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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 2, 2015

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

Delaware
(State or other jurisdiction
of incorporation)

001-36485
(Commission
File Number)

26-1303944
(IRS Employer
Identification Number)

34175 Ardenwood Blvd., Suite 200
Fremont, CA 94555
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (510) 745-1700

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01 Entry into a Material Definitive Agreement.***Termination Agreement with AstraZeneca***

On June 2, 2015, Ardelyx, Inc. (the “Company”) entered into a Termination Agreement with AstraZeneca AB (“AstraZeneca”) pursuant to which the Company and AstraZeneca agreed to terminate the License Agreement dated as of October 4, 2012, as amended December 23, 2013 (the “Collaboration Agreement”). The Collaboration Agreement was entered into for the worldwide development and commercialization of tenapanor, the Company’s lead product candidate which in clinical studies has demonstrated the ability to improve the symptoms of constipation-predominant irritable bowel syndrome (“IBS-C”) and to reduce the absorption of dietary sodium as well as phosphorus, a key component in the management of hyperphosphatemia in dialysis patients, and certain other NHE3 inhibitor compounds. AstraZeneca was responsible for all of the development and commercialization costs for tenapanor and the Company had retained an option to co-promote in the United States.

Pursuant to the Termination Agreement, all licenses granted by the Company to AstraZeneca under the Collaboration Agreement were terminated, except for the limited purpose of allowing AstraZeneca to satisfy its obligations under the Termination Agreement. In addition, AstraZeneca will assign certain agreements and licenses to the Company and will provide the Company with licenses, data, records and other materials to facilitate the Company’s continued development and commercialization of tenapanor and the portfolio of NHE3 inhibitors licensed to AstraZeneca under the Collaboration Agreement. AstraZeneca will also supply the Company with clinical trial material and certain other materials, drug substances and drug products using transfer pricing for the aggregate amount of up to \$10 million.

The Company has agreed to pay certain amounts to AstraZeneca for the return of the licenses previously granted to it, including (a) an upfront fee of \$15 million, (b) future royalties at a royalty rate of 10% of net sales of tenapanor or other licensed products by the Company and its licensees and (c) 20% of non-royalty revenue received from a new collaboration partner should the Company elect to license, or otherwise provide rights, to a third party to develop and commercialize tenapanor. These amounts payable by the Company are capped at the aggregate amount of \$90 million.

The Company has also agreed to pay AstraZeneca \$10 million as reimbursement for research and development expenses incurred by AstraZeneca under the Collaboration Agreement during 2015, and in consideration of the accelerated transfer of information, data and materials to Ardelyx.

Securities Purchase Agreement

On June 2, 2015, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with the purchasers named therein (the “Purchasers”). Pursuant to the Purchase Agreement, the Company agreed to sell an aggregate of 7,242,992 shares of common stock (the “Shares”) and warrants (the “Warrants”) to purchase 2,172,898 shares of common stock (“Warrant Shares”) for aggregate gross proceeds of approximately \$77.8 million (the “Offering”). The purchase price for each Share is \$10.70, which is equal to the consolidated closing bid price on the NASDAQ Global Market on the day of pricing, June 2, 2015. The purchase price for each Warrant is equal to \$0.125 for each Warrant Share, consistent with NASDAQ Global Market requirements for an “at the market” offering, and the Warrants are exercisable at an exercise price of \$13.91 per share. The Company expects the Offering to close by June 5, 2015 subject to satisfaction of specified customary closing conditions. The Purchasers have irrevocably committed to purchase the securities, subject to satisfaction of the closing conditions. Investors participating in the offering include entities associated with New Enterprise Associates, a venture capital firm that is a significant shareholder in the Company, and a combination of new and existing investors, including RA Capital Management, Broadfin Capital LLC, Cormorant Asset Management LLC, Foresite Capital Management, LLC, Rock Springs Capital Management LP, and a fund managed by Sabby Capital, LLC.

In connection with the Purchase Agreement, the Company will enter into a Registration Rights Agreement (the “Registration Rights Agreement”) with the Purchasers. Pursuant to the Registration Rights Agreement, the Company will agree to prepare and file a registration statement with the Securities and Exchange Commission (the “SEC”) within 45 days after the closing of the Offering for purposes of registering the resale of the Shares, the shares of common stock issuable upon exercise of the Warrants, and any shares of common stock issued as a dividend or other distribution with respect to the Shares or shares underlying the Warrants. The Company will agree to use its commercially reasonable efforts to cause this registration statement to be declared effective by the SEC within 90 days after the closing of the Offering (120 days in the event the registration statement is reviewed by the SEC). The Company will also agree, among other things, to indemnify the selling holders under the registration statements from certain liabilities and to pay all fees and expenses (excluding underwriting discounts and selling commissions and all legal fees of any selling holder) incident to the Company’s obligations under the Registration Rights Agreement.

The financing is exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Regulation D under the Securities Act.

The securities sold and issued in connection with the Purchase Agreement will not be registered under the Securities Act or any state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements.

The foregoing description of the transaction is only a summary and is qualified in its entirety by reference to the Purchase Agreement, the Form of Warrant and the Registration Rights Agreement, copies of which will be filed as exhibits to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2015.

Item 1.02 Termination of a Material Definitive Agreement.

The information called for by this item is contained in Item 1.01, which is incorporated herein by reference.

Item 3.02 Unregistered Sale of Equity Securities.

The information called for by this item is contained in Item 1.01, which is incorporated herein by reference.

Item 8.01 Other Events.

In connection with the Termination Agreement described in Item 1.01, the Company plans to accelerate the clinical development path for tenapanor in constipation-predominant IBS-C by initiating a Phase 3 clinical trial in IBS-C patients in the fourth quarter of 2015. Additionally in the fourth quarter of 2015, Ardelyx expects to begin a Phase 2b clinical trial to evaluate the optimal dosing regimen for tenapanor for the treatment of hyperphosphatemia in dialysis patients.

A copy of the Company's press release announcing its entry into the Termination Agreement and describing its development plans for tenapanor and its portfolio of NHE3 compounds is attached as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

The Company also plans to develop a new product candidate, RDX022, for the treatment of hyperkalemia, or elevated potassium, a potentially dangerous problem common among patients with chronic kidney disease and heart failure. RDX022 is a novel form of polystyrene sulfonate that has been designed with improved chemical and physical properties as well as with formulation improvements with the goal of a more efficient binding of potassium and a more palatable dosage form than currently-marketed polystyrene sulfonate products. The Company will be pursuing a 505b(2) regulatory pathway in the United States for RDX022. It anticipates beginning clinical trials in mid-2015 and, assuming a successful completion of the early-stage clinical trials, expects to commence a Phase 3 clinical trial as early as the second half of 2016.

A copy of the Company's press release announcing its new product candidate for the treatment of hyperkalemia and its development timeline is attached as Exhibit 99.2 to this Current Report on Form 8-K, and is incorporated herein by reference.

The Company plans to use the proceeds from its private placement to develop both tenapanor and RDX022, two wholly-owned programs that have potential to be in Phase 3 clinical trials in the fourth quarter of 2015 and second half of 2016, respectively. The Company currently anticipates that development costs to advance tenapanor through clinical trials based on its current development plan and a new drug application ("NDA") submission will be approximately \$65-80 million for the treatment of IBS-C and \$40-50 million for the treatment of hyperphosphatemia and that the development costs to advance RDX022 through clinical trials based on its current development plan and NDA submission for the treatment of hyperkalemia will be approximately \$40-50 million.

The Company will host a live conference call and webcast at 8:30 a.m. eastern time on Wednesday, June 3, 2015 to discuss the Termination Agreement, private placement and proposed development plans for tenapanor, RDX022 and its other research and development programs. The live webcast and a replay may be accessed by visiting the Company's website at <http://ir.ardelyx.com/>.

Conference call information is as follows: (855) 296-9612 (U.S.) or (920) 663-6277 (international). Conference ID number is 59352386.

Statements made in this current report on Form 8-K, other than statements of historical fact, are forward-looking statements, including, for example, statements relating to the Company's clinical development programs, its spending plans, including the intended use of the proceeds from the financing and for the timing of the closing of the financing. Forward-looking statements are subject to a number of known and unknown risks and uncertainties that might cause actual results to differ materially from those expressed or implied by such statements. For example, there can be no assurances with respect to the commencement, pace of enrollment, cost, rate of spending, completion or success of clinical trials; there can be no assurance with respect to the consummation of financing activities; financial projections may not be accurate; and there can be no assurances that the Company will pursue further activities with respect to the clinical development of tenapanor or RDX022. These and other risk factors are set forth in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2014 and subsequent SEC filings, including the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2015. The Company disclaims any intention or duty to update any forward-looking statement made in this current report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated June 3, 2015
99.2	Press Release dated June 3, 2015

SIGNATURES

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

Date: June 3, 2015

ARDELYX, INC.

By: /s/ Mark Kaufmann

Mark Kaufmann
Chief Financial Officer

EXHIBIT INDEX

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Ardelyx Regains Worldwide Development and Commercialization Rights for Its Late-Stage Development Candidate, Tenapanor, and Related Portfolio of NHE3 Compounds

Ardelyx to Initiate a Phase 3 Clinical Program in IBS-C Patients in the Fourth Quarter of 2015

Conference Call and Webcast Today at 8:30 am ET

FREMONT, Calif., June 3, 2015 - Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on cardio-renal, gastrointestinal and metabolic diseases, today announced that it has entered into a termination agreement with AstraZeneca (LSE: AZN, SSE: AZN, NYSE: AZN), such that all the rights to Ardelyx's portfolio of NHE3 inhibitors, including Ardelyx's lead product candidate, tenapanor, are returned to Ardelyx. Ardelyx has agreed to pay AstraZeneca \$15 million upfront along with other future contingent payments. Concurrently, Ardelyx will pay an additional \$10 million in R&D costs and for the acceleration of the transfer of the program back to Ardelyx. Ardelyx formed a partnership with AstraZeneca in October 2012 to develop and commercialize Ardelyx's internally discovered portfolio of NHE3 inhibitors including tenapanor.

With the acquisition of worldwide rights from AstraZeneca, Ardelyx plans to accelerate the clinical development path for tenapanor in constipation-predominant irritable bowel syndrome (IBS-C) by initiating a Phase 3 clinical program in IBS-C patients in the fourth quarter of this year. Additionally, Ardelyx is planning to begin a Phase 2b clinical trial in the fourth quarter of this year to evaluate the optimal dosing regimen for tenapanor for the treatment of hyperphosphatemia in dialysis patients.

"By regaining the worldwide rights to tenapanor, we now have a late-stage clinical asset that has demonstrated significant promise for the treatment of IBS-C and hyperphosphatemia, both of which are conditions where we believe tenapanor could potentially transform the treatment paradigm," said Mike Raab, President and Chief Executive Officer.

"Ardelyx can now accelerate the clinical development of tenapanor to meet the needs of two underserved patient populations. We are grateful for the substantial investment that AstraZeneca has made in the NHE3 program, and we have been fortunate to have them as a partner," Mr. Raab added.

In a separate press release, Ardelyx announced today a new product candidate, RDX022, for which it will be pursuing a 505b(2) regulatory pathway in the United States. Ardelyx is developing RDX022 for the treatment of elevated potassium, or hyperkalemia. Ardelyx expects to initiate clinical trials with RDX022 in mid-2015. Ardelyx also announced today that it has entered into an agreement to sell shares of common stock and warrants to purchase common stock for the aggregate gross proceeds of approximately \$77.8 million in a private placement. Proceeds from the private placement will be used to develop both tenapanor and RDX022, two wholly-owned programs that are targeted to begin Phase 3 clinical trials in the fourth quarter 2015 and second half of 2016, respectively.

About the Termination Agreement

Ardelyx and AstraZeneca have executed a termination agreement under which Ardelyx regained all rights for all NHE3 inhibitors previously licensed to AstraZeneca, including tenapanor.

Under the terms of the termination agreement, Ardelyx has agreed to pay AstraZeneca certain amounts for the return of the rights, including \$15 million up front, royalties equal to 10% of net sales of tenapanor by Ardelyx or a licensee, and 20% of non-royalty payments that Ardelyx receives from a new partner should it elect to license, or otherwise provide rights to develop and commercialize tenapanor, with all such amounts not to exceed \$90 million. Ardelyx has also agreed to pay AstraZeneca \$10 million in R&D costs, and in consideration of the acceleration of the transfer of the information, data and materials to Ardelyx. In addition, AstraZeneca is obligated to complete the manufacture of clinical trial material necessary for the Phase 3 clinical program in IBS-C patients, and Ardelyx has agreed to purchase the Phase 3 clinical trial material and other drug product inventory from AstraZeneca for up to \$10 million.

Tenapanor's Clinical Development

Tenapanor is a minimally-absorbed small molecule inhibitor of NHE3, a transporter of sodium in the gastrointestinal tract. Orally administered tenapanor has been shown in clinical trials to reduce the intestinal absorption of both dietary sodium and phosphorus. A total of 14 clinical trials of tenapanor have been completed, and over 1,000 subjects have been administered tenapanor to date.

In October 2014, Ardelyx reported positive Phase 2b data for the use of tenapanor in treating patients with IBS-C. At the twice-daily 50mg dose of tenapanor, the study met its primary efficacy endpoint of an increase in the complete spontaneous bowel movement (CSBM) responder rate ($p < 0.001$). Most secondary endpoints, including abdominal pain, the overall responder rate and other abdominal and IBS-C symptoms, demonstrated statistically significant and clinically meaningful improvements. Ardelyx plans to initiate a Phase 3 clinical program to further evaluate tenapanor in IBS-C patients in the fourth quarter of 2015, assuming the successful transfer of clinical trial material from AstraZeneca. In February 2015, Ardelyx announced results from a Phase 2b clinical study in hyperphosphatemic patients on dialysis with end stage renal disease, or CKD-5D. In the study, there was a statistically significant dose-related decrease in serum phosphate levels for tenapanor-treated patients compared to patients receiving placebo ($p = 0.012$). It was noted, however, that the rate of diarrhea and the rate of discontinuations due to diarrhea were higher than expected based on previous clinical trials. Higher discontinuations rates due to diarrhea were observed primarily in the 30mg once daily and 30mg twice daily dose groups. Ardelyx plans to begin a second Phase 2b dose-ranging clinical program for tenapanor in hyperphosphatemia in dialysis patients during the fourth quarter of 2015 assuming successful transfer of clinical trial material from AstraZeneca.

Additional details on tenapanor and Ardelyx's research and development programs will be presented at Ardelyx's upcoming R&D Investor Day, planned for July 14, 2015, in New York, NY.

Conference Call & Webcast Information

Ardelyx will host a live conference call and webcast today at 8:30am Eastern Time. The live webcast and a replay may be accessed by visiting Ardelyx's website on the investor page of the Company's website at <http://ir.ardelyx.com/>

Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 1-855-296-9612 (US) or 920-663-6277 (International) to listen to the live conference call. The conference ID number for the live call is 59352386. Please dial in approximately 10 minutes prior to the call. An archived webcast replay will be available on the Company's website for two weeks.

About Ardelyx

Ardelyx is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, minimally-systemic, small molecule therapeutics that work exclusively in the gastrointestinal tract to treat cardio-renal, gastrointestinal and metabolic diseases. Ardelyx has developed a proprietary drug discovery and design platform enabling it, in a rapid and cost-efficient manner, to discover and design novel drug candidates. Utilizing this platform, the Company has discovered and designed tenapanor. In addition to tenapanor, Ardelyx is developing RDX022, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, in kidney and heart disease patients, and has discovered small molecule NaP2b inhibitors for the treatment of hyperphosphatemia in CKD-5D, a program licensed to Sanofi. Ardelyx is also independently advancing several research programs focused in cardio-renal, gastrointestinal and metabolic diseases. Ardelyx is located in Fremont, California. For more information, please visit Ardelyx's website at www.ardelyx.com.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Ardelyx, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including the potential for tenapanor in treating IBS-C patients, the potential for tenapanor in treating hyperphosphatemia in patients with end stage renal disease on dialysis, Ardelyx's future development plans for tenapanor and the timing thereof, the potential for RDX022 in treating hyperkalemia, Ardelyx's future development plans for RDX022 and the timing thereof, and the potential of Ardelyx's drug discovery and design platform. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of tenapanor, or Ardelyx's future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical development process, Ardelyx's reliance upon AstraZeneca for the timely delivery of clinical trial material required for the initiation of the Phase 3 clinical program in IBS-C and the Phase 2b clinical trial in hyperphosphatemia, and Ardelyx's reliance upon AstraZeneca to facilitate a complete and

timely transition of the tenapanor program from AstraZeneca to Ardelyx. Ardelyx undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Ardelyx's business in general, please refer to Ardelyx's quarterly report filed on Form 10-Q with the Securities and Exchange Commission on May 12, 2015, and its future periodic reports to be filed with the Securities and Exchange Commission.

Investor and Media Contact:

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Burns McClellan on behalf of Ardelyx
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SOURCE: ARDELYX

Ardelyx, Inc.

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Ardelyx to Raise \$77.8 Million in a Private Placement and Announces New Product Candidate for the Treatment of Hyperkalemia to Begin Clinical Development in Mid-2015

Ardelyx to Pursue an Accelerated 505b(2) Regulatory Pathway for RDX022 with Initiation of Phase 3 Program to Begin as Early as Second Half 2016

Conference Call and Webcast Today at 8:30am ET

FREMONT, Calif., June 3, 2015 - Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on cardio-renal, gastrointestinal and metabolic diseases, today announced that it has entered into an agreement to sell shares of its common stock and warrants to purchase shares of common stock for aggregate gross proceeds of approximately \$77.8 million in a private placement. New Enterprise Associates (NEA), the Company's largest shareholder and one of the largest biotechnology investors worldwide, has committed to invest approximately \$50.2 million in the private placement and a combination of new and existing investors, including RA Capital Management, Broadfin Capital LLC, Cormorant Asset Management LLC, Foresite Capital Management, LLC, Rock Springs Capital Management LP, and a fund managed by Sabby Capital, LLC, have committed to invest the remaining \$27.6 million. Additionally, Ardelyx announced a new program, RDX022, a non-absorbed polymer, for the treatment of hyperkalemia.

"Ardelyx's clinical programs hold great promise, and we are excited to continue to play an important role in the Company's growth," said David Mott, Head of the Healthcare Practice at NEA and Chairman of Ardelyx. "Since our initial investment in 2008, Ardelyx is transforming into an emerging biotech company with a pipeline of proprietary and novel drug candidates that have a clear path to commercialization. The Company has an exceptional team that can advance its clinical programs and execute on its business strategy." Mr. Mott added.

"Given the extensive expertise of the Ardelyx team in developing and commercializing minimally-absorbed products including polymers in the cardio-renal field, we are uniquely positioned to develop an improved potassium binder to manage hyperkalemia in chronic kidney and heart disease patients," noted Mike Raab, President and CEO of Ardelyx. "Together with tenapanor and RDX013, our small molecule hyperkalemia program, RDX022 is an exciting program that augments a formidable pipeline of innovative products. This is a pivotal point in the history of Ardelyx and an exciting time for our company as we focus our efforts towards building a commercially-driven, fully-integrated company with wholly-owned products to transform the treatment paradigm in the indications that they treat."

In a separate press release, the Company announced today it has regained from AstraZeneca the worldwide development and commercialization rights for its late-stage development candidate, tenapanor, and its related portfolio of NHE3 compounds. Proceeds from the private placement will be used to develop tenapanor and RDX022, two wholly-owned programs that have the potential to be in Phase 3 clinical trials in the fourth quarter of 2015 and second half of 2016, respectively.

About the Private Placement

Ardelyx will sell approximately 7.24 million shares of the common stock and warrants to purchase approximately 2.17 million shares of common stock for aggregate gross proceeds of approximately \$77.8 million in the private placement. The price to be paid for the common stock, \$10.70 per share, is equal to the consolidated closing bid price on the Nasdaq Global Market on the day of pricing, June 2, 2015. The warrants are exercisable at a price of \$13.91 per share. The Company expects the offering to close by June 5, 2015 subject to satisfaction of specified customary closing conditions. Leerink Partners LLC is acting as the sole placement agent of the offering and Wedbush PacGrow acted as a financial advisor to Ardelyx in connection with this offering.

The securities to be sold in this private placement have not been registered under the Securities Act of 1933, as amended, or any state securities laws, and will be sold in a private placement pursuant to Regulation D of the Securities Act. The securities may not be offered or sold in the United States absent registration or pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws. Ardelyx has agreed to file a registration statement covering the resale of the shares of common stock acquired by the investors and shares of common stock issuable upon exercise of the warrants acquired by the investors.

About RDX022

RDX022 is a novel, non-absorbed polystyrene sulfonate polymer being developed by Ardelyx to treat elevated potassium, or hyperkalemia, a potentially dangerous problem common among patients with chronic kidney disease (CKD) and heart failure. RDX022 is designed with improved chemical and physical properties as well as formulation improvements that may allow for a more palatable dosage form.

The Company will be pursuing a 505b(2) regulatory pathway in the United States for RDX022, allowing Ardelyx a faster path to approval by referencing the literature and the U.S. Food and Drug Administration's previous findings of safety and effectiveness of the referenced drug product. Ardelyx will supplement this approach with nonclinical and Phase 3 clinical data on RDX022 to provide information for inclusion in the product label. The Company plans to progress RDX022 into late stage clinical development over the next 12-18 months.

Ardelyx will begin early stage clinical trials in mid-2015. Assuming the successful completion of those trials, the Company expects to commence a Phase 3 clinical program to evaluate RDX022 for treatment in hyperkalemia patients as early as the second half of 2016.

Ardelyx is also continuing research on its RDX013 small molecule drug candidate for hyperkalemia. This agent, a potential potassium secretagogue, is intended to enhance potassium secretion or prevent potassium absorption with a much lower pill burden than potassium binders and may provide significant advantages as a stand-alone agent or used in combination with the potassium binders, including RDX022.

Additional details on RDX022 and Ardelyx's research and development programs will be presented at Ardelyx's upcoming R&D Investor Day, planned for July 14th, 2015, in New York, NY.

About Hyperkalemia

Hyperkalemia is defined as the presence of blood potassium levels greater than 5.0mEq/L. Normal levels are 3.5 to 5.0 mEq/L. When hyperkalemia is severe, or above 7.0mEq/L, there is a significantly increased risk of death because of the potential for heart conduction problems.

Hyperkalemia can be caused by a variety of sources. Kidney disease can result in the build-up of potassium in the blood. Also, certain drugs such as the common blood pressure medications known as RAAS inhibitors, or inhibitors of the renin-angiotensin-aldosterone system, can cause hyperkalemia. RAAS inhibitors, though quite effective for controlling blood pressure, are often significantly reduced in patients, such as in those with CKD and congestive heart failure, or CHF, whose potassium levels are elevated because of the fear that elevated potassium can cause significantly worse problems than hypertension including sudden cardiac arrest in severe cases.

According to Einhorn et al, about 21% and 42% of patients with CKD Stage 3b and Stage 4 had a hyperkalemic event during a 12-month period suggesting that acute hyperkalemia affects about 900,000 individuals with CKD stage 3b or 4 in the United States. There are approximately 1.9 million patients with stage 3b or 4 CKD who are taking RAAS inhibitors and about 10% of these patients, or about 190,000 patients, tend to have chronic problems with hyperkalemia. There are about 1.7 million stage 3b or 4 CKD patients who are not prescribed RAAS inhibitors. Given that hypertension is present in a majority of these patients, the Company believes that many of these patients are not prescribed RAAS inhibitors because of the risk of hyperkalemia. Recent data (Fraser 2013) suggests that of the 88% of CKD stage 3 patients with hypertension, only 36% achieved the target of 130/80 with over 35% not taking any RAAS inhibitors despite their known success in achieving blood pressure control. This supports the concept that a million or more CKD patients may be prescribed suboptimal doses of RAAS inhibitors with at least one reason being the avoidance of hyperkalemia.

Additionally, of the 5.7 million patients with heart failure, over half are prescribed RAAS inhibitors. Again, these patients tend to receive suboptimal doses of RAAS inhibitors suggesting a large opportunity in this market as well.

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SOURCE: ARDELYX

Ardelyx, Inc.

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