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Arrowhead Pharm (ARWR-NASDAQ)

ARWR: Broad-Based Pipeline Progress. Three Pivotal Studies, Value-Inflection Opportunities In View. Moving PT to $36/Share

Relative valuation metrics indicates fair value of $36/share.

Current Price (09/26/19)	$28.26
Valuation	**$36.00**

OUTLOOK

Arrowhead continues to make rapid progress across most of their pipeline. There has been no shortage of positive product development related events as of late – and, importantly, the progress continues to be broad based with successes being experienced by nearly all the company's programs. Additionally, ARWR remains committed to and is delivering on their prior guidance of expanding their TRiM clinical development pipeline. With another three clinical trial agreement (CTA) filings anticipated, the company could soon have eight TRiM clinical programs ongoing. ARO-HSD, targeting HSD17B13 for potential indications in alcohol and non-alcohol related liver diseases, is the most recent addition and which ARWR hopes to have in clinical studies next year.

With APOC3, ANG3 and AAT all possibly entering pivotal studies in the near-term and JNJ-3989 now in what could prove to be a curative study (for HBV, which could draw massive appeal), we could soon have a lot more information to gauge the potential commercializability (and value) of Arrowhead's development portfolio. This, by extension, also bolsters the potential likelihood of significant value-inflection events / announcements (over the same timeframes). Moving PT to $36/share.

SUMMARY DATA

52-Week High	**$36.80**
52-Week Low	**$10.41**
One-Year Return (%)	**46.94**
Beta	**1.53**
Average Daily Volume (sh)	**1,326,898**
Shares Outstanding (mil)	**95**
Market Capitalization ($mil)	**$2,693**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**64**
Insider Ownership (%)	**9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**354.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**38.7**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Mid-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2017	4.37 A	8.99 A	9.34 A	8.71 A	31.4 A
2018	3.50 A	0.65 A	0.73 A	11.26 A	16.14 A
2019	34.66 A	48.15 A	42.70 A	40.87 E	166.37E
2020					90.20 E

Price/Sales Ratio (Industry = 2.5x)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2017	-$0.21 A	-$0.08 A	-$0.08 A	-$0.14 A	-$0.50 A
2018	-$0.18 A	-$0.18 A	-$0.18 A	-$0.12 A	-$0.65 A
2019	$0.13 A	$0.24 A	$0.21 A	$0.15 E	$0.73 E
2020					-$0.26 E

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

WHAT'S NEW

Pipeline Highlights: ***APOC3/ANG3 Topline Data, Orphan Desig. JNJ-3989 in Ph2b, Cohort 12 Data Upcoming. And More…***

Arrowhead continues to make rapid progress across most of their pipeline. There has been no shortage of positive product development related events as of late – and, importantly, the progress continues to be broad-based with successes being experienced by nearly all the company's programs. Additionally, ARWR remains committed to and is delivering on their prior guidance of expanding their TRiM clinical development pipeline. With another three clinical trial agreement (CTA) filings anticipated, the company could soon have eight TRiM clinical programs ongoing. ARO-HSD, targeting HSD17B13 for potential indications in alcohol and non-alcohol related liver diseases, is the most recent addition and which ARWR hopes to have in clinical studies next year.

The last few months has also been highly productive from an FDA regulatory standpoint with two Ph1 clinical candidates (ARO-APOC3 and ARO-ANG3) receiving Orphan Drug designation and a third, ARO-AAT, which recently commenced testing in the Ph2/3 SEQUOIA study, granted Fast Track status (ARO-AAT also has Orphan Drug designation).

Meanwhile, JNJ-3989 (targeting chronic HBV and the initial program under the Janssen collaboration) not only continues to progress through an ongoing Ph1/2 clinical study – which includes completion of enrollment of the (recently added) triple combination cohort ('cohort 12', 12 patients over 12 weeks) – but is also now being used in a large (n=450) Ph2b triple combination study which is evaluating different combination drug regimens in the treatment of chronic HBV for up to 48 weeks. ARWR received a $25M milestone payment upon initiation of this study. The development success to-date of JNJ-3989 may have other positive implications for the company, including bolstering the relationship with Janssen. Perhaps to that point, work just recently began on 'JNJ1' (discussed below) – which represents the first (of up to three) program that Janssen optioned to pursue under the duos' October 2018 development collaboration agreement.

With APOC3, ANG3 and AAT all possibly entering pivotal studies in the near-term and JNJ-3989 now in what could prove to be a curative study (for HBV, which could draw massive appeal), we could soon have a lot more information to gauge the potential commercializability (and value) of Arrowhead's development portfolio. This, by extension, also bolsters the potential likelihood of significant value-inflection events/announcements (over the same timeframes).

ARO-APOC3 / ARO-ANG3 Orphan Designation, Positive Ph1 Data: Pivotal Studies in 2020?
Arrowhead received orphan drug designation for ARO-APOC3 for the treatment of familial chylomicronemia syndrome (FCS) and for ARO-ANG3 for the treatment of homozygous familial hypercholesterolemia (HoFH) in June and July, respectively. FCS and HoFH are both rare metabolic disorders with high unmet needs and are associated with impaired quality of life and certain potentially serious health complications that, if left untreated, can result in death.

FCS is a genetic disorder characterized by inability to properly break down fats (as a result of dysfunctional lipoprotein lipase), which can result in severe hypertriglyceridemia (dangerously high levels of triglycerides), pancreatitis and even death. Worldwide prevalence of FCS is estimated at between 1 in 1M and 1 in 2M people.

HoFH is an inherited disorder which impairs the body's ability to remove low-density lipoprotein. This can lead to severely elevated LDL, early and rapid narrowing / blockage of the arteries and eventually, death. It is estimated that HoFH affects between 1 in 160k to 1 in 1 million people around the world.

Orphan status, combined with the recently announced positive topline Ph1 data, sets the stage for what could be further acceleration of these programs through mid/late-stage development. In fact, ARWR

expects to pursue respective orphan designated clinical programs immediately which, if all goes well, could potentially include pivotal trials for both APOC3 and ANG3 as soon as next year.

The most recent significant pipeline news came last week when ARWR announced positive topline data from Phase I studies of ARO-APOC3 and ARO-ANG3, the company's two newest clinical RNAi TRiM candidates which target cardio metabolic diseases.

Presented at The Global Summit on Cardiology and Heart Diseases in Dubai, the data provided the first substantive look at safety and target activity in the clinical setting and results appear to have been exactly what had been hoped for – more specifically, that each candidate effectively reduced their respective targets and triglyceride levels and did so without any serious side effects. Perhaps just as encouraging, this initial topline data – which is from just a single dose (in healthy volunteers) - also suggests long duration of activity.

AROAPOC31001 is a Ph1 (n= ~80) single and multiple dose-escalating study evaluating the safety, tolerability, pharmacokinetics and pharmacodynamic effects of ARO-APOC3 in adult healthy volunteers, patients with hypertriglyceridemia and patients with FCS. AROANG1001 is a Ph1 (n= ~94) single and multiple dose study evaluating the safety, tolerability, pharmacokinetics and pharmacodynamic effects of ARO-ANG3 in adult healthy volunteers and patients with dyslipidemia.

As a reminder of the background of these programs and hypothesis behind their respective targets - large genetic studies discovered that certain rare mutations that disrupt the functioning of apolipoprotein C3 (i.e. APOC3) and angiopoietin-like 3 gene (i.e. ANGPTL3) are associated with lower levels of plasma triglycerides and, in the case of ANGPTL3, also decreased plasma levels of low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. As these lipid fractions have been shown to be predictors of cardiovascular disease (CVD), targeted therapeutic antagonism of APOC3 and ANGPTL3 is hypothesized to reduce risk of CVD. This theory, already supported by laboratory and rodent models, just became much more compelling as a result of this positive initial human clinical trial data.

While we will wait for results of the larger data set to offer a more determined opinion, **we would characterize these results** – clean safety and initial signs of durability of effect - **as about the best as could have been expected.** Management anticipates additional data from both studies, including the complete treatment course of the single ascending dose (SAD) portions to be announced later this year and, subsequently, from the multiple ascending dose (MAD) portion (in various patient populations). And, as we also anticipate additional activity specific to each candidates' respective orphan drug indications, there could be a regular amount of clinical news flow for APOC3 and ANG3 over the coming quarters - which **we think further benefits the likelihood of potential value-inflection announcements.**

The topline Ph1 data announced last week comes from the SAD portion which, for both studies (i.e. AROAPOC3001 and AROANG1001), included 4 cohorts of 10 adult healthy volunteers with (6 active / 4 placebo). AROAPOC3001 participants received a single dose of either placebo or ARO-APOC3 at dose levels of 10, 25, 50, or 100mg while AROANG1001 participants received a single dose of either placebo or ARO-ANG3 at dose levels of 35, 100, 200, or 300mg.

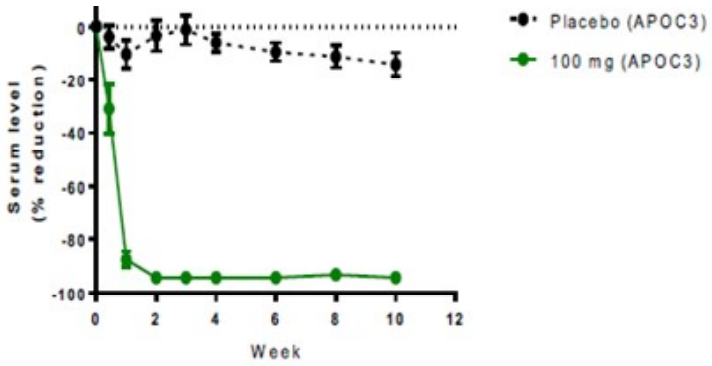
Of note, **AROAPOC3001 was recently amended**, eliminating what had originally included a 200mg as the highest dose. The amendment, which management stressed was based "solely on positive pharmacodynamic activity and not due to any concern or finding with respect to safety or tolerability", also added a 10mg dose (25mg had initially been the lowest dose). Including this lower dose, management noted, should provide additional insight into dose response of APOC3.

Ph1 Topline Results showed:

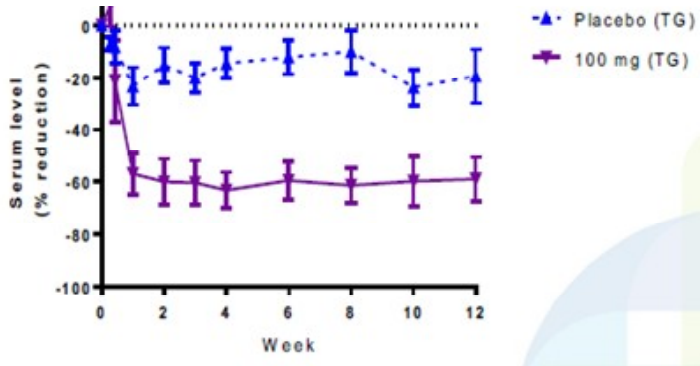
- 100mg of ARO-APOC3 was associated with 63% reduction in plasma triglycerides and 94% reduction in APOC3. Particularly noteworthy is the durability of this robust effect, which appears (see graphs below) to have remained at or near trough level through week 12.

  These results also compare favorably to those of studies of other (non-ARWR associated) clinical stage apolipoprotein C-III-targeting candidates including AKCEA-APOCIII-L_{Rx} (Akcea Ther / Ionis Pharma), in Ph2 testing for the treatment of serious cardiometabolic diseases caused by lipid disorders (see table, below, from ARWR's Ph1 topline results presentation)

APOC3



Triglycerides

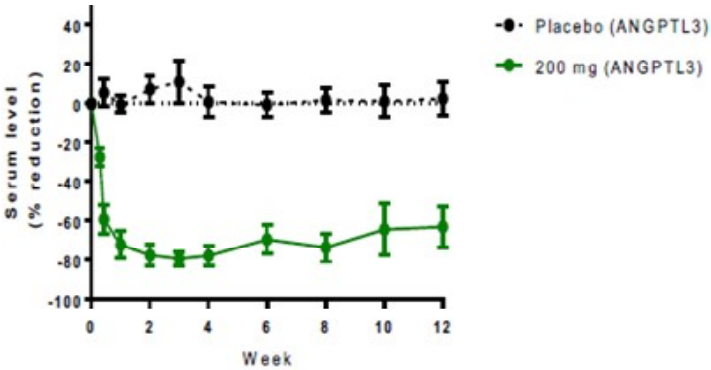


Source: ARWR GSCHD Presentation Sept 2019

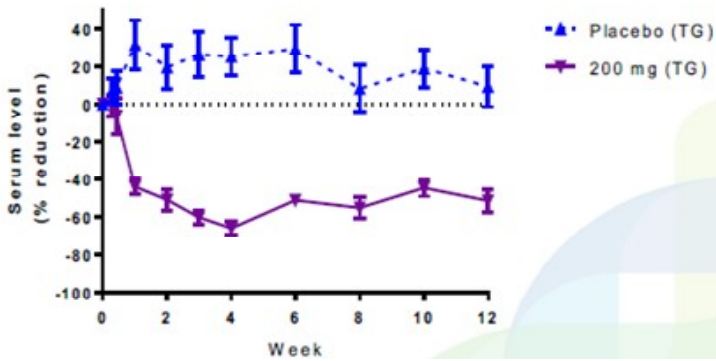
- 200mg of ARO-ANG3 was associated with 66% reduction in plasma triglycerides and 79% reduction in ANGPTL3. Similar to the APOC3 data, ANG3 showed potent durability of effect with maximum reduction largely maintained through 12 weeks.

  These results also compare favorably to those of studies of other (non-ARWR associated) clinical stage angiopoietin like protein 3-targeting candidates including AKCEA-ANGPTL3-L_{Rx} (Akcea Ther / Ionis Pharma) and Evinacumab (Regeneron) - see table, below. AKCEA-ANGPTL3-L_{Rx} is in Ph2 testing for patients with hypertriglyceridemia, type 2 diabetes and nonalcoholic fatty liver disease. Evinacumab is a monoclonal antibody in separate Ph2 trials for patients with severe hypertriglyceridemia as well as those with refractory hypercholesterolemia (also in Ph3 for patients with homozygous familial hypercholesterolemia).

ANGPTL3



Triglycerides



Source: ARWR GSCHD Presentation Sept 2019

- Clean safety profile: In both studies no drug-related serious or severe adverse events were observed

APOC3 Topline Ph1 Data Stacks Up Favorably to Other Clinical Candidates

Mean Maximal % reduction from baseline (SD)	Serum ApoC3	Triglycerides
ARO-APOC3 (100 mg)	94.2% (1.3)	63.2% (16.9)
AKCEA-APOCIII-L_{Rx} (60 mg)*[1]	64.7% (21.7)	43% (19.7)
AKCEA-APOCIII-L_{Rx} (120 mg)**[1]	91.2% (2.5)	79.6% (3.7)

ARO-APOC3 inclusion criteria of TG > 80 mg/dL
*60 mg dose was the highest dose given to subjects with fasting TG ≥ 90 mg/dL
** 120 mg dose was the highest dose given to subjects with inclusion criteria of TG >200 mg/dL
[1]Alexander et al, Eur Heart J, 2019 40:2785-2796.

Source: ARWR GSCHD Presentation Sept 2019

ARO-ANG3 Topline Ph1 Data Stacks Up Favorably to Other Clinical Candidates

Mean Maximal % reduction from baseline (SD) [unless noted]	Serum ANGPTL3	Triglycerides
ARO-ANG3 (200 mg)	79.4% (8.4)	66.2% (7.6)
AKCEA-ANGPTL3-L_{Rx} (80 mg)*[1]	61.7% (1.1)	56.1% (1.1)
Evinacumab (250 mg, SC)[2]	NR**	51.1%[&]
Evinacumab (250 mg, SC)[3]	NR**	55.5%[&]

* Inclusion criteria of TG = 90-150 mg/dL
** Dose-depended increases in ANGPTL3 indicating target binding of evinacumab were observed
[&] Median % change
[1] Graham et al, NEJM 2017 377:222-232
[2] Dewey et al, NEJM 2017 377:211-221
[3] Ahmad et al, Circulation 2019 140: 470-486

Source: ARWR GSCHD Presentation Sept 2019

AROANG1001 and AROAPOC31001 current status and upcoming milestones…

As it relates to AROANG1001, the 200mg dose was chosen to use in the MAD portion, which commenced following recent receipt of requisite IRB and Drug Safety Committee approvals. Management noted on the Q3 earnings call (Aug 5th) that three of the MAD cohorts had been fully recruited and dosing started while recruiting of the fourth cohort was underway.

Of note, the MAD portion was initially designed to enroll up to 4 patient cohorts including those with non-alcoholic fatty liver disease (NAFLD), those on statin treatment with high LDL cholesterol and

triglycerides, those with familial hypercholesterolemia and patients with severe hypertriglyceridemia. ARWR noted on the call that an amendment was in-process to add healthy subjects as well as patients with heterozygous or homozygous familial hypercholesterolemia.

As it relates to AROAPOC31001, management noted on the Q3 call that dosing had completed in all SAD cohorts, including the newly added 10mg. Screening for MAD cohorts had begun with dosing (as of the Q3 call in early August) expected to begin shortly.

ARWR anticipates the complete treatment course of the SAD portion of ANG3 (and APOC3) to be announced later this year – potentially including an abstract at the American Heart Association conference (November 16 – 18th). We could see initial MAD data sometime in 1H 2020. And, as we also anticipate additional activity specific to each candidates' respective orphan drug indications, there could be a regular amount of clinical news flow for APOC3 and ANG3 over the coming quarters. As noted, we think this adds to the chances of potential value-inflection.

ARO-AAT: Fast Track Status Speeds Timeline of Ph2/3 SEQUOIA, Open Label On-Deck
Development of ARO-AAT, the company's second generation subcutaneously administered RNAi therapeutic being developed as a treatment for a rare genetic liver disease associated with alpha-1 antitrypsin deficiency, also continues to rapidly progress. And with Fast Track status granted by FDA in mid-June (complementing Orphan Drug designation in the U.S. and E.U. which was granted in early 2018), we could see the development timeline further accelerate.

Encouragingly, **SEQUOIA**, a Ph2/3 trial which was just announced earlier this year and could serve as a pivotal U.S. registrational study (which would make it the first U.S. pivotal study of ARWR's TRiM platform), appears to be moving quickly. IDE approval came in April and, as of the Q3 call in early August, multiple sites were enrolling and dosing had commenced. ARWR appears intent on leveraging the Fast Track status, noting that they have sped up clinical site activity including getting additional locations operational and enrolling. With U.S. sites now operational, management indicated that they will look to initiate locations in Europe and Canada. With some IRB approvals in-hand and others anticipated shortly, ARWR expects a number of additional OUS trial sites to come online and hopes to have a total of 40 locations (U.S. and OUS) operational in the months ahead.

Meanwhile, the timeline for **ARO-AAT 2002**, the parallel open label study, appears to be tracking prior expectations. The study will be conducted in Europe and per the Q3 call, was nearing commencement with trial sites opening and readying to begin enrolling patients.

JNJ-3989 (fka ARO-HBV): Ph1/2 Cohort 12 Completes Enrollment, New Ph2 Janssen Study
JNJ-3989 (targeting chronic HBV and the initial program under the Janssen collaboration) not only continues to progress through an ongoing Ph1/2 clinical study – which includes completion of enrollment of the (recently added) triple combination cohort ('cohort 12', 12 patients with chronic HBV over 12 weeks) – but is also now being used in REEF-1, Janssen's Ph2b triple combination study (with targeted enrollment of 450) evaluating different combination drug regimens in the treatment of chronic HBV for up to 48 weeks.

All cohort 12 patients had completed dosing as of the Q3 call in early August. While possible that we could see initial data from these patients later this year, we think it is more likely to be a 2020 event. Safety has not been an issue with JNJ-3989 and Janssen's use of it in REEF-1 implies additional confidence in that regard (in our opinion). So, while safety/tolerability may be the formal outcome of interest, we think that any indications of effectiveness and activity-oriented results will be the main attraction from this 12-week/12-patient triple combination cohort. The positive clinical data to-date coupled with the fact that this will be the first glimpse of JNJ-3989 as a triple combo therapy for chronic HBV (which has a great unmet need for finite curative therapies) means that AROHBV1001 cohort 12, while not designed to necessarily tell us anything definitive, could nonetheless be highly informative and value-additive.

Meanwhile, REEF-1, which will treat for up to 48 weeks, could inform on the curative potential of JNJ-3989 as part of a triple combination therapy. REEF-1 (NCT03982186) is a Phase 2b, multicenter, double-blind, active-controlled, randomized study to investigate the efficacy and safety of different combination regimens for the treatment of chronic hepatitis B virus infection. Regimens include JNJ-3989, and/or JNJ-6379, and a nucleos(t)ide analog (NA). REEF-1 is planned to include up to 450 patients who will be randomized to receive up to 48 weeks of treatment. (JNJ-6379 is Janssen's investigational orally administered capsid assembly modulator of the class that forms normal capsid structures).

ARWR received $25M (in August) from Janssen, tied to their collaboration agreement, upon dosing of the fifth patient in REEF-1. This is the second (of two) development-related payments from Janssen (the first of which, also $25M, was received in April and associated with initiation of dosing of Ph1 cohort 12).

And, beyond the milestone payments (which, along with ~$250M upfront, including $175M in cash, have provided ARWR with a rich source of non-dilutive funding since the deal was penned in October 2018), we think inclusion of JNJ-3989 in REEF-1 represents a win in and of itself for ARWR given the potentiality implications (in regards to safety and utility in chronic HBV treatment) as well as it representing another shot on goal towards possible eventual commercialization of the compound (ARWR is eligible for royalties on any eventual sales of JNJ-3989).

In addition, any and all development successes of JNJ-3989 presumably bodes well for ARWR's working relationship with Janssen and furthers the likelihood that they collaborate on additional TRIM-based RNAi targets (and, potentially, expanding their relationship outside of their current agreement). Their October 2018 agreement provides Janssen with the option to collaborate with ARWR on up to three additional RNAi therapeutics (for new targets to be selected by Janssen) – the first of which, 'JNJ1', was just recently announced. JNJ1, per ARWR, is being developed against an undisclosed liver-expressed target. As a reminder, ARWR is responsible for preclinical development (fully funded by Janssen) up to filing of an IND, at which point Jansen has the option to take an exclusivity license and continue development. Additional success of JNJ-3989 and initial progress with JNJ1 (which management indicated has moved swiftly) should further bolster the chances of a long-lasting relationship between ARWR and Janssen in our opinion.

ARO-HSD: latest pipeline addition, CTA filing anticipated this year…

ARO-HSD, targeting HSD17B13 for potential indications in alcohol and non-alcohol related liver diseases, is the most recent addition to ARWR's pipeline. A CTA filing for ARO-HSD, which is currently in IND-enabling GLP-tox studies, is anticipated later this year. With human studies potentially kicking off early next year, ARO-HSD could soon represent ARWR's sixth clinical TRiM program. Additional details about this program (likely including anticipated timelines) are expected to be discussed during Arrowhead's 'Analyst Day' on October 18th.

17β-Hydroxysteroid dehydrogenase type 13 (17β-HSD type 13), an enzyme encoded by the HSD17B13 gene, is involved in lipid metabolism in the liver. Genetic studies have shown that loss-of-function mutations to HSD17B13 are associated with decreased risk of development of alcohol and non-alcohol related liver diseases. Specifically, a study conducted by Regeneron and published in March 2018 in the NEJM found that individuals with two copies of this loss-of-function variant of HSD17B13 had a 53% and 30% lower risk of alcoholic liver disease and nonalcoholic liver disease, respectively, as compared to individuals with two functioning copies of the gene. Non-functioning carriers were also found to have a 73% lower risk of alcoholic cirrhosis and 49% lower risk of nonalcoholic cirrhosis as compared to those with two working copies of the gene.[1]

Clinical Pipeline Could Soon Grow to 8 TriM Programs, Up From 5 Today…

[1] Noura S. Abul-Husn, M.D., Ph.D, et al. A Protein-Truncating HSD17B13 Variant and Protection from Chronic Liver Disease. N Engl J Med 2018; 378:1096-1106

In addition to ARO-HSD, ARWR is aiming for near-term CTA filings for ARO-HIF2 and ARO-ENaC as well. A CTA for ARO-HIF2, the company's candidate targeting renal cell carcinoma which achieved 85% target gene knockdown in a rodent tumor model, is still expected later this year. ARO-HIF2 would represent their seventh TRiM program.

Meanwhile IND-enabling studies of ARO-ENaC, Arrowhead's candidate targeting the epithelial sodium channel (ENaC) alpha subunit for treatment of cystic fibrosis, have experienced delays which has pushed back the CTA filing timeline. Management's most recent guidance is for GLP toxicology studies to commence later this year and, if all goes well, to file a CTA in 1H'20. ARO-ENaC could represent their eighth clinical program.

Amgen Collab: AMG 890 Ph1 Ongoing. Anticipate Initial Data, Development Milestone Pymt…
As a reminder, in August of last year Arrowhead announced that it earned a $10 million milestone payment from Amgen following the administration of the first dose of AMG 890 (fka ARO-LPA) in a Ph1 clinical study designed to assess safety in subjects with elevated levels of lipoprotein (a) [Lp(a)]. AMG 890 is an RNAi therapeutic designed to lower Lp(a) for the treatment of cardiovascular disease. Initial data from the study could be available later this year or early next. Management also noted that Amgen anticipates starting the next phase of development of AMG 890, which would trigger a development milestone payment to ARWR.

Meanwhile, in July 2019 Amgen notified ARWR that they would not be exercising their option to exclusively license ARO-AMG1. As a refresher, Arrowhead received $35M million in upfront payments and $21.5M in equity investments from Amgen related to the ARO-LPA and ARO-AMG1 agreements. ARWR was also eligible to receive up to $617 million in option payments, and development, regulatory and sales milestone payments related to these programs. The company is also eligible for up to low double-digit royalties for sales of products under the ARC-LPA agreement.

FINANCIALS UPDATE

Q3 2019 Financial Results
Total revenue for the period ending June 30, 2019 was $42.7M (versus our $60.2M estimate), representing recognition of another portion of the $222.8M ($197.8M transaction price plus initial $25M milestone) related to the Janssen / JJDC collaboration agreement, which closed in late October 2018. To-date, approximately $125.2M of this total has been recognized as revenue. ARWR received an initial $25M milestone from Janssen in April related to the initiation of dosing of cohort 12 (i.e. triple combination cohort) of the JNJ-3989 Phase 1/2 study and received a second $25M milestone payment in August 2019 (i.e. subsequent to fiscal Q3) following dosing of the fifth patient in (Janssen's Ph2 triple combo chronic HBV) REEF-1 study.

As a reminder, in addition to $250M in upfront payments ($175M cash from Janssen plus $75M equity investment (@ $23.00/share) from Johnson & Johnson Innovation – JJDC, Inc), ARWR is eligible for another $3.5B in potential additional milestones and for royalties on eventual commercial sales. The collaboration has sped the development of ARWR's hepatitis B therapeutic candidate, ARO-HBV (which subsequently changed names to JNJ 3989).

In return, Janssen receives worldwide exclusive license to ARO-HBV and an option to collaborate with ARWR on up to three additional RNAi therapeutics for new targets (to be selected by Janssen) – the first of which, 'JNJ1' was just recently announced. Janssen is solely responsible for development and commercialization beyond ARWR's ongoing Phase 1/2 study. The other optional targets will leverage ARWR's TRIM platform technology but will not include any of the company's current pipeline. For these optioned targets, Janssen will fund initial discovery and preclinical work by ARWR and will take over each program following an IND filing by ARWR.

Specifically, as it relates to potential milestone payments, ARWR is eligible to receive $1.6B for the HBV license, which is inclusive of $50M worth of milestones for a Phase 2 study. Up to another $1.9B could be received for the agreement related to other three targets. Commercial sales royalties would be tiered and at a rate of up to the mid-teens percentage.

Q3 operating expenses were $24.1M (versus our $28.3M estimate), which includes $19.3M ($22.1M E) of R&D expense and $4.8M ($6.2M E) in salary/G&A expense. We continue to expect OpEx, and in particular R&D expense, to increase as ARWR's various studies progress to later stages and as new clinical candidates enter the pipeline.

EPS was $0.21, compared to our $0.34 estimate.

Cash
ARWR exited fiscal Q3 with $237M in cash and investments (which does not account for the August $25M milestone). The company generated $10.5M (or $23.7M excluding changes in working capital) of cash from operations in Q3. Through the first nine months of fiscal 2019 ARWR generated $159.2M (or $67.6M ex-changes in working capital) of cash from operations.

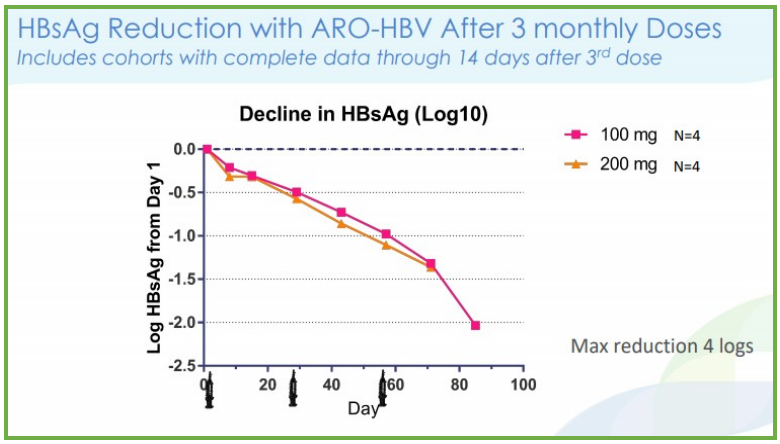
Clinical Programs Refresher

Background of JNJ-3989 (fka ARO-HBV)...
In March 2018, Arrowhead initiated a **Phase 1/2** first-in-human study of **ARO-HBV** for the treatment of chronic hepatitis B virus **(HBV)** infection in New Zealand. Dosing began in May 2018.

The study, **AROHBV1001** (NCT03365947), is a Phase 1/2 study to evaluate the safety, tolerability, and pharmacokinetic effects of single-ascending doses (**SAD**) of ARO-HBV in healthy adult volunteers, and to evaluate the safety, tolerability, and pharmacodynamic effects of multiple-ascending doses (**MAD**) of ARO-HBV in patients with chronic HBV.

The SAD portion is designed to include up to 5 cohorts of 6 subjects per cohort. Each SAD subject will receive a single-dose administration of either placebo or ARO-HBV at up to 5 dose levels (35, 100, 200, 300, 400 mg). The MAD portion is designed to include up to 8 cohorts of 4 HBV patients per cohort. Each MAD patient will receive 3 doses of ARO-HBV at up to 4 dose levels (100, 200, 300, 400 mg).

The Clinical Data Presented at the Summit
On Sep. 6, 2018, Arrowhead presented initial clinical data for **ARO-HBV** at the 18th World Gastroenterologists Summit in Auckland, New Zealand, which included initial data of **eight patients** from the first two MAD dose cohorts of the AROHBV1001 clinical study: 100mg and 200mg.



Source: ARWR Presentation

Following is the summary of the key clinical data presented at the Summit:

- Maximum reduction of HBsAg was 4.0 log10 (99.99%) after three monthly doses of ARO-HBV
- Mean reduction of HBsAg was 2.0 log10 (99%) on day 85 in cohort 2b (100 mg) and 1.4 log10 (96%) on day 71 in cohort 3b (200 mg)
- Minimum HBsAg reduction in all patients from cohorts 2b and 3b was 1.2 log10 (93%)
- Activity was demonstrated in all patient types (HBeAg pos/neg, NUC naïve/treated)

ARO-HBV was generally well-tolerated with generally mild and self-limiting injection site adverse events being the most common reported event in chronic HBV patients, occurring in around 10% of injections. The other most commonly reported events included symptoms consistent with upper respiratory tract infection and headache.

These results represented the first clinical data presented on ARO-HBV, which was very encouraging in our view. The data indicated that ARO-HBV is highly active in the treatment of HBV with good safety profile.

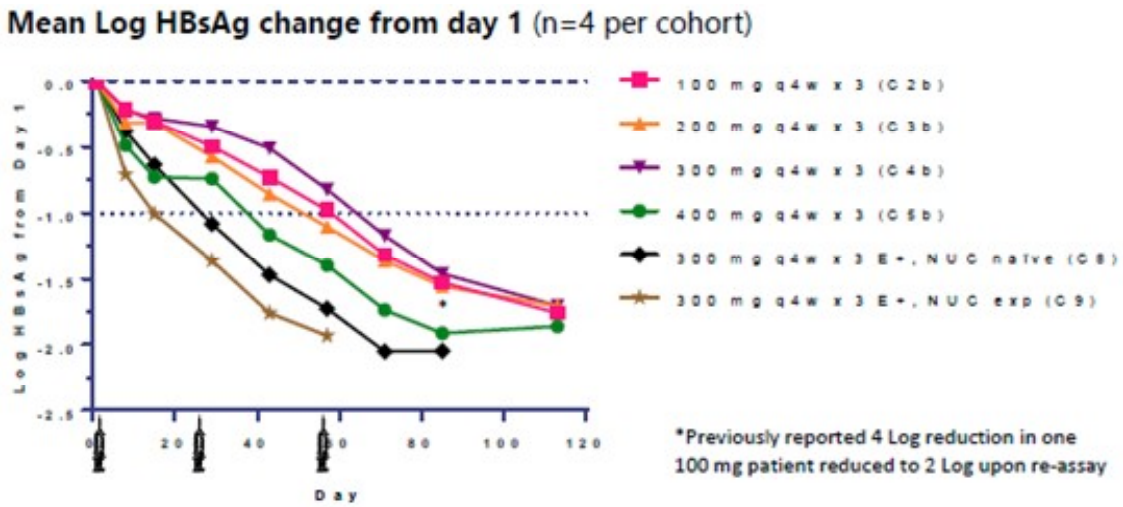
Clinical Data Presented at the AASLD in November 2018

In November 2018 preliminary data from ARWR's Phase 1/2 study of ARO-HBV for the treatment of HBV was presented as a late-breaking poster at the Liver Meeting of AASLD. This is the first data presentation of ARO-HBV since consummating the collaboration with Janssen

Following is the summary of the key clinical data presented at AASLD:

- Well-tolerated: while mild injection-site reactions were reported in ~12% of injections, ARO-HBV appears to be well-tolerated at single and multiple doses up to 400mg
- Strong HBsAg responses in both HBeAg positive and HBeAg negative patients:
    - all patients showed strong response with mean NADIR of -1.9 Log10 (-98.7%) and ranging from -1.3 (-95.0%) to -3.8 Log10 (-99.98%)
    - HBeAg-positive: Mean HBsAg NADIR in HBeAg positive (n=11) -2.1 Log10
    - HBeAg-negative: Mean HBsAg NADIR in HBeAg negative (n=13) -1.8 Log10
- Reductions similar for NUC naïve and NUC experienced patients
    - Mean HBsAg reduction on day 57 for cohort 8 (n=4) -1.7 Log10
    - Mean HBsAg reduction on day 57 for cohort 9 (n=4) -1.9 Log10
- Improved response from 1st-gen: responses observed were superior to those of the first-generation (ARC-520), which targeted only HBV transcripts
- Response silences HBV: investigators believe that the observed responses are consistent with the ability of ARO-HBV to silence HBV mRNA from cccDNA and host integrated viral DNA
- Other viral parameters showed response: including HBV DNA, HBV RNA, HBeAg and HBcrAg
- While no strong dose response…was observed between 100mg and 400mg, additional patients are enrolling to hopefully better understand possible dose response

AASLD Poster: Strong Response Observed in All Patients



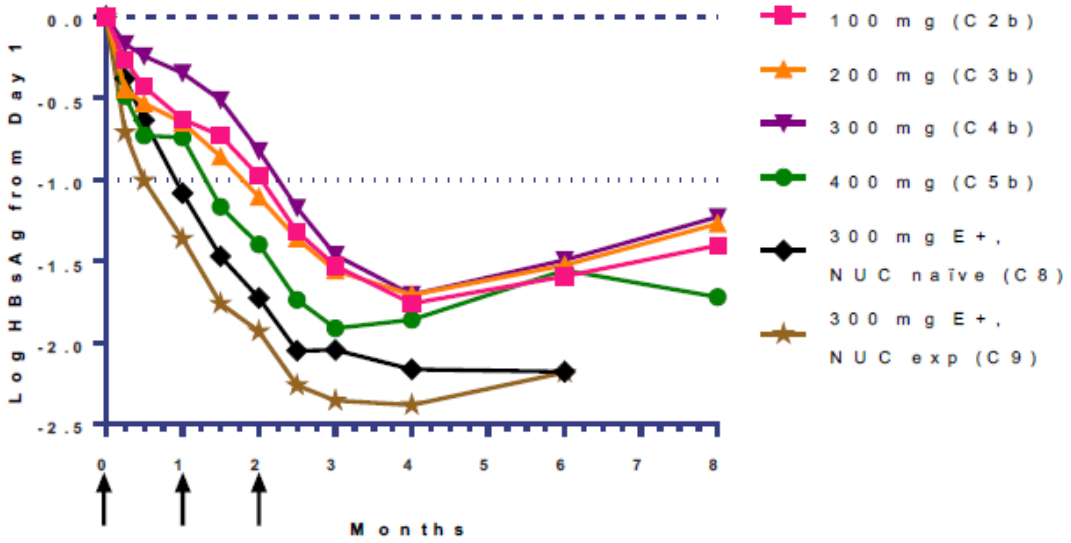
SOURCE: Gane, E. et al. ARWR. AASLD Poster Presentation. Nov 2018

40-Patients at 24+ Weeks Follow-Up Presented at EASL in April 2019

In April 2019 ARWR presented additional data from its ongoing JNJ-3989 Phase 1/2 study at EASL International Liver Congress. The data is from 40 patients through 24+ weeks follow-up. Results showed that JNJ-3989 rapidly reduced hepatitis B surface antigen (HBsAg) in patients that had 24 weeks or more HBsAg assay results. The reductions were to thresholds potentially associated with improved chance of HBsAg clearance after just three doses.

Specifically, all 40 patients achieved ≥ 1.0 log10 IU/mL HBsAg reduction, while 88% (35/40) achieved HBsAg < 100 IU/mL. In terms of safety, there were no drug-related serious adverse events reported while there were 17 mild adverse events at the injection site (such as tenderness and bruising).

Mean HbsAg reductions from baseline[2]



[2] Locarnini S. et al Short term RNA interference (RNAi) therapy in chronic hepatitis B (CHB) using JNJ-3989 brings majority of patients to HBsAg <100 IU/ml threshold. April 2019

With Janssen onboard as a collaboration partner, there is no concern about funding the ARO-HBV development program. And, ARWR expects to recognize revenue in the amount of $223M (~$125M of which has been recognized to-date) as they complete the oversight of the Phase 1/2 study of ARO-HBV. As of August, ARWR received the second of two $25M milestone payments related to the new triple combination cohort and initiation of the Phase 2 portion.

JNJ-3989 Status Update…

JNJ-3989 not only continues to progress through an ongoing Ph1/2 clinical study – which includes completion of enrollment of the (recently added) triple combination cohort ('cohort 12', 12 patients with chronic HBV over 12 weeks) – but is also now being used in REEF-1, a Ph2b triple combination study (with targeted enrollment of 450) evaluating different combination drug regimens in the treatment of chronic HBV for up to 48 weeks.

All cohort 12 patients had completed dosing as of the Q3 call in early August. While possible that we could see initial data from these patients later this year, we think it is more likely to be a 2020 event. Safety has not been an issue with JNJ-3989 and Janssen's use of it in REEF-1 implies additional confidence in that regard (in our opinion). So, while safety/tolerability may be the formal outcome of interest, we think that any indications of effectiveness and activity-oriented results will be the main attraction from this 12-week/12-patient triple combination cohort. The positive clinical data to-date coupled with the fact that this will be the first glimpse of JNJ-3989 as a triple combo therapy for chronic HBV (which has a great unmet need for finite curative therapies) means that AROHBV1001 cohort 12, while not designed to tell us anything definitive, could nonetheless be highly informative and value-additive.

Meanwhile, REEF-1, which will treat for up to 48 weeks, could inform on the curative potential of JNJ-3989 as part of a triple combination therapy. REEF-1 (NCT03982186) is a Phase 2b, multicenter, double-blind, active-controlled, randomized study to investigate the efficacy and safety of different combination regimens for the treatment of chronic hepatitis B virus infection. Regimens include JNJ-3989, and/or JNJ-6379, and a nucleos(t)ide analog (NA). REEF-1 is planned to include up to 450 patients who will be randomized to receive up to 48 weeks of treatment. (JNJ-6379 is Janssen's investigational orally administered capsid assembly modulator of the class that forms normal capsid structures).

Beyond the upfront and milestone payments from Janssen (which have provided ARWR with a rich source of non-dilutive funding), we think inclusion of JNJ-3989 in REEF-1 represents a win in and of itself for ARWR given the potentiality implications (in regards to safety and utility in chronic HBV treatment) as well as it representing another shot on goal towards possible eventual commercialization of the compound (ARWR is eligible for royalties on any eventual sales of JNJ-3989).

In addition, any and all development successes of JNJ-3989 presumably bodes well for ARWR's working relationship with Janssen and furthers the likelihood that they collaborate on additional TRIM-based RNAi targets (and, potentially, expanding their relationship outside of their current agreement). Their October 2018 agreement provides Janssen with the option to collaborate with ARWR on up to three additional RNAi therapeutics (for new targets to be selected by Janssen) – the first of which, 'JNJ1', was just recently announced. JNJ1, per ARWR, is being developed against an undisclosed liver-expressed target. As a reminder, ARWR is responsible for preclinical development (fully funded by Janssen) up to filing of an IND, at which point Jansen has the option to take an exclusivity license and continue development. Additional success of JNJ-3989 and initial progress with JNJ1 (which management indicated has moved swiftly) should further bolster the chances of a long-lasting relationship between ARWR and Janssen in our opinion.

Amgen Collaboration Programs

In August 2018 Arrowhead announced that it earned a $10M milestone payment from Amgen following the administration of the first dose of AMG 890 (fka ARO-LPA) in a Ph1 clinical study designed to assess

safety in subjects with elevated levels of lipoprotein (a) [Lp(a)]. AMG 890 is an RNAi therapeutic designed to lower Lp(a) for the treatment of cardiovascular disease.

Initial data from the study could be available later this year or early next. Management also noted that Amgen anticipates starting the next phase of development of AMG 890, which would trigger a development milestone payment to ARWR.

As a reminder, in September 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 has an option to a worldwide, exclusive license for a RNAi therapy for an undisclosed genetically validated cardiovascular target (AMG1). In July 2019 Amgen notified ARWR that they would not be exercising their option to exclusively license ARO-AMG1.

Arrowhead received $35M million in upfront payments and $21.5M in equity investments from Amgen related to the ARO-LPA and ARO-AMG1 agreements. ARWR was also eligible to receive up to $617 million in option payments, and development, regulatory and sales milestone payments related to these programs. The company is also eligible for up to low double-digit royalties for sales of products under the ARC-LPA agreement. In both agreements, Amgen is wholly responsible for clinical development and commercialization.

ARO-AAT Program for Alpha-1 Liver Disease

Background of the Phase I Study

In February 2018, Arrowhead received approval from the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) and from the local Ethics Committee to proceed with a first-in-human **Phase 1** study of **ARO-AAT** for the treatment of **alpha-1 antitrypsin deficiency (AATD)**. The study began **dosing** patients in March 2018.

The study, which is designated as **AROAAT1001** (NCT03362242), is a Phase I single- and multiple-ascending dose study to evaluate the safety, tolerability, pharmacokinetics, and effect of ARO-AAT on serum alpha-1 antitrypsin levels in healthy adult volunteers. The study has two parts: double blind and unblinded.

DOUBLE BLIND PART

- 4 treatment arms
  - 35, 100, 200 and 300 mg
  - 100, 200, 300 mg receive ***3 monthly doses***
  - 4 active, 4 placebo
- Assessments of safety, tolerability, plasma levels of ARO-AAT, plasma AAT changes

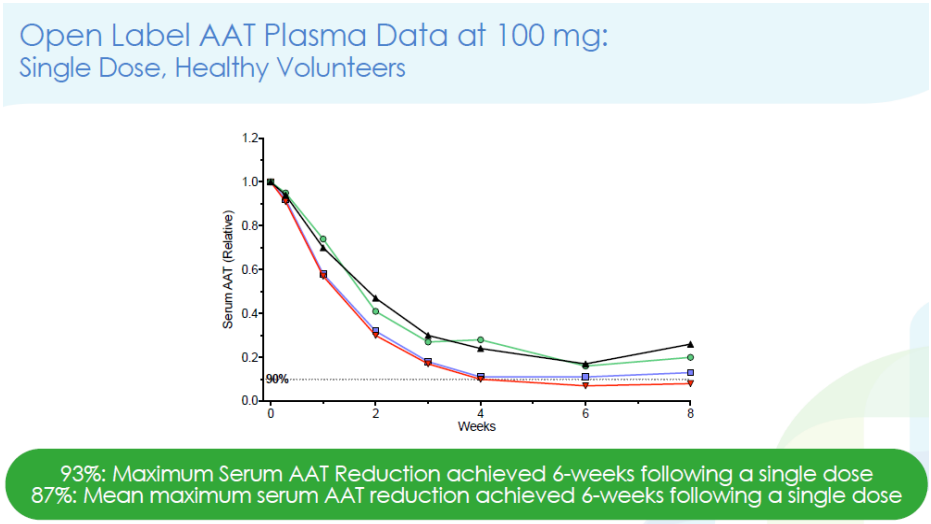
UNBLINDED PART

- No placebo
- 3 groups
  - ***Single doses*** of 100, 200 and 300 mg of ARO-AAT
  - 4 per cohort
- Assessments of safety, tolerability, depth and duration of AAT reductions after a single dose

Source: ARWR Presentation

Key Initial Clinical Data Presented at the Alpha-1 National Education Conference

In the AROAAT1001 **Phase I** clinical study, a single, open-label dose of 100 mg of ARO-AAT in four subjects achieved 93% maximum serum AAT knockdown and 87% mean maximum serum AAT knockdown. At 8 weeks post-dose, mean serum AAT knockdown remained at 83%.



Source: ARWR Presentation

The single 100 mg dose of ARO-AAT equates to an average dose of 1.4 mg/kg (range 1.0-1.6 mg/kg) in the subjects studied, who had an average weight of 72.9 kg (range 61.8-98.9 kg).

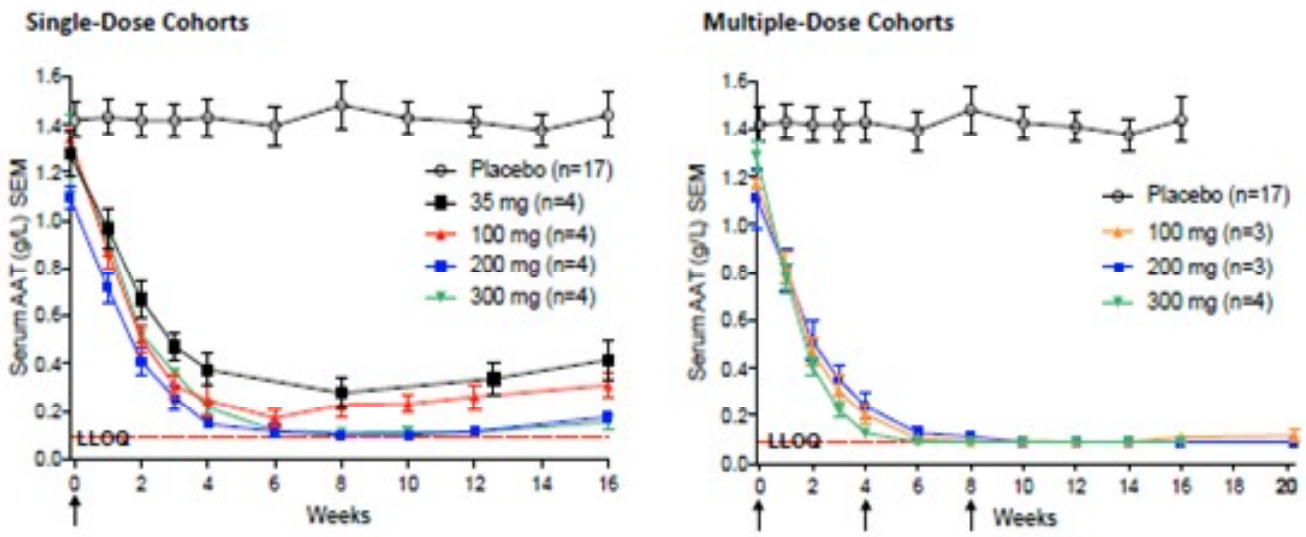
ARO-AAT appeared to be generally well-tolerated and as of the data cutoff of June 11, 2018, the following safety measures were observed in 40 subjects (24 received ARO-AAT and 16 received placebo):

- No serious or severe adverse events (AEs)
- Most AEs reported were mild (one moderate gastroenteritis)
- Two cases of injection site erythema at 100 mg after 1st dose, both were classified as mild and resolved within 48 hours
- No clinically meaningful adverse changes in BUN, creatinine, ALT, AST or total bilirubin
- No dose-related pattern of adverse laboratory changes seen

Poster Presentation at AASLD: No Serious Safety Concerns, Substantial NADIR Serum Reductions…
On Aug. 31, 2018, Arrowhead announced that it completed dosing and in November of that same year updated data from this study was the subject of a late-breaking poster presentation at AASLD (see below). Results showed that ARO-AAT was well tolerated at doses as high as 300mg administered 3x/day for 28 days and no deaths or serious adverse events were reported. Moreover, maximum serum nadir reductions were substantial even among the single-dose cohorts.

Single dose reductions were 79%, 87%, >91% and >91% at 35, 100, 200 and 300mg doses, respectively. Meanwhile, multi-dose nadir reductions were all greater than 91% with most patients below the level of quantification. Maximum serum reduction was 94% (in the 300mg multi-dose cohort). Data to-date has shown that among the 100mg cohort, a 90% reduction was sustained for at least 8 weeks (100mg cohort is the only one so far with this length of post-dosing data).

While no serious adverse events were reported, the most common (non-serious) adverse events were headache (22%) and rhinorrhea (13%), or runny nose. Given the substantial nadir reduction and duration of effect, investigators believe that quarterly or less frequent dosing may be feasible – which presumably would further benefit the safety profile.



Serum AAT Relative Percentage Reduction Summary

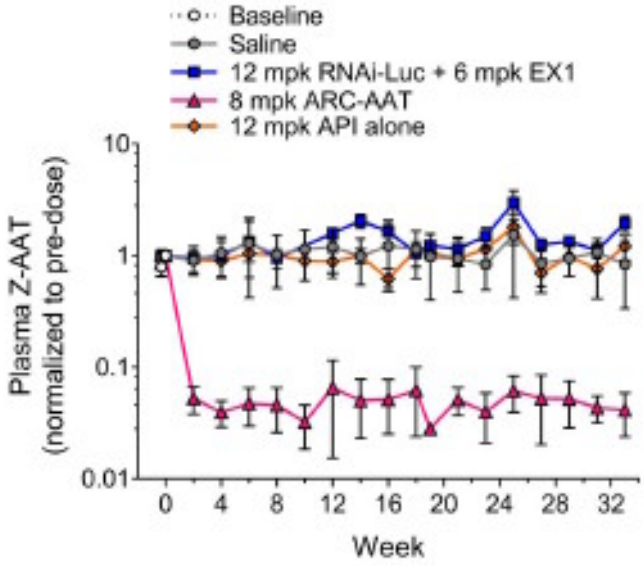
	NADIR Single Dose				NADIR Multiple-Dose		
	35 mg N=4	100 mg N=4	200 mg N=4	300 mg N=4	100 mg N=3	200 mg N=3	300 mg N=4
Average Max	79.0	87.7	>91.5	>91.1	>92.2	>91.2	>93.0
SD	8.5	4.5	0.6	4.0	0.2	2.7	0.7
Max	91.1	93.3	>92.0	>94.9	>92.7	>93.3	>93.7
BLQ, n=	0	0	3	3	2	3	4

SOURCE: ARWR, Schwabe C. et al. AASLD Poster Presentation Nov 2018

AAT EASL Presentation

In April 2019 ARWR presented long-term preclinical data from their prior generation AAT compound at the EASL International Liver Congress. Results demonstrated that adult PiZ mice treated with ARC-AAT showed sustained RNAi reduction of the mutant Z-AAT protein. After 33 weeks of treatment with ARC-AAT, the PiZ mice showed substantial reversal of disease phenotype including deeply reduced monomeric Z-AAT protein in the liver, reduced polymeric Z-AAT in the liver, up to 98% plasma Z-ATT reduction from baseline and restoration of normal endoplasmic reticulum. While this was a prior generation, we think this lends further support for potential efficacy of AAT in the treatment of alpha-1 antitrypsin deficiency.

AAT sustained reduction of mutant Z-AAT protein[3]



ARO-AAT Phase 2/3 Trial Design

In April 2019 ARWR received IND approval to proceed with a Phase 2/3 study of ARO-AAT in alpha-1 antitrypsin deficiency. Management laid out details of the trial design on the Q2 call in May 2019 and noted that they believe it could potentially serve as a pivotal FDA registration study. Along with the Phase 2/3 study, called SEQUOIA, a separate open label study, called ARO-AAT 2002, will be conducted in parallel.

Notably, in June 2019 ARO-AAT received Fast Track status from FDA (complementing Orphan Drug designation in the U.S. and E.U. which was granted in early 2018), which we think could result in further acceleration of the development timeline.

The purpose of ARO-AAT 2002, which ARWR anticipates commencing in Q3 of this year (i.e. slightly after SEQUOIA begins), is to essentially have insight into patient response and safety without having to unblind SEQUOIA (and therefore be susceptible to potential bias) – this, they hope, will provide them with ongoing and current data for planning purposes (it should also, we think, provide investors with potential proxy insight into safety and response of SEQUOIA).

SEQUOIA is a multiple dose, multicenter (hope to have up to 40 sites WW), placebo-controlled, adaptive Phase 2/3 study to evaluate the safety, efficacy, and tolerability of ARO-AAT administered subcutaneously to patients with alpha-1 antitrypsin deficiency. Patient, treating physician and Arrowhead will be blinded. SEQUOIA has two parts, A and B. The goal of (multi-dose) Part A is to select a single dose to be used in the two-arm, placebo controlled Part B portion. The following, taken from ARWR's Q2 2019 conference call, describes the SEQUOIA study and below that, the ARO-AAT 2002 study;

- **SEQUOIA Part A:**
    - The primary objective of Part A is to select a single dose level for use in Part B based on a combined evaluation of safety and pharmacodynamic dose response in each Part A cohort using change from baseline in soluble liver Z-AAT and serum AAT levels as pharmacodynamic metrics.
    - Participants in Part A will require a pre-dose biopsy and those who meet the inclusion criteria will be randomized to receive ARO-AAT or placebo on days 1, 29, 113, and then every 84 days thereafter.

[3] Reduction of hepatic Z alpha1 antitrypsin by RNA interference prevents and reverses liver disease including hepatic mitochondrial injury in the PiZ mouse model. Christine I. Wooddell at al. April 2019 EASL Poster

- There are three cohorts each using a different dose level (25mg, 100mg and 200mg). All three cohorts will be randomized in parallel.
- Once 36 subjects, 12 in each cohort have completed a Day-113 biopsy, the Part A analysis to select a single dose for Part B will occur.
- Enrollment will continue into all cohorts until the Part B dose is chosen.

- **SEQUOIA Part B:**
  - The primary objective for Part B is to evaluate efficacy as assessed by the proportion of ARO-AAT patients relative to placebo achieving a two-point improvement on a histological grading scale of alpha-1 antitrypsin deficiency associated liver disease and no worsening of liver fibrosis on end-of-study biopsy.
  - Patients enrolled during Part A will continue on study and roll over to the Part B dose level or continue to receive placebo.
  - These patients are intended to receive a minimum of six Part B doses and a minimum of nine doses overall.
  - Remaining patients needed to achieve a total enrollment of 120 will be randomized to the selected Part B dose level or placebo and will receive doses on days 1, 29 and then every three months thereafter for a total of nine doses.

- **ARO-AAT 2002 study** (conducted in parallel to SEQUOIA)
  - Open label, multi-dose, Phase 2 study to assess changes in a novel histological activity scale in response to ARO-AAT over time in patients with alpha-1 antitrypsin deficiency associated liver disease.
    - Primary objective is to evaluate effective ARO-AAT on a histologic liver disease activity scale will be assessed at 24 weeks for cohort one and week 48 for cohort two.
    - Multiple secondary 'exploratory objectives' will also be assessed.
    - Expected to include 12 subjects in two sequential cohorts
      - Cohort one consists of four patients and cohort two consists of eight patients.
        - All eligible patients will require a pre-dose biopsy completed as part of the study. Patients that had been enrolled are expected to receive a minimum of three doses of ARO-AAT in cohort one and five doses in cohort two with repeat biopsies approximately one month after the third or fifth dose, respectively.
        - Doses will be administered on days 129, 113 and approximately every 84 days thereafter. Patients who complete cohorts one or two may elect to participate in an extension cohort which would include an additional four doses, again given quarterly followed by repeat liver biopsy.

ARO-AAT SEQUOIA and 2002 Status Update...

Development of ARO-AAT continues to rapidly progress. And with Fast Track status granted by FDA in mid-June (complementing Orphan Drug designation in the U.S. and E.U. which was granted in early 2018), we could see the development timeline further accelerate.

Encouragingly, **SEQUOIA** appears to be moving quickly. IDE approval came in April and, as of the Q3 call in early August, multiple sites were enrolling and dosing had commenced. ARWR appears intent on leveraging the Fast Track status, noting that they have sped up clinical site activity including getting additional locations operational and enrolling. With U.S. sites now operational, management indicated that they will look to initiate locations in Europe and Canada. With some IRB approvals in-hand and others anticipated shortly, ARWR expects a number of additional OUS trial sites to come online and hopes to have a total of 40 locations (U.S. and OUS) operational in the months ahead.

Meanwhile, the timeline for **ARO-AAT 2002**, the parallel open label study, appears to be tracking prior expectations. The study will be conducted in Europe and per the Q3 call, was nearing commencement with trial sites opening and readying to begin enrolling patients.

ARO-ANG3 …

In early January 2019 Arrowhead announced commencement of dosing of the initial subjects enrolled in their Phase 1 study (ARO-ANG1001) evaluating the safety, tolerability, PK and PD effects of ARO-ANG3 in healthy individuals and those with dyslipidemia. As a reminder, ARO-ANG3 is ARWR's subcutaneously-administered RNAi-based candidate developed to target angiopoietin like protein 3 (ANGPTL3), which has shown to be involved in the regulation of lipoprotein levels, including triglycerides, LDL cholesterol, HDL and very low-density lipoprotein cholesterol.

This Phase 1 study, expected to enroll up to 94 subjects, has single and multiple dose phases. The single-dose portion will include 4 cohorts, each consisting of 10 healthy adults (6 treatment, 4 placebo), with each participant receiving a single dose (ARO-ANG3 or placebo) at 35mg, 100mg, 200mg or 300mg. The multi-dose portion encompasses up to 4 patient cohorts including those with non-alcoholic fatty liver disease (NAFLD), those on statin treatment with high LDL cholesterol and triglycerides, those with familial hypercholesterolemia, and patients with severe hypertriglyceridemia.

Preclinical (mouse and monkey models) results have been promising, showing substantial and durable reductions in serum ANGPTL3 and liver mRNA, as well as reductions in triglycerides and LDL levels. Over 90% knock down was observed in mouse models. In addition to representing a potential eventual treatment for dyslipidemia, ARO-ANG3 could have utility in certain metabolic diseases as well, including NAFLD and nonalcoholic steatohepatitis (NASH). All of these represent significantly sized markets and with unmet therapeutic needs.

Current status *(see status update of ANG3 and APOC3, below, which includes recently-announced positive initial human trial data from ongoing Ph1 studies)*

ARO-APOC3 …

On March 11, 2019 ARWR announced that they commenced dosing of their Phase 1 study of ARO-APOC3, their subcutaneously-administered RNAi-based candidate targeting apolipoprotein C-III (apoC-III) and being developed for the treatment of hypertriglyceridemia.

The study, expected to enroll up to 80 subjects, also has single and multiple dose phases and will be used to help inform subsequent development. It is expected to enroll both healthy subjects and various populations of patients with elevated triglycerides. Up to 90% knock down was observed in rodent models.

ARO-APOC 3 1001 is a Phase 1 single and multiple dose study to evaluate the safety, tolerability, PK and PD effects of ARO-APOC3 in up to 63 adult healthy volunteers with elevated triglycerides and patients with severe hypertriglyceridemia and familial chylomicronemia syndrome (FCS).

The single ascending dose portion is expected to include up to four cohorts of 10 adult healthy volunteers per cohort. SAD subject will receive a single-dose administration of either placebo or ARO-APOC3 at dose levels of 25, 50, 100, or 200 mg (note that this was subsequently amended, eliminating the 200mg dose and adding a 10mg dose). The multiple-dose portion is designed to include up to three cohorts of patients with severe hypertriglyceridemia and one cohort of patients with FCS who will receive two monthly doses of ARO-APOC3.

Current status *(see status update of ANG3 and APOC3, below, which includes recently-announced positive initial human trial data from ongoing Ph1 studies)*

Status Update of ANG3 and APOC3

Arrowhead received **orphan drug designation** for ARO-APOC3 for the treatment of familial chylomicronemia syndrome (FCS) and for ARO-ANG3 for the treatment of homozygous familial hypercholesterolemia (HoFH) in June and July, respectively. FCS and HoFH are both rare metabolic

disorders with high unmet needs and are associated with impaired quality of life and certain potentially serious health complications that, if left untreated, can result in death.

FCS is a genetic disorder characterized by inability to properly break down fats (as a result of dysfunctional lipoprotein lipase), which can result in severe hypertriglyceridemia (dangerously high levels of triglycerides), pancreatitis and even death. Worldwide prevalence of FCS is estimated at between 1 in 1M and 1 in 2M people.

HoFH is an inherited disorder which impairs the body's ability to remove low-density lipoprotein. This can lead to severely elevated LDL, early and rapid narrowing / blockage of the arteries and eventually death. It is estimated that HoFH affects between 1 in 160k to 1 in 1 million people around the world.

Orphan status, combined with the recently announced positive topline Ph1 data, sets the stage for what could be further acceleration of these programs through mid/late-stage development. In fact, ARWR expects to pursue respective orphan designated clinical programs immediately which, if all goes well, could potentially include pivotal trials for both APOC3 and ANG3 as soon as next year.

In September 2019 ARWR announced positive topline data from Phase I studies of ARO-APOC3 and ARO-ANG3. Presented at The Global Summit on Cardiology and Heart Diseases in Dubai, the data provided the first substantive look at safety and target activity in the clinical setting and results appear to have been exactly what had been hoped for – more specifically, that each candidate effectively reduced their respective targets and triglyceride levels and did so without any serious side effects. Perhaps just as encouraging, this initial topline data – which is from just a single dose (in healthy volunteers) - also suggests long duration of activity.

AROAPOC31001 is a Ph1 (n= ~80) single and multiple dose-escalating study evaluating the safety, tolerability, pharmacokinetics and pharmacodynamic effects of ARO-APOC3 in adult healthy volunteers, patients with hypertriglyceridemia and patients with familial chylomicronemia syndrome (FCS). AROANG1001 is a Ph1 (n= ~94) single and multiple dose study evaluating the safety, tolerability, pharmacokinetics and pharmacodynamic effects of ARO-ANG3 in adult healthy volunteers and patients with dyslipidemia.

As a reminder of the background of these programs and hypothesis behind their respective targets - large genetic studies discovered that certain rare mutations that disrupt the functioning of apolipoprotein C3 (i.e. APOC3) and angiopoietin-like 3 gene (i.e. ANGPTL3) are associated with lower levels of plasma triglycerides and, in the case of ANGPTL3, also decreased plasma levels of low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. As these lipid fractions have been shown to be predictors of cardiovascular disease (CVD), targeted therapeutic antagonism of APOC3 and ANGPTL3 is hypothesized to reduce risk of CVD. This theory, already supported by laboratory and rodent models, just became much more compelling as a result of this positive initial human clinical trial data.

While we will wait for results of the larger data set to offer a more determined opinion, **we would characterize these results** – clean safety and initial signs of durability of effect - **as about the best as could have been expected.** Management anticipates additional data from both studies, including the complete treatment course of the single ascending dose (SAD) portions to be announced later this year and, subsequently, from the multiple ascending dose (MAD) portion (in various patient populations). And, as we also anticipate additional activity specific to each candidates' respective orphan drug indications, there could be a regular amount of clinical news flow for APOC3 and ANG3 over the coming quarters - which **we think further benefits the likelihood of potential value-inflection announcements.**

The topline Ph1 data announced earlier this month week comes from the SAD portion which, for both studies (i.e. AROAPOC3001 and AROANG1001), included 4 cohorts of 10 adult healthy volunteers with (6 active / 4 placebo). AROAPOC3001 participants received a single dose of either placebo or ARO-

APOC3 at dose levels of 10, 25, 50, or 100mg while AROANG1001 participants received a single dose of either placebo or ARO-ANG3 at dose levels of 35, 100, 200, or 300mg.

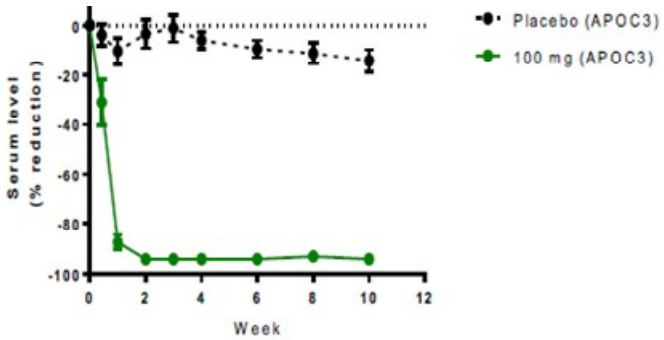
Of note, **AROAPOC3001 was recently amended**, eliminating what had originally included a 200mg as the highest dose. The amendment, which management stressed was based "solely on positive pharmacodynamic activity and not due to any concern or finding with respect to safety or tolerability", also added a 10mg dose (25mg had initially been the lowest dose). Including this lower dose, management noted, should provide additional insight into dose response of APOC3.

Ph1 Topline Results showed:

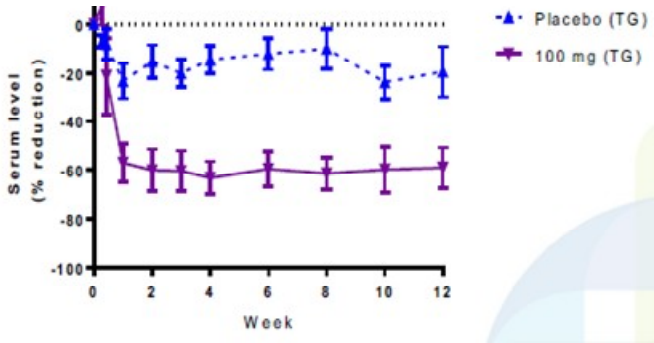
- 100mg of ARO-APOC3 was associated with 63% reduction in plasma triglycerides and 94% reduction in APOC3. Particularly noteworthy is the durability of this robust effect, which appears (see graphs below) to have remained at or near trough level through week 12.

  These results also compare favorably to those of studies of other (non-ARWR associated) clinical stage apolipoprotein C-III-targeting candidates including AKCEA-APOCIII-L_{Rx} (Akcea Ther / Ionis Pharma), in Ph2 testing for the treatment of serious cardiometabolic diseases caused by lipid disorders (see table, below, from ARWR's Ph1 topline results presentation)

APOC3



Triglycerides

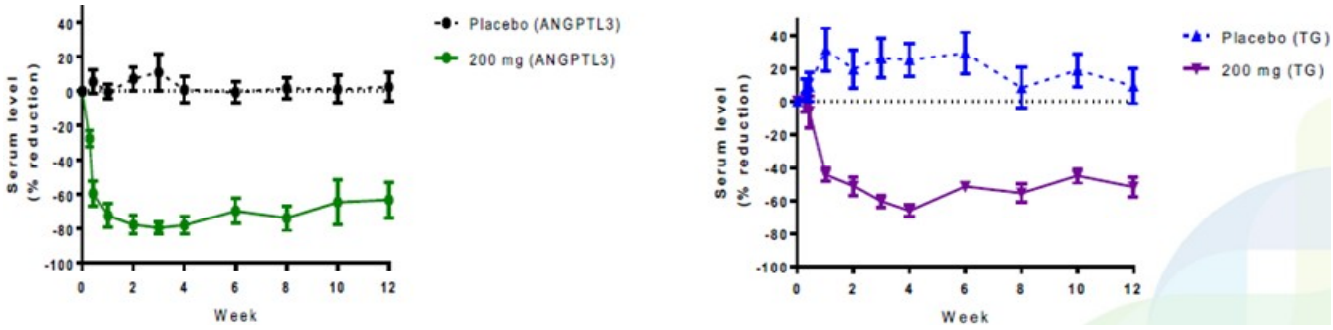


Source: ARWR GSCHD Presentation Sept 2019

- 200mg of ARO-ANG3 was associated with 66% reduction in plasma triglycerides and 79% reduction in ANGPTL3. Similar to the APOC3 data, ANG3 showed potent durability of effect with maximum reduction largely maintained through 12 weeks.

  These results also compare favorably to those of studies of other (non-ARWR associated) clinical stage angiopoietin like protein 3-targeting candidates including AKCEA-ANGPTL3-L_{Rx} (Akcea Ther / Ionis Pharma) and Evinacumab (Regeneron) - see table, below. AKCEA-ANGPTL3-L_{Rx} is in Ph2 testing for patients with hypertriglyceridemia, type 2 diabetes and nonalcoholic fatty liver disease. Evinacumab is a monoclonal antibody in separate Ph2 trials for patients with severe hypertriglyceridemia as well as those with refractory hypercholesterolemia (also in Ph3 for patients with homozygous familial hypercholesterolemia).

ANGPTL3 **Triglycerides**



Source: ARWR GSCHD Presentation Sept 2019

- Clean safety profile: In both studies no drug-related serious or severe adverse events were observed

APOC3 Topline Ph1 Data Stacks Up Favorably to Other Clinical Candidates

Mean Maximal % reduction from baseline (SD)	Serum ApoC3	Triglycerides
ARO-APOC3 (100 mg)	94.2% (1.3)	63.2% (16.9)
AKCEA-APOCIII-L_{Rx} (60 mg)*[1]	64.7% (21.7)	43% (19.7)
AKCEA-APOCIII-L_{Rx} (120 mg)**[1]	91.2% (2.5)	79.6% (3.7)

ARO-APOC3 inclusion criteria of TG > 80 mg/dL
*60 mg dose was the highest dose given to subjects with fasting TG ≥ 90 mg/dL
** 120 mg dose was the highest dose given to subjects with inclusion criteria of TG >200 mg/dL
[1]Alexander et al, Eur Heart J, 2019 40:2785-2796.

Source: ARWR GSCHD Presentation Sept 2019

ARO-ANG3 Topline Ph1 Data Stacks Up Favorably to Other Clinical Candidates

Mean Maximal % reduction from baseline (SD) [unless noted]	Serum ANGPTL3	Triglycerides
ARO-ANG3 (200 mg)	79.4% (8.4)	66.2% (7.6)
AKCEA-ANGPTL3-L_{Rx} (80 mg)*[1]	61.7% (1.1)	56.1% (1.1)
Evinacumab (250 mg, SC)[2]	NR**	51.1%[&]
Evinacumab (250 mg, SC)[3]	NR**	55.5%[&]

* Inclusion criteria of TG = 90-150 mg/dL
** Dose-depended increases in ANGPTL3 indicating target binding of evinacumab were observed
[&] Median % change
[1] Graham et al, NEJM 2017 377:222-232
[2] Dewey et al, NEJM 2017 377:211-221
[3] Ahmad et al, Circulation 2019 140: 470-486

Source: ARWR GSCHD Presentation Sept 2019

AROANG1001 and AROAPOC31001 current status and upcoming milestones…

As it relates to AROANG1001, the 200mg dose was chosen to use in the MAD portion, which commenced following recent receipt of requisite IRB and Drug Safety Committee approvals. Management noted on the Q3 earnings call (Aug 5th) that three of the MAD cohorts had been fully recruited and dosing started while recruiting of the fourth cohort was underway.

Of note, the MAD portion was initially designed to enroll up to 4 patient cohorts including those with non-alcoholic fatty liver disease (NAFLD), those on statin treatment with high LDL cholesterol and triglycerides, those with familial hypercholesterolemia and patients with severe hypertriglyceridemia. ARWR noted on the call that an amendment was in-process to add healthy subjects as well as patients with heterozygous or homozygous familial hypercholesterolemia.

As it relates to AROAPOC31001, management noted on the Q3 call that dosing had completed in all SAD cohorts, including the newly added 10mg. Screening for MAD cohorts had begun with dosing (as of the Q3 call in early August) expected to begin shortly.

ARWR anticipates the complete treatment course of the SAD portion of ANG3 (and APOC3) to be announced later this year – potentially including an abstract at the American Heart Association conference (November 16 – 18th). We could see initial MAD sometime in 1H 2020. And, as we also anticipate additional activity specific to each candidates' respective orphan drug indications, there could be a regular amount of clinical news flow for APOC3 and ANG3 over the coming quarters. As noted, we think this adds to the chances of potential value-inflection.

Additional Pipeline Update

ARO-HSD: latest pipeline addition, CTA filing anticipated this year…
ARO-HSD, targeting HSD17B13 for potential indications in alcohol and non-alcohol related liver diseases, is the most recent addition to ARWR's pipeline. A CTA filing for **ARO-HSD**, which is currently

in IND-enabling GLP-tox studies, is anticipated later this year. With human studies potentially kicking off early next year, ARO-HSD could soon represent ARWR's sixth clinical TRiM program. Additional details about this program (likely including anticipated timelines) are expected to be discussed during Arrowhead's 'Analyst Day' on October 18th.

17β-Hydroxysteroid dehydrogenase type 13 (17β-HSD type 13), an enzyme encoded by the HSD17B13 gene, is involved in lipid metabolism in the liver. Genetic studies have shown that loss-of-function mutations to HSD17B13 are associated with decreased risk of development of alcohol and non-alcohol related liver diseases. Specifically, a study conducted by Regeneron and published in March 2018 in the NEJM found that individuals with two copies of this loss-of-function variant of HSD17B13 had a 53% and 30% lower risk of alcoholic liver disease and nonalcoholic liver disease, respectively, as compared to individuals with two functioning copies of the gene. Non-functioning carriers were also found to have a 73% lower risk of alcoholic cirrhosis and 49% lower risk of nonalcoholic cirrhosis as compared to those with two working copies of the gene.[4]

Clinical Pipeline Could Soon Grow to 8 TriM Programs, Up From 5 Today…
In addition to ARO-HSD, ARWR is aiming for near-term CTA filings for ARO-HIF2 and ARO-ENaC as well. A CTA for ARO-HIF2, the company's candidate targeting renal cell carcinoma which achieved 85% target gene knockdown in a rodent tumor model, is still expected later this year. ARO-HIF2 (see background below) would represent their seventh TRiM program.

Meanwhile IND-enabling studies of ARO-ENaC, Arrowhead's candidate targeting the epithelial sodium channel (ENaC) alpha subunit for treatment of cystic fibrosis, have experienced delays which has pushed back the CTA filing timeline. Management's most recent guidance is for GLP toxicology studies to commence later this year and, if all goes well, to file a CTA in 1H'20. ARO-ENaC could represent their eighth clinical program.

ARO-HIF2 Background
In September 2015, Arrowhead nominated **ARO-HIF2** as its first therapeutic candidate delivered using a new Dynamic Polyconjugate™ (DPC™) designed to target tissues outside of the liver. Arrowhead believes that ARO-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).**

ARO-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 ARO-HIF2 at AACR2016.

The poster presentation described data from various stages of development of ARO-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:

[4] Noura S. Abul-Husn, M.D., Ph.D, et al. A Protein-Truncating HSD17B13 Variant and Protection from Chronic Liver Disease. N Engl J Med 2018; 378:1096-1106

- 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, ARO-HIF2 inhibited tumor growth and promoted tumor cell death and structural degeneration

Valuation

ARWR continues to make rapid, nearly error- and delay-free, progression of their pipeline and has done so without significant dilution to shareholders. Recently secured orphan designations and positive (safety and activity, including duration) initial human trial data of APOC3 and ANG3 sets the stage for a potentially accelerated and an unambiguous regulatory pathway for both candidates. While ARWR had previously guided that they believed APOC3 and ANG3 could possibly enter pivotal studies in 2020, the orphan designations and positive Ph1 data bolsters the potential prescience of that.

The Janssen/J&J collaboration has already shown to be a 'win' for the company (and shareholders), providing over $200M of dilutive-free funds in less than 12 months and facilitating the speedy development pace of ARO-HBV (JNJ-3989). We think it is reasonable to assume that the clean safety (to-date) profile and JNJ-3989 having already moved into a large, potentially curatively-powered Ph2b (triple combo) study, is bolstering Janssen's confidence in both the potential of the therapy (and, perhaps, the TRiM platform as a whole) and their working relationship with ARWR. This is one reason why we believe that read-out of cohort 12 (triple combo therapy cohort in Ph1/2 AROHBV1001) may be more informative and consequential than the data alone. Having now pulled the trigger on the first option to collaborate with ARWR on (up to three) additional RNAi therapeutics is, we think, another indication of the potential upside that Janssen sees in ARWR's technology and capabilities.

ARO-AAT also continues to make rapid development progress and Fast Track status, granted in June, could help accelerate that pace. Encouragingly, SEQUOIA, a Ph2/3 trial which was just announced earlier this year and could serve as a pivotal U.S. registrational study (which would make it the first U.S. pivotal study of ARWR's TRiM platform), appears to be moving quickly. IDE approval came in April and, as of the Q3 call in early August, multiple sites were enrolling and dosing had commenced. ARWR appears intent on leveraging the Fast Track status, noting that they have sped up clinical site activity including getting additional locations operational and enrolling. With U.S. sites now operational, management indicated that they will look to initiate locations in Europe and Canada. With some IRB approvals in-hand and others anticipated shortly, ARWR expects a number of additional OUS trial sites to come online and hopes to have a total of 40 locations (U.S. and OUS) operational in the months ahead.

With APOC3, ANG3 and AAT all possibly entering pivotal studies in the near-term and JNJ-3989 now in what could prove to be a curative study (for HBV, which could draw massive appeal), we could soon have a lot more information to gauge the potential commercializability (and value) of Arrowhead's development portfolio. This, by extension, also bolsters the potential likelihood of significant value-inflection events/announcements (over the same timeframes).

We also remain highly encouraged by ARWR's seeming determination to continue to deepen their development pipeline. With another three CTA filings anticipated, the company could soon have eight TRiM clinical programs ongoing. ARO-HSD, targeting HSD17B13 for potential indications in alcohol and non-alcohol related liver diseases, is the most recent addition and which ARWR hopes to have in clinical studies next year.

The rapid and largely error and delay-free progress of the existing clinical pipeline, coupled with the company continuing to deliver on its guidance related to increasing the number of high-potential TRiM candidates under development, has moved our targeted market capitalization from $2.8B to $3.4B, representing an increase to our per-share target price from approximately $30 to $36.

PROJECTED INCOME STATEMENT

	2018 (Sept)					2019 (Sept)					2020 (Sept)
$ in millions except per share data	Q1	Q2	Q3	Q4	FYE	Q1	Q2	Q3	Q4	FYE	FYE
Revenue	$3.51	$0.65	$0.73	$11.26	$16.14	$34.66	$48.15	$42.70	$40.87	$166.37	$90.20
YOY Growth	*-19.6%*	*-92.8%*	*-92.2%*	*29.2%*	*-48.6%*	*887.5%*	*7306.0%*	*5770.0%*	*263.1%*	*930.7%*	*160.3%*
Total Revenues	**$3.51**	**$0.65**	**$0.73**	**$11.26**	**$16.14**	**$34.66**	**$48.15**	**$42.70**	**$40.87**	**$166.37**	**$90.20**
YOY Growth	*-19.6%*	*-92.8%*	*-92.2%*	*29.2%*	*-48.6%*	*887.5%*	*7306.0%*	*5770.0%*	*263.1%*	*930.7%*	*160.3%*
Cost of Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	**$3.5**	**$0.7**	**$0.7**	**$11.3**	**$16.1**	**$34.7**	**$48.1**	**$42.7**	**$40.9**	**$166.4**	**$90.2**
Gross Margin	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
R&D	$12.9	$12.0	$12.1	$16.0	$53.0	$17.6	$20.8	$19.3	$21.2	$78.8	$94.7
% R&D	*368.1%*	*1846.2%*	*1657.0%*	*142.1%*	*328.1%*	*50.7%*	*43.2%*	*45.2%*	*51.8%*	*47.4%*	*105.0%*
Salary and G&A	$4.4	$3.7	$4.6	$6.4	$19.1	$6.1	$5.3	$4.8	$6.5	$22.8	$25.5
% SG&A	*125.5%*	*566.3%*	*631.6%*	*57.1%*	*118.4%*	*17.7%*	*11.1%*	*11.3%*	*15.9%*	*13.7%*	*28.2%*
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
% Other	*0.0%*	*0.0%*	*0.0%*	*0.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**($13.8)**	**($15.0)**	**($15.9)**	**($11.2)**	**($55.9)**	**$10.9**	**$22.0**	**$18.6**	**$13.2**	**$64.8**	**($30.0)**
Operating Margin	-	-	-	-	-	*31.6%*	*45.7%*	*43.6%*	*32.3%*	*38.9%*	*-33.2%*
Other Income (Net)	$0.6	$0.1	$0.3	$0.4	$1.5	$1.1	$1.9	$1.7	$1.7	$6.4	$3.1
Pre-Tax Income	**($13.2)**	**($14.9)**	**($15.6)**	**($10.8)**	**($54.5)**	**$12.0**	**$23.9**	**$20.3**	**$14.9**	**$71.2**	**($26.9)**
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	**($13.2)**	**($14.9)**	**($15.6)**	**($10.8)**	**($54.5)**	**$12.0**	**$23.9**	**$20.3**	**$14.9**	**$71.2**	**($26.9)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	*34.7%*	*49.6%*	*47.6%*	*36.5%*	*42.8%*	*-29.8%*
Weighted avg. Shares Out	*74.8*	*84.1*	*87.6*	*88.1*	*83.6*	*95.6*	*98.1*	*98.9*	*99.6*	*98.0*	*104.5*
Reported EPS	**($0.18)**	**($0.18)**	**($0.18)**	**($0.12)**	**($0.65)**	**$0.13**	**$0.24**	**$0.21**	**$0.15**	**$0.73**	**($0.26)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-

Zacks Small-Cap Research

HISTORICAL STOCK PRICE

Source: Zacks Investment Research

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