ARROWHEAD PHARMACEUTICALS
Fiscal 2019 Third Quarter Conference Call – Prepared Remarks
August 5, 2019
1:30 PM Pacific time

Operator

Ladies and gentlemen welcome to the Arrowhead Pharmaceuticals conference call. Throughout today's recorded presentation all participants will be in a listen-only mode. After the presentation, there will be an opportunity to ask questions. I will now hand the conference call over to Vincent Anzalone, Vice President of Investor Relations for Arrowhead. Please go-ahead Vince.

Vince Anzalone

Good afternoon everyone. Thank you for joining us today to discuss Arrowhead's results for its fiscal 2019 third quarter ended June 30, 2019. With us today from management are president and CEO Dr. Christopher Anzalone, who will provide an overview of the quarter; Dr. Bruce Given, our chief operating officer and head of R&D, who will discuss our clinical programs; and Ken Myszkowski, our chief financial officer, who will give a review of the financials. We will then open up the call to your questions.

Before we begin, I would like to remind you that comments made during today’s call contain certain forward-looking statements within the meaning of Section 27(A) of the Securities Act of 1933 and Section 21(E) of the Securities Exchange Act of 1934. All statements other than statements of historical fact, including
without limitation those with respect to Arrowhead's goals, plans, and strategies are forward-looking statements. These include statements regarding our expectations around the development, safety and efficacy of our drug candidates, projected cash runway, and expected future development activities. These statements represent management's current expectations and are inherently uncertain. Thus, actual results may differ materially. Arrowhead disclaims any intent and undertakes no duty to update any of the forward-looking statements discussed on today's call.

You should refer to the discussions under risk factors in Arrowhead's annual report on Form 10-K and the Company’s subsequent quarterly reports on Form 10-Q for additional matters to be considered in this regard, including risks and other considerations that could cause actual results to vary from the presently expected results expressed in today’s call.

With that said, I'd like to turn the call over to Christopher Anzalone, President and CEO of the Company.  Chris?

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**Chris Anzalone**

Thanks Vince. Good afternoon everyone and thank you for joining us today.

We made substantial progress during the quarter toward our short-term and longer-term goals. In particular, we took some very important regulatory and clinical steps that I will discuss in a moment. We now have a good mix of early, mid, and later stage programs, both wholly-owned and partnered, and soon we will add candidates targeting cell types outside of the liver. This will be a big step for Arrowhead and, more broadly, for the entire RNAi field. In addition, we have
multiple years of cash on our balance sheet and potentially access to more non-dilutive capital through milestone payments from our two external partnerships. Taken together, we have 3 critical components of success for a company like ours:

1. a platform on which to build a variety of important new medicines;
2. a pipeline of potential medicines spanning early discovery to later stage clinical trials; and
3. the capital to fund development and further innovation.

The fourth critical component is effective and rapid execution. I believe we have clearly demonstrated this over the past few years and during the last quarter. Our overriding focus is on bringing important new medicines to patients who need them, and if we are able to do that, we will continue to build long-term value.

Before I give a review of some of the highlights of the quarter, I want to make a couple announcements.

First, I am proud to announce a previously undisclosed program for which we expect to file a CTA at the end of this year and begin first-in-human studies shortly thereafter. We have never discussed this program publicly. The target is HSD17B13 and potential indications we could address are alcohol related and non-alcohol related liver disease. The candidate is called ARO-HSD, and it is currently in IND-enabling GLP-toxicology studies.

HSD17B13 is a hydroxysteroid dehydrogenase involved in the metabolism of hormones, fatty acids and bile acids. In humans, it is extensively expressed by hepatocytes. Human genetic studies indicate that loss-of-function mutations in HSD17B13 are protective against development of both alcohol related and non-alcohol related liver disease with approximately 30-50% risk reduction compared to non-carriers. Carriers of this variant show lower transaminase levels, both ALT
and AST, compared to non-carriers. This protective effect has inspired therapeutic interest in the treatment of liver disease. We are excited about the program, and I expect that not only will we have the first RNAi candidate against this target in the clinic, but I expect we will be the first to bring any candidate using any modality into the clinic against this target. We have a large and exciting pipeline, and it is now larger and more exciting.

Second, Arrowhead will hold an analyst day in New York on October 18, to give a more in-depth review of some of our programs, including the new ARO-HSD program. We have come so far so fast, so I think it will also be helpful for us to take a step back and give investors a more long-term view of where we see the company over the coming years. We plan on having presentations from folks at Arrowhead as well as some external experts, in addition to panel discussions and interactive question and answer sessions. The event will be open to analysts and institutional investors by invitation, and there will also be a live webcast. We’re planning an engaging event with various presentation formats, so we hope many of you can join us in person or by webcast. Additional details will be available on our website as we approach the event.

Let’s now turn to our preclinical programs. I want to give a quick update on timing for ARO-HIF2 and ARO-ENaC, the first two TRiM-enabled candidates targeting tissues outside the liver. As I mentioned, being able to effectively target tissues outside the liver is a big step forward for us. Broadly, it opens up a vast set of diseases that may not be addressable with small molecule and/or antibody drugs and makes them accessible to Arrowhead. This can drive a significant amount of value for us, and more importantly gives us the opportunity to provide hope for many patients without adequate options. We have believed all along that for RNAi to reach its true potential as a paradigm shifting new modality in medicine, it must
be able to address diseases outside of hepatocytes. Because of this belief, we have spent the last several years improving our technology and finding solutions to the many technical challenges that exist beyond hepatocyte delivery. We think we are there. This gives us a distinct strategic and technical advantage over other RNAi companies.

ARO-HIF2 is being developed as a promising new drug candidate for treatment of the clear cell form of renal cell carcinoma, or ccRCC. ARO-HIF2 is designed to inhibit the production of HIF-2 alpha, which has been linked to tumor progression and metastasis in ccRCC. We believe it is an attractive target for intervention because the overwhelming majority of ccRCC tumors are thought to express a mutant form of the Von Hippel-Landau protein that is unable to degrade HIF-2 alpha, leading to its accumulation during tumor hypoxia and promoting tumor growth.

We are still on schedule to file a CTA for ARO-HIF2 this year. Similar to ARO-HSD, we are currently conducting IND-enabling GLP-toxicology studies. The anticipated completion of these studies should support a CTA filing by the end of the year.

Our second extra-hepatic program to leverage the TRiM™ platform is ARO-ENaC. ARO-ENaC is an inhaled RNAi-therapeutic candidate designed to reduce production of the epithelial sodium channel alpha subunit, or alpha ENaC, in the airways of the lung. In cystic fibrosis patients, increased ENaC activity contributes to airway dehydration and reduced mucociliary transport. ENaC inhibitors have been tried previously in cystic fibrosis, but have not been able to get enough reduction in the lung while sparing the kidney. ENaC inhibition in the kidney can
lead to high levels of potassium in the blood, called hyperkalemia, that can be dangerous and potentially life-threatening.

Consistent with other targets in our pipeline, this is another case where RNAi using our TRiM™ platform may have a distinct mechanistic advantage over prior small molecule approaches, and thus ENaC is an attractive target for us. We have demonstrated in multiple preclinical studies that we can selectively silence pulmonary ENaC expression with no effect on renal expression or serum potassium levels. In addition, RNAi appears to have a much longer duration of effect, which has been a limiting factor for inhaled small molecule inhibitors. Needless to say, we are very excited about the program. We previously presented data at the 2018 North American Cystic Fibrosis Conference, among others. We anticipate additional data presentations at future conferences.

Because of the specialized nature of inhalation studies, there are a small number of high-quality facilities capable of doing activity and toxicology work for ARO-ENaC. This has affected our ability to get studies scheduled and has slowed the program a bit. We expect to begin IND-enabling GLP-toxicology studies for ARO-ENaC next quarter, but they will not be done in time to file a CTA before the end of the year. So, we are adjusting guidance on our CTA filing to the first half of 2020. Keep in mind that this is our first inhaled RNAi therapeutic candidate and the first to target the lung, so while we are disappointed that the program is delayed by about a quarter, it is a small price to pay to ensure that we go into the clinic with a substantial amount of preclinical data and that the animal studies are done well. Further, with the new ARO-HSD CTA filing by the end of this year, we continue to build our clinical pipeline at a speed that meets or exceeds our own aggressive expectations. As we get clinical experience and validation with this first lung-targeted program, we anticipate that new programs will follow more quickly and
we will be able to achieve the same high level of speed that everybody has come to expect from Arrowhead.

Moving on, I want to review some important progress in our clinical stage programs. I will start with ARO-AAT, our later-stage RNAi therapeutic candidate being developed to treat a rare genetic liver disease associated with alpha-1 antitrypsin deficiency. We achieved two important regulatory milestones during the quarter. First, we announced that, following the filing of an IND, we received FDA clearance to begin the SEQUOIA Phase 2/3 trial, with the potential to serve as a pivotal registrational study. Importantly, this is the first potentially pivotal study for a compound using Arrowhead’s TRiM™ platform. We also secured Fast Track Designation for ARO-AAT from the U.S. FDA. Fast Track is designed to facilitate the development and expedite the review of drugs to treat serious conditions that fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. We intend to utilize a number of the important advantages that Fast Track provides. You may also recall that we previously announced that ARO-AAT received orphan designation in both the EU and the U.S.

In addition to these key regulatory achievements, we have also pushed forward with the clinical studies. We have multiple sites that are operational with patients already enrolled. We expect dosing to begin this week. The 2002 open label study is also moving along well, where we continue to open sites. We expect enrollment to begin shortly. Bruce will talk about the status of these studies in a moment.

I want to mention a few things about the ARO-HBV program, being developed in collaboration with Janssen and now called JNJ-3989. The clinical development program has continued to advance. In April, we announced that the AROHBV1001
study was expanded to include a new triple combination cohort, cohort 12, in 12 patients with chronic hepatitis B infection. All 12 patients have been enrolled and have received all planned doses of JNJ-3989. This cohort includes: JNJ-3989; JNJ-6379, Janssen’s investigational orally administered capsid assembly modulator of the class that forms normal capsid structures; and, a NUC. In connection with the start of dosing of cohort 12, Arrowhead earned a $25 million milestone payment.

In addition to the AROHBV1001 study, Janssen is currently initiating a Phase 2b study, called REEF-1, of different combination regimens, including JNJ-3989, and/or JNJ-6379, and/or a NUC for the treatment of chronic hepatitis B virus infection. The study will include up to 450 patients who will be randomized to receive up to 48 weeks of treatment. Arrowhead is eligible to receive an additional $25 million milestone payment from Janssen upon the dosing of the fifth patient in REEF-1. The study is on clinicaltrials.gov if you want additional information.

Part of our October 2018 agreement with Janssen included a research collaboration and option agreement to potentially collaborate for up to three additional RNAi therapeutics against new targets to be selected by Janssen. We are actively working on the first candidate, now referred to as ARO-JNJ1, against an undisclosed liver-expressed target. These potential new candidates leverage Arrowhead’s proprietary TRiM™ platform, and do not include targets in our current pipeline. Arrowhead is responsible to perform discovery, optimization, and preclinical development, entirely funded by Janssen, sufficient to allow the filing of a U.S. IND or equivalent, at which time Janssen will have the option to take an exclusive license. If the option is exercised, Janssen will be wholly responsible for clinical development and commercialization. This is an important opportunity to create novel medicines by leveraging Arrowhead’s speed and expertise in RNAi drug discovery and Janssen’s clinical development and commercial capabilities. We
have made rapid progress on this program and we look forward to working with Janssen further on ARO-JNJ1 and potentially two other programs.

Let’s now move to our Amgen partnership. Amgen continued to make progress on AMG 890, formerly called ARO-LPA, that targets lipoprotein(a), also known as Lp(a). AMG 890 is being investigated as a potential treatment for cardiovascular disease. Amgen has been enrolling patients with elevated Lp(a) in a Phase 1 study and expects to share the initial data late this year or early next year. Amgen also anticipates launching the next phase of development of AMG 890 in the first half of 2020, which would trigger a development milestone payment. We share Amgen’s excitement in this program and believe that AMG 890 could one day be an important new treatment for cardiovascular disease.

Under the terms of our September 2016 agreement, Amgen also received an option to a worldwide, exclusive license for an RNAi therapy against an undisclosed cardiovascular target, which we subsequently called ARO-AMG1. In August 2018, Arrowhead delivered to Amgen a candidate that met or exceeded the activity and safety requirements stipulated in the collaboration agreement. The option period expires on August 7, 2019, and Amgen has advised us that they do not intend to exercise the option. Consequently, we will be removing ARO-AMG1 from our development pipeline.

Let’s now move on to our two wholly-owned cardiometabolic candidates, ARO-APOC3 and ARO-ANG3. These targets both provide some optionality with respect to which patient populations and indications we will pursue. For each target there may be opportunities to treat well-defined orphan diseases, such as familial chylomicronemia syndrome and homozygous familial hypercholesterolemia, as well as higher prevalence diseases. In addition, the Phase 1 studies for both
candidates are designed to provide a readout on safety and tolerability as well as a robust look at the pharmacologic activity and duration of effect in both healthy volunteers and various patient populations, furthering enhancing our optionality at quite an early stage.

To that end, we secured orphan drug designation from the FDA for ARO-APOC3 for the treatment of familial chylomicronemia syndrome, or FCS, and for ARO-ANG3 for the treatment of homozygous familial hypercholesterolemia, or HoFH. Our intention is to pursue these orphan indications immediately, and potentially initiate pivotal studies for both ARO-APOC3 and -ANG3 next year. Beyond these rare disease populations, we also plan to pursue a staged clinical development and go-to-market approach where we study larger indications in parallel, involving larger studies that will take longer to mature.

We like this model. It allows for the possibility of getting to market quickly while also enabling growth into other markets. From a chemical entity standpoint, of course the APOC3 and ANG3 candidates are just one drug each. From an economic and market standpoint, however, these single drugs could behave like multiple drugs. As we do multiple studies to support treatment for and marketing to different indications, we expect to substantially increase our total addressable markets. Importantly, the addition of each new indication area benefits the others because they will all contribute to a single safety database for each candidate, so there is clear leverage here.

So what are some of these larger market opportunities? For ARO-APOC3, it could simply be patients with elevated triglycerides with some history of pancreatitis. For ARO-ANG3, there are many possibilities. For instance, we could look to treat heterozygous FH patients or those who are not meeting their LDL cholesterol goal
while on statins. Because we expect ARO-ANG3 may decrease liver fat and help with insulin resistance, among other things, we could also look to treat patients with NASH, NAFLD, and those with metabolic syndrome. We believe we have a substantial opportunity to help a large number of diverse patients, and that ANGPTL3 is a uniquely powerful target. As a reminder, we are developing the first (and I believe, only) clinical RNAi candidates against both APOC3 and ANGPTL3.

These two programs are essentially on the same schedule and at the same stage currently. We completed dosing in the single-ascending dose portions of both studies and are now enrolling in the multiple-dose portions in various patient populations. We are still on schedule for potential data read-outs starting this year, and likely continuing into next year. Specifically, Bruce will be a keynote speaker at the Global Summit on Cardiology and Heart Disease, taking place in Dubai on September 16 and 17. He will be talking about our ANG3 and APOC3 programs and will include some topline clinical data we have generated. Later this month, we will submit a late breaker abstract for the American Heart Association conference in November. If accepted, we expect to present a fuller data set from the ANG3 and APOC3 clinical programs. These are data-rich studies, so we believe we will have additional readouts through the November AHA conference. We would, therefore, expect to submit abstracts to present more data at the EASL International Liver Conference and/or the American College of Cardiology meeting in April.

At our R&D day last year, we mentioned a breakthrough in targeting skeletal muscle cells. We have continued down this path and are getting closer to designating our first target and entering the clinic. We are not prepared to discuss
data today, but we see the potential to enter the clinic with our first muscle-targeted candidate next year.

With that overview, I’d now like to turn the call over to Dr. Bruce Given. Bruce?

Bruce Given

Thank you, Chris and good afternoon, everyone.

We have made solid progress on all of our development programs during the recent period. I will begin with a status update on our two wholly-owned cardiometabolic candidates, ARO-ANG3 and ARO-APOC3.

ARO-ANG3 is Arrowhead’s subcutaneously administered RNAi therapeutic targeting angiopoietin like protein 3, or ANGPTL3, being developed as a potential treatment for patients with dyslipidemias and possibly metabolic diseases.

The ARO-ANG3 first-in-human study, which began dosing in Q1, is called AROANG1001. It is a Phase 1 single and multiple dose study to evaluate the safety, tolerability, pharmacokinetic, and pharmacodynamic effects of ARO-ANG3 in up to 70 subjects. The single-dose portion of the study is in adult healthy volunteers and the multiple-dose portion is in patients with various types of dyslipidemia, including patients with non-alcoholic fatty liver disease, patients on a stable statin treatment regimen with persistently elevated LDL cholesterol, patients with heterozygous or homozygous familial hypercholesterolemia, and patients with hypertriglyceridermia.
We have completed dosing in all of the single-dose cohorts at 35, 100, 200, and 300 mg. We selected the 200 mg dose level to move forward with in the multiple-dose patient cohorts and subsequently received DSC and IRB clearance to begin enrolling and dosing patients. Three of the multiple-dose patient cohorts are fully recruited and dosing has begun. The recruiting process is in full swing on the other 2 patient cohorts. As we look toward the possibility to accelerate the development program, we have decided to expand the trial, adding dose-ranging multi-dose healthy volunteer cohorts to give us multi-dose PK and pharmacodynamic data and also some dose-ranging multiple dose cohorts in patients with heterozygous or homozygous familial hypercholesterolemia. This amendment should be submitted shortly. As for what we have learned to date, we have seen indications of activity based on reductions in plasma AngPTL3 concentrations and changes in lipid parameters. The safety and tolerability profile has not sent up red flags or caused any protocol changes.

Moving on to ARO-APOC3, which began dosing later in Q1. ARO-APOC3 is Arrowhead’s subcutaneously administered RNAi therapeutic targeting apolipoprotein C-III, or APOC3, being developed as a potential treatment for patients with hypertriglyceridemia.

The ARO-APOC3 first-in-human study, is called AROAPOC31001. It is a Phase 1 single and multiple dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamic effects of ARO-APOC3 in up to 63 subjects. The single-dose portion of the study is in adult healthy volunteers and the multiple-dose portion is in patients with severe hypertriglyceridemia and familial chylomicronemia syndrome.
The study was originally designed to include dose levels of 25, 50, 100, and 200 mg. We have been pleasantly surprised by the activity of the drug at lower doses than expected, so we have since amended the protocol to eliminate the 200 mg dose and have added a 10 mg dose instead. We have now completed dosing in all of the ARO-APOC3 single-dose cohorts, including the new 10 mg cohort. I want to be clear that this protocol amendment was made based solely on positive pharmacodynamic activity and not due to any concern or finding with respect to safety or tolerability. The 10 mg cohort potentially gives us more detail on the dose-response relationship of ARO-APOC3, which is helpful as we move forward with patient dosing in this study, and ultimately, as we design the next clinical studies.

We are now in the process of screening and scheduling patients for the multiple-dose portion of the study. We anticipate that dosing will begin shortly.

Both first-in-human studies of ARO-ANG3 and ARO-APOC3 are designed to provide a readout on safety and tolerability as well as a robust look at the pharmacologic activity and duration of effect. Included in the readout of activity are changes in: APOC3 and ANGPTL3 protein levels, triglycerides, LDL-C, VLDL-C, HDL-C, and other lesser known lipid parameters.

At Arrowhead we always strive to find innovative designs that get the most data as quickly as possible, and these studies are no exception. We are excited about these data and look forward to sharing them publicly in an appropriate forum. The single-dose portion of both ARO-APOC3 and ARO-ANG3 studies we hope will have mature enough data to share in the fourth quarter of the year. Our intention is to submit abstracts and, if accepted, present at the American Heart Association Scientific Sessions 2019 meeting in November. We will see how quickly the
multiple dose cohorts enroll before providing guidance on when those will be available to discuss publicly.

I would now like to give an update on where we are with the ARO-AAT program. ARO-AAT is Arrowhead’s second generation subcutaneously administered RNAi therapeutic being developed as a treatment for a rare genetic liver disease associated with alpha-1 antitrypsin deficiency.

We are in the process of initiating two studies: The first to start is the SEQUOIA Phase 2/3 study and then shortly after that will be the 2002 open label study. These two studies together are designed to strike a balance between the maximum speed to a potential NDA with the desire to see mid-term confirmation that ARO-AAT is doing what it is designed to do.

Let me talk about these designs for a moment.

SEQUOIA is multi-center, multi-dose, 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. The multi-dose, placebo-controlled Part A component of the study is designed to select a single dose level for use in Part B. This will then feed seamlessly into a two-arm placebo-controlled Part B component.

In total, SEQUOIA is designed to enroll 120 patients who will receive at least 9 doses, or approximately two years of treatment, with ARO-AAT or placebo. The primary objective for Part B is to evaluate efficacy, as assessed by the proportion of ARO-AAT treated patients relative to placebo achieving a 2-point improvement
in a histologic grading scale of alpha-1 antitrypsin deficiency associated liver disease AND no worsening of liver fibrosis on end of study biopsy.

The ARO-AAT 2002 study is a pilot 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.

In total, the 2002 study is planned for up to approximately 12 participants in two sequential cohorts. All 12 patients will also be eligible to participate in an extension cohort. Between cohort completion and including the extension, if patients elect to participate in the extension, we plan to conduct a pre-dose liver biopsy and then repeat biopsies after 6 months, 12 months, 18 months, and 24 months of treatment. The primary objective is to evaluate the effect of ARO-AAT on a histological liver disease activity scale over time.

So where are we with initiating these studies? I will start with SEQUOIA because that is slightly further ahead. We have received regulatory clearance in the U.S. and one site has begun screening patients for enrollment and we anticipate additional sites will also begin screening shortly. It is likely that the first patients on study will be in the U.S., but we are also in the process of pursuing regulatory and IRB clearances in multiple European countries and Canada and several of the country clearances have already been secured. We are targeting approximately 40 sites in the North America and Europe, so we anticipate that over the coming months there will be progressively more sites screening and enrolling patients.

For 2002, we have secured national regulatory clearance in the United Kingdom and are pursuing regulatory clearance in multiple other countries as well. Sites are
not yet open for screening and enrollment, but we are diligently working on that. The 2002 open label study will only be in Europe.

The data on ARO-AAT have been highly encouraging. We believe the results suggest that RNAi, and by extension ARO-AAT, holds great promise for the treatment of patients with AATD-associated liver disease. Notably, we presented preclinical data at EASL this year showing that we were able to prevent further liver damage and reverse existing damage in the PiZ mouse model that harbors the human Z-AAT gene and recapitulates many features of human AATD liver disease. This makes us excited about embarking on the 2002 study and on SEQUOIA, which is Arrowhead’s first potentially pivotal study.

We also look forward to talking about these programs and some of our less mature development programs at our analyst day in October.

With that brief review of our clinical programs, I’d like to turn the call over to Ken Myszkowski, Arrowhead’s Chief Financial Officer. Ken?

Ken Myszkowski

Thank you Bruce, and good afternoon everyone.

As we reported today, our net income for the quarter ended June 30, 2019 was $20.3 million or $0.21 per share based on 98.9 million fully-diluted weighted average shares outstanding. This compares with a net loss of $15.6 million, or $0.18 per share based on 87.6 million weighted average shares outstanding, for the quarter ended June 30, 2018.
Revenue for the quarter ended June 30, 2019 was $42.7 million, compared to $727 thousand for the quarter ended June 30, 2018. Revenue in the current period relates to the recognition of a portion of the upfront payments and milestone from our license and collaboration agreements with Janssen, while revenue in the prior period related to the recognition of a portion of the upfront payments from our license and collaboration agreements with Amgen. Revenue from the Janssen agreement will be recognized based on our estimate of the proportion of effort expended toward fulfilling our performance obligations – primarily, overseeing the completion of the current phase 1/2 HBV clinical trial. We expect the majority of the revenue to be recognized in this fiscal year, but we also expect revenue in fiscal 2020 as we will continue to perform certain follow up activities through 2020.

Total operating expenses for the quarter ended June 30, 2019 were $24.1 million, compared to $16.6 million for the quarter ended June 30, 2018. This increase is primarily due to increased drug manufacturing, toxicology and clinical trial costs as our pipeline of clinical candidates has increased.

Net cash provided by operating activities during the quarter ended June 30, 2019 was $10.8 million, compared with net cash used in operating activities of $14.4 million during the quarter ended June 30, 2018. The operating cash generated in the current period reflects the $25M milestone payment we received from Janssen, offset by cash used to fund our operations.

Turning to our balance sheet, our cash and investments totaled $295.5 million at June 30, 2019, compared to $76.5 million at September 30, 2018. The increase in our cash and investments was primarily due to the cash received from Janssen.

Our common shares outstanding at June 30, 2019, were 95.2 million.
With that brief overview, I will now turn the call back to Chris.

Chris Anzalone

Thanks Ken.

We continue to demonstrate Arrowhead’s ability to execute with speed and precision. We gained clinical experience and validation with our TRiM™ platform for liver delivery and then rapidly expanded our pipeline to include 5 programs, which will soon be 6 when we file a CTA for ARO-HSD by the end of this year. We also expect to have a 7th clinical program this year when we file an IND for ARO-Hif2, and an 8th when we file a CTA for ARO-ENaC in the first half of next year. This would be a big position for a company twice our size: 2 partnered and 6 wholly-owned clinical programs, spanning 3 cell types in the near term. Further, we expect to be in 3 pivotal studies and have no less than 10 clinical programs based on the TRiM™ platform by the end of next year. We think we are now on the cusp of the next stage of growth for the company, whereby we expect to rapidly build our pipeline in tumor, lung, muscle, and eventually additional tissue types. The opportunities in front of us feel limitless if we can continue to achieve our long-term strategic goals to do the following:

1. File 2-3 new CTAs every year
2. Target a new cell type with the TRiM™ platform every 18 months
3. Have 10 TRiM™ enabled candidates in clinical studies by the end of 2020
4. Have 3 active pivotal studies in 2020
With all of these programs, people ask us about our development and partnering plans. Simply put, we have no appetite to partner any part of our pipeline right now. Should this change in the future, I expect it to be opportunistic rather than driven by necessity. We have, indeed, come far, and there is still substantial value for us to create by developing and ultimately marketing these important medicines. Together, our strong balance sheet and access to approximately $4 bn of non-dilutive capital via potential development and commercial milestone payments enable us to pursue this strategy at this time. We are building a large but nimble long-term pharmaceutical company and the current pipeline is the core of that transition.

Thanks again for joining us today. This is a uniquely exciting time for us, our shareholders, and the patients we hope to serve. I would now like to open the call to your questions. Operator?

Operator

Operator opens the call to questions …