Zacks Small-Cap Research

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Arrowhead Research (ARWR-NASDAQ)

ARWR: ARC-520 is a viable drug for HBV, three Phase IIb studies initiated, new candidate nominated--- maintaining Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/11/2013
Current Price (09/28/15)	$6.30
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.

ARC-520 is in three Phase IIb trials and a new HBV candidate ARC-521 added to the HBV program. The Company just initiated Phase I trial of its second clinical candidate ARC-AAT for liver disease and identified a new candidate for cancer. The acquisition of Novartis' RNAi assets expands and complements its current RNAi estate.

We maintain our Buy rating on its shares.

SUMMARY DATA

52-Week High	**$16.96**
52-Week Low	**$5.00**
One-Year Return (%)	**-60.04**
Beta	**2.17**
Average Daily Volume (sh)	**1,035,365**
Shares Outstanding (mil)	**60**
Market Capitalization ($mil)	**$343**
Short Interest Ratio (days)	**14.27**
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)
2014	0.04 A	0.04 A	0.04 A	0.04 A	0.18 A
2015	0.17 A	0.04 A	0.12 A	0.04 E	0.38 E
2016					0.30 E
2017					0.50 E

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

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2014	-$0.19 A	-$0.25 A	-$0.24 A	-$0.43 E	-$1.15 A
2015	-$0.37 A	-$0.50 A	-$0.27 A	-$0.31 E	-$1.43 E
2016					-$1.50 E
2017					-$1.51 E

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

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WHAT'S NEW

Update on Arrowhead's ARC-520 Phase IIa HBV Program

On Sept 24, 2015, Arrowhead held an Analyst and Investor Day in NYC to provide recent clinical and non-clinical progress the company has made in its lead HBV program ARC-520.

The Background

The Phase IIa trial **(Heparc-2001)** began doing patients on March 24, 2014 in Hong Kong. The ongoing Phase IIa is a randomized, double blind, placebo controlled study. The original trial plan was to enroll patients in three dose cohorts (1, 2, and 3 mg/kg) with patients receiving either ARC-520 or placebo **in combination with entecavir**. The trial expanded into four doses (1, 2, 3, and 4 mg/kg) in 7 cohorts later with the last three cohorts in HBeAg positive patients. 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.

Cohort	Prior NUCs?	Pat Type	ARC-520 dose	Active	Placebo	Status
1	Yes	HBeAg neg	1.0 mg/kg	6	2	Complete/Unblinded
2	Yes	HBeAg neg	2.0 mg/kg	6	2	Complete/Unblinded
3	Yes	HBeAg neg	3.0 mg/kg	6	2	Complete/Unblinded
4	Yes	HBeAg neg	4.0 mg/kg	6	2	Complete/Unblinded
5	Yes	HBeAg pos	4.0 mg/kg	6	2	Complete/Unblinded
6	Yes	HBeAg pos	2 x 2.0 mg/kg	6	0	Ongoing/Open label
7	No	HBeAg pos/neg	4.0 mg/kg	6 pos/6 neg	0	Ongoing/Open label

New cohorts

Interim Data Presented at AASLD

On November 10, 2014 , Arrowhead presented the interim data from the ongoing Phase IIa ARC-520 in a late-breaking poster titled **"*Phase II, dose ranging study of ARC-520, a siRNA-based therapeutic, in patients with chronic hepatitis B virus infection*"** at the 2014 American Association for the Study of Liver Diseases (AASLD) Liver Meeting being held on November 7-11, 2014, in Boston.

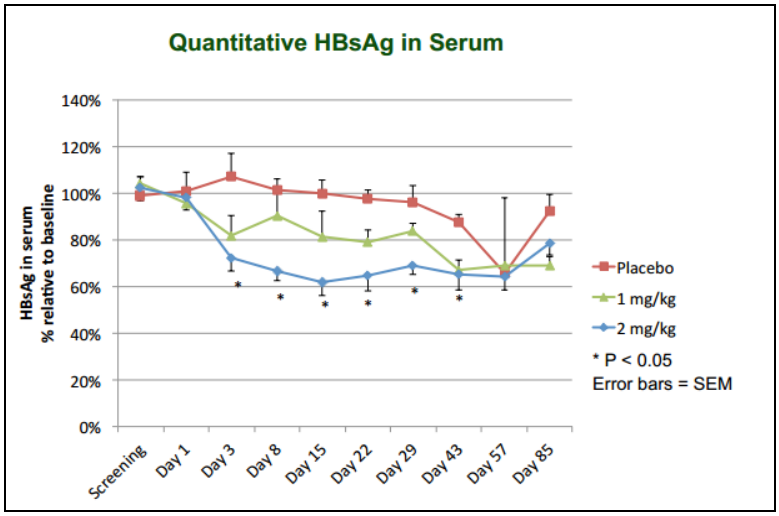
As of the presentation, the Phase IIa study had enrolled three dose cohorts including 24 patients, 18 receiving drug and 6 receiving placebo. Unblinded data were available for the first two cohorts. Cohort 3 data collection was ongoing and this cohort was blinded then. Full results for the first two dose cohorts at **1.0 mg/kg** and **2.0 mg/kg** and partial (blinded) safety results from the **3.0 mg/kg** dose cohort were included in the poster.

Per the poster, 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=6) have been mild or moderate and rated as unrelated to study drug by the investigator.

Adverse Event	Placebo n=4	Cohort 1 n=6	Cohort 2 n=6	Cohort 3 n=8 (blinded)
All	0	1	4	1
Flu like symptoms		1 mild		
CK elevation			1 mild	
Injection extravasation			1 mild	
Near syncope			1 mod	
Malaise			1 mod	
Leg pain				1 mild

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. For cohort 2, the mean day of HBsAg nadir was day 33 with a range of day 8 to day 57.



Update on the Phase IIa ARC-520 on the Analyst Day

On the analyst day, Arrowhead presented the data from the 3rd, 4th and 5th cohorts (3, 4mg/kg).

Based on the animal model, the company interpreted the 1 and 2 mg/kg data as indicating that ARC-520 is on the low end of the response curve. Since dosing in healthy subjects to 4 mg/kg appeared safe, the company added 3 and 4 mg/kg cohorts to the Phase IIa trial, still in HBeAg negative patients on chronic entecavir.

However, the peak knockdown of HBsAg in best responders in HBeAg negative patients in the 3 and 4 mg/kg cohorts continued to be around 60% (cohort 3 and 4). Even with the HBeAg positive patients, the best knockdown of HBsAg is still around 80% after a single dose (cohort 5). This is a surprise to us.

The explanation: NUC treatment and HBeAg loss are associated with sharp reduction in cccDNA. As cccDNA is reduced, integrated DNA emerges as unexpected source of persistent HBsAg production.

Since ARC-520 is specifically designed to silence cccDNA, it shows deep knockdown of cccDNA derived gene products such as HBeAg. However, ARC-520 would not be expected to silence most integrated-derived HBsAg. NUC-naïve HBeAg-positive patients are expected to be richest in cccDNA.

Data form HBeAg Positive/NUC Naive Patients Provide Different Insight into the ACR-520 Program

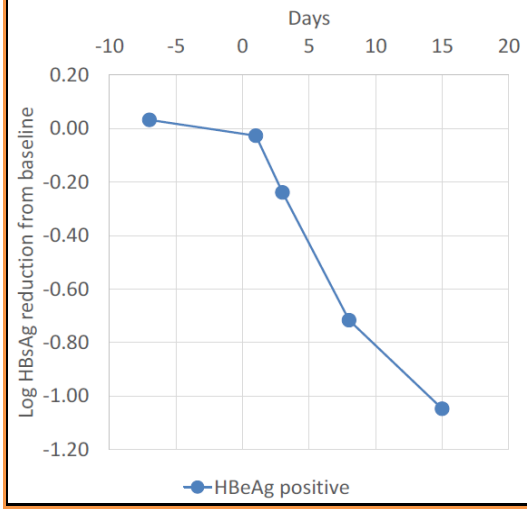
Preliminary data from the HBeAg positive/NUC naïve patients (cohort 7) are encouraging.

HBeAg-positive patients on a background of chronic entecavir receiving a 4 mg/kg single-dose of ARC-520 showed a mean maximal 92% (1.2 log) reduction (knockdown, KD) in circulating HBeAg and a best reduction of 98% (1.7 log).

Single Dose 4mg/kg ARC-520 in HBeAg(+) Patients		
Antigen	mean max KD	max KD
HBeAg	92% (1.2 log)	98% (1.7 log)

In the cohort of **NUC-naïve**, **HBeAg-positive** patients, best peak HBsAg reduction has been 99% (1.9 log) and the mean maximum HBsAg reduction has been 1.05 log through 15 days post ARC-520 treatment. This open-label cohort is fully enrolled; data collection is ongoing and will be continued through Day 85 post ARC-520 treatment. These reductions are substantially higher than results from NUC treatment-experienced cohorts.

NUC-naïve HBeAg(+) patients after ARC-520 administration: Just through Day 15: still following patients		
Antigen	Mean max KD	max KD
HBsAg	1.05 log	99% (1.9 log)



Single dose of 4 mg/kg results in a mean HBsAg reduction of more than 1 log at Day 15

Peak KD likely not yet achieved

Data are still maturing

Maximum KD to date is 1.9 log (99%)

Similar mean maximal reductions were also demonstrated in HBV core-related antigen (HBcrAg) from both HBeAg-negative and -positive patients. ARC-520 is designed to silence all gene products expressed by HBV cccDNA, so this data suggests that it may be substantially disrupting additional viral functions.

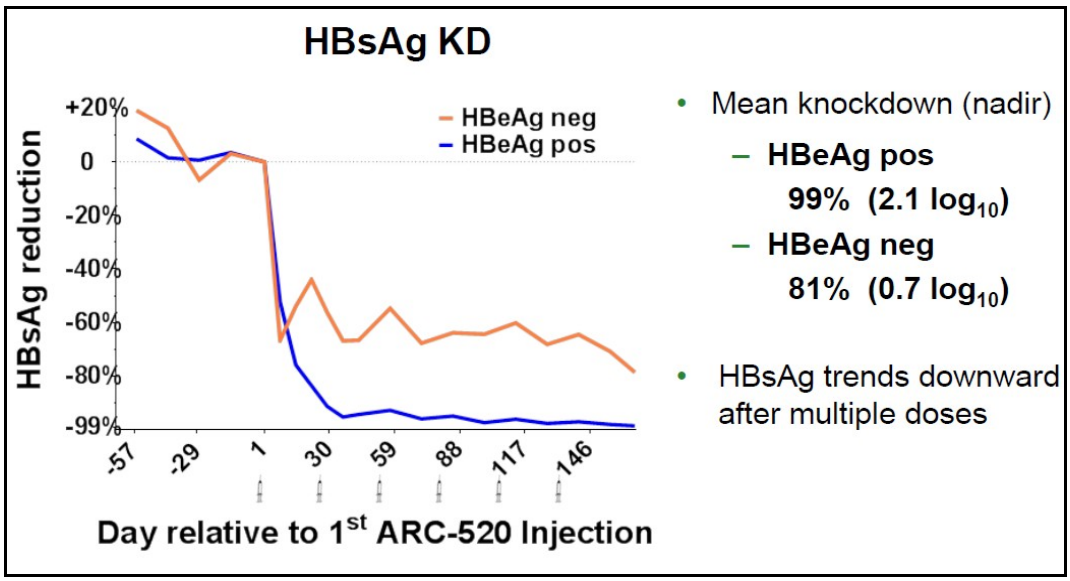
The Rationale for Testing ARC-520 in HBeAg Positive Patients

The rationale for testing ARC-520 in HBeAg positive patients is based on **Chimp study**. Almost at the same time the company was collecting data from the dose cohorts of 3 and 4 mg/kg in HBeAg negative patients, Arrowhead started to receive chimp data from multiple dose of ARC-520.

9 chimps, which are chronically infected with HBV for multiple years, were first suppressed with NUCs and then treated with 6 – 11 monthly doses of ARC-520 (2, 3 and 4 mg/kg).

- 4 HBeAg-positive chimps demonstrated 99% (2 log) mean peak reduction in HBsAg, and 1 of the 4 experienced signs of immune reactivation during therapy;
- 4 HBeAg-negative chimps demonstrated 81% (0.7 log) mean peak reduction in HBsAg; and
- 1 chimp transitioning from HBeAg-positive to HBeAg-negative demonstrated peak HBsAg reduction of 87% (0.9 log).

HBeAg status	HBsAg mean peak KD
HBeAg(+): 4 chimps	99% (2 log)
HBeAg(-): 4 chimps	81% (0.7 log)
HBeAg transitional: 1 chimp	87.4% (0.9 log)



ARC-520 was well tolerated in all 9 chimps.

Clearly, from these chimp data and the data from the last three cohorts of the ARC-520 Phase IIa trial, ARC-520 seems to work better in the HBeAg positive subjects.

ARC-520 has Been Well Tolerated

So far, total of 84 humans have received ARC-520 and to date no adverse events have been rated as serious or severe, no discontinuations have occurred due to an adverse event, and no laboratory results have indicated any end organ toxicity.

Additionally, 9 chimps received 6-11 monthly doses of ARC-520 and no safety signals were detected in any chimp.

New Development Plan for the HBV Program

Based on the chimp data and data from the Phase IIa trial, Arrowhead updated its new development plan for its HBV program.

ARC-520 will continue development including focus on the significant market of **e-antigen positive**, **treatment-naïve** chronic HBV patients.

The company plans to initiate trial Heparc-2008 (**Monarch cohorts**). This study is intended to be a study of various dosing regimens and combinations (multi-drug cocktail). It will have a flexible iterative design, which means that the company can ask specific questions about ARC-520 in small open-label cohorts and quickly initiate additional cohorts based on the answers that it gets or the availability of new agents to be tested in combination.

The company plans to begin **Monarc** as soon as possible. We expect it will be initiated in the fourth quarter. We expect to see deep knockdown of all gene products, especially in HBeAg positive patients.

It is estimated in the U.S. that 95% of people chronically infected with HBV are currently NUC-naïve and at least 50% of them are likely to be HBeAg-positive. In West Europe, 90% of estimated CHB patients are naïve, and about 33% of them are HBeAg positive. The effect on HBsAg in NUC-naïve HBeAg-positive patients makes this group especially attractive to study and a key focus for multi-dose studies going forward.

Arrowhead also has nominated a new candidate **ARC-521,** which is being developed to target both cccDNA and also integrated DNA, which appears to be a more significant producer of HBsAg in patients who have been treated with NUCs or who are **e-antigen negative**.

ARC-521 is also derived from the company's DPC platform; therefore its safety profile is expected to be similar to ARC-520. While ARC-520 is designed to target cccDNA, ARC-521 is designed to target both cccDNA and integrated DNA. Therefore, ARC-521 is a complement to ARC-520.

In HBeAg-negative chimps predicted to have higher levels of integrated DNA, administration of ARC-521 led to 99% (2 logs) of additional HBsAg reduction. ARC-521 is in GMP manufacturing now and is expected to enter GLP toxicity this fall. The Company expects to file an **IND** or equivalent for ARC-521 by **mid-2016.**

Update on Phase IIb of ARC-520 for HBV

The Heparc-2004 Study

In April, 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.

Originally, Arrowhead proposed a **parallel design** multiple-dose Phase IIb study testing doses of 2 mg/kg and 4 mg/kg simultaneously. However, in January 2015, the FDA placed a partial clinical hold on the program. In order to proceed with the proposed parallel design study, the FDA requested that the Company provide additional information including data from the single-dose Phase IIa study in patients who receive 1-4 mg/kg ARC-520, data from an ongoing multiple-dose non-clinical study, and data from Heparc-2004 which is now cleared to begin.

The Heparc-2002 and Heparc-2003 Study will Continue

During the summer, ARC-520 was approved in **Germany and Hong Kong** for two additional **Phase IIb** multiple-dose studies, which will be conducted **in parallel**.

The two studies (**Heparc-2002** and **Heparc-2003**) will enroll patients with chronic HBV infection that are e-antigen (HBeAg) negative and HBeAg positive, respectively. Each study is a multicenter, randomized, double-blind, placebo-controlled, multi-dose study intended to evaluate two dose levels in parallel of ARC-520 in combination with entecavir or tenofovir in patients with immune active chronic HBV infection. The 2002 trial will enroll up to 60 and the 2003 will enroll 90 patients. In each study, patients will be randomized to receive four doses, once every 4 weeks, of either 1 mg/kg ARC-520, 2 mg/kg ARC-520, or placebo at a ratio of 1:1:1.

Per protocol, for each patient, the duration of the study is approximately 33 weeks, from screening to the Day 169 follow-up visit. For each study, a planning interim analysis will be performed when 54 patients have completed their Day 71 visit. This analysis will be used to plan future studies only and will not impact the enrollment or conduct of Heparc-2002 and -2003. Based on the interim results, the company will decide whether higher multiple-doses would be likely to lead to increased activity, in which case higher doses may be evaluated in one or more additional studies.

The **primary objective** of the 2002 and 2003 studies is to evaluate the depth of hepatitis B surface antigen (HBsAg) decline in response to multiple doses of ARC-520 compared to placebo as a measure of drug activity. **Secondary objectives** include the assessment of safety and tolerability and multi-dose pharmacokinetics of ARC-520 when co-administered with entecavir or tenofovir, in addition to other exploratory objectives.

In addition, the company is engaged with regulatory authorities from South Korea to open additional sites for these studies.

Pipeline further Expanded by ARC-HIF2

On Sept 11, 2015, Arrowhead announced that it has 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 in a poster titled "HIF-2α targeting with a novel RNAi delivery platform as therapy for renal cell carcinoma," (abstract #353).

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.

Arrowhead Began Dosing Patients in Part B of ARC-AAT Phase I Trial

In late February, Arrowhead initiated dosing in a **Phase I** clinical trial of ARC-AAT for the treatment of liver disease associated with Alpha-1 Antitrypsin Deficiency (AATD) in **Australia**.

The Phase I trial is a multi-center, randomized, placebo-controlled, double-blind, single dose-escalation study to evaluate the safety, tolerability, pharmacokinetics of ARC-AAT and the effect on circulating alpha-1 antitrypsin (AAT) levels. The study plans to enroll in dose cohorts of six participants each, with participants randomized at a ratio of 2:1 (active:placebo) to receive a single intravenous injection of either ARC-AAT or placebo (normal saline). The study will consist of **two parts**, with **Part A** planned to be conducted in healthy volunteers and **Part B** planned to be conducted in patients with PiZZ genotype AATD. In Part A, dose escalation will proceed until the achievement of certain target knockdown parameters. That target is at least 30% reduction of serum AAT levels in 3 subjects or greater than 60% reduction in a single subject. When these AAT knockdown parameters are achieved, dose escalation in healthy volunteers (Part A) is planned to stop and dosing in patients with AATD (Part B) is planned to begin at the highest dose level used in Part A and then dose escalation will proceed. Participants will be evaluated for 28 days following dosing with additional follow-up every 2 weeks until AAT levels return to baseline.

In early May, the company completed dosing healthy volunteers and will begin dosing patients.

In early July, Arrowhead began dosing the first patient in Part B of the Phase I clinical trial of ARC-AAT in Australia. Arrowhead also received regulatory permission in the United Kingdom and New Zealand to proceed with Part B of the Phase I study of ARC-AAT and is currently awaiting regulatory approval in Germany and the Netherlands.

ARC-AAT is comprised of novel unlocked nucleobase analog containing RNAi trigger molecules (UNA) that are co-administered with Dynamic Polyconjugates (DPCs) to enable the escape of the UNA from endosomes. The ratio of UNA to DPC is 2:1 by weight. In Part A of the study, three cohorts of six participants each received ARC-AAT at doses of 0.38 mg/kg, 1.0 mg/kg, and 2.0 mg/kg of UNA, and 0.19 mg/kg, 0.5 mg/kg, and 1.0 mg/kg of DPC, respectively.

The knockdown target was met during the third cohort. All three dose levels tested appear to be generally well tolerated and the data safety committee has cleared the study to move into patients with AATD. Dosing in patients may now begin at the highest dose level used in Part A and then continued dose escalation may proceed under the protocol.

The company expects to complete enrollment of the Phase I study by **the end of 2015**. Initial data from this study is expected **in late 2016**.

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.

ARC-AAT is Arrowhead's second clinical candidate, which further de-risks 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, the recently acquired RNAi assets from Novartis, as well as a strong balance sheet, we believe Arrowhead is well positioned to further diversify its pipeline down the road.

We Remain Bullish on Arrowhead's Shares

We maintain our Buy rating on Arrowhead shares and reiterate our 12-month price target of $15.

Arrowhead has been busy in the first nine month of 2015 to move forward its clinical programs. We believe the company's lead HBV program ARC-520 is a viable drug for chronic HBV patients and the addition of ARC-521 further expands its HBV franchise.

The acquisition of Novartis' RNAi development portfolio significantly expands and complements the company's current RNAi assets and will provide the opportunity to rapidly expand its clinical pipeline in the coming years.

Arrowhead has a strong balance sheet. As of June 30, 2015, the company held $112 million in cash, which can fund its operations into the end of 2016 according to our financial model.

We think current market price of Arrowhead shares does not reflect the intrinsic value of the company. We believe there is still enough room for further price appreciation at current market price.

Based on the current development plan, we expect Arrowhead will be able to initiate **pivotal Phase III** trial of ARC-520 in late 2016, and data should be available in mid-2017. NDA could be filed in late 2017, and the FDA approval is in late 2018.

We estimate Arrowhead will become profitable in fiscal 2019 with an EPS of $1.09 based on revenue of $250 million. We think a P/E ratio of 34x is appropriate for Arrowhead considering its growth in the next few years. Based on this P/E multiple, we think Arrowhead should be valued at $15.00 per share using 25% discount for 4 years. Our price target values Arrowhead at $893 million in market cap, which we think is appropriate and fare compared to its peers.

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 ongoing 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.

PROJECTED INCOME STATEMENT

_	2014 (Sept)					2015 (Sept)					2016 (Sept)	2017 (Sept)	2018 (Sept)	2019 (Sept)
$ in millions except per share data	Q1	Q2	Q3	Q4	FY	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Revenue	$0.04	$0.04	$0.04	$0.04	$0.18	$0.17	$0.04	$0.12	$0.04	$0.38	$0.30	$0.50	$25.00	$250.00
YOY Growth											-	*66.7%*	*4900.0%*	*900.0%*
Total Revenues	**$0.04**	**$0.04**	**$0.04**	**$0.04**	**$0.18**	**$0.17**	**$0.04**	**$0.12**	**$0.04**	**$0.38**	**$0.30**	**$0.50**	**$25.00**	**$250.00**
YOY Growth	*-73.0%*	*0.0%*	*0.0%*	*1.7%*	*-39.7%*	*297.1%*	*0.0%*	*182.9%*	*-10.1%*	*116.1%*	*-20.7%*	*66.7%*	*4900.0%*	*900.0%*
Cost of Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$3.8	$35.0
Gross Income	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.2**	**$0.2**	**$0.0**	**$0.1**	**$0.0**	**$0.4**	**$0.3**	**$0.4**	**$21.3**	**$215.0**
Gross Margin	*100.0%*	*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	$3.1	$5.2	$6.4	$8.4	$23.1	$17.7	$21.8	$7.5	$10.0	$57.0	$65.0	$75.0	$55.0	$60.0
% R&D	*7286.1%*	*11923.3%*	*14610.7%*	*18868.3%*	*13221.7%*	*10392.0%*	*49791.0%*	*6052.8%*	*25000.0%*	*15074.2%*	*21666.7%*	*15000.0%*	*220.0%*	*24.0%*
Salary and G&A	$3.0	$4.4	$4.0	$7.2	$18.7	$5.2	$5.2	$5.4	$6.5	$22.4	$25.5	$30.0	$37.5	$50.0
% SG&A	*6966.5%*	*10161.3%*	*9227.2%*	*16281.6%*	*10699.1%*	*3067.0%*	*11973.2%*	*4363.6%*	*16250.0%*	*5915.4%*	*8500.0%*	*6000.0%*	*150.0%*	*20.0%*
Other expenses	$0.9	$1.6	$2.3	$2.2	$7.0	$2.3	$2.7	$3.2	$2.0	$10.2	$7.0	$8.5	$10.0	$12.0
% Other	*2150.1%*	*3643.9%*	*5290.8%*	*4962.5%*	*4023.9%*	*1349.9%*	*6067.7%*	*2607.8%*	*5000.0%*	*2693.1%*	*2333.3%*	*1700.0%*	*40.0%*	*4.8%*
Operating Income	**($7.0)**	**($11.2)**	**($12.7)**	**($17.8)**	**($48.7)**	**($25.1)**	**($29.6)**	**($16.0)**	**($18.5)**	**($89.2)**	**($97.2)**	**($113.1)**	**($81.3)**	**$93.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	*37.2%*
Other Income (Net)	($3.6)	($2.7)	$1.1	$0.7	($4.5)	$2.5	$0.9	$0.1	$0.0	$3.5	($0.5)	($0.5)	($0.5)	($0.5)
Pre-Tax Income	**($10.6)**	**($13.9)**	**($11.6)**	**($17.1)**	**($53.3)**	**($22.6)**	**($28.7)**	**($15.9)**	**($18.5)**	**($85.7)**	**($97.7)**	**($113.6)**	**($81.8)**	**$92.5**
Net Taxes (benefit)	$0.0	$0.0	$0.0	$5.4	$5.4	$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%*	*-10.2%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($10.6)**	**($13.9)**	**($11.6)**	**($22.5)**	**($58.7)**	**($22.6)**	**($28.7)**	**($15.9)**	**($18.5)**	**($85.7)**	**($97.7)**	**($113.6)**	**($81.8)**	**$92.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Weighted avg. Shares Out	*37.7*	*44.3*	*51.9*	*53.7*	*46.9*	*54.7*	*55.7*	*59.5*	*59.5*	*57.4*	*65.0*	*75.0*	*80.0*	*85.0*
Reported EPS	**($0.28)**	**($0.31)**	**($0.22)**	**($0.42)**	**($1.25)**	**($0.41)**	**($0.51)**	**($0.27)**	**($0.31)**	**($1.49)**	**($1.50)**	**($1.51)**	**($1.02)**	**$1.09**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
One time charge	$3.62	$2.73	($1.07)	($0.73)	$4.55	$2.54	$0.95	$0.06	$0.00	$3.55	$0.00	$0.00	$0.00	$0.00
Non GAAP Net Income	**($7.0)**	**($11.2)**	**($12.7)**	**($23.3)**	**($54.2)**	**($20.0)**	**($27.7)**	**($15.9)**	**($18.5)**	**($82.1)**	**($97.7)**	**($113.6)**	**($81.8)**	**$92.5**
Non GAAP EPS	**($0.19)**	**($0.25)**	**($0.24)**	**($0.43)**	**($1.15)**	**($0.37)**	**($0.50)**	**($0.27)**	**($0.31)**	**($1.43)**	**($1.50)**	**($1.51)**	**($1.02)**	**$1.09**

Source: Company filing and Zacks estimates

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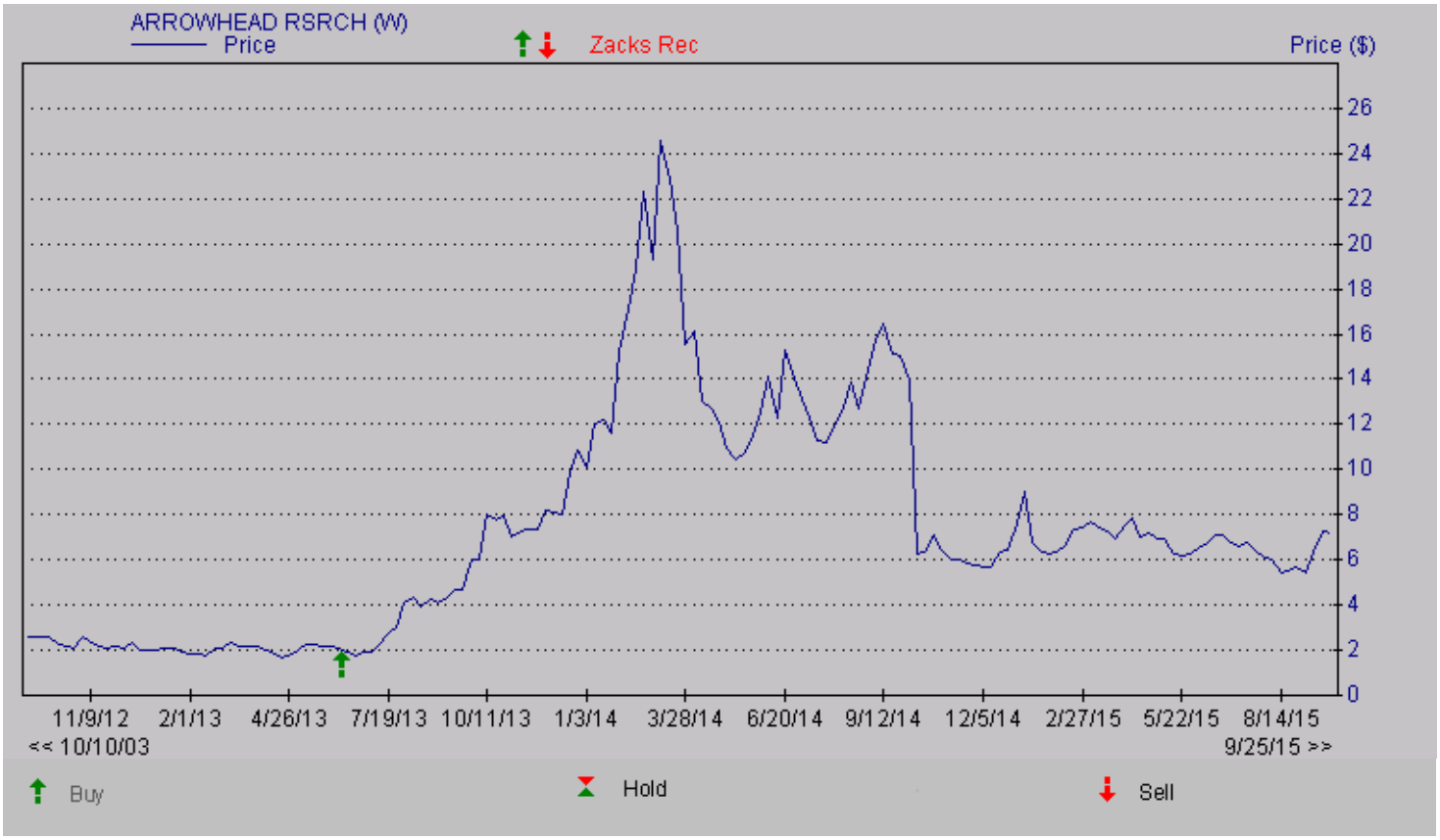

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