UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): October 4, 2018

Arrowhead Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-38042	46-0408024
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

225 South Lake Avenue, Suite 1050, Pasadena, CA 91101
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (626) 304-3400

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)

☐ Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement.

License and Research Collaboration Agreements and Common Stock Purchase Agreement

On October 4, 2018, Arrowhead Pharmaceuticals, Inc., a Delaware corporation (the "Company"), entered into a License Agreement (the "License Agreement") and a Research Collaboration and Option Agreement (the "Collaboration Agreement") with Janssen Pharmaceuticals, Inc., a Pennsylvania corporation ("Janssen"), part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Also on October 4, 2018, the Company entered into a Common Stock Purchase Agreement (the "Stock Purchase Agreement") and Registration Rights Agreement (the "Registration Rights Agreement") with Johnson & Johnson Innovation-JJDC, Inc. ("JJDC"), a New Jersey corporation.

Under the License Agreement, Janssen will receive a worldwide, exclusive license to the Company's ARO-HBV program, the Company's third-generation subcutaneously administered RNAi therapeutic candidate being developed as a potentially curative therapy for patients with chronic hepatitis B virus infection. Beyond the Company's ongoing Phase 1 / 2 study of ARO-HBV (which will remain the responsibility of the Company), Janssen will be wholly responsible for clinical development and commercialization.

Under the Collaboration Agreement, Janssen will be able to select up to three new targets against which Arrowhead will develop clinical candidates. These candidates are subject to certain restrictions and will not include candidates in the Company's current pipeline. The Company will perform discovery, optimization and preclinical development on selected targets, entirely funded by Janssen, sufficient to allow the filing of a U.S. Investigational New Drug application or equivalent, at which time Janssen will have the option to take an exclusive license to the Company's intellectual property rights covering that compound. If the option is exercised, Janssen will be wholly responsible for clinical development and commercialization of each optioned compound.

Under the Stock Purchase Agreement, the Company will sell 3,260,869 shares of common stock (the "Shares") to JJDC at a price of $23.00 per share. The Shares are being sold in a private placement that is exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act"). Pursuant to the Registration Rights Agreement, the Company will be obligated to register the Shares under the Act for resale by JJDC.

Under the terms of the agreements taken together, the Company will receive (i) $175 million as an upfront payment, (ii) $75 million in the form of an equity investment by JJDC in Arrowhead common stock pursuant to the Stock Purchase Agreement, (iii) up to $1.6 billion in development, regulatory and sales milestones payments for the License Agreement, and (iv) up to $1.9 billion in development, regulatory and sales milestone payments for the three additional targets covered under the Collaboration Agreement. The Company is further eligible to receive tiered royalties up to the mid-teens on product sales for products commercialized under the License Agreement and the Collaboration Agreement.

The transactions contemplated under the License Agreement, Collaboration Agreement and Stock Purchase Agreement are subject to customary closing conditions, including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. Closing is expected to occur in the fourth calendar quarter of 2018.

Item 3.02 Unregistered Sales of Equity Securities.

The disclosure set forth above under Item 1.01 regarding the offer and sale of the Shares is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.2 are prepared remarks of the Company, which were presented on a conference call today, October 4, 2018 by Company management to investors, analysts and others. The prepared remarks will be posted on the Company's website, www.arrowheadpharma.com. The information included in Exhibit 99.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 4, 2018
99.2	Prepared Conference Call Remarks, dated October 4, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: October 4, 2018

ARROWHEAD PHARMACEUTICALS, INC.

By: /s/ Kenneth Myszkowski
Kenneth Myszkowski
Chief Financial Officer

EXHIBIT 99.1

PRESS RELEASE
Oct. 4, 2018

Arrowhead Enters $3.7 Billion License and Collaboration Agreements with Janssen

– Upon closing, Arrowhead to receive $250 million, consisting of $175 million upfront payment from Janssen and $75 million equity investment from Johnson & Johnson Innovation – JJDC, Inc.

– Arrowhead eligible to receive additional $3.5 billion in potential milestone payments, and potential further royalties on commercial sales

– Janssen to receive a worldwide exclusive license for ARO-HBV and an option to collaborate on up to three new targets

– Arrowhead will hold a conference call and webcast today, Oct. 4, at 8:30 a.m. ET

PASADENA, Calif., Oct. 4, 2018 – Arrowhead Pharmaceuticals Inc. (NASDAQ: ARWR) today announced that it entered into a license and collaboration agreement with Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize ARO-HBV. In addition, Arrowhead entered into a research collaboration and option agreement with Janssen to potentially collaborate for up to three additional RNA interference (RNAi) therapeutics against new targets to be selected by Janssen. The transactions have a combined potential value of over $3.7 billion for Arrowhead.

Under the terms of the agreement, Arrowhead will receive $175 million as an upfront payment. Separately, Johnson & Johnson Innovation – JJDC, Inc. (JJDC) will make a $75 million equity investment in Arrowhead at a price of $23.00 per share of Arrowhead common stock.

Arrowhead is eligible to receive up to approximately $1.6 billion in milestone payments for the HBV license agreement, including a $50 million milestone payment linked to a Phase 2 study. Arrowhead is also eligible to receive approximately $1.9 billion in option and milestone payments for the collaboration agreement related to up to three additional targets. Arrowhead is further eligible to receive tiered royalties up to mid teens on product sales.

"This agreement represents an important next step for ARO-HBV. Arrowhead has established a leadership position in the field over the past several years, and Janssen's proven development capabilities, global commercial reach, and commitment to HBV make it the ideal partner to potentially accelerate our goal of bringing a functional cure to patients with chronic HBV," said Christopher Anzalone, Ph.D., Arrowhead's president and CEO. "The collaboration also represents further validation of the TRiM™ platform and provides an important opportunity to create up to three additional novel medicines by leveraging Arrowhead's speed and expertise in RNAi drug discovery and Janssen's clinical development and commercial capabilities."

Under the agreement, Janssen receives a worldwide exclusive license to the ARO-HBV program, Arrowhead's third-generation subcutaneously administered RNAi therapeutic candidate being developed as a potentially curative therapy for patients with chronic hepatitis B virus infection. Beyond AROHBV1001, Arrowhead's ongoing Phase 1/2 study of ARO-HBV, Janssen will be wholly responsible for clinical development and commercialization.

Janssen can also select up to three new targets, against which Arrowhead will develop clinical candidates. These potential new candidates will leverage Arrowhead's proprietary TRiM™ platform, and do not include Arrowhead's current pipeline. Arrowhead will perform discovery, optimization, and preclinical development, entirely funded by Janssen, sufficient to allow the filing of a U.S. Investigational New Drug application 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.

The closing of the transactions is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and is expected to close during the fourth quarter of 2018.

Conference Call and Webcast Details

Investors may access a live audio webcast on the Company's website at http://ir.arrowheadpharma.com/events.cfm. For analysts that wish to participate in the conference call, please dial 855-215-6159 or 315-625-6887 and provide Conference ID 2649806.

A replay of the webcast will be available on the company's website approximately two hours after the conclusion of the call and will remain available for 90 days. An audio replay will also be available approximately two hours after the conclusion of the call and will be available for 3 days.

To access the audio replay, dial 855-859-2056 or 404-537-3406 and provide Conference ID 2649806.

About AROHBV1001

AROHBV1001 (NCT03365947) is evaluating the safety, tolerability, and pharmacokinetic effects of single-ascending doses (SAD) of ARO-HBV in healthy adult volunteers, as well as the safety, tolerability, and pharmacodynamic effects of multiple-ascending doses (MAD) of ARO-HBV in patients with chronic HBV. Dosing in the SAD portion of the study is complete and included five cohorts at dose levels of 35, 100, 200, 300, and 400 mg. Dosing in the MAD portion of the study is ongoing and includes cohorts receiving three doses of ARO-HBV either weekly, bi-weekly, or monthly. Arrowhead submitted a late-breaking abstract with clinical data to the Liver Meeting®, the Annual Meeting of the American Association for the Study of Liver Disease (AASLD), being held in November 2018.

About Arrowhead Pharmaceuticals

Arrowhead Pharmaceuticals develops medicines that treat intractable diseases by silencing the genes that cause them. Using a broad portfolio of RNA chemistries and efficient modes of delivery, Arrowhead therapies trigger the RNA interference mechanism to induce rapid, deep, and durable knockdown of target genes. RNA interference, or RNAi, is a mechanism present in living cells that inhibits the expression of a specific gene, thereby affecting the production of a specific protein. Arrowhead's RNAi-based therapeutics leverage this natural pathway of gene silencing.

For more information, please visit www.arrowheadpharma.com, or follow us on Twitter @ArrowheadPharma. To be added to the Company's email list and receive news directly, please visit http://ir.arrowheadpharma.com/email-alerts.

Safe Harbor Statement under the Private Securities Litigation Reform Act:

This news release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are based upon our current expectations and speak only as of the date hereof. Our actual results may differ materially and adversely from those expressed in any forward-looking statements as a result of various factors and uncertainties, including the safety and efficacy of our product candidates, the duration and impact of regulatory delays in our clinical programs, our ability to finance our operations, the future success of our scientific studies, our ability to successfully develop drug candidates, the timing for starting and completing clinical trials, rapid technological change in our markets, and the enforcement of our intellectual property rights. Our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q discuss some of the important risk factors that may affect our business, results of operations and financial condition. We assume no obligation to update or revise forward-looking statements to reflect new events or circumstances.

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Source: Arrowhead Pharmaceuticals, Inc.

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EXHIBIT 99.2

ARROWHEAD PHARMACEUTICALS
Arrowhead/Janssen Collaboration Conference Call – Prepared Remarks
October 4, 2018
5:30 AM 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 morning everyone. We are happy to announce today that Arrowhead and Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson and Johnson, have signed a license agreement whereby Janssen gets an exclusive worldwide license to Arrowhead's ARO-HBV program and also a collaboration agreement for up to three new candidates utilizing our proprietary Targeted RNAi Molecule, or TRiM™, platform against targets to be selected by Janssen. Our president and CEO, Dr. Christopher Anzalone, will provide an overview of the deal and give some color about what it means for Arrowhead, and we will then open up the call to your questions. Also with us today for the Q&A portion of the call are Ken Myszkowski, our chief financial officer, and Patrick O'Brien, our general counsel. Dr. Bruce Given, our COO and head of R&D is away today.

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 by Arrowhead or our partners. 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?

Chris Anzalone

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

This morning we reported that Arrowhead and Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceuticals Companies of Johnson & Johnson, signed a license agreement for ARO-HBV and a collaboration agreement for up to three RNAi therapeutic candidates that use our proprietary TRiM™ platform against new targets to be selected by Janssen. The total potential deal value is approximately $3.7 billion plus royalties on commercial sales.

Under the terms of the HBV license agreement, Arrowhead will receive $175 million as an upfront payment. In addition, Arrowhead will receive $75 million in the form of an equity investment by Johnson & Johnson Innovation – JJDC, Inc., at a price of $23.00 per share of Arrowhead common stock.

Arrowhead is eligible to receive up to approximately $1.6 billion in milestone payments for the HBV license agreement, including a $50 million near-term milestone payment after initiation of a Phase 2 study. Arrowhead is also eligible to receive approximately $1.9 billion in option and milestone payments for the collaboration agreement related to up to three additional targets. Arrowhead is further eligible to receive tiered royalties up to mid teens on product sales.

Janssen will receive a worldwide exclusive license to the ARO-HBV program, Arrowhead's third-generation subcutaneously administered RNAi therapeutic candidate that leverages the TRiM™ platform and is being developed as a potentially curative therapy for patients with chronic hepatitis B infection. Arrowhead will be responsible for running AROHBV1001, our ongoing Phase 1/2 study of ARO-HBV, and Janssen will be wholly responsible for funding and conducting all future clinical development and commercialization activities.

Janssen may select up to three new targets, against which Arrowhead will develop clinical candidates. These potential new candidates will leverage Arrowhead's proprietary TRiM™ platform, and do not include targets in Arrowhead's current pipeline. Arrowhead will 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 funding and conducting all clinical development and commercialization activities.

Let's unpack what this agreement means strategically, and begin with what it means for patients with chronic HBV infection. I believe this partnership maximizes the chances that patients could have access to functional cures, and this is a big thing. I view ARO-HBV as a very exciting experimental agent against chronic HBV infection and we recently presented early data demonstrating that we may be silencing the virus deeper than has ever been reported in hard to treat patient populations such as HBeAg negatives that are increasingly predominating in many regions. We are doing this with a drug candidate that has been well tolerated thus far and with a platform that has also shown impressive activity and tolerability in a different therapeutic environment, alpha-1 antitrypsin deficiency. AASLD has accepted our late breaker submissions on both of these programs and we look forward to presenting data in November.

Our innovation and execution have been unmatched: we went from a standing start to the current clinical evidence of activity involving more than 100 human subjects across both programs in well less than two years. While we have not yet seen functional cures after just 3 doses of ARO-HBV, we believe that we have created something that can be a powerful tool against chronic HBV infection in the near- to mid-term. So the table is set. Much still needs to be done, but we have put ARO-HBV in a position where success against this disease is possible.

Why, then, should we enter into this partnership now? Why not continue the leadership position we have created for ourselves and push deeper in the clinic toward the market? Sometimes leadership is about knowing where you can lead and when you should be part of a team. For this disease at this time in Arrowhead's development, Janssen is simply better positioned to continue our forward progress and push ARO-HBV to market. I believe that Arrowhead did what no other company could have done to get to where we are, and now I think that Janssen is the ideal company to take the baton.

Let's take a closer look at that. The right Phase 2b studies will be large, expensive, and complicated. Combinations with different compound classes should be interrogated and the permutations are extensive because many different dosing schedules for each compound are possible. Further, it is unclear how long treatment would have to be provided in order to possibly induce consistent functional cures, so there is potentially substantial expense and a large clinical team with experience in global infectious disease studies will be required. These would be challenges for Arrowhead at this time, and Janssen has expansive resources and a demonstrated commitment to these types of programs.

As important as this next step is, it represents just the beginning of the value of this partnership for Arrowhead. Should the Phase 2b studies succeed, large pivotal studies would follow, and, ultimately, a global commercial launch. The industry's experience with Hepatitis C is telling: speed, experience in large complex clinical studies, and established commercial infrastructure will be critical for success.

Janssen has these capabilities, while Arrowhead is not tooled for this, at least not yet and not for this disease.

So it clearly makes sense to partner ARO-HBV with Janssen at this time from a strategic standpoint, and the economics, guaranteed and contingent, make this deal transformational for us.

Let's take a closer look at the economics of the deal. As I mentioned, we will receive $250 million upfront between the equity investment and cash payment. We are eligible to receive a $50 million milestone payment linked to the Phase 2b study, giving us a total of potentially $300 million in the near term. Importantly, our HBV cost exposure will stop, saving us at least $25-30 million in 2019 alone, so this is a possible infusion of over $325 million in the near term on top of the nearly $90 million in combined cash that we reported in our last 10-Q and the recently triggered milestone payment from Amgen that we announced in August. This keeps us from needing to access the capital markets any time soon. Add to this the remaining $600 million in potential milestone payments from the current Amgen agreement and the remaining $3.4 billion in potential milestone payments from Janssen and we have potential access to an additional $4 billion plus royalties in the years ahead.

This is a deep well indeed, and it enables us to create substantial value by retaining our pipeline. Do we need to partner our programs against AAT, APOC3, ANGPTL3, Hif 2-alpha, ENaC and more? Potentially not: we now have substantially more flexibility to capture more value from these and future programs. For a small biotech company to make the leap to a large, vertically integrated pharmaceutical company it needs good technology, good drug candidates, a strong balance sheet, and access to growth capital. We now have all of these, and this is where we are headed.

While we certainly may tap the capital markets in the future to help fund large capital expenditures or endeavors such as building a commercial organization, we believe that we may no longer be dependent on them to fund operations. As I mentioned, this deal is transformational for Arrowhead. We now have a strong partner for HBV to maximize our chances of bringing ARO-HBV to a broad market ***and*** we have the capital necessary to control development and commercialize our pipeline.

This is important from a value capture standpoint and a risk tolerance standpoint. HBV, for all its potential economic and public health upside, continues to have target and reimbursement risk associated with it. These risks are better navigated by a larger company that has existing infectious disease expertise. We think the rest of our pipeline is largely based on well validated targets, understandable regulatory pathways, and clear commercial opportunities. Swapping control of ARO-HBV for the financial resources to develop and commercialize all or a large portion of our growing pipeline is a good trade for us. The TRiM™ platform is enormously flexible, and we have numerous opportunities to develop innovative new medicines.

The current deal with Janssen also speaks to extracting additional value from the TRiM™ platform. Janssen will have an option to develop and commercialize 3 additional targets. We view this as further validation of the platform as well as new value creation. The additional targets will be outside of Arrowhead's current pipeline so will be truly novel for us and, therefore, represent found value. Janssen would fully fund and control clinical development and, ultimately, commercialization. As such, Arrowhead would have a strong partner with global reach to take these potential new medicines to market.

Before we take questions, I want to remind everybody that we announced on September 24th that we will be hosting an Analyst R&D Day in New York on October 16. During this event, Arrowhead management and noted lipidologist, Dr. Ira Goldberg, Chief of the Division of Endocrinology, Diabetes and Metabolism at New York University Langone School of Medicine, will discuss what's next in Arrowhead's emerging lipid pipeline. Specifically, our most advanced candidates: ARO-APOC3 for patients with hypertriglyceridemia; and, ARO-ANG3 for patients with dyslipidemia; both of which are on track for CTA filings by the end of 2018. We will also be discussing our first two programs targeting extra-hepatic tissues. These are ARO-ENaC for patients with cystic fibrosis, and ARO-HIF2 for patients with clear cell renal cell carcinoma. Both of these extra-hepatic candidates have CTAs planned for 2019.

We are extremely excited about what's next and hope that you can listen to the webcast or can join us in person. We have accomplished a lot in recent years, but we feel that we are in the very early stages of explosive growth as a company, and the Janssen partnership provides fuel for that growth. Think of that fuel in three ways: capital; expertise; and opportunities. It provides the capital we need to develop a number of new medicines that we will commercialize ourselves; it provides an experienced partner capable of developing and commercializing ARO-HBV and potentially 3 additional new medicines; and it enables us to take advantage of new opportunities by further developing and expanding the TRiM™ platform and revolutionary new medicines built on it.

I would now like to open the call to your questions. Operator?

Operator

Operator opens the call to questions …