Zacks Small-Cap Research

August 26, 2015
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# ContraFect Corp (CFRX-NASDAQ)

***CFRX: Phase 1 Study of CF-301 To Finish Before The End of 2015…***

| | |
|---|---|
| **Current Recommendation** | **Buy** |
| Prior Recommendation | N/A |
| Date of Last Change | 01/13/2015 |
| Current Price (08/26/15) | $5.05 |
| **Target Price** | **$10.00** |

## UPDATE

On August 13, 2015, ContraFect Corp. (CFRX) announced financial results for the first quarter of 2015. Net loss for the quarter was $7.1 million, or $0.33 per share.

On August 11, 2015 the company announced that an independent Data Safety Monitoring Board recommended the continuation of the CF-301 Phase 1 study, which has thus far successfully completed two of out four planned dose levels in healthy volunteers. The study should be completed by the end of 2015.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$5.93** |
| **52-Week Low** | **$2.52** |
| **One-Year Return (%)** | **N/A** |
| **Beta** | **N/A** |
| **Average Daily Volume (sh)** | **52,921** |
| **Shares Outstanding (mil)** | **25** |
| **Market Capitalization ($mil)** | **$127** |
| **Short Interest Ratio (days)** | **2.35** |
| **Institutional Ownership (%)** | **4** |
| **Insider Ownership (%)** | **25** |
| **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 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2015 | 0 A | 0 A | 0 E | 0 E | 0 E |
| 2016 | | | | | 0 E |
| 2017 | | | | | 0 E |

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

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2014 | -$5.15 A | -$8.17 A | -$1.22 A | -$0.01 A | -$3.36 A |
| 2015 | -$0.24 A | -$0.33 A | -$0.29 E | -$0.29 E | -$1.01 E |
| 2016 | | | | | -$0.86 E |
| 2017 | | | | | -$0.77 E |

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## WHAT'S NEW

### Financial Update

On August 13, 2015, ContraFect Corp. (NASDAQ: CFRX) announced financial results for the second quarter of 2015. As expected, the company reported no revenues for the quarter. Net loss was $7.1 million, or $0.33 per share, and was comprised of $4.3 million in R&D expenses and $2.9 million in G&A expenses. Actual cash burn for the quarter was approximately $5.9 million. The company exited the second quarter of 2015 with approximately $35.3 million in cash and cash equivalents. This is due in part to a $20 million private placement in which the company sold 4.73 million shares of common stock for $4.23 per share. In addition, each purchaser of common stock was granted a warrant to purchase one-half share of common stock at an exercise price of $8.00. Based on the current cash position, we estimate that the company has enough cash to fund operations for at least the next 12 months.

Currently, there are approximately 25.1 million shares of common stock outstanding. In addition, there are approximately 4.1 million stock options and 17.1 million warrants for a fully diluted share count of approximately 46.3 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 two 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 17 months of remaining life and are currently trading close to 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

ContraFect's lead candidate is CF-301, a bacteriophage lysin targeted for the treatment of bacteremia (bloodstream infection) caused by *Staphylococcus aureus*, including all drug-resistant phenotypes. The company has commenced a Phase 1 clinical trial of CF-301 in healthy volunteers (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 the first lysin allowed by the U.S. FDA to enter human clinical trials.

#### S. Aureus *Bacteremia*

Infections of the bloodstream, particularly those caused by *S. aureus*, represent a significant medical challenge. While difficult to ascertain an exact figure, most studies estimate the incidence of *S. aureus* bacteremia (SAB) ranging from 20-50 cases/100,000 population (Klevens *et al*., 2007; Benfield *et al*., 2006; El Atrouni *et al*., 2009). Prior to the advent of antibiotics, the mortality rate from SAB was close to 80% (Mendell, 1939). The introduction of antibiotics, coupled with greater standards of care, has reduced the mortality rate, which appears to have stabilized at approximately 20% (Turnidge *et al*., 2009). SAB can frequently lead to infective endocarditis (IE), an infection of the endocardial surface of the heart (Fowler *et al*., 2005). The prevalence of IE is estimated to be anywhere from 11 to 50% of patients with SAB. Development of IE leads to an increased risk of embolic event and death (Miro *et al*., 2005).

The treatment of choice for *S. aureus* infections is penicillin, however in most countries penicillin resistance is extremely common. Thus, first-line treatment for most *S. aureus* infections is a penicillinase-resistant β-lactam antibiotic such as oxacillin. Antibiotic resistance in *S. aureus* was uncommon when penicillin was first introduced; in fact the petri dish that Sir Alexander Fleming first observed the antibacterial activity of the *Penicillium* fungus was growing a culture of *S. aureus*. However, by 1950, 40% of *S. aureus* isolates were penicillin resistant and by 1960 the rate had grown to 80% (Chambers, 2001).

Resistance to penicillin is due to the activity of the enzyme penicillinase, which cleaves the β-lactam ring of the penicillin molecule. Penicillinase-resistant β-lactam antibiotics include methicillin, oxacillin, and flucoxacillin. *S.*

*aureus* strains that have acquired resistance to methicillin have an altered penicillin-binding protein (PBP2a) that has lower affinity for binding β-lactam antibiotics, thus rendering them ineffective. Strains that have acquired this resistance are referred to as methicillin-resistant *S. aureus* (MRSA). *S. aureus* strains that are sensitive to the penicillinase-resistant β-lactam antibiotics are said to be methicillin-sensitive (MSSA). It is currently estimated that more than 40% of SAB are caused by MRSA (Styers *et al*., 2006).

The current gold standard for treatment of MRSA is vancomycin. However, vancomycin is far from ideal due to poor tissue penetration, slow bactericidal activity, and a number of side effects (Gould, 2008). Additional antibiotics utilized include teicoplanin, tegecyline, linezolid, daptomycin, and televancin. Each of those medications has their own shortcomings, including the development of resistance, thus there exists a significant unmet medical need for newer therapies, particularly those that are not susceptible to the development of resistance.

***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 involves the production and purification of a recombinant form of a lysin to use as an anti-bacterial agent. Lysins are delivered to the infected area and lyse the bacterial cell wall from the outside directly upon contact. This 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 the 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 a 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 *S. aureus*, including isolates that are resistant to the antibiotics methicillin (MRSA), vancomycin (VRSA), and daptomycin (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***

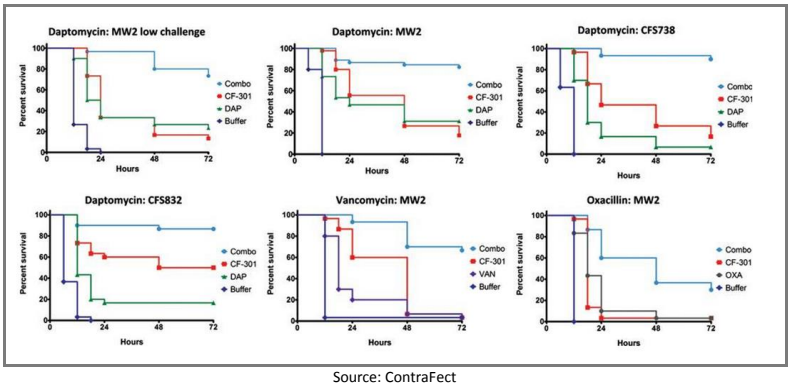
In an *in vitro* study published in the Journal of Infectious Diseases (Schuch *et al*., 2014), CF-301 demonstrated potent inhibitory activity on 250 *S. aureus* strains, including 103 MSSA and 120 MRSA strains (Table below). CF-301 inhibited growth of MRSA strains additionally resistant to daptomycin, 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 *Staphylococcus aureus***

| | CF-301 (mw = 26 000 Da) | | Daptomycin (mw = 1620 Da) | | Vancomycin (mw = 1486 Da) | | Linezolid (mw = 337 Da) | |
|---|---|---|---|---|---|---|---|---|
| Strains (N = 250) | 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 *S. 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 regiments.

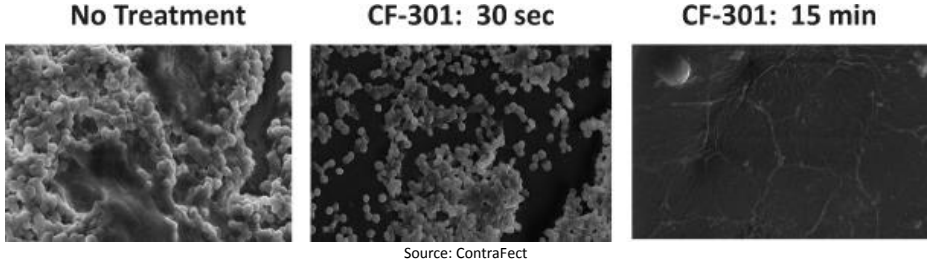



Source: ContraFect

***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

### *Update on Phase 1 Study*

On May 21, 2015, ContraFect initiated dosing of healthy volunteers with CF-301 in a randomized, double blind, placebo controlled, dose ranging Phase 1 study in order to evaluate the safety, tolerability, and pharmacokinetics of CF-301 when administered alone. The company provided the first update on the trial on August 11, 2015, with the announcement that the independent Data Safety Monitoring Board (DSMB) recommended the continuation of the Phase 1 trial. At the time of the announcement, two of the four planned dosing levels had been successfully administered to healthy volunteers. The DSMB is reviewing the data after each dosing level is complete before the study can advance to the next level. We anticipate the Phase 1 study will be complete by the end of 2015 and, if no adverse events are detected, that the company can initiate a Phase 2 study of CF-301 in conjunction with standard of care antibiotics in patients with SAB in 2016.

### *CF-301 Intellectual Property and Fast Track Designation*

On July 17, 2015, ContraFect announced the issuance of U.S. Patent No. 9,034,322 titled "Streptococcus bacteriophage lysins for detection and treatment of gram positive bacteria". The patent, which contains composition claims for CF-301 sequences and variants having at least 80% similarity, was assigned to Rockefeller University and ContraFect is the exclusive licensee. The expiration date for the patent is April 20, 2032, thus providing intellectual property protection for CF-301 for the next 16.5 years.

On August 17, 2015, ContraFect announced that the FDA has granted Fast Track designation to CF-301. The Fast Track program was put into place under the FDA Modernization Act of 1997 and is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. A company that receives Fast Track designation for a drug is eligible for the following:

- More frequent meetings with the FDA to discuss the drug's development plan and ensure that the appropriate data is being collected to support drug approval.
- More frequent written communication from the FDA about things such as clinical trial design.
- Eligibility for accelerated approval and priority review, including the submission of a New Drug Application (NDA) or a Biologics License application (BLA) on a rolling basis. What this means is that a company can submit completed sections of an NDA or BLA as they are completed and have them reviewed by the FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

Resistance to standard of care antibiotics is a danger that necessitates the development of novel anti-bacterial therapies. Since CF-301 is the first lysin to enter clinical testing, the Fast Track designation will be very helpful to ContraFect as it will allow frequent communication between the FDA and the company to ensure that the clinical trials are being performed properly and the necessary data are being obtained that the FDA believes will be important for gaining approval.

### *Conclusion and Recommendation*

CF-301 has demonstrated excellent safety and efficacy in preclinical studies. Thus far, the company has successfully treated healthy volunteers with two different doses of CF-301. If there are no safety issues noted during the rest of the Phase 1 study (which we believe will conclude before the end of 2015), we estimate that CF-301 will be in Phase 2 testing 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 $900 million range with sales in the first three years after approval likely to be in the $100-200 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 $1.1 billion worldwide 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 in Phase 1 testing we assign a 25% probability of eventual approval. We estimate peak sales of $900 million in 2024 and apply a 20% discount rate and approximately 65% operating margins. This leads to a net present value for CF-301 of approximately $207 million.

For CF-404, we forecast that the drug could potentially reach peak sales of $500 million five 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 $56 million.

ContraFect had $35.3 million in cash as of June 30, 2015, and will require approximately $50 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 $248 million, which divided by the current share count of 25.1 million shares results in a target price of approximately $10.

## PROJECTED INCOME STATEMENT

| ContraFect Corp. | 2014 A | Q1 A | Q2 A | Q3 E | Q4 E | 2015 E | 2016 E | 2017 E |
|---|---|---|---|---|---|---|---|---|
| **CF-301 (Bacteremia)** | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *YOY Growth* | - | - | - | - | - | - | - | |
| **CF-404 (Flu)** | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *YOY Growth* | - | - | - | - | - | - | - | |
| **Grants & Collaborative Revenue** | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *YOY Growth* | - | - | - | - | - | - | - | |
| **Total Revenues** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| *YOY Growth* | - | - | - | - | - | - | - | |
| Cost of Sales | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Product Gross Margin* | - | - | - | - | - | - | - | |
| Research & Development | $8.9 | $2.4 | $4.3 | $2.7 | $2.8 | $12.2 | $11.0 | $12.0 |
| General & Administrative | $8.1 | $2.3 | $2.9 | $2.6 | $2.6 | $10.3 | $10.5 | $11.0 |
| Other Expenses | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Operating Income | ($16.9) | ($4.7) | ($7.2) | ($5.3) | ($5.4) | ($22.6) | ($21.5) | ($23.0) |
| *Operating Margin* | - | - | - | - | - | - | - | |
| Non-Operating Expenses (Net) | ($13.2) | ($0.2) | $0.0 | ($0.5) | ($0.5) | ($0.1) | ($0.1) | ($0.1) |
| Pre-Tax Income | ($30.1) | ($4.9) | ($7.1) | ($5.8) | ($5.9) | ($22.6) | ($21.6) | ($23.1) |
| Income Taxes Paid | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **Net Income** | **($30.1)** | **($4.9)** | **($7.1)** | **($5.8)** | **($5.9)** | **($22.6)** | **($21.6)** | **($23.1)** |
| *Net Margin* | - | - | - | - | - | - | - | |
| **Reported EPS** | **($3.36)** | **($0.24)** | **($0.33)** | **($0.29)** | **($0.29)** | **($1.01)** | **($0.86)** | **($0.77)** |
| *YOY Growth* | - | - | - | - | - | - | - | |
| Basic Shares Outstanding | 9.0 | 20.2 | 21.2 | 20.2 | 20.2 | 22.5 | 25.0 | 30.0 |

*Source: Zacks Investment Research, Inc.* *David Bautz, PhD*

Source: Company filings and Zacks estimates

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## HISTORICAL ZACKS RECOMMENDATIONS




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