Event Details

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Company: Halozyme Therapeutics, Inc.
Ticker: HALO-US

Company Participants

Helen I. Torley - Halozyme Therapeutics, Inc., President, Chief Executive Officer & Director

Other Participants

Sean Laaman - Analyst

MANAGEMENT DISCUSSION SECTION

Sean Laaman

00:00:08 Good morning, everyone. Welcome to Morgan Stanley's Global Healthcare Conference. I'm Sean Laaman, Head of SMID Cap Biotech Equity Research team here at the firm. For important disclosures, please see Morgan Stanley Research Disclosure website at www.morganstanley.com/researchdisclosures, and if you have any questions, please reach out to your Morgan Stanley sales representative. Excuse me. For this session, we have Halozyme, President and CEO, Helen Torley. Thank you for your time today. Greatly appreciate you being here. And maybe just to set the scene a little bit, if you'd like to make some opening remarks, wouldn't that be amazing.

Helen I. Torley

00:00:44 Yes. Halozyme is a biotech company, and we have a mission to help important therapies fit into the patient's life rather than the recovery be impacted by some restrictive schedule of having to travel for treatment. We do that with two drug delivery platforms. The first is our ENHANZE platform, it's based on hyaluronidase enzyme, which facilitates large volume delivery of biologics, by delivering up to 50 mls in as little as 3 minutes or 5 mls in just 20 seconds as is the case with VYVGART Hytrulo and the prefilled syringe that you may just have heard about.

00:01:21 We also have auto injector. The small volume auto-injector, which delivers up to 2.25 ml in just seconds. And we have by bringing together the amazing technology of ENHANZE, plus our auto-injector technology created the first ever high-volume vial auto injector that has been demonstrated to be able to deliver up to 10 mls of biologic in just a few seconds. This is a very profitable business for Halozyme in terms of the fact that we are in milestones and royalties, and that has resulted in Halozyme having not just a very high top line revenue growth this year, where we're projecting $1.27 billion to $1.35 billion strong growth, primarily driven by our royalties, which we project this year at $825 million to $860 million, which is a growth of 37 – sorry, 44% to 51% year-over-year, really being driven by three products that have been launched fairly recently. The first one is DARZALEX Faspro, the second one is Phesgo and the third one is VYVGART Hytrulo from argenx, and so these two products are still making remarkable difference in patients' lives and leading to a lot of excellent growth at Halozyme.

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00:02:45 And in terms of capital allocation, all of the important decision, when you've got a high cash flow business like we have. First and foremost, we invest in our business. Secondly, we've been returning capital to our investors through share repurchases. And the third one, we have an ambition to add additional drug delivery platforms to continue to build on the excellent growth we're seeing today with ENHANZE and our auto-injectors and deliver that long term, durable, high profitability growth.

QUESTION AND ANSWER SECTION

Analyst: Sean Laaman

00:03:13 **Question – Sean Laaman:** Wonderful. Thank you, Helen. Just some macro considerations that I'd like to start with, but just, you know, China's biotech innovation, it's really going hot. And how you think about Halozyme's competitive positioning here, are there opportunities there? Has it influenced, if at all, your R&D and business development strategy?

00:03:34 **Answer – Helen I. Torley:** Yes. I mentioned, we're focused on subcutaneous drug delivery, and that is something that is actually gaining traction globally. You can imagine that instead of lengthy hours long intravenous infusion, we're facilitating simple, short subcutaneous injections in seconds to minutes. And certainly in China, we're seeing that trend of people wanting subcu therapy, which can perhaps be done in a doctor's office instead of an expensive hospital infusion suite, or even in the patient's home. That's a trend that is very much present in China. Just earlier this year, Phesgo, which is actually Roche's product for breast cancer, it's a combination of Perjeta and Herceptin got national reimbursement and that actually led to very strong growth of Phesgo in the first and second quarter as China adoption increased.

00:04:27 Other products that we have that are very recently being approved in China that we expect to grow in the same way once all of the reimbursement in place – is in place would be argenx for a generalized myasthenia gravis and also for CIDP. So China very much another market that is seeing the benefit of for the patient, for the healthcare system, and for the healthcare professionals of the short, simple subcu injection.

00:04:52 **Question – Sean Laaman:** Thank you. And a question on AI. How do you currently leverage AI, or think about leveraging AI in your business and how do you see this about as a potential future disruptor?

00:05:03 **Answer – Helen I. Torley:** Yeah. We've certainly been embracing the innovation that comes with AI and it's very much in our operations. It really is, I can highlight that we're seeing benefits already in terms of efficiency, would be and improving document flow and regulatory, signal detection in terms of safety, but also in our operations and manufacturing. And the third one, we're using it to accelerate our decision-making, as well in areas like business development screening. And so certainly a huge benefit in terms of efficiency. And we're just planning to keep expanding that with that focus on improving our operations.

00:05:42 **Question – Sean Laaman:** Wonderful. Thank you, Helen. And a bit more – a lot more debate in the market around this next question, even though it is on the macro side, how much – or how impactful, what's been most impactful on Halozyme from the regulatory side, would it be FDA anything or tariffs?

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00:06:00 **Answer – Helen I. Torley:** I'm going to maintain FDA, and it's actually coming from a very positive (00:25:02) we've seen a lot of very positive impact over the last year in the Food and Drug Administration changes we've made. I'll begin with, when thinking about the ease and simplicity of getting a product approved with subcu, with ENHANZE, know for our partners and a use of Opdivo, Bristol's Opdivo as an example with a single study in renal cell carcinoma, the FDA granted them a very broad set of indications in multiple other solid tumors. And I think that recognition as to how to streamline this development of M-protein at medicine has been a very positive and welcomed change in terms of FDA mindset. And I think it's really just the beginning if we think about Commissioner Makary's comments also about making drug development flexible and common sense. And so we plan to continue to engage with the FDA and further streamlining those efforts on. I think with, also I'll just comment that certainly for us and our partners, we're finding everything proceeding according to the usual timeline. So nothing delayed, everything very, very much according to plan. And so, we deeply appreciate that with some of the changes, no impact in how the regulators are interacting with us.

00:07:23 **Question – Sean Laaman:** So thank you, Helen. Now to get more Halo specific, but how confident are you that the ENHANZE will be treated favorably under same as IRA and the guidance? And sort of how should we think about the steps unfolding to kind of clear that investment thesis over the next three months to six months?

00:07:43 **Answer – Helen I. Torley:** Yeah. Just a little bit of a background context there. Under the IRA, there's an area of it, it focuses on treating fixed combination drugs that are made up of two active ingredients as a separate drug from the individual ingredient. And when the Part D guidance first came out, that was the language that was used there. Importantly, ENHANZE is an active ingredient, it's designated as such by the FDA. If you look at the labels of our products as listed, there was an active ingredient. And, we actually have a separate BLA for HYLENEX, which is the rHuPH20 enzyme. And the area that's under comment at the moment was when the Part B guidance came out a few months ago, while it continue to preserve the recognition of a product with two active ingredients as a fixed combination, it brought some questions for the community to comment on, does the active ingredient need to have a direct impact on the disease, or does it have to have clinical benefit. That we and many of our partners have actually commented to CMS with regard to the fact that the Part B guidance should be kept the same as Part D, there are a number of policy and legal reasons why that makes sense. But very importantly, if you think about the clinical benefit that is and the IRA is looking for a clinically meaningful benefit, which the FDA describes as how a patient feels, functions and survive. We wrote many, many examples of how ENHANZE subcutaneous delivery has done that. And just to give a few examples, you often hear about infusion related reactions with drugs. That sounds like, well, that's just a side effect, but it's a side effect that makes a patient feel very unwell. It causes low blood pressure, headache, breathlessness, and it can lead to anaphylaxis and death. And when we think about some of the drugs we work with like J&J's terrific drug for lung cancer called amivantamab or RYBREVANT with the IV, the rate of infusion related reactions was 67%. It was reduced by a factor of 5%, down to just 13%, with subcu. I think you'll all agree that's a clinically meaningful benefit for patients. Importantly, with RYBREVANT also, there was an overall survival benefit in an analysis, an exploratory analysis that was done, another clinically meaningful benefit. And it's been pretty common throughout all of our partner filings that the rate of serious and serious adverse events is also a lot lower with the subcutaneous. So when we think about all of the clinically meaningful benefits, we feel very strongly that the language should be unchanged between D and B. So we've written a comment letter. We have visited with the OMB to present those arguments. We've had conversations with CMS also about those arguments, also highlighting the reduced cost of care. We did an analysis of Medicare and of course, subcu therapy versus the IV, the average cost savings per year between $12,000 and $66,000 per patient, per year. So if the clinical argument doesn't get you for CNS and for people who are worried about the cost of care, the clinical benefits

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in terms of cost of care are remarkable as well. So lots of arguments on, we very much hope that we do prevail on that.

00:11:07 I'll just mention one thing that's also come out since then, though, that has the potential to impact Halozyme that was causing questions. And that relates to what will happen with the orphan drug designation. And if anybody was watching the One Big Beautiful Bill, it actually did make it clear that if a drug has two orphan indications, it will be excluded from the IRA. Now that's relevant to Halozyme because DARZALEX was one of the first drugs that we're involved in that could be up for inclusion in the IRA price negotiations. Both of the indications are orphan. So under the One Big Beautiful Bill that will no longer be included in the IRA for consideration, and also Opdivo, actually the first indication for Opdivo was an orphan as well, so that pushes out the timeline for Opdivo. So obviously an area we're watching at carefully, Sean, and we're very hopeful that our arguments will prevail. But even beyond that, for Halozyme, the clarity on the orphan drug has also made the IRA outlook less relevant and impactful to Halozyme.

00:12:11 **Question – Sean Laaman:** Sure. That was a wonderfully full answer. But if I can, I might have missed it, it was so full, but just kind of put you on timing, do you have a view on when this might get resolved?

00:12:23 **Answer – Helen I. Torley:** Yeah. There's no official timing comes out with a clock for this. But based on prior precedence of the time between the draft guidance and final, we would expect it in September or October. So in the upcoming weeks will be the final guidance there.

00:12:36 **Question – Sean Laaman:** Wonderful. And I guess on guidance, so the company has raised guidance multiple times and just remind us sort of what have been the key factors behind driving such a big uplift in earnings expectations?

00:12:51 **Answer – Helen I. Torley:** Yeah. I mentioned in my introductory remarks, what our updated guidance for the year is that just to reiterate for total revenue, $1.527 billion to $1.325 billion, and the key driver of that is the royalty revenue, which is growing at remarkably to $825 million to $850 million – sorry, $860 million this year. The key drivers of that are the three products that were launched in 2020 and 2023. And these are products that we expect to continue to grow for multiple years to come. The first is DARZALEX Faspro, which is obviously Johnson & Johnson's terrific drug, primarily for multiple myeloma patients. The subcu version is now 96% of the use of that. And so all of this growth is subcutaneous. And you may say, well, it's already at 96%. It's just going to keep growing. Analysts project that DARZALEX will grow from $13 billion today to $18 billion in 2028. And it's doing that by continuing to increase its penetration into the frontline population. Now the frontline population is the largest population. So there's obviously a lot of growth to come from that. But the compounding effect of the fact that the frontline patients stay on therapy for many years is really, I think, what's causing that accelerated growth over and above frankly, what we had predicted for this year in terms of a very nice story there that's going to continue to grow for years to come.

00:14:21 Phesgo, I mentioned, accelerating this year, because of final reimbursement, but also launched in 20 additional countries in the second quarter and going from 58 launch countries to 78. That's going to continue to grow. And the third one is VYVGART Hytrulo, launched in GMG, more recently launched in CIDP. But we're very excited about the April launch of the prefilled syringe, which has got the formulation of VYVGART Hytrulo with ENHANZE, so delivered subcu in just 20 seconds because of the ENHANZE technology that, based on argenx's comments, is causing new physicians to come into the market to start using VYVGART and more patients able to access the important therapy being able to receive VYVGART. That's another driver of the growth. So all three of those

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products exceeding our initial expectations for this year, and that's what drove the increase in guidance.

00:15:15 **Question – Sean Laaman:** Wonderful. And we still have the long-term guidance out there, 2026 to 2028, which hasn't moved yet. But I believe you revisit that early in the New Year and maybe sort of give us some comments on how to think about that?

00:15:28 **Answer – Helen I. Torley:** Yes. It was actually 2017 where we gave our prediction of being able to achieve $1 billion in royalty revenue by 2027. I think based on my comments I've made, you realize probably that we're probably going to achieve that a bit earlier, and that does bode very well. In addition to these three products that we have, there's also four additional products that we just launched in 2024 and 2025. Those are going to be beginning to contribute in 2026 and beyond and further fuel the strong growth. So as you say, Sean, what we tended to do is update the guidance during the year for any new insights. And at the beginning of the following year, that's where you'll see us update the guidance. So that will reflect the continued strength of DARZALEX Faspro and VYVGART and our expectations for these four new launch products.

00:16:24 **Question – Sean Laaman:** Thank you. And I guess this is one of the hot debates and maybe you get tired of talking about it, but just sort of about the long-term revenue projections, you know, going beyond 2030. And how should investors sort of think about that?

00:16:38 **Answer – Helen I. Torley:** Yeah. I think there's two key trends that underpin our strong confidence in the durability of our revenues. And the first is that secular trend that I've mentioned a couple of time, which is the increasing interest by pharma companies, but also healthcare systems and patients for subcutaneous drug delivery. We obviously are in the licensing business. We get many companies now coming to us saying, can you help us bring our products subcu? Can you help us extend the dosing interval so it's easier for patients to do this and there's a real push for more and more therapies being able to be delivered at home. And so that secular trend is going to continue to have adoption of our current products, but allow us to expand our portfolio and add new royalty streams.

00:17:26 The second one is by combining a product with ENHANZE, you can get new inventions, some new benefit that was unexpected for patients. I talked about RYBREVANT a moment ago. That fivefold reduction infusion related reactions that increased overall survival, both unexpected and unpredicted. If you're delivering a similar amount of the drug, as with the IV. That results in new intellectual property for partners. And for Halozyme, it also results in a longer duration of a royalty and very often can keep the royalty rate maintained at a mid-single digit level. Those two combinations of the increasing trend of subcu use and continuous growth of the current products and new products. And that durability of revenue, Sean, is what gives us a confidence in very robust revenues continuing in 2030 and well beyond that.

00:18:26 **Question – Sean Laaman:** Sure. Thank you. And I sort of have this question later, my question. But I think it's kind of relevant now, so when I look at modeling business and maybe I'm not the best modeler, but when I think about your – I'm not. But when you think about, I guess, sort of the gross margin, it seems sort of pretty stable, you don't see too many changes there versus a traditional, I'll call it traditional biotech companies heavily involved in drug development, then your R&D expenditure is probably light on versus a more drug development type company. And you could argue on the SG&A front as well. It's your partners that really support the OpEx in some senses. And what might get missed about the business therefore is the cash flow that's being generated. We think if you took this very pessimistic long-term view that maybe you apply maybe 100% terminal growth rate to Halozyme's business. You look at the cash generation out of that

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period of time, which is on my math, is much bigger than what the current market cap of the company is, losing stuff that is (00:38:31) the bank and let alone an interest rate. You still got quite a long-term value. So are we thinking about the cash flow generating nature of your business in the right way? Is that the right way to think about it, that the cash that is coming out is going to present potentially the ongoing capital return story and that the business development opportunities potentially numerous, maybe talk us through those big strategic picture?

00:20:00 **Answer – Helen I. Torley:** Yeah. I think it's a great observation, Sean, that we have an unusual business model and a very highly leverageable business model, because our role with our partners is very much advisory. We don't have the R&D cost, we don't have the commercialization costs, but we do participate in the upside of our partner's commercial success with our royalties. And as an example, our predicted adjusted EBITDA margin in 2028 is 73% to 75%, almost all of which is free cash flow to the company. And so it is a very cash flow positive company. So in terms of how we plan to use that cash, we do invest in the business as I mentioned earlier, we do use it to return capital to our shareholders. And we do want to build on the very strong revenue growth we have by adding new platforms. I will just say, you know, you said even if you apply the terminal, a negative terminal value to the company, we do – just to reiterate, because of the nature of the business and because of our contractual agreements and have strong royalty revenues continuing, well past the 2030. And just to kind of give a couple of examples, these co-formulation patents that come because we find these innovations, these unexpected benefits, all of our royalty streams will go to at least 2030, several will go into the mid-2030s and multiple go into the 2040s. And so you're balancing a very strong cash flow business with long durable revenues. It is a great story and importantly the opportunity now for us to use M&A to build on that very strong story to add new revenue streams on top of that, looking again for these more royalty-based businesses which can be so highly profitable.

00:21:56 **Question – Sean Laaman:** Thank you, Helen. Great answer. I think you've got 10 approved products, several more in development. But how do you prioritize, you know, further pipeline investments?

00:22:05 **Answer – Helen I. Torley:** Yeah. I mean, the great news is based on our business model, Sean, we don't really have a challenge with prioritization, because it is not a capital-intensive business supporting ENHANZE. This advisory nature that we have really means that our team, who are excellent, and they work very closely with our partners, they can support multiple partners at once, and so we can add new partnerships without having to expand a lot of people as an example. Because it's an established business, we don't have a lot of capital investment at this stage. So we are obviously continuing to make sure we focus first and foremost on our current business. But beyond that, we have the opportunity to return capital via share repurchases. Now, since 2019, we've returned about $1.85 billion to our shareholders with an average price of $33.72, you know, really buying opportunistically. And we found that. And I find our investors very appreciative of just how successful we've been with share buyback. But we also have retained enough capital for acquisitions. We're very mindful of keeping our net debt-to-EBITDA leverage below 3% in terms of where we're going. But today, we are sitting in the position of looking for additional platforms to acquire to add to our attractive business and can do all three at the same time, because of the strong cash flow of the business.

00:23:37 **Question – Sean Laaman:** Wonderful. And jumping sideways a little bit, but what lessons have you learned from the launch of VYVGART Hytrulo and the prefilled syringe, and, you know, can it be applied to other drugs?

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Answer – Helen I. Torley: Yeah. I think first and foremost, argenx has just done a super job with the entire long term, both in gMG and now looking at CIDP. This is a therapy that is transforming the lives of many patients who haven't had terrific options up to this point in time. What the prefilled syringe launches really do so and not unexpectedly is the patients are ready to embrace being able to treat themselves at home, in the privacy of their own home, on their own time and on their own conditions, because the prefilled syringe, which includes the ENHANZE technology to make it a simple subcu injection is (00:43:27) 20-second subcu 5 ml injection, but now a patient and I think actually Karl mentioned this, the patient is able to if they're working, do it before they go to work. They don't have that disruption. They don't need to be traveling to a doctor's office or an infusion suite, it's just free and allowing patients to get back to their everyday lives. And so, I do think that move in inflammation and immunology, neurology, nephrology, cardiovascular to more at home care, we do see that as just being a great example for other companies to look at and follow and see how argenx is leading in being able to free the patient up even further from the burden of their disease.

00:25:10 What the prefilled syringe has also done is expand the number of prescribers. Over 1,000 people have prescribed the prefilled syringe, 150% or 15% are new to VYVGART and that is something that we are seeing with some of our other products. But the ability of the right delivery to expand the number of prescribers, I'm going to talk about Roche's Ocrevus, where today Ocrevus, which is a great treatment for multiple sclerosis is in multiple our IV infusion. So patients able to take them their entire day. For the subcu version it's given in just 10 minutes. And so what Roche was hoping they would see with the launch and they're seeing just like for VYVGART is, they are getting new prescribers, because some doctors don't have a setup, or don't want to get involved in IV infusions, know the subcu is so simple to give. They've seen that all of the people who have adopted the Ocrevus subcu, 50% were brand new to using Ocrevus. And so market expansion is the other thing I think that is very nicely demonstrated with VYVGART prefilled syringe, but I will say it's happening with Ocrevus subcu. So, subcu in and of itself, it simplifies care, will expand the opportunity for pharmaceutical companies. And that's the other very important lesson we want people to take from this.

00:26:34 **Question – Sean Laaman:** Sure. Do you get much inbound on the PFS, the prefilled syringe and the market expansion opportunities? Do you think it's fairly well-understood part of the Halozyme story, or is it something that's yet to come?

00:26:47 **Answer – Helen I. Torley:** It's definitely growing. I mean, prefilled syringe just launched in April and argenx talked about the results in their quarterly call, but they were, I think, early. So I do think companies are coming to terms with it. But if a company is in inflammation and immunology, they're following argenx and they are talking about it. So, but I don't think everybody's heard about it yet.

00:27:11 **Question – Sean Laaman:** Right. Thank you, Helen. What are the most promising areas of innovation with drug delivery platforms that and beyond subcutaneous delivery, maybe set the scene for us a little bit there?

00:27:22 **Answer – Helen I. Torley:** Yeah. So we talk about adding platforms to our remarkable business. And when we think about drug delivery and did a giant survey to say, what else would be helpful? And we actually came up with 30 different areas, and I'll mention a range of them just so you see the breadth of what we consider drug delivery, and where we think there could be an opportunity for a similar business, which is where pharma and biotech is not investing themselves in a technology, but they're willing to license it for the drugs in their portfolio. They need it. And so, there are therapies that are used as an example in our delivery devices that are used in intraocular

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delivery, lipid nanoparticles, oral delivery of biologics, long-acting delivery for small molecules. These are all platforms that exist that we are on and another 25 on top of that, that we are actively mining to look for the opportunity to either get a platform that is more advanced than de-risked if that exists, which is, you know, more of a challenge, or something earlier on where we can do exactly what we did with ENHANZE, which they take something from the lab or early stage to commercialization using the expertise and the learnings we have as a company to birth a new terrific licensing business model like we've done with ENHANZE. And so that's we're very actively looking at for M&A. Our business is strong. We've got strong growth predicted, so we're not rushing into it. We're going to wait till we find the right type of platform to add to our already terrific business.

00:28:56 **Question – Sean Laaman:** I guess just generally on that front, when it comes to business development, how competitive the space is, you know, I think Halozyme is the biggest business that I'm aware of in the drug delivery platform space. You know, how competitive do you think that space is in terms of business development opportunities?

00:29:15 **Answer – Helen I. Torley:** Without sounding modest on the part of Halozyme, and I don't think there's anyone who is quite like us in terms of being able to take something from the lab to such broad commercial success. And so four I think platforms that have that potential. We don't come across many other companies who are, to our knowledge, kicking the tires and evaluating it, because it's not necessarily a business model people have experience with, and they don't necessarily want to go down that path. And so not too competitive. But I think what the art here, Sean, is identifying that asset that is needed by multiple pharma and biotech companies, where we can replicate the ENHANZE business model and obviously there's a great opportunity there for the relationships we already have and getting some great synergies in terms of the cross-selling. So we're in a, I think a very strong position when we're looking at drug delivery platforms.

00:30:13 **Question – Sean Laaman:** Wonderful. You've historically signed, I believe, one ENHANZE deal per year. How do you view the cadence of those deals going forward?

00:30:22 **Answer – Helen I. Torley:** Now, this year already, I'm very proud to say that we've already signed one small volume auto-injector development agreement, one – and that's with the current partner, one high volume auto-injector development agreement with a current partner. And we're very active in a broad set of discussions on ENHANZE. And so I will say based on the cadence and the progress of those conversations, Sean, I'm very confident we will sign another ENHANZE agreement this year and at least one. We are seeing that there's just a certain period of time of going through the decision-making in the pharma and biotech companies. So you have to be patient. But we're working through that. So I see at least one and we may be successful with getting more than one over the finish line, but I'll be very happy to have an additional one. I'll just mention in addition to new deals, and that's an important metric for us for sure. Recollect of many of our partners also have open slots. We don't necessarily if they want to work in a drug, just take one slot, they take multiple slots. And so we're going to continue to see our pipeline expanding with current partners moving more products into the clinic. One's already happened this year, we're predicting another one by year-end and then another one at the beginning of 2026. And so that's another important source of growth and expansion for our pipeline.

00:31:41 **Question – Sean Laaman:** Thank you. And what criteria to use to evaluate potential partners for ENHANZE or auto-injector technologies?

00:31:50 **Answer – Helen I. Torley:** Yeah. So, when partners come to us, I mentioned we've got such a leverageable business model and so much expertise in our team. We actually evaluate everybody

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and we're very happy to work with everybody, Sean, in terms of potentially having our therapy extend the use of their product for more patients. And so it's a terrific thing about the leverage-ability. No challenges there.

00:32:16 **Question – Sean Laaman:** Thank you. A couple of competitive considerations, but how do you plan to maintain ENHANZE's leadership as competitors explore alternative hyaluronidase?

00:32:25 **Answer – Helen I. Torley:** Yeah. We are the pioneer in hyaluronidase is inventing the whole field, if you like. And with that leadership have come many, many years of progress and success. We talked earlier about there being 10 products already approved. With those comes an incredible depth of knowledge and expertise that is valued by our partners in terms of how to get a drug quickly to the clinic and approved advising on regulatory strategy and CMC strategy. With those 10 approvals has come now an amazing 1 million patients treated, that gives us an extensive safety database and it's something that isn't talked about often. But there's always a worry when you combine two biologics together of a safety issue called immunogenicity, it's an unusual, unexpected event where you need to have a lot of exposure to identify whether or not you're having a problem of immunogenicity. Every partner who comes to us wants to understand that immunogenicity risk. And we're in a position with this joint safety database to assuage those concerns. I think the third area is continuity of supply. I was just in the argenx SAM talk and that was one of the top things mentioned by Karl, the CFO. We have 10 years of reliable, high-quality supply and that's not to be ignored either, that combination, Sean, is what's important to our partners, and because we've been in this leadership position, we have the first mover advantage that will be unassailable in terms of people trying to come in and do similar copycat activities.

00:34:01 **Question – Sean Laaman:** Wonderful. Thank you. Next question, it seems like very isometric risk, but can you remind us what the current status of the Merck litigation is, and how it might impact your royalty streams?

00:34:14 **Answer – Helen I. Torley:** Yeah. We – I mentioned we're the pioneer on hyaluronidase, when we were inventing ENHANZE, we also did a lot of experiments, dozens of experiments actually looking at different modified hyaluronidase. And by that ENHANZE is a human truncated hyaluronidase, so identical amino acid structure to the human, our modified hyaluronidase is have got different amino acid sequences from the human. We've patented those modified hyaluronidase. And so the Merck litigation is that we all have sued Merck for infringing our MDASE portfolio. Importantly, MDASE is totally separate from ENHANZE. So think about MDASE's and this Merck litigation has been all upside. There was zero risk, zero risk to it, because ENHANZE was separate. But we believe Merck is infringing. And so we expect to hear about rescheduling of that court case in the next weeks on. And it will take a number of years to play out unless Merck settle before that. But all upside and protecting our IP.

00:35:12 **Question – Sean Laaman:** Wonderful. Just out of time. But is there anything that you'd like to leave the investor base with?

00:35:18 **Answer – Helen I. Torley:** No, I think we've covered it very nicely, Sean. I would just say that we have these 10 amazing products that are going to be resulting in strong durable royalty revenue growth for the company for years to come. And we've got the opportunity to build on top of that with our strong cash flow allowing us to replicate this brilliant ENHANZE model. And so we're very excited to be focused on that today.

00:35:42

Petitioner Merck, Ex. 1101, p. 9
Merck Sharp & Dohme LLC v. Halozyme Inc.
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Wonderful. Thank you for your time today, Helen, and thanks for contributing to the conference. Appreciate it. Thank you.

Thanks. Appreciate being here. Thank you.

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