Zacks Small-Cap Research

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ContraFect Corp (CFRX-NASDAQ)

CFRX: two unique platform technologies targeting multi-drug resistance induced by bacteria and viruses – initiating with Outperform rating.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/13/2015
Current Price (01/26/15)	$4.40
Twelve-Month Target Price	**$10.00**

OUTLOOK

CFRX is a clinical stage biotech company focused on the discovery and development of proteins and antibodies for infectious diseases. The company's two platforms: lysins and monoclonal antibody target conserved regions of bacteria or viruses, and therefore have the potential to address multi-drug resistance. CFRX's lead lysin candidate CF-301 will enter into Phase I in 1Q15 for the treatment of Staph bloodstream infections including infective endocarditis, caused by MSSA and MRSA. Its second lead candidate, CF-404, is a universal treatment for influenza, and is expected to enter into clinic in 2016.

We are optimistic about CFRX's prospect and rating its shares Outperform.

SUMMARY DATA

52-Week High	**$5.21**
52-Week Low	**$2.52**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**35,675**
Shares Outstanding (mil)	**20**
Market Capitalization ($mil)	**$105**
Short Interest Ratio (days)	**0.13**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**Small-Blend**
Industry	**Med-Drugs**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2014	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2015					0.00 E
2016					0.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$4.36 A	-$3.88 A	-$4.31 A	-$10.8 A	-$23.4 A
2014	-$5.15 A	-$8.17 A	-$1.22 A	-$0.26 E	-$3.95 E
2015					-$0.82 E
2016					-$0.59 E

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

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KEY POINTS

- We are initiating coverage of ContraFect (CFRX) with an Outperform rating. Our 12-month price target is $10.00 per share.

- ContraFect (CFRX) is a clinical stage biotech company focused on the discovery and development of **proteins** and **monoclonal antibodies** for the treatment of drug-resistant, life-threatening infectious diseases. The company's two platform technologies: lysins and monoclonal antibodies target conserved regions of bacteria or viruses respectively, and therefore have the potential to address multi-drug resistance for the treatment of infectious disease.

- The lead candidate from the lysin platform is **CF-301**, which is being developed for the treatment of Staph bloodstream infections including infective endocarditis, caused by MSSA and MRSA. CF-301 is the first lysin to be allowed by FDA to enter human **clinical trials**, and the company expects to enroll the first patient this quarter (1Q15).

- CF-301 is a natural **antibacterial enzyme** that can degrade (lyse) bacterial cell walls resulting in death of the bacteria. CF-301 targets the conserved region of bacteria and is fundamentally different from antibiotics due to its novel mechanism of action.

- CF-301 has the potential to address **multi-drug resistance** induced by currently used antibiotics. ContraFect initially plans to study CF-301 in combination with standard of care antibiotics for the treatment of **invasive Staph infections** and **biofilms**, including drug-resistant infections.

- The second lead candidate, **CF-404,** is a combination of three monoclonal antibodies, which targets the conserved regions of influenza viruses, and therefore has the potential to treat all strains of influenza, including current seasonal and potential pandemic strains.

- Due to targeting the conserved regions in influenza, CF-404 will not require reformulation, which the vaccine requires on an annual basis.

- Results from preclinical studies of CF-404 have demonstrated superior efficacy compared to Tamiflu (from Roche), with CF-404 providing therapeutic benefits when treatment is initiated up to 96 hours post-infection whereas Tamiflu must be used within 24 hours in these models to be effective.

- ContraFect intends to submit an IND of CF-404 to FDA in 2016, and hopes to initiate a **Phase I** trial in 2016.

- ContraFect also has a strong intellectual property estate and a strong balance sheet. Based on its fundamentals, we believe ContraFect's shares are undervalued at current market price and have potential to appreciate in the next 12 months.

OVERVIEW

ContraFect Corporation (NASDAQ: CFRX) is a clinical stage biotechnology company focused on the discovery and development of protein and antibody therapeutic products for the treatment of infectious diseases, with a focus on **drug resistant** pathogens in hospital-based settings.

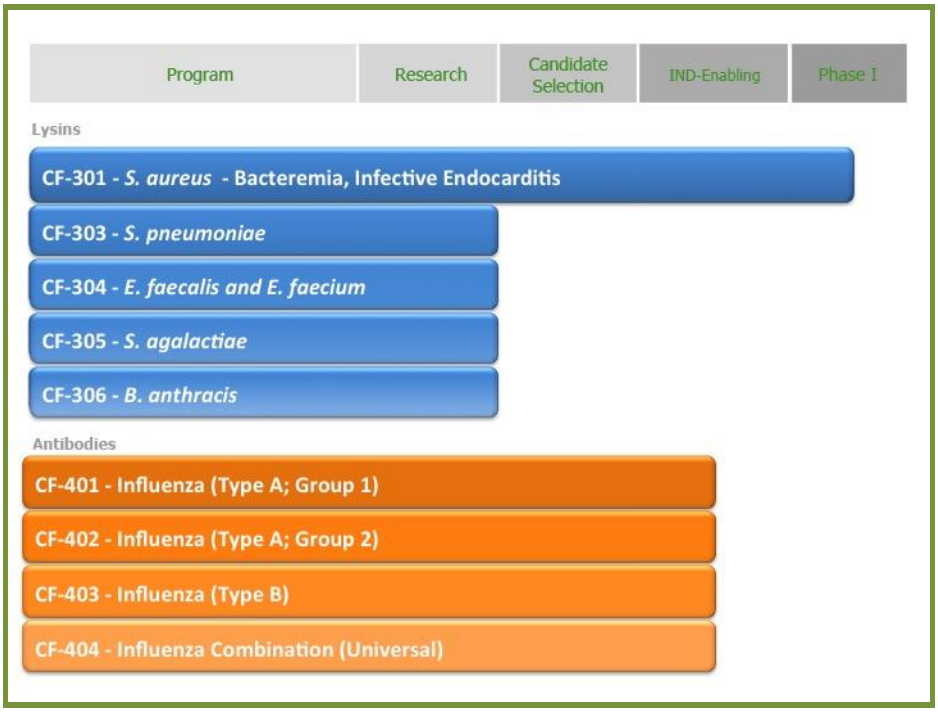
The Company utilizes **two platforms**: lysins and antibody technology, to address multi-drug resistance to currently used antibiotics or antivirals by targeting **conserved regions** of bacteria or viruses.

Lysins are enzymes that “poke holes” in the cell walls of bacteria. We believe ContraFect’s lysin technology may be a new paradigm for the treatment of antibiotic resistant infections, such as Staphylococcus aureus bacteremia, pneumonia, osteomyelitis and infections that are associated with implanted medical devices.

In addition to lysins, ContraFect is also developing **monoclonal antibodies** that target conserved regions of influenza viruses. Unlike vaccines, targeting conserved regions removes the need to reformulate the antibody as the virus naturally mutates over time. Additionally, ContraFect’s antibodies against influenza may be administered several days after infection, unlike current standard of care therapies that require almost immediate administration.

The Company’s most advanced product candidates are **CF-301**, a lysin for the treatment of Staph aureus bacteremia, and **CF-404**, a combination of three mAbs for the treatment of life-threatening seasonal and pandemic varieties of influenza.

ContraFect completed its IPO in August 2014 and is headquartered in Yonkers, NY.



INVESTMENT THESIS

Lysin Platform

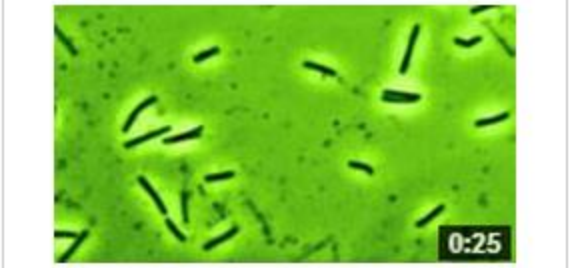
Lysins are the platform ContraFect utilizes to combat **drug resistance** to currently used antibiotics.

Antibiotic resistant bacterial infections are becoming an increasing threat throughout the world. For example, in the US, methicillin-resistant Staphylococcus aureus (MRSA) results in more than 100,000 hospitalizations and 30,000 deaths per year. The average duration in the hospital for a patient is 21 days with costs often exceeding $100,000. Furthermore, MRSA and other bacterial strains are evolving to become resistant to current standard of care therapies; therefore, developing new approaches for treating these diseases is vital to public health.

Lysins are natural anti-bacterial enzymes that are produced from a **bacteriophage**, a virus that infects and kills bacteria. Lysins degrade (lyse) bacterial cell walls resulting in death of the bacteria.



Lysin mechanism of action (Click to view)

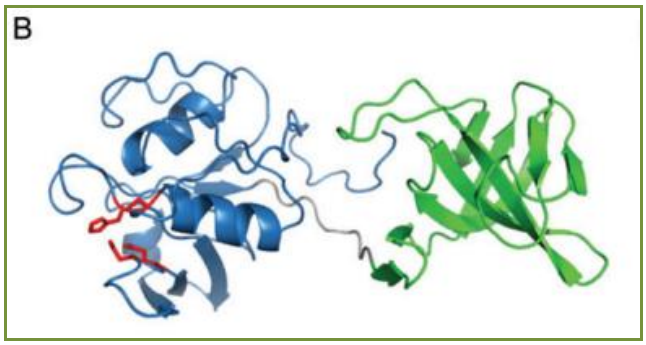


Lysin kills anthrax (Click to view)

Lysins are hydrolytic enzymes produced by bacteriophages in order to cleave the host's cell wall during the final stage of the lytic cycle. Lysins are highly evolved enzymes that are able to target one of the five bonds in peptidoglycan (murein), the main component of bacterial cell walls, which allows the release of progeny virions from the lysed cell.

A typical lysin, such as ContraFect's CF-301, comprises two domains separated by a short linker region. The **N-terminal** domain (blue) catalyzes the hydrolysis of peptidoglycan whereas the **C-terminal** (green) domain binds to the cell wall substrate.

The cell-binding domain (CBD) binds to a specific substrate found in the host bacterium's cell wall, often a carbohydrate. The CBD allows a great specificity and decreases bacterial resistance. Binding affinity to the cell wall substrate tends to be high, possibly so as to limit amount of free enzyme released, which would lyse other bacteria preventing the virus from reproducing.



CF-301 ribbon representation

ContraFect's lysins target the **conserved regions of bacteria**, and therefore have the potential to address **resistance**. Based on currently available data, bacteria have shown minimal resistance to the company's lysins. ContraFect intends to maintain this attribute for all of its lysin product candidates.

ContraFect has developed a large scale screening process enabling the production of lysin banks specific for any particular bacterial pathogen. The ability to rapidly identify lysins specific for any bacteria of interest provides a steady pipeline of novel lysins for consideration as potential antimicrobial therapeutic candidates.

The company's lysins are suitable for the treatment of antibiotic-sensitive and antibiotic-resistant organisms, and the treatment of biofilm-related indications. Lysins currently in development by ContraFect have shown efficacy in *in vitro* assays and in *in vivo* animal models including pharyngitis, pneumonia, otitis media, abscesses, meningitis and many others.

Key Advantages of Lysins

Lysins are **fundamentally different from antibiotics** due to the following features:

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 lyses in a virtually explosive manner due to the high internal osmotic pressure of its cytoplasm, and bacterial cell death ensues.

Rapid Bactericidal Activity

Lysins kill bacteria immediately **upon contact**. In vitro experiments demonstrated CF-301 to be 12-18x faster than the standard-of-care antibiotics used to treat Staph aureus Bacteremia.

Targeted Therapy: Kills Specific "Bad Bacteria"

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., Staph aureus, pneumococcus, 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. 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 Staph aureus, including isolates that are resistant to the antibiotics methicillin (methicillin-resistant Staph aureus; "MRSA"),vancomycin (vancomycin-resistant Staph aureus; "VRSA"), and daptomycin (daptomycin-resistant Staph 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. CF-301 eradicates biofilms that protect bacterial infections in the body (heart valve) and on indwelling devices (prosthetics) from antibiotics.

Synergy with Standard-of-Care Antibiotics

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. The company intends to seek approval for CF-301 in combination with these standard-of-care antibiotics for Staph aureus bacteremia. The use of CF-301 in combination with, rather than as a

replacement for, standard-of-care antibiotics, may help speed adoption of lysins by physicians once approved.

CF-301: The Lead Lysin Candidate to Enter Clinic in 1Q15

The Company's lead lysin, **CF-301,** targets all strains of Staphylococcus aureus, including all drug-resistant phenotypes, and is the first lysin allowed by FDA to enter human clinical trials.

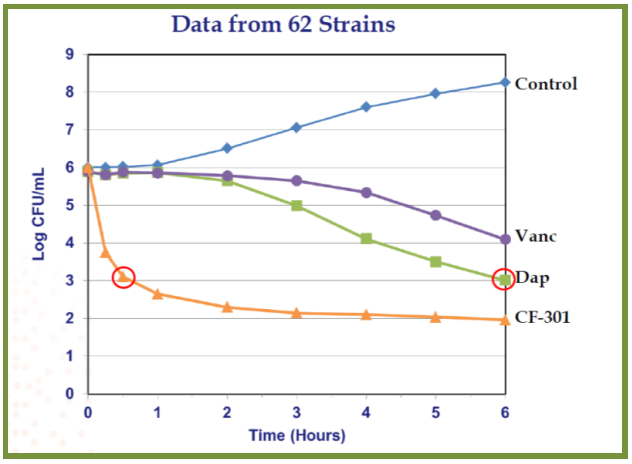
Unlike most recombinant lysins that digest S. aureus, which are often poorly expressed and display low solubilities, ContraFect's CF-301 is a recombinant lysin that is **highly expressed** in E. coli within the **soluble** fraction.

In an **in vitro** study recently published in the Journal of Infectious Diseases, CF-301 demonstrated potent inhibitory activity on 250 S. aureus strains, including 103 methicillin-sensitive S. aureus (MSSA) and 120 MRSA (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

Also, CF-301 showed the ability to kill a large number of different MRSA strains within 30 minutes as compared to 6-12 hours with antibiotics (12X faster) currently used as standard of care therapy.

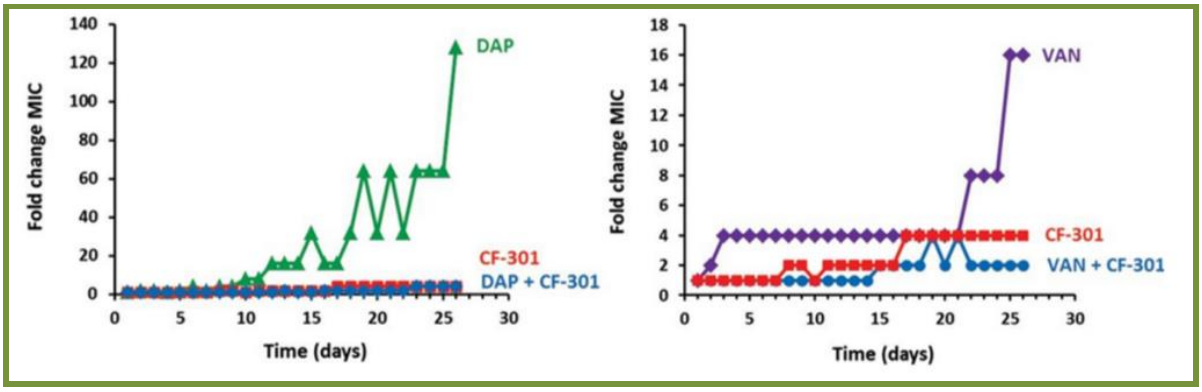


Time kill data illustrating CF-301 treatment against 62 strains of *Staphylococcus* aureus as compared to standard of care treatment daptomycin (Dap) or vancomycin (Vanc). All drugs were tested at 1xMIC.

In addition, the in vitro study showed that resistance to CF-301 was low relative to resistance to SOC antibiotics. After 26 days of passage, the minimal inhibitory concentration (MIC) of CF-301 increased no

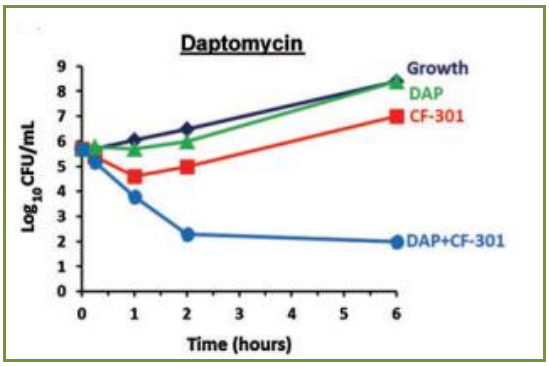
more than 4 times the initial MIC, while resistances to daptomycin and vancomycin increased to 128 and 16 times the initial MIC respectively.

CF-301 also **reduced resistance** to SOC antibiotics when used in combination with these SOC antibiotics. The presence of sub MIC amount of CF-301 resulted in only a 4-fold increase in their resistances, compared to 128 and 16 times increase for Dap and Van respectively in absence of CF-301, demonstrating that growth of MRSA with CF-301 suppressed formation of antibiotic resistances to both vancomycin and daptomycin.

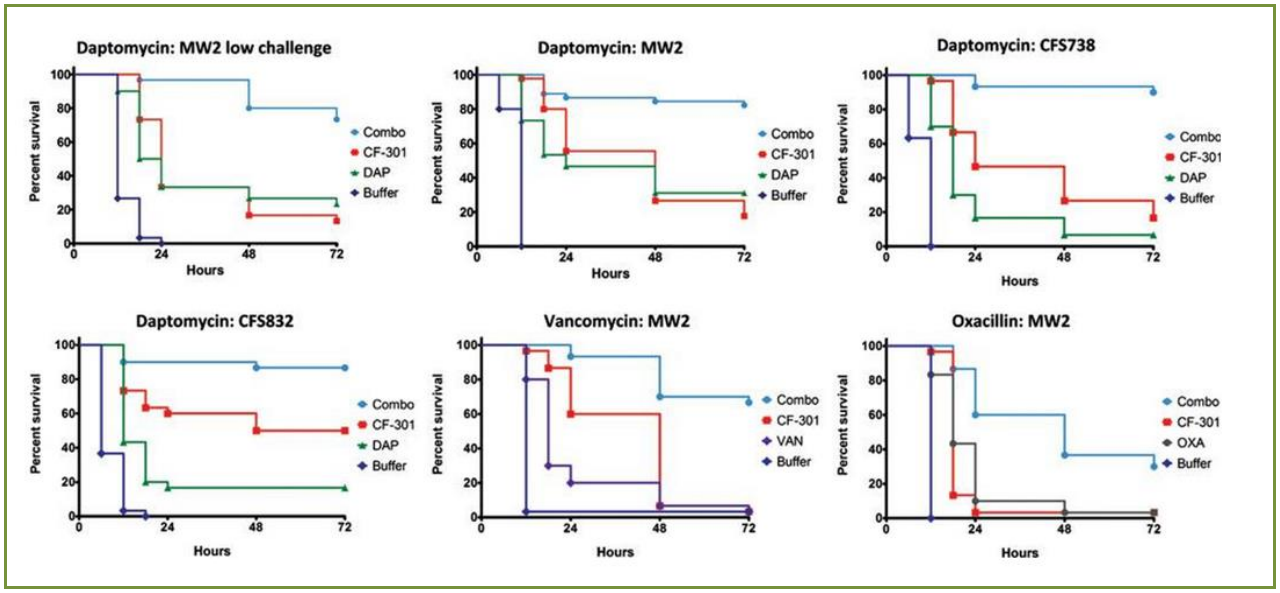


Combination of CF-301 with daptomycin (DAP, left) or vancomycin (VAN, right) reduced resistance to the two antibiotics

Furthermore, the combination of sub MIC amount of CF-301 with standard of care antibiotics (such a daptomycin) worked in synergy and resulted in greater bacterial killing than either agent alone.



These promising **in vitro** results also translated to compelling **animal studies** in which mice were subject 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 regiments.



Percent survival in animals challenged with various strains of *Staphylococcus* aureus with CF-301 treatment alone or in combination with standard of care antibiotics.

In addition to CF-301, the Company also has several other lysin drug candidates in the preclinical stage of development including CF-303 (S. pneumoniae), CF-304 (E. faecalis & E. faecium), CF-305 (S. agalactiae) and CF-306 (B. anthracis).

CF-301 Will Enter Into Clinic in 1Q2015

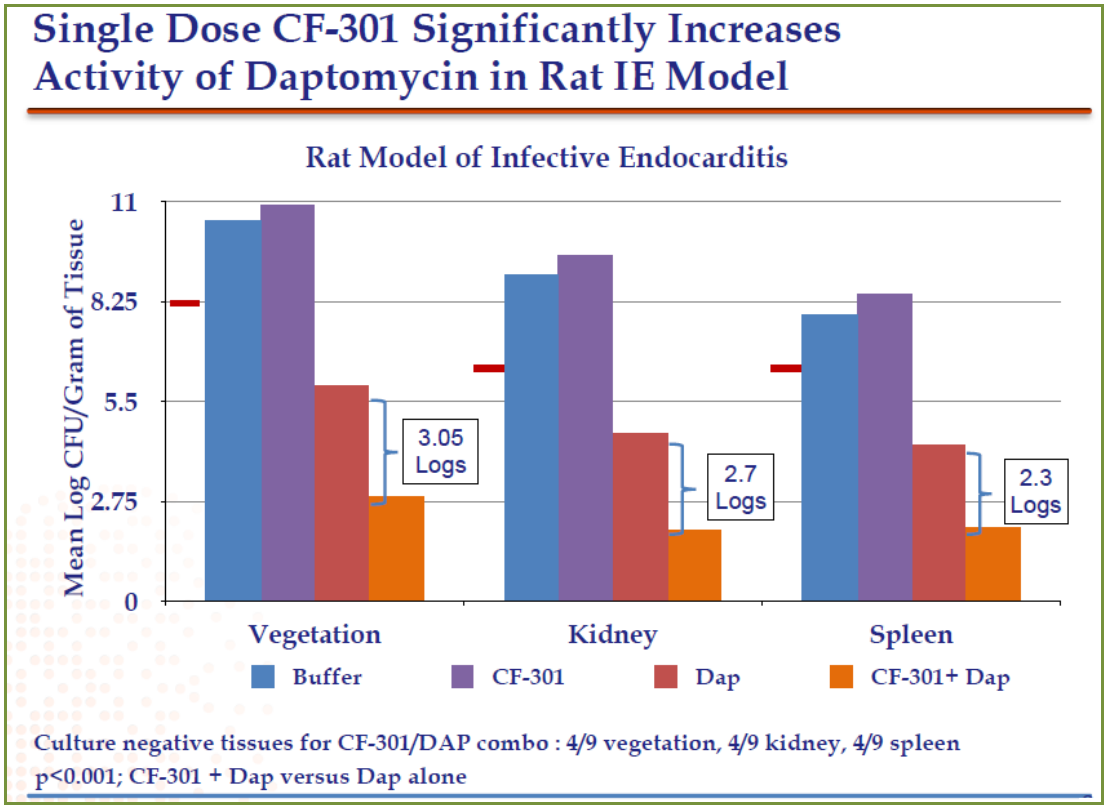
In the first quarter of 2013, ContraFect submitted an Investigational New Drug (IND) application with the FDA for the use of CF-301 **in combination** with standard of care antibiotics for the treatment of **Staph bloodstream infections,** including infective endocarditis, caused by MSSA and MRSA. The FDA responded by requesting additional preclinical studies to provide for a fulsome safety package prior to the initiation of a **Phase I** trial in human subjects.

In early December 2014, ContraFect submitted a complete response to the FDA, addressing all of the issues identified in the IND clinical hold letter issued by the FDA.

Later in December 2014, the FDA completed the review of its submission and removed the full clinical hold on CF-301 clinical trial, enabling CF-301 to be the first lysin to enter an FDA approved human clinical trial. ContraFect expects to commence the **Phase I** clinical trial in **1Q15.**

The initial trial will consist of 16 healthy volunteers and will evaluate safety, tolerability, immunogenicity and the pharmacokinetics of varying dosages of CF-301.

In a recent study in a rat model of infective endocarditis (IE), a single dose of CF-301 significantly increased the activity of daptomycin. This study was designed to mimic the planned clinical approach (single dose CF-301 on top of multiple days of standard of care antibiotics) in a difficult to treat biofilm based infection. In this study, a single dose of CF-301, when combined with four days of daptomycin treatment, resulted in a 3-log drop in bacterial burden in the cardiac vegetations and > 2-log drop in the kidney and spleen of infected animals relative to daptomycin treatment alone. Importantly, in the combination treatment groups 4 of 9 animals were determined to be culture negative, whereas no animals in any other treatment arms approached this level of disease eradication.



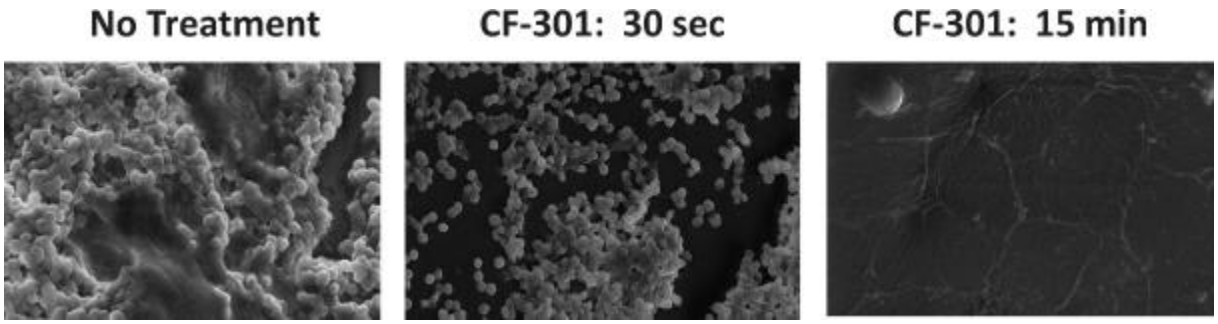
Currently, mortality from Staph bacteremia remains close to 30% with treatment on standard-of-care antibiotics for humans undergoing treatment in the hospital. Based upon currently available data, we believe CF-301 combined with standard of care antibiotics, has the potential to reduce treatment times, improve patient outcomes and shorten hospital stays, while not contributing to the global crisis of drug-resistance.

CF-301 for the Treatment of Biofilms

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, the Company then treated catheters inoculated with biofilms with CF-301 and showed it completely sterilized the catheter within 15 minutes of treatment (Figure below).

The company is pursuing further development of its lysin technology to potentially eradicate biofilms.



Microscopic visualization of catheters inoculated with biofilms and treated with CF-301. No treatment shows viable biofilm growth while CF-301 treatment at 30 seconds resulted in disruption of the biofilm and complete clearance at 15 minutes post treatment.

ContraFect's Antibody Platform

ContraFect's approach to antibody therapy employs a **combination** of monoclonal antibodies that block and disarm virulence factors of bacteria and viruses. The company's antibodies target **conserved regions of the virus or bacteria** which are not prone to mutation and/or target multiple proteins expressed from different genes within a bacteria or virus, to prevent therapeutic escape.

ContraFect's antibodies are isolated directly from **human blood samples**. The company has the ability to develop antibodies with a common backbone structure, providing for a similar pharmacokinetic profile. These properties provide for a unique ability to create a therapeutic utilizing a combination of monoclonal antibodies.

The Company's antibody platform is focused on addressing the unmet need of **influenza**. Influenza results in more than 200,000 hospitalizations and 49,000 deaths annually in the US alone. Globally, on an annual basis 20% of children and 5% of adults develop symptomatic influenza.

Influenza, commonly known as "the **flu**", is an infectious disease caused by the influenza virus, which has a single-stranded segmented **RNA** genome. Symptoms can be mild to severe. The most common symptoms include: a high fever, runny nose, sore throat, muscle pains, headache, coughing, and feeling tired. These symptoms typically begin two days after exposure to the virus and most last less than a week. If untreated, flu can cause complications, which include pneumonia, sinus infections, and worsening of previous health problems such as asthma or heart failure.

The influenza viruses are classified into types A, B, and C on the basis of their core proteins. Type A viruses are further subdivided according to their envelope glycoproteins with haemagglutinin (HA) or neuraminidase (NA) activity. **Influenza A** viruses are the most virulent human pathogens among the three influenza types and cause the most severe disease. The influenza A virus can be subdivided into different serotypes based on the antibody response to these viruses. Occasionally, type A viruses are transmitted to other species and may cause devastating outbreaks in domestic poultry or give rise to human influenza pandemics. **Influenza B** almost exclusively infects humans, and while it is less common than influenza A, can result in death. **Influenza C** infects humans, dogs and pigs. However, influenza C is less common than the other types and usually only causes mild disease in children.

One key problem for effectively targeting influenza is the high rate of **mutation** in the virus. The high mutation rates and frequent genetic re-assortment in influenza A lead to variability in HA and NA antigens. Minor changes in the protein structure in influenza A strains occur frequently, enabling the virus to cause repetitive influenza outbreaks by evading immune recognition. Major changes in the influenza type A HA antigen are caused by re-assortment from different influenza A subtypes, such as between animal and human subtypes, and in rare events, such shifted viruses can result in strains capable of causing large regional or global pandemic outbreaks. Influenza B mutates slower than influenza A.

These mutations usually result in immunological escape from immunity to previous viruses or vaccines, and are the reasons why the influenza vaccine requires constant reformulation. Influenza can grow in a variety of species (e.g. human, swine and bird) and may result in novel strains of influenza entering into circulation. These new viruses have the potential to cause worldwide pandemics.

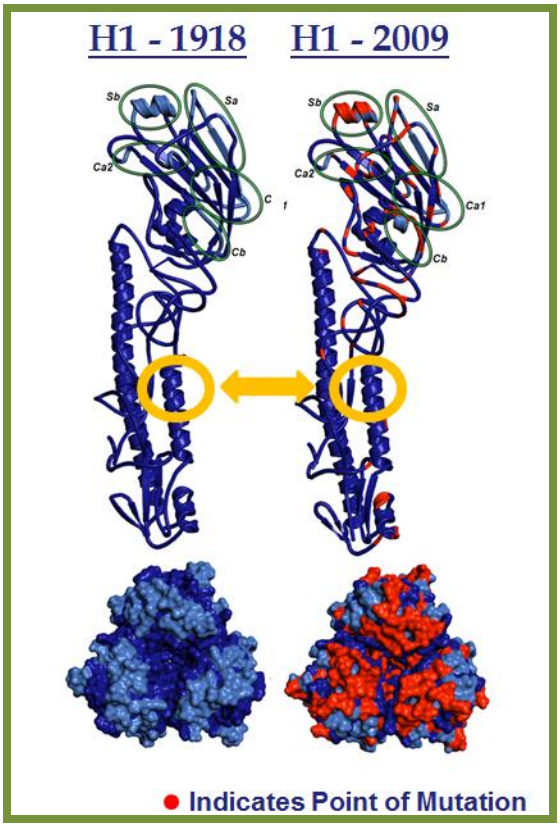
In addition, the efficacy of anti-flu drugs such as Tamiflu is questionable due to the need for treatment within 48 hours of symptom onset and the potential for drug resistance.

Lead Candidate CF-404 Will Enter into Clinic in 2016

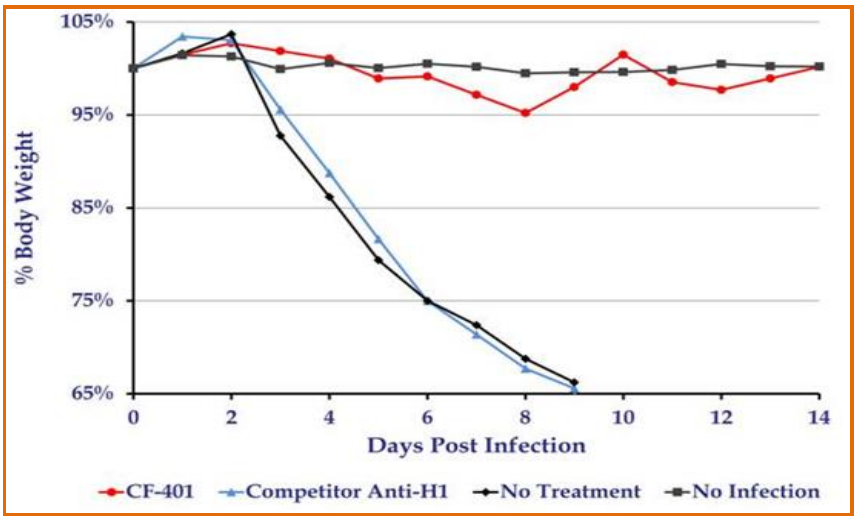
ContraFect's **lead candidate** for influenza is **CF-404**, which is a cocktail of three monoclonal antibodies (CF-401, CF-402, and CF-403). With the breadth of reactivity of its components, CF-404 is a **universal therapeutic** cocktail for the treatment of life-threatening seasonal and pandemic varieties of influenza. Moreover, as a therapeutic, CF-404 should provide immediate therapeutic benefits, which is unachievable by vaccination.

The Company's influenza pipeline consists of CF-401 (targets Type A; Group 1 influenza), CF-402 (targets Type A; Group 2 influenza), CF-403 (targets Type B influenza) and CF-404 (cocktail of CF-401, 402 and 403).

ContraFect's antibodies differ from current technologies as they target **conserved regions** of influenza (circled with yellow) thus preventing the need to frequently reformulate the antibody.

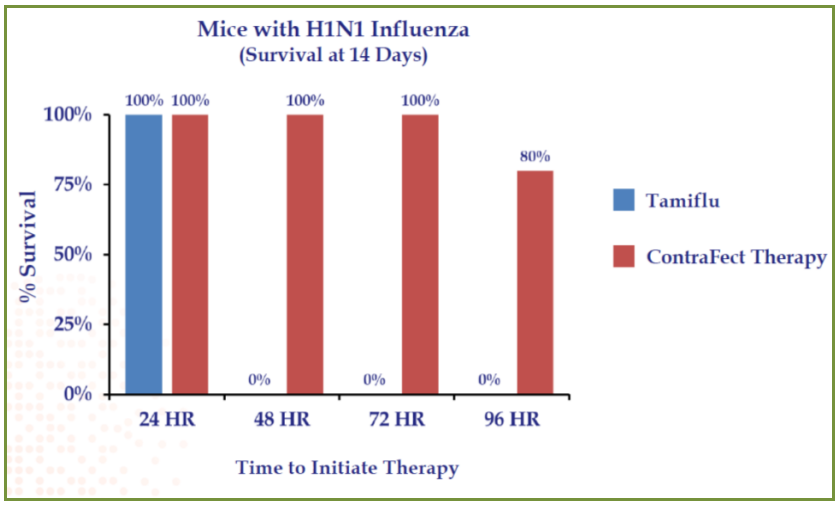


Preclinical **animal data** using CF-401 resulted in 100% survival in mice exposed to lethal doses of H1N1. Even more compelling, CF-401 was far superior to a competitor's H1 antibody, currently in clinical trials, which showed no benefit when compared to untreated animals in these studies.



Side by side comparison of CF-401 versus competitor's H1 antibody

Furthermore, CF-401 can also been administered at time points exceeding 48 hours post-infection, whereas, administration of small molecule anti-flu drugs after 48 hours results in limited to no therapeutic benefit. Animal data utilizing CF-401 revealed the antibody administered up to 96 hours post infection was still efficacious. By comparison, Tamiflu showed no efficacy when administered more than 24 hours post-infection.



Mice infected with H1N1 and treated with Tamiflu or CF-401 at varying time points after infection. CF-401 elicits protection up to 96 hours after infection whereas Tamiflu is only effective within 24 hours of infection.

As further validation of their technology, ContraFect recently received a $3.3 million grant from the National Institute of Allergy and Infectious Disease (NIAID) from the National Institutes of Health (NIH) to develop CF-404. The company also entered into a collaborative research agreement with the National Institute for Viral Disease Control and Prevention, China CDC ("IVDC") to advance research and development of CF-404.

The Company hopes to file an IND with the FDA in **2016** and initiate a **Phase I** trial with these antibodies shortly thereafter.

Strong Intellectual Property

ContraFect has an exclusive worldwide license agreement with **The Rockefeller University** against nine lysins as well as a first right research agreement for discovering new lysins through 2016. ContraFect's intellectual property estate includes seven issued patents for the protection of lysins to target Staph aureus, pneumococcus, group B streptococcus, enterococcus and anthrax alone or in combination with antibiotics.

Additionally, the protection goes further with the use of lysins to treat biofilms in implants and medical devices.

ContraFect's influenza patent portfolio consists of four active patent applications, three of which are licensed from **Trellis Biosciences**. The three active patent applications filed by Trellis cover compositions and methods relating to influenza antibodies. Upon issuance, these patents are expected to expire between June 2031 and February 2035. The Company also filed an additional application for its antibody technology in March 2014 and upon issuance it is expected to expire in March 2034.

Strong Balance Sheet

In August 2014, the Company completed its initial public offering (IPO), raising net proceeds of $35.0 million.

As of September 30, 2014, ContraFect held $31.3 million in cash. Net cash burn is estimated at $1.5 million per month. We estimate that cash balance should be at $26 million at the end of 2014. Current cash balance should last into 2Q16.

There was no debt sitting on the balance sheet as of September 30, 2014.

Also keep in mind, ContraFect has two separate short term warrants which are traded on NASDAQ with ticker CFRXZ and CFRXW. CFRXZ expires in October 2015 and CFRXW expires in Jan 2017. These two securities are in or near being in the money and can bring proceeds exceeding $40 mil to the company upon exercise.

Huge Market Potential

Antibiotic-resistant bacterial infections are widely recognized as an urgent public health threat (WHO, CDC, etc.) as they limit the effectiveness of many current standard of care therapies. The discovery of new therapies to address resistance must be pursued to keep pace with the ever-increasing incidence of these diseases throughout the world. The Infectious Diseases Society of America (IDSA) estimates the cost of antibiotic-resistant infections is approximately $21 billion to $34 billion in the US alone. The majority of these costs are due to extensive hospital stays. **ContraFect's lysin technology** has the potential to penetrate this market alone or in combination with current standard of care therapies.

In addition to systemic infections, **biofilms** on prosthetic and medical devices have plagued the medical device industry for years resulting in billions of dollars per year spent on device revisions and failures. It's estimated that biofilms cost the medical device industry in upwards of $39 billion. **ContraFect's novel lysin** therapy could also enter the double-digit billion dollar market for the eradication on biofilms.

The **monoclonal antibody** market is also quite large and expected to exceed $56 billion by 2016. ContraFect's antibody platform has key advantages over current vaccines and antiviral drugs as it does not require frequent reformulations as they target conserved regions of the virus and are also effective when administered days after infection unlike current therapies that need to be administrated within 48 hours.

Both ContraFect's lysins and antibodies have the potential to target **multi-drug resistant** bacteria or viruses. The synergistic combination of the company's lysins and monoclonal antibodies opens up the potential for partnerships with big pharma or biotech companies.

Multiple Near Term Catalysts

The Company has several near term catalysts in 2015 that will advance the company from a development stage to a clinical stage company. Milestones for 2015 include the following:

- Initiate and complete Phase I clinical trial for CF-301;
- Initiate Phase II clinical trial for CF-301 by end of year 2015
- Advance new lysins to clinical candidates;
- Conduct pre-IND meeting with the FDA for CF-404 program for influenza;
- Prepare for CF-404 IND submission;

Strong Management Team

Julia P. Gregory, Chief Executive Officer

Ms. Gregory has been Chief Executive Officer since November 2013. Prior to that time, she was Executive Vice President and Chief Financial Officer, since July, 2012. Prior to ContraFect, Ms. Gregory was President and CEO of Five Prime Therapeutics, Inc., a clinical-stage biotechnology company discovering and developing innovative protein and antibody therapeutics in the fields of oncology and immunology. Prior to Five Prime, Ms. Gregory was Executive Vice President, Corporate Development and Chief Financial Officer of Lexicon Pharmaceuticals, Inc. Ms. Gregory has been actively involved in a variety of public and private financings, including a private equity agreement designed to provide financing of up to $550 million for Lexicon and Lexicon's $220 million initial public offering. While at FivePrime and Lexicon, she led transactions for several strategic partnerships including those with GlaxoSmithKline, Human Genome Sciences, Genentech, Inc., Bristol-Myers Squibb Company and Takeda Pharmaceutical Company Limited. In addition, she led the negotiations for Lexicon's acquisition of the chemistry company that provided the foundation for Lexicon's novel drug programs. Prior to joining Lexicon, Ms. Gregory was an investment banker where she served as the head of investment banking for Punk, Ziegel & Company, a specialty technology and healthcare investment banking firm and was an investment banker with Dillon, Read & Co., Inc. She currently serves as a Director on the board of Clinipace on behalf of and as Special Advisor to Morgan Stanley Expansion Capital and on the board of The Global TB Alliance for Drug Development, primarily funded by the Gates Foundation.
Ms. Gregory received her B.A. from George Washington University's Elliott School of International Affairs where she was elected to Phi Beta Kappa and her M.B.A. from the Wharton School of the University of Pennsylvania.

Michael Wittekind, Ph.D., Chief Scientific Officer

Dr. Wittekind has more than 20 years of industry experience in biotechnology research and management. Prior to joining ContraFect, Dr. Wittekind served as the Executive Director of Research for Amgen Inc, where he directed the Protein Science Department at the Amgen-Seattle site. While at Amgen, he was involved in the discovery efforts for multiple protein therapeutics currently undergoing clinical trials, including antibodies, antibody-drug conjugates, and protein fusions. Previously, Dr. Wittekind was the Director of Process Development for Phylos Inc, where he played a key role in the development of alternate scaffold therapeutic discovery, design, and production. Dr. Wittekind has also served as the Associate Director of the Gene Expression & Protein Biochemistry Department of the Bristol-Myers Squibb Pharmaceutical Research Institute, directing groups in both the Lawrenceville and Hopewell NJ sites leading structural biology research as well as protein and small molecule therapeutic efforts.

Dr. Wittekind received his Ph.D. from the University of Wisconsin-Madison in Biochemistry and followed with postdoctoral studies at the University of Washington. Dr. Wittekind's research interests have

encompassed genetics, molecular biology, structural biology, and engineering of novel antibodies and proteins, resulting in over 40 publications and patents.

Barry Kappel, Ph.D., MBA, Senior Vice President, Business Development

Dr. Kappel joined ContraFect in 2009 as the company's second employee and the Head of Business Development. Since the beginning, Dr. Kappel has been involved in all aspects of the company, including licensing of the company's key technologies, participation in the financings of the company, and establishing scientific collaborations with academic and corporate partners.

Dr. Kappel previously was a Senior Consultant at Easton Associates, LLC, a life science consulting firm. In this capacity, he performed a wide range of activities, including the assessment of preclinical and clinical compounds for Pharmaceutical and Biotechnology companies.

Dr. Kappel received his B.A. in chemistry from Emory University. He subsequently obtained his Ph.D. in immunology and pharmacology from the Weill Graduate School of Medical Sciences and the Memorial Sloan-Kettering Cancer Center. Dr. Kappel holds an MBA from the S.C. Johnson Graduate School of Management at Cornell University.

Daniel Couto, Senior Vice President, Manufacturing & Facility Operations

Mr. Couto has more than 20 years of experience in operations management. Prior to joining ContraFect, he served as a Vice President of Commercial Manufacturing Operations for Merck Sharp & Dohme Biologics UK Ltd. Previously, he was Director of Manufacturing for Nuvelo Inc., where he was responsible for 7 World Wide Contract Manufacturing sites. Mr. Couto also served in Director positions at Genzyme Transgenics Corp., Advanced Biosystems Corp., ImmuCell Corp., and Sepracor Corp. Mr. Couto holds patents for several novel separation technologies such as Bulk Protein Crystallization, HPTFF, and SMB.

Mr. Couto received his B.S. degree in chemical engineering from Rensselaer Polytechnic Institute.

Nancy Dong, Vice President, Controller

Ms. Dong has more than 20 years of experience in accounting, strategic planning, budgeting and forecasting, organizational development, financial systems and controls. She served as controller at XL Marketing and Alley Corp prior to her role as Vice President of Finance and Administration at DCM, a tele-services firm supporting the performing arts. Ms. Dong also held the positions of COO/CFO at Semaphore, a project management software development firm.

Ms. Dong received her B.A. degree from Yale University and a MPPM degree from The Wharton School at the University of Pennsylvania. She started her career as a management consultant at Ernst & Young.

Michael Messinger, CPA, Vice President, Finance

Mr. Messinger has more than 15 years of experience in finance, accounting and forecasting for clinical development. He served as Controller of Coelacanth Corporation prior to his role as Director of Finance for Lexicon Pharmaceuticals, Inc. In this capacity, he was responsible for the financial management of Lexicon's partnership with Symphony Capital, LLC, in addition to coordinating fiscal and program management concerning Lexicon's development programs.

Mr. Messinger received his B.B.A degree in accounting from the University of Michigan. He started his career as an auditor at Ernst & Young, LLP.

Natalie Bogdanos, Esq., General Counsel

Ms. Bogdanos has more than 15 years of in-depth legal experience across many areas of law including contract, intellectual property, licensing, regulatory, corporate governance, securities and litigation.

Prior to joining ContraFect, Ms.Bogdanos served as Associate General Counsel at Memorial Sloan-Kettering Cancer Center (MSKCC). At MSKCC, she held a joint appointment with the Office of the General Counsel and the Office of Technology Development (OTD), providing legal counsel and guidance to various departments throughout the institution while having sole responsibility for the legal oversight of the OTD.

Previously, Ms. Bogdanos served as General Counsel at Enzo Biochem, Inc. (Enzo), a publicly traded international biotechnology & life sciences company focused on developing research tools, diagnostics & therapeutics, and providing test services to the medical community. During her tenure at Enzo, she provided legal guidance and business advice regarding all aspects of research, development, manufacture, use, licensing and marketing of innovative health care products, platforms and services based on molecular and cellular technologies.

Ms. Bogdanos is an attorney licensed to practice before the United States Patent and Trademark Office. She is admitted to practice law in New York, the United States District Court, Southern & Eastern District of New York and the United States Court of Appeals for the Federal Circuit. Ms. Bogdanos received her Juris Doctor from New York Law School and her Bachelor of Arts in Biology, with honors, from Queens College of the City University of New York.

VALUATION AND RECOMMENDATION

We are initiating coverage of ContraFect (CFRX) with an Outperform rating. Our 12-month price target is $10.00 per share. Our bullish call is based on the company's fundamentals and attractive valuation.

ContraFect is a development stage biotech company focused on the development and commercialization of drugs for the treatment of life threatening infectious diseases caused by bacteria and virus.

ContraFect has developed two platforms: **lysins** and **monoclonal antibodies**, which target **conserved regions** of bacteria and virus respectively, therefore have the potential to address the issue of multi-drug resistance, an industry problem and unmet medical needs.

Based on these two platforms, ContraFect has built a decent pipeline. Its lead candidate **CF-301** is a lysin derived from bacterial killing virus. CF-301 is fundamentally different from antibiotics, it targets the conserved region of bacteria, therefore has the potential to address antibiotic related resistance. CF-301 has demonstrated excellent safety and efficacy in preclinical studies and will enter into Phase I in 1Q15. We estimate CF-301 will get the FDA approval in late 2018 or early 2019.

We estimate peak sales of CF-301 will be in the neighborhood of $500 million. Specifically, we estimate sales of CF-301 will be around $50 million and $100 million in 2019 and 2010 respectively, the first two full years for CF-301 launch. Our estimates are based on the initial sales ramps for **Cubicin** and **Vancocin** marketed by Cubist Pharma and ViroPharma respectively.

Cubicin was launched at the end of 2003, sales for 2004 and 2005 were $58.60 and $113.50 respectively, the first two full years after launch. Cubicin US sales reached $971.2 million in 2013 and is estimated to surpass $1 billion in 2014.

ViroPharma acquired Vancocin from Eli Lilly in Nov 2004 and launched the antibiotics at the end of 2004. Sales of Vancocin were $125.9 and $166.6 million respectively, the first two full years after launch. Sales of Vancocin reached $288.9 million in 2011 and dropped to $90.8 million in 2012 due to the introduction of generic versions.

	2004	2005	2006	2007	2008	2009
Cubicin (Daptomycin) US Sales	$58.60	$113.50	$189.50	$285.06	$414.68	$523.97
Vancocin US Sales		$125.85	$166.62	$203.77	$232.28	$213.14

Its lead candidate **CF-404** is a cocktail of three monoclonal antibodies targeting the conserved region of influenza virus. CF-404 has the potential to address the mutation of virus therefore solve the problem of constant drug reformulation for viral infection. ContraFect plans to submit an IND of CF-404 to the FDA by the end of 2015 or early 2016 with the intention to initiate Phase I studies in early 2016.

We do not model sales of CF-404 for our valuation due to its early stage of development. But it doesn't mean that we do not realize the value of CF-404. If we look at the sales of two anti-flu agents by GSK, we know that CF-404 has potential peak sales of $500 million if approved.

Company Name	Drugs	2011	2012	2013
GSK	**Flulaval**	$359.38	$322.58	$418.33
GSK	**Relenza**	$42.19	$53.23	$116.67

In addition, ContraFect also has a strong intellectual property estate and strong balance sheet.

Then, it comes to the valuation. We believe ContraFect's shares are undervalued based on the company's relatively strong fundamentals. Currently, shares of the company are trading at around $4.40 per share which values the company at $90 million in market cap based on 20.2 million outstanding shares. Even with the two exchanged traded warrants, market cap of the company is only $105 million. We think this undervalue the company based on what we have discussed above.

Based on our long term financials, ContraFect will become profitable in 2019 with an EPS of $0.18 based on total revenue of $50 million. EPS will grow to $0.88 while revenue will double to $100 million in fiscal 2020. If we use the average biotech P/E ratio of 35x, using 25% discount rate for five years, we come up with our price target of $10.00 per share.

One **wild card** for the valuation of ContraFect is that it may be a potential buyout target by big pharma or biotech companies. Two recent high profile deals, Cubist acquired **by Merck** in Dec 2014 valued at $9.5 billion and ViroPharma acquired **by Shire** in January 2014 valued at $4.2 billion, further convince us that ContraFect may be on the shopping list of big pharma or biotech companies who want to boost their anti-infection business.

But keep in mind **the risks**.

Our price target assumes the final approval of CF-301 in late 2018 or early 2019, and CF-404 later. However, the risks associated with drug development are high, especially for early stage candidates. Both CF-301 and CF-404 have a high hurdle to overcome both clinically and regulatorily. Any delay or failure in clinical development or regulatory approval will cost share price to decline dramatically.

Cash burn is also a concern. Though current cash can last into calendar 2Q16, ContraFect must raise new funds to finance its clinical programs. Any equity financing will dilute existing shareholder base and may cause share price to fall.

However, we remind investors that ContraFect has two exchange-traded warrants with ticker CFRXZ and CFRXW, which will expire in October 2015 and in Jan 2017 respectively. If exercised, these two warrants will provide over $40 million to the company, which will greatly boost the company's balance sheet and relieve the cash burn concern.

PROJECTED INCOME STATEMENT

	2012 (Dec)	2013 (Dec)	2014 (Dec)					2015 (Dec)	2016 (Dec)	2017 (Dec)	2018 (Dec)	2019 (Dec)	2020 (Dec)
$ in million except per share data	FY	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE	FYE	FYE
Grant revenue	$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
Collaboration revenue	$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
Product revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$50.00	$100.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$50.00**	**$100.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	7.50	15.00
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$42.50**	**$85.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	85.0%	85.0%
R&D	$13.21	$9.13	$2.67	$1.52	$2.36	$2.50	$9.05	$9.50	$10.50	$12.00	$14.50	$18.00	$22.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	-	-
SG&A	$5.94	$10.16	$2.12	$1.16	$2.27	$2.30	$7.86	$8.50	$9.00	$10.00	$13.50	$17.50	$22.50
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	$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
Operating Income	**($19.2)**	**($19.3)**	**($4.8)**	**($2.7)**	**($4.6)**	**($4.8)**	**($16.9)**	**($18.0)**	**($19.5)**	**($22.0)**	**($28.0)**	**$7.0**	**$40.5**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.1)	($4.4)	($0.4)	($5.6)	($11.8)	($0.5)	($18.3)	($0.1)	($0.1)	($0.1)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($19.3)**	**($23.7)**	**($5.2)**	**($8.3)**	**($16.4)**	**($5.3)**	**($35.2)**	**($18.1)**	**($19.6)**	**($22.1)**	**($28.1)**	**$6.9**	**$40.4**
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
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($19.3)**	**($23.7)**	**($5.2)**	**($8.3)**	**($16.4)**	**($5.3)**	**($35.2)**	**($18.1)**	**($19.6)**	**($22.1)**	**($28.1)**	**$6.9**	**$40.4**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-					
Diluted Shares Out	1.0	1.0	1.0	1.0	13.4	20.2	8.9	22.0	33.0	35.0	38.0	45.0	48.0
Reported EPS	**($19.16)**	**($23.38)**	**($5.15)**	**($8.17)**	**($1.22)**	**($0.26)**	**($3.95)**	**($0.82)**	**($0.59)**	**($0.63)**	**($0.74)**	**$0.15**	**$0.84**
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*	*$1.00*	*$2.00*
Non GAAP Net Income	**($19.3)**	**($23.7)**	**($5.2)**	**($8.3)**	**($16.4)**	**($5.3)**	**($35.2)**	**($18.1)**	**($19.6)**	**($22.1)**	**($28.1)**	**$7.9**	**$42.4**
Non GAAP EPS	**($19.16)**	**($23.38)**	**($5.15)**	**($8.17)**	**($1.22)**	**($0.26)**	**($3.95)**	**($0.82)**	**($0.59)**	**($0.63)**	**($0.74)**	**$0.18**	**$0.88**

Source: Company filings and Zacks estimates

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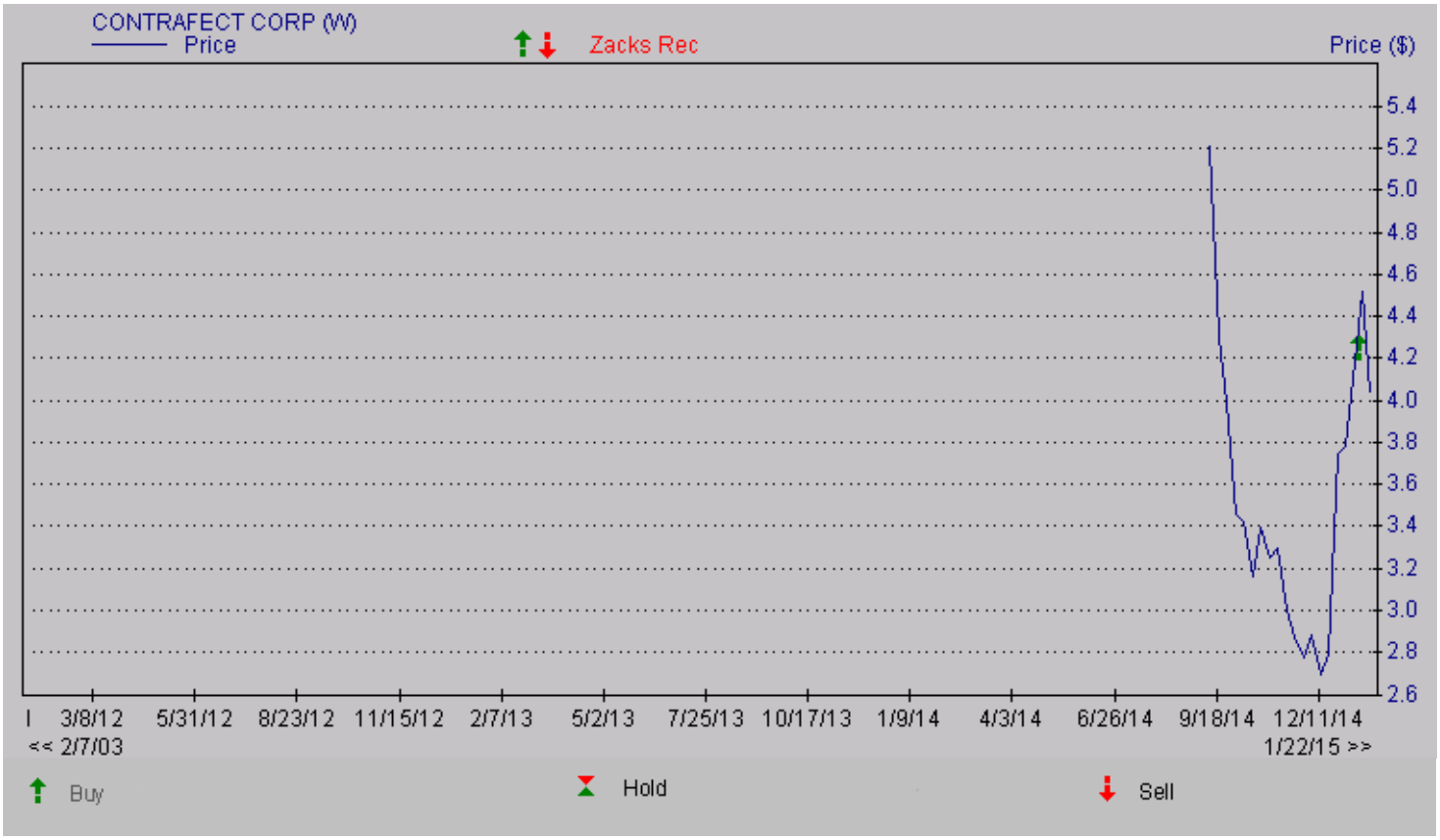
HISTORICAL ZACKS RECOMMENDATIONS



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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.

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.