.37 E	-$0.38 E	-$1.39 E
2016					-$1.65 E
2017					-$0.28 E

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

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WHAT'S NEW

- ***Enrollment in the Cynviloq™ Registrational TRIBECA™ Study Completed;***
- ***Alliance with Nantworks not only boosts balance sheet ,but also validates Sorrento's antibody technology;***
- ***Positive initial PK data for TIBECA study reported, modifies protocol to accelerate approval of Cynviloq;***
- ***Collaboration with Conkwest further expands pipeline;***
- ***We maintain our Outperform rating and raise our PT to $20.00 per share from previous $15.00 per share;***

Enrollment in the Cynviloq™ Registrational TRIBECA™ Study Completed

In January, Sorrento announced the completion of enrollment in the Cynviloq registrational TRIBECA study. Total of 111 patients has been randomized. Patients were enrolled globally from sites in USA, Eastern Europe, and Asia. The ongoing safety assessment from treated patients continues to reveal no unexpected adverse events and the data is consistent with the toxicity profile reported in the literature with albumin-bound paclitaxel.

In October 2014, Sorrento announced positive pharmacokinetic (PK) data from the first eight patients enrolled in the TRIBECA study.

The Original Design of Pivotal Trial of Cynviloq

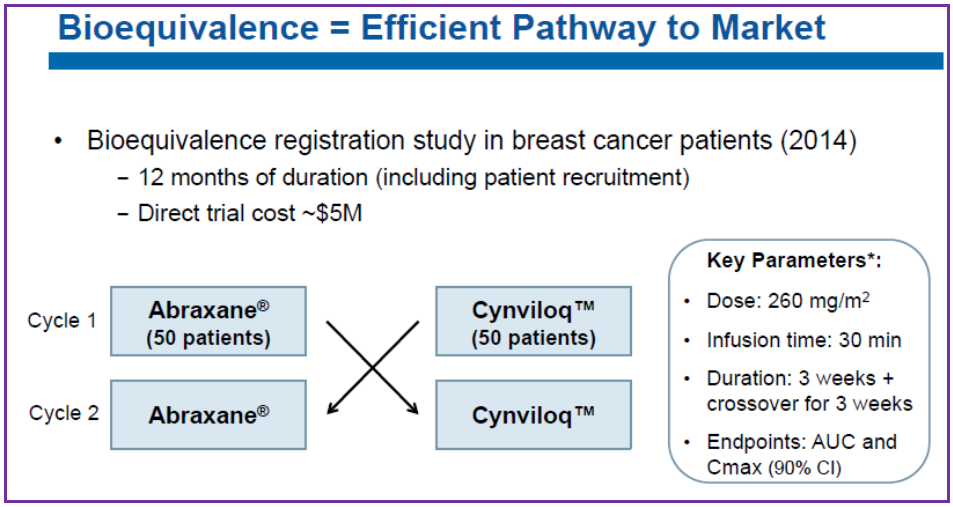
In March, 2014, Sorrento initiated the **pivotal clinical trial** of **Cynviloq** for the treatment of metastatic breast cancer and non-small cell lung cancer.

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.

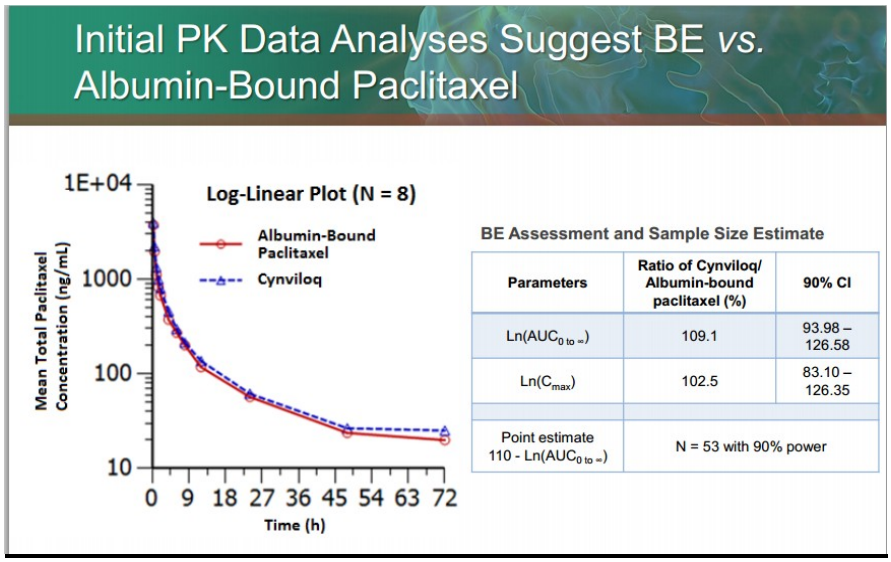


Source: company presentation

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.

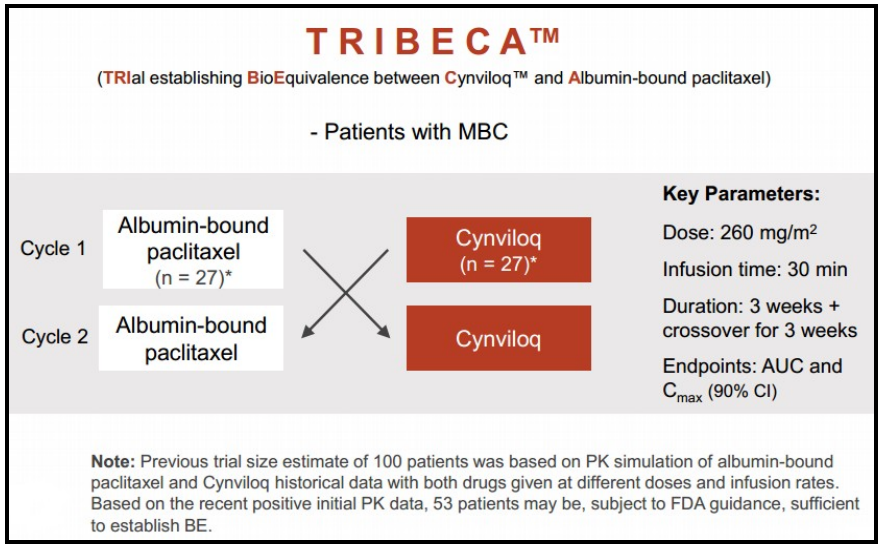
These data support earlier completion of the study.



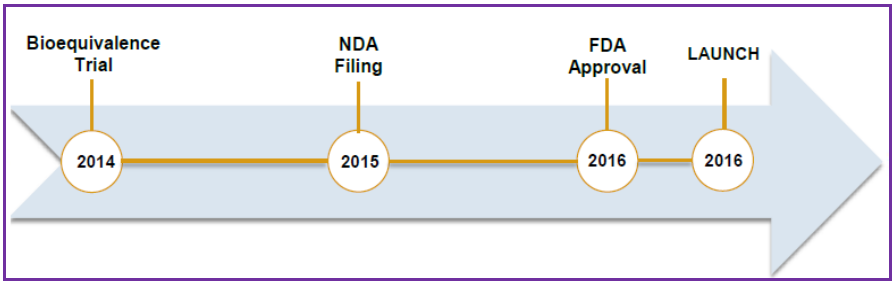
The Modified Trial Protocol

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 Establishes Collaboration with Nantworks

The Deals

In Dec, 2014, Sorrento entered into a binding agreement with NantWorks founder, physician scientist, and biotechnology entrepreneur Dr. Patrick Soon-Shiong.

Pursuant to the agreement, NantWorks and Sorrento will establish a first joint venture **NantiBody, LLC** to jointly develop next generation immunotherapies for the treatment of cancer and auto-immune diseases. The Immunotherapy Antibody JV will be an independent biotechnology company with **$20** million initial joint funding. As part of a strategic investment, Dr. Soon-Shiong's affiliated entity will acquire a **19.9%** equity stake in Sorrento by purchasing common stock priced at $5.80 per share. In addition, Sorrento granted the investor a 3-year warrant to purchase 1,724,138 shares of common stock at an exercise price of $5.80 per share.

The JV will focus on the development of multiple immuno-oncology monoclonal antibodies (mAbs) for the treatment of cancer, including but not limited to anti-PD-1, anti-PD-L1, anti-CTLA4 mAbs, and other immune-check point antibodies as well as antibody drug conjugates (ADCs) and bispecific antibodies.

It's our belief that Nantworks will provide the majority of the initial $20 million funding for the joint venture and that Sorrento will provide its technology and some cash funding for the JV.

In Mar, 2015, the two companies entered into another binding agreement to initiate a **global collaboration** to discover and develop novel anti-cancer immunotherapies derived from Sorrento's proprietary G-MAB® library against neoepitopes of tumor-specific antigens discovered using NantWorks' proprietary pan-omics based, precision medicine approach.

Under the terms of the agreement, Sorrento will exclusively license to **NantCell, LLC**, a NantWorks company, certain antibodies and CAR-TNK™ products in exchange for $10 million in cash and $100 million in NantCell's equity. In addition to the equity and cash payments, Sorrento will also have a share of all future profits resulting from the collaboration.

Our Takeaways from the Two Deals

This is extremely exciting news for Sorrento in a few aspects.

First, the deals immediately boosts Sorrento's balance sheet. Proceeds from the 19.9% equity investment generates over $40 million cash to Sorrento. The warrants will generate another $10 million for Sorrento if Nantworks chooses to exercise. The second deal also provides $10 million in cash and $100 million in NantCell's equity for Sorrento. As of December 31, 2014, Sorrento had $72 million in cash and cash equivalents. Current cash balance can at least last into mid-2016.

Second, the deal with NantWorks further validates Sorrento's antibody technology. Over the years, Sorrento has developed two important drug development platforms: **G-MAB®** library and antibody drug conjugate (**ADC)** technology. Sorrento's G-MAB® library is one of the industry's most diverse **fully human** antibody libraries available in the market today. And its proprietary C-lock™ and K-lock™ **conjugation chemistries** enable site-specific conjugation of toxins to the antibody, which will produce next generation **homogenous ADCs** with well-defined drug antibody ratios (DAR).

Third, the collaborations will accelerate the development of Sorrento's diverse portfolio of fully human monoclonal antibodies, ADCs, and bispecific antibodies. Management of Sorrento has been actively seeking strategic alliance in order to accelerate the development of its programs. The deal underscores Sorrento's commitment. Combination of Sorrento's antibody technology with Nantworks' proprietary genomic and molecular profiling technologies will bring drug candidates into clinic more quickly.

Fourth, this is the first JV between Sorrento and Nantworks. This JV could go public soon. Based on the advancement of the first JV, the two companies could establish more joint ventures in the future in different therapeutic areas to develop first-in-class drug candidates.

Collaboration with Conkwest Expands Sorrento's Pipeline

In Dec 2014, Sorrento and **Conkwest** entered into a definitive agreement to jointly develop next generation CAR-TNK™ immunotherapies for the treatment of cancer.

Conkwest is a privately-held immuno-oncology company focused on developing proprietary Neukoplast®(NK-92™), a Natural Killer (NK) cell-line based therapy. The CAR-TNK technology platform combines Conkwest's proprietary Neukoplast cell line with Sorrento's proprietary G-MAB® fully human antibody technology and CAR designs to further enhance the potency and targeting of Neukoplast.

Under the terms of the agreement, Sorrento and Conkwest will establish an exclusive global strategic collaboration focused on accelerating the development of CAR-TNKs for the treatment of cancers. Both companies will jointly own and share development costs and revenues from any developed CAR-TNK products. As part of the transaction, Sorrento will make a $9 million strategic equity investment in Conkwest and provide $2 million in research credit payments towards the development of novel CAR-TNK cell lines.

Conkwest's "off-the-shelf" CAR-TNK approach utilizes bioreactor-grown NK-92 cell line, Neukoplast, as the immune effector cells. These Neukoplast cells can be re-engineered in a virus-free process to express surface receptors using Sorrento's G-MAB library to yield a stable line of effector cells that recognize and target specific antigens on tumor cells. The CAR-TNK cells can also be generated and produced in large quantities, thereby obviating the need for expensive, decentralized 'biologistics'- a critical drawback of current CAR-T and dendritic cell therapies.

Sorrento plans to rapidly move several of the CAR-TNK cell lines into the clinic to offer patients suffering from hematological malignancies and solid tumors an innovative immunotherapy to fight their cancers.

We Maintain Our Outperform Rating on Sorrento Shares

We maintain our Outperform rating on Sorrento share and raise our 12-month price target to $20.00 from previous $18.00 per share.

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. At the end of 2014, the company held $72 million in cash, which can last at least into mid-2016 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 $13 values the company at $468 million in market cap based on 36 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 30x which is the biotech industry average P/E ratio. Based on our 2018 EPS of $1.26, we arrive at a price of $20.00 per share using 25% discount rate for three years.

Our target price values Sorrento at $720 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.

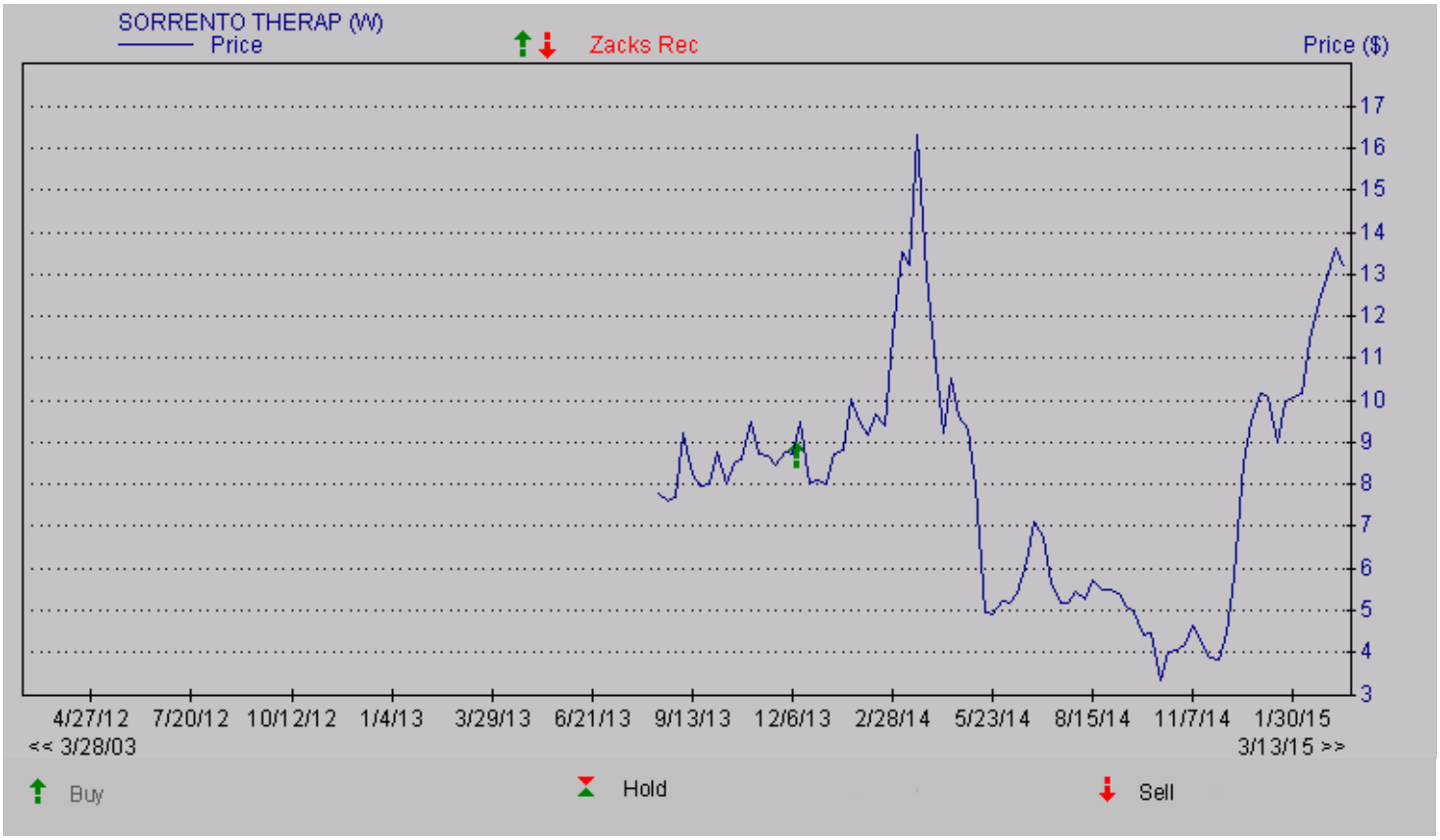
PROJECTED INCOME STATEMENT

	2014 (Dec)					2015E (Dec)					2016E (Dec)	2017E (Dec)	2018E (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE
Grant revenue	$0.10	$0.08	$0.15	$0.16	$0.49	$0.15	$0.15	$0.15	$0.15	$0.60	$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
Product/Service revenue	$0.88	$0.69	$1.13	$0.64	$3.34	$0.75	$0.85	$0.95	$1.05	$3.60	$5.00	$85.00	$175.00
Total Revenues	**$0.98**	**$0.78**	**$1.28**	**$0.80**	**$3.83**	**$0.90**	**$1.00**	**$1.10**	**$1.20**	**$4.20**	**$6.80**	**$86.80**	**$176.80**
YOY Growth	628.0%	447.3%	1422.8%	692.5%	731.3%	-7.8%	29.0%	-13.8%	50.4%	9.8%	61.9%	1176.5%	103.7%
CoGS	0.56	0.51	0.53	0.44	2.04	0.50	0.55	0.61	0.66	2.31	1.02	13.02	26.52
Gross Income	**$0.41**	**$0.27**	**$0.75**	**$0.36**	**$1.78**	**$0.41**	**$0.45**	**$0.50**	**$0.54**	**$1.89**	**$5.78**	**$73.78**	**$150.28**
Gross Margin	42.3%	34.2%	58.7%	44.5%	46.6%	45.0%	45.0%	45.0%	45.0%	45.0%	85.0%	85.0%	85.0%
R&D	$6.32	$5.31	$5.44	$7.13	$24.19	$7.50	$8.00	$8.50	$9.00	$33.00	$35.50	$32.00	$30.00
% R&D	647.1%	685.0%	426.3%	893.1%	632.5%	833.3%	800.0%	772.7%	750.0%	785.7%	522.1%	36.9%	17.0%
SG&A	$3.39	$2.36	$1.85	$2.39	$9.99	$3.00	$3.50	$4.50	$5.00	$16.00	$30.00	$50.00	$60.00
%SG&A	347%	305%	145%	299%	261%	333%	350%	409%	417%	381%	441%	58%	34%
Amortization	$0.59	$0.59	$0.59	$0.59	$2.35	$0.59	$0.59	$0.59	$0.59	$2.36	$2.90	$2.90	$2.90
Operating Income	**($9.9)**	**($8.0)**	**($7.1)**	**($9.7)**	**($34.7)**	**($10.7)**	**($11.6)**	**($13.1)**	**($14.1)**	**($49.5)**	**($62.6)**	**($11.1)**	**$57.4**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	32.45%
Other Net	($0.2)	($0.5)	($0.5)	($0.5)	($1.6)	($0.5)	($0.5)	($0.5)	($0.5)	($2.0)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($10.1)**	**($8.5)**	**($7.6)**	**($10.2)**	**($36.4)**	**($11.2)**	**($12.1)**	**($13.6)**	**($14.6)**	**($51.5)**	**($62.7)**	**($11.2)**	**$57.3**
Income taxes(benefit)	$0.0	$0.0	$0.0	($1.7)	($1.7)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.5
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($10.1)**	**($8.5)**	**($7.6)**	**($8.5)**	**($34.7)**	**($11.2)**	**($12.1)**	**($13.6)**	**($14.6)**	**($51.5)**	**($62.7)**	**($11.2)**	**$56.8**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-608.2%
Net Margin	-	-	-	-	-	-	-	-	-	-			
Diluted Shares Out	23.1	25.3	28.5	29.8	26.7	36.2	36.5	37.0	38.0	36.9	38.0	40.0	45.0
Reported EPS	**($0.44)**	**($0.33)**	**($0.27)**	**($0.29)**	**($1.30)**	**($0.31)**	**($0.33)**	**($0.37)**	**($0.38)**	**($1.39)**	**($1.65)**	**($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*
Non GAAP Net Income	**($10.1)**	**($8.5)**	**($7.6)**	**($8.5)**	**($34.7)**	**($11.2)**	**($12.1)**	**($13.6)**	**($14.6)**	**($51.5)**	**($62.7)**	**($11.2)**	**$56.8**
Non GAAP EPS	**($0.44)**	**($0.33)**	**($0.27)**	**($0.29)**	**($1.30)**	**($0.31)**	**($0.33)**	**($0.37)**	**($0.38)**	**($1.39)**	**($1.65)**	**($0.28)**	**$1.26**

Source: Company filings and Zacks estimates

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 17.2%, Hold/Neutral- 76.3%, Sell/Underperform – 5.6%. Data is as of midnight on the business day immediately prior to this publication.