Zacks Small-Cap Research

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OncoSec Medical (ONCS-OTC)

ONCS: initiating landmark Phase II combination study, exited fiscal 2014 with a strong balance sheet, positive Phase II data of ImmunoPulse reported-----maintaining Outperform rating.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/27/2014
Current Price (11/24/14)	$0.52
Twelve- Month Target Price	**$2.00**

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 three Phase II clinical trials for melanoma, Merkel cell carcinoma, and cutaneous T-cell lymphoma respectively. Data have shown that ImmunoPulse is safe and can elicit both local and systemic immune-response.

ONCS just initiated a Phase II study of ImmunoPulse in combination with 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	**$0.94**
52-Week Low	**$0.28**
One-Year Return (%)	**84.34**
Beta	**1.34**
Average Daily Volume (sh)	**682,829**
Shares Outstanding (mil)	**245**
Market Capitalization ($mil)	**$127**
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)
2014	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2015	0.00 E	0.00 E	0.00 E	0.00 E	0.00 E
2016					0.00 E
2017					5.00 E

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

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2014	-$0.01 A	-$0.01 A	-$0.02 A	-$0.01 A	-$0.06 A
2015	-$0.01 E	-$0.01 E	-$0.02 E	-$0.02 E	-$0.06 E
2016					-$0.07 E
2017					-$0.06 E

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

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WHAT'S NEW

- ***An landmark Phase II study of ImmunoPulse in combination with PD-1 inhibitor Keytruda initiated for metastatic melanoma;***
- ***We maintain Outperform rating and raise our PT to $4.00 per share;***
- ***OncoSec exits fiscal 2014 with a strong balance sheet;***
- ***Reported positive results at 2014 ASCO from ongoing Phase II study of ImmunoPulse for metastatic melanoma;***

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

Earlier today, OncoSec Medical announced the initiation of a landmark **Phase II** combination trial in collaboration with the **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** therapy (intratumoral IL- 12) for the treatment of **metastatic melanoma** patients, who are non-responsive to KEYTRUDA®.

This Phase II clinical trial will be a multicenter investigator sponsored trial (IST), with UCSF and Dr. Alain Algazi as the sponsor. Merck will supply pembrolizumab, and OncoSec will provide electroporation devices and plasmid IL-12. Enrollment is expected to begin in **1Q15**.

Immune checkpoint inhibition is the one of the most promising area 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) and **Keytruda** (PD-1 antibody from Merck) demonstrated the importance of immune checkpoint inhibitors in the treatment of cancer. We think the cancer immunotherapy by immune checkpoint inhibitors will enter widespread clinical use and will 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.

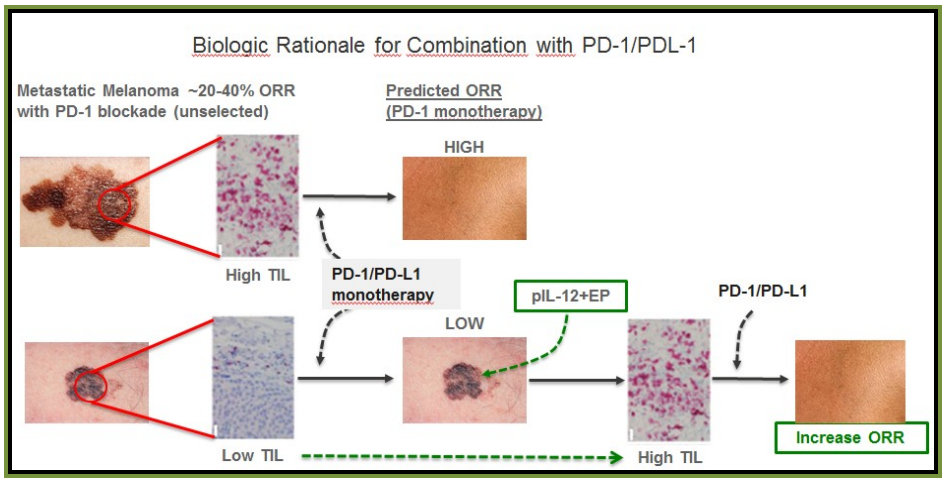
Tumor Type	Anti-PD1 or Anti-PDL1 mAb
Melanoma	~20 to 40%
Renal cell carcinoma (RCC)	~29%
Lung carcinoma (NSCLC)	~17 to 21%
H&N	~20%[1]
Bladder	~26%[2]

[1] Patients were preselected by Merck PD-L1 IHC assay
[2] 11% in PD-L1 (Roche) negative; 43% in PD-L1+ population

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® to kill tumor in patients, who would otherwise be PD-1 unresponsive.

This Phase II combo study presents a potential to address the vast majority of the metastatic melanoma patients, as well as, has profound implications on many other tumor indications.

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 for OncoSec. It is estimated that about 50% to 80% 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 tumors, 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 business.

The **Phase II combination** study will provide the Company with information for a key inflection point in the development of this program. If the Phase II study can confirm safety and efficacy of ImmunoPulse, **pivotal trial** could start in early 2016. And we estimate approval of ImmunoPulse for the treatment of melanoma may be obtained as early as **in late 2017** if the pivotal trial data prove to be positive.

We think positive data from the Phase II combination study may lead to a major **license deal** for OncoSec.

We Maintain Outperform Rating and Raise Our Price Target to $4

We maintain our Outperform rating on OncoSec shares and raise our 12-month price target to $4.00 from previous $2.00 due to the clinical advancement of the combination study with the PD-1 inhibitor.

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, 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 is currently in three Phase II clinical trials for melanoma, Merkel cell carcinoma and cutaneous T-cell lymphoma respectively. OncoSec 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 early 2016, and approval of this indication could be obtained as early as in 2017.

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 $0.50 per share, which values the company at $122 million in market capitalization based on 244 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 2017, we model OncoSec will become profitable in fiscal 2018 with earnings per share (EPS) of $0.01 based on ImmunoPulse sales of $50 million. Revenue will increase to $215 million in fiscal 2020 and EPS will grow into $0.22 per share according to our estimates. We think a 45 x P/E multiple is appropriate for OncoSec. Using this P/E ratio and a 20% discount rate for five years, we arrive at our price target of $4.00 per share for OncoSec, which values the Company at $900 million in market cap. This valuation is appropriate 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.

OncoSec Exits Fiscal 2014 with a Strong Balance Sheet

Recently OncoSec (ONCS) reported its financial results for the fiscal year ended July 31, 2014.

There was no revenue reported for the fiscal year ended July 31, 2014, or July 31, 2013.

Research and development expenses were $5.8 million for the fiscal year ended July 31, 2014, compared to $3.2 million for the same period in 2013.

General and administrative expenses were $6.2 million for the fiscal year ended July 31, 2014, compared to $3.9 million for the same period in 2013.

The Company recorded a net loss of $12.0 million ($0.06 per share) for fiscal year ended July 31, 2014, compared to a net loss of $7.2 million ($0.07 per share) for the same period last year.

On June 6, 2014, OncoSec closed a registered direct offering of 22,535,212 shares of its common stock at a price of $0.71 per share and warrants to purchase up to an aggregate of 7,887,325 shares of common stock at an exercise price of $0.90 per share for a term of five years.

Net proceeds, after deducting the placement agent's fee and other estimated offering expenses payable by OncoSec, were approximately $14.9 million.

OncoSec intends to use proceeds from the offering for general corporate purposes, including clinical trial expenses and research and development expenses.

We are pleased with this financing which not only strengthens OncoSec's cash position, but also validates the company's technology and clinical programs.

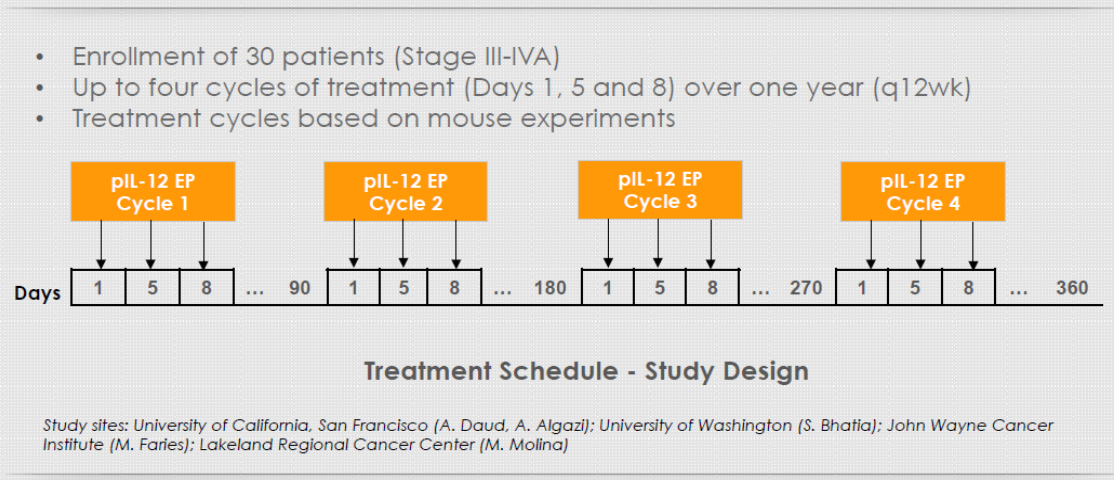
At July 31, 2014, OncoSec had $37.9 million in cash and cash equivalents, which will last through the end of fiscal 2017 according to our financial model.

Positive Phase II Interim Data of ImmunoPulse in Melanoma Reported

On June 2, 2014, at the ASCO meeting, OncoSec announced interim data from its **Phase II** melanoma study.

OncoSec's **ImmunoPulse** locally delivers plasmid-DNA encoding **IL-12** into tumor cells.

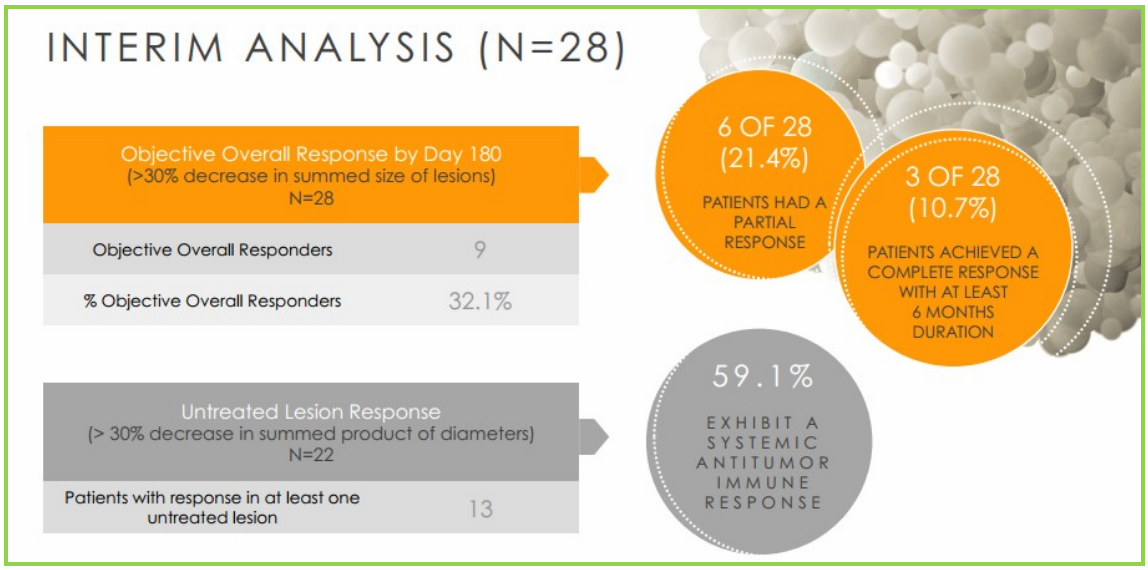
OncoSec initiated a **Phase II** clinical trial in patients with **melanoma** in Feb 2012. The Phase II melanoma trial (**OMS-I100**) is a single dose trial treating approximately 30 patients, who are eligible to receive one **treatment cycle every 12 weeks**. The **primary endpoint** is objective response 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**, which delivers the anti-tumor agent pIL-12 directly into the tumor via in-vivo electroporation (EP), 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 the reporting date, **30 patients** was enrolled and received at least one cycle of treatment. At the time of this interim analysis, **28 patients** were evaluable for objective response rate (ORR) at 24-week primary time point.

Best **ORR was 32.1%** (9/28), which included a complete response rate of 10.7% (3/28) and a partial response rate of 21.4% (6/28).



Importantly, intratumoral treatment with IL-12 EP 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 that were left untreated in order to evaluate the induction of a systemic response. Regression was documented in at least one non-injected tumor in 59 percent (13/22) 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 percent reduction in the longest diameter of the tumor, while stable disease was defined as ≤30 percent reduction and <20 percent 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 IL-12 electroporation 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).

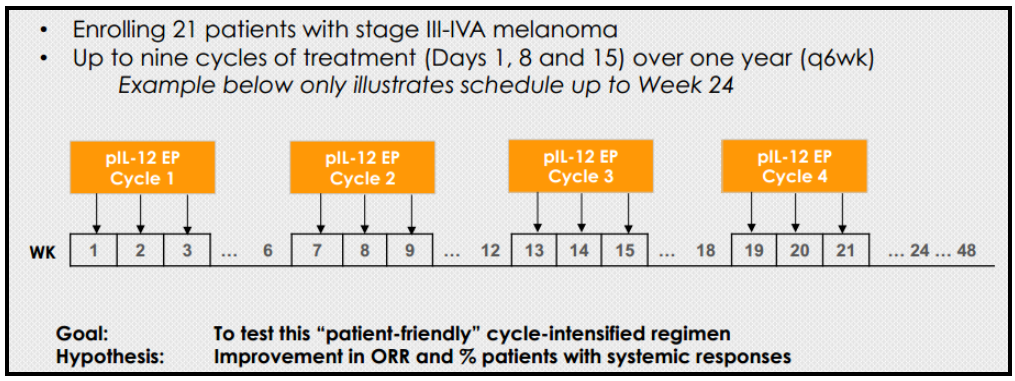
We are encouraged by the safety and efficacy data of ImmunoPulse in the Phase II study in melanoma patients. The positive Phase II data further validates results from previous Phase I study. We are especially impressed with the response rate of untreated tumors, which suggests an induction of **systemic 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.

OncoSec Plans to Evaluate Increased Dose Frequency of ImmunoPulse in Ongoing Phase II Melanoma Trial

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 expects to enroll up to **21 patients** in this expansion.

The protocol addendum will allow for the assessment of 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, which is expected to initiate in late 2014.
- Safety of this intensified dose regimen will also be assessed.

Data from this expansion study will be available **in late 2015.**

PROJECTED INCOME STATEMENT

	2013A (Jul)	2014A (Jul)	2015E (Jul)					2016E (Jul)	2017E (Jul)	2018E (Jul)	2019E (Jul)	2010E (Jul)
$ in million except per share data	FYA	FYA	Q1	Q2	Q3	Q4	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
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
Product revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$5.00	$50.00	$105.00	$215.00
Total Revenues	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$5.00**	**$50.00**	**$105.00**	**$215.00**
YOY Growth	-	-	-	-	-	-	-	-	-	900.0%	110.0%	104.8%
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.75	7.50	15.75	32.25
Gross Income	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$4.25**	**$42.50**	**$89.25**	**$182.75**
Gross Margin	-	-	-	-	-	-	-	-	85.0%	85.0%	85.0%	85.0%
R&D	$3.16	$5.80	$1.90	$1.95	$2.10	$2.20	$8.15	$12.50	$15.00	$20.00	$25.00	$30.00
% R&D	-	-	-	-	-	-	-	-	300.0%	40.0%	23.8%	14.0%
SG&A	$3.91	$6.15	$1.70	$1.75	$1.85	$1.95	$7.25	$8.50	$12.50	$17.50	$20.00	$30.00
%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
Operating Income	**($7.1)**	**($11.9)**	**($3.6)**	**($3.7)**	**($4.0)**	**($4.2)**	**($15.4)**	**($21.0)**	**($23.3)**	**$5.0**	**$44.3**	**$122.8**
Operating Margin	-	-	-	-	-	-	-	-	-	10.00%	42.14%	57.09%
Other Net	($0.1)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	($0.1)	($0.1)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	**($7.1)**	**($11.9)**	**($3.6)**	**($3.7)**	**($4.0)**	**($4.2)**	**($15.4)**	**($21.1)**	**($23.3)**	**$4.9**	**$44.2**	**$122.7**
Income taxes(benefit)	$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	**($7.1)**	**($11.9)**	**($3.6)**	**($3.7)**	**($4.0)**	**($4.2)**	**($15.4)**	**($21.1)**	**($23.3)**	**$4.9**	**$43.7**	**$121.2**
YOY Growth	-	-	-	-	-	-	-	-	-	-	784.4%	177.4%
Net Margin	-	-	-	-	-	-	-	-				
Diluted Shares Out	106.6	190.5	244.6	250.0	255.0	260.0	252.4	300.0	400.0	450.0	500.0	550.0
Reported EPS	**($0.07)**	**($0.06)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.06)**	**($0.07)**	**($0.06)**	**$0.01**	**$0.09**	**$0.22**
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*
Non GAAP Net Income	**($7.1)**	**($11.9)**	**($3.6)**	**($3.7)**	**($4.0)**	**($4.2)**	**($15.4)**	**($21.1)**	**($23.3)**	**$4.9**	**$43.7**	**$122.2**
Non GAAP EPS	**($0.07)**	**($0.06)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.06)**	**($0.07)**	**($0.06)**	**$0.01**	**$0.09**	**$0.22**

Source: company filing and Zacks estimates

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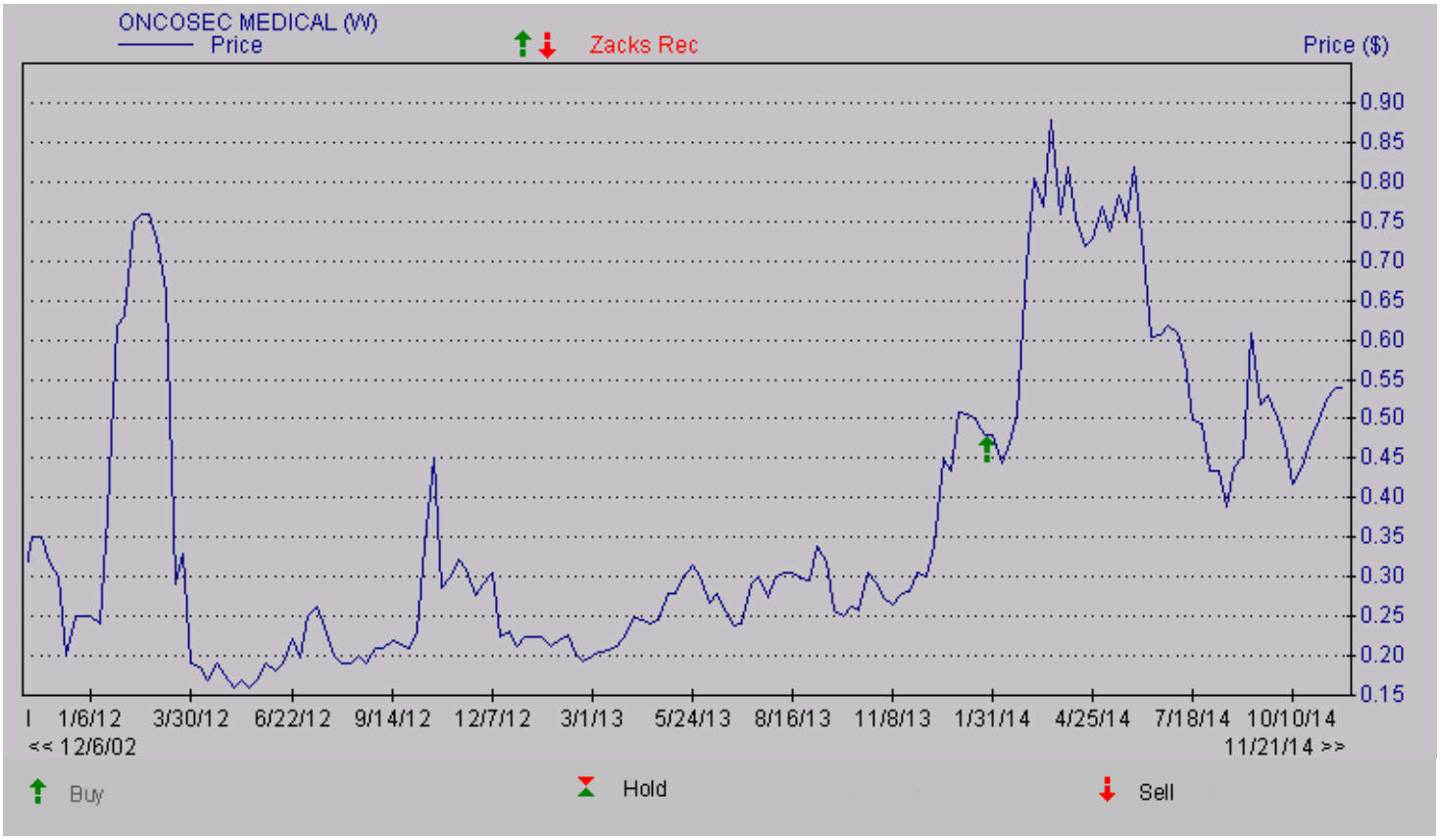
HISTORICAL ZACKS RECOMMENDATIONS



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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
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- 16.3%, Hold/Neutral- 76.9%, Sell/Underperform – 6.0%. Data is as of midnight on the business day immediately prior to this publication.