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

SCHEDULE TO

Tender Offer Statement Under Section 14(d)(1) or 13(e)(1)
of the Securities Exchange Act of 1934

FORTE BIOSCIENCES, INC.

(Name of Subject Company – Issuer)

AVENA MERGER SUB INC.

a wholly owned subsidiary of

ARGENX BV

a wholly owned subsidiary of

ARGENX SE

(Names of Filing Persons — Offerors)

Common Stock, par value $0.001 per share
(Title of Class of Securities)

34962G208
(CUSIP Number of Class of Securities)

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☒ Check the box if the filing relates solely to preliminary communications made before the commencement of a tender offer.

Check the appropriate boxes below to designate any transactions to which the statement relates:

☒ third-party tender offer subject to Rule 14d-1.

☐ issuer tender offer subject to Rule 13e-4.

☐ going-private transaction subject to Rule 13e-3.

☐ amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer. ☐

If applicable, check the appropriate box(es) below to designate the appropriate rule provision(s) relied upon:

☐ Rule 13e-4(i) (Cross-Border Issuer Tender Offer)

☐ Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

This Tender Offer Statement on Schedule TO relates solely to preliminary communications made before the commencement of a planned tender offer for all outstanding shares of common stock, par value $0.001 per share, of Forte Biosciences, Inc., a Delaware corporation ("Forte"), by Avena Merger Sub Inc., a Delaware corporation ("Purchaser") and a wholly owned subsidiary of argenx BV, a private company with limited liability (*besloten vennootschap*) organized under Belgian law ("argenx") to be commenced pursuant to the Agreement and Plan of Merger, dated as of July 26, 2026, by and among Forte, argenx and Purchaser.

Additional Information and Where to Find It

The tender offer has not yet commenced. This document is for informational purposes only and is neither a recommendation, nor an offer to purchase nor a solicitation of an offer to sell any securities of Forte or any other entity, nor is it a substitute for any tender offer materials that argenx, Purchaser or Forte will file with the U.S. Securities and Exchange Commission ("SEC"). A solicitation and an offer to buy securities of Forte will be made only pursuant to an offer to purchase and related materials that argenx and Purchaser intend to file with the SEC. At the time the tender offer is commenced, argenx and Purchaser will file a Tender Offer Statement on Schedule TO, including an offer to purchase, a letter of transmittal and related documents, with the SEC, and Forte thereafter will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. SECURITYHOLDERS AND OTHER INVESTORS ARE URGED TO READ THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9 REGARDING THE OFFER, AS THEY MAY BE AMENDED FROM TIME TO TIME, WHEN THEY BECOME AVAILABLE CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT INVESTORS AND SECURITYHOLDERS SHOULD READ CAREFULLY BEFORE ANY DECISION IS MADE WITH RESPECT TO THE TENDER OFFER. The Tender Offer Statement on Schedule TO, the Solicitation/Recommendation Statement on Schedule 14D-9 and other related documents will be made available for free at the SEC's website at https://www.sec.gov/ and under the "SEC filings" section of argenx's investor relations website at https://argenx.com/investors/sec-filings. The Solicitation/Recommendation Statement on Schedule 14D-9 and other related documents that Forte has filed with or furnished to the SEC will be made available for free at the SEC's website at https://www.sec.gov/ and under the "SEC Filings" section of Forte's investor relations website at https://www.fortebiorx.com/investor-relations/sec-filings/default.aspx.

Forward Looking Statements

The contents of this Tender Offer Statement include statements that are, or may be deemed to be, "forward-looking statements." These forward-looking statements generally can be identified by the use of forward-looking words, such as "aim", "anticipate", "aspire", "believe", "can", "continue", "could", "estimate", "expect", "entail", "forecast", "future", "goals", "hope", "intend", "is designed to", "likely", "may", "might", "objective", "plan", "possible", "potential", "pursue", "project", "predict", "seek", "should", "strategy", "target", "will" and other words and terms of similar meaning and expression, including in connection with any discussion of future operating or financial performance. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. Forward-looking statements include, without limitation, statements regarding the tender offer, the merger and other related matters; prospective performance and opportunities; post-closing operations and the outlook for the businesses of Forte and argenx, including, without limitation, results from clinical trials, regulatory applications and related timelines, the ability of argenx to advance Forte's product pipeline; and any assumptions underlying any of the foregoing. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including but not limited to, uncertainties as to the timing of the tender offer and the merger; the risk that the tender offer or the merger may not be completed in a timely manner or at all; uncertainties as to the percentage of Forte's stockholders tendering their shares in the tender offer; the possibility that competing offers or acquisition proposals for Forte will be made; the possibility that any or all of the various conditions to the consummation of the tender offer or the merger may not be satisfied or waived, including the failure to receive any required regulatory approvals from any applicable governmental entities (or any conditions, limitations or restrictions placed on such approvals); the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement, including in circumstances that would require Forte to pay a termination fee or other expenses; the effect of the announcement or pendency of the transactions contemplated by the merger agreement on argenx's business; the effect of the announcement or pendency of the transactions contemplated by the merger agreement on Forte's business, its ability to retain and hire key personnel, its ability to maintain relationships with its suppliers and others with whom it does business, or its operating results and business generally; risks related to diverting management's attention from argenx's ongoing business operations; the risk that stockholder litigation in connection with the transactions contemplated by the merger agreement may result in significant costs of defense, indemnification and liability.

A further list and description of these and other risks, uncertainties, and factors that could cause actual results to differ materially from those referred to in the forward-looking statements can be found in argenx's SEC filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these risks and uncertainties, the reader is advised not to place undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this Tender Offer Statement. argenx undertakes no obligation to publicly update or revise the information in this Tender Offer Statement, including any forward-looking statements, except as may be required by law.

Item 12. Exhibits.

Exhibit	Description
99.1	Transcript of argenx Investor Presentation, dated July 27, 2026.

argenx Business Update | 27th July, 2026

Moderator:

Good morning. My name is Leila and I will be your conference operator today. I would like to welcome everyone to the call. At this time, all lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a question and answer session. Thank you.

I'd like to introduce Beth DelGiacco, Vice President of Corporate Affairs. You may now begin your call.

Beth DelGiacco:

Thank you Leila, and thank you to everyone joining us today, especially on short notice. Earlier this morning argenx announced that we have entered into an agreement to acquire Forte Biosciences. The announcement press release can be found on our website, along with a slide presentation that you can follow as you listen to the call. I'm joined today by Karen Massey, Chief Executive Officer, Arjen Lemmen, Vice President of Corporate Development and Strategy, and Peter Ulrich, Chief Scientific Officer. Karl Gubitz, our Chief Financial Officer, will be available during the Q&A.

Before we begin on slide two, I'd like to remind you that forward-looking statements may be presented during this call. These may include statements about our future expectations, clinical developments, regulatory timelines, the potential success of our product candidates, financial projections, upcoming milestones, and the anticipated benefits and timing of the proposed transaction. Actual results may differ materially from those indicated by these statements. argenx is not under any obligation to update statements regarding the future or to confirm these statements in relation to actual results unless required by law.

I'll now turn the call to Karen.

Karen Massey:

Thank you, Beth, and welcome everyone. I'll begin on slide three.

Today's announcement is an important milestone for argenx and an important investment in our next chapter of growth. It's also an important day for patients and our commitment to raise expectations of what a treatment can deliver in autoimmune disease. We have entered into an agreement to acquire Forte Biosciences, adding FB102, a first in class anti-CD122 antibody to our immunology pipeline. FB102 has demonstrated clinical proof of concept in diseases that have lacked meaningful innovation like vitiligo and celiac disease, and we believe there is broader potential across multiple autoimmune diseases.

Before I talk about our conviction in FB102 and recognize the impressive work the Forte team has done to advance the programs through proof of concept, I want to start with our strategy. Our Vision 2030 strategy is well-defined and on track. Last week, we shared our second quarter results. Vyvgart continues to reach more patients around the world as we progress towards our goal of treating 50,000 patients. With the approval of Vyvgart in seronegative gMG, we now have four labeled indications on our path to 10 by 2030. And we continue investing in our innovation engine to advance five new molecules to late stage that we believe can become the future growth drivers of argenx and shape the future of immunology. It is the success of this strategy that makes today possible.

Over the last several years, we have built an incredible foundation, pioneering the FcRn class, and we've demonstrated that we can translate promising biology into transformational outcomes and new treatment paradigms for patients. And now we have an opportunity and a responsibility to build on that foundation. Our ambition has never been limited to a single molecule, a single target, or a single therapeutic area. Our ambition is to become the leading immunology innovator, building a pipeline across multiple targets and multiple dimensions of the immune system.

The acquisition of Forte fits directly into this ambition and is a continuation of a strategy that has guided argenx from the beginning. Stay close to great science, pursue the best ideas wherever they originate, and build conviction through data, all to bring immunology breakthrough to patients. This principle helped create argenx, and this principle brought us to Forte Biosciences. It will continue to guide how we build our next chapter.

Slide four. At argenx, innovation has never been limited to what happens inside our own walls. We pursue the best science through our immunology innovation program and partnering with leading academic collaborators and research institutions, and with biotech partners through partnering deals, strategic investments, and now an acquisition. This is how our pipeline has been built and it's proof that breakthrough innovation does not happen alone. It is how we discovered and developed Efgartigimod, it's how we're advancing in the rest of our pipeline, and it's also how we came to know about FB102.

We've been following closely CD122 biology for several years, and this year in April, we made a strategic investment in Forte based on our belief in the science. More recently, with the positive phase 1B data in vitiligo, we saw the opportunity to bring FB102 into argenx. The Forte team has done an impressive job in advancing this program. We believe great science and great people go hand in hand, which is why we are excited not only about FB102, but also to continuing to work alongside the team that helps bring the asset this far. So with that, I'll turn the call over to Arjen to discuss the transaction and why Forte and FB102 are such a natural fit for argenx. Arjen?

Arjen Lemmen:

Thank you, Karen. Slide five.

When we think about bringing in new pipeline programs, we always start with the same questions. Is the biology and mechanism of action differentiated? Is there evidence that it can translate into meaningful benefits for patients? And can argenx help realize its full potential? FB102 stands out across all these dimensions. What initially attracted us was the combination of novel biology, a targeted mechanism, and early clinical validation. We're also attracted to the broader potential of the program to be a pipeline in the product opportunity across vitiligo, celiac disease, alopecia areata, and other autoimmune diseases. Just as important is why we believe FB102 is a strong fit for argenx. First, FB102 complements our existing portfolio. Our strategy as an immunology leader is to play across important pathways of the immune system. For example, we have Efgartigimod and argenx 121 in the antibody compartment targeting FcRn and IgA. And addressing complement activation FC2.

FB102 adds another important dimension, targeting pathogenic T-cell and NK cell activity through CD122 biology while preserving beneficial regulatory T-cells.

Second, we believe this is the right moment to bring the molecule into argenx. The program has generated clinical validation in two indications, while still leaving meaningful opportunity for us to shape development strategy, expand the indication footprint, and build the full value of the program alongside the Forte team. And third, we believe argenx is uniquely positioned to help realize the full potential of FB102. We are specifically organized to execute and maximize pipeline in a product development programs. We have an established product presentation, playbook and strategy, and we have demonstrated that when we enter underserved markets, we establish leadership and shape treatment paradigms. We believe these capabilities can expand the impact of FB102 for patients and maximize the opportunity.

Slide six. Turning briefly to the transaction. Under the terms of the agreement, argenx will commence a cash tender offer to acquire all outstanding shares of Forte for $77 per share, representing a total equity value of approximately $2.2 billion. The transaction is not subject to a financing condition and will be funded entirely from cash on hand. The board of directors of both companies have approved the transaction and we expect it to close in the third quarter subject to customary closing conditions. This transaction also reflects how we think about investing for the future. We've always taken a disciplined approach to capital allocations and our priorities remain clear.

First, we continue to maximize the opportunity for Vyvgart and build the future of FcRn medicines. Second, we continue to advance our broad and growing pipeline. And third, we continue to pursue differentiated biology wherever we find it to strengthen our future growth trajectory and expand what we can deliver for patients. Ultimately, this transaction reflects the simple belief that science should set the pace for investments. Where we find an opportunity of raising the bar for patients and strengthening the future of argenx, we have the flexibility and the conviction to act. We found this with Forte.

Now I'll turn the call to Peter to walk through the science behind the program.

Peter Ulrich:

Thank you, Arjen. Slide seven.

Building on what you said, our interest in FB102 begins with the biology and as antibody engineers with the quality of the molecule. FB102 is uniquely designed to inhibit IL-2 and IL-15 mediated activation and proliferation of pathogenic T-cells and NK cells, while sparing beneficial IL-2 signaling on regulatory T-cells.

The scientific question we seek to answer is whether we can reduce the activity of the self-driving diseases like vitiligo and celiac disease while preserving the immune regulation we want to keep. At argenx, our goal is not broad immune suppression. Our goal is to target the underlying drivers of disease in a precise way. FB102 gives us the potential to do that through a different stated approach leveraging CD122 biology. The clinical data generated today have been important in building our conviction on FB102. Let me briefly walk through those data before turning the call back to Karen.

Slide eight. First on vitiligo. In the study, FB102 demonstrates the rapid and sustained benefits, with statistical significance reached by day 64. Patients continue to show improvement through week 24, 12 weeks after the last dose. On the slide, I would like to show the week 24 results. 29.6% mean FRV improvement for FB102 compared with 7.9% for placebo. These data provide early evidence that targeting CD122 may address the underlying immune activity and reinforce our conviction in the mechanism.

Celiac disease provides another example. This is a systemic autoimmune disease driven by a T-cell mediated response to gluten. FB102 has a strong mechanistic rationale in celiac disease because CD122 blockades simultaneously suppress IL-15 driven epithelial damage and an IL-2-driven gluten-specific T-cell activation. The slide shows that the phase 1B study met the primary BCAL endpoints and showed fewer gluten-induced GI symptoms versus placebo. FB102 is now being studied in a phase two trial in celiac disease, which will read out before the end of the year. Together, the biology, the translational evidence, and the clinical data provide a strong foundation for continued development of FB102. And with

Peter:

And with that, I'll turn the call back to Karen.

Karen Massey:

Thank you, Peter. Slide nine. The biology Peter described is what first attracted us to FB102. The opportunity to bring that science to patients at scale is what excites us about the future. Vitiligo has too often been misunderstood as a cosmetic condition. It is not. It is a chronic autoimmune disease driven by pathogenic immune activity. Current treatment is limited to a subpopulation, and many patients do not achieve complete or lasting repigmentation with these options. More than two million people in the United States live with vitiligo. While awareness of vitiligo has increased and new therapies have emerged, outcomes are far from where patients want them to be. Celiac disease represents another significant opportunity. More than 2.5 million patients in the United States live with celiac, yet they have no approved treatments beyond a strict gluten-free diet. Even with careful management, many patients continue to experience symptoms and anxiety around accidental exposure.

In addition, there are long-term complications beyond the digestive tract and an increased chance of other autoimmune diseases. We believe these are diseases where argenx can play an important role. We have demonstrated with Vyvgart that we can successfully establish leadership and transform underserved markets so that patients can spend less time managing their disease and more time living their lives. That experience gives us confidence, not only in the opportunity ahead for FB102, but in our ability to execute, expand its potential, and maximize impact for patients. Slide 10. Before we start Q&A, I want to leave you with three key takeaways. First, this transaction is firmly aligned with our strategy. Vision 2030 is on track. Our conviction in Vyvgart and our existing pipeline remains unchanged. FB102 builds on that foundation and supports our ambition to be a leading immunology innovator. Second, we believe FB102 is the right molecule.

It combines novel biology, a targeted mechanism, and an elegant design with potential across multiple autoimmune diseases. Third, these are serious systemic diseases where patients need better outcomes and where argenx can help shape the future standard of care, just as we have done with Vyvgart. Forte has advanced impressive science. Our role is to build on that foundation and work alongside the team as we advance FB102. This is an important milestone for argenx, for Forte, and most importantly for patients. Thank you for joining us today. An operator will now open for questions.

Moderator:

At this time, we will open the floor for questions. If you would like to ask a question, please press star five on your telephone keypad. You may remove yourself at any time by pressing star five again. We would like to remind callers to please limit themselves to one question so we can accommodate as many participants as possible. And we'll pause just a moment. Okay. Our first question will come from Yatin Suneja with Guggenheim Securities. Your line is now open. Please go ahead.

Yatin Suneja:

Good morning everyone. Thank you for taking my questions and congratulations on bringing this important mechanism into your portfolio. Always good to see one of your companies getting acquired by another company that you cover. So the question that I have is mostly around the indication. So if you could frame for us how much weight you are putting on the areas where we have already seen proof of concept like vitiligo, EoE, and celiac. What about other areas that are opening up with this mechanism, whether it's alopecia areata or atopic dermatitis that other companies are going after and how much visibility you had into some of the ongoing studies that Forte was running? So just basically frame to us the investment you're going to make across that might open up with this indication. Thanks.

Karen Massey:

Yes. Thank you for the question. And I like starting with that questions because I think it really makes us zero in on the value that FB102 can bring to a broad range of patients and very much aligned with our mission. So one of the things, the parts of argenx strategy and one of the reasons that this looks like an argenx molecule is that it is a pipeline in a product molecule. We like molecules where we can pursue multiple indications. One of the reasons for that is that it gives us multiple paths to success and multiple paths to growth. With this molecule, when we looked at it, one of the key gating factors for us was the recent data, a phase 1B data in vitiligo, and obviously also the data, the phase 1B data in celiac. So those will be two of the lead indications.

But exactly as you say, we think that this target has the opportunity to open up more indications beyond that. We're not in a position today to share what those indications would be, but what we can say is that we'll take the exact same approach with FB102 that we've taken with our other pipeline in a product assets like Vyvgart. And we have a very clear and disciplined approach to indication selection. So we always start with a strong biology rationale and we like to see indications that are de-risked with preclinical or translational data. We like it when there's a clear development and regulatory pathway and always use that as a gate. And last but not least, there needs to be a high unmet need and a high commercial potential. So over the coming months, we'll be looking at a broad range of indications for FB102 through these lenses. But as you point out, I think what we'll find is that there's opportunity beyond celiac and vitiligo for FB102. Thanks for the question.

Moderator:

Our next question will come from Tazeen Ahmad with Bank of America. Please go ahead.

Tazeen Ahmad:

Hey, good morning. Thanks for taking my question. Karen, I just wanted to get your thoughts about what you mentioned about vitiligo. So Incyte does have a product available currently. They have had a bit of a slower than expected launch into that space. Is it your view that it's still because it's viewed as a cosmetic indication as opposed to something that needs medical treatment? And then can you just remind us what specifically gives you confidence at this juncture that this could be differentiated from what's already out there? Thank you.

Karen Massey:

Yeah. Thanks for the question, Tazeen. I will just, touch on it, I mentioned it in the script. We do not believe that vitiligo is simply a cosmetic skin condition. It is a chronic and systemic autoimmune disease. And I think the opportunity ahead is to make that clear to the healthcare system and to treating physicians. What we see is that vitiligo impacts quality of life, especially where there's significant body area that's impacted and when symptoms like severe photosensitivity are involved. So we think that there is a clear opportunity to elevate expectations for patients with that condition. And I think we have some learning for how we've done that from elevating expectations and transforming markets in some areas with Vyvgart. But perhaps Peter, you could talk to the strength of the data that we see in vitiligo.

Peter Ulrich:

Yeah. First and foremost, of course, there is the 1B data which shows the clear effect. And I think also from a biology point of view, the molecule is hitting two parts which are well established to be active in vitiligo, the IL-15 arm and the IL-2 arm. So that combines with a favorable safety profile, which we've seen today, which we obviously need to confirm, gives us some differentiated angles as compared to what's out there. And that's why we're quite bullish on this biology.

Moderator:

Our next question will come from Derek Archila with Wells Fargo.

Derek Archila:

Hey, good morning and congrats on the transaction. Just wondering if you could discuss your view on FB102's rationale and opportunity in alopecia. And was wondering if reviewing the blinded data from the ongoing trial was part of the diligence process. Thanks.

Karen Massey:

Yeah. In terms of when we were looking at FB102, we had the opportunity obviously to look at all of the data, the public data. And we look forward to seeing the alopecia data that is for later this year that will also inform our position. And as part of diligence, we were able to work closely with the Forte team. I would say while I have the opportunity right now that we were very impressed with the Forte team, the quality of the science, the quality of the execution, and how they're bringing this asset forward. And so we were able to look at all of the standard types of data that you can look at through due diligence. And that really gave us confidence in this asset and in the data package behind it. Thank you.

Moderator:

Our next question will come from Yaron Werber with TD Cowen.

Yaron Werber:

Yeah, congrats on really a terrific deal based on really good data, especially given this is your first deal. So maybe Karen, for you, the celiac data, phase two data is expected to come pretty soon. The phase 1B, as noted, was really positive. There's going to be even more of a gluten challenge in this phase two. So the potential to even show more outsized effect. Can you maybe frame your expectations for this data and maybe give us a little bit of a sense how big do you think celiac is as an indication? Thank you.

Karen Massey:

Yes. Thanks for the question. We're looking forward to seeing the celiac data as well. Obviously with the phase 1B proof of biology, we have confidence going into that data, but you're always turning a data card. And I think it's important that we note that this is a phase two study. So phase two studies are a learning study. So what we'll be looking for alongside the Forte team is to make sure that we can get really good insights into celiac, including, as you said, with the gluten challenge and the impact of FB102 so that we can design a strong phase three development program moving forward. And I think the way that the clinical trial is designed, the insights that we'll get, including the primary and secondary endpoints, will give us the information that we need to design a good phase three clinical development program. So let's wait and see. The data from that program will be coming in Q4. And when we turn that data card, we'll be able to share those top line results and what the future program looks like. Thanks, Yaron.

Moderator:

Our next question will come from Gavin Clark-Gartner with Evercore.

Gavin Clark-Gartner:

Hey, guys. Congrats on the deal and thanks for taking the question. So you definitely talked through the pipeline and a potential in a lot of detail. If you were to pick one indication where you see the largest commercial opportunity, what would that be? Because from an investor point of view, I think it's celiac at the moment. And I'm curious if you share that perspective. Thank you.

Karen Massey:

Yeah. I think one of the strengths of this molecule is that it is a pipeline in a product. And what I would say is that we see the opportunity for multiple blockbuster indications. And it's one of the reasons that we like this molecule, is that we have multiple paths to success across indications. So like you, we're certainly looking forward to the celiac data, but I wouldn't underestimate the opportunity in vitiligo and some of those other indications as well. Thanks, Gavin.

Moderator:

Our next question will come from Samantha Semenkow with Citi.

Samantha Semenkow:

Hi, good morning. Thanks very much for taking the question and congratulations on the deal. I wanted to ask just about these indications being significantly larger than the typical rare disease indications that you've gone after for Vyvgart and some of your other molecules. Just how are you thinking about evolving the commercial engine to really work into your playbook for building these meaningful indications? Thanks very much.

Karen Massey:

Karen Massey:

Yeah, thanks for the question. It's an important part of our consideration when we were thinking about these indications. I mean, we do see these indications as very argenx-like indications. They are severe autoimmune conditions and there is significant unmet need. But as you say, we will need to continue to augment our commercialization capabilities. I think we've built a strong commercialization engine and we continue to build that with Vyvgart. Of course, we'll start, pending positive data, with Sjögren's disease, for example, we'll start entering larger markets with FcRn as well. I think the key to that will be to continue on the path that we've been launching our medicines on with our commercial engine that's focused on a patient-centric approach. So what's going to be really important here is making sure that we're empowering patients to expect and to ask more from their medicines. And that's something we already do with Vyvgart very actively.

The second piece that will be important is continued evidence generation, even post-approval or post-launch. These are markets that need to be built and where the real world evidence needs to be generated to demonstrate the impact of expanding treatment and expanding treatment with biologics. And we have experience also with that most recently in MG, expanding, for example, into ocular MG.

And last but not least, I think in these markets, proven payer execution will be key. And what we've seen is that that's a core capability here at argenx. And we think that we can redeploy that capability indication by indication with FB102 as well. So there's a long way to go before we get to commercialization of this asset, but we think we're well positioned and have the commercialization capabilities to do it.

Moderator:

Your next question will come from Akash Tewari with Jefferies.

Akash Tewari:

Hey, thanks so much. So for vitiligo, what's your confidence 102 that data holds up in a larger data set, particularly for patients with less facial involvement? And will those under 0.75 patients be excluded from your further trials? And then can you talk about the delta between the protocol-defined versus ITT data and what imputation method you're going to be using in your further studies? And then finally, did Forte measure total vitiligo area scoring, not just facial? And if so, what did that data look like? Thank you.

Karen Massey:

Yeah. Thanks for the question. So what I will say is the call today, we're focused on our initial insights on the program. And what we'll be working on over the next couple of months is going much deeper with Forte and also being able to define the program in the future. So we'll refrain from commenting on all of the detailed questions that you have. But maybe, Peter, you could share why you have confidence in vitiligo and what you see the benefit of the program.

Peter Ulrich:

Yeah. Again, I think the biology fits nicely with the pathophysiology of vitiligo. And to comment, we have at least one element on your question. Indeed, you do see really great activity at the high end of the disease severity. I think what we're going to do now is indeed take a deep dive in all this data and define what potential next steps could be, including the question on which patients to include yes or no in future trials.

Moderator:

Your next question will come from Alex Thompson with Stifel.

Alex Thompson:

Hey, great. Congrats on the deal. Maybe another question for Peter, could you talk a little about your confidence in the therapeutic index here with the blockade of T effector and natural killer cell activity and that we're maybe out of the woods for infection risk at this point? Thanks.

Peter Ulrich:

I think that is indeed a concern of the biology or a broad targeting of NK cells and some of the T-cells. I think first and foremost, based on the current exposure, which is three months, we don't see any increase in infectious risk. So, so far the safety profile looks good. Secondly, it is not a total NK cell depletion, and it's a specific subset of NK cells which are depleted with this mode of infection, which gives also some confidence on the safety element. Obviously we need to see longer term treatment data to fully explore the risk-benefit profile of this molecule. Thank you for the question.

Moderator:

Our next question will come from the line of Suzanne van Voorthuizen with Kempen. Suzanne, your line is unmuted. Please feel free to go ahead. Well, we'll return to Suzanne later. Our next question will come from Matt Phipps with William Blair.

Matt Phipps:

Good morning. Thanks for taking my question. Congrats on the deal. There was a mention of data at the recent Society for Investigative Dermatology Conference with an IL-15 antibody showing a lot of benefit when combined with UVB in vitiligo patients. Is that something that you would look to explore? Just curious if you were familiar with that data. Thanks.

Karen Massey:

Yeah. I'll let Peter comment on the data. But I think in general, what you bring up is something interesting in the immunology space, which is combination therapy. And so we haven't started down that path yet, given where we are with FB102. But as you know, it's a key and core part of our strategy with the rest of our pipeline, and I think an area that will continue to emerge of importance in the future. But Peter, I don't know if you want to comment on that information.

Peter Ulrich:

Yeah. I think we obviously are also ahead of this data and it's an element which we are considering, or will be considering when drafting plans for the next phases of clinical development.

Moderator:

Our next question will come from Douglas Tsao with HC Wainwright.

Douglas Tsao:

Hi, good morning. Thanks for taking my question. Just maybe as a follow-up to Matt Phipps' question in terms of this representing a little bit of a shift for the company in terms of its focus on more common prevalent diseases than orphan indications. I guess I'm just curious, is that going to be reflected in the business development strategy and how you're prioritizing things? Or is it going to still be through a lens of biology?

Karen Massey:

Yeah. Thanks for the question. And I'll let Arjen comment in a moment. But I would say at the highest level, our strategy for building our pipeline and for becoming a leading immunology innovator is to focus on novel biology in areas of high unmet need. And our capital allocations priority, internal as well as business development, follow that strategy. But Arjen, maybe you want to talk in a little more detail about how we think about business development within that context.

Arjen Lemmen:

Yeah, absolutely. So partnering has been a fundamental tool in how we've built our pipeline to date. It's how the immunology innovation program works. And we've consistently done that around biology with academic institutions and other biotech companies. I think this represents an ability to also do that at a later stage. And ultimately our business development strategy will be tailored for the target space or the molecule for its stage of development to do the right thing, to augment our Vision 2030 objectives.

Karen Massey:

And maybe the last thing to add is that what we do like with these assets is being able to put, let's say, the argenx fingerprint on them. We think we have a differentiated capability in developing this pipeline in our product assets. Our product presentation playbook, for example, how we go through indication, selection, sequencing. And so assets that are early enough in their development that we can still put our fingerprints on them, I think is an important component to the strategy. Thanks, Doug.

Douglas Tsao:

Great.

Moderator:

Our next question will come from Sean Laman with Morgan Stanley.

Sean Laman:

Good morning, Karen and team. Hope everyone's well. Karen, strategically, or maybe sizing, what role do you expect CD122 biology to play relative to FcRn complement and your other pipeline franchises?

Karen Massey:

Yeah. I mean, I think what we're building is a broad immunology portfolio, as you say, that is where we have assets across different compartments of the immunology system or of the immune system, I should say. And Peter, maybe you want to talk about how you see the strategy of covering different immune targets as we develop our pipeline?

Peter Ulrich:

Yeah. I think what we like is first-in-class biology on key elements of the immune system. So with FcRn, we're tackling the antibodies. We're hitting the complement system hard. It's one-to-one, it's the IgA element. I think FB102 gives us the opportunity to tackle pathogenic T-cell biology, pathogenic NK cell biology with this molecule. So it really fits that immune portfolio approach which we're taking and which we continue to build.

Sean Laman:

Sure.

Moderator:

Our next question will come from Thomas Smith with Leerink Partners.

Brian Swanson:

Hey guys, good morning. This is Brian on for Tom. Thanks for taking our question. Just wondering if the team can comment or elaborate on their confidence in a potential regulatory path in celiac given there are currently no FDA approved treatments. Thanks so much.

Karen Massey:

Yeah. And certainly when I was talking earlier about the fact that we like to focus on novel biology in areas of high unmet need, navigating these types of regulatory situations is not new to us, and I think something that we've demonstrated we can navigate in the past. Maybe Arjen, you want to talk to some of the due diligence and what we learned around the path forward to celiac?

Arjen Lemmen:

Yeah. Like I said, that really starts with the Phase Ib data and the conviction that we have. From there, you can start to think about different patient populations and a way forward. I think at this stage for celiac, the next step will really be for the Phase II data card to turn. And from there, we will set the right Phase III plan forward.

Moderator:

Our next question will come from Danielle Brill with Truist.

Danielle Brill:

Hi guys. Good morning. Congrats on the deal. Thanks for the question. Maybe as a more specific follow up to an earlier question, just wondering what specifically makes FB102 differentiated in your view versus the other molecules in the pipeline? Are there meaningful differences in the magnitude of CD122 blockade, or any other mechanistic attributes that support a best-in-class profile? Thanks.

Karen Massey:

Yeah, certainly. I'll hand it over to Peter to comment on this, but one thing that we do see as differentiated that is important is that it's on track to be first in class. And we know how important that is when launching medicines into areas of high unmet need in competitive spaces. But the potential for best-in-class, Peter.

Peter Ulrich:

Yeah, that I think indeed based on some in vitro data, but also of course as Karen indicated, the clinical data gives us confidence on the potency of the molecule.

Moderator:

Our next question will come from Sophie Graff with JP Morgan.

Sophie Graff:

Good afternoon. Thanks for taking my question. One on route of administration. So we've seen our argenx be very successful in innovating on route of administration with Vyvgart. How important was the possibility of similar innovation for FB102 in terms of the decision to acquire the asset? And how important do you see this innovation given the development of oral JAKs and vitiligo?

Karen Massey:

Yeah, certainly when we were looking at this asset

Karen Massey:

And also at what argenx could bring to this asset, the question of product presentation comes to the forefront.

So I think what we saw in FB102 was an asset that's complementary to our immunology portfolio, but also an asset where I mentioned earlier, we can put our fingerprints on the development and leverage the experience that we've had with Vyvgart in really maximizing the value of the asset.

And as you say, one of those places is through product presentation. So I think with Vyvgart, we've seen the playbook of launching with IV, very quickly being able to bring a subcutaneous, a prefilled syringe.

Next year we're launching an auto-injector. And you can imagine that we have the opportunity to take that same playbook and apply it to FB102, which will be important, especially in these autoimmune conditions in larger patient population.

Moderator:

Our next question will come from Victor Floc'h with BNP Paribas.

Victor Floc'h:

Oh, thanks for taking my question and congrats on the deal as well. Maybe just a quick follow up on the population for celiac disease.

So should we assume that it will be limited to the patient non-responsive to gluten-free diet? Or are you anticipating that at some point you should be able to bring that product to maybe earlier lines treatment patients? Thank you very much.

Karen Massey:

Yeah. It's too early to comment specifically on the clinical development program, but certainly what you can look at is the approach that we've taken with other indications in the past as a model.

And so what I would think about, for example, in MG, where we started with a clearly defined patient population in the ACHR positive, we were able to, over time, generate the evidence and expand that population.

Now we'll have to make the strategy specific to each of the indications that we look at for FB102. But with the different patient populations within celiac, you can imagine that there could be different ways that we could break down the patient population and align the clinical development program beyond that.

But we'll do that work over the next couple of months and we'll share when it's ready. Thanks, Victor.

Victor Floc'h:

Thank you.

Moderator:

Our next question will come from Luca Issi with RBC.

Kathy:

Hi, team. Good morning and afternoon. This is Kathy for Luca. Congrats on closing such an amazing deal. This is a follow-up on indication production anti-CD122 mechanism has shown clinical proof of concept in celiac disease and vitiligo as we've seen.

But how broadly do you think this data read through to the other disclosed indications like alopecia areata and type one diabetes and your conviction in a rationale for a case who going after these two indications? Any thought there? Much appreciated.

Karen Massey:

Yeah, certainly. Maybe I can hand over to Peter to comment on that.

Peter:

Yeah. And alopecia, I think that is IL-15 data out there showing that angle is definitely involved in the disease. For type one diabetes, there are preclinical data sets out there.

Obviously, I think that's the work we are going to start now with the 1b alopecia data. How good are they? And what is then the next step is one element for type one diabetes.

As for other potential autoimmune indications, we are going to follow the same playbook as we always do, look into biology as number one. Then okay, what is the path towards approval there? How does it look like? And is there indeed an unmet need?

Moderator:

Your next question will come from Andy Chen with Wolfe.

Jason:

Hi, thank you for taking my question. This is Jason taking it for Andy. I just want to ask if you guys have done any evaluations of FB102 against other CD122 programs, maybe like tracks, for example? And what do you think differentiates it on safety, efficacy, and maybe Treg preservation?

And do you have any confidence that FB102 will hold against their cohort two and CeD for their phase 1b data in terms of SF and healing capability for CD122 targets? Thank you.

Karen Massey:

Yeah, thanks for the question. So when we look at assets and when we assess them, including FB102, we're looking across a few different parameters.

One of them is do we think that there's a path to a best-in-class asset? And that best-in-class asset can be defined by what do we see as the mechanism of action and the design of the molecule?

I think you heard from Peter earlier, we see this as an elegant design and a very elegant mechanism of action. And the design of the molecule is certainly important to us as we selected it.

But then, of course, you need to prove that out with clinical data. And so we see the strongest clinical de-risking data for FB102. So, of course, we have the vitiligo data as well as the celiac data.

And when you look into that, when you look at the efficacy that we've seen, when you look at the safety that Peter spoke to early, we think that we have the potential for a best-in-class asset here.

Of course, what contributes to developing a best-in-class asset is in fact how you develop that asset. What are the indications you select, in what order, in what sequence? How do you develop things like the product presentations that you'll bring to market?

And I think that's where we have the opportunity to really accelerate this asset and put the argenx fingerprints on it to bring a best-in-class asset to market.

The last thing that I'll say that was compelling to us and that I think is important, and I've mentioned a few times, is that this is a first-in-class asset. So we'll be acting with urgency because we see that patients are waiting and we want to bring FB102 to those patients as quickly as possible.

Moderator:

For our next question, we'll return to the line of Suzanne van Voorthuizen from Kempen. Please ensure your line is unmuted locally.

Suzanne van Voorthuizen:

Hi, team. Can you hear me now?

Moderator:

We can, please go ahead.

Karen Massey:

Yes, we can hear you now.

Suzanne van Voorthuizen:

Okay, perfect. Sorry about that. Congrats on the deal and many thanks for taking my question. I may be last, but hopefully not least. Can you elaborate a bit more on the differentiation of FB102 that you see versus other molecules that are pursuing the same or similar mechanism of action?

You mentioned an elegant design. What is it exactly about the molecule that you find holding potential for best-in-class potential? Thank you.

Karen Massey:

Yes, thank you. As I mentioned earlier, there are a number of different reasons that we think this could be a best-in-class asset, but Peter, maybe you want to speak about the elegant design in particular.

Peter:

Yeah, I think it's hitting hearts on the IL-2 and IL-15 signaling while sparing the Tregs. I think that's an important element in the design of that asset. How ultimately, from a design perspective, it will pan out as compared to other CD122 molecules in development, that's I think we should wait for clinical data, for fresh clinical data to make that comparison.

Suzanne van Voorthuizen:

Got it. Thank you.

Moderator:

Our next question will come from Xian Deng with UBS.

Xian Deng:

Hey, thank you for taking my question. So maybe sort of a broader question for the rest of the argenx portfolio. So given this one, it's going to the broad autoimmune diseases where the payer dynamics are quite different from rare disease and rebate wall, et cetera.

So just wondering, could you highlight any other assets you also plan to go for broad autoimmune diseases? Maybe one to four. Yeah, thank you very much.

Karen Massey:

Yeah, thanks for the question. And it's great to have the opportunity to talk about our pipeline more broadly, because it is an exciting pipeline and a broad pipeline.

So what I would start with first is within FcRn. So when you look at Vyvgart, I mentioned earlier that the indications such as Sjögren's and Graves for Vyvgart start to make steps into larger patient populations.

When we think about our FcRn strategy more broadly, where we have argenx 213 and argenx 124 as next-gen FcRn molecules, we also have the opportunity to explore broader and larger patient populations with those assets within the FcRn space.

In addition to that, when you look at beyond FcRn into the rest of the pipeline, you can look at argenx 121 is a molecule that we're moving into phase two. It's an IgA sweeper. First molecule IgAN, but that's also a pipeline in a product with potential for larger indications.

And then as you mentioned, we haven't been public on our indications or our target for 124. And we're also moving other INDs forward into the clinic very rapidly this year.

And I think what you'll see is a consistent theme that we're expanding the population that we can have impact on and where we can transform outcomes with novel biology. Thanks for the question.

Moderator:

Our final question will come from Henrietta Boeg with Deutsche Bank.

Henrietta Boeg:

Hi, good afternoon. A question for Peter, please. So in celiac disease, we saw Amgen's IL-15 antibody didn't prevent mucosal injury. So it'd be good to know what makes you confident on the phase one data and the proof of concept, given that you said IL-15 is a key target. And does that mean IL-2 is more of an important disease driver? Thank you.

Peter:

I think that both pathways are involved in celiac disease. I think with the endpoint, with the composite endpoint, it touches upon gut morphology, but also lymphocyte infiltration. There are still movements on both of these elements. I think from that aspect, the 1b is quite convincing. Thank you.

Moderator:

This concludes our conference today. Thank you for participating. You may now disconnect.

Additional Information and Where to Find It

The tender offer has not yet commenced. This document is for informational purposes only and is neither a recommendation, nor an offer to purchase nor a solicitation of an offer to sell any securities of Forte Biosciences or any other entity, nor is it a substitute for any tender offer materials that argenx, Avena Merger Sub Inc. or Forte Biosciences will file with the U.S. Securities and Exchange Commission (SEC). A solicitation and an offer to buy securities of Forte Biosciences will be made only pursuant to an offer to purchase and related materials that argenx and Avena Merger Sub Inc. intend to file with the SEC. At the time the tender offer is commenced, argenx and Avena Merger Sub Inc. will file a Tender Offer Statement on Schedule TO, including an offer to purchase, a letter of transmittal and related documents, with the SEC, and Forte Biosciences thereafter will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. SECURITYHOLDERS AND OTHER INVESTORS ARE URGED TO READ THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9 REGARDING THE OFFER, AS THEY MAY BE AMENDED FROM TIME TO TIME, WHEN THEY BECOME AVAILABLE CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT INVESTORS AND SECURITYHOLDERS SHOULD READ CAREFULLY BEFORE ANY DECISION IS MADE WITH RESPECT TO THE TENDER OFFER. The offer to purchase, the related letter of transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement on Schedule 14D-9, will be sent to all stockholders of Forte Biosciences at no expense to them. The Tender Offer Statement on Schedule TO, the Solicitation/Recommendation Statement on Schedule 14D-9 and other related documents will be made available for free at the SEC's website at https://www.sec.gov/ and under the "SEC filings" section of argenx's investor relations website at https://argenx.com/investors/sec-filings. The Solicitation/Recommendation Statement on Schedule 14D-9 and other related documents that Forte Biosciences has filed with or furnished to the SEC will be made available for free at the SEC's website at https://www.sec.gov/ and under the "SEC Filings" section of Forte Biosciences' investor relations website at https://www.fortebiorx.com/investor-relations/sec-filings/default.aspx.

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