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As filed with the Securities and Exchange Commission on January 30, 2020

Registration No. 333-

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

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ARTARA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-4580525**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1 Little West 12th Street
New York, New York 10014
(646) 844-0337
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Jesse Shefferman
Chief Executive Officer
ArTara Therapeutics, Inc.
1 Little West 12th Street
New York, New York 10014
(646) 844-0337
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

Ryan S. Sansom, Esq.
Karen E. Deschaine, Esq.
Cooley LLP
4401 Eastgate Mall
San Diego, California 92121
(858) 550-6000

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer ☒	Smaller reporting company ☒ 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 7(a)(2)(B) of the Securities Act. ☒

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered[(1)]	Proposed Maximum Offering Price per Share[(2)]	Proposed Maximum Aggregate Offering Price[(2)]	Amount of Registration Fee
Common stock, par value $0.001 per share	5,776,244	$33.31	$192,406,688	$24,974.39

(1) Consists of an aggregate of 5,776,244 shares of the registrant's common stock, including 3,879,356 shares of common stock issuable upon the conversion of an aggregate of 3,879.356 shares of Series 1 convertible non-voting preferred stock, par value $0.001 per share, of the registrant, all of which were acquired by the selling stockholders in a private placement. Pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares of common stock being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares of common stock being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Pursuant to Rule 457(c), calculated on the basis of the average of the high and low prices per share of common stock reported on The Nasdaq Capital Market on January 29, 2020.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JANUARY 30, 2020

PROSPECTUS

5,776,244 shares of Common Stock

This prospectus covers the offer and resale by the selling stockholders identified in this prospectus of up to an aggregate of 5,776,244 shares of our common stock, which includes 3,879,356 shares of our common stock issuable upon the conversion of our Series 1 convertible non-voting preferred stock, sold to the selling stockholders in a private placement on January 9, 2020, or the Private Placement.

We are not selling any shares of common stock under this prospectus and will not receive any proceeds from the sale by the selling stockholders of such shares.

Sales of the shares by the selling stockholders may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. The selling stockholders may sell shares to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders, the purchasers of the shares, or both.

We are paying the cost of registering the shares of common stock covered by this prospectus as well as various related expenses. The selling stockholders are responsible for all selling commissions, transfer taxes and other costs related to the offer and sale of their shares.

Our common stock is listed on The Nasdaq Capital Market under the symbol "TARA." On January 29, 2020, the last reported sale price of our common stock was $33.50 per share.

Investing in our common stock involves a high degree of risk. Before making an investment decision, please read the information under "Risk Factors" beginning on page 7 of this prospectus and under similar headings in any amendment or supplement to this prospectus or in any filing with the Securities and Exchange Commission that is incorporated by reference herein.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2020

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC, using a "shelf" registration process. Under this registration statement, the selling stockholders may sell from time to time in one or more offerings the common stock described in this prospectus.

We have not authorized anyone to provide you with information other than the information that we have provided or incorporated by reference in this prospectus and your reliance on any unauthorized information or representation is at your own risk. This prospectus may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that the information appearing in this prospectus is accurate only as of the date of this prospectus and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, or any sale of our common stock. Our business, financial condition and results of operations may have changed since those dates.

Unless otherwise stated, all references in this prospectus to "we," "us," "our," "ArTara," the "Company" and similar designations refer to ArTara Therapeutics, Inc. This prospectus contains references to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and any applicable prospectus supplement or free writing prospectus, including the documents that we incorporate by reference herein and therein, contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. As such, our actual results may differ significantly from those expressed in any forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

We discuss many of these risks in greater detail under "Risk Factors" in this prospectus, in the "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections incorporated by reference from our most recent Annual Report on Form 10-K and in our Quarterly Reports on Form 10-Q for the quarterly periods ended subsequent to our filing of such Annual Report on Form 10-K, the Company's prospectus filed with the SEC on December 19, 2019 pursuant to Rule 424(b)(3) under the Securities Act, as well as any amendments thereto reflected in subsequent filings with the SEC.

Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should read this prospectus, any applicable prospectus supplement, together with the documents that we have filed with the SEC that are incorporated by reference and any free writing prospectus we have authorized for use in connection with this offering, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

PROSPECTUS SUMMARY

This summary highlights certain information about us, the Private Placement and selected information contained elsewhere in or incorporated by reference into this prospectus. This summary is not complete and does not contain all of the information that you should consider before making an investment decision. For a more complete understanding of our company, you should read and consider carefully the more detailed information included or incorporated by reference in this prospectus and any applicable prospectus supplement, including the factors described under the heading "Risk Factors" beginning on page 7 of this prospectus, as well as the information incorporated herein by reference, before making an investment decision.

Company Overview

ArTara is a development-stage, clinical biopharmaceutical company focused on bringing life-saving therapies to patients who suffer from rare diseases. The Company's core strategy is to identify and acquire or license overlooked or undervalued products or product candidates and modernize or optimize development programs for these assets. ArTara's current development programs focus on therapeutics for rare structural disorders as well as rare hepatology/gastrointestinal and metabolic disorders.

TARA-002 / OK-432

TARA-002, ArTara's lead program, is a follow-on biologic of the immunotherapy OK-432 (marketed as Picibanil® in Japan and Taiwan by Chugai Pharmaceutical Co., Ltd., or Chugai Pharmaceutical). ArTara will utilize the same regulatory starting materials as OK-432 and will manufacture TARA-002 using an updated version of the same proprietary processes used to manufacture OK-432. Functionally, ArTara's lead product is OK-432. ArTara has designated this product as TARA-002 in order to differentiate the regulatory path in the United States and other geographies from that of OK-432 in Japan.

TARA-002 is a cell therapy developed from the master cell line of the same genetically distinct *Streptococcus pyogenes* (group A, type 3) Su strain as OK-432 and will be manufactured in a similar manner following Good Manufacturing Practices, or GMP. The Company believes that these two factors will result in a product that is comparable enough to OK-432 such that for the development and regulatory applications of TARA-002, it can use the historic data and literature amassed for OK-432 in the four decades since it was first approved in Japan.

ArTara entered into an agreement with Chugai Pharmaceutical in June 2019 to support ArTara's development of TARA-002. The agreement provides ArTara with exclusive access, for a limited period, to certain materials and documents relating to OK-432 including the master cell bank of *Streptococcus pyogenes* used in the manufacture of OK-432. Additionally, the agreement provides technical support during a certain period. ArTara plans to utilize the materials, proprietary manufacturing process and technical support provided by Chugai Pharmaceutical to produce TARA-002 at a GMP-compliant facility in the United States. Under the agreement with Chugai Pharmaceutical, ArTara will have sole responsibility for the development and commercialization of TARA-002.

In Japan, OK-432 is indicated for: the treatment of lymphangiomas; the prolongation of survival time in patients with gastric cancer (postoperative cases) or primary lung cancer in combination with chemotherapy; and the reduction of cancerous pleural effusion or ascites in patients with lung cancer or gastrointestinal cancer respectively, head and neck cancer (maxillary cancer, laryngeal cancer, pharyngeal cancer, and tongue cancer) and thyroid cancer that are resistant to other drugs.

ArTara plans to pursue development of TARA-002 for the treatment of lymphatic malformations, or LMs. ArTara also plans to explore the potential of TARA-002 in other indications where its utility as

a sclerosant (an injectable irritant) or as a systemic immunostimulant has been hypothesized to be of therapeutic benefit.

Lymphatic Malformations

ArTara intends to initially seek approval of TARA-002 for the treatment of lymphatic malformations. Lymphatic malformations are rare, non-malignant cystic masses that primarily form in the head and neck region of children before the age of two. The International Society for the Study of Vascular Anomalies categorizes LMs as macrocystic, microcystic, or mixed. Macrocystic LMs are characteristically large, fluid-filled cysts with a thin endothelial lining. Microcystic LMs have very limited internal space with a thick, irregular endothelial lining. Mixed LMs are comprised of varying degrees of both macrocystic and microcystic LMs.

In the United States, LMs are present in approximately one in every 4,000 live births. Outside of Japan and Taiwan, the standard of care for LMs is surgical excision, which is associated with high rates of recurrence and complications. There are no pharmacotherapies currently approved for lymphatic malformations except in Japan and Taiwan, where OK-432 is marketed. In these countries, OK-432 has been the standard of care for LMs for almost 25 years. When OK-432 is administered locally for LMs, it is hypothesized that innate immune cells within the cyst are activated and produce a strong immune cascade. Neutrophils and monocytes infiltrate the cyst and various cytokines, including interleukins IL-6, IL-8, IL-12, interferon (IFN)-g, tumor necrosis factor (TNF)-a, and vascular endothelial growth factor (VEGF) are secreted by immune cells within the cyst in response to the presence of OK-432. In concert, these immune activities induce a strong local inflammatory reaction in the cyst wall, resulting in fluid drainage, shrinkage and fibrotic adhesion of the cyst.

The University of Iowa led a multi-year study in LMs beginning in the late 1990s that included three separate studies including a randomized, controlled safety and efficacy study. In this phase 2 clinical trial, 151 patients with LMs (>90% pediatric) were treated with OK-432. A clinically successful outcome was demonstrated in 94% (74/79) of patients with macrocystic LMs and 63% (25/40) of patients with mixed LMs who completed treatment per protocol. Following these results, an additional 500 pediatric patients were treated with OK-432 in the United States at 27 different pediatric referral centers. ArTara has entered into an exclusive license agreement with the University of Iowa for the data from these clinical trials and is currently analyzing such data.

ArTara plans to request a meeting with the U.S. Food and Drug Administration, or FDA, in 2020 to determine if additional clinical data are needed to support the submission of a Biologics License Application for TARA-002 for the treatment of LMs.

IV Choline Chloride

IV Choline Chloride is an intravenous, or IV, substrate replacement therapy initially in development for patients receiving parenteral (typically intravenous) nutrition, or PN, who have intestinal failure associated liver disease, or IFALD.

Choline is a known important substrate for phospholipids that are critical for healthy liver function. Because PN patients cannot sufficiently absorb adequate levels of choline and no available PN components contain sufficient amounts of choline to correct this deficit, PN patients often experience a prolonged progression to hepatic failure and death, with the only known intervention being a dual small bowel / liver transplant. If approved, IV Choline Chloride would be the first approved therapy for IFALD. It has been granted Orphan Drug Designations, or ODDs, by the FDA for the treatment of IFALD and the prevention of choline deficiency in PN patients.

ArTara entered into a license agreement with Dr. Alan Buchman for exclusive rights to the IND, ODDs and other regulatory assets related to IV Choline Chloride, as well as exclusive rights to the data from previously conducted phase 1 and phase 2 clinical trials led by Dr. Buchman.

Intestinal Failure Associated Liver Disease

IFALD is associated with significant morbidity in patients who rely on PN for long-term survival. It is believed that there are multiple contributing factors to the development of IFALD with a substantial body of literature pointing to choline deficiency as a key cause.

IFALD is uniquely characterized by the presence of both steatosis (toxic fat accumulation in liver cells) and cholestasis (damage to the biliary system in the liver) in patients who are chronic (greater than six months) PN users.

The results of a randomized, controlled, phase 2 clinical trial demonstrated that treatment with IV Choline Chloride resulted in normalization of plasma-free choline concentrations, improvement of hepatic steatosis, and a clinically meaningful and statistically significant improvement in cholestasis in patients dependent on PN. ArTara had an end of phase 2 meeting with the FDA in November 2018 and received the FDA's support for the design of studies necessary to complete the registration package for IV Choline Chloride for the treatment of IFALD.

Company Information

We were originally incorporated in March 2006 in the State of Delaware under the name Proteon Therapeutics, Inc., and at that time, acquired Proteon Therapeutics, LLC, our predecessor, which was formed in June 2001. In January 2020, we effected a reverse merger, pursuant to which a wholly owned subsidiary of ours merged with and into ArTara Therapeutics, Inc., with ArTara surviving as a wholly owned subsidiary of ours. In January 2020, we changed our name from Proteon Therapeutics, Inc. to ArTara Therapeutics, Inc. Our principal executive offices are located at 1 Little West 12th Street, New York, New York 10014, our telephone number is (646) 844-0337 and our website address is www.artaratx.com. The information contained in or accessible through our website does not constitute part of this prospectus.

Merger Transaction

On January 9, 2020, ArTara Therapeutics, Inc., formerly known as Proteon Therapeutics, Inc., completed its previously announced merger transaction with ArTara Subsidiary, Inc. (formerly ArTara Therapeutics, Inc., "ArTara") in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of September 23, 2019, by and among the Company, REM 1 Acquisition, Inc., and ArTara (as amended on November, 19, 2019, the "Merger Agreement"), pursuant to which REM 1 Acquisition, Inc. merged with and into ArTara, with ArTara surviving as a wholly owned subsidiary of the Company (the "Merger").

On January 9, 2020, in connection with, and prior to the completion of, the Merger, the Company effected a 1-for-40 reverse stock split of its common stock (described below), ArTara changed its name from "ArTara Therapeutics, Inc." to "ArTara Subsidiary, Inc.", and the Company changed its name from "Proteon Therapeutics, Inc." to "ArTara Therapeutics, Inc." In addition, immediately following the closing of the Private Placement (described below), all of the outstanding shares of the Company's Series A Preferred Stock were converted into shares of the Company's common stock.

Private Placement

On September 23, 2019, we entered into a Subscription Agreement, as amended by a First Amendment to Subscription Agreement dated as of November 19, 2019, or collectively, the Subscription Agreement, with the selling stockholders named in this prospectus, pursuant to which we sold and issued shares of our common stock and shares of our Series 1 convertible non-voting preferred stock. Concurrently with the execution of the Subscription Agreement, we entered into a Registration Rights Agreement dated September 23, 2019 with the selling stockholders named in this prospectus, or the Registration Rights Agreement.

At the closing under the Subscription Agreement that occurred on January 9, 2020, we sold and issued to the selling stockholders (i) 1,896,888 shares of our common stock at a purchase price of approximately $7.01 per share, and (ii) 3,879.356 shares of our Series 1 convertible non-voting preferred stock, in lieu of shares of our common stock, at a price of $7,011.47 per share. The total purchase price paid by the selling stockholders in the closing was approximately $40.5 million. Each share of Series 1 convertible non-voting preferred stock is convertible into 1,000 shares of our common stock, subject to certain beneficial ownership conversion limitations.

Under the terms of the Registration Rights Agreement, we agreed to prepare and file, within 60 days after the closing, one or more registration statements with the SEC to register for resale the shares of our common stock issued under the Subscription Agreement and the shares of our common stock issuable upon conversion of the Series 1 convertible non-voting preferred stock issued pursuant to the Subscription Agreement, and generally to cause the applicable registration statements to become effective within 90 days after the closing under the Subscription Agreement.

Selected Financial Data of Proteon Therapeutics, Inc. Reflecting Reverse Stock Split

On January 9, 2020, in connection with, and prior to the completion of, the Merger, the Company effected a 1-for-40 reverse stock split of its common stock (the "Reverse Stock Split"). No fractional shares have been issued in the Reverse Stock Split and the remaining fractions were paid out in cash.

Please see below selected financial data presenting selected share and per share data reflecting the effect of the 1-for-40 reverse stock split on all periods previously reported. We derived the selected financial data for the three and nine months ended September 30, 2019 and 2018 from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019. We derived the selected financial data for the years ended December 31, 2018, 2017, 2016, 2015 and 2014 set forth below from our Annual Report on Form 10-K and Amendment No. 1 to our Annual Report on Form 10-K/A for the year ended December 31, 2018. Our results for interim periods are not necessarily indicative of the results that may be expected for the entire year. There were no changes to the selected balance sheet data presented in the aforementioned Annual Report on Form 10-K or in the aforementioned Quarterly Report on Form 10-Q, resulting from the reverse stock split. The share and per share

information below is preliminary and has not been reviewed or audited by our independent registered public accounting firm.

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands, except share and per share data)			
Net Loss	$ (1,536)	$ (4,510)	$ (13,382)	$ (15,470)
Net Loss attributable to common stockholders	$ (1,536)	$ (4,510)	$ (13,382)	$ (15,470)
Net loss per share attributable to common stockholders—basic and diluted	$ (3.14)	$ (10.12)	$ (27.48)	$ (34.91)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders—basic and diluted	489,634	445,604	486,912	443,127

	For the Years Ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except share and per share data)				
Net Loss	$ (20,729)	$ (29,964)	$ (28,526)	$ (21,377)	$ (3,342)
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ —	$ —	$ —	$ (6,353)
Accretion of convertible preferred stock to redemption value	$ —	$ (6,747)	$ —	$ —	$ —
Net Loss attributable to common stockholders	$ (20,729)	$ (36,711)	$ (28,526)	$ (21,377)	$ (9,695)
Net loss per share attributable to common stockholders —basic and diluted	$ (45.80)	$ (85.01)	$ (68.90)	$ (51.94)	$ (126.55)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders—basic and diluted	452,555	431,858	414,044	411,603	76,612

The Offering

Common stock offered by the selling stockholders	5,776,244 shares(1)
Terms of the offering	Each selling stockholder will determine when and how it will sell the common stock offered in this prospectus, as described in "Plan of Distribution."
Use of proceeds	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus.
Risk factors	See "Risk Factors" beginning on page 7, for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq Capital Market symbol	TARA

(1) Includes 3,879,356 shares of common stock issuable upon conversion of an aggregate of 3,879.356 shares of Series 1 convertible non-voting preferred stock held by certain of the selling stockholders named in this prospectus.

The selling stockholders named in this prospectus may offer and sell up to 5,776,244 shares of our common stock. Our common stock is currently listed on The Nasdaq Capital Market under the symbol "TARA." Shares of our common stock that may be offered under this prospectus will be fully paid and non-assessable. We will not receive any of the proceeds of sales by the selling stockholders of any of the common stock covered by this prospectus. Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholders for offer and resale, we are referring to the shares of common stock issued to the selling stockholders, including in connection with the conversion of the Series 1 convertible non-voting preferred stock issued in the Private Placement as described above. When we refer to the selling stockholders in this prospectus, we are referring to the selling stockholders identified in this prospectus and, as applicable, their permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below and described in the sections entitled "Risk Factors" in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, as filed with the SEC, which are incorporated herein by reference in their entirety, as well any amendment or updates to our risk factors reflected in subsequent filings with the SEC, including any applicable prospectus supplement. Our business, financial condition, results of operations or prospects could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose all or part of your investment. This prospectus and the documents incorporated herein by reference also contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks mentioned elsewhere in this prospectus. For more information, see the section entitled "Where You Can Find Additional Information." Please also read carefully the section entitled "Special Note Regarding Forward-Looking Statements."

ArTara's business depends on the successful clinical development, regulatory approval and commercialization of TARA-002 and IV Choline Chloride.

The success of ArTara's business, including its ability to finance itself and generate revenue in the future, primarily depends on the successful development, regulatory approval and commercialization of TARA-002 and IV Choline Chloride. The clinical and commercial success of TARA-002 and IV Choline Chloride depends on a number of factors, including the following:

- timely and successful completion of required clinical trials not yet initiated, which may be significantly slower or costlier than ArTara currently anticipates and/or produce results that do not achieve the endpoints of the trials;
- whether ArTara is required by the FDA or similar foreign regulatory agencies to conduct additional studies beyond those planned to support the approval and commercialization of TARA-002 and IV Choline Chloride;
- achieving and maintaining, and, where applicable, ensuring that ArTara's third-party contractors achieve and maintain compliance with their contractual obligations and with all regulatory requirements applicable to TARA-002 and IV Choline Chloride;
- ability of third parties with whom ArTara contracts to manufacture adequate clinical trial and commercial supplies of TARA-002 and IV Choline Chloride, to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices ("cGMP");
- a continued acceptable safety profile during clinical development and following approval of TARA-002 and IV Choline Chloride;
- ability to obtain favorable labeling for TARA-002 and IV Choline Chloride through regulators that allows for successful commercialization, given the drugs may be marketed only to the extent approved by these regulatory authorities (unlike with most other industries);
- ability to successfully commercialize TARA-002 and IV Choline Chloride in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration others;
- acceptance by physicians, insurers and payors, and patients of the quality, benefits, safety and efficacy of TARA-002 and IV Choline Chloride, if either is approved, including relative to alternative and competing treatments;

- existence of a regulatory environment conducive to the success of TARA-002 and IV Choline Chloride;
- ability to price TARA-002 and IV Choline Chloride to recover ArTara's development costs and generate a satisfactory profit margin; and
- ArTara's ability and its partners' ability to establish and enforce intellectual property rights in and to TARA-002 and IV Choline Chloride.

If ArTara does not achieve one or more of these factors, many of which are beyond its control, in a timely manner or at all, ArTara could experience significant delays or an inability to obtain regulatory approvals or commercialize TARA-002 and IV Choline Chloride. Even if regulatory approvals are obtained, ArTara may never be able to successfully commercialize TARA-002 and IV Choline Chloride. Accordingly, ArTara cannot assure you that it will be able to generate sufficient revenue through the sale of TARA-002 and IV Choline Chloride to continue its business.

ArTara has never conducted a clinical trial itself and may be unable to successfully do so for TARA-002 or IV Choline Chloride.

The conduct of a clinical trials is a long, expensive, complicated and highly regulated process. Although ArTara's employees have conducted successful clinical trials in the past across many therapeutic areas while employed at other companies, ArTara as a company has not conducted any clinical trials, and as a result may require more time and incur greater costs than it anticipates. Failure to commence or complete, or delays in, ArTara's planned clinical trials would prevent it from or delay ArTara in obtaining regulatory approval of and commercializing TARA-002 and IV Choline Chloride, which would adversely impact its financial performance, as well as subjecting it to significant contract liabilities.

TARA-002 is an immunotherapy, the first indication for which ArTara plans to pursue is the treatment of lymphatic malformations, an indication for which there are no FDA-approved therapies. This makes it difficult to predict the timing and costs of clinical development for TARA-002, as well as the regulatory approval path.

To date, there are no FDA-approved therapies for the treatment of lymphatic malformations and the standard of care is surgery. The regulatory approval process for novel product candidates such as TARA-002 can be more expensive and take longer than for other, better known or extensively studied therapeutic approaches. In addition, the clinical trials conducted on TARA-002 in the United States to date, included a control arm in which treatment was initially delayed. It is unclear whether this trial design could support FDA approval or whether a placebo-control or other randomization will be required by the FDA. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring TARA-002 to market could decrease ArTara's ability to generate sufficient revenue to maintain its business.

The regulatory path to approval of TARA-002 is atypical.

The proposed regulatory strategy for the TARA-002 program is combination of demonstrating comparability to a product that is not FDA approved. By demonstrating that TARA-002 is, in fact, OK-432, ArTara believes that the large volume of data published on OK-432 including the data generated by the University of Iowa led study will then apply to TARA-002. This strategy will rely on some components of a biosimilar pathway, with a significant difference being that the same genetically distinct strain and proprietary manufacturing processes will be used to produce TARA-002 as OK-432. If comparability is demonstrated and accepted by regulatory authorities, ArTara will attempt to rely on existing OK-432 safety and efficacy data to file the Biologics Licensing Application (BLA). There is no example of a biologic product that was approved utilizing this regulatory approach.

Clinical drug development is very expensive, time-consuming and uncertain.

Clinical development for ArTara's product candidates is very expensive, time-consuming, difficult to design and implement, and the outcomes are inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization and of those that are approved many do not cover their costs of development. In addition, ArTara, any partner with which it may in the future collaborate, the FDA, an institutional review board (IRB), or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate ArTara's clinical trials at any time.

ArTara's product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.

Unforeseen side effects from TARA-002 or IV Choline Chloride could arise either during clinical development or, if approved, after it has been marketed. Undesirable side effects could cause ArTara, any partners with which ArTara may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm ArTara's business, financial condition, operating results and prospects.

Additionally, if ArTara or others identify undesirable side effects, or other previously unknown problems, caused by a product after obtaining U.S. or foreign regulatory approval, a number of potentially negative consequences could result, which could prevent ArTara or its potential partners from achieving or maintaining market acceptance of the product and could substantially increase the costs of commercializing such product.

If ArTara or any partners with which ArTara may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for TARA-002 or IV Choline Chloride following regulatory approval, their commercial success may be hindered severely.

If TARA-002 and IV Choline Chloride only becomes available by prescription, successful sales by ArTara or by any partners with which ArTara may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and private third-party payors is often critical to new product acceptance. Coverage decisions may depend on clinical and economic standards that disfavor new drug products when more established or lower-cost therapeutic alternatives are already available or subsequently become available, or may be affected by the budgets and demands on the various entities responsible for providing health insurance to patients who will use TARA-002 and IV Choline Chloride. Even if ArTara obtains coverage for its products, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use a product unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost.

In addition, the market for ArTara's products will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies and there may be time limitations on when a new drug may even apply for formulary inclusion. Also, third-party payors may refuse to include products in their formularies or otherwise restrict patient access to such products when a less costly generic equivalent or other treatment alternative is available in the discretion of the formulary.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities and which will require ArTara to provide scientific, clinical and health economics support for the use of its products compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what time frame.

Further, ArTara believes that future coverage and reimbursement likely will be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for ArTara's products may not be available or adequate in either the United States or international markets, which could harm ArTara's business, financial condition, operating results and prospects.

Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of both TARA-002 and IV Choline Chloride, if approved, will depend significantly on the broad adoption and use of them by physicians and patients for approved indications, and neither may be commercially successful even though the product is shown to be safe and effective. The degree and rate of physician and patient adoption of a product, if approved, will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat the indication for which a product is approved;
- the effectiveness of the product compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors;
- the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients;
- in the case of TARA-002, overcoming physician or patient biases toward surgery for the treatment of lymphatic malformations;
- insurers' willingness to see the applicable indication as a disease worth treating;
- proper administration;
- patient satisfaction with the results, administration and overall treatment experience;
- limitations or contraindications, warnings, precautions or approved indications for use different than those sought by ArTara that are contained in the final FDA-approved labeling for the applicable product;

- any FDA requirement to undertake a risk evaluation and mitigation strategy;
- the effectiveness of ArTara's sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts;
- adverse publicity about a product or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals; and
- potential product liability claims or other product-related litigation.

If either of TARA-002 or IV Choline Chloride is approved for use but fails to achieve the broad degree of physician and patient adoption necessary for commercial success, ArTara's operating results and financial condition will be adversely affected, which may delay, prevent or limit its ability to generate revenue and continue its business.

ArTara's product candidates, if approved, will face significant competition and their failure to compete effectively may prevent them from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, less effective patent terms, and a strong emphasis on developing newer, fast-to-market proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that ArTara is developing, including TARA-002 and IV Choline Chloride. ArTara will face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, regulatory expertise, clinical trial expertise, intellectual property portfolios, more international reach, experience in obtaining patents and regulatory approvals for product candidates and other resources than ArTara. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with ArTara's target physicians, which could inhibit ArTara's market penetration efforts. attention within their clinical practices.

With respect to ArTara's lead product candidate, TARA-002, for the treatment of LMs, the active ingredient in TARA-002 is a genetically distinct strain of *Streptococcus pyogenes* (group A, type 3) Su strain. TARA-002 is produced through a proprietary manufacturing process. ArTara anticipates that, if approved by the FDA, TARA-002 will be protected by 12 years of biologic exclusivity. In addition, TARA-002 is likely to have seven years of Orphan Drug Designation exclusivity if deemed comparable to OK-432 by the FDA or based on the prevalence of the disease . There are no pharmacotherapies currently available for the treatment of LMs and the current standard of care is a high-risk surgical procedure. There are a handful of drug development companies and academic researchers exploring oral formulations of various agents including macrolides, phosphodiesterase inhibitors, and calcineurin/ mTOR inhibitors. These are in early development and earlier experiments in LMs utilizing other compounds utilizing these mechanisms have not produced conclusive evidence of safety or efficacy.

There are no treatments currently available for IFALD. With respect to IV Choline Chloride for the treatment of IFALD, IV Choline Chloride is the only sterile injectable form of choline chloride that can be combined with parenteral nutrition. Further, if approved, IV Choline Chloride will be protected by Orphan Drug Designation exclusivity for seven years.

TARA-002 and any future product candidates for which ArTara intends to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, or Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes are intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for ArTara's biological products.

ArTara believes that any of its product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider ArTara's product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of ArTara's reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

ArTara expects to rely on third-party CROs and other third parties to conduct and oversee its clinical trials. If these third parties do not meet ArTara's requirements or otherwise conduct the trials as required, ArTara may not be able to satisfy its contractual obligations or obtain regulatory approval for, or commercialize, its product candidates.

ArTara expects to rely on third-party contract research organizations (CROs) to conduct and oversee its TARA-002 and IV Choline Chloride clinical trials and other aspects of product development. ArTara also expects to rely on various medical institutions, clinical investigators and contract laboratories to conduct its trials in accordance with ArTara's clinical protocols and all applicable regulatory requirements, including the FDA's regulations and good clinical practice (GCP) requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties will play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. ArTara will rely heavily on these parties for the execution of its clinical trials and preclinical studies and will control only certain aspects of their activities. ArTara and its CROs and other third-party contractors will be required to comply with GCP and good laboratory practice (GLP) requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If ArTara or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal noncompliance from an audit or inspection, the clinical data generated in

ArTara's clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require ArTara to perform additional clinical trials before approving ArTara's or ArTara's partners' marketing applications. ArTara cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of ArTara's clinical or preclinical trials comply with applicable GCP and GLP requirements. In addition, ArTara's clinical trials generally must be conducted with product produced under cGMP regulations. ArTara's failure to comply with these regulations and policies may require it to repeat clinical trials, which would delay the regulatory approval process.

If any of ArTara's CROs or clinical trial sites terminate their involvement in one of its clinical trials for any reason, it may not be able to enter into arrangements with alternative CROs or clinical trial sites or do so on commercially reasonable terms. In addition, if ArTara's relationship with clinical trial sites is terminated, it may experience the loss of follow-up information on patients enrolled in its ongoing clinical trials unless ArTara is able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for ArTara's clinical trials may serve as scientific advisors or consultants to it from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

ArTara currently has no marketing capabilities and no sales organization. If ArTara is unable to establish sales and marketing capabilities on its own or through third parties, ArTara will be unable to successfully commercialize its product candidates, if approved, or generate product revenue.

ArTara currently has no marketing capabilities and no sales organization. To commercialize ArTara's product candidates, if approved, in the United States, Canada, the European Union, Latin America and other jurisdictions it seeks to enter, ArTara must build its marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and ArTara may not be successful in doing so. Although ArTara's employees have experience in the marketing, sale and distribution of pharmaceutical products, and business development activities involving external alliances, from prior employment at other companies, ArTara as a company has no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including its ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of ArTara's internal sales, marketing, distribution and pricing/reimbursement/access capabilities would impact adversely the commercialization of these products.

ArTara has a very limited operating history and has never generated any revenues.

ArTara is an early-stage biotechnology company with a very limited operating history that may make it difficult to evaluate the success of its business to date and to assess its future viability. ArTara was incorporated in 2017 and its operations, to date, have been limited to organizing and staffing the company, business planning, raising capital and in-licensing rights to TARA-002 and IV Choline Chloride, have been limited to business planning, raising capital, developing ArTara's pipeline assets (TARA-002 and IV Choline Chloride), identifying product candidates, and other research and development. ArTara has not yet demonstrated an ability to successfully complete any clinical trials and has never completed the development of any product candidate, nor has it ever generated any revenue from product sales or otherwise. Consequently, ArTara has no meaningful operations upon which to evaluate its business, and predictions about its future success or viability may not be as accurate as they could be if it had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

Any adverse developments that occur in patients undergoing treatment with OK-432 / Picibanil or in patients participating in clinical trials conducted by third parties may affect ArTara's ability to obtain regulatory approval or commercialize TARA-002.

Chugai Pharmaceutical Co., Ltd., over which ArTara has no control, has the rights to commercialize TARA-002 and it is currently marketed in Japan and Taiwan, under the name Picibanil for various indications. In addition, clinical trials using Picibanil are currently ongoing in various countries around the world. If serious adverse events occur with patients using Picibanil or during any clinical trials of Picibanil conducted by third parties, the FDA may delay, limit or deny approval of TARA-002 or require ArTara to conduct additional clinical trials as a condition to marketing approval, which would increase its costs. If ArTara receives FDA approval for TARA-002 and a new and serious safety issue is identified in connection with use of Picibanil or in clinical trials of Picibanil conducted by third parties, the FDA may withdraw their approval of the product or otherwise restrict ArTara's ability to market and sell TARA-002. In addition, treating physicians may be less willing to administer TARA-002 due to concerns over such adverse events, which would limit ArTara's ability to commercialize TARA-002.

ArTara has only received the exclusive rights to the materials required to commercialize TARA-002 in territories other than Japan and Taiwan until June 17, 2024, or an earlier date if Chugai terminates the agreement with ArTara for any number of reasons, including for convenience after June 2020, following which such rights become nonexclusive.

Pursuant to an agreement with Chugai Pharmaceutical Co., Ltd. dated June 17, 2019, Chugai agreed to provide ArTara with exclusive access to the starting material necessary to manufacture TARA-002 as well as technical support necessary for ArTara to develop and commercialize TARA-002 anywhere in the world other than Japan and Taiwan. However, this agreement does not prevent Chugai from providing such materials and support to any third party for medical, compassionate use and/or non-commercial research purposes and this agreement is not exclusive following June 17, 2024 or following any termination of the agreement by either party, which includes a termination by Chugai for convenience, which it has the right to do upon 90 days' notice after June 2020. Once ArTara's rights to the materials and technology necessary to manufacture, develop and commercialize TARA-002 are not exclusive, third parties, including those with greater expertise and greater resources, could obtain such materials and technology and develop a competing therapy, which would adversely affect ArTara's ability to generate revenue and achieve or maintain profitability.

ArTara currently has no products approved for sale, and it may never obtain regulatory approval to commercialize any of its product candidates.

The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post-market information related to its biopharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country and frequently are revised.

Even after ArTara achieves U.S. regulatory approval for a product candidate, if any, ArTara will be subject to continued regulatory review and compliance obligations. For example, with respect to ArTara's product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. ArTara also will be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, pharmacovigilance and adverse event reporting, storage, advertising, promotion and recordkeeping for ArTara's product candidates.

These requirements include submissions of safety and other post-marketing information and reports, registration, continued compliance with cGMP requirements and with the FDA's GCP requirements and GLP requirements, which are regulations and guidelines enforced by the FDA for all of ArTara's product candidates in clinical and preclinical development, and for any clinical trials that it conducts post-approval, as well as continued compliance with the FDA's laws governing commercialization of the approved product, including but not limited to the FDA's Office of Prescription Drug Promotion (OPDP) regulation of promotional activities, fraud and abuse, product sampling, scientific speaker engagements and activities, formulary interactions as well as interactions with healthcare practitioners. To the extent that a product candidate is approved for sale in other countries, ArTara may be subject to similar or more onerous (i.e., prohibition on direct-to-consumer advertising that does not exist in the United States.) restrictions and requirements imposed by laws and government regulators in those countries.

In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If ArTara or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the manufacturing, processing, distribution or storage facility where, or processes by which, the product is made, a regulatory agency may impose restrictions on that product or ArTara, including requesting that ArTara initiate a product recall, or requiring notice to physicians or the public, withdrawal of the product from the market, or suspension of manufacturing.

If ArTara, its product candidates or the manufacturing facilities for its product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the sale, marketing or manufacturing of the product, amend, suspend or withdraw product approvals or revoke necessary licenses;
- mandate modifications to promotional and other product-specific materials or require ArTara to provide corrective information to healthcare practitioners or in its advertising;
- require ArTara or its partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, penalties for noncompliance and, in extreme cases, require an independent compliance monitor to oversee ArTara's activities;
- issue warning letters, bring enforcement actions, initiate surprise inspections, issue show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- place restrictions on the kind of promotional activities that can be done;
- delay or refuse to approve pending applications or supplements to approved applications filed by ArTara or its potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or

- seize or detain products or require ArTara or its partners to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change, and new or additional statutes or government regulations may be enacted, including at the state and local levels, which can differ by geography and could prevent or delay regulatory approval of ArTara's product candidates or further restrict or regulate post-approval activities. ArTara cannot predict the likelihood, nature or extent of adverse government regulations that may arise from future legislation or administrative action, either in the United States or abroad. If ArTara is not able to achieve and maintain regulatory compliance, it may not be permitted to commercialize its product candidates, which would adversely affect its ability to generate revenue and achieve or maintain profitability.

ArTara may in the future conduct clinical trials for its product candidates outside the United States, and the FDA and applicable foreign regulatory authorities may not accept data from such trials.

ArTara may in the future choose to conduct one or more of its clinical trials outside of the United States. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions or exclusion. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of ArTara's business plan.

ArTara may face product liability exposure, and if successful claims are brought against it, ArTara may incur substantial liability if its insurance coverage for those claims is inadequate.

ArTara faces an inherent risk of product liability or similar causes of action as a result of the clinical testing of its product candidates and will face an even greater risk if ArTara commercializes any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority and notwithstanding ArTara complying with applicable laws on promotional activity. ArTara's products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with ArTara's product candidates could result in injury to a patient or potentially even death. ArTara cannot offer any assurance that it will not face product liability suits in the future, nor can it assure that its insurance coverage will be sufficient to cover its liability under any such cases.

In addition, a liability claim may be brought against ArTara even if its product candidates merely appear to have caused an injury. Product liability claims may be brought against ArTara by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with its product candidates, among others, and under some circumstances even government agencies. If ArTara cannot successfully defend itself against product liability or similar claims, it will incur

substantial liabilities, reputational harm and possibly injunctions and punitive actions. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire trial programs;
- the inability to commercialize ArTara's product candidates;
- decreased demand for ArTara's product candidates;
- impairment of ArTara's business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from ArTara's primary business;
- significant delay in product launch;
- substantial monetary awards to patients or other claimants against ArTara that may not be covered by insurance;
- withdrawal of reimbursement or formulary inclusion; or
- loss of revenue.

ArTara intends to obtain product liability insurance coverage for its clinical trials. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. ArTara's insurance coverage may not be sufficient to cover all of its product liability-related expenses or losses and may not cover it for any expenses or losses it may suffer. Moreover, insurance coverage is becoming increasingly expensive, restrictive and narrow, and, in the future, ArTara may not be able to maintain adequate insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect it against losses due to product liability or other similar legal actions. ArTara will need to increase its product liability coverage if any of its product candidates receive regulatory approval, which will be costly, and it may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all and for all geographies in which ArTara wishes to launch. A successful product liability claim or series of claims brought against ArTara, if judgments exceed its insurance coverage, could decrease its cash and harm its business, financial condition, operating results and future prospects.

ArTara's employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with whom ArTara may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

ArTara is exposed to the risk that its employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with which ArTara may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless, gross or negligent misconduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; anticorruption laws, antikickback and Medicare/Medicaid rules, or laws that require the true, complete and accurate reporting of financial information or data, books and records. If any such or similar actions are instituted against ArTara and ArTara is not successful in defending itself or asserting ArTara's rights, those actions could have a significant impact on ArTara's business, including the imposition of civil, criminal and administrative and punitive penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and

other federal healthcare programs, debarments, contractual damages, reputational harm, diminished profits and future earnings, injunctions, and curtailment or cessation of ArTara's operations, any of which could adversely affect ArTara's ability to operate ArTara's business and ArTara's operating results.

ArTara may be subject to risks related to off-label use of its product candidates.

The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product's approved labeling. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, members of Congress and the public. Violations, including promotion of ArTara's products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by relevant foreign regulatory authorities.

Even if ArTara obtains regulatory approval for its product candidates, the FDA or comparable foreign regulatory authorities may require labeling changes or impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In the United States, engaging in impermissible promotion of ArTara's product candidates for off-label uses can also subject it to false claims litigation under federal and state statutes, which can lead to civil, criminal and/or administrative penalties and fines and agreements, such as a corporate integrity agreement, that materially restrict the manner in which ArTara promotes or distributes its product candidates. If ArTara does not lawfully promote its products once they have received regulatory approval, ArTara may become subject to such litigation and, if it is not successful in defending against such actions, those actions could have a material adverse effect on its business, financial condition and operating results and even result in having an independent compliance monitor assigned to audit ArTara's ongoing operations for a lengthy period of time.

ArTara's or third party's clinical trials may fail to demonstrate the safety and efficacy of its product candidates, or serious adverse or unacceptable side effects may be identified during their development, which could prevent or delay marketing approval and commercialization, increase ArTara's costs or necessitate the abandonment or limitation of the development of the product candidate.

Before obtaining marketing approvals for the commercial sale of any product candidate, ArTara must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidate is both safe and effective for use in the applicable indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and are associated with side effects or have characteristics that are unexpected. Based on the safety profile seen in clinical testing, ArTara may need to abandon development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more tolerable from a risk-benefit perspective. The FDA or an IRB may also require that ArTara suspend, discontinue, or limit clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for the product candidate. Many pharmaceutical candidates that initially showed promise in early stage testing and which were efficacious have later been found to cause side effects that prevented further development of the drug candidate and, in extreme cases, the side effects were not seen until after the drug was marketed, causing regulators to remove the drug from the market post-approval.

ArTara's regulatory strategy for TARA-002 requires first that it can demonstrate that TARA-002 is the same biologic substance as OK-432, which is currently manufactured in Japan and marketed in Japan and Taiwan by Chugai. In order to demonstrate comparability, ArTara plans to conduct studies using batches of OK-432 from Japan and batches of TARA-002 manufactured in the United States by its CMO. If ArTara can demonstrate comparability, it plans to engage with the FDA to seek its agreement to use OK-432's safety and efficacy data from clinical trials previously conducted by third parties for its BLA filing. There can be no assurances that ArTara's CMO will be able to produce a sufficiently comparable product or that the FDA will find such substances comparable or permit ArTara to use any of the data from prior clinical trials as part of the BLA filing for TARA-002.

ArTara may choose not to continue developing or commercializing any of its product candidates at any time during development or after approval, which would reduce or eliminate its potential return on investment for those product candidates.

At any time, ArTara may decide to discontinue the development of any of its product candidates for a variety of reasons, including the appearance of new technologies that make its product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If ArTara terminates a program in which it has invested significant resources, ArTara will not receive any return on its investment and it will have missed the opportunity to have allocated those resources to potentially more productive uses.

Healthcare reform measures could hinder or prevent the commercial success of ArTara's product candidates.

The current presidential administration and certain members of the majority of the U.S. Congress have sought to repeal all or part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "Affordable Care Act"), and implement a replacement program. For example, the so-called "individual mandate" was repealed as part of tax reform legislation adopted in December 2017, such that the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Code was eliminated beginning in 2019. In addition, litigation may prevent some or all of the Affordable Care Act legislation from taking effect. For example, on December 14, 2018, the U.S. District Court for the Northern District of Texas held that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the tax reform legislation, the remaining provisions of the Affordable Care Act are invalid as well. The impact of this ruling is stayed as it is appealed to the Fifth Circuit Court of Appeals. While the ruling will have no immediate effect, it is unclear how this decision, and subsequent appeals, if any, will impact the law. In 2019 and beyond, ArTara may face additional uncertainties as a result of likely federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the Affordable Care Act. There is no assurance that the Affordable Care Act, as amended in the future, will not adversely affect ArTara's business and financial results.

Additionally, in October 2018, the U.S. President proposed to lower Medicare Part B drug prices, in addition to contemplating other measures to lower prescription drug prices. While this proposal has not yet been enacted, ArTara expects that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for its product candidates if approved or additional pricing pressures.

There are also calls to ban all direct-to-consumer advertising of pharmaceuticals, which would limit ArTara's ability to market its product candidates. The United States is in a minority of jurisdictions that allow this kind of advertising and its removal could limit the potential reach of a marketing campaign.

ArTara may also be subject to stricter healthcare laws, regulation and enforcement, and its failure to comply with those laws could adversely affect its business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to ArTara's business. ArTara is subject to regulation by both the federal government and the states in which it or its partners conduct business. The healthcare laws and regulations that may affect ArTara's ability to operate include: the federal Anti-Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act; the Prescription Drug Marketing Act (for sampling of drug product among other things); the federal physician sunshine requirements under the Affordable Care Act; the Foreign Corrupt Practices Act as it applies to activities outside of the United States; the new federal Right-to-Try legislation; and state law equivalents of many of the above federal laws.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of ArTara's business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the recently enacted Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against ArTara for violation of these laws, even if ArTara successfully defends against it, could cause ArTara to incur significant legal expenses and divert its management's attention from the operation of its business and result in reputational damage. If ArTara's operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to ArTara, it may be subject to penalties, including administrative, civil and criminal penalties, damages, including punitive damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of its operations, and injunctions, any of which could adversely affect ArTara's ability to operate its business and its financial results.

ArTara intends to in-license and acquire product candidates and may engage in other strategic transactions, which could impact its liquidity, increase its expenses and present significant distractions to its management.

ArTara's strategy is to in-license and acquire product candidates and it may engage in other strategic transactions. Additional potential transactions that ArTara may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require ArTara to incur non-recurring or other charges, may increase its near- and long-term expenditures and may pose significant integration challenges or disrupt its management or business, which could adversely affect its operations and financial results. Accordingly, there can be no assurance that ArTara will undertake or successfully complete any transactions of the nature described above, and any transaction that it does complete could harm its business, financial condition, operating results and prospects. ArTara has no current plan, commitment or obligation to enter into any transaction described above, and ArTara is not engaged in discussions related to additional partnerships.

ArTara's failure successfully to in-license, acquire, develop and market additional product candidates or approved products would impair its ability to grow its business.

ArTara intends to in-license, acquire, develop and market additional products and product candidates. Because ArTara's internal research and development capabilities are limited, it may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to it. The success of this strategy depends partly on ArTara's ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with ArTara for the license or acquisition of product candidates and approved products. ArTara has limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into its current infrastructure. Moreover, ArTara may devote resources to potential acquisitions or licensing opportunities that are never completed, or ArTara may fail to realize the anticipated benefits of such efforts. ArTara may not be able to acquire the rights to additional product candidates on terms that it finds acceptable or at all.

Further, any product candidate that ArTara acquires may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, ArTara cannot provide assurance that any approved products that it acquires will be manufactured or sold profitably or achieve market acceptance.

ArTara expects to rely on collaborations with third parties for the successful development and commercialization of its product candidates.

ArTara expects to rely upon the efforts of third parties for the successful development and commercialization of ArTara's current and future product candidates. The clinical and commercial success of ArTara's product candidates may depend upon maintaining successful relationships with third-party partners which are subject to a number of significant risks, including the following:

- ArTara's partners' ability to execute their responsibilities in a timely, cost-efficient and compliant manner;
- reduced control over delivery and manufacturing schedules;
- price increases and product reliability;
- manufacturing deviations from internal or regulatory specifications;
- quality incidents;
- the failure of partners to perform their obligations for technical, market or other reasons;
- misappropriation of ArTara's current or future product candidates; and
- other risks in potentially meeting ArTara's current and future product commercialization schedule or satisfying the requirements of its end-users.

ArTara cannot assure you that it will be able to establish or maintain third-party relationships in order to successfully develop and commercialize its product candidates.

ArTara relies completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for its product candidates, which may include sole-source suppliers and manufacturers; ArTara intends to rely on third parties for commercial supply, manufacturing and distribution if any of its product candidates receive regulatory approval; and ArTara expects to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.

ArTara does not currently have, nor does it plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Additionally, ArTara has not entered into a long-term commercial supply agreement to provide it with such drug substances or products. As a result, ArTara's ability to develop its product candidates is dependent, and ArTara's ability to supply its products commercially will depend, in part, on ArTara's ability to obtain the APIs and other substances and materials used in its product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If ArTara fails to develop and maintain supply and other technical relationships with these third parties, it may be unable to continue to develop or commercialize its products and product candidates.

ArTara does not have direct control over whether its contract suppliers and manufacturers will maintain current pricing terms, be willing to continue supplying ArTara with APIs and finished products or maintain adequate capacity and capabilities to serve its needs, including quality control, quality assurance and qualified personnel. ArTara is dependent on its contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMPs for production of both APIs and finished products. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, ArTara may not be able to commercialize or obtain regulatory approval for the affected product or product candidate successfully, and ArTara may be held liable for injuries sustained as a result.

In order to conduct larger or late-stage clinical trials for its product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, ArTara's contract manufacturers and suppliers will need to produce its drug substances and product candidates in larger quantities, more cost-effectively and, in certain cases, at higher yields than they currently achieve. If ArTara's third-party contractors are unable to scale up the manufacture of any of its product candidates successfully in sufficient quality and quantity and at commercially reasonable prices, or are shut down or put on clinical hold by government regulators, and ArTara is unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and ArTara is unable to transfer the processes successfully on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm its business, financial condition, operating results and prospects.

ArTara expects to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. ArTara's supply and manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for its needs. Additionally, any damage to or destruction of ArTara's third-party manufacturer's or suppliers' facilities or equipment, even by force majeure, may significantly impair its ability to have its products and product candidates manufactured on a timely basis. ArTara's reliance on contract manufacturers and suppliers further exposes it to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate ArTara's trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of ArTara's suppliers may be located outside of the United States. This may give rise to difficulties in importing ArTara's products or product candidates or their components into the United States or other countries.

The manufacture of biologics is complex and ArTara's third-party manufacturers may encounter difficulties in production. If ArTara's CMO encounter such difficulties, the ability to provide supply of TARA-002 for clinical trials, ArTara's ability to obtain marketing approval, or its ability to obtain commercial supply of TARA-002, if approved, could be delayed or stopped.

ArTara's has no experience in biologic manufacturing and does not own or operate, and it does not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. ArTara is completely dependent on CMOs to fulfill its clinical and commercial supply of TARA-002. The process of manufacturing biologics is complex, highly regulated and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of ArTara's manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely harm its business. Moreover, if the FDA determines that ArTara's manufacturer is not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or it replaces the manufacturer in its BLA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if ArTara obtains regulatory approval for TARA-002 or any future product candidates, there is no assurance that its manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If ArTara's manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on ArTara's business, financial condition, results of operations and growth prospects. Scaling up a biologic manufacturing process is a difficult and uncertain task, and any CMO ArTara contracts may not have the necessary capabilities to complete the implementation and development process of further scaling up production, transferring production to other sites, or managing its production capacity to timely meet product demand.

The audit report of ArTara's independent registered public accounting firm expresses substantial doubt about ArTara's ability to continue as a going concern.

The audit report from ArTara's independent registered public accounting firm expresses substantial doubt that it can continue as an ongoing business due to uncertainties that ArTara's cash flows generated from its operations will be sufficient to meet its current operating costs and ArTara's future financial statements may include a similar qualification about its ability to continue as a going concern. ArTara's audited financial statements were prepared assuming that it will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty.

If ArTara is unable to meet its current operating costs, ArTara would need to seek additional financing or modify its operational plans. If ArTara seeks additional financing to fund its business activities in the future and there remains substantial doubt about its ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to ArTara on commercially reasonable terms or at all.

ArTara has identified material weaknesses in its internal control over financial reporting. If ArTara's internal control over financial reporting is not effective, it may not be able to accurately report its financial results or file its periodic reports in a timely manner, which may cause adverse effects on ArTara's business and may cause investors to lose confidence in its reported financial information and may lead to a decline in ArTara's stock price.

Effective internal control over financial reporting is necessary for ArTara to provide reliable financial reports in a timely manner. In connection with the audits of ArTara's financial statements for the quarters ended June 30, 2019 and September 30, 2019, ArTara concluded that there were material weaknesses in its internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

If ArTara is unable to successfully remediate its material weaknesses or identify any future significant deficiencies or material weaknesses, the accuracy and timing of ArTara's financial reporting may be adversely affected, a material misstatement in its financial statements could occur, ArTara may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, which may adversely affect its business and ArTara's stock price may decline as a result.

In addition, even if ArTara remediates its material weaknesses, following the completion of this Merger, ArTara will be required to expend significant time and resources to further improve its internal controls over financial reporting, including by further expanding its finance and accounting staff to meet the demands that will be placed upon ArTara as a public company, including the requirements of the Sarbanes-Oxley Act. If ArTara fails to adequately staff its accounting and finance function to remediate its material weaknesses, or fails to maintain adequate internal control over financial reporting, any new or recurring material weaknesses could prevent ArTara's management from concluding its internal control over financial reporting is effective and impair ArTara's ability to prevent material misstatements in its financial statements, which could cause ArTara's business to suffer.

ArTara will need to raise additional financing in the future to fund ArTara's operations, which may not be available to it on favorable terms or at all.

ArTara will require substantial additional funds to conduct the costly and time-consuming clinical efficacy trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of TARA-002 and IV Choline Chloride in new indications or uses. ArTara's future capital requirements will depend upon a number of factors, including: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit ArTara's ability to achieve its business objectives. If ArTara raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely the rights of its common stockholders. Further, to the extent that ArTara raises additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest in ArTara will be diluted. In addition, any debt financing may subject ArTara to fixed payment obligations and covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If ArTara raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, ArTara may have to relinquish certain valuable intellectual property or other rights to its product candidates, technologies, future revenue streams or research programs or

grant licenses on terms that may not be favorable to it. Even if ArTara were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to ArTara or its stockholders.

ArTara expects its stock price to be highly volatile.

The market price of ArTara's shares could be subject to significant fluctuations. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. Some of the factors that may cause the market price of ArTara's shares to fluctuate include, but are not limited to:

- the ability of ArTara to obtain timely regulatory approvals for TARA-002, IV Choline Chloride or future product candidates, and delays or failures to obtain such approvals;
- failure of TARA-002 or IV Choline Chloride, if approved, to achieve commercial success;
- issues in manufacturing TARA-002, IV Choline Chloride or future product candidates;
- the results of current and any future clinical trials of TARA-002 or IV Choline Chloride;
- failure of other ArTara product candidates, if approved, to achieve commercial success;
- the entry into, or termination of, or breach by partners of key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- announcements of any dilutive equity financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- failure to elicit meaningful stock analyst coverage and downgrades of the company's stock by analysts; and
- the loss of key employees.

Moreover, the stock markets in general have experienced substantial volatility in our industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of ArTara's shares.

In the past, following periods of volatility in the market price of a company's securities, shareholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm ArTara's profitability and reputation. In addition, such securities litigation often has ensued after a reverse merger or other merger and acquisition activity. Such litigation if brought could impact negatively ArTara 's business.

ArTara will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

ArTara will incur significant legal, accounting and other expenses that ArTara did not incur as a private company, including costs associated with public company reporting and other SEC requirements. ArTara also will incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new rules implemented by the SEC and Nasdaq.

These rules and regulations are expected to increase ArTara's legal and financial compliance costs and to make some activities more time-consuming and costly. ArTara's executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations may also make it expensive for ArTara to operate its business.

ArTara is expected to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in its common stock being less attractive to investors.

ArTara expects to have a public float of less than $250 million and therefore will qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, ArTara will be able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in its SEC filings. Decreased disclosures in ArTara's SEC filings due to its status as a smaller reporting company may make it harder for investors to analyze its results of operations and financial prospects. We cannot predict if investors will find ArTara's common stock less attractive if it relies on these exemptions. If some investors find its common stock less attractive as a result, there may be a less active trading market for its common stock and its stock price may be more volatile. ArTara may take advantage of the reporting exemptions applicable to a smaller reporting company until it is no longer a smaller reporting company, which status would end once it has a public float greater than $250 million. In that event, ArTara could still be a smaller reporting company if its annual revenues were below $100 million and it has a public float of less than $700 million.

ArTara does not anticipate paying any dividends in the foreseeable future.

The current expectation is that ArTara will retain its future earnings to fund the development and growth of the Company's business. As a result, capital appreciation, if any, of the shares of ArTara will be your sole source of gain, if any, for the foreseeable future.

If ArTara fails to attract and retain management and other key personnel, it may be unable to continue to successfully develop or commercialize its product candidates or otherwise implement its business plan.

ArTara's ability to compete in the highly competitive pharmaceuticals industry depends on its ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. ArTara is highly dependent on its management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of ArTara's product pipeline, completion of its planned clinical trials, commercialization of its product candidates or in-licensing or acquisition of new assets and could impact negatively its ability to implement successfully its business plan. If ArTara loses the services of any of these individuals, it might not be able to find suitable replacements on a timely basis or at all, and its business could be harmed as a result. ArTara might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

ArTara's ability to use its net operating loss carry-forwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2018, for U.S. federal and state income tax reporting purposes, ArTara has approximately $4.1 million of unused net operating losses ("NOLs") available for carry forward to future years. The 2018 federal and New York City NOLs may be carried forward indefinitely, but utilization will be subject to an annual deduction limitation of 80% of taxable income. These 2018 losses will not be allowed to be carried back. The 2018 state NOLs may be carried forward through the year 2037 and may be applied against future taxable income. The 2017 federal and New York City

NOLs will begin to expire during the year ended December 31, 2037. It is possible that ArTara will not generate taxable income in time to use these loss carry-forwards before their expiration. ArTara's net operating loss carryforwards may also be subject to limitation as a result of prior shifts in equity ownership and/or the Merger. In addition, ArTara may experience ownership changes in the future as a result of offerings of stock or subsequent shifts in its stock ownership, some of which are outside of its control. In that case, the ability to use net operating loss carry-forwards to offset future taxable income will be limited following any such ownership change.

ArTara may be adversely affected by natural disasters and other catastrophic events and by man-made problems such as terrorism that could disrupt its business operations, and its business continuity and disaster recovery plans may not adequately protect it from a serious disaster.

ArTara's corporate office is located in New York, New York. If a disaster, power outage, computer hacking, or other event occurred that prevented ArTara from using all or a significant portion of an office, that damaged critical infrastructure, such as enterprise financial systems, IT systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for it to continue its business for a substantial period of time. ArTara's contract manufacturer's and suppliers' facilities are located in multiple locations where other natural disasters or similar events, such as tornadoes, fires, explosions or large-scale accidents or power outages, or IT threats, could severely disrupt ArTara's operations and have a material adverse effect on its business, financial condition, operating results and prospects. In addition, acts of terrorism and other geo-political unrest could cause disruptions in ArTara's business or the businesses of its partners, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if ArTara does not implement a disaster recovery plan or its partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of TARA-002 or IV Choline Chloride, its business, financial condition, operating results and prospects would suffer.

ArTara's business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in its cyber-security.

Despite the implementation of security measures, ArTara's internal computer systems and those of its current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While ArTara has not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in ArTara's operations, it could result in a material disruption of its development programs and its business operations. In addition, since ArTara sponsors clinical trials, any breach that compromises patient data and identities causing a breach of privacy could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in the company to recruit for future clinical trials. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in ArTara's regulatory approval efforts and significantly increase its costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, ArTara's data or applications or inappropriate disclosure of confidential or proprietary information, ArTara could incur liability and the further development and commercialization of its products and product candidates could be delayed.

Anti-takeover provisions in ArTara's charter documents and under Delaware law could make an acquisition of ArTara more difficult and may prevent attempts by ArTara stockholders to replace or remove ArTara's management.

Provisions in ArTara's certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because ArTara's is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding ArTara voting stock from merging or combining with ArTara. These provisions may frustrate or prevent any attempts by ArTara's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

The certificate of incorporation of ArTara provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between ArTara and its stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with ArTara or its directors, officers or other employees.

The certificate of incorporation of ArTara provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on ArTara's behalf, any action asserting a breach of fiduciary duty owed by any of its directors, officers or other employees to the ArTara or its stockholders, any action asserting a claim against it arising pursuant to any provisions of the DGCL, its certificate of incorporation or its bylaws, or any action asserting a claim against it that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with ArTara or its directors, officers or other employees, which may discourage such lawsuits against ArTara and its directors, officers and other employees. If a court were to find the choice of forum provision contained in the certificate of incorporation to be inapplicable or unenforceable in an action, ArTara may incur additional costs associated with resolving such action in other jurisdictions.

Certain stockholders have the ability to control or significantly influence certain matters submitted to ArTara's stockholders for approval.

Certain stockholders have consent rights over certain significant matters of ArTara's business. These include decisions to effect a merger or other similar transaction, changes to the principal business of ArTara, and the sale or other transfer of TARA-002 or other assets with an aggregate value of more than $2,500,000. As a result, these stockholders, have significant influence over certain matters that require approval by ArTara's stockholders.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about ArTara, its business or its market, its stock price and trading volume could decline.

The trading market for ArTara's common stock is influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts may elect not to provide research coverage of ArTara's common stock after the completion of the Merger, and such lack of research coverage may adversely affect the market price of its common stock. In the event it does have equity research analyst coverage, ArTara will not have any control over the analysts or the content and opinions included in their reports. The price of ArTara's common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of ArTara or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline.

If ArTara fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

ArTara is subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that ArTara maintain effective disclosure controls and procedures and internal control over financial reporting. ArTara must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, ArTara was not required to test its internal controls within a specified period. This will require that it incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expend significant management efforts. ArTara may experience difficulty in meeting these reporting requirements in a timely manner.

ArTara may discover weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its financial statements. ArTara's internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If ArTara is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal controls, ArTara may not be able to produce timely and accurate financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

ArTara may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover its product candidates and technologies that are of sufficient breadth to prevent third parties from competing against ArTara.

ArTara's success with respect to its product candidates will depend, in part, on its ability to obtain and maintain patent protection in both the United States and other countries, to preserve its trade secrets and to prevent third parties from infringing on its proprietary rights. ArTara's ability to protect its product candidates from unauthorized or infringing use by third parties depends in substantial part on its ability to obtain and maintain valid and enforceable patents around the world.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and ArTara and its current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that ArTara or its current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of ArTara's patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of its business. Moreover, ArTara's competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to ArTara patents that would not constitute infringement. Any of these outcomes could impair ArTara's ability to enforce the exclusivity of its patents effectively, which may have an adverse impact on its business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, ArTara's ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions especially across countries. Accordingly, rights under

any existing patents or any patents ArTara might obtain or license may not cover its product candidates or may not provide ArTara with sufficient protection for its product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over-the-counter pharmaceutical companies. In addition, ArTara cannot guarantee that any patents or other intellectual property rights will issue from any pending or future patent or other similar applications owned by or licensed to ArTara. Even if patents or other intellectual property rights have issued or will issue, ArTara cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide ArTara with any significant protection against competitive products or otherwise be commercially valuable to ArTara in every country of commercial significance that ArTara may target.

Competitors in the field of immunology and oncology therapeutics have created a substantial amount of prior art, including scientific publications, posters, presentations, patents and patent applications and other public disclosures including on the Internet. ArTara's ability to obtain and maintain valid and enforceable patents depends on whether the differences between its technology and the prior art allow its technology to be patentable over the prior art. ArTara does not have outstanding issued patents covering all of the recent developments in its technology and is unsure of the patent protection that it will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents ArTara owns or licenses, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents ArTara holds or pursues with respect to its product candidates is challenged, it could dissuade companies from collaborating with ArTara to develop or threaten its ability to commercialize or finance its product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the United States, and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. If ArTara encounters such difficulties in protecting or are otherwise precluded from effectively protecting its intellectual property in foreign jurisdictions, its business prospects could be substantially harmed, especially internationally.

Proprietary trade secrets and unpatented know-how are also very important to ArTara's business. Although ArTara has taken steps to protect its trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or enforced by courts, that ArTara would have adequate remedies for any breach, including injunctive and other equitable relief, or that its trade secrets and unpatented know-how will not otherwise become known, inadvertently disclosed by ArTara or its agents and representatives, or be independently discovered by its competitors. If trade secrets are independently discovered, ArTara would not be able to prevent their use and if ArTara and its agents or representatives inadvertently disclose trade secrets and/or unpatented know-how, ArTara may not be allowed to retrieve this and maintain the exclusivity it previously enjoyed.

ArTara may not be able to protect its intellectual property rights throughout the world.

Filing, prosecuting and defending patents on ArTara's product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States, especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, ArTara may not be able to prevent third parties from practicing its inventions in all countries outside the United States and even in launching an identical version of

ArTara's product notwithstanding ArTara has a valid patent in that country. Competitors may use ArTara's technologies in jurisdictions where it has not obtained patent protection to develop their own products, or produce copy products, and, further, may export otherwise infringing products to territories where ArTara has patent protection but enforcement on infringing activities is inadequate or where ArTara has no patents. These products may compete with ArTara's products, and ArTara's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, and the judicial and government systems are often corrupt, which could make it difficult for ArTara to stop the infringement of its patents or marketing of competing products in violation of its proprietary rights generally. Proceedings to enforce its patent rights in foreign jurisdictions could result in substantial costs and divert its efforts and attention from other aspects of its business, could put its global patents at risk of being invalidated or interpreted narrowly and its global patent applications at risk of not issuing, and could provoke third parties to assert claims against it. ArTara may not prevail in any lawsuits that ArTara initiates or infringement actions brought against ArTara, and the damages or other remedies awarded, if any, may not be commercially meaningful when ArTara is the plaintiff. When ArTara is the defendant it may be required to post large bonds to stay in the market while it defends itself from an infringement action.

In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patent holder's patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. In these situations, the royalty the court requires to be paid by the license holder receiving the compulsory license is not calculated at fair market value and can be inconsequential, thereby disaffecting the patentholder's business. In these countries, ArTara may have limited remedies if its patents are infringed or if ArTara is compelled to grant a license to its patents to a third party, which could also materially diminish the value of those patents. This would limit its potential revenue opportunities. Accordingly, ArTara's efforts to enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that ArTara owns or licenses, especially in comparison to what it enjoys from enforcing its intellectual property rights in the Unites States. Finally, the company's ability to protect and enforce its intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals For example, in Brazil, pharmaceutical patents require initial approval of the Brazilian health agency (ANVISA). Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application.

Obtaining and maintaining ArTara's patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and its patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary,

fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and/or timely pay a prosecution fee. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If ArTara or its licensors fail to maintain the patents and patent applications covering its product candidates for any reason, the Company's competitors might be able to enter the market, which would have an adverse effect on ArTara's business.

If ArTara fails to comply with its obligations under its intellectual property license agreements, it could lose license rights that are important to its business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of its rights to the relevant intellectual property or technology or increase its financial or other obligations to its licensors.

ArTara has entered into in-license arrangements with respect to certain of its product candidates. These license agreements impose various diligence, milestone, royalty, insurance and other obligations on ArTara. If ArTara fails to comply with these obligations, the respective licensors may have the right to terminate the license, in which event ArTara may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect its business, financial condition, operating results and prospects. For more information about these license arrangements, see "*Description of ArTara's Business—Collaborations and License Agreements*."

If ArTara is sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay it from developing or commercializing its product candidates.

ArTara's commercial success depends on its ability to develop, manufacture, market and sell its product candidates and use its proprietary technologies without infringing the proprietary rights of third parties. ArTara cannot assure that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S.- and foreign-issued patents and pending patent applications owned by third parties exist in the fields relating to its product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that its product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents and other intellectual property rights cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in ArTara's fields across many countries, there may be a risk that third parties may allege they have patent rights encompassing ArTara's product candidates, technologies or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by ArTara's product candidates or proprietary technologies notwithstanding patents ArTara may possess. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, ArTara cannot be certain that others have not filed patent applications for technology covered by its own and in-licensed issued patents or its pending applications. ArTara's competitors may have filed, and may in the future file, patent applications covering ArTara's own product candidates or technology similar to ArTara's technology. Any such patent application may have priority over ArTara's own and in-licensed patent applications or patents,

which could further require ArTara to obtain rights to issued patents covering such technologies, which may mean paying significant licensing fees or the like. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, ArTara or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

ArTara may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that its product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act or other countries' laws similar to the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug, and this type of litigation can be costly and could adversely affect its operating results and divert the attention of managerial and technical personnel, even if ArTara does not infringe such patents or the patents asserted against ArTara is ultimately established as invalid. There is a risk that a court would decide that ArTara is infringing the third party's patents and would order ArTara to stop the activities covered by the patents. In addition, there is a risk that a court will order ArTara to pay the other party significant damages for having violated the other party's patents.

Because ArTara relies on certain third-party licensors and partners and will continue to do so in the future, if one of its licensors or partners is sued for infringing a third party's intellectual property rights, ArTara's business, financial condition, operating results and prospects could suffer in the same manner as if ArTara were sued directly. In addition to facing litigation risks, ArTara has agreed to indemnify certain third-party licensors and partners against claims of infringement caused by ArTara's proprietary technologies, and ArTara has entered or may enter into cost-sharing agreements with some its licensors and partners that could require ArTara to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by its proprietary technologies. In certain instances, these cost-sharing agreements could also require ArTara to assume greater responsibility for infringement damages than would be assumed just on the basis of its technology.

The occurrence of any of the foregoing could adversely affect ArTara's business, financial condition or operating results.

ArTara may be subject to claims that its officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to ArTara alleged trade secrets of their former employers or their former or current customers.

As is common in the biotechnology and pharmaceutical industries, certain of ArTara's employees were formerly employed by other biotechnology or pharmaceutical companies, including its competitors or potential competitors. Moreover, ArTara engages the services of consultants to assist ArTara in the development of ArTara's products and product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including its competitors or potential competitors. ArTara may be subject to claims that these employees and consultants or ArTara has inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although ArTara has no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if ArTara is successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to its management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale or other disposition of shares of our common stock held by the selling stockholders pursuant to this prospectus.

We will bear the out-of-pocket costs, expenses and fees incurred in connection with the registration of shares of our common stock to be sold by the selling stockholders pursuant to this prospectus. Other than registration expenses, the selling stockholders will bear underwriting discounts, commissions, placement agent fees or other similar expenses payable with respect to sales of shares of our common stock.

SELLING STOCKHOLDERS

We are registering the resale of 5,776,244 shares of common stock, including shares of our common stock that are issuable upon conversion of our Series 1 convertible non-voting preferred stock, held by the selling stockholders identified below, to permit each of them, or their permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part, to resell or otherwise dispose of these shares in the manner contemplated under the section entitled "Plan of Distribution" in this prospectus (as may be supplemented and amended).

The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale or other disposition of any of the shares. The shares covered hereby may be offered from time to time by the selling stockholders. As a result, we cannot estimate the number of shares of common stock each of the selling stockholders will beneficially own after termination of sales under this prospectus. In addition, each of the selling stockholders may have sold, transferred or otherwise disposed of all or a portion of its shares of common stock since the date on which it provided information for this table.

We filed a Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock with the Delaware Secretary of State on January 9, 2020. Thereunder, each share of Series 1 convertible non-voting preferred stock will be convertible into 1,000 shares of our common stock subject to adjustment for any stock splits, stock dividends and similar events, at any time at the option of the holder, provided that any conversion of Series 1 convertible non-voting preferred stock by a holder into shares of our common stock would be prohibited if, as a result of such conversion, the holder, together with its affiliates and any other person or entity whose beneficial ownership of the common stock would be aggregated with such holder's for purposes of Section 13(d) of the Exchange Act would beneficially own more than 4.99% of the total number of shares of our common stock issued and outstanding after giving effect to such conversion. Upon written notice to the Company, the holder may from time to time increase or decrease such limitation to any other percentage not in excess of 19.99% specified in such notice.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to our common stock. Generally, a person "beneficially owns" shares of our common stock if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days.

The information in the table below and the footnotes thereto regarding shares of common stock to be beneficially owned after the offering assumes the sale of all shares being offered by the selling stockholders under this prospectus. The percentage of shares owned prior to and after the offering is based on 5,843,203 shares of common stock outstanding as of January 30, 2020. Unless otherwise

indicated, the address for the persons and entities listed in the table below is c/o ArTara Therapeutics, Inc., 1 Little West 12th Street, New York, NY 10014.

	Before Offering			After Offering	
Name and Address[1]	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	Number of Shares Offered[2]	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Entities affiliated with Baker Brothers Investments c/o Baker Brothers Investments 860 Washington St., 3rd Floor New York, NY 10014 Attention: Scott Lessing, President	296,402(3)	4.99%	2,852,466(4)	—	—
Entities affiliated with Boxer Capital, LLC 11682 El Camino Real, Suite 320 San Diego, CA 92130	296,402(5)	4.99%	1,426,233(6)	—	—
Ikarian Capital c/o Ikarian Healthcare Master Fund, L.P. 200 Crescent Court, Suite 455 Dallas, TX 75201	138,801	2.38%	57,049	81,752	1.40%
James F. Reddoch	30,612	*%	14,262	16,350	*%
Opaleye, L.P. c/o Opaleye Management Inc. One Boston Place, 26th Floor Boston, MA 02108	2,280,472(7)	39.02%	1,426,234	854,238	14.62%

* Less than one percent.

(1) If required, information about other selling stockholders, except for any future transferees, pledgees, donees or successors of the selling stockholders named in the table above, will be set forth in a prospectus supplement or amendment to the registration statement of which this prospectus is a part. Additionally, post-effective amendments to the registration statement will be filed to disclose any material changes to the plan of distribution from the description contained in this prospectus.

(2) Assumes sale of all shares available for sale under this prospectus and no further acquisitions of shares by the selling stockholders.

(3) Consists of 199,671 shares of common stock and 96,731 shares of common stock issuable upon the conversion of shares of Series 1 convertible non-voting preferred stock held collectively by 667, L.P. and Baker Brothers Life Sciences, L.P. Baker Bros. Advisors LP ("BBA") is the management company and investment advisor to 667, L.P. and Baker Brothers Life Sciences, L.P. and may be deemed to beneficially own these shares. The number of shares beneficially owned by BBA, in the aggregate, is limited by beneficial ownership limitations applicable to the conversion of shares of Series 1 convertible non-voting preferred stock, which limit the number of shares BBA can beneficially own after the conversion of shares of Series 1 convertible non-voting preferred stock to a maximum of 4.99% of our outstanding common stock. As a result of such limitations, the number of shares beneficially owned does not include up to an aggregate of 2,556,064 shares of common stock issuable upon the conversion of our Series 1 convertible non-voting preferred stock held by BBA.

(4) Consists of: (i) 16,562 shares of common stock and 220,049 shares of common stock issuable upon the conversion of shares of Series 1 convertible non-voting preferred stock held by 667, L.P. and (ii) 183,109 shares of common stock and 2,432,746 shares of common stock issuable upon the conversion of shares of Series 1 convertible non-voting preferred stock held by Baker Brothers Life Sciences, L.P.

(5) Consists of 199,672 shares of common stock and 96,730 shares of common stock issuable upon the conversion of shares of Series 1 convertible non-voting preferred stock held collectively by Boxer Capital, LLC and MVA Investors, LLC. Boxer Asset Management Inc. ("Boxer Management") is the managing member and majority owner of Boxer Capital, LLC, and Joe Lewis is the sole indirect beneficial owner of and controls Boxer Management. MVA Investors, LLC ("MVA Investors" and, together with Boxer Management, Joe Lewis and Boxer Capital, LLC, the "Boxer Group") is the independent, personal investment vehicle of certain employees of Boxer Capital, LLC. The number of shares beneficially owned by the Boxer Group, in the aggregate, is limited by beneficial ownership limitations applicable to the conversion of shares of Series 1 convertible non-voting preferred stock, which limit the number of shares the Boxer Group can beneficially own after the conversion of shares of Series 1 convertible non-voting preferred stock to a maximum of 4.99% of our outstanding common stock. As a result of such limitations, the number of shares beneficially owned does not include up to an aggregate of 1,129,831 shares of common stock issuable upon the conversion of our Series 1 convertible non-voting preferred stock held by the Boxer Group.

(6) Consists of: (i) 193,842 shares of common stock and 1,190,746 shares of common stock issuable upon the conversion of shares of Series 1 convertible non-voting preferred stock held by Boxer Capital, LLC. and (ii) 5,830 shares of common stock and 35,815 shares of common stock issuable upon the conversion of shares of Series 1 convertible non-voting preferred stock held by MVA Investors.

(7) Represents outstanding shares of common stock beneficially owned by Opaleye, L.P., Opaleye Management Inc., which serves as the investment manager of Opaleye, L.P., and Mr. James Silverman, who serves as the President of Opaleye Management Inc. This information has been obtained from the selling stockholders or in Schedules 13G or 13D and other public documents filed with the SEC.

Relationship with Selling Stockholders

As discussed in greater detail above under the section "Prospectus Summary—Private Placement," on September 23, 2019, we entered into the Subscription Agreement with the selling stockholders, as amended by a First Amendment to Subscription Agreement on November 19, 2019, pursuant to which, on January 9, 2020, we sold shares of common stock and shares of Series 1 convertible non-voting preferred stock to the selling stockholders and agreed with the selling stockholders to file a registration statement to enable the resale of the shares of common stock covered by this prospectus. Other than Richard Levy, M.D., who is a member of our Board of Directors, none of the selling stockholders or any persons having control over such selling stockholders has held any position or office with us or our affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years, other than as a result of the ownership of our shares or other securities.

PLAN OF DISTRIBUTION

We are registering the shares of common stock issued to the selling stockholders to permit the resale of these shares of common stock by the holders of the shares of common stock from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 5110.

In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and if such short sale shall take place after the date that this registration statement is declared effective by the SEC, the selling stockholders may deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling stockholders have been advised that they may not use shares registered on this registration statement to cover short sales of our common stock made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the SEC.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer or agents participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling stockholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Exchange Act.

Each selling stockholder has informed the Company that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. Upon the Company being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of

common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the shelf registration statement, of which this prospectus forms a part.

Each selling stockholder and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholder and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the Registration Rights Agreement, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; provided, however, that each selling stockholder will pay all underwriting discounts and selling commissions, if any, and any legal expenses incurred by it. We will indemnify the selling stockholders against certain liabilities, including some liabilities under the Securities Act, in accordance with the Registration Rights Agreement, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholders specifically for use in this prospectus, in accordance with the related Registration Rights Agreement, or we may be entitled to contribution.

EXPERTS

The consolidated financial statements of ArTara Therapeutics, Inc. as of December 31, 2018 and 2017 and for the year ended December 31, 2018 and for the period from June 2, 2017 (inception) through December 31, 2017 appearing in the Prospectus filed on a Registration Statement pursuant to Rule 424 (b)(3) of ArTara Therapeutics, Inc. (formerly Proteon Therapeutics, Inc.) on December 19, 2019 and incorporated by reference in this prospectus have been audited by Marcum, LLP, an independent registered public accounting firm, as set forth in their report, thereon (which contains an explanatory paragraph relating to substantial doubt about the ability of ArTara Therapeutics, Inc. to continue as a going concern as described in Note 1 to the financial statements) appearing elsewhere in this prospectus, and are incorporated by reference in reliance on such report given upon such firm as experts in auditing and accounting.

The consolidated financial statements of ArTara Therapeutics, Inc. (formerly Proteon Therapeutics, Inc.) at December 31, 2018 and 2017, and for each of the years then ended, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

LEGAL MATTERS

Certain legal matters, including the validity of the shares of common stock offered pursuant to this registration statement, will be passed upon for us by Cooley LLP, San Diego, California.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We must comply with the informational requirements of the Exchange Act, and we are required to file reports and proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information on the SEC's website at http://www.sec.gov, which contains reports, proxy and information statements and other information regarding issuers like us that file electronically with the SEC. We maintain a website at www.artaratx.com. The information contained in, or that can be accessed through, our website is not incorporated by reference herein and is not part of this prospectus.

Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete, and in each instance we refer you to the copy of the contract or document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. We also incorporate by reference into this prospectus the documents listed below and any future filings made by us with the SEC (other than current reports or portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items and other portions of documents that are furnished, but not filed, pursuant to applicable rules promulgated by the SEC) that are filed by us with the SEC pursuant to

Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of the registration statement, and (ii) after the effectiveness of the registration statement but prior to the termination of the offering of the securities covered by this prospectus:

- our Annual Report on Form 10-K and Amendment No. 1 to our Annual Report on Form 10-K/A for the year ended December 31, 2018, filed with the SEC on March 13, 2019 and April 12, 2019, respectively;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2019, June 30, 2019 and September 30, 2019, filed with the SEC on May 8, 2019, August 7, 2019 and October 31, 2019, respectively;
- our Current Reports on Form 8-K filed on March 28, 2019, April 15, 2019, May 15, 2019, August 15, 2019, September 23, 2019, September 24, 2019, October 2, 2019, October 10, 2019, November 21, 2019, December 23, 2019, December 31, 2019, and January 10, 2020;
- the Company's prospectus filed with the SEC on December 19, 2019 pursuant to Rule 424(b)(3) under the Securities Act; and
- the description of our common stock in our registration statement on Form 8-A filed with the SEC on October 16, 2014, including any amendments or reports filed for the purpose of updating such description.

We will furnish without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, a copy of any document incorporated by reference. Requests should be addressed to 1 Little West 12th Street, New York, NY 10014, Attn: Secretary or may be made telephonically at (646) 844-0337.

In accordance with Rule 412 of the Securities Act, any statement contained in a document incorporated by reference herein shall be deemed modified or superseded to the extent that a statement contained herein or in any other subsequently filed document that also is or is deemed to be incorporated by reference herein modifies or supersedes such statement.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following is a statement of the estimated expenses to be incurred by us in connection with the registration of the securities under this registration statement, all of which will be borne by us.

Securities and Exchange Commission Registration Fee	$ 24,974
Legal Fees and Expenses	$ 40,000
Accounting Fees and Expenses	$ 30,000
Miscellaneous	$ 5,026
Total	$ 100,000

Item 15. Indemnification of Directors and Officers.

The registrant's certificate of incorporation and bylaws provide for indemnification of the registrant's directors and officers to the fullest extent permitted by law. Insofar as indemnification for liabilities under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or controlling persons of the registrant pursuant to the registrant's certificate of incorporation, bylaws and the Delaware General Corporation Law, or DGCL, the registrant has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Section 102(b)(7) of the DGCL provides that a certificate of incorporation may include a provision that eliminates or limits the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Company or its stockholders, (ii) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, relating to prohibited dividends or distributions or the repurchase or redemption of stock or (iv) for any transaction from which the director derives an improper personal benefit. The registrant's certificate of incorporation includes such a provision. As a result of this provision, the registrant and its stockholders may be unable to obtain monetary damages from a director for breach of his or her duty of care.

As permitted under the DGCL, the registrant has entered into indemnification agreements with each of its directors and executive officers that require the registrant to indemnify such persons against any and all expenses (including attorneys', witness or other professional fees), and unless in connection with a proceeding by or in the right of the registrant, any and all judgments, fines and amounts paid in settlement, actually and reasonably incurred by such persons or on such persons' behalf in connection with any proceeding, whether actual or threatened, to which any such person may be involved as a party or otherwise by reason of the fact that such person is or was a director or an executive officer of the registrant or is or was serving at the request of the registrant as a director, officer, employee, agent or fiduciary of another enterprise, provided such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful. Under these agreements, the registrant is not required to provide indemnification for certain matters, including:

- indemnification beyond that permitted by applicable law;
- except as provided in the indemnification agreements, an accounting of profits made from the purchase and sale (or sale and purchase) by such director or executive officer of securities of the

registrant within the meaning of Section 16(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or similar provisions of state statutory law or common law;

- except as provided in the indemnification agreements, any reimbursement of the registrant by such director or executive officer of any bonus or other incentive-based or equity-based compensation or of any profits realized by such director or executive officer from the sale of securities of the registrant, as required in each case under the Exchange Act; or

- except as provided in the indemnification agreements, in connection with any proceeding initiated by such director or executive officer, unless (i) the registrant's board of directors authorized the proceeding prior to its initiation or (ii) the registrant provides the indemnification, in its sole discretion, pursuant to the powers vested in the registrant under applicable law.

The indemnification agreements also set forth certain procedures, presumptions and remedies that will apply in the event of a claim for indemnification thereunder.

Item 16. Exhibit Index.

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated September 23, 2019, by and among the Registrant, ArTara Therapeutics, Inc. and REM 1 Acquisition, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 24, 2019).
3.1	Sixth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 27, 2014).
3.2	Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
3.3	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 3, 2017).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
4.2	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
4.3	Fifth Amended and Restated Investors' Rights Agreement, dated as of June 22, 2017 by and among the Registrant and the stockholders party thereto (incorporated by reference to Exhibit 4.18 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 23, 2017).
4.4	Registration Rights Agreement, dated as of August 2, 2017, by and among the Registrant and the investors party thereto (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 3, 2017).

Exhibit No.	Description
4.5	Registration Rights Agreement, dated as of September 23, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 24, 2019).
5.1	Opinion of Cooley LLP.
10.1*	Subscription Agreement, dated September 23, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 24, 2019).
10.2*	First Amendment to Subscription Agreement, dated November 19, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 99.12 to the Registrant's Registration Statement on Form S-4 (File No. 333-234549)).
23.1	Consent of Independent Registered Public Accounting Firm.
23.2	Consent of Independent Registered Public Accounting Firm.
23.3	Consent of Cooley LLP (included in legal opinion filed as Exhibit 5.1).
24.1	Power of Attorney (included on signature page).

* Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedules will be furnished to the SEC upon request.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(a) (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") that are incorporated by reference in the registration statement, or is

contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(b) The undersigned registrant undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person of the registrant in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on January 30, 2020.

ArTara Therapeutics, Inc.

By: /s/ JESSE SHEFFERMAN

Jesse Shefferman
President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Jesse Shefferman as his/her true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for him/her and in his/her name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this Registration Statement on Form S-3, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ JESSE SHEFFERMAN Jesse Shefferman	President and Chief Executive Officer and Director (Principal Executive, Financial and Accounting Officer)	January 30, 2020
/s/ LUKE BESHAR Luke Beshar	Chairman of the Board of Directors	January 30, 2020
/s/ SCOTT BRAUNSTEIN, M.D. Scott Braunstein, M.D.	Director	January 30, 2020
/s/ ROGER GARCEAU, M.D. Roger Garceau, M.D.	Director	January 30, 2020
/s/ RICHARD LEVY, M.D. Richard Levy, M.D.	Director	January 30, 2020

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Name	Title	Date
/s/ GREGORY P. SARGEN Gregory P. Sargen	Director	January 30, 2020
/s/ MICHAEL SOLOMON, PH.D. Michael Solomon, Ph.D.	Director	January 30, 2020

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Exhibit 5.1

Karen E. Deschaine
+1 858 550 6088
kdeschaine@cooley.com

January 30, 2020

ArTara Therapeutics, Inc.
1 Little West 12th Street
New York, NY 10014

Ladies and Gentlemen:

We have acted as counsel to ArTara Therapeutics, Inc., a Delaware corporation (the "***Company***"), in connection with the filing by the Company of a Registration Statement on Form S-3 (the "***Registration Statement***") with the Securities and Exchange Commission, covering the registration for resale by certain selling stockholders of (i) 1,896,888 shares (the "***Common Shares***") of Common Stock, $0.001 par value, of the Company ("***Common Stock***"), and (ii) 3,879,356 shares (the "***Conversion Shares***") of Common Stock issuable upon the conversion of shares (the "***Preferred Shares***") of Series 1 Convertible Non-Voting Preferred Stock. The Common Shares and Preferred Shares were issued by the Company pursuant to that certain Subscription Agreement, dated September 23, 2019, as amended on November 19, 2019, by and among the Company and the purchasers named therein (the "***Purchase Agreement***").

In connection with this opinion, we have examined and relied upon the Registration Statement, the Prospectus included in the Registration Statement, the Company's Sixth Amended and Restated Certificate of Incorporation, as amended, the Company's Second Amended and Restated Bylaws, the Purchase Agreement, the Certificate of Designation for the Series 1 Convertible Non-Voting Preferred Stock and originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness and authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as copies thereof; the accuracy, completeness and authenticity of certificates of public officials; and the due authorization, execution and delivery of all documents by all persons other than by the Company where due authorization, execution and delivery are a prerequisite to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

Our opinion is expressed only with respect to the General Corporation Law of the State of Delaware. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

With regard to our opinion regarding the Conversion Shares, we express no opinion to the extent that, notwithstanding its current reservation of shares of Common Stock, future issuances of securities, including the Conversion Shares, and/or antidilution adjustments to outstanding securities, including the Preferred Shares, cause the Preferred Shares to be convertible into more shares of Common Stock than the number that then remain authorized but unissued.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that (i) the Common Shares have been validly issued and are fully paid and nonassessable and (ii) the Conversion Shares, when issued upon conversion of the Preferred Shares in accordance with the terms of the Preferred Shares, will be validly issued, fully paid and nonassessable.

We consent to the reference to our firm under the caption "Legal Matters" in the Prospectus and to the filing of this opinion as an exhibit to the Registration Statement.

Sincerely,

Cooley LLP

By: /s/ KAREN E. DESCHAINE

Karen E. Deschaine

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-3) and related Prospectus of ArTara Therapeutics, Inc. for the registration of 5,776,244 shares of its common stock and to the incorporation by reference therein of our report dated March 13, 2019, with respect to the consolidated financial statements of Proteon Therapeutics, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 2018, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Boston, Massachusetts
January 30, 2020

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Exhibit 23.2

Independent Registered Public Accounting Firm's Consent

We consent to the incorporation by reference in this Registration Statement of ArTara Therapeutics, Inc. on Form S-3 of our report dated November 6, 2019, except as to Notes 4 and 7 as to which the date is December 4, 2019, which includes an explanatory paragraph as to the Company's ability to continue as a going concern with respect to our audits of the consolidated financial statements of ArTara Therapeutics, Inc. as of December 31, 2018 and 2017 and for the year ended December 31, 2018 and for the period from June 2, 2017 (inception) through December 31, 2017, appearing in the Prospectus filed on a Registration Statement pursuant to Rule 424 (b)(3) of ArTara Therapeutics, Inc. (formerly Proteon Therapeutics, Inc.) on December 19, 2019. We also consent to the reference to our firm under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Marcum LLP

Marcum LLP
New York, New York
January 30, 2020

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