Zacks Small-Cap Research

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# Arrowhead Research (ARWR-NASDAQ)

**ARWR:** ARC-520 is still alive**,** Strong balance sheet, new clinical candidate nominated, on track initiate Phase IIb of ARC-520 – maintaining Outperform

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 06/11/2013 |
| Current Price (10/08/14) | $7.03 |
| **Twelve- Month Target Price** | **$15.00** |

## OUTLOOK

ARWR is a clinical stage biotech company focused on RNAi targeted therapy using DPC platform technology. We are optimistic about the Company's lead program ARC-520 for HBV.

ARWR just released initial Phase IIa data, which were as strong as expected, but the program is still viable in our view. The Company plans to initiate Phase IIb of ARC-520 in 4Q14. The Company just announced its second clinical candidate ARC-AAT for liver disease.

Balance sheet is strong.

We maintain our Outperform rating on its shares.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$26.57** |
| **52-Week Low** | **$5.86** |
| **One-Year Return (%)** | **3.08** |
| **Beta** | **2.77** |
| **Average Daily Volume (sh)** | **2,856,907** |
| **Shares Outstanding (mil)** | **53** |
| **Market Capitalization ($mil)** | **$372** |
| **Short Interest Ratio (days)** | **3.29** |
| **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 A | 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 | -$0.24 A | -$0.25 E | -$0.94 E |
| 2015 | | | | | -$0.86 E |
| 2016 | | | | | -$0.87 E |

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

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## WHAT'S NEW

- **Initial Phase IIa data released, not as strong as expected, but the program sill viable;**
- **Reiterate Outperform rating with lowered price target;**
- **On track to initiate ARC-520 Phase IIb study at the end of 2014; ;**
- **New clinical candidate announced and targeting liver disease;**
- **Balance sheet remains strong;**

### *Efficacy of ARC-520 Phase IIa not as Strong as Expected, But the Program Is still Viable*

On October 8, Arrowhead announced that it will present the data from the ongoing **Phase IIa** study of **ARC-520** for the treatment of **chronic hepatitis B** (HBV) infection in the late-breaking poster session at the 2014 American Association for the Study of Liver Diseases (AASLD) Liver Meeting being held on November 7-11, 2014, in Boston.

This phase IIa is a randomized, double blind, placebo controlled study, which will enroll up to 24 chronic HBV patients in **three dose cohorts** with patients receiving either ARC-520 or placebo **in combination with entecavir**. Patients are randomized to placebo or ARC-520 at a ratio of 1:3 and continue daily 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.

The Phase IIa trial began doing patients on March 24, 2014 in Hong Kong. Three single doses of ARC-520 at 1 mg/kg (Cohort 1, 8 patients), 2 mg/kg (Cohort 2, 8 patients) and 3 mg/kg (Cohort 3, 6 patients) have been evaluated. Cohorts 1 and 2 have been evaluated through Day 85 and are unblinded. Cohort 3 is enrolling and remains blinded.

The Company released the data from its abstract for the meeting.

According to the abstract, ARC-520 was **safe and well tolerated** in all three cohorts. There were no SAEs, no signs of hypersensitivity, no dose limiting toxicities and no discontinuations due to AEs. There were no treatment emergent changes in vital signs, physical exams or ECGs rated clinically significant by the investigator. There have been few abnormal laboratory values, with no clinically significant, treatment emergent, changes in ALT, AST, GGT, LDH, bilirubin, BUN or creatinine or apparent trends. All AEs reported to date (n=4) have been mild or moderate and rated as unrelated to study drug by the investigator.

**Efficacy** of ARC-520 was measured as HBsAg decline from baseline. In the 1 mg/kg cohort, mean nadir HBsAg was -39% (range -22 to -57) with a mean change on day 85 of -31% (range -14 to -39). In the 2 mg/kg cohort, mean nadir HBsAg was – **51%** (range -46 to -59) with a mean change on day 85 of -22% (range -7 to -40). For 2 mg/kg cohort, the HBsAg reduction was statistically significant vs placebo for Days 3 through 43 post dose.

### *Our Takeaways from the Preliminary Phase IIa Data*

Following the release of the initial Phase IIa data, share price of Arrowhead declined more than 50%. We think this is an **overreaction**.

First, we think that in general the preliminary data are positive. ARC-520 demonstrated a strong safety profile and a modest efficacy for chronic HBV patients in the Phase IIa study. Remember, this is the first time that an HBsAg reduction is mediated through RNAi in chronic HBV patients.

Second, we have seen the dose dependent reduction of HBsAg in the Phase IIa study with a 39% reduction in the 1 mg/kg dose and 51% reduction in the 2 mg/kg dose. We expect further HBsAg reduction in the 3 mg/kg dose when the data are unblinded later this year.

Thirdly, according to management, if ARC-520 is safe in the 3 mg/kg dose, an increase of dose to 4 mg/kg is possible, which could further reduce HBsAg in HBV patients.

Further, the multi-dose, multi-national Phase IIb trial will proceed as planned.

With the positive data, why the market overreacted to the positive data negatively? We think there is a misunderstanding the market has about the anticipated data.

**Misunderstanding number 1**: the market has been anticipating a much deeper knockdown of HBsAg (about 1 log, 90%). Management did say in recent conference calls, that their goal is to **identify a dose** of ARC-520 capable of achieving HBsAg reduction of around 1 log after a single administration.

On the surface of it, the 51% reduction (about 0.3 log) at the 2 mg/kg dose is far from the 1 log (90% reduction) goal. But we remind investors that the Company is still waiting for data from the 3 mg/kg dose. Since ARC-520 has demonstrated excellent safety profile in healthy humans at 4 mg/kg dose, a dose increase to 4 mg/kg is possible if ARC-520 is safe and tolerated at the 3 mg/kg dose.

Further, our understanding is that the goal of 1 log reduction is based on scientific literature. A small number of patients who achieve functional cure from Interferon therapy demonstrate ½ log reduction in HBsAg (70% knockdown) after 12 weeks and 1 log (90% knockdown) after 24 weeks. If ARC-520 can lead to more rapid reduction, particularly on repeat dosing, a 1 log reduction may not be needed after a single administration. A 0.5 log to 0.8 log (70% to 85%) reduction in HBsAg may still work for ARC-520 after single administration.

**Misunderstanding number 2**: The Phase IIa data are weak than data from animal model.

In the chimpanzee study, ARC-520 achieved 80-85 reduction in HBsAg at the dose of 3 mg/kg. At 2 mg/kg dose, ARC-520 achieved 50% reduction in HBsAg, which was similar to the reduction in the Phase IIa trial. With the data from 3 mg/kg coming in, we may see similar knockdown of HBsAg in humans compared to that in chimpanzee.

***Our Conclusion***

We think the initial data from the ongoing Phase IIa trial were not that bad and market overreacted to the generally positive data.

Arrowhead just completed the first two dose cohorts in the Phase IIa dosing finding study, and has not yet identified a dose in humans that will meet the HBsAg knockdown goal.

Arrowhead just finished dosing all 8 patients in the 3 mg/kg cohort. The Company will decide whether to escalate to 4 mg/kg after seeing the actual data from the 3 mg/kg does. Even with the dose increase to 4 mg/kg, the **Phase IIb** will proceed as planned.

That said, we do see increased uncertainty in this program due to the not that strong data from the first 2 cohorts. The increase of the dose may increase safety risks and impact the timeline of this program. Also the increase of dose may not guarantee an increased efficacy.

With all these in mind, we think the ARC-520 program is still viable, but with increased risks. Therefore we reiterate our **Outperform** rating on Arrowhead shares but lower our **price target to $15** per share reflecting the increased risks.

### *Phase IIb Will Be Initiated in 4Q14 As Planned*

As discussed above, Arrowhead does not expect timing of the program to be impacted and will submit regulatory filings **by the end of the year** in support of the multi-dose Phase IIb study whether or not to escalate to 4mg/kg in the Phase IIa study.

The **Phase IIb** study of ARC-520 will test two dose levels in e-antigen negative anti-antigen positive patients on entecavir or tenofovir. 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 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.

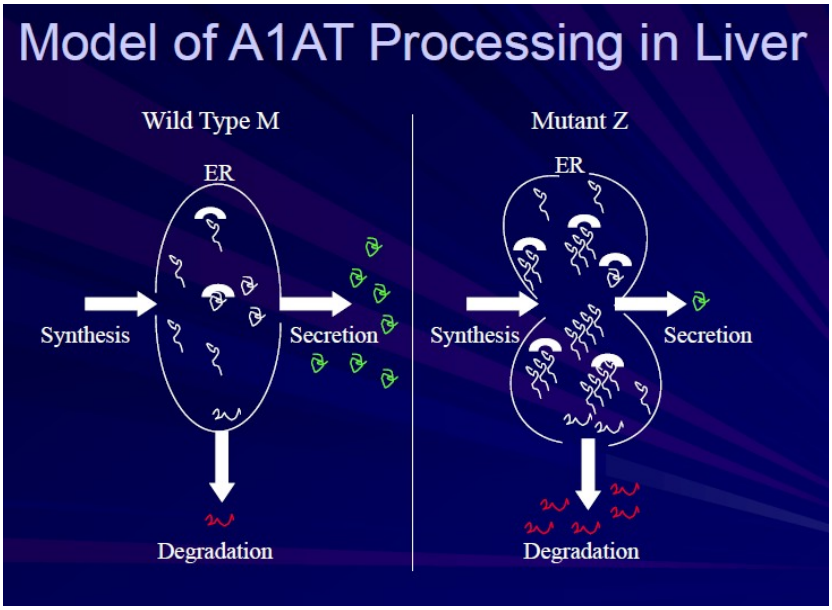
In this regard, the completion of the Phase IIa study and the initiation of the Phase IIb of ARC-520 represent an important milestone for Arrowhead in achieving its long term growth goal. One of the attractive features of RNAi and of DPCs specifically is once the safety profile in man for the delivery system has been established, additional targets and candidates can be studied rapidly. Therefore the Phase II trials 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.

### *New Clinical Candidate ARC-AAT Announced*

On June 19, 2014 at Analyst Day held in New York City, Arrowhead announced its second clinical candidate **ARC-AAT** for the treatment of Alpha-1 antitrypsin deficiency (**AATD**)-associated **liver disease.**

AATD is an autosomal recessive genetic disorder associated with liver disease in children and adults and pulmonary disease in adults. Alpha-1 antitrypsin is a **protease inhibitor** of a circulating glycoprotein of the serpin family encoded by the AAT gene and primarily synthesized in the liver. The physiologic function of AAT is inhibition of neutrophil proteases to protect healthy tissues during inflammation and prevent tissue damage. This is especially important **in the lung**.

The Z mutant is the most common disease variant and has a single amino acid substitution that results in improper protein folding causing severe impairment of secretion from hepatocytes. This lack of secretion leads to **accumulation** of mutant **Z-AAT** polymers, which form globules in the hepatocyte endoplasmic reticulum. This triggers continuous hepatocyte injury, leading to fibrosis, cirrhosis, and increased risk of hepatocellular carcinoma.




*Source: Company presentation*

Approximately 96-98% of AATD-related disease is due to the homozygous PiZZ genotype. The mean estimated prevalence of AATD in the U.S is 1 per 3000-5000, or approximately 100,000 patients.

| Estimated U.S. PiZZ AATD Prevalence | Publication |
|---|---|
| 80,000 | Stolk et al, Internat J COPD, 2006 |
| 70,000 | Stoller J, Aboussouan L, Am J Respir Crit Care Med, 2012 |
| 47,000 | De Serres FJ Chest, 122,5(2002) |
| 34,000 | De Serres FJ, Ther Adv Respir Dis 6(5) 2012, 277-295 |
| 100,000 | Alpha-1 Antitrypsin Deficiency Diagnosis and Standards, American Thoracic Society, 2003. |
| 70,500 | Stoller J, Lancet 2005; 365: 2225-36 |
| 62,800-157,000 | Teckman, COPD 10(S1):35-43 2013 |
| 61,605 | O Brien ML et al, J Pediatric 1978 |
| Mean U.S. Prevalence ~76,000 | |

*Source: Company presentation*

AATD is also an important cause of **pediatric liver disease** with an estimated prevalence in children of approximately 20,000 patients, and 50-80% likely to manifest liver disease during childhood.

| AATD Liver Disease in Children | Estimated U.S. Prevalence |
|---|---|
| Total PiZZ prevalence in children | 20,000 |
| Liver disease during childhood (50-80%) | 10,000-16,000 |
| Severe liver disease (20%) | 2,000-3,200 |
| Liver Fibrosis | 500-800 |
| Transplant | 250-400 |

*Source: Company presentation*

AATD is considered to be a relatively **high prevalence orphan disease**, and it is frequently misdiagnosed or undiagnosed. European prevalence is estimated to be 1 per 2500.

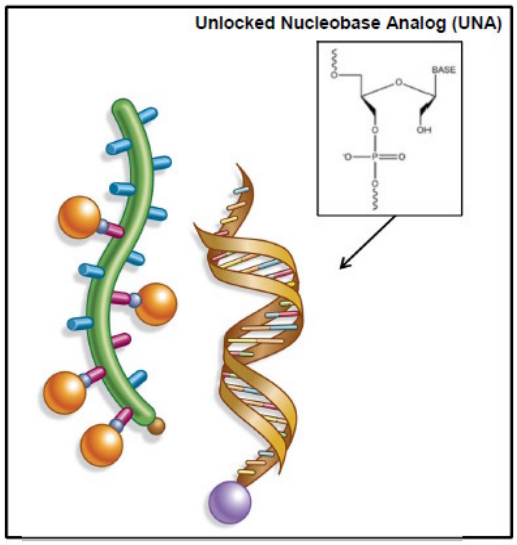
PiZZ individuals have severe deficiency of functional AAT leading to pulmonary disease and hepatocyte injury and liver disease. **Lung disease** is frequently treated with AAT **augmentation therapy**. However, augmentation therapy does nothing to treat liver disease, and there is no specific therapy for hepatic manifestations. There is a significant unmet need as **liver transplant** is currently the only available cure.

### *Arrowhead's ARC-AAT Targets the AAT Gene*

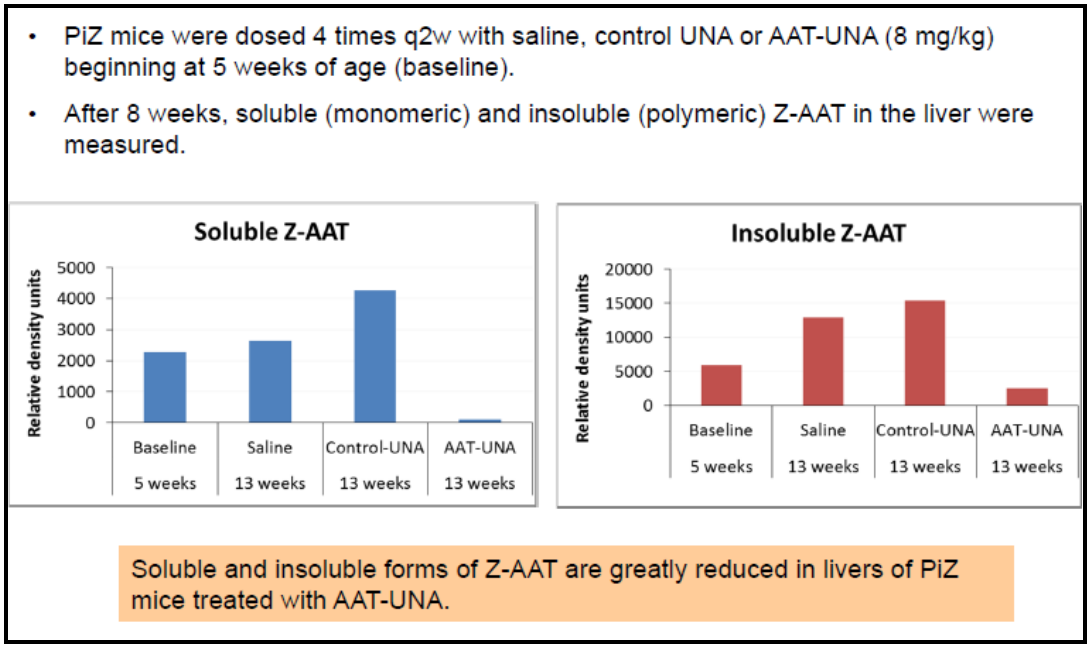
ARC-AAT is an RNAi therapeutic based on the Company's Dynamic Polyconjugate **(DPC**) platform technology. ARC-AAT is designed to treat liver disease associated with Alpha-1 antitrypsin deficiency (AATD). The rational for the design of ARC-AAT is based on the following assumptions: inhibition of Z-AAT production by silencing AAT gene can

- Prevent accumulation of disease causing protein,
- Allow clearance of accumulated protein,
- Prevent repeated cycles of cellular damage and tissue repair,

The RNAi selection process is rigorous for ARC-AAT. Arrowhead has developed a novel unlocked nucleobase analog (**UNA)**-containing RNAi molecule designed for systemic delivery using the DPC delivery system. Incorporation of UNA into the ARC-ATT is associated with improved duration.

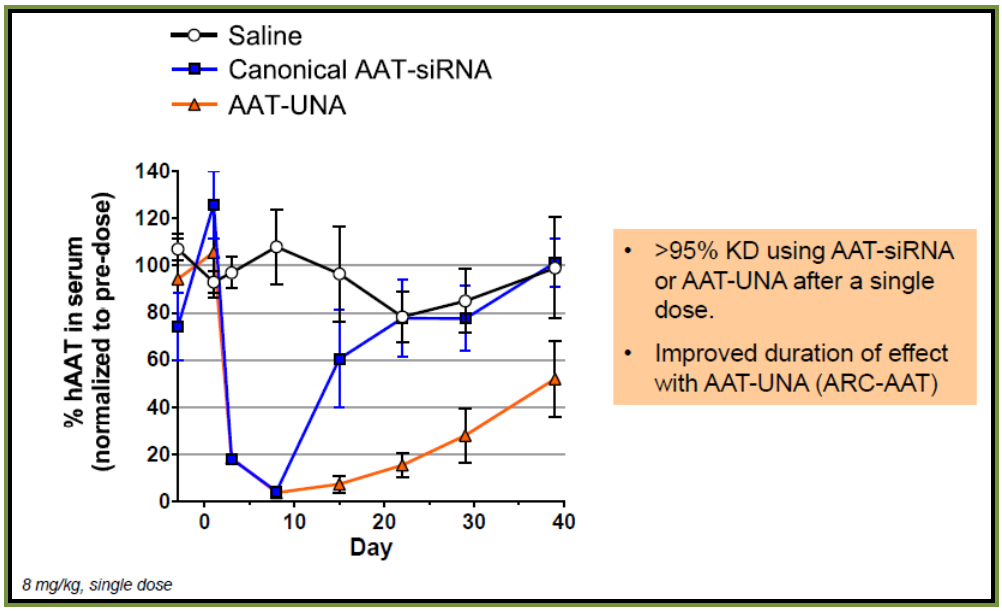



In preclinical PiZ **mouse model**, which is genetically modified to produce the mutant human AAT (Z-AAT), ARC-AAT induced a greater than 95 percent reduction in circulating AAT after a single dose. After eight weeks of treatment in multi-dose studies, soluble (monomeric) and insoluble (polymeric) forms of Z-AAT were greatly reduced in the livers of PiZ mice treated with ARC-AAT. In addition, liver globule burden was substantially reduced from baseline levels and in comparison to treatment with saline, which showed progressive globule formation.




*Source: Company presentation*

The addition of the UNA slowed the rebound in production of AAT compared to canonical siRNAs, and produced a substantially improved duration of effect. In **primate** studies, knockdown of AAT in serum persisted for over ten weeks with greater than 80 percent knockdown observed at the six-week time point.




*Source: Company presentation*

## *Clinical Development Plan for ARC-AAT*

Based on the preclinical results, Arrowhead plans to file an IND application for ARC-AAT in 4Q14.

According to management, initial testing will be in **adult patients** with signs of liver injury, with the intention of preventing additional injury and improving liver histology. In the future, additional studies may

be initiated to investigate treatment of children, including those with severe hepatic disease who may otherwise require liver transplant.

Arrowhead has signed an agreement with the Alpha-1 Project (TAP), a subsidiary of the **Alpha-1 Foundation**. Under the terms of the agreement, TAP will partially fund the development of ARC-AAT. In addition to the funding, TAP will make its scientific advisors available to Arrowhead, assist with patient recruitment for clinical trials thanks to the Alpha-1 Foundation Patient Research Registry, and engage in other collaborative efforts that support the development of ARC-AAT.

We are pleased to see that Arrowhead is diversifying its pipeline by nominating a second clinical candidate, which further de-risk its pipeline. In the absence of specific therapy other than liver transplant for AATD associated liver disease, we believe RNAi holds great potential.

With the experience of two candidates ARC-520 and ARC-AAT, the DPC platform, as well as a strong balance sheet, we believe Arrowhead is well positioned to further diversify its pipeline down the road.

***Balance Sheet Remains Strong***

On August 12, 2014, Arrowhead Research Corporation (ARWR) announced financial results for its fiscal 2014 third quarter ended June 30, 2014 and provided an update on the **Phase IIa** study of ARC-520.

There was no meaningful revenue for the fiscal third quarter of 2014.

R&D expenses were $6.4 million for fiscal 3Q14, compared to $1.8 million for fiscal 3Q13.

SG&A expenses were $4.0 million for fiscal 3Q14, compared to $2.6 million for fiscal 3Q13.

Total operating expenses for the quarter were $12.7 million, compared to $6.4 million for the quarter ended June 30, 2013.

Net loss for the fiscal third quarter of 2014 was $11.6 million ($0.22 per share), compared to a net loss of $6.1 million ($0.23 per share) for the quarter ended June 30, 2013.

Net cash used in operating activities for the first nine months of fiscal 2014 was $24.5 million, compared with $13.6 million in the prior year period.

**The Company's balance sheet remains strong**. As of June 30, 2014, the company's cash and investments of cash were $188.5 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.

## PROJECTED INCOME STATEMENT

| – | | 2014 (Sept) | | | | | 2015 (Sept) | 2016 (Sept) | 2017 (Sept) | 2018 (Sept) | 2019 (Sept) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| $ in millions except per share data | FY | Q1 | Q2 | Q3 | Q4 | FYE | FYE | FYE | FYE | FYE | FYE |
| Revenue | $0.29 | $0.04 | $0.04 | $0.04 | $0.04 | $0.17 | $0.30 | $0.30 | $10.00 | $125.00 | $250.00 |
| *YOY Growth* | | | | | | | | - | *3233.3%* | *1150.0%* | *100.0%* |
| **Total Revenues** | **$0.29** | **$0.04** | **$0.04** | **$0.04** | **$0.04** | **$0.17** | **$0.30** | **$0.30** | **$10.00** | **$125.00** | **$250.00** |
| *YOY Growth* | *97.6%* | *-73.0%* | *0.0%* | *0.0%* | *-1.7%* | *-40.2%* | *72.9%* | *0.0%* | *3233.3%* | *1150.0%* | *100.0%* |
| *Cost of Revenue* | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $1.5 | $18.8 | $35.0 |
| **Gross Income** | **$0.3** | **$0.0** | **$0.0** | **$0.0** | **$0.0** | **$0.2** | **$0.3** | **$0.3** | **$8.5** | **$106.3** | **$215.0** |
| *Gross Margin* | *100.0%* | *100.0%* | *100.0%* | *100.0%* | *100.0%* | *100.0%* | *100.0%* | *100.0%* | *85.0%* | *85.0%* | *86.0%* |
| R&D | $8.7 | $3.1 | $5.2 | $6.4 | $7.2 | $21.9 | $23.0 | $25.0 | $15.5 | $17.0 | $20.0 |
| *% R&D* | *2999.2%* | *7286.1%* | *11923.3%* | *14610.7%* | *16744.2%* | *12646.5%* | *7666.7%* | *8333.3%* | *155.0%* | *13.6%* | *8.0%* |
| SG&A | $10.2 | $3.0 | $4.4 | $4.0 | $4.5 | $16.0 | $18.5 | $20.0 | $25.0 | $27.5 | $32.0 |
| *% SG&A* | *3499.0%* | *6966.5%* | *10161.3%* | *9227.2%* | *10465.1%* | *9209.3%* | *6166.7%* | *6666.7%* | *250.0%* | *22.0%* | *12.8%* |
| Other expenses | $6.0 | $0.9 | $1.6 | $2.3 | $1.4 | $6.2 | $5.5 | $7.0 | $8.5 | $10.0 | $12.0 |
| *% Other* | *2073.1%* | *2150.1%* | *3643.9%* | *5290.8%* | *3255.8%* | *3592.8%* | *1833.3%* | *2333.3%* | *85.0%* | *8.0%* | *4.8%* |
| **Operating Income** | **($24.6)** | **($7.0)** | **($11.2)** | **($12.7)** | **($13.1)** | **($44.0)** | **($46.7)** | **($51.7)** | **($40.5)** | **$51.8** | **$151.0** |
| *Operating Margin* | - | - | - | - | - | - | - | - | - | - | *60.4%* |
| Other Income (Net) | ($6.6) | ($3.6) | ($2.7) | $1.1 | ($0.5) | ($5.8) | ($0.5) | ($0.5) | ($0.5) | ($0.5) | ($0.5) |
| **Pre-Tax Income** | **($31.1)** | **($10.6)** | **($13.9)** | **($11.6)** | **($13.6)** | **($49.8)** | **($47.2)** | **($52.2)** | **($41.0)** | **$51.3** | **$150.5** |
| 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 |
| *Tax Rate* | *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** | **($31.1)** | **($10.6)** | **($13.9)** | **($11.6)** | **($13.6)** | **($49.8)** | **($47.2)** | **($52.2)** | **($41.0)** | **$51.3** | **$150.5** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - |
| *Net Margin* | - | - | - | - | - | - | - | - | - | - | - |
| *Weighted avg. Shares Out* | *24.0* | *37.7* | *44.3* | *51.9* | *53.0* | *46.7* | *55.0* | *60.0* | *70.0* | *80.0* | *85.0* |
| **Reported EPS** | **($1.30)** | **($0.28)** | **($0.31)** | **($0.22)** | **($0.26)** | **($1.06)** | **($0.86)** | **($0.87)** | **($0.59)** | **$0.64** | **$1.77** |
| *YOY Growth* | - | - | - | - | - | - | - | - | - | - | - |
| One time charge | $7.00 | $3.62 | $2.73 | ($1.07) | $0.50 | $5.78 | $0.00 | $0.00 | $0.00 | $0.00 | $0.00 |
| **Non GAAP Net Income** | **($24.1)** | **($7.0)** | **($11.2)** | **($12.7)** | **($13.1)** | **($44.0)** | **($47.2)** | **($52.2)** | **($41.0)** | **$51.3** | **$150.5** |
| **Non GAAP EPS** | **($1.01)** | **($0.19)** | **($0.25)** | **($0.24)** | **($0.25)** | **($0.94)** | **($0.86)** | **($0.87)** | **($0.59)** | **$0.64** | **$1.77** |

*Source: Company filing and Zacks Investment Research estimates*

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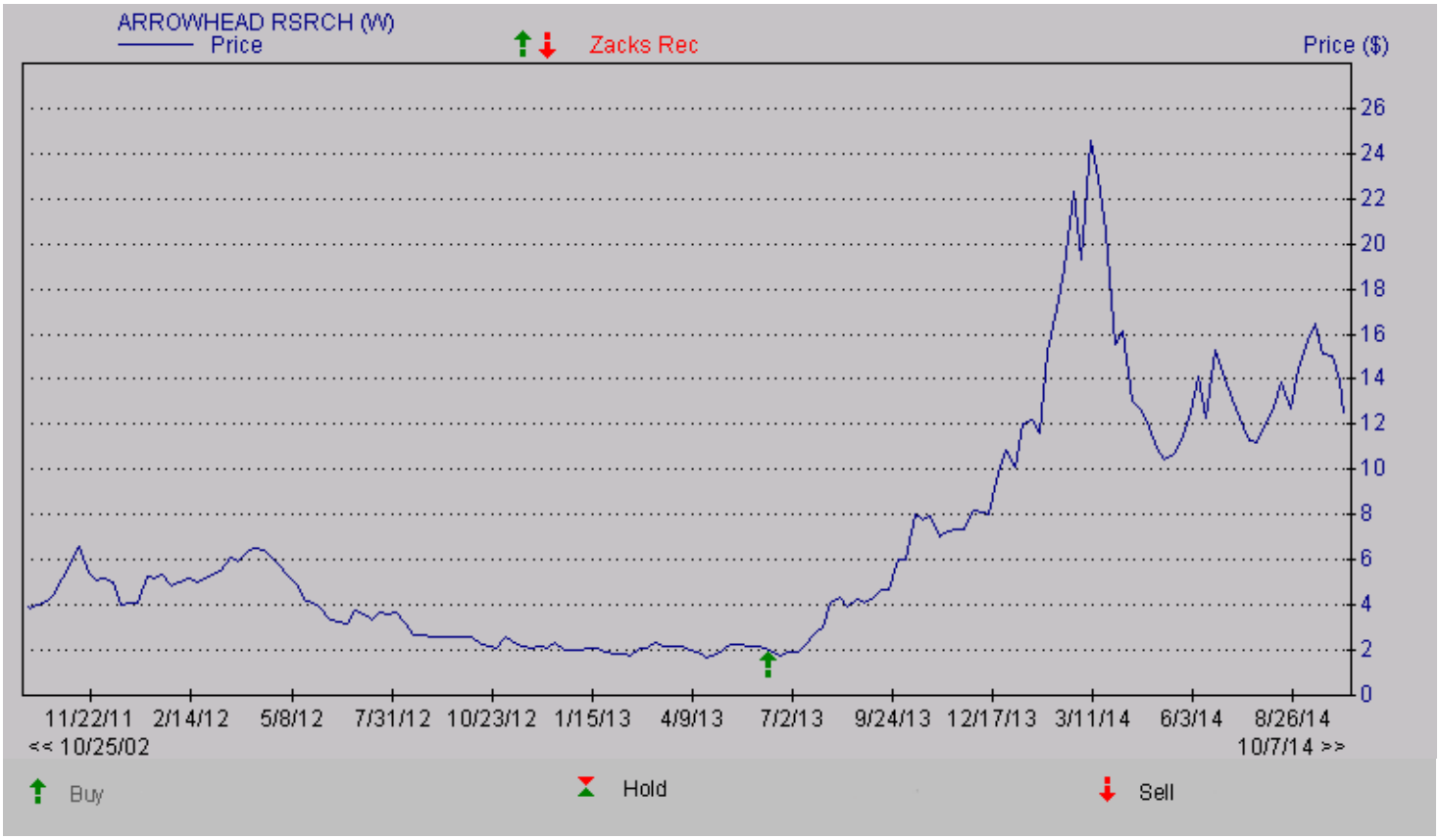
## HISTORICAL ZACKS RECOMMENDATIONS

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