Zacks Small-Cap Research

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OncoSec Medical (ONCS-NASDAQ)

ONCS: Unique electroporation delivery technology for cancers coupled with robust mid-stage pipeline; positive Phase II data of ImmunoPulse™ reported----Buy.

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	09/24/2015
Current Price (03/09/16)	$2.01
Twelve- Month Target Price	**$8.00**

OUTLOOK

ONCS is a mid-stage biotech company focused on electroporation delivery technology for cancers. Its lead candidate ImmunoPulse™ locally delivers a plasmid DNA encoding IL-12. Currently ImmunoPulse™ is in several Phase II clinical trials. Data have shown that ImmunoPulse™ is safe and can elicit both a local and systemic immune-response.

ONCS recently initiated a Phase II study of ImmunoPulse™ IL-12 in combination with Merck's approved PD-1 inhibitor KEYTRUDA®.

We are optimistic with the technology and the prospect of OncoSec, and are positive on the company's shares.

SUMMARY DATA

52-Week High	**$7.81**
52-Week Low	**$1.48**
One-Year Return (%)	**-71.69**
Beta	**1.93**
Average Daily Volume (sh)	**70,384**
Shares Outstanding (mil)	**17**
Market Capitalization ($mil)	**$34**
Short Interest Ratio (days)	**N/A**
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 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2015	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2016	0.00 A	0.00 A	0.00 E	0.00 E	0.00 E
2017					0.00 E
2018					25.00 E

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

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2015	-$0.33 A	-$0.38 A	-$0.48 A	-$0.47 A	-$1.67 A
2016	-$0.47 A	-$0.42 A	-$0.43 E	-$0.44 E	-$1.77 E
2017					-$1.78 E
2018					-$0.99 E

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

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WHAT'S NEW

OncoSec Exited Fiscal Second Quarter with a Strong Balance Sheet

On March 8, OncoSec reported its financial results for the fiscal second quarter ended Jan 31, 2016.

There was no revenue for the fiscal 2Q16 as compared with no revenue for the same period of last year.

R&D expenses were $4.1 million for the second quarter of fiscal 2016, compared to $2.9 million for the same periods in 2015.

G&A expenses were $2.9 million for the second quarter of fiscal 2016, compared to $1.7 million for the same period in 2015.

Net loss for the second quarter of fiscal 2016 was $7.0 million ($0.42 per share), compared to a net loss of $4.6 million ($0.38 per share) for the same periods last year.

At January 31, 2016, OncoSec had $28.8 million in cash and cash equivalents. Current cash will last through the first quarter of calendar 2017 according to our financial model.

In November, 2015, OncoSec closed a registered direct offering with two healthcare focused funds for the purchase of 2,142,860 shares of its common stock at a price of $3.50 and warrants to purchase up to an aggregate of 1,071,430 shares of common stock at an exercise price of $4.50 per share. The warrants have a term of 5.5 years and become exercisable after 6 months.

Net proceeds were approximately $6.9 million.

On June 8, 2015, OncoSec closed a registered direct offering of 2,469,091 shares of its common stock at a price of $5.50 per share. Net proceeds from the offering were approximately $12.6 million.

We are pleased with these two financings which not only strengthen OncoSec's cash position, but also validate the company's technology and clinical programs.

OncoSec's Technology Has the Potential to Transform PD-1/PDL-1 Non-Responder to Responder

Background of Immune Checkpoint Inhibition

Immune checkpoint inhibition is the one of the most promising areas for the treatment of cancer. Both CTLA-4 and PD-1/PDL-1 inhibitors have shown impressive results in clinical care and in ongoing clinical studies. Recent approval of **Yervoy** (CTLA-4 antibody from BMS), **Opdivo** (PD-1 antibody from BMS), and **Keytruda** (PD-1 antibody from Merck), demonstrated the importance of immune checkpoint inhibitors in the treatment of cancer. We think the cancer immunotherapy – through immune checkpoint inhibitors – will enter widespread clinical use and command a large market share of the cancer care market within the next decade.

Studies have demonstrated that tumors (specifically melanoma) can be divided into a high and low TIL (tumor infiltrating lymphocyte) phenotype. Tumors with high TIL are referred to as **immunogenic**, while tumors with low TIL are referred to **non-immunogenic**. Ongoing clinical trials of PD-1/PDL-1 inhibitors suggest that response correlates with high TIL phenotype. Tumors with low TIL have low response rate to PD-1/PDL-1 inhibitors.

Anti-PD-1 **non-responders** constitute the majority of patients even in "immune therapy" tractable tumors like melanoma and RCC. Recent melanoma studies have reported response rates in the range of 20-40% using anti-PD-1 or anti-PDL-1, and the argument is that the majority of the responders are the high-

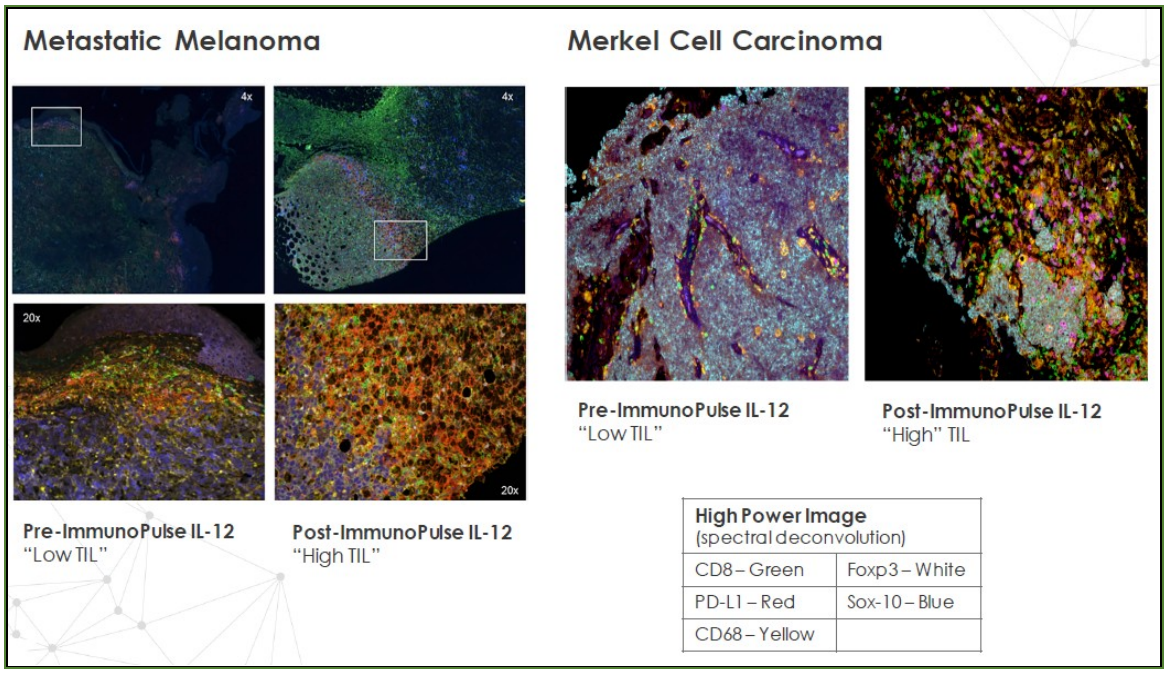
TIL population. If this is the case, then the question becomes how to make those **non-immunogenic tumors** into immunogenic tumors so that they can respond to PD-1/PDL-1 or similarly effective T cell checkpoint agents.

Tumor Type	Anti-PD-1/PD-L1 mAb Non-Response
Melanoma	~ 60 - 80%
Triple Negative Breast (TNBC)	~ 70 - 82%[1]
Renal Cell Carcinoma (RCC)	~ 71%
Lung Carcinoma (NSCLC)	~ 79 - 83%
Head & Neck (H&N)	~ 80%[2]
Bladder	~ 84%[3]
Gastric	~ 69%[2]

ImmunoPulse™ IL-12: A Potential Paradigm Shift in Cancer Immunotherapy

We believe OncoSec's platform technology and lead candidate **ImmunoPulse™ IL-12** has the potential to transform the non-immunogenic tumors (non-responders) into immunogenic tumors (responders) to prime the immune system for PD-1/PDL-1 inhibitors, such as Opdivo and Keytruda.

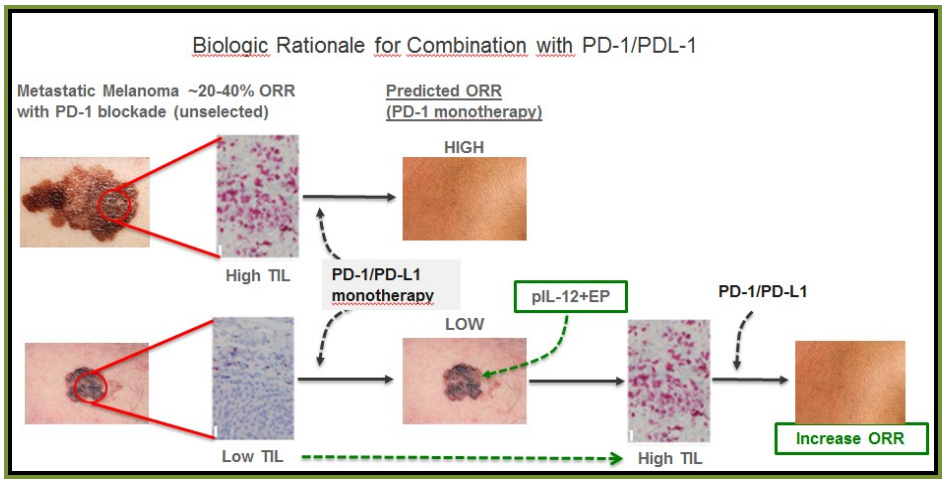
ImmunoPulse™ IL-12 has demonstrated strong efficacy to convert T cell poor tumors to T cell rich tumors in both metastatic melanoma and Merkel cell carcinoma.



Since IL- 12 promotes tumor immunogenicity and increases the number of TILs in the tumor, the combination therapeutic concept is that ImmunoPulse™ will convert low TIL tumors into high TIL ones, thus allowing Keytruda/Opdivo to kill tumor in patients, who would otherwise be PD-1 unresponsive.

The potential ability of ImmunoPulse™ to convert the non- or weakly immune-responsive cancer into strongly immune-responsive cancer may represent a **paradigm shift** in cancer therapy. This area is an

enormous unmet medical need and represents a huge market opportunity for OncoSec. It is estimated that about 50% to 80% of cancer patients will not have TIL infiltrate at baseline or even after PD-1/PDL-1 treatment. This is where OncoSec's ImmunoPulse™ can get in and convert those non-immunogenic tumors into immunogenic tumors. In addition to melanoma, ImmunoPulse™ can virtually target any solid tumor, which represents a **multi-billion dollar market** for OncoSec.



There is a huge **unmet medical need** for OncoSec's ImmunoPulse™ in combination with checkpoint inhibitors. If we look at the melanoma indication alone, this is a disease that has the highest response rates with PD-1 inhibitor monotherapy. But still there are about **60% to 80%** of patients who will not respond to PD-1 checkpoint inhibitors. This powerful combination is expected to treat the larger population of approximately **70% of the patients**.

In **other solid tumors**, the percentage of PD-1 non-responders/non-immunogenic tumors is likely to be even greater. Thus, there is a tremendous unmet medical need, across many solid tumors.

We estimate the market for the combination therapy will be a multi-billion dollar business.

Results from Newly Initiated Phase II Combination Trial Could Lead to a Big License Deal

In November 2014, OncoSec initiated a landmark **Phase II** combination trial in collaboration with the **University of California, San Francisco** (UCSF) and **Merck** to evaluate the safety, tolerability and efficacy of Merck's anti-PD-1 drug, **KEYTRUDA®** (pembrolizumab) in combination with OncoSec's ImmunoPulse™ IL-12 therapy for the treatment of **metastatic melanoma** patients, who are non-responsive to KEYTRUDA®.

This Phase II clinical trial is an investigator sponsored trial (IST), with UCSF and Dr. Alain Algazi as the lead investigator. This is a multi-center, open label, single-arm trial, which will enroll approximately **42 patients** with unresectable, "low-TIL" metastatic melanoma. The key endpoints of the study include: best Overall Response Rate by RECIST v1.1 and immune related-Response Criteria (irRC); safety and tolerability; duration of response; 24-week landmark progression-free survival; median progression-free survival; and overall survival.

The treatment schedule for the trial follows the standard schedule for pembrolizumab. Pembrolizumab will be administered systematically once every three weeks and ImmunoPulse™ IL-12 will be administered on three separate days every six weeks. ImmunoPulse™ IL-12 employs intratumoral delivery of DNA-based IL-12 followed by electroporation. Merck will supply pembrolizumab, and OncoSec will provide ImmunoPulse™ IL-12.

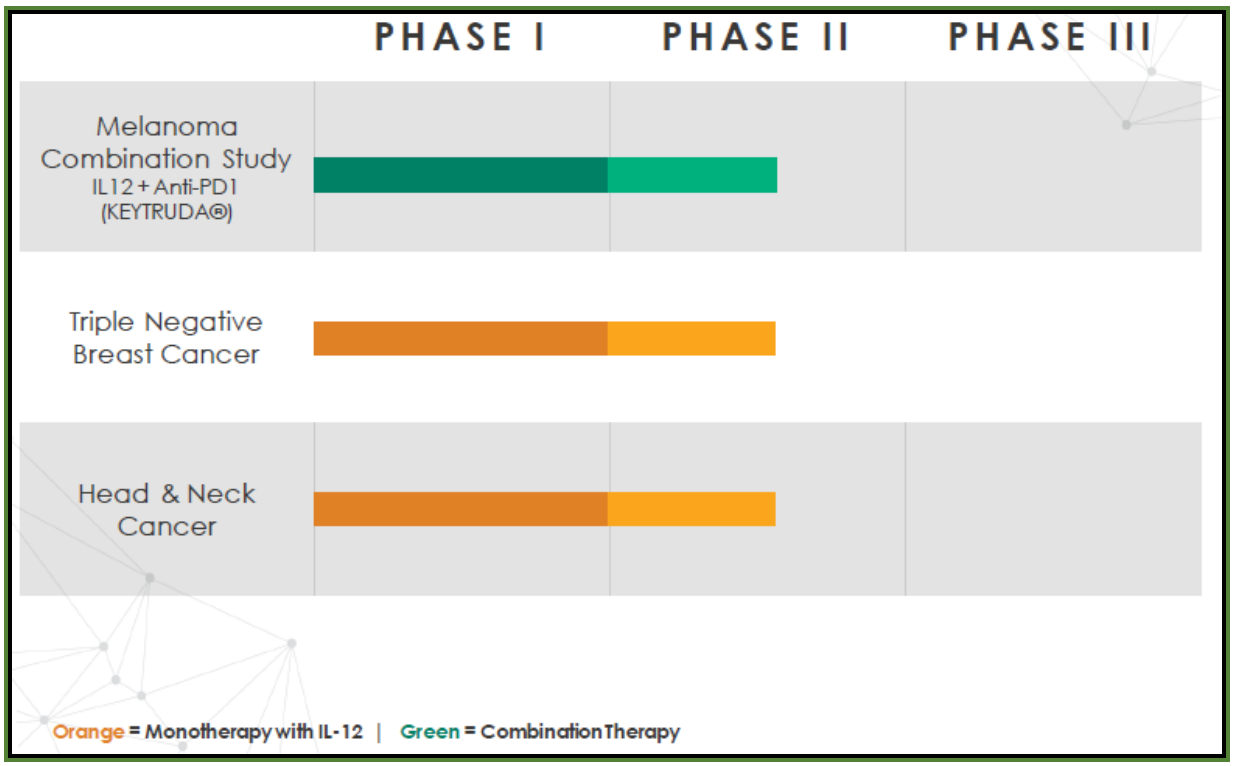
This is the first study in the field of immuno-oncology to evaluate the combination of DNA-based interleukin-12 with electroporation and an anti-PD-1/PD-L1 inhibitor.

The **Phase II combination** study will provide the Company with information for a key inflection point in the development of its lead ImmunoPulse™ program. We believe positive data from the Phase II combination study may lead to a major **license deal** for OncoSec. If the Phase II combination study can confirm safety and efficacy of both agents, a **pivotal trial** could follow by either OncoSec or Merck in 2016. And we estimate approval of ImmunoPulse™ for the treatment of melanoma may be obtained as early as **in 2018** if the pivotal trial data prove to be positive.

We believe the combination has the potential to be a powerful approach in the fight against melanoma and other cancers. This Phase II combo study presents a potential to address the unmet medical need of vast majority of the metastatic melanoma patients and has profound implications on many other tumor indications.

Update on Phase I Trial of ImmunoPulse™ for TNBC

In addition to the ongoing Phase II combination study of ImmunoPulse™ IL-12 with KEYTRUDA, OncoSec is also developing ImmunoPulse™ as a monotherapy for other cancers. This chart summarizes the status of the company's ongoing clinical trials.



In the summer of 2015, a **pilot biomarker study** of ImmunoPulse™ in patients with triple negative breast cancer **(TNBC)** was initiated at Stanford University with Melinda L. Telli, MD serving as lead investigator. The trial enrolled the first patient on Oct 29, 2015.

Previous studies have demonstrated that breast cancer patients whose tumors are associated with markers of inflammation, such as the presence of TILs, have better clinical outcomes. Further, preliminary data reported at the 2014 San Antonio Breast Cancer Symposium indicated that TNBC is responsive to cancer immunotherapies, such as anti-PD-1/PD-L1 checkpoint therapies. However, response rates in these TNBC patients, who were selected for study participation based upon TIL status, were only 18 to 33 percent.

This pilot study will evaluate the pharmacodynamic effects of intratumoral injection of pIL-12 followed immediately by electroporation (IT-pIL12-EP). A minimum of **ten patients** with biopsy-accessible triple negative breast cancer will be treated in this study. Additional patients, up to a maximum of **25 patients**, may be enrolled based upon pharmacodynamic observations and at the discretion of the principal investigator, in consultation with OncoSec. All patients will receive a single 28-day treatment cycle. One lesion will remain untreated (the control lesion). Treatment will be administered on Days 1,5, and 8 of the single 28-day cycle. Treatments will consist of direct injection of pIL-12 into tumor lesions, followed immediately by electroporation of the lesions. At the end of the treatment cycle, patients will return to clinic for a final safety evaluation and tumor biopsy. This end of study (EOS) visit will occur prior to initiating any new anti-cancer therapy/regimen.

All patients will undergo tumor biopsies at two separate time points for molecular and histological analyses associated with the primary endpoint. At least one lesion will be biopsied at Screening (pre-treatment sample). Biopsies of the untreated control lesion and at least one treated lesion will be obtained at the EOS visit (post-treatment samples). Additional tumor biopsy samples may be requested if there is either tumor regression or progression prior to EOS.

The primary endpoints include:

- Changes in the proportion of intratumoral lymphocyte subsets by quantitatively analyzing the number and distribution of tumor infiltrating lymphocytes (TILs) in paired tumor biopsy samples.
- Comparison of NanoString-based gene expression profiles will be completed from paired tumor samples obtained pre- and post-treatment.

Secondary outcome will measure:

- Number of participants with treatment-related adverse events;
- Anti-tumor activity; and
- Detection of plasmid IL-12 in untreated lesions.

This pilot study is designed to assess whether ImmunoPulse™ IL-12 increases TNBC tumor immunogenicity by driving a pro-inflammatory cascade of events that leads to increases in cytotoxic tumor-infiltrating lymphocytes (TILs). The presence and number of TILs is thought to be a key requirement for promoting the anti-tumor activity of antibodies like anti-PD-1/PD-L1. By driving cytotoxic immune cells into the tumor, ImmunoPulse™ IL-12 may be an ideal candidate to combine with checkpoint blockade therapies which reported some activity in TNBC (only about 20-30% TNBC patients respond to checkpoint inhibitor treatment).

Based on the data from the pilot study, we believe OncoSec may initiate a follow-up **Phase II** combination study of ImmunoPulse™ IL-12 with checkpoint inhibitors.

TNBC is defined by a lack of expression of both estrogen (ER) and progesterone (PgR) receptors as well as human epidermal growth factor receptor 2 (HER2). Therefore, they don't respond well to hormone therapy. According to American Cancer Society, the five-year survival rate for stage 4 TNBC is only 22%.

TNBC accounts for approximately 20 percent of all breast cancer. Worldwide, TNBC amounts to approximately 200,000 cases each year. Advanced TNBC remains a significant area of unmet medical need and there is no established standard-of-care. Treatment generally includes chemotherapy, with or without radiation and/or surgery. However, no treatment regimen has clearly demonstrated superiority.

We believe ImmunoPulse™ IL-12 may have the potential to become an important treatment regimen for TNBC.
We expect data from the pilot study will be available in 3Q16.

Update on Phase II Trial of ImmunoPulse™ IL-12 for the Treatment of Squamous Cell Carcinoma of the Head and Neck

On June 16, 2015, OncoSec enrolled the first patient into a **Phase II** clinical trial (**OMS-I130)** of ImmunoPulse™ IL-12 in patients with treatment-refractory, metastatic and unresectable squamous cell carcinoma of the head and neck (HNSCC).

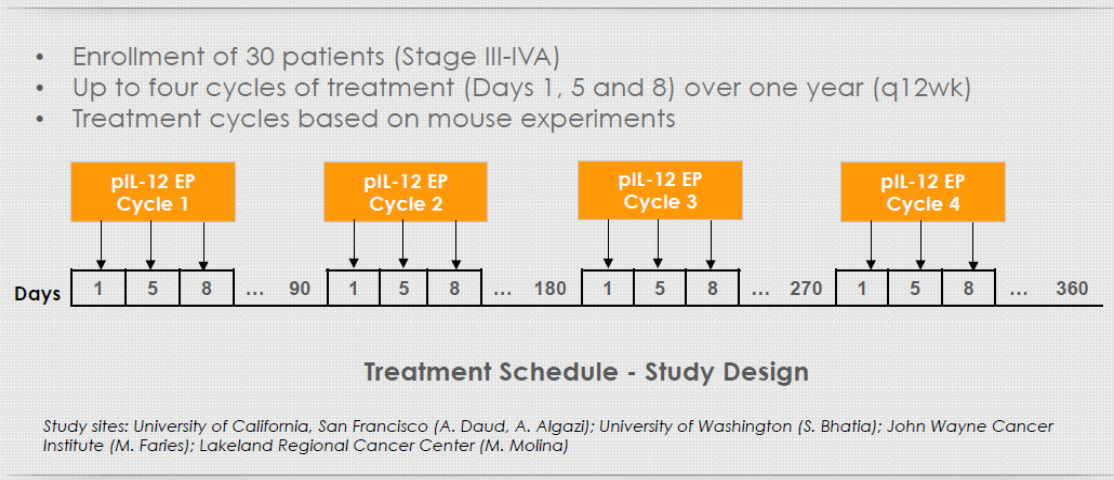
OMS-I130 is a single-arm, open-label study evaluating the safety and anti-tumor activity of intratumoral DNA-based IL-12 with electroporation in approximately **30 patients** with treatment-refractory metastatic and unresectable HNSCC. The key endpoints include: objective response evaluations by RECIST v1.1 and immune-related Response Criteria (irRC); biomarker comparisons of pre- and post-treatment tumor biopsies, including NanoString® gene expression profiling and immunohistochemistry for tumor-infiltrating lymphocytes (TILs); duration of response to treatment; overall survival; progression-free survival; and safety.

The lead investigators for OMS-I130 are Tanguy Seiwert, MD, from the University of Chicago and lead author of the presentation outlining the key gene signature for anti-PD-1 responders with HNSCC, and Alain Algazi, MD, from the University of California, San Francisco.

Top line data from this trial will be available in mid-2017.

Update on Phase II Trial of ImmunoPulse™ IL-12 for Metastatic Melanoma

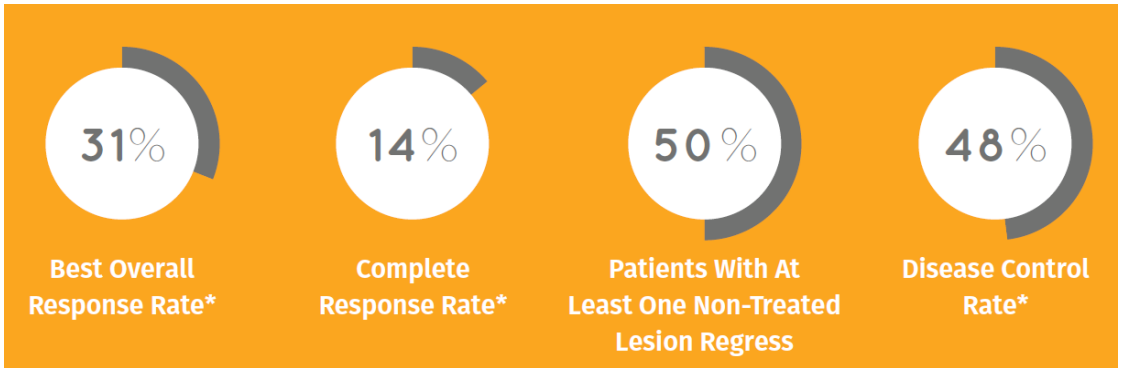
OncoSec initiated a **Phase II** clinical trial in patients with **melanoma** in Feb 2012. The Phase II melanoma trial (**OMS-I100**) is a single dose trial treating approximately 25 patients. The **primary endpoint** is objective response rate (local and distant) at six months. Secondary trial endpoints include time to objective response (complete and partial responses), duration of distant response and overall survival.



Data from the multicenter, open-label, single-arm study confirmed the safety of **ImmunoPulse™** IL-12 with no treatment-related serious adverse events or deaths having been reported. Regression of treated and non-treated tumors suggests successful induction of systemic anti-tumor response.

As of this writing, **30 patients** were enrolled and received at least one cycle of treatment. **29 patients** were evaluable for objective response rate (ORR) at 24-week primary time point.

Best **ORR was 31%** (9/29), which included a complete response rate of 14% (4/29) and a disease control rate of 48% (14/29).



Importantly, ImmunoPulse™ IL-12 resulted in the development of a systemic anti-tumor effect in the majority of patients. Twenty-two of the enrolled patients presented with baseline lesions were left untreated in order to evaluate the induction of a systemic response. Regression was documented in at least one non-injected tumor in **50 percent of patients**. These results suggest that intratumoral therapy with IL-12 can induce systemic anti-tumor responses while avoiding the toxicities observed with systemic recombinant IL-12 therapy.

In addition to best overall response and systemic response, an assessment of best local response in treated lesions was conducted. Complete response was defined as complete regression of a treated lesion. Partial response was defined as >30% reduction in the longest diameter of the tumor, while stable disease was defined as ≤30% reduction and <20% increase in the longest diameter of the tumor.

Treated Lesion Best Local Response

Number of Evaluable Treated Lesions	Stable Disease (%)	Partial Response (%)	Complete Response (%)
85	26/85 (31%)	7/85 (8%)	38/85 (45%)

Correlative data were also presented, including gene expression in a subset of eight patients, where adequate paired pre- and post-treatment biopsy samples were available. A focused analysis of immunomodulatory cell types and pathways supported the hypothesis that ImmunoPulse™ IL-12 leads to induction of interferon-γ and downstream interferon-γ-inducible genes, including key modulators of antigen presentation and processing machinery and chemokines. Additional genes of interest were also up-regulated, including PD-1, PD-L1 and T cell markers, confirming the Phase I data, indicating that treatment results in T cell infiltration.

These data strengthen and expand upon previously reported Phase I results, which indicated a complete response in 16% of patients (3/19) and disease stabilization in 38% (7/19).

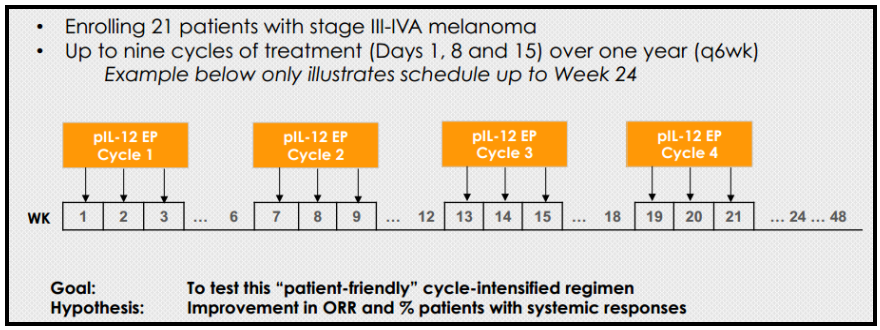
We are encouraged by the safety and efficacy data of ImmunoPulse™ in the Phase II study in melanoma patients. The positive Phase II data further validates results from previous Phase I study. We are especially impressed with the response rate of untreated tumors, which suggests an induction of **systemic antitumor response**, without systemic toxicity.

Systemic response is significant for two main reasons. **First**, it suggests that unlike most locally administered melanoma treatments, ImmunoPulse™ may induce antitumor response throughout the entire body, which would have clear benefits in the treatment of metastatic disease. **Secondly**, the favorable safety profile of ImmunoPulse™ indicates its potential to deliver systemic benefit, without the toxicities associated with many other systemic treatments.

Update on the Phase II Extension Study of Melanoma

In March 2014, OncoSec submitted a protocol addendum to the FDA and Institutional Review Board (IRB) to evaluate an **increased dose frequency** for ImmunoPulse™ in an expansion of its ongoing **Phase II melanoma trial**. The Company has completed enrollment of **21 patients** in this expansion.

The objective of this extension study is to assess the safety and efficacy of a **six-week treatment cycle** with ImmunoPulse™ in up to 21 melanoma patients. Each cycle will consist of treatments on Days 1, 8 and 15. Subjects will be eligible for an additional cycle as early as six weeks from the first treatment up to a maximum of nine treatment cycles.



There are **three goals** of the trial expansion:

- It will provide an opportunity to assess whether more frequent treatment with ImmunoPulse™ can provide additional clinical benefit to melanoma patients.
- The expansion is also intended to help optimize the treatment design of the Company's **Phase IIb** study in melanoma patients.
- Safety of this intensified dose regimen will also be assessed.

We expect that data from this extension study will be available **in 3Q2016.**

Update on the Phase II Trial of ImmunoPulse™ IL-12 in Merkel Cell Carcinoma

On Sept. 27, 2015, OncoSec announced positive results from the Phase II trial of ImmunoPulse™ IL-12 in patients with Merkel cell carcinoma (MCC).

The Phase II trial was an open-label study that enrolled 15 patients with MCC. The primary endpoint of the trial was IL-12 protein expression following treatment with ImmunoPulse™ IL-12. Secondary endpoints included: safety and tolerability; overall response rate evaluated by RECIST-modified criteria for MCC; distant lesion regression; and biological markers of pro-inflammatory changes in the tumor microenvironment.

Patients enrolled into this study were separated into two cohorts. Cohort A (N=3) was comprised of patients whose disease status was amenable to definitive surgery or radiation following a single cycle of ImmunoPulse™ IL-12 treatment (i.e., neo-adjuvant). Patients with more advanced disease were enrolled into Cohort B (N=12) and permitted to receive up to four cycles of ImmunoPulse™ IL-12.

In this Phase II study, 79% of patients (11/14) showed an increase in IL-12 protein levels in tumor biopsy samples obtained approximately 22 days after treatment compared to baseline, indicating that ImmunoPulse™ IL-12 leads to successful DNA transfection and sustained protein expression within the tumor microenvironment.

ImmunoPulse™ IL-12 was well-tolerated, with no treatment-related adverse events above Grade 2 and no treatment-related serious adverse events. The most common adverse event was Grade 1 transient pain associated with the treatment procedure.

Analysis of individual lesions found that 30% of patients (3/10) who were evaluable for systemic anti-tumor immunity had regression of at least one distant, non-injected/non-electroporated lesion. In patients considered evaluable for objective response by modified RECIST criteria (i.e., Cohort B, N=12), 25% of patients (3/12) had an objective partial response (PR) and one patient had stable disease (SD) for a disease control rate (PR + SD) of 33%. In Cohort A (N=3), one patient had a pathologic complete response and continues to be recurrence-free at six months. Another patient has been recurrence-free for over three years. Immune correlative data suggest that ImmunoPulse™ IL-12 can increase tumor-infiltrating lymphocytes and may promote a tumor-specific CD8+ T-cell response.

We are pleased to see that ImmunoPulse™ IL-12 continues to demonstrate that intratumoral treatment with IL-12 DNA can induce anti-tumor immune effects both locally and systemically. These results are consistent with previous data in metastatic melanoma and underscore the broad-reaching potential of ImmunoPulse™ IL-12 in driving immunogenicity. We are also pleased to see that ImmunoPulse™ IL-12 is safe and well tolerated.

Uplisting to NASDAQ Raises Company Visibility and Investor Awareness

In May 2015, OncoSec's shares were approved to trade on the NASDAQ Stock Market.

Before the uplisting, OncoSec's shares were quoted on the over-the-counter (OTC) market. We all know that trading in stock quoted on the over-the-counter market is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with the Company's operations or business prospects.

Moreover, the over-the-counter market is not a stock exchange, and trading of securities there is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like NYSE. There is no assurance that a sufficient market will develop or remain stable in the stock, in which case it could be difficult for stockholders to resell their stocks. Liquidity is also an issue for institutional investors.

However, we are pleased with management's effort to seek uplisting to NASDAQ over the past year. In order to fulfill the uplisting requirements, the company completed the capital restructuring in May 2015. Specifically, OncoSec completed the 1-for-20 reverse split of its common stock effective at the close of trading on May 18, 2015. As a result of the stock split, every 20 shares of issued and outstanding common stock will be converted into 1 share of common stock.

We believe the uplisting raises the company's visibility and investor awareness dramatically. As the company becomes a NASDAQ-listed company, it is now able to communicate its progress with a broader audience and attract a broader, more diverse shareholder base.

We Maintain Buy Rating and Adjust Our Price Target to $8 Post the Reverse Split

We maintain our Buy rating on OncoSec shares and adjust our 12-month price target to $8.00 after the 20-to-1 reverse stock split.

OncoSec is an emerging biotech company focused on developing and commercializing innovative approaches for the treatment of cancers. OncoSec's key platform technology is its proprietary **electroporation delivery system** to locally deliver DNA or chemotherapeutics into tumor cells. But what makes the technology unique is that this locally delivered DNA has demonstrated systemic response for the treatment of melanoma and MCC meaning that the technology can be used to treat **metastasis** of cancers.

OncoSec's lead candidate **ImmunoPulse**™ is a delivery device encoding for IL-12. ImmunoPulse™ IL-12 is currently in four Phase II clinical trials for melanoma (one monotherapy, one combination therapy), TNBC and Head and Neck cancer. The company already reported positive data from the Phase II melanoma trial.

One important application of ImmunoPulse™ is that it can be **combined** with **checkpoint inhibitors** such as PD-1/PDL-1 for the treatment of melanoma and other solid tumors. In this case, the combination therapy can convert non-immunogenic cancers into immunogenic cancers, which can be killed by the combination therapy. The Company already initiated a Phase II combination trial for melanoma. If data are positive from the combination study, pivotal trial for melanoma could start in 2017, and approval of this indication could be obtained as early as in 2018.

The market for ImmunoPulse™ is huge even for the melanoma indication alone. If we consider other indications for solid tumors, the market is much bigger.

Based on OncoSec's fundamentals, we think its shares are undervalued at current market price. Currently, OncoSec shares are trading at about $1.80 per share, which values the company at $31 million in market capitalization based on 16.9 million outstanding shares. This certainly is a huge discount compared to its peers. We understand that valuing a development stage biotech company is always difficult. But if we look at similar companies in the cancer space, the value of a typical development stage biotech firm with similar fundamentals to OncoSec is usually from $50 million to $1 billion depending on how advanced the programs are and how big the markets are for its candidates. OncoSec is a mid-stage development biotech company. The market of melanoma and/or other solid tumors is huge for its lead candidate ImmunoPulse™.

With the estimated approval of ImmunoPulse™ in 2018, we model OncoSec will become profitable in fiscal 2020 with earnings per share (EPS) of $0.65 based on ImmunoPulse™ sales of $100 million. We think a 30 x P/E multiple is appropriate for OncoSec. Using this P/E ratio and a 25% discount rate for four years, we arrive at our price target of $8.00 per share for OncoSec, which values the Company at $135 million in market cap. This valuation is still conservative in our view considering the relatively strong fundamentals of the Company.

Recent interest in electroporation technology from big pharma could serve as a wildcard for OncoSec valuation. In September 2013, **Roche** entered into collaboration with **Inovio Pharmaceuticals** with an over $400 million investment in Inovio's electroporation technology. Also in Feb 2014, **Pfizer** entered into a collaboration agreement with **Ichor Medical Systems** to utilize Ichor's intramuscular electroporation technology. With proven clinical data, OncoSec's ImmunoPulse™ could be the next target for big pharma companies.

INVESTMENT THESIS

ImmunoPulse™: OncoSec's Unique, Proprietary Platform Technology

OncoSec's core technology for cancer treatment is called **ImmunoPulse**™. This breakthrough technology hinges on a proprietary process called **electroporation**, which uses an electrical pulse to create temporary pores in cancer cells. After the electroporation, DNA-encoded cytokines or other immunomodulatory molecules are delivered through these pores, leading to sustained expression of these molecules in the tumor, leading to lower "doses" than what would normally be delivered systemically. The result is a more potentially effective treatment with fewer side effects.

Supported by extensive research and development and a comprehensive patent portfolio, OncoSec is now a world leader in this emerging technology. This technology includes the design and manufacture of

medical-grade electrical pulse generators, treatment applicators, and software that are adaptable for different clinical applications. The technology and methods of use are all patented intellectual property.

These proprietary elements, along with the company's clinical trial experience and expertise in using these technologies, have helped OncoSec to consolidate its position as the leading proponents of this promising treatment for solid tumors.

ImmunoPulse™ is developed based on the following rationale. Many drugs and DNA-based therapeutics must enter the target cell through its membrane in order to perform their intended function. However, the effectiveness of these medicines is limited since gaining entry into target cells through the outer membrane can be a significant challenge. In the 1970s, it was discovered that the brief application of high-intensity, pulsed electric fields to the cell resulted in a temporary and reversible increase in the permeability of the cell membrane, enabling the intracellular delivery of a variety of payloads, most notably, DNA constructs (i.e. plasmids) encoding biologically active molecules such as cytokines.

This transient and reversible **electrical permeabilization** of cell membranes and the resulting increase in intracellular delivery of immune-activating DNA plasmids is the underlying basis of OncoSec's therapeutic approach. While the extent of membrane permeabilization depends on various electrical, physical, chemical, and biological parameters, research with ImmunoPulse™ has demonstrated an increase of cellular uptake in chemical molecules from **1,000 to 8,000**-fold above baseline. The enhanced delivery of these agents may result in the ability to not only improve cytotoxicity and therapeutic value but also to lower the required doses, and thereby providing a potentially safer treatment.



DNA Delivery with Electroporation — ImmunoPulse

The greatest obstacles to making conventional immunotherapy and DNA-based immunotherapies a reality has been the limited data supporting safe, efficient, and economical delivery and expression of plasmid-DNA constructs into the target cells. The use of ImmunoPulse™ in this approach has been validated from multiple clinical studies assessing DNA-based immunotherapies against cancers. Together with its collaborators, OncoSec plans to be the leader in establishing electroporation-delivered DNA immunotherapies. Based on existing data generated, electroporation could become the method of choice for plasmid-DNA delivery into cells in many clinical applications.

The ImmunoPulse™ approach utilizes an **optimized electroporation system** to deliver plasmid DNA encoding immunotherapeutic cytokines into tumor cells which in turn promote anti-cancer responses. The cytokine-encoding plasmid is first injected with a syringe/needle into the selected tumor. Using a remote control, the pulse generator is switched on and electrical pulses are generated and delivered through an attached electrical cord into the injected tissue through an electrode-needle array on the applicator. Studies have shown that when DNA injection is followed by electroporation of the

target tissue, transfection is significantly greater with resultant gene expression generally enhanced from 100 to 1000-fold. This increase makes many DNA-based candidates potentially feasible without unduly compromising safety or cost.

The lead candidate based on the electroporation delivery technology is **ImmunoPulse™ IL-12**, which delivers DNA-based interleukin-12 (IL-12), a naturally occurring protein with immune-stimulating functions. The treatment is designed to produce a controlled, localized expression of IL-12 in the tumor microenvironment, which in turn, enables the immune system to target and attack tumors throughout the body. A **Phase I** clinical trial in **metastatic melanoma** has been completed using ImmunoPulse™ to deliver plasmid-DNA encoding for the **IL-12** cytokine. The study was designed to assess both the adaptive and innate immunity responses from the targeted delivery of the IL-12 into melanoma tumor cells. The findings demonstrated not only regression of treated melanoma skin lesions, but also regression of distant untreated lesions, suggesting a **systemic immune response** to the localized treatment. Based on the positive Phase I data, OncoSec is conducting Phase II clinical trials of ImmunoPulse™ IL-12 for various tumors.

Advantages of ImmunoPulse™

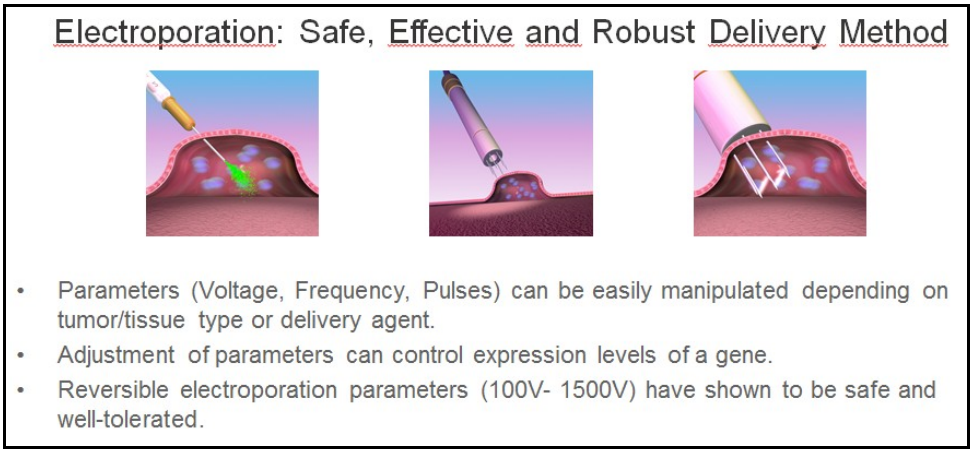
Cancer is a disease of uncontrolled cell growth. The primary front line treatment of solid tumors involves surgical resection and/or radiation to eliminate or debulk tumor growth prior to initiating systemic therapy with chemotherapeutic agents. When detected early and still confined to a single location, cancer may be cured by surgery or radiation. However, neither surgery nor radiation can cure cancer that has spread throughout the body. Although chemotherapy can sometimes effectively treat cancer that has spread throughout the body, a number of non-cancerous cells, such as bone marrow cells, are also highly susceptible to chemotherapy. As a result, chemotherapy often has fairly significant side effects. In addition, it is common to see cancer return after apparently successful treatment by each of these means.

We believe that OncoSec's **ImmunoPulse™** could offer a solution for cancers with an improvement in safety and quality of life for patients over conventional systemic treatments such as chemotherapy.

OncoSec's ImmunoPulse™ is an **immunotherapy**, which may have advantages over surgery, radiation, and chemotherapy. Immunotherapy is a process which uses the patient's own immune system to treat cancer. Many cancers appear to have developed the ability to "hide" from the immune system. A treatment that can augment the immune response against tumor cells by making the cancer more "visible" to the immune system would likely represent a significant improvement in cancer therapy. Immune-enhancing proteins such as interleukin-2 (**IL-2**) and interferon-alpha (**IFN- a**) have shown encouraging results. However, these agents often require frequent doses that may result in severe side effects.

ImmunoPulse™ approach consists of directly injecting solid tumors with a DNA plasmid, which, upon uptake into cells, directs the production of the encoded immunostimulatory cytokine **(IL-12)** to generate a loco-regional immune response against the tumor, which can potentially induce a systemic immune response. The ease of manufacture, convenience, and ability to repeat administration may offer advantages over current modalities of therapy. In addition, cancer therapies using **non-viral DNA** delivery may offer an added margin of safety compared with viral-based delivery, as no viral particles or other potentially infectious agents are contained in the formulation.

OncoSec's electroporation technology is a safe, effective and robust tool for delivering payloads into cells. Because of this, the company is able to deliver potentially toxic payloads, like IL-12, locally into the tumor as a gene, and have it expressed in the tumor microenvironment. The beauty of electroporation is its ability to modify and manipulate the parameters and the payloads to target any indication, thus making it a well-defined, safe and effective delivery tool.



Another advantage of ImmunoPulse™ is that this technology has the potential for broad application. The use of electroporation to deliver immune-modulating DNA agents directly and safely into tumors provides for a robust and flexible technology that can be applied towards the treatment of numerous solid tumor indications either alone or in combination.

PROJECTED INCOME STATEMENT

	2015A (Jul)					2016E (Jul)					2017E (Jul)	2018E (Jul)	2019E (Jul)	2020E (Jul)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	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	$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	$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	$25.00	$55.00	$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**	**$25.00**	**$55.00**	**$100.00**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	120.0%	81.8%
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	3.75	8.25	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**	**$21.25**	**$46.75**	**$85.00**
Gross Margin	-	-	-	-	-	-	-	-	-	-	-	85.0%	85.0%	85.0%
R&D	$2.50	$2.86	$3.93	$3.84	$13.13	$3.66	$4.11	$4.15	$4.25	$16.17	$20.00	$23.00	$30.00	$35.00
% R&D	-	-	-	-	-	-	-	-	-	-	-	92.0%	54.5%	35.0%
SG&A	$1.56	$1.76	$2.05	$2.74	$8.11	$3.38	$2.92	$3.20	$3.50	$13.00	$15.50	$20.00	$25.00	$30.00
%SG&A	-	-	-	-	-	-	-	-	-	-	-	80.0%	45.5%	30.0%
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	$0.00
Operating Income	**($4.1)**	**($4.6)**	**($6.0)**	**($6.6)**	**($21.2)**	**($7.0)**	**($7.0)**	**($7.4)**	**($7.8)**	**($29.2)**	**($35.5)**	**($21.8)**	**($8.3)**	**$20.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-15.00%	20.00%
Other Net	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	($0.1)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($4.1)**	**($4.6)**	**($6.0)**	**($6.6)**	**($21.2)**	**($7.0)**	**($7.0)**	**($7.4)**	**($7.8)**	**($29.2)**	**($35.6)**	**($21.8)**	**($8.3)**	**$19.9**
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	$0.5	$1.5
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($4.1)**	**($4.6)**	**($6.0)**	**($6.6)**	**($21.2)**	**($7.0)**	**($7.0)**	**($7.4)**	**($7.8)**	**($29.2)**	**($35.6)**	**($21.8)**	**($8.8)**	**$18.4**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-59.6%	-309.3%
Net Margin	-	-	-	-	-	-	-	-	-	-				
Diluted Shares Out	12.2	12.3	12.3	13.9	12.7	14.8	16.8	17.0	17.5	16.5	20.0	22.0	25.0	30.0
Reported EPS	**($0.33)**	**($0.38)**	**($0.48)**	**($0.47)**	**($1.67)**	**($0.47)**	**($0.42)**	**($0.43)**	**($0.44)**	**($1.77)**	**($1.78)**	**($0.99)**	**($0.35)**	**$0.61**
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$1.00*
Non GAAP Net Income	**($4.1)**	**($4.6)**	**($6.0)**	**($6.6)**	**($21.2)**	**($7.0)**	**($7.0)**	**($7.4)**	**($7.8)**	**($29.2)**	**($35.6)**	**($21.8)**	**($8.8)**	**$19.4**
Non GAAP EPS	**($0.33)**	**($0.38)**	**($0.48)**	**($0.47)**	**($1.67)**	**($0.47)**	**($0.42)**	**($0.43)**	**($0.44)**	**($1.77)**	**($1.78)**	**($0.99)**	**($0.35)**	**$0.65**

Source: company filing and Zacks estimates

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