Zacks Small-Cap Research

November 30, 2016
Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Arrowhead Pharm (ARWR-NASDAQ)

ARWR: Zacks Company Report

ARWR: Strategic shift to subQ and extra-hepatic programs, Collaborations with Amgen announced

Current Price (11/30/16)	$1.76
Valuation	**$7.00**

OUTLOOK

After discontinuation of three DPCiv programs, Arrowhead shifted its focus on subcutaneous and extra-hepatic therapeutics.

The company is close to nominating new candidates and moving into IND enabling studies. Clinical trial could happen in 2017.

Cost cutting measures will extend its cash runway into 2019.

We remain optimistic about Arrowhead's prospect.

SUMMARY DATA

52-Week High	**$8.08**
52-Week Low	**$3.18**
One-Year Return (%)	**-29.43**
Beta	**2.42**
Average Daily Volume (sh)	**1,407,533**
Shares Outstanding (mil)	**70**
Market Capitalization ($mil)	**$311**
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 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Biotechnology**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2015	0.17 A	0.04 A	0.12 A	0.04 A	0.38 A
2016	0.04 A	0.04 A	0.04 A	0.04 E	0.17 E
2017					0.50 E
2018					5.00 E

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

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2015	-$0.37 A	-$0.50 A	-$0.27 A	-$0.51 A	-$1.64 A
2016	-$0.32 A	-$0.35 A	-$0.32 A	-$0.34 E	-$1.34 E
2017					-$1.51 E
2018					-$1.23 E

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

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WHAT'S NEW

Strategic Shift to Subcutaneous and Extra-Hepatic RNAi Programs

The Announcement

On November 29, 2016, Arrowhead announced a strategic redeployment of resources to support the development of RNAi programs that utilize the company's new proprietary subcutaneous (subQ) and extra-hepatic delivery systems.

As a result, Arrowhead will discontinue the ongoing development of clinical stage drug candidates ARC-520, ARC-521, and ARC-AAT, which utilize the intravenous-administered platform, called **DPCiv or EX1**.

As of this announcement all patient recruitment for ARC-520, ARC-521, and ARC-AAT has been halted and dosing discontinued. The company will work together with investigators and clinical sites to ensure a smooth transition of study closure and patient medical care.

Because of the discontinuation of the existing clinical programs, the company is reducing its workforce by approximately 30%, while maintaining full resourcing necessary to support current and potential future partner-based programs and Arrowhead's burgeoning pipeline. Management believes that this more streamlined structure should enable the company to continue to develop its programs rapidly, and is intended to extend its cash runway into 2019.

The Rationale for the Shift

During the conference call, the company provided two reasons for the strategic shift.

- First, in early November, the FDA decided to place a **clinical hold** on **Heparc-2004**. During ongoing discussions with regulatory agencies and outside experts, it became apparent that there would be substantial delays in all clinical programs that utilize EX1, while the company further explored the cause of deaths in a non-clinical toxicology study in non-human primates.
- Second, Arrowhead has made substantial advances in RNA chemistry and targeting resulting in large potency gains for subQ administered and extra-hepatic RNAi-based development programs. In preclinical studies with the subQ platform, the company has obtained depth and duration of target gene knockdown approaching that of intravenously administered EX1-containing candidates, at lower doses and with good safety margins.

Therefore, the company believes it is prudent now to focus its development resources entirely on its subQ and extra-hepatic pipeline, which includes programs in HBV, AAT, Factor 12, HIF-2alpha, and other unannounced programs. In addition to its own pipeline, Arrowhead is also focused on providing full resources to support its partnership with Amgen and potential future partnerships for its subQ and extra-hepatic delivery systems.

We Remain Optimistic about the Prospect of Arrowhead

We continue to be optimistic about the prospect of Arrowhead and adjust our valuation at $7 per share due to the strategic shift.

We believe management decision to focus on the subQ and extra-hepatic programs is prudent.

The discontinuation of the DPCiv programs is not based on the safety or efficacy of the three candidates. Instead, the safety profile of ARC-520, ARC-521, and ARC-AAT in human clinical trials appeared to be favorable, and supported advancing the programs, with a small minority (6%) of infusions being

associated with infusion reactions. In addition, across the ARC-520, ARC-521, and ARC-AAT clinical programs, laboratory values have not been deemed indicative of drug induced organ toxicity.

In addition, each candidate was highly active against its respective target. For example, ARC-AAT achieved 90% knockdown of serum AAT, which is believed to be near full suppression of liver production of the protein, in a **Phase I** clinical study. For ARC-520, it was previously reported that reductions in surface antigen (HBsAg) of almost 99%, or 2 logs, were achieved after a single dose. In subsequent multiple dose studies, for which data have not yet been reported, reductions of almost 3 logs were observed, with several patients being tracked that appear poised to possibly seroclear HBsAg, representing potential function cures.

The major reason for discontinuing the DPCiv programs is that it may takes more than 18 months to obtain actionable results to lift the clinical hold on the DPCiv programs. Even after this long delay, the possibility remains that the study could be inconclusive or fall short of satisfying the regulators in some way.

Therefore, management decided to focus entirely on its SubQ and extra-hepatic programs. These include SubQ programs against HBV, AAT, Factor 12, ARCHif2, and several undisclosed subcutaneous and extra-hepatic programs. It also includes partnered programs with Amgen, ARC-LPA and ARCAMG1.

We believe it is a natural transition because the company's SubQ platform is capable of achieving similar results as the EX1 delivery vehicle, with the added benefit of a more convenient mode of administration and expected improved safety margins.

The company is in advanced subQ development in programs against **Factor 12**, **HBV**, and **AAT**. The company plans to declare lead candidates and move toward IND enabling studies soon. Arrowhead is also active in extra-hepatic delivery program **ARC-Hif2**.

The discontinuation of the three advanced DPCiv programs certainly negatively impacts Arrowhead valuation. But the sharp decline (60%) in share price (currently at $1.76) is an overreaction in our view. We believe current market price does not reflect the intrinsic value of the company. We estimate Arrowhead will move at least one subQ candidate into clinic in 2017.

Our new price target $7 per share values the company at $490 million in market capitalization, which we think is appropriate at this time. As long as management remains committed, value will be generated for shareholders in the coming quarters.

The Clinical Hold on Heparc-2004 is Probably Temporary

On November 8, Arrowhead announced that the company was notified verbally by the FDA of its decision to place a **clinical hold** on **Heparc-2004**.

The Heparc-2004 Study

In April 2015, the FDA cleared the multiple-dose **Phase IIb** clinical study of **ARC-520** for the treatment of chronic hepatitis B infection.

The clinical study, titled **Heparc-2004**, is a multicenter, randomized, double-blind, placebo-controlled, multi-dose study of ARC-520 administered intravenously to patients with chronic immune active HBV infection maintained on entecavir or tenofovir therapy. The study is planned to enroll up to **12 patients** who will be randomized at a ratio of 2:1 with 8 patients receiving **1 mg/kg** of ARC-520 and 4 patients receiving placebo. Each patient will receive 3 total doses, once every 4 weeks. Patients will be followed through Day 147.

The **primary objective** of Heparc-2004 is to evaluate the depth of hepatitis B surface antigen (HBsAg) decline in response to multiple doses of ARC-520 compared to placebo in patients with chronic, immune active HBV infection as a measure of drug activity. **Secondary objectives** are to measure safety and tolerability and pharmacokinetics of ARC-520, and to evaluate the effect of ARC-520 on entecavir or tenofovir pharmacokinetics, in addition to other exploratory safety and pharmacodynamic objectives.

The Clinical Hold

The clinical hold was prompted by deaths at the highest dose of an ongoing **non-human primate** toxicology study. This study involves higher doses of EX1 than those used clinically in humans and higher than those used in the company's previous animal toxicology studies. The cause of these animal deaths is unknown and under investigation. Because ARC-520, ARC-521, and ARC-AAT all use EX1, the findings in this toxicology study were reported to regulatory agencies globally with oversight for all of the programs.

The FDA did not indicate the clinical hold was based on any human findings. To date, EX1 has been administered over 800 times in more than 300 human study subjects and patients. Across this substantial clinical experience, only 3 serious adverse events (SAE) have been observed. Two of these were fevers, treated with acetaminophen, after which the patients continued on the study with no further complications. The other SAE was an instance of hepatic carcinoma in a patient with chronic HBV and cirrhosis, judged by the treating physician to be unrelated to the drug. A small minority (6%) of infusions in ARC-520 studies have been associated with infusion reactions, with 4 patients discontinuing ARC-520 treatment. In addition, across the ARC-520, ARC-521, and ARC-AAT clinical programs, laboratory values have not been deemed indicative of any drug-induced organ toxicity.

Collaborations with Amgen for Two Cardiovascular Programs

On Sept. 29, 2016, Arrowhead announced two license and collaboration agreements with Amgen to develop and commercialize two cardiovascular programs based on Arrowhead's RNAi platform.

These programs will utilize Arrowhead's proprietary **subcutaneous RNAi delivery technology**.

Pursuant to one agreement, Amgen receives a worldwide, exclusive license to Arrowhead's novel, RNAi **ARC-LPA program**, which is designed to reduce production of apolipoprotein A, a key component of lipoprotein(a), which has been genetically linked with increased risk of cardiovascular diseases, independent of cholesterol and LDL levels. ARC-LPA is Arrowhead's first drug candidate to use a subcutaneously administered delivery construct. Elevated lipoprotein(a), or Lp(a), is widely viewed as a key risk factor for cardiovascular diseases, including coronary artery disease, atherosclerosis, thrombosis and stroke.

Under the second agreement, Amgen receives an option to a worldwide, exclusive license for a RNAi therapy for an **undisclosed genetically validated cardiovascular target**.

In both agreements, Amgen will be wholly responsible for clinical development and commercialization.

In connection with the two collaborations, Arrowhead will receive $35 million in upfront payments; $21.5 million in the form of an equity investment by Amgen in Arrowhead common stock (about 3 million shares); and up to $617 million in option payments, and development, regulatory and sales milestone payments. Arrowhead is further eligible to receive single digit royalties for sales of products against the undisclosed target and up to low double digit royalties for sales of products under the ARC-LPA agreement.



Our Takeaways from the Deal

We welcome this deal and think it's positive to Arrowhead in the following aspects:

First, the collaborations immediately boost the company's balance sheet with the $56.5 million upfront payment. In the long run, milestone payment and royalty will further enhance the company's cash position in a non-dilutive way.

As of June 30, 2016, Arrowhead has $44.5 million in cash and investment.

On August 12, Arrowhead closed a private offering with a select group of investors including Orbimed, RA Capital Management, Perceptive Advisors, RTW Investments and certain other institutional investors. Gross proceeds were $45 million. Approximately 7.63 million shares of common stock were issued at a price of $5.90 per share.

Current cash plus the new proceeds can support the company's operations into calendar 2019 according to our financial model.

Second, the deal with Amgen further validates Arrowhead's RNAi technology and its clinical application.

Third, with a great partner Amgen, this deal could serve as a signal of renewed interest in RNAi technology and similar deal could be signed in the future for Arrowhead.

We will provide further updates on this deal for investors when they are available.

Update on ARC-HIF2 for Kidney Cancer

In September, 2015, Arrowhead nominated **ARC-HIF2** as its first therapeutic candidate delivered using a new Dynamic Polyconjugate™ (DPC™) designed to target tissues outside of the liver. Arrowhead believes that ARC-HIF2, which uses RNA interference to silence transcription factor hypoxia-inducible

factor 2α (HIF-2α), is a promising new candidate for the treatment of clear cell renal cell carcinoma **(ccRCC).**

ARC-HIF2 is designed to inhibit the production of HIF-2α, which has been linked to tumor progression and metastasis in ccRCC. Using ARC-HIF2 in a preclinical ccRCC tumor model, mice treated with weekly injections led to greater than 80% knockdown of HIF-2α mRNA in tumors. Furthermore, tumors from treated mice exhibited statistically significant reductions in size and weight, extensive tumor cell death, reduction in the tumor-expressed VEGF-A biomarker, and destruction of the blood vessels feeding the tumors.

The company presented positive preclinical data at the European Cancer Congress 2015 (ECC2015) in Vienna on September 27, 2015 in a poster titled "HIF-2α targeting with a novel RNAi delivery platform as therapy for renal cell carcinoma," (abstract #353).

The company further presented positive preclinical data on ARC-HIF2 at AACR2016.

The poster presentation described data from various stages of development of ARC-HIF2, including RNAi trigger selection, HIF2-α target validation, delivery and targeting ligand validation, and multiple RCC tumor models. These data show that important advancements are being made in this program and for Arrowhead's Dynamic Polyconjugate™ (DPCTM) delivery platform generally, including the following key findings:

- Proof-of-concept ligand dependent, functional delivery was demonstrated using the DPC targeted delivery platform
- Silencing HIF2-α expression by RNA interference resulted in reduction of HIF-2α regulated genes
- In two different RCC tumor bearing mouse models, ARC-HIF2 inhibited tumor growth and promoted tumor cell death and structural degeneration

The company is in the process of manufacturing scale up to allow for initiation of IND-enabling studies. Timing for anticipated regulatory submission will be announced in the future.

Update on ARC-LPA for Cardiovascular Disease

Arrowhead's RNAi-based candidate ARC-LPA is in preclinical development as a potential treatment for cardiovascular diseases. ARC-LPA is designed to reduce production of apolipoprotein(a), a key component of lipoprotein(a), or Lp(a). Lp(a) levels in humans are genetically defined and higher levels correlate with increased risk of **cardiovascular diseases**, independent of cholesterol and LDL levels. ARC-LPA is Arrowhead's first drug candidate to use a subcutaneously administered delivery construct.

In May 2016, Arrowhead presented additional promising preclinical data on ARC-LPA at the Arteriosclerosis, Thrombosis and Vascular Biology | Peripheral Vascular Disease (ATVB|PVD) 2016 Scientific Sessions in Nashville.

The poster presentation described data from **in vitro** screening of RNAi triggers and multiple in vivo models, including transiently transgenic mice, transgenic mice (Tg), and non-human primates (NHPs). Key findings from these studies include the following:

- Screening of RNAi triggers in Tg mice identified those that exhibited substantial and sustained knockdown of serum apo(a) and Lp(a) levels
- RNAi trigger sequences were active in both intravenous and SQ platforms
- Structure activity relationship (SAR) studies looking at chemical modifications to the RNAi trigger identified a lead that demonstrated **greater than 98%** maximum knockdown after a single 3 mg/kg SQ dose in transgenic mice
- Duration of effect gains were also made with greater than 85% knockdown still seen at 6 weeks post dose

- In NHPs, 85-90% reduction of serum Lp(a) levels was observed after three weekly 3 mg/kg SQ doses
- Duration of effect in NHPs was long, with Lp(a) levels still reduced by 75% 6 weeks after the final dose

Update on ARC-F12 for Hereditary Angioedema

Arrowhead is also developing a preclinical program **ARC-F12** for hereditary angioedema.
ARC-F12 is in preclinical development as a potential treatment for **factor XII (F12) mediated diseases**. There are clear unmet needs in hereditary angioedema (HAE) and thromboembolic diseases. The biology of factor 12 as part of the coagulation cascade and the kinin-kallikrein system suggest that its reduction through RNAi may present opportunities in both disease areas.

In May 2016, Arrowhead presented promising preclinical data on ARC-F12 at AAAAI 2016.

In a carrageenan-induced paw edema model in rats, treatment with ARC-F12 seven days prior to carrageenan challenge led to a significant reduction in edema ($p < 0.001$). The reduction in swelling in ARC-F12 treated rats is similar to that seen in rats treated with a kallikrein-targeted antibody. This supports Arrowhead's position that F12 inhibition could be an attractive target for the rare genetic disorder, hereditary angioedema (HAE).

In a mouse model of **thrombosis**, a dramatic increase in occlusion times was observed in mice receiving ARC-F12. The time to blood flow occlusion is measured as a clinically relevant indicator of physiological response to F12 knockdown and is a measure of the inhibition of thrombus formation. Further, in multiple relevant models of bleeding risk, ARC-F12 did not cause an increase in bleeding times or bleeding risk. Anticoagulants can be used to reduce thrombus formation and thromboembolism occurrence, but also can cause an increase in serious bleeding risk. ARC-F12 may be able to reduce the risk of blood clot formation, without the undesirable bleeding risk caused by anticoagulants.

In vivo studies in wild type mice showed that a single 2 mg/kg dose of ARC-F12 achieved greater than 95% knockdown of F12 levels. In multi-dose primate studies, a 4 mg/kg dose resulted in greater than 90% knockdown with even greater knockdown following subsequent doses. Knockdown was also highly durable with greater than 80% reduction maintained between monthly doses. ARC-F12 appeared to be generally well-tolerated and no drug-related changes in toxicity markers were observed as measured by clinical chemistry and hematologic parameters.

The company is currently conducting studies in order to advance ARC-F12 into **clinical trials**.

With a platform technology, we believe the pipeline can be further expanded with ease.

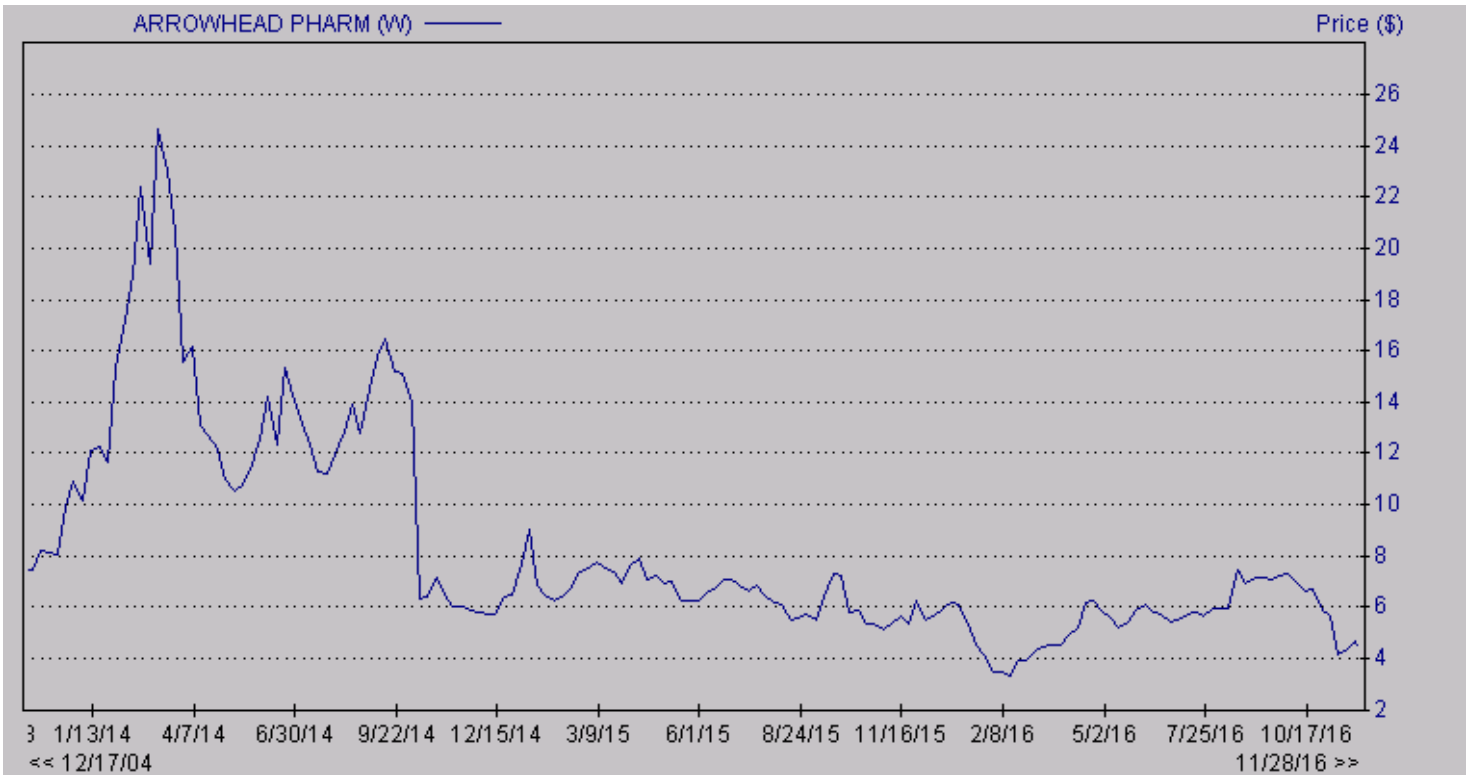
PROJECTED INCOME STATEMENT

_	2015 (Sept)					2016 (Sept)					2017 (Sept)	2018 (Sept)	2019 (Sept)
$ in millions except per share data	Q1	Q2	Q3	Q4	FYE	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE
Revenue	$0.17	$0.04	$0.12	$0.04	$0.38	$0.04	$0.04	$0.04	$0.04	$0.17	$0.50	$5.00	$210.00
YOY Growth						-	-	-	-	-	*199.3%*	*900.0%*	*4100.0%*
Total Revenues	**$0.17**	**$0.04**	**$0.12**	**$0.04**	**$0.38**	**$0.04**	**$0.04**	**$0.04**	**$0.04**	**$0.17**	**$0.50**	**$5.00**	**$210.00**
YOY Growth	*297.1%*	*0.0%*	*182.9%*	*-1.7%*	*118.3%*	*-74.4%*	*0.0%*	*-68.0%*	*-8.6%*	*-56.3%*	*199.3%*	*900.0%*	*4100.0%*
Cost of Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.8	$29.4
Gross Income	**$0.2**	**$0.0**	**$0.1**	**$0.0**	**$0.4**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.2**	**$0.4**	**$4.3**	**$180.6**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*85.0%*	*85.0%*	*86.0%*
R&D	$17.7	$21.8	$7.5	$10.4	$57.4	$10.3	$10.0	$9.4	$12.0	$41.8	$75.0	$55.0	$60.0
% R&D	*10392.0%*	*49791.0%*	*6052.8%*	*23752.8%*	*15028.8%*	*23631.6%*	*22904.8%*	*23806.2%*	*30000.0%*	*25007.3%*	*15000.0%*	*1100.0%*	*28.6%*
Salary and G&A	$5.2	$5.2	$5.4	$8.6	$24.5	$5.9	$8.1	$6.4	$7.5	$27.8	$30.0	$37.5	$50.0
% SG&A	*3067.0%*	*11973.2%*	*4363.6%*	*19680.4%*	*6409.7%*	*13420.6%*	*18438.9%*	*16141.4%*	*18750.0%*	*16655.1%*	*6000.0%*	*750.0%*	*23.8%*
Other expenses	$2.3	$2.7	$3.2	$4.4	$12.6	$3.2	$3.2	$3.6	$3.7	$13.7	$8.5	$10.0	$12.0
% Other	*1349.9%*	*6067.7%*	*2607.8%*	*10017.0%*	*3290.3%*	*7256.4%*	*7361.7%*	*9016.5%*	*9250.0%*	*8178.2%*	*1700.0%*	*200.0%*	*5.7%*
Operating Income	**($25.1)**	**($29.6)**	**($16.0)**	**($23.3)**	**($94.1)**	**($19.3)**	**($21.3)**	**($19.3)**	**($23.2)**	**($83.1)**	**($113.1)**	**($98.3)**	**$58.6**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	*27.9%*
Other Income (Net)	$2.5	$0.9	$0.1	($5.4)	($1.9)	$0.1	$0.4	($0.1)	($0.1)	$0.3	($0.5)	($0.5)	($0.5)
Pre-Tax Income	**($22.6)**	**($28.7)**	**($15.9)**	**($28.8)**	**($96.0)**	**($19.3)**	**($20.8)**	**($19.4)**	**($23.3)**	**($82.8)**	**($113.6)**	**($98.8)**	**$58.1**
Net Taxes (benefit)	$0.0	$0.0	$0.0	($4.0)	($4.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*14.0%*	*4.2%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($22.6)**	**($28.7)**	**($15.9)**	**($24.7)**	**($91.9)**	**($19.3)**	**($20.8)**	**($19.4)**	**($23.3)**	**($82.8)**	**($113.6)**	**($98.8)**	**$58.1**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*54.7*	*55.7*	*59.5*	*59.5*	*57.4*	*59.5*	*59.8*	*60.0*	*68.0*	*61.8*	*75.0*	*80.0*	*85.0*
Reported EPS	**($0.41)**	**($0.51)**	**($0.27)**	**($0.42)**	**($1.60)**	**($0.32)**	**($0.35)**	**($0.32)**	**($0.34)**	**($1.34)**	**($1.51)**	**($1.23)**	**$0.68**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One-time charge	$2.54	$0.95	$0.06	($5.44)	($1.89)	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Non GAAP Net Income	**($20.0)**	**($27.7)**	**($15.9)**	**($30.2)**	**($93.8)**	**($19.3)**	**($20.8)**	**($19.4)**	**($23.3)**	**($82.8)**	**($113.6)**	**($98.8)**	**$58.1**
Non GAAP EPS	**($0.37)**	**($0.50)**	**($0.27)**	**($0.51)**	**($1.64)**	**($0.32)**	**($0.35)**	**($0.32)**	**($0.34)**	**($1.34)**	**($1.51)**	**($1.23)**	**$0.68**

Source: Company filing and Zacks estimates

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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- 16.7%, Hold/Neutral- 77.0%, Sell/Underperform – 5.6%. Data is as of midnight on the business day immediately prior to this publication.