Biogen Inc.

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Salveen Richter Analyst

Great. Good morning, everyone. Thank you so much for joining us. Really pleased to have the Biogen team here with us. We have Alisha Alaimo who's the President, Head of North America; and Chuck Triano, Head of IR.

With that, let me turn it over to you, Chuck, for any opening comments.

Charles Triano Executive

Great. Thanks, Salveen. Good morning, everybody. Thanks for having us. Obviously, we'll be making some forward-looking remarks.

So I just want to let everybody know that actual results might be different.

But I'll just start just really quickly with Biogen has been on a journey for the last few years. And it's all really been about returning to growth and really almost taking a view of survive, stabilize and then thrive, right? Went through the ADUHELM issue came out of that, but had a company that was really declining, took a really hard look at the company. New CEO came in and what we saw in terms of really looking at how the company was focused, the mindset of the company, excellent science, excellent commercial capability. We think what was lacking was probably a little financial discipline and looking at capital allocation.

So rather than going on the same course, we really came through a whole reengineering of the organization. I think what you see today, we're in the stabilized mode. We had some earnings growth that we showed. But one thing I'd just highlight before we get into the questions, the whole fit for growth opportunity for the organization was really a reengineering

of the company, not just a cost-cutting program. And I think a real focus is on the company now optimizing capital allocation decisions for the long-term benefit of our shareholders.

So now stabilized and moving to thrive, we've got product launches, we've got a pipeline with a different risk profile. We've done some business development. I'm sure we'll continue to do business development. But now we're really on the execution phase and really looking to deliver that growth story for investors. And again, a hard focus on delivering those long-term returns for our shareholders.

So a different view, a different leadership team, Board composition is different as well. So really a whole reengineering here on the organization and a lot of good assets that we can talk about.

So thanks for having us and happy for us to both jump in.

Salveen Richter Analyst

Great. So Alisha, I mean, you're now -- you've come in to head the U.S. Commercial Operations. Could we start here given you have 3 key ongoing launches. Let's start with LEQEMBI.

At your last earnings, you noticed an acceleration in patients on drug since the end of last quarter, particularly in March. What were the drivers behind this? And then how do you plan to continue the momentum here?

Alisha Alaimo Executive

Thank you for the question. Thank you for having me here and a big thank you for everyone who joined in the room today and who's listening online. I think when I look at the story of LEQEMBI, which we've now been launched for 10 months, and I know we talked about it all the time on how the launch is going.

And on the last earnings call, I really sort of came out and told people the story of how these offices are moving through 2 phases, right? You have a staged and phased approach and then you have the extend and expand approach. So if I go back to launch back in July of last year and you think about these neurologists or these large IDNs or academic centers, all of a sudden having a monoclonal antibody to treat Alzheimer's disease to slow the decline of this disease. They didn't really know what to do with it in the beginning. And that's why it took so much time.

In fact, if you look at the pattern that's emerged, even from a P&T approval to first patient, you're looking at about 8 months or at the 10-month mark, but it took a long time to get them through sort of a staged and phased approach. They had to first worry about reimbursement, which we're clearly through. I think that even CMS moved very quickly, which was positive. But then secondarily, they had to really work through what's my protocol and how am I going to manage these patients. One physician in the Midwest said, Alisha, you're pushing me on how quickly we can go, but at the end of the day, I've been in this career for over 30, 35 years where it's been high touch and low tech and all of a sudden, it's high touch, high tech.

So they had to really work through how do I rescreen them to make sure they're MCI mild.

How do we make sure that amyloid-beta confirmed? Is it PET? Is it CSF? How do I use a blood-based biomarker?

And then when they go to do infusions, how do they schedule MRIs at the exact timing of the infusion and how do I manage for ARIA. That takes a lot of doctors. And I have to say for any physician or neurologists listening today, I have to give them a big thank you because it is heroic efforts because they're changing and transforming the Alzheimer space. I think if you look at today and you even think of something like cancer, we take for granted that you go in, you get diagnosed quickly. There's all these biomarkers.

You go to a subspecialist, you get treated really fast. That took a while to get there. That's exactly what we're going through with Alzheimer's now. And you're seeing these centers get through the staged and phased approach where they've run a couple of patients through and they're now ready for expanding and extending. So that leads me to March.

In the March time frame is when we started to see a critical number of HCPs writing the product, a critical number of sites ordering but also getting depth. So you saw IDNs now going deeper on how much volume they were ordering week to week.

And thirdly, you started seeing that they were through these patients, and they have either extended by adding more patients in their queue and rather than testing 3 to 5, you now see today, if you fast forward and read reports, you have them up to 50, 150 physicians down in the Southeast, it's 350. So you're starting to see a lot of these numbers come on board. But more importantly, after they've allowed that, the IDNs are now and you fast forward to today, they're what we're calling expanding. So a lot of these flagship accounts had one physician only that could do all of the treatment and the monitoring. Now that a lot of them because we're 10 months out, have 6 months under their belt of the patient being on product, they're also seeing what can I expect with ARIA.

And now that they've had the experience, they're now one, allowing other neurologists to also see patients; and two, opening up child accounts that sit within the IDN but in the community. So for example, I spoke to one in the Midwest about a month ago. And this one very large IDN now has opened 12 different offices to allow same patients. And so in March, we saw the beginning of that. And as I look at the past several months, it's also been sustained up until today.

So those are really the critical factors, I think, that affected the March time frame.

Salveen Richter Analyst

Help us understand how to think on the forward about the entry of another player and Lilly just had their FDA AdCom panel this week?

Alisha Alaimo Executive

Yes. So I think, first and foremost, in a space like this, where there has been such a heavy lift by the physician community. A competitor or another option is always really a good thing. It's a good thing for physicians. It's a good thing for patients.

But more importantly, the market will develop faster with Lilly in play. Now I can't speculate at

all what's going to happen with their label. I think even from the AdCom you don't know, we'll have to wait and see what the FDA does put in the label. But with the progress that we've seen with LEQEMBI up to date for us, at least, we believe in the benefit risk advantages that we do have is we're seeing patients now get on product, and we're starting to see the outcome of it.

LEQEMBI can be used across a wide range of patients whether they're low or no tau. Also, we believe in the safety of our ARIA data. And even at AAIC coming up in July, you're going to see a 36-month readout also over a long-term extension. So we do believe that LEQEMBI is going to do very well in the market regardless of whether a competitor will come or not come, but it will help grow the market.

Salveen Richter Analyst

How are you thinking about the reliability for a third-party script data for tracking the launch just given that we tend to look at that?

Alisha Alaimo Executive

Well, I would say it depends on which script data you are looking at. Some don't have a lot of coverage, as you know, especially some of the claims data you might get from IQVIA or Symphony and some of the other data though, like NSP and DDD is directionally accurate and can have probably a 90% coverage, which is good. But even though you look at those indicators, what I would say, and I think you've probably heard Chris say this, revenue and patients on product right now for us is more of a lagging indicator because it's really getting the market ready to prescribe that is the leading indicator. And so a lot of what we look at, which we triangulate all the data that you buy, plus we look at what are biomarker companies, what are they saying about biomarker data be blood-based biomarkers, PET companies will tell us what their PET scans look like. We have patient services that give us feedback on what's happening with the patients.

We see reimbursement and claims and of course, ordering patterns. We get all the real-time orders. And so we triangulate all of that. And I will say that the data that becomes really important for us now that is a leading indicator to all the numbers I know that everyone wants to see are how many HCPs are writing for us to get to the kind of patient numbers, we need a lot of doctors to come online.

How many sites are ordering out of all of the sites that are out there. And last but not least, the one that has really moved ahead is now that we see physicians getting 50 or more patients on product, we're really looking at how many are hitting that mark because that's when they start expanding further. And so those are some of the things that we look at for the longevity of the launch.

Salveen Richter Analyst

Could you provide us a broad update on launch metrics such as the number of patients on drug and on the waiting list, the proportion of top IDNs placing LEQEMBI orders and unique prescribers. And any other signals that we can use to kind of understand and think about the inflection as we watch this launch move along?

Alisha Alaimo Executive

Yes. So that's another great question. I think like I said, the number of patients on product is probably not nearly as important for me right now at this stage as how many offices and HCPs are coming online because that will give us the large number of patients sort of going through. And so when you look at the launch and you look at like bottlenecks, a lot of people ask about bottlenecks, which has varied amongst every IDN, every IDN had a different one, and it's definitely through the staging and phasing approach. But the one that is consistent is the number of neurologists writing or the ones that have access.

So it's the wait times for patients. And we're starting to see that work itself out and so physicians are either hiring medical assistants to help get patients through or nurse practitioners but more importantly, as I referred to earlier, it's these big flagship accounts that are allowing more than one physician now to diagnose, screen and prescribe and also opening up the child accounts. Now the other interesting thing that we've seen developed since the earnings call, is a lot of our smaller accounts, which at the beginning of launch accounted for about 70% of our patient population and writing, they have now also expanded to partnering with multiple infusion centers so that the infusion centers can take on a lot of their patient population. And we spoke to a very large infusion company the other day, and they said they're now expanding into parts of the country they've never been in before because there are demands now from rural doctors where these patients need to be infused. And so for us, the number of patients coming on sort of happens after all of this.

And I will say that what we saw in March has been sustained up until today before walking in the room, I'm looking at the numbers on a daily basis. And I think where we're really starting to see some traction as number of HCPs coming online every week is a very healthy number. And I think another thing that is important is when I was on the earnings call, I talked about how we've seen several or a few IDNs open up to child accounts. We're now into very high double digits on the number of IDNs that have opened up to either 2 or more child accounts as well. So things are happening in real time and you really start to see the move once they really figure out how they want to get their patients through.

Charles Triano Executive

So I think even as we look now the comment about smaller practices being on average, 70% of the prescribing, probably closer moving down to 60% now in IDNs, integrated delivery network still being in the minority. We believe that's going to shift and invert at some point. So I think as we look at the momentum in the markers that we're seeing, all at this point are pointing toward that reversal whereas one would expect, the integrated delivery networks ultimately, we believe, become the majority of the prescribing. So still a ways to go here.

Salveen Richter Analyst

And how is the expansion of the U.S. sales force helping in this effort?

Alisha Alaimo Executive

So there's two things to the expansion actually, and we were very mindful as to when we would pull this trigger and when we would invest. So first and foremost, we want to make sure

the market was right for expansion. And I say market was right, the last thing you want to do is send either a bunch of reps or force patients into an office and the offices aren't ready yet. And so we waited until we hit sort of a really nice math, and we started to see these offices open up to child accounts and open up to other neurologists. So we knew that was sort of coming.

We could see it in the metrics. And so there's two parts to this. I think first is we've now increased our neurology account specialist field force by about 30%. We know exactly which offices, and which IDNs we want them to call on and they are the ones exactly what I was describing as ready to expand in patient numbers, but also the one in the Midwest, where I said they had 12 child accounts someone also needs to help the 12 accounts, right?

So we know exactly where to go. Some of them are going to be within IDNs that are doing that and other territories will have new offices that they will call on that we believe also have a large number of patients waiting to be treated. So one of that, which we believe an acceleration will happen, I can tell you that we did a small pilot with this [indiscernible], and we did see that acceleration happen once you added those heads. So we knew this was the right move. The second thing that we're doing that I think is critically important is we also know there are about 2 million patients sitting with around 7,000 or 8,000 neurologists that have suspected mild AD or MCI.

So we have now launched a DTC directed at the exact basically 2 million that sit with neurologists that will drive them into the neurology office. So with both of those efforts, we believe that is what will help accelerate the launch. As for the teams, they're basically all hired on. In fact, they're in training right now. I had some feedback that the tests were a little difficult but they all are in training, and they will hit the field probably a little later this summer.

Salveen Richter Analyst

Great. Could you outline the timelines here for the potential regulatory approvals of the IV maintenance and subcutaneous induction and induction and maintenance filings and provide an update to the ex-U.S. expansion strategy here for LEQEMBI.

Charles Triano Executive

Yes. Sure, Salveen. So the IV maintenance filing was accepted for review, PDUFA date is January 25 of next year. And then the subcutaneous formulation, we have 2 separate applications there. We have got the subcutaneous maintenance filing that is part of a rolling submission.

We have to get some immunogenicity data, which we will generate. And we expect that, that application, we should be able to complete in the third quarter, and then we'll get a PDUFA date there. So that's subcutaneous maintenance filing. And then on subcutaneous induction, when we saw the initial

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as we looked at the data, the partnership

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potentially look for a lower dose for subcutaneous induction. So less drug into the patient perhaps a better patient experience based on some of the safety and efficacy data that we saw. So we are still working to optimize that dose. And importantly, this was not a request from the FDA, this was something the partnership saw and said, we think perhaps we can find maybe a more optimal dose. So we're doing some more work on that with modeling, and we'll generate some data there.

So that is on the [indiscernible] in terms of a filing there. So subcutaneous maybe Alisha can talk a little bit about it, it will be a nice option for patients. Certainly, there will be some need there. We don't see the lack of a subcutaneous formulation at this point, as holding anything up. But I think patients and physicians like options.

And by the time these formulations hopefully get to market, the prescribing community, the patient community is going to have a lot more experience with LEQEMBI. So we think it'll have a nice place in the continuum and especially as we look at the potential for maintenance dosing out there. This will be a nice part of the story.

Salveen Richter Analyst

And how are you thinking about potential impact from Medicare Part D redesign, maybe help us understand the dynamics here as it relates to the pricing and coverage of the subcutaneous formulation in particular?

Alisha Alaimo Executive

Well, we're in the middle of obviously discussing with the FDA right now, the subcu formulation, and we won't know what ends up in the label, of course. But Part D won't come into play for quite some time yet until we actually have that on the market. And there are still some unanswered questions with Part D and IRA. I will say on the side that I think is excellent for patients, I think the cap that has been put into place and the option of smoothing payments throughout the year are really a good thing for patients under the new IRA.

Now on the other side, of course, CMS has decided to offload some of those costs to PBMs and manufacturers, which in the end, you hope sort of offset each other, but we won't really know until we get subcu in the market, and it's not going to be for a little while. So we have some time to understand how we want to do pricing and see what some unanswered questions are from CMS as well with IRA.

Charles Triano Executive

And as a biologic under current IRA, you'd have a 13-year window before you could be eligible for negotiation. So with post-approval 13 years that would be 2036 by the time this could come into play on the IRA negotiation.

Salveen Richter Analyst

Turning to SKYCLARYS in Friedreich's ataxia, could you just provide an update here on the patients on drug in the U.S. and penetration into the addressable populations geographically to date?

Alisha Alaimo Executive

So SKYCLARYS has really been such an excellent acquisition for us and especially for rare disease. If you think about SPINRAZA, thank goodness we've had 8 years with that product. It's performing obviously very well. But because of that, the team has an extraordinary amount of expertise when it comes to rare disease and patient finding. So in the earnings call in quarter 1, we had mentioned that we were over 1,100 patients and penetrated the market 24%, we continue to penetrate the market as I sit here today and clearly add on more patients every single week.

The interesting part, though, of this launch, which is normal with any rare disease is once you get through the catch-up population, which you saw that happen in sort of quarter 4 and quarter 1, we now enter a phase where we are searching for patients who are sitting outside of centers of excellence. So we still have a queue of them coming through, of course, every month that have the ICD-10 code of Friedreich's ataxia. But there are large proportion of patients who have a general ataxia code because those codes did change, I think, in 2022. And so with the ICD-10 code that our general ataxia, we have put in place a lot of tactics to basically

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I can say that the ataxia we've put in place, we've already started to see that benefit in the last 2 weeks, which has been really amazing to watch. But I think first and foremost, it's going to be a very broad population we have to call on now from general neurologists who may only have the one patient or PCPs who have one patient. We've learned in this ataxia population that some of these patients are actually an older population, if you know the average age of when someone may passes 35 years old, the first patient we found with all of the tactics we deployed was a 70-year-old in New York City, and I had to called the physician actually myself and said, how did this happen?" He said, "Well, I knew I had one patient with ataxia, I just didn't know what kind of ataxia it was. So I called the man, had him genetically tested and he has Friedreich's ataxia. So that is what we're now going to see for the next tranche of patients and how we've deployed really a very sophisticated model, again, very grateful for SPINRAZA in an AI model where we have mapped out millions of patient journeys for these patients that have general ataxia.

For example, something that they just have a balance disorder, and they go to an ENT. They think it's an inner ear problem, but they may have Friedreich's ataxia. A lot of them sit with their cardiologists because they do have heart complications. And so we've now deployed this model where we're able to send in people or go through omnichannel or a maybe push that's either driving the patient to the office or the office already knows, they're having ataxia patient, let me call them in. So that is really the phase that we're in now.

And like I said in the last 2 weeks, we've seen a nice outcome from some of the tactics that we've deployed.

Salveen Richter Analyst

Great. And when you add the need for identification, as you just mentioned, you have to go out and find these patients with rare diseases but also there's compliance and logistical

factors that could play out. How do you think this could affect quarterly trends regarding new patient adds on the forward?

Alisha Alaimo Executive

So for quarterly trends, we've reported before that it will be slightly lumpy. When I say lumpy, that's mostly because every week is a different week on how you add new patients. For an example, we could go out and I'd mentioned the 70-year-old in New York, it took him 3 months because the doctor said, Alisha, they have a real life, right? Like he was hospitalized for his kidney. He had to somehow find his way in for the appointment.

It takes some time. And so you could have a week where you're getting a couple of patients on. But then, for example, recently, we had one patient diagnosed, they said they thought the whole family had it. So they're now going in for genetic testing. And you could have several people come on in one day sort of thing.

So the quarterly lumpiness will come from new -- finding those new patients and getting them into the offices. When it comes to compliance, we have a team of people that support the patient community on staying compliant with medication, making sure shipments go out on time and educating on how they take their pills, when they take their pills, which, of course, the HCPs are hand-in-hand with them on that.

So compliance thus far, we do track and monitor to make sure that they get their shipments on time. But the lumpiness quarter-over-quarter will come from new patients feeding into the funnel.

Salveen Richter Analyst

Can you comment on the feedback you're getting from real-world experience from these patients?

Alisha Alaimo Executive

So the SKYCLARYS patients, the feedback has been very good. You really see nothing that is outside of the label when it comes to safety or anything like that. But I will say recently, we had a meeting and we had 3 patients basically on stage talking to the executives of the company. And I think for them, the objective is obviously slow to decline, but they do see differences, they see differences in their daily activities. And I will say the other thing it does is gives them hope, especially the younger population in late teens and early 20s, it definitely gives them a different renewed sense of hope.

Salveen Richter Analyst

And how could label expansion to the pediatric population potentially help here as a lever of growth? Maybe help us understand the magnitude.

Alisha Alaimo Executive

Well, you'll have U.S. and ex U.S., which Chuck can talk about ex U.S. But in the U.S., we do believe that we have about 500 patients that are -- will be a part of the pediatric label expansion. So it will give us another 500 patients. I think more importantly, though, the

heartbreaking stories that you hear are parents who may have a child that gets diagnosed at 13, and there's nothing that can be done, right?

And we do believe that the earlier you get them on products are better as with many of these products that you see in rare disease. And so for the U.S., that label expansion will be of around 500 patients.

Charles Triano Executive

Yes. And I think in the EU, I mean, the epidemiology would suggest that in Europe, the prevalence is maybe a little more than 1.5x what it is in the U.S., given genetically this is European descent. But already out of the gate, approval earlier this year, now we go in a country-by-country basis, but we're recognizing revenue now in Germany, France, Austria, Czech Republic and Poland. Those countries alone are about 40% of the prevalence already, big ones to still come on are going to be France and Spain. But very good uptake here.

And we said previously that this is -- Europe is, give or take, our view, we believe, could be 40% of the business for SKYCLARYS. So it's an important add here. And so continuing to roll out in Europe. So some revenue recognition this year, probably a slightly bigger impact next year, but it's already coming online here. And then Latin America, notably Brazil will be another opportunity here for SKYCLARYS.

So really a global contributor for Biogen here. So very pleased with everything we've been seeing really across the globe. And again, more to come on that as we get more approvals and more countries coming online.

Salveen Richter Analyst

And on the launches, lastly here with ZURZUVAE. Help us understand the division of responsibilities between yourself and Sage as well as how the early launch metrics are tracking and just your confidence in the outlook here?

Alisha Alaimo Executive

So ZURZUVAE for PPD, we are in alliance with Sage and it is a 50-50 split. So they have half the field force. We have half the field force. They have half marketing. We have half marketing.

So it is a good 50-50 split. And we work very closely with them on decisions and tactics and deployment. And so that is on the alliance front. I talked to my counterpart there quite regularly. I think when it comes to a launch metrics, the fascinating thing about this launch is out of the gate, if you were to look at the data that you pull on prescription data, your first inclination is to think that psychiatrists would have really been the largest writers because of the volumes that sit with them.

We always knew that data, we call it dirty data. The data wasn't going to be totally accurate because sometimes there's a miscoding. It could be MDD, but they put down PPD. You're not really sure and sometimes with OB/GYNs, you also have some miscoding going on. Well, fast forward to now being in launch since early January is full force, OB/GYNs are the main prescribers here.

And what we're finding is you may call on one target in that office but there are 8 or 9 other doctors that are also in that office that will either know about the product via a lunch or breakfast or they have heard through the physicians they've been detailed. And so you're seeing a lot of non-targets right on top of targets because these office practices are so large. And so when you look at the actual launch, we have been surprised that OB/GYNs have been the largest segment. Now psychiatrists are the second largest and they've also come online, but we definitely thought that they'd be bigger out of the gate. When it comes to the actual launch performance, I think we've said that it's beaten all of our internal expectations so far.

In fact, what has been very special about this launch is that there's been tailwinds. If you look at market access, I mean the big PBMs have moved faster than I've probably ever seen them move and especially Medicaid, I mean, 2/3 of the states have already reviewed this product to put a policy in place, and a lot of them even moved up their review period. So that's also been interesting to see that the actual market wants to help these patients. Also, when policies weren't in place, a lot of the product went through as commercial and not as free drug. So we've also been surprised that they've been allowing it to go through and especially NCD blocks and things like that were supposed to be in place and they've allowed the patients to get on product.

I think where you see some education that needs to happen is we're in psychiatrist's office, they are very used to doing prior auth and very used to doing specialty pharmacy. For OB/GYNs, they aren't, right? So there's been a lot of education with OB/GYNs on what the prior auth is, how you use a specialty pharmacy. We can ship it directly to the patient and things like that. So that's really what we're working on now.

We believe we've got a very good year ahead for both teams. They're executing very well. They're working well together but we still have a lot of potential that we can tap into than where we are today. But right now, it's looking very promising.

Salveen Richter Analyst

Great. And one last question here. What do you believe that investors should be paying attention to outside of these launches as it relates to the base business? And help us in that answer, kind of understand how you think about the margin trajectory in 2025 and beyond, given the cost savings and post the recent deals that you've done, whether there is appetite for more?

Charles Triano Executive

Sure, Salveen. Yes, I think a couple of things. And I think overarching is, again, we're looking to optimize capital allocation for the long-term benefit of our shareholders. So I think come back to quickly just that whole fit for growth view and what that's going to do with margins. We took a whole layer of management out and the company is running very, very smoothly and efficient and very focused.

So I think the ability there, and we know we were way below peer average on margin. So I think this is going to really help energize that transition when we can get back to revenue growth really leveraged to the bottom line. We've already got earnings growth, which was really largely due to the fit for growth on a year-over-year basis last quarter.

So I think looking at that and taking a sharp pencil to where our margins can go, product mix will help our gross margin as well. So I think that's one focus point. Two, just our size, it doesn't take a lot to move the needle at Biogen. And three, really the focus -- again, we get a lot of questions on business development. We're not done.

HI-Bio was a very interesting acquisition. Obviously, that's later in the decade. So we're not sitting here and saying, we have everything we need in-house.

So we'll be very prudent with our capital allocation but we're still casting a pretty wide net to build on the growth. So I think the appetite to build a revenue growth company and persistent durable and visible revenue growth for the street and then leverage that to the bottom line, really efficiently managing this company. That's why I said earlier, great science, regulatory, commercial, now we're adding that fine point to the financial and capital allocation aspects. So I think putting all 3 of those together, really, I think can yield a pretty nice growth trajectory. At least we believe as we look through the rest of the decade, the return to growth objective is really what we're driving at here as a leadership team.

Salveen Richter Analyst

Great. Well, with that, Alisha and Chuck, thank you so much.

Alisha Alaimo Executive

Thank you.

Charles Triano Executive

Thank you, Salveen. Thanks, everybody.