Zacks Small-Cap Research

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Arrowhead Research (ARWR-NASDAQ)

ARWR: On track to complete Phase II a and initiate Phase IIb of ARC-520 – maintaining Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/11/2013
Current Price (05/06/14)	$10.22
Twelve- Month Target Price	**$18.75**

OUTLOOK

ARWR is a clinical stage biotech company focused on RNAi targeted therapy using three proprietary platform technologies.

We are optimistic about the Company's lead program ARC-520 for HBV. ARWR presented Phase I data recently and is on track to complete Phase IIa in 2Q14. The Company plans to initiate Phase IIb of ARC-520 in 2H14. Balance sheet is strong.

We are optimistic about the prospect of ARWR. Recent pullback provides buying opportunity.

SUMMARY DATA

52-Week High	**$26.57**
52-Week Low	**$1.84**
One-Year Return (%)	**445.27**
Beta	**2.58**
Average Daily Volume (sh)	**1,892,940**
Shares Outstanding (mil)	**52**
Market Capitalization ($mil)	**$531**
Short Interest Ratio (days)	**1.20**
Institutional Ownership (%)	**59**
Insider Ownership (%)	**2**
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)
2013	0.16 A	0.04 A	0.04 A	0.04 A	0.29 A
2014	0.04 A	0.04 A	0.04 E	0.04 E	0.17 E
2015					0.30 E
2016					0.30 E

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

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2013	-$0.33 A	-$0.41 A	-$0.18 A	-$0.35 A	-$1.24 A
2014	-$0.19 A	-$0.25 A	-$0.22 E	-$0.23 E	-$0.90 E
2015					-$0.85 E
2016					-$0.87 E

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

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WHAT'S NEW

- **Arrowhead reports fiscal 2Q14 financials with strong balance sheet;**
- **First cohort enrollment of the Phase IIa trial of ARC-520 completed, top line data expected in 3Q14;**
- **A multi-dose, multi-national Phase IIb study of ARC-520 will begin in 2H14;**
- **Data from Phase I clinical trial of ARC-520 presented at HepDART 2013**
- **Valuation is attractive; recent pullback provides buying opportunity;**

Arrowhead Reports Fiscal 2Q14 Financial Results with Strong Balance Sheet

On May 5, ARWR reported fiscal 2014 second quarter financial results ended March 31, 2014.

Research and development expenses for the fiscal second quarter ended March 31, 2014 were $5.2 million, compared to $2.1 million for the fiscal second quarter ended March 31, 2013.

Salary, general and administrative expenses were $4.4 million for the current quarter compared to $2.5 million for the same quarter last year.

Total operating expenses for the fiscal second quarter ended March 31, 2014 were $11.3 million, compared to $5.4 million for the quarter ended March 31, 2013.

Net loss attributable to Arrowhead for the current quarter was $13.9 million, or $0.31 per share based on 44.3 million weighted average shares outstanding. This compares with a net loss attributable to Arrowhead of $6.8 million, or $0.41 per share based on 16.5 million weighted average shares outstanding, for the quarter ended March 31, 2013.

Net cash used in operating activities for the first six months of fiscal 2014 was $14.7 million, compared with $8.3 million in the prior year period.

The Company's balance sheet remains strong. As of March 31, 2014, cash and investments of cash were $194.7 million. In February, 2014, Arrowhead closed an underwritten offering of 6,325,000 shares of common stock. The offering was priced at $18.95 per share and the company received gross proceeds of approximately $120 million.

The Company's current cash should be able to fund the planned Phase IIb and Phase III trial. The strengthened balance sheet will allow the Company to accelerate the development of its pipeline.

Phase IIa Trial of ARC-520 Is On Schedule To be Completed

On April 1, 2014, Arrowhead announced that that the **first cohort of 8 patients** has been fully enrolled and dosed in the Phase IIa clinical trial of ARC-520 for the treatment of chronic hepatitis B virus (HBV) infection.

The Phase IIa trial began doing patients on March 24, 2014 in Hong Kong. The pace of patient accrual has been very encouraging with the first dose group being enrolled and dosed in just over a week. According to the study protocol, the trial will begin dosing the next cohort in May.

The Phase IIa study is planned to enroll up to 16 chronic HBV patients in **two dose cohorts** with patients receiving either ARC-520 or placebo **in combination with entecavir**. **Primary endpoints** will be safety and tolerability as well as depth and duration of surface antigen knock down. Patients will be followed until surface antigen levels return to baseline.

We are pleased to see that the trial remains on schedule to meet the previously stated goal of completing **dosing** in the second quarter and releasing **top line** results in the third quarter.

Phase IIb Will Be Initiated in 2H14

Based on the Phase IIa data, **Phase IIb** study of ARC-520 will begin in the **2H14,** probably in 4Q14. Preparation of this Phase IIb study is underway. The Phase IIb will be a multi-dose, multi-national, and will likely include sites in the US, Europe and Asia. The Phase IIb study is designed to provide a read out on ARC-520's ability to achieve functional cure, among other outcome measures. We estimate top line results from the Phase IIb trial will be available in **mid-2015**.

We are pleased that the company is on track to advance ARC-520. Based on preclinical and the Phase I clinical studies, we are highly confident that the Phase IIa and Phase IIb trial will have a high possibility to be successful.

We expect Arrowhead will be able to initiate **pivotal Phase III** trial of ARC-520 in late 2015 or early 2016, and data should be available in late 2016. NDA could be filed in 1H2017, and the FDA approval is in late 2017 or early 2018.

We think ARC-520 is the primary value driver in near- and mid-term for Arrowhead. The successful development of ARC-520 is critical to Arrowhead because the HBV market offers opportunities for substantial revenues, and because validation of the Company's RNAi delivery technology opens broad opportunities both for other therapeutic programs and licensing opportunities.

In this regard, the completion of the Phase I study and the initiation of the Phase IIa of ARC-520 represent an important milestone for Arrowhead in achieving its long term growth goal. One of the attractive features of RNAi and of DPCs specifically is once the safety profile in man for the delivery system has been established, additional targets and candidates can be studied rapidly. Therefore the Phase I trial of ARC-520 will provide the company with the data needed to accelerate the development of its pipeline and bring additional candidates into the clinic.

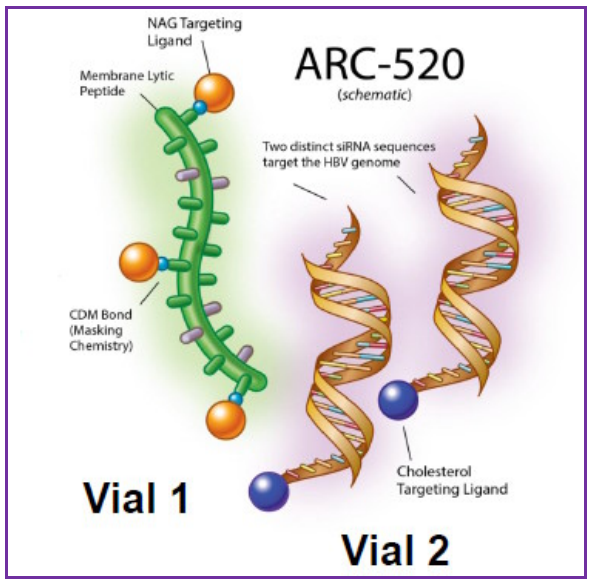
Phase I Data on ARC-520 Presented at HepDART 2013

On December 9, 2013, Arrowhead presented data from the **Phase I** clinical study of **ARC-520**, the company's clinical candidate for the treatment of **chronic hepatitis B** infection, at the HepDART 2013 conference being held on The Big Island, Hawaii.

ARC-520 is an **RNAi-based therapeutic** in development by Arrowhead for the treatment of hepatitis B virus (HBV) infection using the Company's Dynamic Polyconjugate **(DPC)** technology.

ARC-520 consists of two siRNA (siHBV-74 and siHBV-77) trigger molecules which target a sequence that is shared by all four of the mRNAs produced by the HB virus. The targeted sequence is highly conserved across HBV. The duplexes provide coverage of over 99.6% of known sequences. These RNAi triggers incorporate structural modifications to enhance stability in biological fluids and are conjugated to cholesterol, which acts as a **liver-targeting group**. These conjugated RNAi triggers (siHBV-74 and siHBV-77) are co-injected with a targeted endsomolytic agent, NAG-MLP. NAG-MLP is composed of the amphipathic polymer bee venom melittin, to which the targeting ligand N-acetylgalactosamine has been attached via acid-sensitive linkers. Once the siRNAs and the active excipient are taken up by the hepatocytes, the polymeric amines are unmasked in the endosome and disrupt the endosomal membrane, releasing the siRNA to the cytoplasm where it can engage the RNAi machinery of the cell.

The siRNAs in ARC-520 target the mRNAs that produce HBsAg proteins, the viral polymerase, the core protein that forms the capsid, and the HBeAg.



Arrowhead began dosing in the **Phase I** clinical trial of **ARC-520** on July 23, 2013 in Australia and completed enrollment in October 2013.

The Phase I study was designed to characterize the safety profile of ARC-520 across a range of doses and evaluate pharmacokinetics. It is a single-center, randomized, double-blind, placebo-controlled, single dose-escalation, first-in-human study of ARC-520 administered intravenously to healthy adult volunteers. **36 subjects** have been enrolled in 6 groups randomized at a ratio of 2:1 to receive ARC-520 or placebo: Placebo (n=12), ARC-520 0.01 mg/kg (n=4), 0.1 mg/kg (n=4), 0.3 mg/kg (n=4), 0.6 mg/kg (n=4), 1.2 mg/kg (n=4), and 2.0 mg/kg (n=4). The placebo group included 7 male and 5 female subjects with average of 28.1 +/- 9.6 years. The treatment group included 12 male and 12 female subjects with average age of 26.9 +/- 6.7 years. Subjects were admitted to the unit overnight pre-dose and vital signs, telemetry, ECGs, safety labs, PK, and adverse events were monitored for 24 hours post-dose. Return visits occurred for repeat safety evaluations and recording of adverse events at 48 hrs, 72 hours, day 7, day 14 and day 28 post dosing.

	Placebo	ARC-520
Gender	7M, 5F	12M, 12F
Age	28.1+/-9.6	26.9+/-6.7
Weight	70.6+/-9.8	73.2+/-12.8
BMI	23.2+/-1.9	23.4+/-2.4
Caucasian	11	22
Asian	1	2

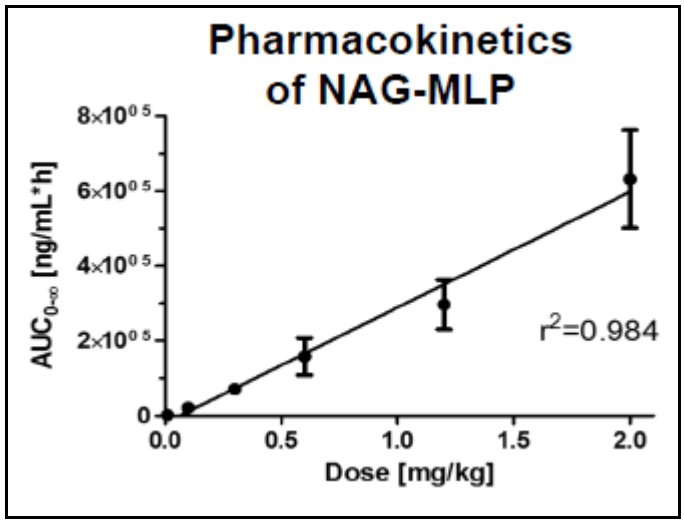
Preliminary results from the phase I clinical study of ARC-520 indicate that to date there have been no serious AEs, no dose limiting toxicities, no discontinuations, and a modest occurrence rate of AEs with no dose related increase in frequency or severity, with the possible exception of mild lightheadedness which occurred in two subjects in the 2 mg/kg dose group. There were no general differences observed or findings rated clinically significant on vital signs, ECGs, physical examinations, or clinical laboratories in the ARC-520 groups relative to placebo. Adverse event frequency and severity did not differ between placebo and ARC-520, with 75% of both treated and placebo subjects reporting mild or moderate AEs.

There was a low occurrence rate of abnormal laboratory tests, with no observed relationship to timing or dose.

Adverse Event	Placebo N=12	0.01 mpk N=4	0.1 mpk N=4	0.3 mpk N=4	0.6 mpk N=4	1.2 mpk N=4	2.0 mpk N=4
Subjects reporting any AE	5 (42%)	0 (0%)	1 (25%)	4 (100%)	1 (25%)	1 (25%)	3 (75%)
Headache	2 Mild, 1 Mod		1 Mod			1 Mild	
Lightheadedness							2 Mild
Abdominal pain				1 Mild			
Generalized flushing				1 Mod			
Hypotension*				1 Mod			
Infusion reaction							1 Mod
Lethargy	1 Mild						
Lost appetite	1 Mild						
Muscle ache							1 Mild
Sinus pause				1 Mod			
Sweet taste in mouth				1 Mild			
Tingling in tongue	1 Mild						
Upper respiratory tract infection					1 Mild		

*BP machine malfunction

PK results appear to indicate that C0(equivalent to CMax) and AUC0-∞ increase linearly with dose (r^2=0.984).



The Phase I study has thus demonstrated that a single intravenous administration of ARC-520 appears to be safe and well tolerated up to and including a dose of 2 mg/kg, the highest dose tested.

New Candidate Will be Nominated in 2Q14

Beyond ARC-520, Arrowhead is actively working on designating its next clinical candidate that will use its DPC platform technology. The company has consulted with expert advisors on targets of interest.

Arrowhead will host an **Investor and Analyst R&D Event** on June 19 in New York City. On that day, the Company will disclose this clinical candidate, which will be an **orphan liver indication**. The Company will provide information about the disease area, present preclinical data, and give more guidance about timing for the clinical program. Arrowhead hopes to file an IND for the new candidate in **4Q14**.

Market Opportunity for ARC-520

Currently **seven drugs** are available in the US for the treatment of HBV. They are classified as two classes:

- **Interferons** include Pegasys and Intron A,
- **Nucleosides/Nucleosides** include Lamivudine, Telbivudine, Entecavir, Tenofovir, and Adefovir dipivoxil.

Brand Name	Generic Name	Company	Approval Year	Patent Expiration	2012 WW Sales
Pegasys	pegylated α-interferon-2a	Roche	2005	2018	$692M
Intron A	α-interferon-2b	Roche	1992	2002	< $5M
Viread	tenofovir	Gilead	2008	2018	$701M
Tyzeka	telbivudine	Novartis	2006	2019	$136M
Hepsera	Adenovir	Gilead	2002	2014	$108M
Epivir	lamivudine	GSK	1998	2010	$13M
Barraclude	entecavir	Bristol-Myers	2005	2015	$1388M

Drug	Admin.	Treatment Duration	Tolerability	Resistance Develop.	Efficacy of Treatment on		
					Viral Load	HBeAg	HBsAg
Pegasys	Sub-Q	1 Year	Poor	Very Good	Fair	Fair	Poor
Intron A	Sub-Q	1 Year	Poor	Very Good	Fair	Fair	Poor
Barraclude	Oral	Indefinite	Good	Good	Good	Poor	Poor
Tyzeka	Oral	Indefinite	Good	Fair	Good	Poor	Poor
Hepsera	Oral	Indefinite	Good	Good	Poor	Poor	Poor
Epivir	Oral	Indefinite	Good	Poor	Fair	Poor	Poor
Viread	Oral	Indefinite	Good	Good	Good	Poor	Poor

None of the above available treatment options offers a significant opportunity for HBsAg clearance, which is considered a **functional cure**.

In summary, treatment with peginterferon provides a modest chance at a long term sustained response, but is associated with severe side effects in a treatment regimen that generally lasts a full year. Nucleosides and nucleotides dramatically reduce viral load and have a mild side effect profile, but must be taken for many years or for life, because viral rebound usually occurs when therapy is stopped. Furthermore, nucleotides have only a modest effect on other markers of infection such as HBeAg and HBsAg.

The observation that peginterferon is much more likely to provide a sustained post-treatment antiviral response than nucleotides in spite of its more modest effect on serum viral load, suggests that approaches that reduce viral replication and accelerate clearance of infected hepatocytes are more likely to be successful in producing a post-treatment sustained response, HBeAg seroconversion, and possibly HBsAg seroconversion as well. A treatment that shared interferon's ability to enhance immune system-mediated clearance of infected hepatocytes without its severe side effect profile would be a valuable addition to the armamentarium of anti-HBV drugs.

Apparently, HBV market represents a multi-billion dollar opportunity and current therapeutic regimes have limitations. There is an unmet medical need for HBV patients, especially for patients with chronic HBV infection. Any new medicine with increased efficacy and/or safety profile will be in high demand.

ARC-520 is a siRNA therapeutic in development which may provide a meaningful alternative for the treatment of chronic HBV. ARC-520 has a differentiated mechanism of action compared to that of

existing anti-HBV drugs. The mechanism of RNA interference could provide a powerful new treatment for hepatitis B through the unique ability to specifically reduce the amount of circulating HBV antigens.

ARC-520 has already demonstrated the ability to reduce HBsAg, HBeAg, and viral DNA dramatically in multiple animal models with excellent safety profile. With the data from chimpanzees, we expect to see similar data in human trials.

Listing Upgraded to NASDAQ Global Select Market

On February 21, 2014, the NASDAQ Listing Qualifications Department has approved an application to upgrade the listing of the Company's securities from the NASDAQ Capital Market to the NASDAQ Global Select Market, effective with the opening of business on February 21, 2014. The NASDAQ Global Select Market is the segment for public companies that meet the highest listing standards of NASDAQ.

The upgrading further increases Arrowhead's visibility and liquidity.

Current Price Does Not Reflect Value

We maintain our Outperform rating on Arrowhead shares, and reiterate our price target of $18.75 per share.

Recent pullback provides a buying opportunity. Current market price does not reflect the intrinsic value of the Company. At current market price, we think there is still enough room for further price appreciation.

Recent clinical advancement from RNAi companies such as Alnylam Pharmaceuticals and other small companies has validated the RNAi platform. The $700 million investment by Sanofi in Alnylam pushed the valuation of Alnylam to as high as $5 billion, and currently settled at $3.5 billion.

Currently, Arrowhead shares are trading at around $10 per share, which values the Company at about $520 million in market cap based on 52 million outstanding shares. Of course, ARWR's pipeline is not as diversified as that of Alnylam and its lead program of ARC-520 is still in Phase II trial. But ARWR looks more like an early stage Alnylam. The Company's DPC platform technology has the potential to target any indication.

The Company's anti-HBV drug candidate ARC-520 has demonstrated compelling efficacy data and safety profile in animal studies and is safe and well tolerated in humans. The positive Phase I data of ARC-520 further de-risk Arrowhead. ARC-520 has the potential for functional cure of HBV infection. We estimate that ARC-520 could be approved in the US in 2017 and has a blockbuster potential.

Our financial model indicates that ARWR will be profitable in 2018 with EPS of $0.11 per share. EPS will grow to $1.04 per share in 2019 based on total revenue of $175 million. We think ARWR shares should be valued using 45 x P/E multiple, and 20% discount rate. Based on this relative value metrics, our model shows that ARWR should be valued at $18.75 per share. Our price target values Arrowhead at $975 million in market cap, which we think is a fair value to Arrowhead.

Following are the near term catalysts:

- 2Q14, to complete dosing in the Phase IIa study;
- 2Q14, to nominate a second candidate, present preclinical data and discuss clinical plan;
- 3Q14, to release top line results from the Phase IIa study;
- 4Q14, to initiate multi-dose Phase IIb study or ARC-520;
- 4Q14, to file an IND for the next candidate.

PROJECTED INCOME STATEMENT

	2011 (Sep)	2012 (Sep)	2013 (Sep)	2014 (Sept)					2015 (Sept)	2016 (Sept)	2017 (Sept)	2018 (Sept)	2019 (Sept)
$ in millions except per share data	FY	FY	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE	FYE
Revenue	$0.30	$0.15	$0.29	$0.04	$0.04	$0.04	$0.04	$0.17	$0.30	$0.30	$5.00	$75.00	$175.00
YOY Growth										-	*1566.7%*	*1400.0%*	*133.3%*
Total Revenues	**$0.30**	**$0.15**	**$0.29**	**$0.04**	**$0.04**	**$0.04**	**$0.04**	**$0.17**	**$0.30**	**$0.30**	**$5.00**	**$75.00**	**$175.00**
YOY Growth	-	*-50.4%*	*97.6%*	*-73.0%*	*0.0%*	*-1.7%*	*-1.7%*	*-40.5%*	*73.7%*	*0.0%*	*1566.7%*	*1400.0%*	*133.3%*
Cost of Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.8	$11.3	$24.5
Gross Income	**$0.3**	**$0.1**	**$0.3**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.2**	**$0.3**	**$0.3**	**$4.3**	**$63.8**	**$150.5**
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	$3.3	$5.4	$8.7	$3.1	$5.2	$5.5	$6.0	$19.8	$22.5	$25.0	$15.5	$17.0	$20.0
% R&D	*1106.8%*	*3670.8%*	*2999.2%*	*7286.1%*	*11923.3%*	*12790.7%*	*13953.5%*	*11490.3%*	*7500.0%*	*8333.3%*	*310.0%*	*22.7%*	*11.4%*
SG&A	$3.8	$6.4	$10.2	$3.0	$4.4	$4.8	$5.0	$17.2	$18.5	$20.0	$25.0	$27.5	$30.0
% SG&A	*1281.6%*	*4384.2%*	*3499.0%*	*6966.5%*	*10161.3%*	*11162.8%*	*11627.9%*	*9980.4%*	*6166.7%*	*6666.7%*	*500.0%*	*36.7%*	*17.1%*
Other expenses	$3.1	$9.4	$6.0	$0.9	$1.6	$1.2	$1.4	$5.1	$5.5	$7.0	$8.5	$10.0	$12.0
% Other	*1031.0%*	*6403.6%*	*2073.1%*	*2150.1%*	*3643.9%*	*2790.7%*	*3255.8%*	*2963.1%*	*1833.3%*	*2333.3%*	*170.0%*	*13.3%*	*6.9%*
Operating Income	**($9.8)**	**($21.1)**	**($24.6)**	**($7.0)**	**($11.2)**	**($11.5)**	**($12.4)**	**($42.0)**	**($46.2)**	**($51.7)**	**($44.8)**	**$9.3**	**$88.5**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	*50.6%*
Other Income (Net)	$6.7	($0.0)	($6.6)	($3.6)	($2.7)	($0.5)	($0.5)	($7.3)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)
Pre-Tax Income	**($3.1)**	**($21.1)**	**($31.1)**	**($10.6)**	**($13.9)**	**($12.0)**	**($12.9)**	**($49.4)**	**($46.7)**	**($52.2)**	**($45.3)**	**$8.8**	**$88.0**
Net 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	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($3.1)**	**($21.1)**	**($31.1)**	**($10.6)**	**($13.9)**	**($12.0)**	**($12.9)**	**($49.4)**	**($46.7)**	**($52.2)**	**($45.3)**	**$8.8**	**$88.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*7.2*	*11.1*	*24.0*	*37.7*	*44.3*	*52.0*	*53.0*	*46.8*	*55.0*	*60.0*	*70.0*	*80.0*	*85.0*
Reported EPS	**($0.44)**	**($1.90)**	**($1.30)**	**($0.28)**	**($0.31)**	**($0.23)**	**($0.24)**	**($1.06)**	**($0.85)**	**($0.87)**	**($0.65)**	**$0.11**	**$1.04**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	($5.49)	$0.00	$7.00	$3.62	$2.73	$0.50	$0.50	$7.35	$0.00	$0.00	$0.00	$0.00	$0.00
Non GAAP Net Income	**($8.6)**	**($21.1)**	**($24.1)**	**($7.0)**	**($11.2)**	**($11.5)**	**($12.4)**	**($42.0)**	**($46.7)**	**($52.2)**	**($45.3)**	**$8.8**	**$88.0**
Non GAAP EPS	**($1.20)**	**($1.90)**	**($1.01)**	**($0.19)**	**($0.25)**	**($0.22)**	**($0.23)**	**($0.90)**	**($0.85)**	**($0.87)**	**($0.65)**	**$0.11**	**$1.04**

Source: Company filing and Zacks Investment Research estimates

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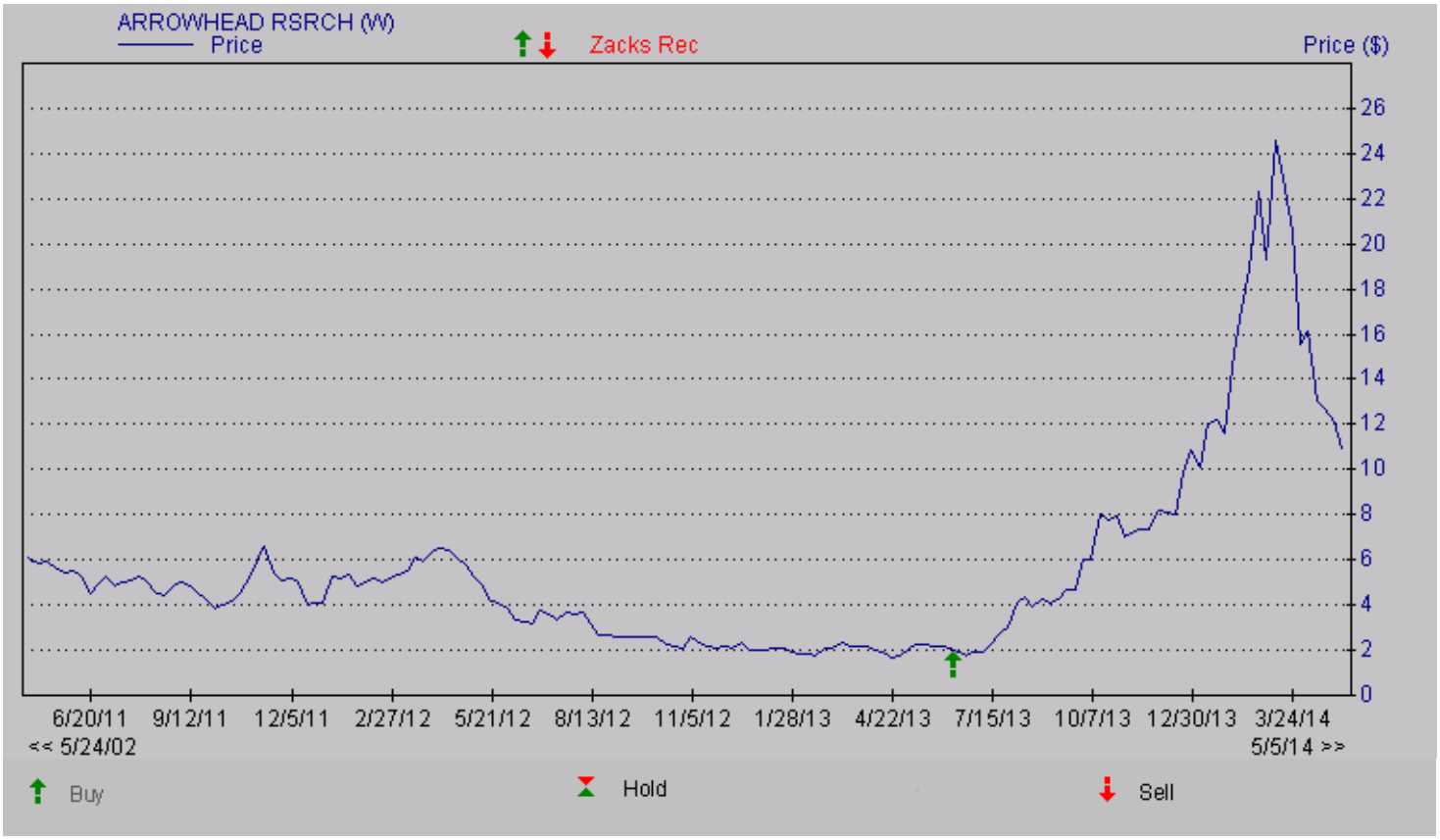
HISTORICAL ZACKS RECOMMENDATIONS



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