Zacks Small-Cap Research

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Rosetta Genomics (ROSG-NASDAQ)

ROSG: New commercial partnerships will accelerate revenue growth in 2015 and beyond, and patent extension will provide sustainable growth---Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	02/26/2014
Current Price (02/18/15)	$3.80
Twelve- Month Target Price	**$10.50**

OUTLOOK

Rosetta is a molecular diagnostics company focused on microRNA-based tests for cancers and other indications. The company is currently marketing four cancer assays with focus on its lead cancer origin test. The company also has commercial partnerships with two companies.

We are optimistic with its microRNA platform technologies, which serve as the basis of continued development of molecular diagnostics. Revenue should get boosted in 2014 and beyond due to focused marketing strategy. Long term pipeline will provide sustainable growth for the years to come.

We maintain Outperform rating. Our price target is $10.50.

SUMMARY DATA

52-Week High	**$6.55**
52-Week Low	**$2.19**
One-Year Return (%)	**-3.55**
Beta	**-3.13**
Average Daily Volume (sh)	**1,418,687**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$45**
Short Interest Ratio (days)	**0.67**
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	**Above Avg.,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013		0.19 A		0.21 A	0.41 A
2014		0.55 A		1.00 E	1.55 E
2015					5.50 E
2016					12.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013		-$0.68 A		-$0.69 A	-$1.37 A
2014		-$0.66 A		-$0.69 E	-$1.35 E
2015					-$1.11 E
2016					-$0.83 E

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

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WHAT'S NEW

- ***Broad Patent Allowances Assure Sustainable Growth***
- ***New Commercial Partnerships Will Help Revenue Growth in the Coming Quarters***
- ***Valuation is Attractive***

Broad Patent Allowances Assure Sustainable Growth

Recently, Rosetta Genomics (ROSG) received a Notice of Allowance from the US Patent and Trademark Office for a patent claiming the use of **miR-34a** for the treatment of **p53-associated cancers**. In addition, the Company received its first allowance from the European Patent Office for a patent claiming the specific composition for **miR-451**, a miR relating to the Company's Cancer of Unknown Primary (CUP) testing franchise.

The **miR-34a** patent covers a core element of Rosetta Genomics' microRNA technology in the development of cancer therapeutics relating to cancers associated with the p53 gene. This patent is broader than the previous patent issued last year in that it covers the treatment of any p-53 associated cancer using miR-34a or its variants, delivered by any kind of formulation. This patent is jointly owned with Yeda Research and Development, the technology transfer company of the Weizmann Institute of Science in Rehovot, Israel.

The miR-451 patent covers miR-451 and its complement, as well as a probe comprising the claimed miR. Therapeutic and diagnostic uses of the miR and/or the probe are also covered in the allowed claims.

Earlier in Feb, Rosetta Genomics received a Notice of Allowance from the Japan Patent Office (JPO), which relates to **human miR-92b**. The composition of matter patent claims the sequence of miR-92b and its complement, as well as its use as a probe, including in biochips. miR-92b has been shown to be elevated in cancer and is a key element of the Company's lead oncology diagnostic, the Rosetta Cancer Origin Test™ (COT). The claims allowed cover an isolated nucleic acid having the sequence of human miR-92b and its complement, as well as to variants being at least 90% identical to miR-92b. In addition, the allowed claims encompass a vector and a probe comprising miR-92b, a composition and a biochip comprising probes specific to miR-92b.

We are encouraged by broad patent protection around the world about Rosetta's core mRNA related oncology IP. We believe the company will continue to fortify its leading intellectual property position in microRNA technology. These patents expand, strengthen and complement the company's growing portfolio of over 40 patents worldwide.

These patents support the company's broader oncology strategy to develop and commercialize microRNA-based diagnostics, therapeutics and biomarkers on a global basis in order to enhance clinicians' ability to identify and treat cancers. We believe these patents will allow for sustainable growth for the company.

New Commercial Partnerships Will Help Revenue Growth in the Coming Quarters

In early Feb 2015, Rosetta entered into a co-promotional commercial partnership with **Precipio Diagnostics** for the sales and marketing of Precipio's oncology tests, which include bone marrow and peripheral blood testing for hematological malignancies, such as leukemias and lymphomas.

Rosetta Genomics will promote these products in California, Connecticut, New Jersey, Oklahoma, Texas, Virginia and Washington, D.C., and expects to expand nationally over time.

This co-promotion partnership expands Rosetta's oncology diagnostics business and provides the company opportunity to access the expertise of renowned pathology department at Yale School of Medicine. The promotion of Precipio's diagnostics products will also enhance awareness of and demand for the Rosetta Cancer Origin Test™. Rosetta sales reps will promote the Precipio diagnostic services to the same doctors who prescribe the Rosetta cancer origin test.

In addition to the co-promotion partnership with **Precipio, i**n October 2014, Rosetta Genomics partnered with **Admera Health** to market and sell Admera Health's molecular tests to oncologists and pathologists. The company launched the first three oncology testing services from Admera **in early Jan 2015**: PGxOne™, a pharmacogenomics test that predicts patients' responses to drugs based on their personal genetic makeup to avoid adverse effects; and EGFR and KRAS clinical sequencing, which provides genomic analysis of those tumor-based mutations from patient tissue to provide clinically relevant information relating to potential response to therapy.

We believe these two partnerships will generate significant revenue growth in the coming quarters.

Specifically, we expect revenue will grow 372% in 2H14. Revenue will reach $5.5 million in in 2015, an increase of 254%. Longer term, we model revenue will grow at a compound annual growth rate (CAGR) of 108% from 2014 to 2020, when revenue will reach $125 million.

Balance Sheet Remains Strong

As of June 30, 2014, Rosetta Genomics had $19.8 million in cash and cash equivalents, restricted cash and short-term bank deposits, compared with $24.5 million as of December 31, 2013.

The Company used approximately $7.5 million in cash to fund operations during the first six months of 2014. During the first half of 2014 the Company raised net proceeds of $3.0 million from the sale of approximately 750,000 ordinary shares through the previously announced Sales Agreements with Cantor Fitzgerald & Co.

Rosetta estimates that total net cash requirements to fund operations for the 2014-year will be between $14 million and $15 million, which includes the $7.5 million in net cash used to fund operations for six months ended June 30, 2014. We estimate that its cash balance, combined with projected revenue growth, will be sufficient to fund operations **into 2016**.

Long-term Pipeline Provides Sustainable Growth

We are very pleased to see the strong financial performance in 1H14 for the company. Management has made meaningful advances across the three key areas for growth: **current product sales**, **new product development** and **third-party collaborations**.

In addition to strong product sales in 1H14, Rosetta also made great progress in **new product development**.

Diagnostics

In addition to the four marketed molecular cancer tests, Rosetta is also developing both tissue and body fluid based microRNA tests for other indications. Rosetta is also developing microRNA-based **therapeutics**. We believe the long term pipeline will provide sustainable growth for the company in the years to come.

Rosetta Genomics' clinical development programs continued to advance. The company plans to launch at least one new diagnostic assay per year beginning in 2015. The company has a number of promising product candidates under development.

The company is on track to publish proof-of-concept data for **thyroid neoplasia assay** by the end of the year. These data and other information are expected to highlight the advantages of the company's assay compared with current alternatives. Rosetta's specimen collection process is a competitive differentiator, as it can utilize the actual smear used by the cytologist as opposed to taking additional Fine Needle Aspirates and preserving them in specialized tubes as is now required by currently marketed thyroid tests. Importantly, the company remains on track to begin final validation testing in early 2015 and to launch its microRNA-based thyroid neoplasia assay in the **third quarter of 2015**.

In 2016, the company plans to launch at least one of the following cancer diagnostics: a) **Bladder cancer** assay that predicts risk of invasiveness, for which the company has done two studies that have been published; b) **ovarian cancer** assay that predicts response to platinum treatment, for which the company has done a study and has a publication; and c) **breast cancer**, which the company is currently assessing.

The company has two published studies relating to an assay for **bladder cancer** risk of invasiveness. Based on these studies, Rosetta is moving forward with additional feasibility and validation studies, with an aim for commercial launch in 2016.

The third diagnostic product under development is for early diagnosis and refined risk stratification of patients following **myocardial infarction (MI).** Such a test has the potential to influence clinical management in a cost effective manner, by improving diagnosis, refining risk stratification and guiding therapy.

Heart Failure (HF) is a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricles to fill with or eject blood. It is the most prevalent disease in the western world and its prevalence continues to rise. It is estimated that 5 million Americans are diagnosed with HF and each year there are approximately 500,000 new HF patients. Besides its high prevalence, HF is also the most expensive disease in western countries.

Rosetta Genomics has so far performed two studies. The first study was published in the European Journal of Heart Failure (Goren et. al., 2012), showing that elevated serum levels of specific microRNAs identify heart failure patients. The second one was published in Am J Cardiology (Goren et al., 2013), correlating miR-150 to atrial fibrillation in patients with chronic systolic heart failure.

The company plans to launch HF diagnostics in **2017**.

The company is also developing diagnostic candidates for **chronic kidney rejection** and **Alzheimer's** disease. Progress will be updated over the coming months.

Therapeutic Products

microRNAs are important regulators of gene and protein expression, and as such, they represent potential targets for the development of drugs. Expression studies have indicated significant changes in microRNA expression in different disease states in comparison to normal tissue. Therefore microRNAs can serve as a basis for a new class of therapeutic products.

Rosetta Genomics has demonstrated this in liver cancer, ovarian cancer and pancreatic cancer, where differential microRNAs that were shown in tissues of patients were used to find drug candidates that could inhibit those cancers through either microRNA inhibition or mimetics.

Those microRNAs served to design modified oligonucleotides with anti-sense sequences that were used in vitro in proliferation assays. If the microRNA inhibition can lead to reduction in proliferation of cancer cell lines, the anti- microRNAs with the strongest effect over cell proliferation were chosen as the drug candidates with most potential. The ability to specifically silence virtually every gene including previously non-druggable targets has made RNAi-based therapeutics a very attractive approach for treating diseases in many therapeutic areas.

Rosetta Genomics is developing a therapeutic for cytomegalovirus **(CMV) infection**.

In January 2011, Rosetta joined the **Rimonim Consortium**, which is supported by the Office of the Chief Scientist at the Ministry of Industry, Trade and Labor of the State of Israel (OCS). The purpose of the consortium is to develop RNA interference (RNAi)-based therapeutics. As a member of the consortium, Rosetta is entitled to certain grants to support its research and development activities.

We believe the long term pipeline will provide sustainable growth for the company.

Collaborations Accelerate Product Development and Represents New Avenue for Revenue Growth

A third **revenue growth platform** for Rosetta is through collaboration with biotech/pharmaceutical companies to monetize its microRNA platform technologies.

On September 2, 2014, Rosetta Genomics entered into a strategic alliance with **Moffitt Cancer Center** to discover, develop and commercialize a variety of **microRNA-based cancer diagnostics**.

This is a three-year alliance. Rosetta will provide funding for Moffitt investigator-initiated projects that align with Rosetta's strategic priorities. This strategic alliance will leverage Rosetta's capabilities and expertise.

In June 2014, Rosetta Genomics also entered into an agreement with **Moffitt Cancer Center** to advance the development and commercialization of Rosetta's **thyroid neoplasia assay**.

Under the agreement, Rosetta will work with Marino Leon, M.D., associate member of the Department of Anatomic Pathology at Moffitt.

An estimated 4-7 percent of the general population develops nodules in the thyroid that can be felt on examination, though fewer than 10 percent are malignant. A fine needle aspiration (FNA), a non-surgical procedure used to obtain tissue for analysis by a pathologist, is the standard technique for detecting cancer. However, interpretation of FNA samples is not always conclusive, and up to 30 percent of samples have indeterminate results.

In April 2014, Rosetta Genomics entered into a strategic alliance with **Marina Biotech** to identify and develop microRNA-based products designed to **diagnose** and **treat** various **neuromuscular diseases** and **dystrophies**.

The Alliance is exclusive as it relates to neuromuscular diseases and dystrophies, with both Companies free to develop and collaborate outside this field both during and after the terms of the Alliance. The Companies' initial efforts are expected to be focused on Becker and Duchenne muscular dystrophies as well as myotonic dystrophy. Financial terms and other details of the agreement are not being disclosed at this time.

Under the terms of the Alliance, Rosetta will apply its industry leading microRNA discovery expertise for the identification of microRNAs involved in the various dystrophy diseases. If the microRNA is determined to be correlative to the disease, **Rosetta** may further develop the microRNA into a **diagnostic** for patient identification and stratification. If the microRNA is determined to be involved in the disease pathology and

represents a potential therapeutic target, **Marina** may develop the resulting microRNA-based **therapeutic** for clinical development.

In January 2014, Rosetta Genomics announced that it signed a **master service provider agreement** with an undisclosed major global biopharmaceutical company, under which, Rosetta will provide its microRNA profiling and other services pursuant to a collaboration in important areas of unmet medical need utilizing a novel therapeutic approach.

Rosetta Genomics has successfully completed the feasibility phase of the master service agreement with the global biopharmaceutical company and is now advancing to the next stage of this collaboration, which is expected to **generate revenues by the end of 2014**. In addition, the company has initiated proof-of-concept studies with its global pharmaceutical partner to advance the development of an assay for the earlier detection of **Alzheimer's disease** which could have applications both as a diagnostic as well as for patient selection for clinical trials.

This agreement leverages Rosetta's microRNA biomarker platform and expertise to assist one of the world's leading biopharmaceutical companies to advance their research and development efforts on this important, novel therapeutic approach.

In addition to the company's current cancer testing services and new products from its own, internal research and development initiatives, collaborations such as these represent **third major platform** for revenue growth for the company.

Moving forward, we believe Rosetta will enter into additional similar agreements as the company seeks to monetize its leading microRNA platform and expertise.

Valuation Attractive

We maintain our Outperform rating on Rosetta Genomics (ROSG) shares and reiterate our 12-month price target of $10.50 per share.

Rosetta is a revenue generating, emerging molecular diagnostics biotech company focused on molecular testing of cancers and other life threatening diseases. The company develops its diagnostic products based on the unique and proprietary microRNA platform technology.

Currently Rosetta is marketing four cancer tests with focus on its lead Cancer Origin Test. This Cancer Origin Test is covered by Medicare reimbursement and other payors covering over 170 million lives. The company is negotiating for expanded coverage for the Cancer Origin Test as well as for reimbursement for its three other marketed cancer tests.

In addition to currently marketed tests, Rosetta is also developing other tissue or body fluid based molecular diagnostics using its microRNA technologies. Furthermore, Rosetta is developing microRNA based therapeutics. These long term pipeline will provide sustainable growth for the company in the years to come.

Rosetta is also collaborating with pharmaceutical/biotech companies to assist these companies to develop microRNA based therapeutics. This collaboration creates the third avenue for revenue growth.

With a focused marketing strategy in place, revenue will be boosted in 2H2014 and beyond. Specifically, we model $1.55 million in revenue for fiscal 2014 and revenue will grow to $125 million in 2020, a tremendous compound annual growth rate (CAGR) of 108%. With accelerated revenue growth, Rosetta will become profitable in fiscal 2018 with earnings per share (EPS) of $0.32 based on total revenue of $50 million. EPS will grow to $1.31 per share in fiscal 2010 based on total revenue of $125 million, a 102% increase in the two year period. Recent two partnerships will accelerate revenue growth in 2015 and beyond.

Rosetta has a relatively strong balance sheet. Current cash is sufficient to fund operations into 2016 according to our model.

With all these in mind, we think Rosetta's shares are undervalued at current market price. Currently, Rosetta shares are trading at about $3.8 per share, which values the company at about $46 million in market cap based on 12 million outstanding shares. This is apparently a huge discount compared to its peers. As we said, Rosetta is a revenue generating diagnostics company targeting the high growth market of molecular diagnostics. The company's microRNA platform technology has broad applications targeting both diagnostics and therapeutics. We don't think the Street has recognized the potential of high revenue growth in the coming years for Rosetta.

Based on our financial model, we think a P/E multiple of 25x is appropriate for Rosetta. If we apply this P/E coupled with EPS of $1.31 in 2020, discounted at 25% for 5 years, we come up with our price target of $10.50 per share. Our price target values Rosetta at $126 million in market cap, which we think is still conservative.

Execution is the key to achieve expected growth and will have a significant impact on the share price. The fluctuation of the broader market in the US will also have impact on the company's share price in the next 6 to 12 months. In general, we think the company has a favorable risk/award profile at this time with downside risk relatively low and high upside potential.

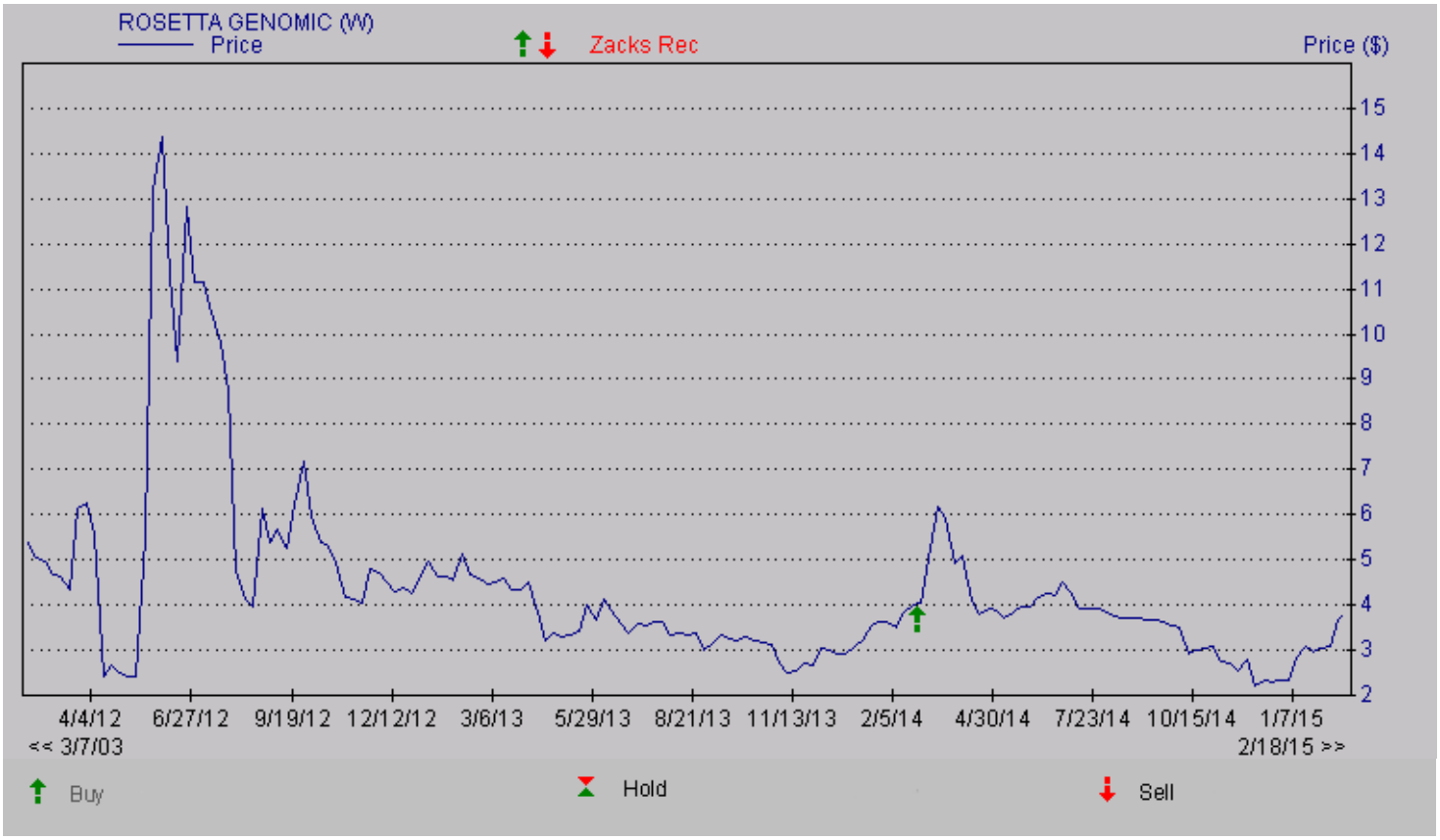
PROJECTED INCOME STATEMENT

	2011A (Dec)	2012A (Dec)	2013A (Dec)			2014E (Dec)			2015E (Dec)	2016E (Dec)	2017E (Dec)	2018E (Dec)	2019E (Dec)	2020E (Dec)
$ in million except per share data	FYA	FYA	1H13	2H13	FYE	1H14	2H14	FYE	FYE	FYE	FYE	FYE	FYE	FYE
Total Revenues	**$0.10**	**$0.20**	**$0.19**	**$0.21**	**$0.41**	**$0.55**	**$1.00**	**$1.55**	**$5.50**	**$12.50**	**$25.00**	**$50.00**	**$80.00**	**$125.00**
YOY Growth	-63.1%	95.1%	278.4%	41.3%	101.5%	187.0%	371.7%	283.7%	253.9%	127.3%	100.0%	100.0%	60.0%	56.3%
CoGS	0.32	0.26	0.43	0.28	0.71	0.77	0.15	0.92	0.72	1.56	3.13	6.25	10.00	15.63
Gross Income	**($0.22)**	**($0.06)**	**($0.24)**	**($0.06)**	**($0.30)**	**($0.22)**	**$0.85**	**$0.63**	**$4.79**	**$10.94**	**$21.88**	**$43.75**	**$70.00**	**$109.38**
Gross Margin	-214.6%	-28.4%	-124.9%	-29.7%	-75.1%	-39.0%	85.0%	40.8%	87.0%	87.5%	87.5%	87.5%	87.5%	87.5%
R&D	$3.39	$1.25	$0.88	$0.87	$1.74	$1.01	$1.15	$2.16	$3.50	$5.00	$7.50	$10.00	$13.00	$15.50
% R&SD	3287.4%	620.4%	454.4%	409.0%	430.6%	182.5%	115.0%	139.1%	63.6%	40.0%	30.0%	20.0%	16.3%	12.4%
SG&A	$5.17	$6.96	$5.55	$5.75	$11.30	$6.01	$7.50	$13.51	$17.50	$20.00	$22.50	$25.00	$30.00	$45.00
% SG&A	-	3464.2%	2876.7%	2710.8%	2789.9%	1085.4%	750.0%	869.6%	318.2%	160.0%	90.0%	50.0%	37.5%	36.0%
Other Expense	$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	**($8.8)**	**($8.3)**	**($6.7)**	**($6.7)**	**($13.3)**	**($7.2)**	**($7.8)**	**($15.0)**	**($16.2)**	**($14.1)**	**($8.1)**	**$8.8**	**$27.0**	**$48.9**
Operating Margin	-8521.4%	-4112.9%	-3456.0%	-3149.5%	-3295.6%	-1306.9%	-780.0%	-967.8%	-294.8%	-112.5%	-32.5%	17.5%	33.8%	39.1%
Other Net	($0.1)	($2.2)	$0.4	($0.2)	$0.2	$0.1	$0.0	$0.1	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)
Pre-Tax Income	**($8.8)**	**($10.5)**	**($6.3)**	**($6.9)**	**($13.2)**	**($7.2)**	**($7.8)**	**($15.0)**	**($16.7)**	**($14.6)**	**($8.6)**	**$8.3**	**$26.5**	**$48.4**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0	$4.5	$9.0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	12.1%	17.0%	18.6%
Reported Net Income	**($8.8)**	**($10.5)**	**($6.3)**	**($6.9)**	**($13.2)**	**($7.2)**	**($7.8)**	**($15.0)**	**($16.7)**	**($14.6)**	**($8.6)**	**$7.3**	**$22.0**	**$39.4**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-184.1%	203.4%	79.0%
Net Margin	-	-	-	-	-	-	-	-	-	-	-34.5%	14.5%	27.5%	31.5%
Diluted Shares Out	0.5	4.4	9.2	10.0	9.6	10.8	11.3	11.1	15.0	17.5	20.0	22.5	25.0	30.0
Reported EPS	**($17.39)**	**($2.35)**	**($0.68)**	**($0.69)**	**($1.37)**	**($0.66)**	**($0.69)**	**($1.35)**	**($1.11)**	**($0.83)**	**($0.43)**	**$0.32**	**$0.88**	**$1.31**
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*	*$0.00*
Non GAAP Net Income	**($8.8)**	**($10.5)**	**($6.3)**	**($6.9)**	**($13.2)**	**($7.2)**	**($7.8)**	**($15.0)**	**($16.7)**	**($14.6)**	**($8.6)**	**$7.3**	**$22.0**	**$39.4**
Non GAAP EPS	**($17.39)**	**($2.35)**	**($0.68)**	**($0.69)**	**($1.37)**	**($0.66)**	**($0.69)**	**($1.35)**	**($1.11)**	**($0.83)**	**($0.43)**	**$0.32**	**$0.88**	**$1.31**

Source: Company filing and Zacks estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
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- 16.7%, Hold/Neutral- 77.5%, Sell/Underperform – 5.2%. Data is as of midnight on the business day immediately prior to this publication.