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): **September 24, 2019**

Proteon Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36694**	**20-4580525**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

200 West Street, Waltham, MA 02451
(Address of Principal Executive Offices) (Zip Code)

(781) 890-0102
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	PRTO	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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. ☐

Introductory Comment

Throughout this Current Report on Form 8-K, the terms "we," "us," "our", "Company" and "Proteon" refer to Proteon Therapeutics, Inc., a Delaware corporation.

Item 8.01. Other Events.

Proteon and ArTara Therapeutics, Inc. ("ArTara") held a joint conference call and webcast with investors at 8:30 a.m., Eastern Time, on September 24, 2019, during which they provided supplemental information regarding the proposed combination via merger of Proteon and ArTara and related transactions. A transcript of the conference call is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of Investor Conference Call held on September 24, 2019

SIGNATURE

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 hereunto duly authorized.

Proteon Therapeutics, Inc.

Date: September 24, 2019

By: /s/ George A. Eldridge
George A. Eldridge
Senior Vice President & Chief Financial Officer

Exhibit 99.1

ArTara Therapeutics and Proteon Therapeutics Proposed Combination Webcast

Tuesday, September 24th 2019

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this presentation regarding matters that are not historical facts are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, or the PSLRA. These include statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, stockholders are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. We use words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. Such forward-looking statements are based on management expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the forward-looking statements due to a number of factors, including, but not limited to, risks relating to the completion of the proposed transaction, including the need for Proteon's and ArTara's stockholder approval and the satisfaction of certain closing conditions; the anticipated financing to be completed concurrently with the closing of the proposed transaction; the cash balance of the combined company following the closing of the proposed transaction and the financing, and expectations with respect thereto; the potential benefits of the proposed transaction; the business and prospects of the combined company following the proposed transaction; and the ability of Proteon to remain listed on the Nasdaq Global Market. Risks and uncertainties that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to: the closing of the proposed transaction and the financing; ArTara's plans to develop and commercialize its product candidates, including TARA-002, and Choline Chloride; the timing, costs and outcomes of ArTara's planned clinical trials; expectations regarding potential market size; the timing of the availability of data from ArTara's clinical trials; the timing of any planned investigational new drug application or new drug application; ArTara's plans to research, develop and commercialize its current and future product candidates; ArTara's ability to successfully collaborate with existing collaborators or enter into new collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of ArTara's product candidates; ArTara's commercialization, marketing and manufacturing capabilities and strategy; ArTara's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to ArTara's competitors and industry; the impact of government laws and regulations; ArTara's ability to protect its intellectual property position; and ArTara's estimates regarding future revenue, expenses, capital requirements, and the need for and timing of additional financing following the proposed transaction. These risks, as well as other risks associated with the proposed transaction, will be more fully discussed in the proxy statement/prospectus that will be included in the registration statement on Form S-4 that will be filed by Proteon with the SEC in connection with the proposed transaction. Additional risks and uncertainties are identified and discussed in the "Risk Factors" section of Proteon's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed from time to time with the SEC. Forward-looking statements included in this presentation are based on information available to Proteon and ArTara as of the date of this call. Neither Proteon nor ArTara undertakes any obligation to update such forward- looking statements to reflect events or circumstances after the date of this call.

This statements in this presentation do not constitute an offer to sell, or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No public offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

This presentation is made in respect of a proposed transaction involving ArTara and and Proteon, and Proteon intends to file a registration statement on Form S-4 with the SEC, which will contain a proxy statement/prospectus and other relevant materials, and plans to file with the SEC other documents regarding the proposed transaction. The final proxy statement/prospectus will be sent to the stockholders of Proteon in connection with the Proteon's special meeting of stockholders to be held to vote on matters relating to the proposed transaction. The proxy statement/prospectus will contain information about Proteon, ArTara, the proposed transaction, and related matters. **STOCKHOLDERS OF PROTEON ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE, AS THEY WILL CONTAIN IMPORTANT INFORMATION THAT STOCKHOLDERS OF PROTEON SHOULD CONSIDER BEFORE MAKING A DECISION ABOUT THE PROPOSED TRANSACTION AND RELATED MATTERS.** In addition to receiving the proxy statement/prospectus and proxy card by mail, Proteon stockholders will also be able to obtain the proxy statement/prospectus, as well as other filings containing information about Proteon, without charge, from the SEC's website at www.sec.gov or, without charge, by directing a written request to: Proteon Therapeutics, Inc., 200 West St. Waltham, MA 02451, Attention: Investor Relations.

Proteon, ArTara and their respective executive officers, directors, certain members of management and certain employees may be deemed, under the SEC rules, to be participants in the solicitation of proxies from Proteon stockholders with respect to the matters relating to the proposed transaction. Information regarding Proteon's executive officers and directors is available in Proteon's proxy statement on Schedule 14A for its 2018 annual meeting of stockholders, filed with the SEC on April 26, 2018 and Proteon's Annual Report on Form 10-K and the amendment thereto for the year-ended December 31, 2018. These documents are available free of charge at the SEC's website at www.sec.gov or by going to Proteon's investor and media page on its corporate website at www.proteontherapeutics.com. Additional information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of proxies in connection with the proposed transaction, and a description of their direct and indirect interests in the proposed transaction, which may differ from the interests of Proteon's stockholders generally, will be set forth in the proxy statement/prospectus that Proteon intends to file with the SEC in connection with its stockholder vote on matters relating to the proposed transaction. Proteon stockholders will be able to obtain this information by reading the proxy statement/prospectus when it becomes available.

Safe Harbor Statement
George Eldridge
Chief Financial Officer, Proteon Therapeutics

Thank you, good morning and welcome to the call. Before we begin, I would like to remind everyone that our remarks during this call may include forward-looking statements. These forward-looking statements, including statements regarding the timing of the transaction, the cash balance of the combined company at closing, the potential benefits of the combined company to the stockholders, the ability of Proteon to remain listed on the Nasdaq Global Market, are subject to risks and uncertainties. Actual results may differ materially from our expectations. For a discussion of these risks and uncertainties, please review the cautionary statements regarding forward-looking statements included in our earnings release and the cautionary statements and risk factors included in our 2018 Form 10-K filed with the SEC. These are also available on our website. All forward-looking statements are made as of today's date. Except to the extent required by law, we do not undertake any obligation to update any forward-looking statements. We also caution you against relying on any forward-looking statements.

Joining me on today's call are Tim Noyes, Proteon's Chief Executive Officer and Jesse Shefferman, ArTara Therapeutics Chief Executive Officer who will become the Chief Executive Officer of the combined company following the anticipated close of this transaction.

Now I will turn the call over to Tim who will be going over some of the details of the purpose of today's call.

ArTara Therapeutics and Proteon Therapeutics Merger
Tim Noyes
Chief Executive Officer, Proteon Therapeutics

Thanks George. Good morning everyone and thanks for joining our call today. We will discuss the merger agreement that we have entered into for a transaction to combine Proteon and ArTara and provide you with an overview of ArTara and its pipeline. This transaction is one that Proteon's board and management team are excited about for several reasons which we will outline in a moment.

As you know, yesterday we issued a press release announcing that Proteon has entered into a definitive merger agreement with privately-held ArTara Therapeutics.

The proposed transaction will result in a combined company expected to focus on development of immunological therapies for rare and specialty disorders, as well as therapies for rare hepatology and metabolic disorders, under the leadership of Jesse Shefferman, ArTara's CEO.

Under the terms of the agreement, ArTara's stockholders have agreed to exchange their shares of ArTara for newly-issued shares of Proteon Therapeutics common stock. On a pro

forma basis, current Proteon stockholders are expected to own approximately 10% of the combined company and current ArTara stockholders are expected to own approximately 29% of the combined company. Investors in the PIPE financing that will close concurrently with the merger will own approximately 61% of the combined company, in each case subject to certain adjustments based on net cash of Proteon and ArTara prior to closing.

The transaction has been approved by the boards of directors of both companies and is expected to close in the fourth calendar quarter of 2019, subject to the approval of each of Proteon and ArTara stockholders and other customary conditions. ArTara has organized a syndicate of healthcare-dedicated investors who have committed to invest $42.5 million in the combined company concurrently with the closing of this transaction. The closing of the transaction is also subject to the satisfaction of the closing conditions pursuant to such financing.

Upon closing, the combined company will be known as ArTara Therapeutics and applied for a ticker symbol TARA on the Nasdaq Capital Market. The combined company will be headquartered in New York City and its board of directors will be comprised of seven directors, with five such members designated by ArTara, one member designated by Proteon and finally Mr Shefferman. The decision to pursue this agreement with ArTara follows an extensive review of strategic alternatives by the board and management of Proteon. We believe this transaction offers our stockholders compelling opportunity for long-term value creation.

Here to tell you more about ArTara, let me introduce Jesse Shefferman, the CEO of ArTara Therapeutics. Jesse?

ArTara Therapeutics
Jesse Shefferman
Chief Executive Officer, ArTara Therapeutics

Opening remarks

Thanks Tim and thanks to all of you joining this morning's call.

Before I begin my comments, I would like to remind our listeners that I will be following a presentation uploaded to our webcast. It is also available on Proteon's website at www.proteontherapeutics.com. You can also find this presentation on the ArTara website at www.artaratx.com.

Experienced leadership

At ArTara, we are steadfastly working to bring life-saving therapies to patients who suffer from rare diseases. Our leadership team is comprised of a core group of seasoned biopharma veterans with diverse backgrounds across clinical, business, early development and operations.

Our board of directors is comprised of a strong team with a diverse set of skills and the leadership and insight to help us grow for years to come.

Pipeline

We are especially skilled at identifying and acquiring overlooked or undervalued assest and modernizing or optimizing development programs for these de-risked assets. Today we are developing two late-stage pipeline candidates supported by significant human safety and efficacy data and real-world evidence of value to patients.

Our lead program is a therapeutic preparation of an attenuated, genetically distinct strain of streptococcus pyogenes, essentially the same as a Japan-approved product called OK-432. We are calling this comparable strep pyogenes program TARA-002. It is in development for the treatment of lymphatic malformations, or LMs.

Our second asset is IV Choline Chloride, a phospholipid substrate replacement intended to treat intestinal-failure-associated liver disease, or IFALD. IFALD links to choline deficiency in patients with intestinal failure who require long-term parenteral nutrition known as PN.

We hold the INDs for both OK-432 and IV Choline Chloride and both have been granted orphan drug designation by the FDA.

TARA-002

So, let us dive deeper on our programs. As I mentioned, our lead asset is TARA-002. TARA-002 will employ the same genetically-distinct strain of strep pyogenes as used in the manufacturing of the Japan-approved product OK-432. OK-432 is the standard of care in Japan and Taiwan for LM's and we hold worldwide rights ex-Japan and Taiwan for its underlying technology and active material.

OK-432 was originally approved in Japan in the 1970s as an oncology agent. In the mid-1990s its anti-tumoral properties were interrogated in Japan in children with LMs and it demonstrated powerful efficacy, leading to an approval index indication.

We have begun propagating our strep pyogenes cell bank and are building a modern manufacturing process intended to be substantively comparable to that used in manufacturing OK-432. Once we demonstrate this comparability, we plan to to utilize the extensive data and literature generated by OK-432 over the years for TARA-002's regulatory strategy. Principal among that, we have licensed data generated by a multicenter study led by the University of Iowa in over 600 LM patients treated with OK-432 in the United States. This included a well-designed randomized clinical study of 117 pediatric patients. We are currently digitizing over 20,000 patient records from the study to begin the process of building our regulatory data package. This data and our manufacturing comparability to OK-432 will be the basis of our regulatory approach.

Lymphatic malformation

On the next slide, a little bit more about lympatic malformation. As you can see in this photo, LMs are a significantly burdensome condition and almost exclusively affect children. As I mentioned before, LMs are rare, non-malignant lesions consisting of dilated, lymphatic fluid-filled sacs caused by abnormal development of the lymphatic vasculature system.

LMs are typically observed in utero and, outside of Japan or Taiwan, the standard of care is surgical excision. Given that these masses occur most frequently as antero-lateral cervical masses, as you can see here in this child, we believe that this is not an optimal treatment. Indeed, the literature suggests that these surgeries demonstrate a mean complication rate of

about 33% and a mean recurrence rate of 55%. Our view is that this creates significant unmet need for a more effective treatment for these children; a treatment such as TARA-002.

Clinical experience

So, the next seven slides detail the design, results and conclusions of the multi-center study of OK-432 led by Iowa.

Randomized controlled study

On this slide, we demonstrate the design of the randomized controlled study conducted at 27 pediatric referral centers across the US. There were 151 patients included in the study with 117 patients randomized two-to-one to either immediately receive OK-432 treatment or six months of observation for spontaneous regression. If no regression was observed, then these patients in the delayed treatment group were treated with OK-432. Treatment consisted of up to four injections of OK-432 in eight-week intervals, with imaging conducted 14 days after each injection.

The study's primary endpoint measured clinical success, defined as a substantial or complete response at six months in the immediate treatment group or compared to spontaneous regression in the delayed treatment group.

A successful outcome was defined as response rate quantified by percentage reduction in volume or lesion shrinkage. A complete response was 90-100% volume reduction and substantial response was defined as a 60-89% reduction.

Patient disposition

On slide ten, we show that 92 patients and 27 open-label patients completed the study. The open-label patients did not meet inclusion criteria, typically owing to inappropriate lesion type or age. Note in the demographics chart to the right that the oldest patient in the randomized segment of the trial was 15.5 years old, so this was a true pediatric study.

Compelling efficacy in large, eight-year study

The next slide reports the results of the study. On the left-hand side we show that, of the 117 intent-to-treat patients, 68% in the immediate treatment group showed a complete or substantial response. Comparatively, zero patients in the delayed treatment group demonstrated complete or substantial response after six months. This is the primary endpoint and it was obviously achieved. On the right side of the page we show the final results in all groups after the control group was treated with OK-432. Here we can see that, of the patients who completed the study, 86% of the immediate treatment group demonstrated a complete or substantial response, 82% of the open-label group had a complete or substantial response, and 75% of the delayed treatment group, once treated with OK-432, demonstrated a complete or substantial response. 91% of patients demonstrated durability of effect at a median 2.9 years and the median duration of response was not met.

On the next slide we further illustrate the effectiveness of OK-432 in appropriate lesions. 79 patients had macrocystic lesions and 94% of these patients had a complete or substantial response. In fact, 71% of these patients had a complete response, which represented better than 90% shrinkage of the lesion. In the 40 patients with mixed lesions, 63% still had a complete or substantial response. Finally, no patients with microcystic LMs demonstrated a complete or substantial response.

Images, before and after treatment

Slide 13 puts these numbers into perspective. These before and after pictures represent the robust results generated in patients with appropriate lesion types. This treatment, of course, improved these children's health but there is a bigger story about the impact of treatment with OK-432. We hear many anecdotal stories about these children's lives and indeed their whole families being set on a new trajectory after only 1-4 injections of this product versus an expensive, complicated surgery. There are hundreds of children who have been treated and experienced similar life-changing results.

Compelling safety with up to eight-year follow-up

However, back to the study. Slide 14 here describes the safety experience of the study for which there is eight years of long-term follow-up data in 99 patients. Most treatment-related AEs were typical of an injected immunostimulant. The most common were injection site reactions, fever and fatigue which resolved within days. Other minor treatment-related AEs included temporary brachial plexus compression, myalgia, infections treated with oral antibiotics, intra-cystic hemorrhage and dehydration. There were 11 treatment-related SAEs including infection, edema, airway obstruction and intra-cystic hemorrhage. There were two SAEs deemed not related to treatment and these included a death due to tracheotomy tube obstruction and loss of vision in one eye following proptosis.

Conclusion

In conclusion, on slide 15, 94% of patients with macrocystic LMs who completed the study and 63% of completing patients with mixed LMs had clinical meaningful improvement. No patients in the delayed treatment group experienced spontaneous resolution prior to treatment, and 75% of patients in the delayed treatment group received a clinical benefit after they were treated with OK-432

The response to OK-432 immunotherapy was durable in 91% of patients who demonstrated a complete or substantial response to therapy over a median follow-up period of 2.9 years. There were no serious hematologic, renal, hepatic, or cardiac adverse side effects noted upon pre-treatment, concurrent and post-treatment analysis.

IV Choline Chloride

So, let us shift gears to our second program, IV Choline Chloride. IV Choline Chloride is being developed for the treatment of intestinal-failure-associated liver disease, or IFALD. IFALD is a progressive liver disease that impacts a large number of patients who rely on parenteral nutrition for long-term survival. The etiology of IFALD is considered multifactorial with a substantial body of literature implicating choline deficiency as a key cause.

Choline: a key factor in IFALD

So, what is choline? It is an essential nutrient in that it is integral to multiple processes in the body through its activity as a key methyl donor. Our focus is on its role as the root precursor to phosphatidylcholine, or PC, which is the most ubiquitous phospholipid in mammalian cells.

In the liver, PC is hypothesized to play critical roles in transport of fats from the liver and for healthy balanced mixed micelles in bile. It is important to note that the only reliable way to replenish choline and thus PC stores in the body is through exogenous consumption. For most people, a normal diet is typically sufficient to meet these choline needs. However,

patients with intestinal failure that depend on parenteral nutrition are unable to absorb choline adequately; and further, no parenteral nutrition preparation contains sufficient amounts of choline to meet this shortfall. Thus, we believe this insufficiency plays a key role in IFALD.

FDA-accepted definition of IFALD

Slide 20 provides the definition of IFALD which was confirmed by the FDA in an end-of-phase-two meeting we held with them in November of last year. In the meeting and in the division's final written minutes, the agency agreed that IFALD is characterized by, one, more than six months of intestinal failure; two, the presence of cholestasis defined by either elevated levels of alkaline phosphatase, bilirubin or by histology; three, the presence of steatosis or fatty liver, as confirmed by MRI-PDFF, other imaging or biopsy. There may be other signs of liver injury as well but these are the key characteristics of the disease.

Choline substrate replacement IFALD studies

On slide 19 we summarize work done in the 1990s by a pioneering researcher, Dr Alan Buchman. Dr Buchman's working hypothesis was that insufficent exogenous choline consumption drives insufficient phosphatidylcholine and in turn, insufficient PC causes injury to hepatocytes and the biliary system.

Dr Buchman began testing the hypothesis that IV choline substrate replacement could be a treatment for IFALD. In total, Dr Buchman conducted four studies testing this hypothesis. He conducted an oral lecithin study. Lecithin is the most common foodborne version of choline. He also conducted an IV choline PK study, a four-patient IV choline pilot study and a 15-patient randomized, controlled IV choline study. We have licensed all of the data to these studies and own the IND and the ODDs associated with them.

These studies produced compelling raw data but needed some modernization and clean up by the time we licensed the data and took over the IND. We will talk about that; but first, an overview of the original study.

Multi-center phase 2A study

Study design

Here we summarize the design of the original 15-patient randomized placebo-controlled study in PN patients. It was conducted over 24 weeks where patients were randomized one-to-one, with the treatment arm receiving a 2-gram dose of choline per day, with the control arm being given placebo. As I said, it was a 24-week study, with follow-up at week 34. The study was funded by the FDA and carried out at Emory, Baylor and UCLA.

Patient disposition

Page 21 illustrates patient demographics; and you can see that the study was randomized one-to-one, with just over half the patients completing the study.

Phase 2A reanalysis

Updated methods and formats

Back to the raw data. As I said, the study produced compelled raw data but needed modernization and clean up by the time we licenced the data package and took over the IND. Here we have relayed some of those steps. Specifically, we retrospectively gathered additional patient records to bolster the data quality. We digitized each individual patient

record, similar to what we're doing with TARA-002. We converted older CT imaging data to MRI-PDFF via a validated algorithm and focused on patients whose cholestasis measures fit the profile of more advanced disease. Finally, we utilized modern statistical methods to impute values for some of the missing data from this older study.

Improvement in steatosis

Here we show some of the outcomes of that reanalysis of the raw data. On this slide, you can see significant improvement in liver fats in the active group versus placebo. Imaging supports this significant improvement, as you can see in the scans on the right-hand side. At the beginning, a patient with a very sick liver; 24 weeks later a full resolution of steatosis.

Improvement in cholestasis

On slide 24, we show the marked separation between the active and placebo group in cholestasis from the study, as measured by alkaline phosphatase levels. Perhaps more striking in this comparison is that of active to placebo in patients whose alk phos levels were greater than 1.5 times upper limit of normal, which is widely viewed as the point at which physicians become concerned about these biomarkers. Even at only seven total patients, the difference was still meaningful in a number of observation weeks.

Most importantly, these results achieved the definition of clinically meaningful improvement for both steatosis and cholestasis based on our dialogue with the FDA. Improvement in steatosis demonstrated of 31-54% in the active group exceeded the FDA agreed threshold of 30% and improvement in cholestasis of 20-30% met or exceeded the FDA's view that 20% constitutes a clinically meaningful improvement.

Safety

There were a handful of SAEs in the study, mostly in the placebo group. These included catheter sepsis, hepatic failure resulting in death and peroneal pain due to recurrent desmoid tumor. In the active group one patient was hospitalized for dehydration and fever but none of the AEs were deemed related to study drug.

Conclusion

In conclusion, in a phase-two study, IV choline substrate replacement was found to be safe and produced statistically and clinically meaningful improvements in the defining pathologies of IFALD. We are continuing our discussions with the FDA regarding the protocol and statistical analysis plan for the next phase of development for this program. We expect those to conclude in 2020. Most encouraging for us is that the agreement on the overall clinical development plan for IV Choline in IFALD was reached with the FDA at our end-of-phase-two meeting in late 2018. We are ready to get started on next steps with this very important program.

Closing remarks

In closing, as ArTara looks forward, we have a lot of wood to chop over the next several months and beyond as we work through the mechanics of closing this deal and as we continue to build an organization capable of supporting our goals.

We are very excited by the prospects afforded by the combination of ArTara with Proteon. We look forward to making an impact on our patients' lives and, in doing so, build value for them, for our employees and for our stockholders.

That concludes my prepared remarks. Please reach out to us if you have any additional questions and thank you everybody for joining our call today.