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Zacks Small-Cap Research

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Cocrystal Pharma, Inc. (COCP-NASDAQ)

COCP: Cocrystal Pharma reports 1st quarter 2023 financial results and provides updates on drug pipeline.

Utilizing a DCF valuation process containing conservative estimates combined with other valuation methodologies, we believe COCP could be worth $7.00. There is a wide range of outcomes which could materially increase or decrease our target price.

Current Price (5/16/23)	$2.57
Valuation	**$7.00**

OUTLOOK

Cocrystal Pharma is a clinical stage biotechnology company focused on novel antiviral treatments in the areas of coronavirus, influenza, hepatitis, and norovirus. The company has a proprietary drug discovery platform technology that provides more rapid and efficient drug discoveries. The company has a seasoned management team and an experienced science advisory board that includes two Nobel laureates. Cocrystal has been successful at raising capital throughout its history and runs a cost-efficient operation with a clean capital structure and no debt. We believe that the company has sufficient funding for planned operations through 2023.

SUMMARY DATA

52-Week High	**$6.24**
52-Week Low	**$1.74**
One-Year Return (%)	**-46.5**
Beta	**1.19**
Average Daily Volume (sh)	**74,726**
Shares Outstanding (mil)	**10.173**
Market Capitalization ($mil)	**$26.1**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**16.0**
Insider Ownership (%)	**25.3**
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 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Biotechnology**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0.46 A	0.55 A	0.49 A	0.51 A	2.01 A
2021	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2022	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2023	0.00 A	0.80 E	1.20 E	2.00 E	4.00 E

Adjusted EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020					
2021					
2022	-$0.52 A	-$0.46 A	-$0.70 A	-$0.55 A	-$2.33 A
2023	-$0.64 A	-$0.47 E	-$0.45 E	-$0.39 E	-$1.95 E

Quarterly revenues may not equal annual revenues due to rounding.
Quarterly EPS may not equal annual EPS due to rounding or dilution.

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WHAT'S NEW

1st Quarter 2023 Financial & Operating Results

No revenues were reported in the 1st quarter of 2023 as the company's drug candidates are still in development stage and milestone payments from Merck have not been received. Research and development expenses for the quarter increased to $3.9 million compared to $2.9 million in the 1st quarter of 2022. The increase was largely due to preparations for a Phase 2a clinical trial with CC-42344 for pandemic and seasonal influenza A and a Phase 1 clinical trial with CDI-988 for COVID-19 as well as advancing the preclinical norovirus program. The increase was partially offset by a reduction in R&D tax credits.

General and administrative expenses for the quarter were $1.2 million compared to $1.3 million for the 1st quarter of 2022. The decrease was primarily due to lower stock compensation, litigation, financial, listing and insurance expenses.

The net loss for the 1st quarter of 2023 was ($5.2) million, or ($0.64) per share, compared with a net loss for the 1st quarter of 2022 of ($4.2) million, or ($0.52) per share.

Cocrystal reported unrestricted cash of $34.0 million as of March 31, 2023 compared to $37.1 million at the end of 2022. Net cash used in operating activities for the quarter was ($3.1) million. Net working capital was $33.8 million and there were 8.143 million common shares outstanding as of March 31, 2022. Subsequent to the close of the 1st quarter, the company raised $4 million in a private placement offering of common stock which was priced "at-the-market" under Nasdaq Listing Rules (see below). Outstanding shares as of May 12, 2023, were 10,173,790.

Private Placement

On April 10th, 2023, the company announced the completion of a private placement of 2,030,458 shares of common stock at a price of $1.97 per share for proceeds of $4.0 million. Investors in the private placement were Cocrystal Director and co-founder Phillip Frost who serves as Chairman and CEO of OPKO Health, and Fred Hassan who is Chairman of the investment firm Caret Group and Director of the private equity firm Warburg Pincus. Dr. Frost and Mr. Hassan each invested $2.0 million.

Co-CEO and CFO Jim Martin stated, *"This investment by two highly accomplished, active industry leaders is a vote of confidence in our approach to developing novel drug candidates that address a global need for effective treatment of acute and pandemic viral diseases with safe antiviral therapeutics. Through this private placement Dr. Frost has increased his holdings and we welcome Mr. Hassan as a new shareholder. We have multiple near-term clinical milestones in our key development programs and have strengthened our financial position to achieve our goals."*

Other Corporate Updates

On May 12, 2023, the company filed a registration statement on Form S-3 with the SEC to replace the previous Form S-3 which was expiring. The replacement shelf registration statement is subject to potential review and comment from, and must be declared effective, by the SEC before it can be used for new offerings.

On April 24, 2023, the company announced the appointment of Fred Hassan as a new Board member. Mr. Hassan's distinguished 40-year career includes serving in senior executive and director positions at global pharmaceutical companies and leading investment firms. He currently is Chairman of the investment firm Caret Group and a Director of Warburg Pincus LLC, a global private equity firm.

On March 29, 2023, the United States Court of Appeals for the Third Circuit ruled in favor of the company's previously disclosed litigation with an insurance company, which vacated the trial court's prior grant of summary judgment in favor of the insurer. As a result of this ruling, the case will be remanded to the District Court for trial on the merits of coverage claims for defense costs. The company intends to file a motion to seek the return of the $1.6 million that was paid to the District Court to stay the judgment. The company is evaluating all options, including a potential settlement with the insurance company.

Program Updates

Cocrystal is developing antiviral therapeutics that inhibit the essential viral replication function of ribonucleic acid (RNA) viruses that cause acute and chronic diseases. The drug discovery process focuses on the highly conserved regions of the viral enzymes and inhibitor-enzyme interactions at the atomic level. It differs from traditional, empirical medicinal chemistry approaches that often require iterative high-throughput compound screening and lengthy hit-to-lead processes. By designing and selecting drug candidates that interrupt the viral replication process and have specific binding characteristics, the company seeks to develop drugs that are effective against both the virus and possible mutants of the virus, and also have reduced off-target interactions that may cause adverse side effects.

Influenza Programs

Influenza is a severe respiratory illness caused by either the influenza A or B virus that results in disease outbreaks mainly during the winter months. The global seasonal influenza market was valued at $6.5 billion in 2021 and is projected to reach up to $28.0 billion by 2029, according to Data Bridge Market Research.

Pandemic and Seasonal Influenza A

Cocrystals novel oral PB2 inhibitor, CC-42344, has shown excellent antiviral activity against influenza A strains including pandemic and seasonal strains, as well as strains resistant to popular drugs Tamiflu® and Xofluza®.

In March 2022 the company initiated enrollment in a randomized, double-controlled, dose-escalating Phase 1 clinical trial to evaluate the safety, tolerability and pharmacokinetics (PK) of orally administered CC-42344 in healthy adults.

In April 2022 the company announced preliminary Phase 1 clinical trial data demonstrating a favorable safety and PK profile in the first two cohorts in the single-ascending dose portion of the study.

In July 2022 the company reported PK results from the single-ascending dose of the study supporting once-daily dosing.

In December 2022 the company reported favorable safety and tolerability results from the Phase 1 trial with CC-42344 for influenza A.

Cocrystal has entered into an agreement with a UK-based clinical research organization to conduct a Phase 2a human challenge study evaluating safety, and viral and clinical measures of orally administered CC-42344 in influenza A-infected subjects. Under the human challenge model, healthy adults will be infected with the influenza A virus under carefully controlled conditions which is believed to accelerate the trial enrollment.

The company expects to submit an application with the UK Medicines and Healthcare Products Regulatory Agency in the first half of 2023 to conduct this study and pending clearance, the study is expected to be initiated in the 2nd half of 2023.

In addition, preclinical development is underway with an inhaled formulation of CC-42344 as a treatment and prophylaxis for influenza A. Phase 1 clinical trial for this is expected to commence in the 1st half of 2024.

Pandemic and Seasonal Influenza A/B Program

In January 2019 the company entered into an Exclusive License and Research Collaboration Agreement with Merck to discover and develop certain proprietary influenza antiviral agents that are effective against both influenza A and B strains. This agreement includes milestone payments of up to $156 million plus royalties on sales of products discovered under the agreement.

In January 2021 the company announced they had completed all their research obligations under the agreement which makes Merck solely responsible for further preclinical and clinical development of these compounds.

In early 2023 Merck notified the company of its intent to continue development of the proprietary compounds discovered under this agreement and that they have filed multiple U.S. and international patent applications associated with these compounds on behalf of both companies. Merck continues to be responsible for managing the patents. It's possible that milestone payments may occur in 2023.

COVID-19 and Other Coronavirus Programs

By targeting viral replication enzymes and protease, Cocrystal believes it is possible to develop an effective treatment for all coronavirus diseases including COVID-19, Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). The company's main SARS-CoV-2 protease inhibitors showed potent in vitro pan-viral activity against common human coronaviruses, rhinoviruses and respiratory enteroviruses that cause the common cold, as well as against noroviruses that can cause symptoms of acute gastroenteritis.

Oral Protease Inhibitor CDI-988

The company selected CDI-988 as our lead candidate for development as a potential oral treatment for SARS-CoV-2. Designed and developed using a proprietary structure-based drug discovery platform technology, CDI-988 targets a highly conserved region in the active site of SARS-CoV-2 3CL (main) protease required for viral RNA replication.

CDI-988 exhibited superior in vitro potency against SARS-CoV-2 with activity maintained against variants of concern, and demonstrated a safety profile and PK properties that are supportive of daily dosing.

The company submitted an application to the Australian regulatory agency for a planned randomized, double-blind, placebo-controlled Phase 1 clinical trial. Pending regulatory clearance, a study is expected to be initiated in the first half of 2023. The company believes the FDA's guidance for further development antiviral candidate CDI-45205 (described below) also provides a clearer pathway for this planned study, as well as directives for designing a subsequent Phase 2 clinical trial.

Intranasal/Pulmonary Protease Inhibitor CDI-45205

An IND-enabling study is ongoing with CDI-45205, a novel SARS-CoV-2 3CL (main) protease inhibitor being developed as a potential treatment for SARS-CoV-2 and its variants.

Guidance was received from the FDA regarding further preclinical and clinical development of CDI-45205 that provides a clearer pathway for future development.

CDI-45205 and several analogs showed potent in vitro activity against the main SARS-CoV-2 variants to date, surpassing the activity observed with the original Wuhan strain.

CDI-45205 demonstrated good bioavailability in mouse and rat PK studies via intraperitoneal injection, and no cytotoxicity against a variety of human cell lines. CDI-45205 also demonstrated a strong synergistic effect with the FDA-approved COVID-19 medicine remdesivir.

An IND-enabling study with CDI-45205 is ongoing.

CDI-45205 was among the broad-spectrum viral protease inhibitors obtained from Kansas State University Research Foundation (KSURF) under an exclusive license agreement announced in April 2020. The company believes the protease inhibitors obtained from KSURF have the ability to inhibit the inactive SARS-CoV-2 polymerase replication enzymes into an active form.

Replication Inhibitors

Cocrystal is using our proprietary structure-based drug discovery platform technology to discover replication inhibitors for orally administered therapeutic and prophylactic treatments for SARS-CoV-2. Replication inhibitors hold potential to work with protease inhibitors in a combination therapy regimen.

Norovirus Program

The company is developing proprietary broad-spectrum, non-nucleoside polymerases for the treatment of human norovirus infections using a proprietary structure-based drug design technology platform. The company also holds exclusive rights to norovirus protease inhibitors for use in humans under the KSURF license. The company is targeting the selection of an oral preclinical lead in the first half of 2023.

Norovirus is a global public health problem that's responsible for nearly 90% of epidemic, non-bacterial outbreaks of gastroenteritis around the world.

Hepatitis C Program

Cocrystal is seeking a partner to advance the development of CC-31244 following the successful completion of a Phase 2a clinical trial. This compound has shown favorable safety and preliminary efficacy in a triple-regimen Phase 2a clinical trial in combination with Epclusa (sofosbuvir/velpatasvir) for the ultra-short duration treatment of individuals infected with the hepatitis C virus (HCV).

HCV is a viral infection of the liver that causes both acute and chronic infection. In June 2022 the World Health Organization estimated that 58 million people worldwide have chronic HCV infection.

Valuation & Estimate Changes

The company's current cash position of $34.0 million should be sufficient to fund their operations through the end of 2023, and possibly into 2024, depending on R&D spending levels and possible milestone payments from Merck. We slightly adjusted our loss per share for 2023 to ($1.95).

We are maintaining our price target of **$7.00** per share based on higher prevailing interest rates affecting our discounted cash flow calculation as well as uncertainty related to the timing of receiving Merck milestone payments.

KEY INVESTMENT POINTS

- Founded in 2006, Cocrystal Pharma (COCP) is a clinical stage biotechnology firm headquartered in Bothell, WA with approximately 13 employees at this time.
- The company's product pipeline targets large addressable markets globally for the effective treatment of acute and pandemic viral diseases. These technologies are designed to efficiently deliver small molecule therapeutics that are safe, effective, and convenient to administer.
- Cocrystal has a strong and promising therapeutic drug development pipeline covering treatments for Covid-19, influenza, hepatitis, and norovirus. At this time, the company has not pursued antiviral vaccine development.
- The company has developed a proprietary drug discovery platform technology that accelerates the timeline for drug discovery and development. This technology has been largely developed based on the work of Nobel laureate Roger Kornberg, PHD.
- Phase 1 clinical trials are expected to commence in 2022 for three of the company's drug development programs including two for the treatment of Covid-19 and one for Influenza A.
- A collaboration with Merck related to influenza A/B treatments has the potential to generate up to $156 million in milestone payments and royalties and further validates Cocrystal's advanced drug discovery platform.
- The company has been successful in accessing the equity capital markets over the past 24 months raising approximately $74 million in cash to fund future operations.
- We believe Cocrystal has cash and available liquidity to fund current planned operations until 2023.

OVERVIEW

COCRYSTAL PHARMA, INC.

Source: cocrystalpharma.com/

Cocrystal Pharma is a pre-revenue, clinical-stage biotechnology company that is leveraging its core competencies and decades of management experience in antiviral therapeutics to fight not only the global Covid-19 health crisis, but other complex and problematic viral related infections and disease.

Founded in 2006 by Gary Wilcox (d. 2021), Dr. Sam Lee, Roger Kornberg and Philip Frost, the company focuses on therapeutics and treatments for serious or chronic viral diseases. The company has pursued both therapeutic and prophylactic avenues of fighting viral diseases, but not in the vaccine market as that area is currently established and competitive. Preventing viral replication is a key tenet of the company's research and development.

The company was originally privately funded by entrepreneur and pharmaceutical executive Dr. Phillip Frost who was involved with Ivax Corporation and Teva Pharmaceuticals. Cocrystal went public in 2014 through a reverse merger with an existing shell company at the time. In 2015, they merged with RFS Pharma, a privately owned biotech company founded by renowned drug developer, Dr. Raymond Schinazi. The company has generally been successful at raising capital through equity financing

transactions since going public. More recently, in 2021 the company raised $38.5 million through a normal course secondary offering under a current shelf registration. Additionally, in 2020, they raised $35.8 million through a secondary ATM offering.

The company has developed a proprietary drug discovery platform technology that provides potential for viable drug candidates at reduced costs and with shorter discovery and development timelines. This involves utilizing high throughput x-ray crystallography at near atomic resolution to deliver potent and effective molecules that can evade viral resistance.

Cocrystal currently has seven active programs in its product pipeline of which three of these are devoted to treatments for SARS-CoV-2. Two programs are related to effective antiviral treatments for pandemic and seasonal influenza infections, and one is a legacy approach to shortening treatments for Hepatitis C. The final program deals with Norovirus Gastroenteritis, a highly contagious widespread virus that causes diarrhea, nausea and stomach pain.

The company has been successful in creating a growing patent portfolio wall that protects its research and covers the areas of coronavirus, pandemic influenza, seasonal influenza, norovirus and hepatitis C. Cocrystal has issued patents, or pending patent applications in the U.S. and around the world.

Although the path to commercialization of its drug prospects may be long as it progresses through its pre-clinical development and clinical trials, the company is confident it has the capital to fund currently planned operations. The option to license its discoveries to larger pharmaceutical or biotechnology companies remains a viable option which would occur on a closer time frame than commercialization.

In the Influenza A program, the patent portfolio consists of four patent families, including two pending international (PCT) applications and two families of pending applications in the U.S. and various foreign countries.

In the Influenza A/B program, the patent portfolio consists of a number of patent families pending, variously, as international (PCT) applications and in Taiwan. Aspects of this program are developed in collaboration with Merck.

In the Norovirus and Coronavirus programs, the patent portfolio consists of three pending families of U.S. provisional applications, and a portfolio of patent families licensed through KSURF.

RISK FACTORS

- The company has never generated revenue from product sales and all product candidates are currently in the pre-clinical and early clinical stage. The ability to generate revenue from product sales and achieve profitability depends on their ability, alone or with partners, to successfully complete the development of, obtain the regulatory approvals for, and commercialize pharmaceutical product candidates.

- The company may continue to incur significant losses for the foreseeable future and never generate revenue from product sales. As an early-stage drug development company, the company's focus is on developing product candidates, obtaining regulatory approvals, and commercializing pharmaceutical products. As a result, the company has an accumulated deficit of $259,093,000 from inception through December 31, 2021.

- The company's Covid-19 program is in the preclinical stage. The company initiated preclinical studies during the second quarter of 2020 and selected the lead preclinical molecule in the fourth quarter of 2020. The company may be unable to produce an effective therapy in a timely manner or at all.

Additionally, they are committing substantial financial and other resources to the Covid-19 program, which may negatively impact other drug development programs.

- Many of the company's competitors that are also developing treatments for the Covid-19 virus, and other viruses, have substantially more resources including government funding than the company does and have existing products in significantly more advanced stages of development.

- The company relies on 3rd parties for many, or all aspects of compound formulation, research and preclinical testing. These included Clinical Research Organizations (CROs) as well as outside organizations that own and maintain advanced devices for x-ray crystallography.

- The company relies on a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to future products and drug product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain.

- The company will continue to generate significant operating losses for the foreseeable future and likely until its drug products reach commercialization or licensure arrangements. Capital financing to support these losses, either from the equity or debt markets, may not always be available based on economic or market conditions.

VALUATION

Our primary valuation tool utilizes a Discounted Cash Flow process and produces three different scenarios.

Bull Case – The company experiences some form of success in all of its seven key programs currently in the development pipeline over a 10-year time frame. This includes full realization of the $156 million in Merck milestone payments related to the Influenza A/B program. It also assumes commercialization revenues or partnership licensure revenues from the Oral and Nasal Covid-19 treatment programs will occur starting in 2024 and will become a material source of revenues in 2025. The value in this scenario is $10.00 and we apply a probability factor of 45%.

Base Case – The company experiences success in programs currently planned for clinical trials over the next 12-18 months but does not make progress in programs currently in pre-clinical or lead discovery phase. The value in this scenario is $6.00 and we apply a probability factor of 40%.

Bear Case – The company fails to create material revenue or profit opportunities over the next five years in the majority of its drug development programs and must raise additional equity capital. The value in this scenario is the current stock price of $2.61 and we apply a probability factor of 15%.

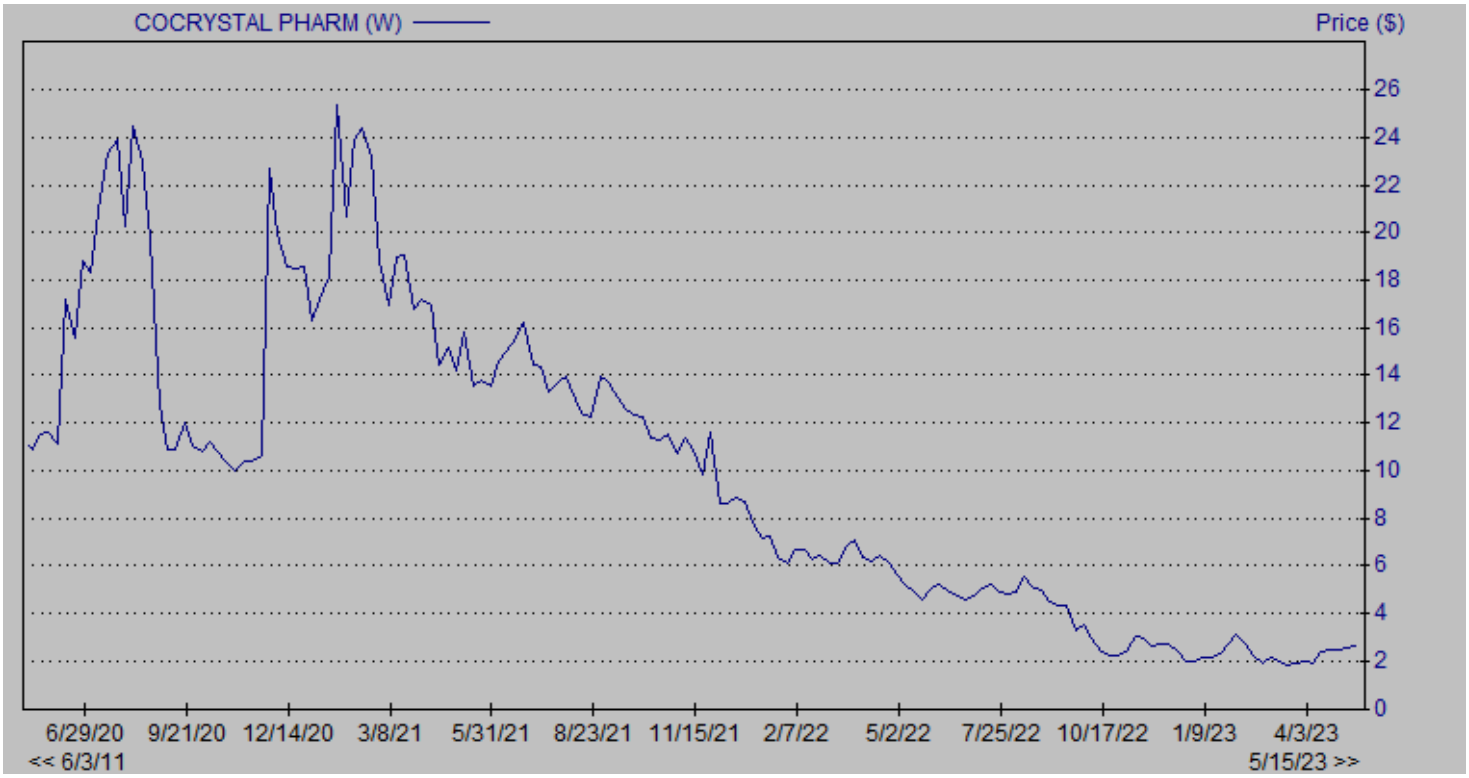
The weighted average price target of these three scenarios is approximately **$7.00**. It is notable that the DCF calculation incorporates a 20% discount rate due to higher prevailing global interest rates.

It's also important to note the stock is selling at 76% of tangible book value at this time as well as selling below cash per share.

PROJECTED INCOME STATEMENT

Income Statement	Dec-21	Dec-22	Dec-23	Dec-24	Dec-25
Net Sales	**0**	**0**	**4,000,000**	**9,500,000**	**21,250,000**
Growth	*-100.0%*	*#DIV/0!*	*#DIV/0!*	*137.5%*	*123.7%*
Cost of Goods Sold	**0**	**0**	**800,000**	**2,275,000**	**5,862,500**
%	*N/A*	*N/A*	*20.0%*	*23.9%*	*27.6%*
Depreciation & Amort	**0**	**0**	**0**	**0**	**0**
Gross Profit	**0**	**0**	**3,200,000**	**7,225,000**	**15,387,500**
Margin	*N/A*	*N/A*	*80.0%*	*76.1%*	*72.4%*
Sales & Marketing Expenses	**0**	**0**	**0**	**1,000,000**	**2,024,342**
% of sales	*N/A*	*N/A*	*0.0%*	*10.5%*	*9.5%*
General & Administrative Expenses	**5,045,000**	**5,745,000**	**5,059,810**	**4,300,839**	**3,655,713**
% of sales	*#DIV/0!*	*#DIV/0!*	*126.5%*	*45.3%*	*17.2%*
Research & Development	**8,794,000**	**12,392,000**	**16,337,531**	**15,520,654**	**15,132,638**
% of sales	*#DIV/0!*	*#DIV/0!*	*408.4%*	*163.4%*	*71.2%*
Amortization	**382,000**	**0**	**0**	**0**	**0**
% of sales	*N/A*	*N/A*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**(14,221,000)**	**(18,137,000)**	**(18,197,341)**	**(13,596,493)**	**(5,425,193)**
Margin	*#DIV/0!*	*#DIV/0!*	*-454.9%*	*-143.1%*	*-25.5%*
EBITDA	**(13,839,000)**	**(18,137,000)**	**(18,197,341)**	**(13,596,493)**	**(5,425,193)**
Margin	*N/A*	*N/A*	*-454.9%*	*-143.1%*	*-25.5%*
Other Expenses/(Income)	**(40,000)**	**6,000**	**312,000**	**(64,898)**	**(22,899)**
%	*N/A*	*N/A*	*7.8%*	*-0.7%*	*-0.1%*
EBIT	**(14,181,000)**	**(18,143,000)**	**(18,509,341)**	**(13,531,594)**	**(5,402,294)**
%	*N/A*	*N/A*	*-462.7%*	*-142.4%*	*-25.4%*
Total Interest Exp (net)	**4,000**	**2,000**	**0**	**0**	**0**
%	*N/A*	*N/A*	*0.0%*	*0.0%*	*0.0%*
Net Profit Before Tax	**(14,185,000)**	**(18,145,000)**	**(18,509,341)**	**(13,531,594)**	**(5,402,294)**
%	*N/A*	*N/A*	*-462.7%*	*-142.4%*	*-25.4%*
Income Tax	**0**	**0**	**0**	**0**	**(810,344)**
% Effective Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*
% Cash Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*
Minority Interests	**0**	**0**	**0**	**0**	**0**
Net Profit	**(14,185,000)**	**(18,145,000)**	**(18,509,341)**	**(13,531,594)**	**(4,591,950)**
%	*N/A*	*N/A*	*-462.7%*	*-142.4%*	*-21.6%*
Non-recurring income (expense)		(20,692,000)			
Average Diluted Shares Outstanding	7,364,000	8,143,000	9,500,000	10,173,000	10,173,000
Reported FD EPS		(4.09)			
Zacks Cash EPS	**(1.87)**	**(2.23)**	**(1.95)**	**(1.33)**	**(0.45)**
Zacks EPS	**(1.93)**	**(2.23)**	**(1.95)**	**(1.33)**	**(0.45)**

HISTORICAL STOCK PRICE



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