

ContraFect Corp

(CFRX-NASDAQ)

CFRX: ContraFect Begins Phase 1 Study of CF-301...

UPDATE

On May 15, 2015, ContraFect Corp. (CFRX) announced financial results for the first quarter of 2015. Net loss for the quarter was \$4.9 million, or \$0.24 per share.

On April 29, 2015 the company announced the commencement of a Phase 1 study of CF-301 for the treatment of Staph blood infections. CF-301 is a bacteriophage lysin, and is being developed as an adjunct to standard of care antibiotics. The study will evaluate safety and pharmacokinetics in healthy volunteers.

| | |
|-------------------------------|----------------|
| Current Recommendation | Buy |
| Prior Recommendation | N/A |
| Date of Last Change | 01/13/2015 |
| Current Price (05/15/15) | \$4.95 |
| Target Price | \$10.00 |

SUMMARY DATA

| | |
|---------------------------|---------|
| 52-Week High | \$5.80 |
| 52-Week Low | \$2.52 |
| One-Year Return (%) | N/A |
| Beta | N/A |
| Average Daily Volume (sh) | 118,086 |

| | |
|-------------------------------|------|
| Shares Outstanding (mil) | 20 |
| Market Capitalization (\$mil) | \$96 |
| Short Interest Ratio (days) | 1.79 |
| Institutional Ownership (%) | 14 |
| Insider Ownership (%) | 5 |

| | |
|----------------------|--------|
| 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 2015 Estimate | N/A |
| P/E using 2016 Estimate | N/A |

| | |
|----------------------|--------------------|
| Risk Level | High, |
| Type of Stock | Small-Blend |
| Industry | Med-Drugs |

ZACKS ESTIMATES

Revenue

(in millions of \$)

| | Q1 | Q2 | Q3 | Q4 | Year |
|------|-------|-------|-------|-------|-------|
| | (Mar) | (Jun) | (Sep) | (Dec) | (Dec) |
| 2014 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2015 | 0 A | 0 E | 0 E | 0 E | 0 E |
| 2016 | | | | | 0 E |
| 2017 | | | | | 0 E |

Earnings per Share

(EPS is operating earnings before non recurring items)

| | Q1 | Q2 | Q3 | Q4 | Year |
|------|-----------|-----------|-----------|-----------|-----------|
| | (Mar) | (Jun) | (Sep) | (Dec) | (Dec) |
| 2014 | -\$5.15 A | -\$8.17 A | -\$1.22 A | -\$0.01 A | -\$3.36 A |
| 2015 | -\$0.24 A | -\$0.28 E | -\$0.29 A | -\$0.29 E | -\$0.92 E |
| 2016 | | | | | -\$0.86 E |
| 2017 | | | | | -\$0.77 E |

WHAT'S NEW

Financial Update

On May 15, 2015, ContraFect Corp. (NASDAQ: CFRX) [announced](#) financial results for the first quarter of 2015. As expected, the company had no revenues during the first quarter. Net loss was \$4.9 million, or \$0.24 per share, and consisted of \$2.4 million in R&D expenses and \$2.3 million in G&A expenses. Actual cash burn for the quarter was approximately \$4.5 million. The company exited the first quarter of 2015 with approximately \$22.9 million in cash and cash equivalents. We estimate that the company has enough cash to fund operations for the next 12 months.

There are currently approximately 20.3 million shares outstanding. In addition, there are approximately 3.8 million stock options and 14.6 million warrants for a fully diluted share count of approximately 37.0 million shares. We remind investors that ContraFect has two separate short term warrants which are traded on NASDAQ with ticker CFRXZ and CFRXW. The Class-B CFRXZ warrants are exercisable at \$4.00 per share and expire on October 31, 2015. Given that these warrants are currently in-the-money and expire in six months, we expect they will be exercised in full at points over the next several months. In total, these warrants would pull in roughly \$13.7 million in new cash (before fees).

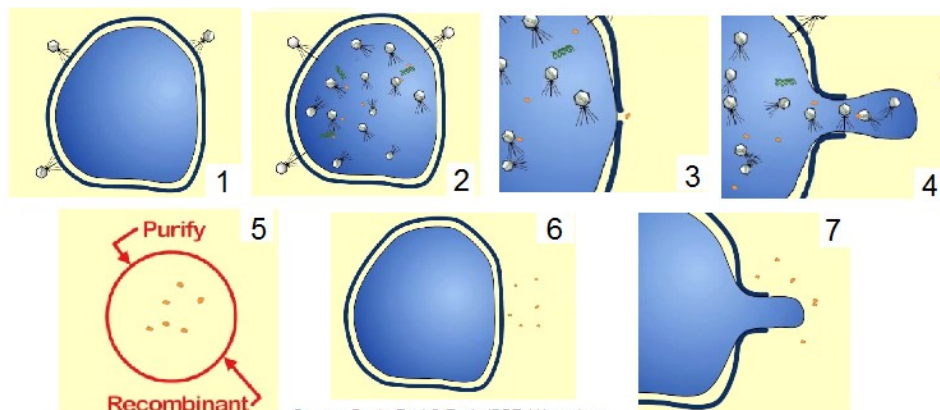
The Class-A CFRXW warrants are exercisable at \$4.80 per share and expire on January 31, 2017. Given that these warrants still have roughly 22 months of remaining life and are currently trading right around the strike price, we are not anticipating any exercising of these warrants in the near-term. However, we note these warrants are callable by ContraFect management should the stock ever trade at 2x the exercise price, or at \$9.60 per share, for a period of 20 trading days. If called, these warrants would pull in roughly \$33.0 million in new cash (before fees).

CF-301 Update

On April 29, 2015, ContraFect [announced](#) that it commenced screening of healthy volunteers for the Phase 1 clinical trial of CF-301 ([NCT02439359](#)). This is a randomized, double blind, placebo controlled, dose ranging trial that is taking place in the U.S. and is designed to test the safety, tolerability, and pharmacokinetics of a single intravenous dose of CF-301. CF-301 is being developed for the treatment of blood infections cause by all strains of *Staphylococcus aureus*, including all drug-resistant phenotypes, and is the first lysin allowed by the U.S. FDA to enter human clinical trials.

...Brief Background on Lysins...

Lysins are natural anti-bacterial hydrolytic enzymes that are produced from a bacteriophage, a virus that infects and kills bacteria. Once inside the bacteria, bacteriophages replicate and produce lysins. Lysins degrade (lyse) bacterial cell walls from the inside, resulting in the bursting of the bacteria. The bursting of the bacteria releases the bacteriophage to infect neighboring bacteria, and so on and so forth. ContraFect's technology is slightly different from the use of bacteriophages as therapeutics. Instead, the company produces and purifies a recombinant form of the lysin to use as an anti-bacterial agent. Lysins are delivered to the infected area and lyse the bacterial cell wall from the outside. The cartoon below ([see video](#)) shows both how lysins produced by bacteriophage and recombinant lysins introduced exogenously destroy bacteria cells:



...Key Advantages of Lysins...

- ✓ **Novel Mechanism of Action:** Lysins represent a first-in-class approach to treatment of bacterial infections. Traditional antibiotics require bacterial cell division and metabolism to occur in order to exert their effect (i.e., cell death or cessation of growth). Lysins are recombinant forms of naturally occurring bacteriophage enzymes that directly digest the cell wall of bacteria. Based on *in vitro* tests, once the cell wall is breached, the bacteria lyse in a [virtually explosive manner](#) due to the high internal osmotic pressure of the cytoplasm, and bacterial cell death ensues.
- ✓ **Rapid Bactericidal Activity:** Lysins kill bacteria immediately upon contact. *In vitro* experiments demonstrated ContraFect's CF-301 to be 12-18x faster than the standard-of-care antibiotics used to treat *Staphylococcus aureus* bacteremia.
- ✓ **Targeted Therapy:** Unlike standard-of-care antibiotics, which are "broad spectrum" and kill the body's natural flora (including the good bacteria) in addition to the disease-causing bacteria, lysins are "narrow spectrum, broad-acting" anti-infective agents. Due to the specificity of a lysin's binding domain and catalytic activity, they are highly specific for given species of bacteria (i.e., *S. aureus*, *S. pneumoniae*, etc.), making them a narrow spectrum anti-infective. However, lysins possess full activity against all resistant strains of those bacteria and are considered broad acting. Consider lysins to be target-specific smart bombs, as opposed to the carpet-bombing effect of broad-spectrum antibiotics. The narrow spectrum of activity will avoid damaging side effects that often occur when conventional antibiotic treatments kill the body's healthy, desirable bacteria.
- ✓ **Active on Drug Resistant Bacteria:** Preclinical studies have demonstrated that ContraFect's lysin candidate CF-301 exhibits activity specific to all forms of *Staphylococcus aureus*, including isolates that are resistant to the antibiotics methicillin (methicillin-resistant *S. aureus*; "MRSA"), vancomycin (vancomycin-resistant *S. aureus*; "VRSA"), and daptomycin (daptomycin-resistant *S. aureus*; "DRSA").
- ✓ **Eradicates Biofilms:** Biofilms render infections up to 1,000-fold more resistant to penetration by antibiotics. Infected human tissues, such as the heart valve in endocarditis or bone in osteomyelitis, or indwelling medical devices, such as central venous catheters, prosthetic joints, and pacemakers, are common sites for biofilm formation, providing a hurdle for effective treatment with antibiotics alone. There are currently no therapeutics available to eradicate biofilms.
- ✓ **Synergy with Standard-of-Care Antibiotics:** Because lysins offer a different mechanism of action with minimal safety or tolerability issues, they can be used in combination with traditional antibiotics. For example, ContraFect's lead lysin candidate, CF-301, has demonstrated a strong synergistic effect in *in vitro* studies when combined with several standard-of-care antibiotics, including daptomycin, vancomycin, and oxacillin.

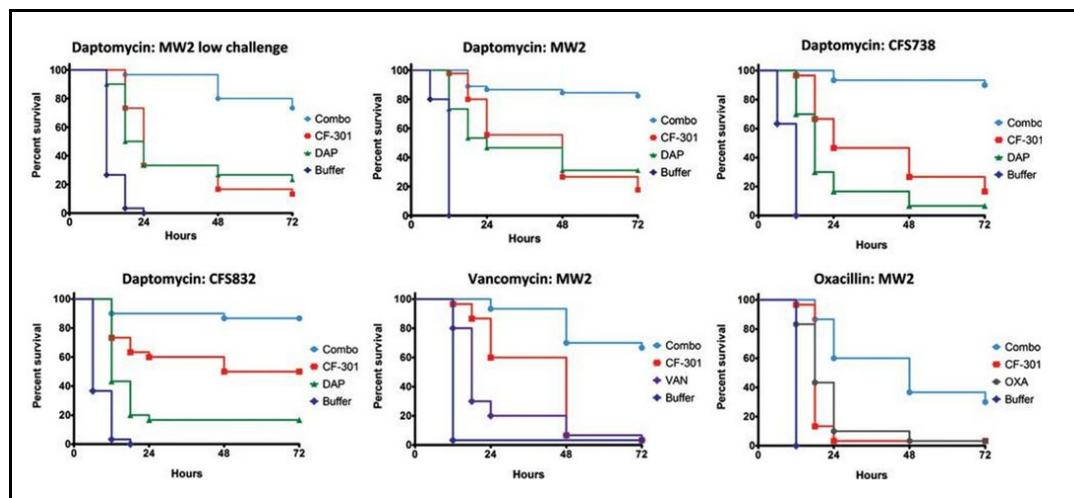
...Preclinical Studies Support the Use of CF-301...

In an *in vitro* study recently published in the Journal of Infectious Diseases ([Schuch et al., 2014](#)), CF-301 demonstrated potent inhibitory activity on 250 *S. aureus* strains, including 103 methicillin-sensitive *S. aureus* (MSSA) and 120 MRSA strains (Table below). CF-301 inhibited growth of MRSA strains additionally resistant to daptomycin, vancomycin, or linezolid. On a molar basis, CF-301 was 2- to 40-fold more potent than the standard of care antibiotics.

| In Vitro Activity of CF-301 and Standard-of-Care Antibiotics Against <i>Staphylococcus aureus</i> | | | | | | | | |
|---|----------------------------|------|------------------------------|------|------------------------------|-------|----------------------------|------|
| Strains (N = 250) | CF-301 (mw = 26 000 Da) | | Daptomycin (mw = 1620 Da) | | Vancomycin (mw = 1486 Da) | | Linezolid (mw = 337 Da) | |
| | µg/mL | µM | µg/mL | µM | µg/mL | µM | µg/mL | µM |
| MSSA (n = 103) | 8 | 0.31 | 1 | 0.62 | 1 | 0.67 | 1 | 3.0 |
| MRSA (n = 120) | 8 | 0.31 | 1 | 0.62 | 1 | 0.67 | 2 | 5.9 |
| DRSA (n = 8) | 4 | 0.15 | 16 | 9.88 | 1 | 0.67 | 2 | 5.9 |
| VRSA (n = 14) | 4 | 0.15 | 1 | 0.62 | >16 | >10.8 | 2 | 5.9 |
| LRSA (n = 5) | 2 | 0.08 | 1 | 0.62 | 1 | 0.67 | >64 | >190 |

Source: Schuch et al., 2014

These promising *in vitro* results also translated to compelling animal studies in which mice were subjected to various *Staphylococcus aureus* strains with CF-301 alone or in combination with various antibiotics currently in the clinic today. In all cases, the combination of CF-301 and antibiotic therapy resulted in increased survival when compared to single drug treatment regimens.

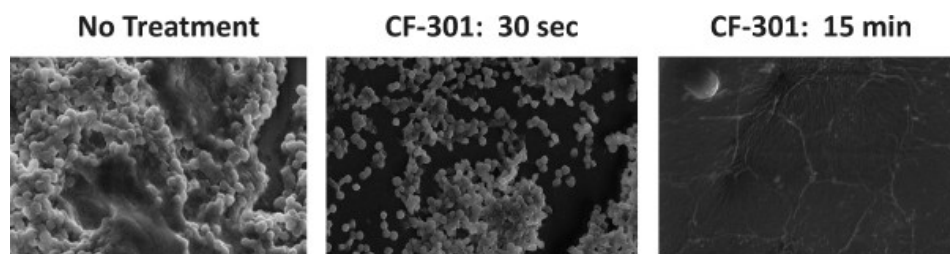


Source: ContraFect

...Biofilm Mechanism Key...

Biofilms are thin and slimy films containing bacteria that adhere to human tissues such as heart valves and bone as well as implanted devices such as catheters, prosthetic joints, and medical devices. These biofilms have been known to be 1000-fold more resistant to antibiotics and have plagued the implant and medical device industry for decades. Biofilms are the root cause for implant failure often resulting in surgery or even death with no viable treatments. Thus, biofilms cost the healthcare system billions of dollars which creates a high unmet need for therapies to alleviate them.

In vitro experiments using CF-301 against cellular cultures of biofilms showed it was a million-fold more potent than antibiotics at destroying biofilms. To further assess CF-301, ContraFect treated catheters inoculated with biofilms with CF-301 and showed it completely neutralized the biofilm on the catheter within 15 minutes of treatment (see below). As a result of this data, the company is pursuing further development of its lysin technology to potentially eradicate biofilms.



Source: ContraFect

Conclusion and Recommendation

CF-301 has demonstrated excellent safety and efficacy in preclinical studies. Looking ahead, we estimate that CF-301 will be in Phase 1 testing in 2015, Phase 2 in 2016, Phase 3 in 2017, with an NDA filing occurring in 2018 and approval in 2019. We also believe that ContraFect is likely to initiate additional lysin programs against other infectious agents that, if successful, would be approved in the years following CF-301 approval.

We forecast peak sales for CF-301 in the \$600 million range with sales in the first two years after approval likely to be in the \$50-100 million range. We base this on the initial sales figures for Cubicin® and Vancocin®, two antibiotics that are utilized for the treatment of MRSA infections. It should be noted that sales of Cubicin® reached \$931 million in 2013 and are estimated to have passed \$1 billion in 2014.

One other consideration for a company such as ContraFect is that there have been a number of acquisitions of companies developing antibiotics in the past couple of years. The table below highlights some of these acquisitions, along with the price and what premium, if any, the acquiring company paid.

| Deal Announced | Purchaser | Co. Acquired | Price | Premium |
|----------------|-----------|--------------|--------|---------|
| 7/30/13 | Cubist | Trius | \$707M | 15% |
| 7/30/13 | Cubist | Optimer | \$535M | - |
| 10/6/14 | Actavis | Durata | \$675M | 66% |
| 12/8/14 | Merck | Cubist | \$9.5B | 35% |

Source: Zacks SCR / Bautz

At this point it is likely premature to discuss ContraFect as a takeover candidate; however, this is certainly something for investors to keep in mind as the company moves CF-301 through clinical trials. A novel anti-bacterial agent that could be utilized in conjunction with currently available antibiotic treatments would likely be an attractive addition for a larger pharmaceutical company.

...CF-404 Offers Additional Upside...

CF-404 is a mixture of monoclonal antibodies that target different strains of the influenza virus. The distinguishing characteristic of CF-404 is that the antibodies target conserved regions of the virus that are not prone to high rates of mutation. A new influenza vaccine is necessary each year due as the different strains of the influenza virus are constantly changing. By targeting the portions of the virus that are not prone to mutation, the company is able to develop one therapeutic that will not need to be continually reformulated.

ContraFect will be positioning CF-404 as a therapeutic option for the approximately 200,000 individuals who are hospitalized each year due to influenza. Preclinical data shows that CF-404 is effective in a mouse model of the H1N1 virus even when dosed up to 96 hours post-infection. This is in stark contrast to Tamiflu® (oseltamivir), an antiviral medication that must be administered within 24 hours of infection in the same model.

The company is planning on conducting additional manufacturing and pre-clinical studies to support filing an investigational new drug (IND) application in 2016, with initiation of Phase 1 clinical trials shortly thereafter.

Given that CF-404 is currently still in pre-clinical development, it is difficult to forecast potential sales figures, although this does not mean that we assign it no value. An analysis of currently available influenza treatments shows that CF-404 likely has the potential to be a \$500 million drug.

| Drug | 2011 | 2012 | 2013 |
|----------|-------|-------|-------|
| Tamiflu* | \$359 | \$560 | \$635 |
| Flulaval | \$359 | \$323 | \$418 |

* in CHF // Source: Zacks SCR / Bautz

...Valuation Methodology for ContraFect...

For CF-301, we forecast the drug will be approved in 2019 and given that the compound is set to enter Phase 1 testing we assign a 25% probability of eventual approval. We estimate peak sales of \$600 million in 2023 and apply a 20% discount rate and approximately 65% operating margins. This leads to a net present value for CF-301 of approximately \$163 million.

For CF-404, we forecast that the drug could potentially reach peak sales of \$500 million four years after approval in 2020. Since CF-404 is still in pre-clinical testing we assign a 15% probability of eventual approval. We estimate 65% operating margins and apply a 20% discount rate that results in a net present value of approximately \$70 million.

ContraFect had \$22.9 million in cash as of March 31, 2015, and will require approximately \$60 million of capital to get both products approved. Adding up all of the assets gives us a total net present value for the company of approximately \$195 million, which divided by the current share count of 20.3 million shares results in a target price of approximately \$10.

PROJECTED INCOME STATEMENT

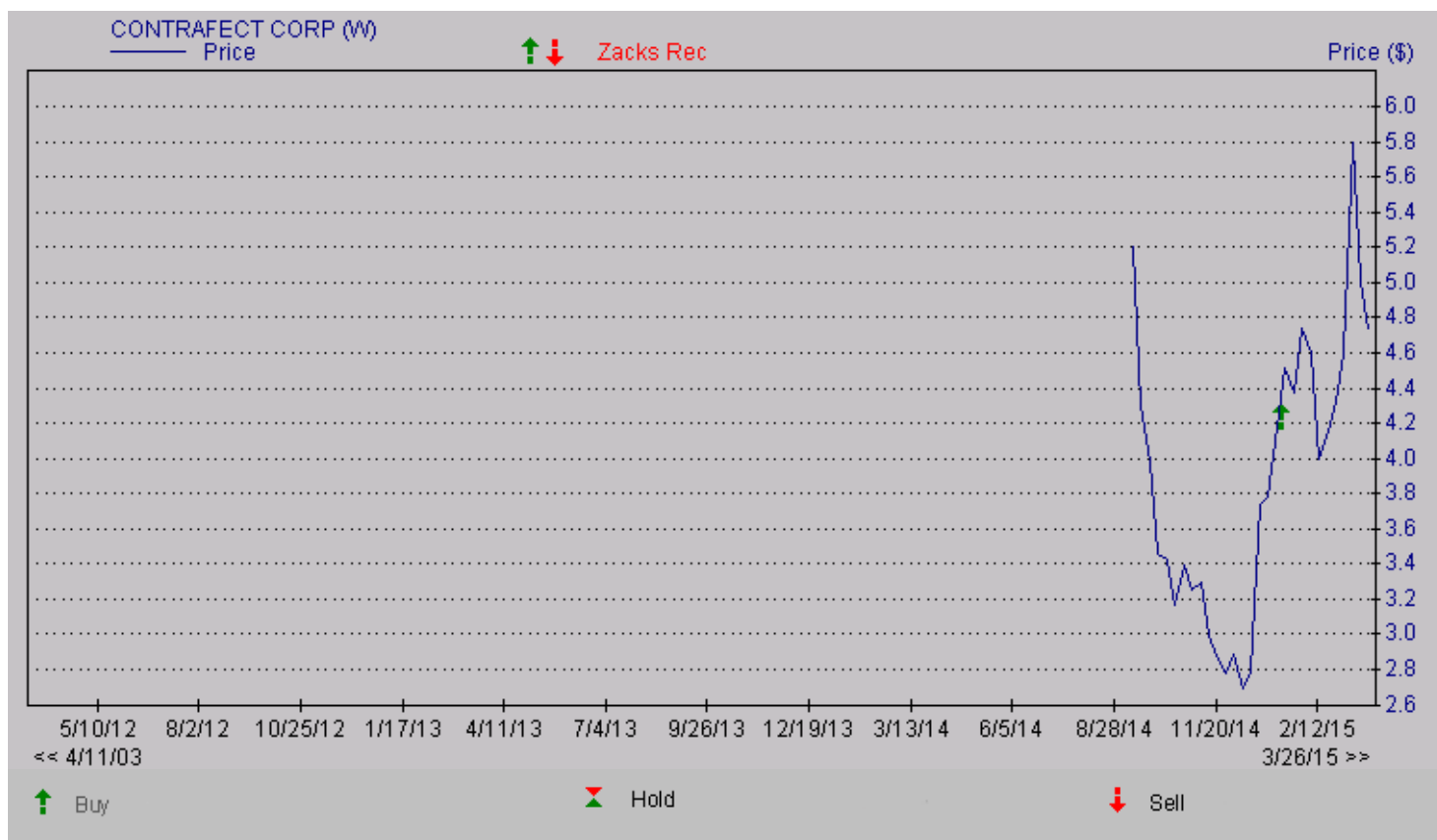
| ContraFect Corp. | 2014 A | Q1 A | Q2 E | Q3 E | Q4 E | 2015 E | 2016 E | 2017 E |
|--------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| CF-301 (Bacteremia) | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| <i>YOY Growth</i> | - | - | - | - | - | - | - | - |
| CF-404 (Flu) | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| <i>YOY Growth</i> | - | - | - | - | - | - | - | - |
| Grants & Collaborative Revenue | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| <i>YOY Growth</i> | - | - | - | - | - | - | - | - |
| Total Revenues | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| <i>YOY Growth</i> | - | - | - | - | - | - | - | - |
| Cost of Sales | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| <i>Product Gross Margin</i> | - | - | - | - | - | - | - | - |
| Research & Development | \$8.9 | \$2.4 | \$2.6 | \$2.7 | \$2.8 | \$10.5 | \$11.0 | \$12.0 |
| General & Administrative | \$8.1 | \$2.3 | \$2.6 | \$2.6 | \$2.6 | \$10.1 | \$10.5 | \$11.0 |
| Other Expenses | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| Operating Income | (\$16.9) | (\$4.7) | (\$5.2) | (\$5.3) | (\$5.4) | (\$20.6) | (\$21.5) | (\$23.0) |
| <i>Operating Margin</i> | - | - | - | - | - | - | - | - |
| Non-Operating Expenses (Net) | (\$13.2) | (\$0.2) | (\$0.5) | (\$0.5) | (\$0.5) | (\$0.1) | (\$0.1) | (\$0.1) |
| Pre-Tax Income | (\$30.1) | (\$4.9) | (\$5.7) | (\$5.8) | (\$5.9) | (\$20.7) | (\$21.6) | (\$23.1) |
| Income Taxes Paid | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| <i>Tax Rate</i> | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Net Income | (\$30.1) | (\$4.9) | (\$5.7) | (\$5.8) | (\$5.9) | (\$20.7) | (\$21.6) | (\$23.1) |
| <i>Net Margin</i> | - | - | - | - | - | - | - | - |
| Reported EPS | (\$3.36) | (\$0.24) | (\$0.28) | (\$0.29) | (\$0.29) | (\$0.92) | (\$0.86) | (\$0.77) |
| <i>YOY Growth</i> | - | - | - | - | - | - | - | - |
| Basic Shares Outstanding | 9.0 | 20.2 | 20.2 | 20.2 | 20.2 | 22.5 | 25.0 | 30.0 |

Source: Zacks Investment Research, Inc.

Jason Napodano, CFA

Source: Company filings and Zacks estimates

HISTORICAL ZACKS RECOMMENDATIONS



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The current distribution is as follows: Buy/Outperform- 15.3%, Hold/Neutral- 78.6%, Sell/Underperform – 5.9%. Data is as of midnight on the business day immediately prior to this publication.