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): March 15, 2018

Akcea Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-38137	**47-2608175**
(Commission File No.)	(IRS Employer Identification No.)

55 Cambridge Parkway, Suite 100
Cambridge, MA 02142
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(617) 207-0202**

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

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

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

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

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

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

Emerging growth company ☒

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

Item 8.01 Other Events.

On March 15, 2018, Akcea Therapeutics, Inc. (the "Company") conducted a press conference concerning the Company's previously announced transaction with its affiliate, Ionis Pharmaceuticals, Inc. ("Ionis"), with respect to its entry into a development, commercialization, collaboration and license agreement and a stock purchase agreement, each dated March 14, 2018, with Ionis.

A copy of the conference call transcript is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

IMPORTANT INFORMATION FOR INVESTORS AND SECURITY HOLDERS

This communication may be deemed to be solicitation material in respect of the proposed transaction of the Company and Ionis. In connection with the proposed transaction, the Company has filed a preliminary proxy statement on Schedule 14A. Following the filing of a definitive proxy statement with the SEC, the Company will mail the definitive proxy statement and a proxy card to each stockholder entitled to vote at the special meeting relating to the proposed transaction. INVESTORS AND SECURITY HOLDERS OF THE COMPANY ARE URGED TO READ THESE MATERIALS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND ANY OTHER RELEVANT DOCUMENTS IN CONNECTION WITH THE PROPOSED TRANSACTION THAT THE COMPANY WILL FILE WITH THE SEC WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE COMPANY AND THE PROPOSED TRANSACTION. The preliminary proxy statement, the definitive proxy statement and other relevant materials in connection with the proposed transaction (when they become available), and any other documents filed by the Company with the SEC, may be obtained free of charge at the SEC's website at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC or by sending a request to Investor Relations at Akcea Therapeutics, Inc., 55 Cambridge Parkway, Suite 100, Cambridge, Massachusetts 02142.

The Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the Company's stockholders with respect to the proposed transaction. Information regarding the identity of the potential participants, and their direct or indirect interests in the transaction, by security holdings or otherwise, including Ionis, will be set forth in the proxy statement and other materials to be filed with the SEC in connection with the proposed transaction.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Conference Call Transcript, dated March 15, 2018

INDEX TO EXHIBITS

SIGNATURE

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, thereunto duly authorized.

Akcea Therapeutics, Inc.

Dated: March 16, 2018

By: /s/ Paula Soteropoulos

Paula Soteropoulos

Chief Executive Officer

Exhibit 99.1

IMPORTANT INFORMATION FOR INVESTORS AND SECURITY HOLDERS
This communication may be deemed to be solicitation material in respect of the proposed transaction of the Company and Ionis. In connection with the proposed transaction, the Company has filed a preliminary proxy statement on Schedule 14A. Following the filing of a definitive proxy statement with the SEC, the Company will mail the definitive proxy statement and a proxy card to each stockholder entitled to vote at the special meeting relating to the proposed transaction. INVESTORS AND SECURITY HOLDERS OF THE COMPANY ARE URGED TO READ THESE MATERIALS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND ANY OTHER RELEVANT DOCUMENTS IN CONNECTION WITH THE PROPOSED TRANSACTION THAT THE COMPANY WILL FILE WITH THE SEC WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE COMPANY AND THE PROPOSED TRANSACTION. The preliminary proxy statement, the definitive proxy statement and other relevant materials in connection with the proposed transaction (when they become available), and any other documents filed by the Company with the SEC, may be obtained free of charge at the SEC's website at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC or by sending a request to Investor Relations at Akcea Therapeutics, Inc., 55 Cambridge Parkway, Suite 100, Cambridge, Massachusetts 02142.

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Ionis Pharmaceuticals
Ionis and Akcea Webcast on Inotersen Commercial Collaboration
Thursday, March 15, 2018, 8:30 AM Eastern Time

Officers
Wade Walke; VP, Corporate Communications & IR
Stan Crooke; Ionis; Chairman, CEO
Paula Soteropoulos; Akcea; CEO
Lynne Parshall; Akcea, Ionis; Board Member
Sarah Boyce, Chief Business Officer
Beth Hougen; CFO

Analysts
Stephen Willey; Stifel
Jim Birchenough; Wells Fargo
Laura Christianson; Cowen & Co.
Jessica Fye; J.P. Morgan
Yale Jen; Laidlaw & Co.
Unknown Analyst;

Presentation

Operator: Welcome to Ionis Pharmaceuticals and Akcea Therapeutics conference call to discuss the new transaction to globally commercialize inotersen.

As a reminder, this call is being recorded.

At this time, I would like to turn the call over to Wade Walke, Vice President of Corporate Communications and Investor Relations, to lead off the call. Please begin.

Wade Walke: Thank you. Good morning, everyone. Before I turn the call over to Stan Crooke, Chief Executive Officer and Chairman at Ionis, I will read the forward-looking language statement.

This presentation includes forward-looking statements regarding the recently announced transaction between Ionis and Akcea, Ionis and Akcea's business and the therapeutic and commercial potential of inotersen, IONIS-TTR-L_{Rx} and other products in development. Any statement describing Ionis' or Akcea's goals, expectations, financial or other projections, intentions or beliefs, including the commercial potential of inotersen, volanesorsen or other of Ionis' or Akcea's drugs in development, is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing, and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs.

Ionis' and Akcea's forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Ionis' and Akcea's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Ionis and Akcea. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Ionis' and Akcea's programs are described in additional detail in Ionis' and Akcea's annual reports on Form 10-K for the year ended December 31st, 2017, on Form 10-K, and in Akcea's preliminary proxy statement for this transaction, which are on file with the SEC. Copies of these and other documents are available from each company.

And now I'll turn the call over to Stan.

Stan Crooke: Thanks, Wade, and good morning, everyone. Thanks so very much for joining us. We are pleased to announce that we have chosen our affiliate, Akcea, to commercial inotersen and IONIS-TTR-L_{Rx}, which we now refer to as AKCEA-TTR-L_{Rx}.

We believe this transaction will maximize the commercial success of inotersen and our entire TTR franchise and should bring back a substantial value to both companies.

Today's announcement reflects our increasing confidence in the value inotersen will bring to patients, confidence honed by the feedback we've received from physicians and patients, and, as we've had these conversations, a deepening understanding of the needs of these patients.

As I've said before, our goal is for the ideal partner for inotersen have been to rapidly deliver inotersen to patients who desperately need this treatment, to maximize the commercial success of inotersen, and to optimize our commercial participation in our entire TTR franchise. We believe this collaboration meets all those goals. In short, we believe this transaction is a win for patients, a win for shareholders, and a win for both companies.

We conducted a thorough process to evaluate potential partners and types of transactions for inotersen. Our focus was on what solution assures the greatest commercial success, and a key component of that is the question, could a potential partner be launch-ready. This is even more important to us because we know that we have a strong competitor coming. As we evaluated each of these potential partners, the conclusion we came to was that no partner other than the combined Ionis inotersen team and the Akcea team could guarantee being launch-ready in Europe and the U.S.

As you might expect, interest in inotersen took a variety of forms from larger companies who wanted global rights with no Ionis participation to more regional transactions from companies with substantial rare disease expertise and those with less. In the meantime, inotersen was progressing rapidly through registration and the Ionis team was making remarkable progress in preparing to launch inotersen in the U.S.

At the conclusion of this process, it was clear that taking advantage of our Ionis inotersen team and preparations in partnering with Akcea was the best choice. And remember that when we created Akcea, it was with an eye to just this type of collaboration for our late-stage assets. With the carefully selected management team and a board of directors with strong commercial background, Akcea is building an accomplished team and an efficient, effective, rare disease commercial organization in the U.S., Europe, and Canada.

Moreover, this transaction is transformative for Akcea. The opportunity to add inotersen to Akcea's pipeline strengthens and accelerates our first commercial affiliate even more rapidly than we had planned.

Akcea's expertise and focus is exactly what is necessary to support the inotersen launch. The strength and experience of the joint inotersen and volanesorsen teams and Akcea's global capabilities further enhance our potential to maximize inotersen's benefit to patients with hATTR.

Sarah Boyce, Chief Business Officer, will transition at the close of this transaction, becoming President and a member of the board of Akcea. The combination of Paula and Sarah's leadership with this highly skilled joint team should benefit inotersen, AKCEA-TTR-L_{Rx}, and the rest of the Akcea portfolio.

The synergy between the inotersen and Akcea teams that developed as the teams working together to solve issues that are common to both volanesorsen and inotersen added to our confidence that this transaction will maximize the commercial success of both drugs.

Joining me on the call are Paula Soteropoulos, Chief Executive Officer at Akcea, Sarah Boyce, Chief Business Officer, and Lynne Parshall, Board Member at both Akcea and Ionis and a strategic senior advisor to Ionis. Also joining us on the call for Q&A are Brett Monia, Chief Operating Officer at Ionis, Beth Hougen, Chief Financial Officer at Ionis, and Mike MacLean, Chief Financial Officer at Akcea.

On this morning's call I'll discuss in a bit more detail the transaction with Akcea and why we picked Akcea to commercial inotersen. Paula will discuss the significant value adding a second launch-ready drug to Akcea will have and how inotersen fits personally with Akcea's rare disease focus. Lynne will discuss the transactions financial benefits to both companies. Sarah will update you on inotersen launch progress and the opportunities created by combining the Ionis and Akcea teams. Finally, Paula and I will finish with brief concluding remarks and open up the call for Q&A.

We had significant partnering interest in inotersen from a range of companies and we received multiple offers. In parallel with our partnership discussions, the inotersen and volanesorsen commercial teams were making substantial progress preparing for the anticipated launches of these two drugs. They were collaborating on numerous launch activities and finding many areas of synergy. This increased our confident in each team's ability to be successful in launching its drug as well as the combined teams' ability to launch both drugs. Their progress raised the bar for potential partners.

After careful evaluation of our options, we decided that partnering with Akcea puts us in the strongest position to achieve all our goals. Partnering with Akcea enables us to accelerate our promotional preparations. Building on Akcea's existing infrastructure makes more high-quality resources available immediately, which should enable a strong and rapid launch upon approval.

We believe combining the accomplished focus passionate Ionis and Akcea teams to launch inotersen globally will maximize the commercial success of inotersen. We plan to continue to leverage the strong relationships Ionis has built in the medical and patient advocacy communities and we can best utilize the inotersen's team deep understanding of hATTR and the burden it places on patients and their families as a result of this combination.

Combining the Akcea and inotersen commercial expertise, experience, and leadership brings the firepower we need to successfully launch inotersen and volanesorsen. Each team brings substantial experience in launching drugs for rare diseases in the U.S. and globally. Each has brought experience building high-quality global teams to support physicians and patients. We've seen what they can do individually, and we think they will bring even more value working together. This team will benefit not only from the imminent anticipated launches of inotersen and volanesorsen, but also the pipeline of Akcea drugs following them, including AKCEA-TTR-L_{Rx}.

Finally, this transaction optimizes our commercial participation in the TTR franchise. As you know, we formed Akcea to enable our participation in the larger commercial upside of certain drugs where working closely with a carefully selected and accomplished management team could maximize their commercial value. The close collaboration between the companies assures that Ionis can continue to add value to our drugs even after launch.

Although Lynne will talk about the details of the transaction in just a little while, I want to describe the substantial value we believe this transaction creates for Ionis shareholders. This is a transaction worth approximately $1.7 billion to Ionis plus 60% of future profits of Ionis and 50% of the future profits of AKCEA-TTR-L_{Rx}. This year we look forward to adding inotersen and volanesorsen commercial revenue to our growing SPINRAZA royalty revenue, which will help us achieve our goal of being a multiproduct profitable company.

It is remarkable that in less than two years we may have three first-in-class antisense drugs successfully launched.

The Ionis shareholders will benefit in two ways. First, through the mutually attractive licensing terms, and, second, through our equity ownership in Akcea, as Akcea's expanded pipeline achieves success and Akcea's stock appreciates, the value of Ionis' ownership in Akcea will also appreciate.

In addition, with our increased ownership in Akcea, as Akcea's earnings grow so will our earnings. We can't think of a better way to leverage our financial success in investing in these two important drugs and creating an even strong foundation for the rest of Akcea's pipeline.

And now I'll turn the call over to Paula.

Paula Soteropoulos: Thank you, Stan. This is such an exciting moment for Akcea and the inotersen team. I am pleased that we reached agreement on what we believe will be a value-creating transaction for both companies. We believe Akcea's nimble, patient-focused team, complemented by the expert Ionis inotersen team will add substantial value to the TTR franchise.

We pursued this transaction because in one step it creates significant value by strengthening our product portfolio, our commercialization capacity, and our team. Further, it increases our options to scale our business, given the expansion of our call points in sales force as we work with this new physician community.

We have a strong collaboration with Ionis that will strengthen with these additional drugs.

To give stockholders a chance to weigh in on this transaction, we are holding a stockholder vote which I will explain in more detail later in the call.

This transaction accelerates Akcea's growth and plays to our sweet spot of treating patients with rare, underserved diseases. This transaction immediately transforms Akcea with two rare disease drugs potentially on the market this year and a substantial pipeline of drugs coming behind them.

Based on our extensive due diligence, we believe that inotersen has the potential to truly transform the lives of patients with hATTR, a severe and fatal disease that progressively robs patients of their independence and dignity. As part of the diligence, we heard from patients that this disease has severely impacted every aspect of their lives. And we spoke to several treating physicians who are excited about inotersen's potential for their patients.

Remarkably, for many patient's, inotersen has been shown to not only slow disease progression but also improve both disease and quality of life as measured by the mNIS+7 score, the Norfolk Quality of Life Diabetic Neuropathy Questionnaire and the SF-36 Health Survey.

We believe these observed benefits provide renewed hope for patients living with hATTR and the ability to dose at home truly empowers patients to take control of their disease and their lives.

We are confident that we will add value to inotersen by applying our unique capabilities and focus to commercialize this promising drug.

Bringing inotersen into Akcea and building upon the commercial foundations of volanesorsen makes complete sense. Inotersen's a drug with a clear and measurable impact to patients. We see incredible promise and unmet need for inotersen and are thrilled to now undertake the important step of delivering inotersen to patients.

As part of this transaction, Sarah Boyce, along with the inotersen team she's been building will be joining Akcea. At the closing, Sarah will join as President and will also be joining on our Board of Directors. As part of her responsibilities, she will lead global commercialization for both inotersen and volanesorsen.

Sarah started at Ionis the same day as I started at Akcea over three years ago. In that time, as Ionis' Chief Business Officer, she has played an important role in building Akcea. She was instrumental in accomplishing our collaboration with Novartis. She brings substantial experience to the organization from her time at Forest, Alexion, and Novartis, and her patient-centric view of developing and commercializing important medicine is exactly in sync with ours. She embodies the energy, passion, and enthusiasm that is the hallmark of the Akcea culture.

I'm impressed with how quickly and seamlessly our teams have rolled up their sleeves and come together to accelerate the commercial preparations for inotersen while we have been assessing and working toward completing the transaction. We're thrilled to have Sarah and her colleagues as part of Akcea.

Our two teams bring expertise from both large and small commercial organizations where they have large products and manage organizations that support several products across multiple diseases. We have a tremendous amount of launch experience with leaders and employees from preeminent companies focused on rare diseases, like Alexion, Genzyme, and Shire, to name a few.

The inotersen, volanesorsen combination further strengthens Akcea bringing together institutional knowledge around inotersen and leveraging common commercial operations already built for volanesorsen. For example, for volanesorsen in the U.S., we've built a high-touch patient and healthcare provider support through dedicated case managers providing reimbursement assistance. We've established partnerships with specialty pharmacies and will be offering injection training and assistance with routine platelet monitoring. We expect to use this infrastructure to support inotersen by simply using the systems already in place and hiring additional case managers and support personnel.

In addition to inotersen, we have also obtained the rights to commercialize the AKCEA-TTR-L_{Rx} program. We see great potential for this program to expand our TTR franchise beyond hATTR to wild-type ATTR patient populations.

Based on AKCEA-TTR-L_{Rx}'s profile and the other 11 LICA programs in the Ionis pipeline, we believe our inotersen follow-ons will have the ideal profile for the much larger wild-type ATTR patient population. This is because AKCEA-TTR-L_{Rx} is designed to achieve the desired efficacy with substantially smaller doses to be well-tolerated and to be dosed monthly, less frequently, thereby providing even greater patient convenience.

We in Ionis plan to rapidly develop AKCEA-TTR-L_{Rx} with extreme blind clinical program while expanding access to the largest patient population. We look forward to sharing more news on this program and other pipeline updates as the year progresses.

The newly combined commercial teams, I believe will be the best possible foundation for inotersen's success, and I'm glad Ionis believes this as well. Not all rare disease companies are the same. And we believe through our work on volanesorsen and FCS we bring a highly valued, high-touch approach to working in rare disease through partnership, advocacy, and connection.

We have witnessed the impact of this approach, enabling people living with these devastating diseases to take more control and to live beyond how their disease defines them. This approach is consistent with the work the inotersen team has already done for patients with hATTR, including creating disease management tools and resources to help these patients to control even the simplest aspects of daily living on their own terms and on their own schedule.

In summary, we believe this transaction provides incredible value to Akcea and Ionis, and, above all, to the patients who could potentially benefit from inotersen, volanesorsen, and our entire pipeline of drugs. In addition, this transaction accelerates Akcea's trajectory to be a significant player in rare diseases.

Before I turn the call over to Lynne, let me talk briefly about some important details of the transaction. This transaction was a careful and thoughtful business development process for both Ionis and Akcea. The Ionis-Akcea relationship is further developed by this transaction. And because of that, it was important that we followed and completed a traditional partnering process.

Our board formed a special transaction committee of disinterested directors to decide if we wanted to pursue this transaction and, if so, to lead negotiations with Ionis. The committee hired Cowen to counsel them through this process, including providing an independent transaction fairness opinion. The committee also engaged independent counsel to advise them on the legal aspects of the transaction.

We, along with outside consultants, performed formal due diligence on inotersen and AKCEA-TTR-L_{Rx}. This included assessing the clinical risk benefit, reviewing in detail the regulatory status, and completing independent commercial assessments of market potential and strategy. This work served to make us even more confident in the substantial value that adding these assets to the Akcea pipeline could generate.

We will conduct a stockholder vote where we will seek a majority of the disinterested shares to vote in favor of the transaction. We are asking stockholders to approve the stock purchase agreement, the license agreement, and related agreements in the contemplated transaction.

One of our larger shareholders, Novartis, has agreed to vote in favor of our proposal. We have filed a preliminary proxy statement this morning and we hope that our stockholders will show their support for this partnership. This transaction cannot close without a positive stockholder vote. For more information, please reach out to Kathleen Gallagher, our Head of IR and Communications, who can help with any questions.

And now I'll pass the call onto Lynne.

Lynne Parshall: Thank you, Paula. The transaction we put together for Ionis to license inotersen to Akcea truly benefits patients, shareholders, and both companies, because, as Paula said, this is a transaction between affiliates, of course, both companies and their boards were represented by independent advisors and received fairness opinions.

However, the determining factors for this successful transaction were the close collaborative relationship between the two companies, the ability to build on Ionis' key relationships and deep understanding of hATTR and the patients. And the shared focus of both companies on effectively bringing new medicines to patients who desperately need them.

This transaction has a fairly traditional structure. Akcea will pay Ionis $150 million upfront license fees and milestone payments of $50 million and $40 million on approval of inotersen in the U.S. and Europe, respectively, both of which are expected this year. There are additional milestone payments on approval of both drugs in various geographies that are very standard.

The transaction also includes sales milestones of up to nearly $1.3 billion. The transaction has a value to Ionis of approximately $1.7 billion plus a profit share.

Reflecting the substantial contributions of Ionis in discovering and developing inotersen and the significant future contributions of Akcea in bringing it to patients around the world, the companies will share commercial profits and losses 60% to Ionis and 40% to Akcea for inotersen until the first commercial sales of AKCEA-TTR-L_{Rx}, after which profits and losses will be shared 50%/50%.

We believe the profit split structure appropriately incentivizes and rewards each company. Because both Ionis and Akcea want Akcea to invest fully in optimizing the commercial success of inotersen and volanesorsen, the initial payments from Akcea to Ionis will be paid in Akcea stock at fair market value. This has the benefit of conserving Akcea's cash to make those important investments. And of course, as these drugs are successful, that success should be reflected in Akcea's stock price and the value of Ionis stockholdings.

In addition, Ionis will be making a $200 million investment in Akcea to provide additional capital to support these two anticipated drug launches. As a result of this investment and the $150 million upfront payment, Ionis ownership position will increase by 7% from 68% to 75%. While as a public company Akcea could access public markets for this additional capital, both companies believe that this is the optimal path without distracting Akcea management from the exciting opportunities they have in front of them.

From Ionis' perspective, our strong financial position enables us to make these investments in inotersen, a drug we believe has substantial commercial potential and we believe it's one of the best investments we could make.

This transaction includes not only inotersen but also our LICA follow-on drug, AKCEA-TTR-L_{Rx}. Ionis plans to conduct the development of this drug with substantial input from Akcea, particularly as it moves into later phases of development. The cost of the AKCEA-TTR-L_{Rx} development as well as the profits from its commercialization will be shared 50%/50% between the two companies. Typical approval milestones will also apply to this program and the sales milestones I described will apply to sales of the TTR franchise, including both drugs.

Looking at accounting, Akcea will book 100% of inotersen revenue and expenses. Because of Ionis ownership in Akcea, Ionis will continue to consolidate Akcea's financial performance. As a result, Ionis will also book 100% of inotersen revenue and expenses, while adjusting its net income for the portion of Akcea that Ionis does not own. However, we understand that showing the effects of our transactions with Akcea is valuable to Ionis shareholders, we're already doing that in our earnings press releases where we show Ionis standalone, Akcea standalone, and Ionis consolidated financials.

We intend to continue to do this and to provide additional explanations in our quarterly earnings press releases and calls beginning with our first quarter call in May.

From a financial perspective, obviously, this transaction is very valuable to Akcea also, adding the potential for commercial revenue from a second drug, with substantial commercial potential this year and taking advantage of a larger pipeline to both achieve synergies between the two programs and to accelerate some infrastructure build to the benefit of both drugs.

From the Ionis perspective, we were already planning for Inotersen and volanesorsen commercial revenue this year to add to our growing SPINRAZA revenue and our substantial base of R&D revenue. The transaction with Akcea will allow us to add substantially more of the commercial upside of inotersen to these other sources of commercial revenue while also benefiting from the synergies created by Akcea. We believe this transaction should maximize the commercial value of both inotersen and volanesorsen and Ionis commercial participation in both drugs.

With this transaction, Ionis is investing in inotersen and demonstrating its confidence in the inotersen as well as Akcea. Paula and Sarah are creating the right group to maximize the value of the TTR franchise and the value of the entire Akcea pipeline going forward.

As Stan mentioned earlier, Ionis shareholders benefit in two ways - first, through mutually attractive licensing terms, and, second, through equity ownership in Akcea. In other words, as Akcea and the TTR franchise succeed, shareholders of both Akcea and Ionis benefit.

And now I'll turn the call over to Sarah.

Sarah Boyce: Thank you, Lynne. I want to start by echoing Stan, Paula, and Lynne's confidence in this transaction. As the leader of the inotersen team, I, too, believe that this new Akcea-Ionis commercial partnership is the ideal opportunity for inotersen and for both companies.

We have a drug with the potential to transform lives and the team in place to best serve these patients. I have had the privilege of being part of the Ionis executive leadership team for the past three years. I have led the formation of the inotersen team and I am now excited to transition into the role of company president and board member of Akcea, following the close of the transaction.

I look forward to partnering with Paula, Jeff, Louis, and Mike as we embrace the opportunity to launch two rare disease drugs that we expect to be approved this year, inotersen and volanesorsen.

Focusing on inotersen, we will see immediate value added to our commercial preparations as we join forces with Akcea. With this partnership, we'll be able to leverage the global infrastructure and capability that Akcea has been building for the past three years. This includes medical affairs, patient advocacy, patient support services, sales and marketing operations, and market access expertise.

Inotersen is filed in the U.S. and EU and has been granted priority review by the FDA with a July 6 producer date. And the agency has told us that they don't plan to host an advisory board to review inotersen.

As in the U.S., EU regulator authorities provided a faster path to approval with accelerated assessment. Conversations with regulators continue to be productive and we see a clear path to the market. We have launched our expanded access program across numerous sites in the U.S. Importantly, we have received an enthusiastic response from clinical sites who want to participate in our EAP. And given the interest, we have expanded to include more sites.

We are continuing our efforts to understand the value inotersen represents to the TTR community by conducting numerous advisory panels and discussions with key opinion leaders, other physicians, patients, and patient advocacy groups. We have built strong relationships with these groups. This is just one aspect that the Ionis inotersen team brings to Akcea as we join forces.

From what we have heard, we believe that inotersen has great potential to transform the lives of patients. Many of those we have spoken to feel that inotersen will be the drug of choice for many patients because of the combination of its clinical benefit and its once-weekly self administration. This disease has taken so much. Patients have told us that it is important to them to be able to take something back, administering their own treatment on their own schedule.

We have expanded our disease awareness and education campaign for healthcare providers to further spread the urgency to diagnose patients suffering from this devastating disease. We continue to gain momentum with our patient disease education efforts to fill the unmet need for more patient-facing education support and resources.

Additionally, our patient education efforts continue to bear fruit as we see the demand building for an effective medicine globally. In the U.S., we have medical science liaisons in field, we have regional sales leadership in place, and we are rapidly building and training our sales force and patient-facing team.

As Paula mentioned earlier, this new Akcea partnership brings an important advance in developing our patient services program. Akcea has already built a high-touch patient services program in preparation to launch volanesorsen. By combining Akcea's global patient support capabilities with our intimate understanding of the needs of the hATTR community, we are tailoring our program to uniquely support the holistic needs of patients with hATTR. Our program is designed to help patients maximize the benefits of inotersen treatment as well as the convenience of self administration, reducing their time spent in the clinic.

We are poised to roll out this high-touch patient program upon launch to immediately support patient starts.

In Europe we see substantial ground to be gained from the outset with the new partnership with Akcea. We expect to immediately integrate our global launch strategy for inotersen into the European team's commercial preparations and work stream. The Akcea European country heads are rapidly coming up to speed with inotersen strategy, and we are wasting no time implementing this.

We are gaining important insights from the expertise across the Akcea Europe team that further strengthens our position to launch inotersen this year.

We have a consistent supply chain for both inotersen and volanesorsen. Our supply chain plan is in place with specialty pharmacy and distributors selected and ready for launch upon approval. Importantly, we already have our launch supply of inotersen ready and waiting to be labeled.

By utilizing the same supply chain strategy for both drugs, we will be able to streamline the process for both launches and create efficiencies across disease franchises.

With all of these critical activities ongoing, we are well-positioned to bring inotersen to patients quickly following approval. We believe inotersen can address the dire unmet needs for the hATTR community, given the robust benefit it has demonstrated in the quality of life measures of disease progression in the Neuro TTR Study combined with its simple and quick administration.

Finally, at Ionis Rare Disease Day Celebration last month, I had the chance to talk with patients who participated in the Neuro TTR Study. It was very moving to hear their stories when they talked about their experience with inotersen and to see how well they are doing physically compared to how they talked about their state of health before the study.

One patient's GI and polyneuropathy symptoms had gotten so bad prior to the treatment that at night he slept on the floor next to the toilet. He no longer left his house and had given up hope. He was ready to die. On Rare Disease Day, he was able to stand in front of the whole company and tell his story. He was with us for the day and talked about how when he entered the study he did so for his children with no expectation of seeing any real benefit himself. Today he is hopeful that his children won't have to suffer from hATTR in the same way he did.

These are real reminders of why we are here today and underscore Akcea and Ionis' mission to deliver this important medicine broadly to people with hATTR.

And now I'll turn over the call to Stan and Paula to close.

Stan Crooke: Thanks, Sarah. Just to reiterate what Sarah just discussed, we have had multiple patient advisory boards in which we discussed inotersen and became even more familiar with the needs of these patients. And on Rare Disease Day, we hosted a number of patients who spoke at the company, many of whom are being treated with inotersen. And I had the opportunity to spend quite a bit of time personally with these patients.

These conversations strengthen our resolve to bring better health to these patients and confirm to us that the inotersen profile will make it the preferred therapy for many. The reacquisition of inotersen and partnering with Akcea accelerates the maturation of our unique business model. The experience that we're gaining in building Akcea convinces us that our model can bring great value and sets us up nicely to take advantage of the Akcea experience as we advance our 16 wholly owned drugs toward the marketplace.

For Ionis, this transaction achieves all the goals we laid out at the outset of our inotersen process. The overwriting objective, the most important objective, was to create a solution that would maximize the commercial success of our TTR franchise and, of course, inotersen itself, creating value for both companies. We're very confident that this transaction achieves that important set of objectives.

So Paula, why don't you bring the conversation to a close with comments about the meaning of this for Akcea?

Paula Soteropoulos: Thanks, Stan. In summary, we do believe inotersen has tremendous potential. Like Stan and Sarah, I recently was able to listen to patients' compelling stories about this devastating disease and the impact of inotersen. I share in Ionis' drive to deliver a treatment to improve the lives of people with hATTR. And adding Sarah and the inotersen team at Akcea, our capabilities and strengths brings the best of what we can offer to both inotersen and volanesorsen.

For Akcea, this transaction is transformational with two rare disease drugs potentially on the market this year. It increases our options to scale our business, given the expansion of our call points and sales force as we work with this new physician community. And with the addition of AKCEA-TTR-L_{Rx} to our existing pipeline of drugs, we believe we are positioned to be a leader in rare diseases while creating value for our shareholders and the patient communities we serve.

So with that, I'd like to open up the line to questions.

Stan Crooke: Kate, if you could set us up for questions, please.

Questions and Answers

Operator: Yes, sir. (Operator Instructions) Stephen Willey of Stifel.

Stephen Willey: Congratulations on the transaction, quite interesting. Paula, can you maybe just talk about how big the Akcea commercial organization was, I guess prior to this, and what the size of the organization is expected to be post the closing of this transaction?

Paula Soteropoulos: Thank you, Steve. The Akcea commercial organization was in the U.S. already fully in place. And so we are looking at about 50 people in the U.S., inclusive of commercial, medical affairs, market access, and case management support. And Canada is fully built out, because, as you know, that will be our first country launch that we're expected in early summer. And in Europe we have teams in place in the major markets in Europe and we're continuing to build in Europe. And we expected at the time, Canada plus Europe to be about another 50 with those same types of field-facing functions.

And with the addition of inotersen, we're bringing over a team, as Sarah described, that already has field leadership in place, the medical affairs as well, and we'll be augmenting our case management.

And maybe, Sarah, if you want to talk about in terms of inotersen how we look at that field, because this is separate field forces, but where we have the efficiency across the organization in some of the functions in the leadership, case management, market access, but specifically on the sales, Sarah.

Sarah Boyce: Yes, absolutely. So Steve, the sale teams will be very focused on a by-product basis. The inotersen sale teams consist of the MSL team, which is already trained and deployed in the field. We have our sales leadership in place. We're in the process of recruiting the sales team and training the sales team as well as the patient-facing team through the case management group which builds on the group that's already existing at Akcea.

Paula Soteropoulos: And so just to give you a sense of numbers, you can think of it as we're at least doubling the size of what we had planned for volanesorsen.

Stephen Willey: Understood. And should we expect the breadth of the organization to expand in ex-U.S. markets meaningfully outside of Europe as well?

Paula Soteropoulos: Yes. And that actually is one of the benefits of bringing these two drugs together, because it allows us to accelerate our plans outside of our initial markets with the strength of both of these drugs. We had always planned with volanesorsen to expand out of our initial markets in Europe, look at J-Pac, Latin America. And with inotersen with both drugs, this really allows us to accelerate how we think about expanding in some additional markets.

Stephen Willey: Great. And then maybe a question for Stan or Lynne. I know there had been some prior commentary around perhaps the creation of another subsidiary to house some of the Ionis orphan assets. Should we now kind of presume on a going-forward basis that perhaps Akcea is the most logical repository for wholly owned Ionis orphan assets that are approaching commercialization?

Stan Crooke: The strategy remains the same, Steve. Our goal long term is to have multiple or at least several commercial affiliates which could commercialize the drugs that we believe are appropriate for a focused information transfer high-touch sales effort as well as multiple large pharma partners to deal with the drugs that really need the scale that those partners bring.

Clearly, Akcea has an enormous agenda today and they'll certainly be a strong bidder, I'm sure, and a strong candidate for additional drugs in the future. But our plan remains to have more than one, several of these commercial affiliates.

Stephen Willey: Okay. And maybe just one more quick question just on the transaction, specifically around the sales milestones. Can you just maybe provide a little bit of color around how that remaining $1.3 billion may be weighted towards either inotersen or the follow-on LICA product? Thanks.

Paula Soteropoulos: Steve, the sales milestones are for the franchise because we're beginning to build the franchise with inotersen and hope to significantly expand it with the LICA. The sales milestones are applied to the combination of both drugs.

Stephen Willey: Understood. Thanks for taking my questions, and congrats on the transaction.

Stan Crooke: Thanks, Steve.

Operator: Jim Birchenough of Wells Fargo.

Jim Birchenough: Congrats on the deal and appreciate all the detail. So one of the questions I'm getting is if I think about the success that Sarah's had within Ionis with building the inotersen sales force, what are you getting from Akcea that you couldn't have got just doing it yourselves internally? That's question number one.

And I think the second part is just as we think about the consolidated reporting of the businesses together, it seems like there's some risk of double counting when you consider Akcea booking 100% of revenues and Ionis booking 100% of revenues. And so is the standalone financial statements for Ionis the most conservative way to view this transaction?

So if you could address those two and then I have one follow-up.

Stan Crooke: Let me address the first question and then Sarah can amplify on it, if necessary.

The critical driving force here is to maximize the commercial success of inotersen and the essential challenge is time, because the approval process for inotersen is moving along at a rapid pace. So what we have to be is ready to launch in the markets that we're planning to launch.

So adding the inotersen team to the Akcea team brings all the European infrastructure that had been built by Akcea, all of the distribution and safety monitoring, pharmacovigilance and all of those activities, as well as, of course, sales force activities and sales force people which can be deployed as well, because we expect inotersen to be approved first.

So it is a central advantage of this transaction that all of that synergy can take place. And that finishes then our preparation for launch in Europe, U.S., and Canada in a way that we think is ideal.

Sarah, do you want to add anything to that?

Jim Birchenough: I was just going to ask one about just the accounting for this and the risk of double counting on the consolidated side and whether the standalone reporting is something that we should focus on to be more conservative.

Stan Crooke: Lynne?

Lynne Parshall: Stan, do you want me to answer that? Or does Beth want to answer that?

Stan Crooke: Yes. Lynne, no, you should. I'm sorry.

Lynne Parshall: So Jim, I do think the easiest way to see the benefit of the transaction to both companies is to look at the standalone accounting. And Ionis has been reporting on Ionis standalone, Akcea standalone, and Ionis consolidated. Obviously up to this point in time when there hasn't been, yet, inotersen or volanesorsen revenue, that's sort of, of less interest. But beginning in the first quarter with this transaction, that will be much more informative to shareholders in looking at where the dollars from the transaction actually go. And we do that both for the P&L and for the balance sheet.

So I think looking at the individual components, Ionis standalone and Akcea standalone as well as the consolidated, which we will very transparently be making available, is the right way to look at it, as you suggest.

Jim Birchenough: Just one follow-up question for Sarah and maybe for Paula as well. As you think about the expanded access program as a head start to the commercial launch, could you give any comment on how many centers you're in or how many patients are under expanded access or just what you're seeing at centers where both patiseran and inotersen are available, just as a proxy for how we might expect the launch to go? Thanks.

Sarah Boyce: Yes. So I mean first off, Jim, we expanded the number of sites that we originally anticipated. We also have made sure that there is no limit on the patient numbers from an expanded access perspective. The feedback that we're getting from sites and sort of patients themselves is that they, I mean, they're very enthusiastic about having inotersen becoming available to them through the EAP.

And one of those biggest things, and I talked about it in the call as well, is this aspect of being able to get out of the clinic to have their treatments. That is so important to patients. And we're seeing that replicate through the expanded access. Next on our agenda is also expanding that program into Europe as well and into additional geographies.

Jim Birchenough: Great. Thanks for taking the questions.

Operator: Laura Christianson of Cowen and Company.

Laura Christianson: Just to follow up on an earlier one, I'm curious what additional territories specifically beyond the U.S. and EU, you expect to gain inotersen approval in and which ones you're targeting.

Paula Soteropoulos: Thanks, Laura. We are --

Stan Crooke: Sarah?

Paula Soteropoulos: Sorry. This is Paula. I just started to speak.

Sarah Boyce: You may go ahead.

Paula Soteropoulos: Yes. No, we expect to launch or expand in all territories. And that goes to say with both volanesorsen and inotersen. And we will look strategically at where it makes sense to accelerate which markets based on the patients, the access and reimbursements and also how quickly we can bring on a country.

Sarah Boyce: Yes. I mean, I would say certainly as we look outside of the U.S. and Europe, there are obviously some key countries that are very much on our radar because of the endemic patient population, most notably being Brazil.

Laura Christianson: Great. That's helpful. Thanks.

Operator: Jessica Fye of J.P. Morgan.

Jessica Fye: Two questions for me. Can you just elaborate on the evolution of the partnering talks over the past six months or so and how competitive of a process this was? Were there many other partners in the running? Just a few?

And then second question is, you previously talked about exploring multiple options to reduce the burden of platelet monitoring on physicians. What are the commercial preparations that are being done on that front? Thank you.

Stan Crooke: I'll have Sarah handle the second. Let me deal with the first, and then Lynne can amplify.

We were very pleased with the interest that we had. And as we said, it came in the form of two or three different shapes, large companies. And our central question with the large companies was, are they committed to rare disease? Are they committed to TTR as a disease entity that is going to matter long term to them? And can they be ready to launch?

So in the large company arena, all of the companies that we expected to be bidders were bidders. All of the discussions proceeded in interesting ways. And obviously there aren't that many large companies that have demonstrated commitment to rare diseases, and that was our primary determinant with whom we spoke.

Then there were a number of smaller regional and rare disease-focused companies. After we came to the preliminary decision to commercialize ourselves in the U.S. and partner in the rest of the world, those took center stage. And we sort of staged it with the large companies and then the more regional and rare disease companies. And there were quite a number of those. And those conversations have proceeded quite far down the road. Many of those companies are still anxious to bid on other territories.

So the partnering was robust. It was time-consuming. After we got the drug back from GSK, of course what we had to do was put all the data together and get a data room put together, schedule companies and so on, and so it took time. And I would say we were ready to entertain companies in November/December, and we've had many, many companies in, and that's, of course, the time that it took.

So that's sort of my sense of the process. Lynne, do you want to add anything to that?

Lynne Parshall: Yes. The only thing I would add is you've considered inotersen as an important asset. We did have, actually, a formal auction process. And as Stan described, it had players with many different complexions. And as we went through the process, particularly some of the questions we asked for the big companies, were they going to be sufficiently focused? Or is it going to be sufficiently committed, understanding that we're going to be involved in a competitive launch. And so making sure that that launch is going to be as strong as possible is a key focus for ours.

And as we looked at some of the smaller companies, the question really was, looking at the team we had between the Akcea team and what we had built in Ionis for our inotersen team, whether any of them could even come close to doing as good a job. And so we concluded that the team that was already working together on many of the aspects of the two drugs, that combining them was going to be the best way to achieve value.

Sarah Boyce: Maybe I should take that --

Stan Crooke: Sarah, do you want to discuss monitoring?

Sarah Boyce: Yes.

Stan Crooke: She was wondering about monitoring.

Sarah Boyce: Yes, absolutely, Stan. So Jess, from a monitoring perspective, our goal is twofold, to make it as simple and as straightforward for patients and physicians as possible. With that goal in mind, we have both consulted with our multidisciplinary key opinion leader advisory board and our patient advisory board as well to really understand their needs and how they want the program to look to best support them.

We have our partners in place both from a distribution perspective and also we have selected a partner for mobile phlebotomy services that can reach any patient anywhere in the United States, where we'll be able to have a service if a patient wants to use it, whereby the same phlebotomist will come to their house to do the blood draw for them. All of that program will be quarterbacked by our case management group who will have that one-to-one discussion with the patients, making sure that they're getting what they need. And we'll also be working with the physicians to make sure they get the information that they need.

We're absolutely targeted on making that simple and straightforward. We have our plan in place and we have all of our vendors in place to do it, and we've received great feedback from both physicians and patients as to our plans.

Stan Crooke: The other thing that's been impressive to us has been the attitude about monitoring in both the physicians and patients. And it's just not considered a significant issue for these patients or the physicians. And I'm very pleased with the information management system that is being put in place. I think that will assure a seamless test to result to decision process.

So we think we have it well in hand and we're looking forward to seeing it executed.

Operator: Yale Jen of Laidlaw and Company.

Yale Jen: My congrats to the deal. There's a lot of question being answered, so I have two brief ones. The first one is, I guess for Sarah. Congrats to become the President of Akcea.

My question is that are you going to be responsible for launching just inotersen? Or are you also responsible for the -- both drugs or just the one drug?

Sarah Boyce: Thanks, Yale. I'm really excited as well. So thanks for the congratulations.

I'll be taking a part of my responsibilities leadership of all of commercial at Akcea. So that will be both drugs as well as the rest of the Akcea pipeline.

Yale Jen: Okay, great. And also sort of housekeeping question. In the press release that indicated that director approval of inotersen or the LICA version of the drug in the U.S. and Europe will trigger a milestone of $50 million and $40 million, respectively.

So these two milestone payment is for just Europe and U.S.? Or actually for both drugs? So I just want to create in terms of potential timeline for those milestone payments.

Lynne Parshall: Those are milestone payments just for inotersen for approval in the U.S. and Europe.

Yale Jen: Okay, great. That's all. I appreciate it.

Stan Crooke: Yes, we expect both milestones this year.

Yale Jen: Okay, great. Thank you.

Operator: Gena Wang of Barclays.

Unknown Analyst: I'm on for Gena. Also two quick, brief questions. Number one just following up on the comments you made regarding the interest from partners. Are you also looking for additional partners moving forward from this current transaction, into other trajectories? And how are you thinking about that? Is this going to be from the previous interest?

And secondly, how should we think about the accounting for the milestone payments? How are they going to be booked? And how does the transaction look like from Akcea's and Ionis' accounting? Thanks.

Stan Crooke: So our goal in the rest of the world is exactly the same as our goal in the U.S., Europe, and Canada - that is to maximize commercial success. And essentially territory by territory, area by area, our teams are going through options, including partnering or building our own infrastructure. And so that'll be a territory-by-territory decision, and that process is well along the way.

And the accounting, Beth, if you want to handle that.

Beth Hougen: Sure. So the accounting for the milestones would be similar to the way Ionis has done it in the past. So on Ionis' books, as Lynne described a bit ago, we'll show the milestones in Ionis' standalone P&Ls as revenue. Akcea will show those milestones in their standalone books as expenses. And then on the consolidated P&Ls for Ionis, you won't see the two of those because they'll essentially net out. And we'll show all of that to you when the milestones are earned, in very clear schedules to our press releases and discuss them in our earnings calls.

Stan Crooke: Thank you. Next question?

Operator: There are no additional questions at this time. This concludes our question-and-answer session. I would like to turn the conference back over to Paula for closing remarks.

Paula Soteropoulos: Well, thank you for your time today. We're very excited about the tremendous potential of the TTR franchise. Together, we believe the Ionis and Akcea partnership has the potential to bring great value to both Ionis and Akcea. So we look forward to sharing our progress with you. So thank you very much.

Operator: The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.