AUTL Earnings Call Transcript

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Quarter: 3

Operator: Good day. Thank you for standing by.
Amanda Cray: Welcome to Autolus Therapeutics plc Third Quarter 2025 Financial Results Governance Call. At this time, participants are in a listen-only mode. After the speakers' presentation, there will be a question and answer session. To ask a question during the session, you will need to press star 11 on your telephone. You will then hear an automated message by seeing your hand is raised. Please note that today's conference is being recorded. I will now hand the conference over to your first speaker, Amanda Cray, Executive Director of Investor Relations. Please go ahead.
Amanda Cray: Thank you, Olivia. Good morning or good afternoon, everyone. And thank you for joining us on today's call. With me are Chief Executive Officer, Dr. Christian Itin and Chief Financial Officer, Rob Dolski. I'd like to remind you that during today's call, we will make statements related to our business that are forward-looking under federal securities laws and the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. These may include, but are not limited to, statements regarding the status of the ongoing commercial launch of Obe-cel in the U.S., Autolus Therapeutics plc's manufacturing, sales, and marketing plans for Obe-cel, market potential for Obe-cel, the status of clinical trials development, and/or regulatory timelines and market opportunities for our other product candidates. These statements are subject to a variety of risks and uncertainties that could cause actual results to differ materially from expectations and reflect our views only as of today. We assume no obligation to update any such forward-looking statements. For a discussion of the material risks and uncertainties that could affect our actual results, please refer to the risks identified in today's press release and in our SEC filings, both available on the Investors section of our website. On Slide three, you'll see the agenda for today's call. As usual, Christian will provide an overview of our operational highlights, Rob will then discuss the financial results, and Christian will conclude with upcoming milestones and closing remarks. We'll then take questions. With that, I'll turn it over to Christian.
Christian Itin: Thank you very much, Amanda, and let's move to slide number four. Welcome, everybody, and thank you for joining us at the third quarter financial results. We had a very good quarter, and I think we're off to an excellent launch with Obe-cel in the U.S., treating or targeting patients with relapsed refractory ALL. We managed, in the first nine months, to achieve broad market access and coverage and established reliable product delivery. We also believe that there is a significant opportunity to grow the CAR T market in this indication, and we're very pleased with the feedback we're receiving from physicians using the product and the interest expressed in conducting investigator-sponsored trials in frontline settings in ALL as well. We're now at the point where we have achieved a significant amount of stability in our operation and our ability to deliver product in a timely and high-quality manner. And we're now actually focusing on optimizing our operation and really leveraging the investments that we've made in our infrastructure and our systems and have now an opportunity with a lot of data that we collected along the way in these first nine months to optimize our process and with that, drive efficiencies going forward. Importantly, in parallel, we're expanding the opportunity that we believe we have with Obe-cel and are looking to build a pipeline in a product and are working on three current indications. The first one is in pediatric ALL where we're initiating a potentially pivotal study, a phase two study in lupus nephritis, also with an intent to drive towards a label, and an exploratory phase one study in progressive multiple sclerosis. In short, we're focusing on

driving market share in ALL, improving the margins, and expanding beyond ALL. Moving to slide number five. Quick view on the performance that we have to date. In our launch of Obe-cel in the U.S., we have achieved $21.1 million in net sales in the third quarter, and we have deferred revenue of $7.6 million, indicating that there is a good number of products currently sitting at the centers at the end of the third quarter, not yet infused and ready for infusion in the fourth quarter. The nine months ended September 30, we achieved $51 million in sales for the product. When we look at how we're executing on product delivery and patient access, we're tracking very well. We had, at the beginning of the year, told you that we're targeting to authorize 60 centers by the end of this year. We achieved that goal. So we're at 60 centers today. And we will keep adding additional centers to fill out the geographic gaps that we're having across the U.S. and with that, minimize the travel distances for patients to access therapy. The manufacturing success rate is well above 90%, and we have attained patient access for more than 90% of U.S. covered lives. So this gives us a very strong foundation, both from a rollout perspective, but also from a dynamic perspective as we're looking into the fourth quarter and into 2026. Moving to slide six. We believe there's a significant opportunity to increase the penetration and grow the CAR T market share. When we look at the level of CAR T use before our product entered commercialization in 2024, we're seeing about 15% market share for CAR T therapies in this indication. When we look in the treatment centers, the 60 treatment centers that we're active in now, which actually cover the vast majority of the relapsed refractory ALL patients, we believe that the market share within that group of 60 centers at this point is probably around 20%. This gives us an opportunity for substantial growth within the centers that we're already present in and the footprint we already built. This is about relationship building and deepening those relationships to really drive the uptake further and actually drive towards the types of levels of uptake that we've seen a few years ago, BLINCYTO achieve in this particular indication. The importance, I think, of the experience the physicians are making with the product really cannot be overstated. The actual hands-on experience is critical here. And we believe that the way that we're seeing the product perform and also what we're seeing being reported or planned to be reported at ASH from the Rocket Consortium indicates that there's a very positive experience that the physicians are making with the product consistent with the experience that we have gained through our development and, in particular, also within our registration study, the Felix study. Moving to slide number seven. We're going now focusing we had a quick look at the launch. We're now focusing on the key approaches here that we're looking to optimize our operation and really improve the overall margins and efficiency. When we look at slide number eight, first, a quick look at changes that we have made within the leadership team. We have three new key members in the team that joined us over the and during the course of the third quarter. First off, Miranda Neville, who some of you may actually have met in the past, has been actually with the company for about five years. And initially worked on the planning and setup of the nucleus facility. Then actually took over the overall program team for Obe-cel and drove the program through the registrations and getting us the approvals in the U.S., in Europe, and also in the UK. And now actually returns back to product delivery in the role of chief technology officer leading the entire team. Cynthia Pigina has taken over from Brent Rice as the U.S. chief commercial and country manager and has an extensive set of experience in oncology, in immunology, but most importantly for us, in cell and gene therapy. She has extensive experience launching products in this space and we believe is extremely well positioned to actually grow the opportunity for Obe-cel from here forward. And then, Patrick Milveni, who's taken over from Andrew Mercika as the chief accounting officer reporting into Rob Dolski, Patrick joins us from Horizon Pharma where he's been going through the very significant growth that that company went through and also increasing complexity and belief is a has an excellent background to really help us actually go through the next phase of optimization and also of growth for the company. Now I would like to sort of highlight also the three members of our team that actually handed over the responsibilities to Miranda, Cynthia, and Patrick. Dave Brochu, who's been the chief technical officer, handing over to Miranda, has done an excellent job building our product delivery team, building also the nucleus facility, taking it into operation, and launching the product. It was a huge accomplishment to actually go through that entire growth phase. And building that entire part of the operation from the ground up. And there's a huge thanks that goes to Dave for that incredible achievement. Brent Rice, predecessor of Cynthia, has done a fantastic job building a very strong commercial team and the systems required, and actually executed

an excellent launch of the product. And getting us really rolling, now, I think, in a way that is quite remarkable and gives us, I think, a great outlook as we're sort of looking into 2026 now under the leadership of Cynthia. And, also, Andrew Mercyca had built, obviously, a lot of the infrastructure pieces for a corporate side perspective that Patrick's now taken over. And, also, great thanks going to Andrew as well. So with that, I'd like to move to slide number nine. And just a few thoughts, in terms of the ability to really drive efficiencies and cost savings. I think where we are is that have now built a very strong foundation through the strong launch performance, with a highly reliable product supply. That's been the critical piece that we had to actually build and establish this year. And frankly, has been a very significant challenge for most companies launching cell therapy and in particular CAR T products. Having established that, now gives us an ability also with all the learnings that come out of that experience to really streamline the processes. The training wheels can go off, and we can now focus on making sure that we're just simple, that we're as simple as possible, as straightforward as possible in terms of the processes that we run. Take those processes that we decided that are necessary, optimize them, and automate them to the extent we can. And importantly, innovate. And one of the two key areas that we're planning to and we're focusing to innovate on is really on manufacturing where there's a lot of activity going on. On technology and on automation, but also on the biology side. And on market access, to make sure that we can actually increase the geographic footprint for the product and the ability to actually serve a substantially larger group of patients going forward. So with that, I'd like to go to slide number 10. And we're now actually moving forward looking at the opportunities to expand the potential for and realize the potential of Obe-cel in additional sets of indications. With that, heading to slide 11, a quick overview of clinical trials that are ongoing to expand the use of Obe-cel in additional sets of indications. Starting with the pediatric B ALL study, called CATALUS that is ongoing. We are reporting the phase one portion of that trial at ASH. And we also have just received, a few weeks ago, an RMAT, basically, designation for the program as well. We're in the process of starting up the phase two portion of this trial, and we're excited about the opportunity and, obviously, the opportunity to share the initial experience from our phase one. The second study is the Carlyle study, in severe systemic lupus patients. We had initial data presented at ACR, and I'll briefly talk about that in the upcoming slides, and we're planning for an oral presentation at ASH with a slightly expanded dataset. Lupus nephritis is the focus for our first pivotal study. In autoimmune disease. The study is called LUMINA. And we expect to have the first patient in the study before the end of the year. And then finally, our exploratory phase one study in progressive multiple sclerosis called BOBCAT, BOBCAT started in the third quarter, and we had our first patient dosed in October. Now in addition to the internal studies, we're obviously are gonna support the investigator-sponsored trials. Exploring the use of Obe-cel in frontline settings, but also are obviously, will follow the real-world experience that the ROCCAT consortium is collecting for Obe-cel in relapsed refractory adult ALL, and it's truly a reflection of the real-world experience of our customers collected by them and analyzed by them. So with that, we're going to slide number 12. And just a few words on the data that we actually presented at the conference in Chicago, just at the October. We did present the experience that we had with the product at the 50 million fixed dose level that we have evaluated in six patients. These patients are patients with very advanced disease, very high SLED I scores at inclusion, very significant impact on their kidney function. We have at least six months of follow-up with the patients that we reported on, and we have seen that five out of the six patients achieved DORIS remission, We have 50% of three out of six achieved a complete renal remission. And we have no evidence of new disease activity up to forty months of follow-up and the patients do not receive any lupus-directed therapy. Also, obviously, when you have a, you know, a DORIS remission, your the steroid levels that patients may receive are at or below five milligrams per day. The safety profile with the product was very positive. The patients had no ICANS, no high-grade cytokine release syndrome, no DLTs at fifty million cell dose level. PK and biomarkers, we showed a quick B cell depletion after infusion. We saw then obviously that after at the point when the CAR T cells stopped persisting, that the B cells started to recover, and we do see a predominance of naive B cells and reconstitution more of that data, is expected to be shown at ASH. When we look in terms of now the next steps with the study, there are two directions that we're gonna go, that we're sort of exploring further. One, is actually at fifty million cell dose, adolescent patients aged 12 to 17. A lot of for a lot of these patients with early onset of lupus, they have a particularly

challenging course of the disease. And there's a very significant medical need. In fact, when you look at the population, the highest medical need is in the youngest patients. So this will be explored at fifty million cell dose, which is obviously equivalent to, as you may remember, the pediatric level that we would use and just translate it into a fixed dose level. And we're also exploring, one additional dose level, on the adult side to sort of round out the experience. In the SLE patients. The recommended phase two dose is already defined as 50 million cells. Moving to the next slide, slide 13. This is a more detailed look at the safety, for the product. And as you can see, it's a very good safety profile. No ICANS. We only had observed one grade one or grade one CRS, in half of the patients. A short period of neutropenia following lymphodepletion, which was resolved by day twenty two. And no high-grade infections that we have observed in the patients and not unusual for patients that have significant kidney involvement. We have seen patient five patients with transient hypertension, three had pre-hypertension of the five. When we now look on slide 14, this is a view of the I scores and the progression of the SLADE I scores over time looking at each individual patient. And what we're looking at, if you look at the screening, bars, which are on the left-hand side of the respective charts, you can see that every one of these patients had a significant kidney component. This is the blue part of the bar. And then the other colors actually relate in part to increased DNA binding, as well as low complement, which is the black and yellow. And the other colors are linked to other forms of autoimmune manifestation and inflammatory processes, whether this would be mucosal ulcers, rashes, arthritis, alopecia. That we have seen in these patients. So as you can see, these patients have not just actually a renal component, they have a multitude of disease manifestations, And you can see as these patients progress over time, these manifestations actually are very quickly reduced. And we then actually see, with a bit of a lag also in a the majority of the patients, a reduction of the renal signal as well. So all very encouraging. What's important is, again, none of these patients actually had any form of relapse or 15. This is a quick look at the DORIS assessment, and you can see that five out of six patients had a median, achieved a DORIS remission with a median onset of five months. And, again, in terms of the steroid dose, that by month six, all patients had steroid tapered to less than or equal of five milligrams per day. And no other medic no other, lupus medication, of course. Now when we look at the upcoming data presentations on slide six, 16 in oncology, pediatric ALL poster presentation phase one experience from the CATALYST study, adult ALL first, an oral presentation from the Felix trial looking at the impact of the product cell phenotype, so the actual features of the product, and the linkage to the longer-term outcome in these patients. And then second, a poster, which is looking at CAR T cell persistence at month three and the ability to actually predict outcome based on that data, for these patients, the longer-term outcomes. Again, experience from the Felix, from the Felix study. On the autoimmune side, as mentioned, we have an oral presentation for the CARLyle trial. And we just wanna highlight the fact that the ROCCAT consortium has several presentations, one of which looks at the patient characteristics toxicity response after real-world administration of both Obe-cel and brexicel alongside the same time horizon. Centers, which at least to my knowledge is probably the first time we're seeing basically data collection of two CAR Ts in the real-world setting in parallel. With that, we're heading to financial results and, heading over to Rob.

Rob Dolski: Thanks, Chris. And good morning or good afternoon to everyone. It's my pleasure to review our financial results for the 2025, I'll be moving in the slide deck to slide number 18. In the third quarter, product revenue for the three months ended 09/30/2025, was $21.1 million, compared with $20.9 million in the second quarter. Our deferred revenue balance at the end of Q3 was $7.6 million compared to $2.1 million in Q2. As a reminder, the deferred revenue balance represents products delivered to the authorized treatment centers but not yet infused for the purposes of revenue recognition in the P&L.; Moving on to cost of sales in the third quarter. That amount totaled $28.6 million. As we've discussed previously, this amount includes the cost of all commercial product delivered to the authorized treatment centers, including the product delivered but not yet administered to patients. Essentially, the manufacturing costs related to that deferred revenue I just mentioned. Additionally, cost of sales includes any canceled orders in the period, patient access program product, inventory reserves or write-offs, third-party royalties for certain technology licenses, as well as idle capacity. Our expectation is to see cost of sales improvements as volumes increase and as we improve efficiencies in our own manufacturing operations, as Chris spoke about earlier. Moving on, our research

and development expense was $27.9 million for the three months ended September 30, 2025. That's compared to $40.3 million during the same period in 2024. This change was primarily driven by the commercial manufacturing-related employee and infrastructure costs that have shifted from R&D; into our cost of sales and inventory accounting. Our selling and general and administrative expenses increased to $36.3 million for the three months ending September 30, 2025. And that's compared to $27.3 million in the same period 2024. This increase was primarily due to the salaries and other employee-related costs driven by increased headcount supporting our commercialization activities. Our loss from operations for the three months ending September 30, 2025, was $71.6 million, as compared to $67.9 million for the same period in 2024. And finally, net loss was $79.1 million for the three months ending 09/30/2025, reduced from a loss of $82.1 million for the same period in 2024. Our cash, cash equivalents, and marketable securities at 09/30/2025 totaled $36.067 billion as compared to $588 million at the end of December 2024. This decrease was primarily driven by net cash used in operating activities and also impacted by a delayed cash receipt of approximately $2.12 billion in our R&D; tax credit from the UK HMRC. We continue to believe that with our current cash, cash equivalents, and marketable securities, we are well capitalized to drive the launch and commercialization of Obe-cel in relapsed refractory adult ALL and to generate data in the two pivotal trials in lupus nephritis and pediatric ALL as well as the exploratory phase one trial in MS. I'll now hand back to Christian to wrap up with a brief outlook on expected milestones.

Christian Itin: Thanks, Rob. Moving to Slide 20. We expect two, I would say, key data points from our key trials, at ASH related to the pediatric study and the SLE Carlyle study. Also, there's the additional two presentations I already mentioned, coming from the Felix study. We then actually are in the start-up, obviously, of two additional trials, the LUMINA trial in lupus nephritis, our phase two study. And the ALARIC trial in patients with light chain which we're doing in collaboration with Both of those programs expected to have their first patient before year-end. So with that, moving to slide 21, the focus is clearly for us to drive market share in adult ALL, improve margins, and expand beyond ALL. And with that, I think we're ready to open up for questions.

Operator: Thank you. And wait for your name to be announced. To withdraw your question, simply press 11 again. As a reminder, please limit yourself to one question and one follow-up. You may get back into the queue for additional questions if time permits. Please stand by while we compile the Q&A; roster. Now first question coming from the line of Asthika Goonewardene with Joyce. Your line is now open.

Asthika Goonewardene: Hey, guys. Good morning. Thanks for taking my question. I got a simple one. Can you maybe just talk just a little bit about the patient flow that you're getting in here? And the anticipated patient flow going forward. What proportion of these patients do you think are patients who might have been who were in the near term were planned to give Ticartis and or maybe had a treatment decision changed by the physicians to give Obe-cel? Thank you.

Christian Itin: That's it. I'm not quite sure whether we can have whether we have that level of resolution. What we do know is, first of all, that we have a good proportion of patients that, clearly, were not initially considered for CAR T therapy, and this is I think we're seeing part of that. We're seeing expansion already of the prior market penetration in the space. Overall, we see, I think, very consistent access of the product and I think very consistent use across the centers. And we're looking forward to all obviously getting, with the additional centers that are opened, you know, so preparing running through this quarter, but also preparing for 2026. And, I'm very excited with the dynamic we're seeing, and I think, we'll have a nice, I think, reception of the additional data that we're expecting at ASH, including the real-world experience with the program.

Operator: Thank you. And our next question coming from the line of Gil Blum with Needham and Company. Your line is now open.

Gil Blum: Good morning, everyone, and thanks for taking our question. Just maybe a quick one on competitive positioning for Obe-cel. Pediatric patients. Is this a similar concept to what we're seeing in the adult relapsed refractory patients? Meaning differentiating on safety or are you thinking about this? Thank you.

Christian Itin: Yeah, thanks, Gil. Good question. So I think that the first part, I think, is to look at the actual patients that are eligible, pediatric patients that are eligible for CAR T therapy. And one of the

key groups of patients that are actually not eligible for CAR T therapy are high-risk patients. So, the patient population that we're focusing on is certainly, in the high-risk patients as well. What we do obviously know, and you've seen that, from our prior publications going all the way back to the CARPAL study, in 2019, is that we do have, obviously, also in children, very good safety profile and a very good efficacy profile. Think having consistent, reliable access to product is absolutely critical with pediatric patients. And expanding the access to patients or high-risk patients I think is particularly important that's the group that currently has very limited options. So that's kind of the key focus for the program and, you know, is frankly reflected also by, frankly, the physician interest. That, we have seen and received and were behind the decision that we took here also to move into the pediatric setting, understanding that there is a very significant need that they see for a product with the properties that they see for Obe-cel.

Gil Blum: Thank you. Very helpful.

Operator: Thank you. Thanks, Gil. Our next question coming from the line of Salim Syth with Mizuho Group. Your line is now open.

Salim Syth: Great. Congrats on the progress, guys. Christian, Rob, maybe just I'll ask one and then the follow-up as well. I guess the first one, just I'm thinking about 3Q over 2Q performance of Obe-cel. Was there something in particular that drove the more or less flattish, especially since ATC has ticked up quite meaningfully quarter over quarter? Are you starting to see some seasonality in the business with holidays, etcetera, and you know, how does this relate all to 4Q's or pent-up demand there? I know there's deferred revenue. So that's a question one. And then just on the follow-up question on gross margins. Rob, curious how you're handling D and A in the COGS. We learned from Iovance this quarter that they had loaded a bunch of DNA into their COGS. They are now stripping it out. To at least optically improve gross margins. Curious how much of your COGS is DNA or how you're exactly handling that? Thank you.

Christian Itin: Alright. Well, thanks a lot. First off, questions related to sort of the sales numbers. And possible seasonality, in the fourth quarter. So as you remember, as we went through the second quarter, one of the things that we reported on is the fact that CMS had changed from precedence in terms of their reimbursement policy. And that required us to actually change our trade policy, adjust that, and it did lead to a reduction of patients enrolled in the second quarter, which meant that as we went into the third quarter, we had a limited amount of product waiting to be infused and ready to go. And so we had an impact from that CMS decision and sort of the subsequent workup of that. In the second half of the second quarter. But also going through the first half of the third quarter because, obviously, the patients that were not involved, they had not yet been manufactured, And, obviously, that, you know, had contributed to the performance that we were seeing, for the third quarter as well. And we did highlight that also at the Q2 call that this is likely going to be the dynamic we're seeing. What is obviously very encouraging is when you look at the deferred revenue is that, obviously, we have had a very healthy amount of patients that actually got manufactured for and were active that were ready also then for infusion into the fourth quarter. So that's you know, kind of, I think, tells us we're kind of behind that impact you have from CMS, which was sort of bridging, between the second and the third quarter. In terms of seasonality, in the fourth quarter, I think, you know, this is gonna be our first fourth quarter we're gonna be running. And so at this point, I don't think we can easily judge, what the impact what it look like, if there is impact, and what it would look like. We're obviously going now into the Thanksgiving week, in a short in a short while. ASH conference, which also impacts a number of the physicians that we're working with, but also then, obviously, the Christmas break. I think at this point, it's hard to it's hard to actually estimate. And, you know, we'll need to sort of actually go through that and actually gain that experience. I don't think there's something that's easy to sort of actually sort of estimate or adjudicate at this point. With that, I'm handing over to Rob for the growth margin question.

Rob Dolski: Yes. So, Salim, thanks for the question. So currently, with respect to any kind of depreciation amortization, it's kind of very typical accounting treatment. So you absolutely see depreciation from the nucleus, the manufacturing facility. Flowing through cost of sales, There are, you know, kind of noncash stock-based comp. That's also in there, as well as, some commercial milestone amortization that occurs in the cost of sales line. So we haven't broken that out. I think it's certainly as

we look into next year, you know, we are already starting to think about you know, how do we adjust or how do we think about communications for next year. And so might be something that we can think through a little bit more, but right now, it's it's kinda presented at very typical standard way.
Salim Syth: Okay. Thanks so much, guys.
Christian Itin: Thank you.
Operator: Thank you. And our next coming from the line of Yanan Zhu with Wells Fargo Securities. Your line is now open.
Yanan Zhu: Great. Thanks for taking our questions. Was wondering if you could talk about share the CAR T share growth a little more. As you alluded to in your prepared remarks. Where do you think the share growth will come from in the current kind of treatment landscape, in B ALL. And also if you could comment on any frontline consolidation use that you see in the real world. And maybe, as a follow-up, in terms of autoimmune diseases, you give us an updated thinking on the lay of land based on new data from various CAR T players as well as bispecifics players. And how does that affect the positioning of Obe-cel? Going forward. Thank you.
Christian Itin: Okay. Thanks, Yanan. I think these are three questions, so I'll try to tackle those, in one go. So first of all, the question of growth, where the where can growth come from? I think what's important to understand is that when we look at the CAR T penetration at this point in time, in the relapsed refractory adult ALL setting, at the centers that we're already present in, it is at approximately 20%. To put it differently, the majority of the patients at this point are not yet receiving CAR T therapy. And that gives you a significant opportunity for growth in the current centers that we're already active in. And that has to do, obviously, in a change of practice because, obviously, these patients get treated today, typically without a transplant or other, sort therapeutic modalities. And so there is a significant opportunity to keep growing the centers to gain experience, for the physician to get comfortable with the treatment modality, and to grow from there. Into the broader set that's captured in our label and that is currently, at this point, many of these patients receiving other types of treatment. Obviously, what's very helpful here is the fact that the product is well manageable. It has obviously a good safety profile. It's well manageable. And that builds confidence. So the experience that we think actually well, one of the key elements of experience is obviously the safety versus the immediate experience. But the second part is also that these centers have obviously started treating, the early centers starting treating patients in the, you know, first half of this year. They now start to actually get a feel for the longer-term outcome of these patients and efficacy, not just the responses, but also the longer-term outcome. And we also believe that that, visibility for those centers and the physicians of their own patients reaching longer-term outcomes I think, will actually have a reinforcing effect. And so those are the key parameters that we're working on, and it's not just the way that we're thinking about it. It's also when you look at the ROCA data or also then we'll see the actual presentation. You'd start to get a good sense of indeed that that's actually also reflecting very much of what the physicians are seeing and how they're thinking about the product. Those physicians that actually have already gained substantial experience are thinking actually already quite a bit beyond the current setting, and they're considering running, investigator-sponsored trials in the frontline consolidation setting. So that's already happening, which tells you something about what the perception is of these physicians the product actually should go in their view. What we do not see, and I wouldn't expect to see, is actually any form of frontline use for an extended period of time because, obviously, we do not have data in frontline setting nor do we have the label in frontline setting. So it's not something that we expect to see. For the upcoming period ahead of us. And, you know, certainly with more experience and potentially changes in guidelines, that may change over time, but that will take time to develop. And then the last question is related to the competitive landscape in autoimmune disease. I think it was very interesting. To see the data that was presented in the, at the ACR conference. I think encouraging that there's been obviously, there's a good overall I think, shared view around the data that indeed the CAR T irrespective of the nature of the CAR T therapies, do give a positive outcome, a bright positive outcome for patients with autoimmune disease. However, when you look at the data more closely, you do see there's a lot of differences within the datasets. There's differences in terms of the patients and the severity that the patients actually have for their respective disease. And then we see differences in safety. We see flares coming up in independent programs and so on. So it's worthwhile taking a closer look and actually look at that look at

the data and keep following the data as it evolves. But I well, the sense that we have from our own dataset is that we're actually stacking up very well with our data. Both on safety as well as in efficacy, and believe we're very well positioned in the indications that we've chosen to move into. In terms of other modalities beyond CAR T, there's very little data that was actually published. I would expect to see more data emerge during the course of the year. And it'll be interesting to see where some of that data lands. I would assume part of it will certainly be our programs that are looking to position against monoclonal antibodies and try to sort of basically go into that space. As you remember, the way that we're positioning our product is actually after the patients have gone through monoclonal antibody therapy and sort of relapsed, and have recurring disease after that. And so it is a more advanced group of patients that we're looking at, the patient that has actually at this point, no approved treatment options. So it is a it's a different form of severity and level of severity that we're actually developing in, and so we may see different modalities at slightly different places as we see it today with, you know, going starting with steroids going to antimalarials, going to monoclonal antibodies. We see that whole range and then the calciomerin inhibitors we see that whole range, actually evolve and deposition across the severity grade and the development of the disease. We're focusing on the most severe patients where we think we can have a profound impact. That's the initial approach. And then, obviously, once we have data in that setting, we'll certainly consider to broaden out.

Yanan Zhu: Great. Thanks for all the insights.

Christian Itin: Thank you very much.

Operator: Thank you. And our next question coming from the line of James Chen with Deutsche Bank. Your line is now open.

James Chen: Hi. This is Sam on for James. I'm just wondering if you can provide more color on the data you're expecting at ASH?

Christian Itin: Yeah. Happy to do that. Hi, Sam. Thanks for joining. So I did mention on the pediatric ALL study, that is obviously the phase one experience. So we have, you know, around 20 patients' worth of data in that dataset that we're gonna be presenting, in a poster. Obviously, it has longitudinal data, response data, safety data. So I think it'll give us a good view, I think it'll be, I think, very clear by we decided to actually move forward into, into the second stage of that study, the phase two stage of that study. With regards to the Carlyle study, the Carlyle study, obviously, we had, the data presented and a poster of ACR that I just referenced earlier in the prepared remarks. We're gonna expand on that data, certainly look at additional pharmacodynamic recovery data, etcetera, to sort of actually round out the picture and, I think, tell frankly, through one, the impact on the disease, but then also the ability of the immune system to reset without, obviously, the disease to recur. So that's gonna be a key part of the focus of that presentation. And then when we're looking at the product profile, versus, longer-term outcome. Obviously, an analysis we've done where we look at a range of product parameters to see which one of these product parameters actually are tracking with long-term outcome, and I think that's gonna be an interesting, oral presentation because it obviously has substantial dataset behind it. And with that, I think, you know, meaningful meaningful, I think, learning things from that, from that analysis. And then, the final part is, obviously, the when you actually induce a response in the, in the ALL patients, you obviously would like to know whether it would or would like to have early information or indication about the likelihood that the patient will remain in remission going forward. And so the teams and the physicians have been looking at various parameters to see what might actually track, and one of the areas that they thought was interesting is to actually look at the persistence of the product at three months and act as sort of an indicator. And so we'll need to see obviously, we'll there's more analysis there is being conducted, but that's gonna be a part of the focus of a particular poster presentation. So those, think, are the key parts of the presentation. And then, as I pointed out, please go have a look, at the presentations from the Rocket Consortium I think very insightful, and I think, give you a good sense for what the actual reception is of the product and why it resonates the way it does.

James Chen: Thanks very much.

Operator: Thank you. And our next question coming from the line of Matt Phipps with William Blair. Your line is now open.

Operator: Matt, we can't hear you. Please check your mute button. Alright. I will go to the next person. Can I please requeue? If you can? And our next question coming from the line of Clara Dunn with

Jefferies. Your line is now open.
Clara Dunn: Hi. Good morning. Thanks for taking our question. So one for me. So you mentioned the potential pivotal studies in pediatric ALL. So just wondering whether you've had any regulatory dialogue or what kind of interactions have you had with the FDA in terms of this pivotal trial, and would be the requirement for the trial to be pivotal? Thank you.
Christian Itin: Yeah. Thanks a lot, Clara, for joining. Much appreciated. Yes. Of course, we had we reviewed the Phase I data with the agency, and reviewed with them the trial design, which is a trial design that we have developed with COG, the Children's Oncology Group, the leading oncology group in the U.S. And there's been agreement that, you know, this first of all, that the medical need in the high-risk patients, obviously, is significant. And that it would be it would be beneficial to actually have a product that actually could include these patients in therapy. Provided a therapeutic option. So very clear conversation around the patient population, the type of data that we need to have, as well as the size of the study. So very consistent, and it was only after we had those conversations and we had clarity on the path forward that we actually communicated, that indeed this what we're gonna do, which I think is what we did for the first time at the Q2 call.
Clara Dunn: Okay. Thank you.
Operator: Thank you. Next in queue is Matt Phipps from William Blair. Your line is now open.
Matt Phipps: Hi. Can you hear me now?
Christian Itin: Yes. We can.
Matt Phipps: Great. Sorry for the technical issues. This is Madeline on for Matt. Thanks for taking the question. For the pediatric opportunity, do you have any rough timelines at this point for completing the pivotal cohort? And then related to that, what do you think is the sort of the total market opportunity across both adult and pediatric ALL patients? Thank you.
Christian Itin: Thanks, Madeline, for joining. So the, with regards to the pediatric opportunity, we do believe that the, when you look at the current sort of medical needs segment, it's about a thousand patients all in. Between Europe and U.S. So it's about 500 in the U.S. And, there is a, you know, a good proportion of these patients are in the high-risk category and are currently not being treated. Or not being not actually having direct access to CAR T therapy. So we'd expect that we'd be able to sort of capture and support that part as well as having an opportunity to sort of actually broaden out, the, the use of the product more broadly across the population. I think at this point, I think it's not quite straightforward to give you a number. What we're seeing in general is think there's an opportunity for a few 100 patients that could be actually reached. Through that type of a label. In terms of the study itself, we're starting up the phase two portion of the study. We have certainly, the phase one seen a good, rate of enrollment, and we hope that that will continue, and we expect that that is something we can actually build on in the phase two, so that you know, we should actually be in follow-up period or get into the follow-up period in 2027 and know, hopefully have data maybe at the '27 or early twenty eight.
Matt Phipps: Thank you.
Operator: Thank you. Our next question coming from the line of Shyam Kotadia with Goldman Sachs. Your line is now open.
Shyam Kotadia: Hi there. Shyam here from Goldman Sachs on behalf of Roger. So I'm just had a, a question on Obe-cel dynamics for for the remainder of '25. So you mentioned already the CMS coding impacts that impacted 03/2025. So I just wanted to get a bit more color. Were you expecting revenues to be flat quarter on quarter? Or was this above your expectations? And therefore, given that the CMS lag was expected to be resolved in 04/2025, how should we think about Obe-cel sales 4Q? Should we still expect to see some upside to 3Q? Or Would it likely be broadly flat? So that's the first one. And then a follow on, going forward, you've mentioned that you're entering a new phase of growth. So how should we think about capital trajectory for 2026? Thank you.
Christian Itin: Thanks a lot for joining, and thanks for the question. So in terms of the Q3, dynamic, we did highlight already at the Q2 call that we expect it to have, an impact in terms of the recovery from the CMS event and actually going through that. And we did guide to I think relatively flat trajectory at that point in time because we did know that there clearly was a lag in patients that were actually coming into the third quarter, which obviously will have, I was clear that would have an impact on the overall dynamic in the third quarter? We saw that actually in the second half of the quarter actually being fully

reversed and actually the second half of the quarter actually running at the expected clip. For Q4, I don't think we're going to give guidance on Q3 four. The basic reason, as I mentioned before, is that the the first time we're going through the end of the year stretch. With, you know, certainly, you know, Thanksgiving week, which leads to a slowdown typically at the clinics. Ash tends to have an impact, then, the holiday season. So it's something that I think we just need to experience. We don't think that we have a good a good way to handicap that at this point. And give a good sense around that, what what to expect at this point. We're still in the first year of launch. There's a steep learning curve. And I think the fourth quarter certainly will be, will be important to sort of understand the dynamic we're seeing there in the market, which is too early to call.

Shyam Kotadia: Thank you.

Operator: Thank you. Our next question coming from the line of Simon Baker with West Charles and Company Redburn. Your line is now open.

Simon Baker: Thank you for taking my question. One related two-parter, if I may, please. Just going back to the question of revenues and deferred revenues. Well, you said it was the deferred revenue balance was about $7.6 million. Could you just give us any idea as to how typical that is, if there are any if any factors in there. I'm just trying to get an idea of is this simply the effectively the timing of a of the back end of the quarter just from when you book it, which gets into the next, or whether there are any other factors within that. Just in really from a modeling perspective. And then related to that, clearly, this stage, the cost of cruise line is understandably noisy. But I just wonder if you could give us an idea of the of the underlying sequential trends here. Are you is it too early to be seeing an underlying improvement in gross margin? And over what time period do you expect to see an improvement in the gross margin?

Christian Itin: Yes. Very good question, Simon. I'll start and then I will hand hand over to Rob to sort of add to that. So first of all, with regards to revenue and deferred revenue, obviously one of the, I think, characteristics of this type of a therapy is that, you obviously have quite a time period between the inclusion of a patient and apheresis of a patient and the actual dosing. And what that does is that as you get towards the end of the quarter, you obviously continue to actually include patients. You manufacture for those patients. The products actually get released and then get shipped to the centers. Typically, when the product is at the centers, there's still you know, scheduling to be done to get the patient in. You may have situations where the patient may have picked up an infection. If that's the case, then the patient first needs to sort of get rid of the infection before you could actually, start the lymphodepletion and then the treatment. So there is a gap. There is a lag. Between, and depending on the condition of the patient, you may have a set of products that actually are shipped but not yet dosed. And so, these sit basically at the center and they're in the process of scheduling the patient or managing the patient through the crisis the patient may have experienced before the patient actually can receive the product. And it's only when the patient actually gets the product infused and in fact, know, I would with the first and then the second infusion, that in fact the full payment actually becomes true, and the revenue will be recognized in our numbers. So that's why there is a lag there. And while you have a buildup towards the end of the quarter, you have a good proportion of product that is either still, you know, finishing manufacturing or has already finished manufacturing, has been shipped, and it's that portion of the ones that are finished and shipped and received at the centers that go into the deferred revenue bucket. So that's dynamic. And I think that's the dynamic we're just going to see and it's sort of a reflection of sort of the continuous flow of activity that we see you know, quarter into from one quarter into the next quarter. The COGS, to your point, obviously, are noisy, and that's true. And, obviously, one of the key elements, particularly as you start as you launch, is that you launch, obviously, initially have a number of patients going through your manufacturing setup that is not, obviously, anywhere close to the setup, that you actually designed for the larger opportunities. In other words, there is a significant portion of the infrastructure that is not actually utilized for commercial supply. Particularly early on in the launch and into you know, and early on is still, you know, certainly within the first year of the launch. And as you obviously then keep on growing the opportunity and you run more product, through the facility, that's actually where you're you're sort of your overhead cost, your overall cost for the facility obviously gets divided by a larger number. You see a decrease over time. So that's one dynamic. So volume is one of the key drivers that actually will reduce sort of the

actual cost of goods. Line overall and improves the ratio between revenue and cost of goods. The other part is actually the improvements in the actual operations itself. So in other words, in very simplistic terms, you know, there work that goes in, which are work hours, and there is materials that go in. And then there is some operating cost in terms of running the clean rooms. But time and the cost of materials are key elements. Cost of materials obviously is one of the drivers that you actually drive down and you get more efficient. But one of the biggest elements that you actually look at and you look to improve on is the time you spent per product released. And that has a lot to do with experience with optimizing your operating model, and actually really take all the experience we've now gained and take that and actually create, develop a more efficient operating model over time. And so that's a significant improvement you're gonna run through, and we are going to run through. And that gives us an ability to actually reduce on a per batch basis the actual cost that is driven by actually producing this particular batch in terms of the work and the materials that go in. So those are key parameters that impact. So we expect to actually see, as we're increasing, sales during the course of next year, we actually expect that we also see a decrease in the ratio of COGS that we have or cost of sales versus what we're seeing in the first year of launch. So that's the dynamic we're looking at. And I'm handing over to Rob to sort of add on, maybe some of the more technical accounting points.

Rob Dolski: Yeah. Thanks, Christian, and thanks, Simon. The other thing I might add, think Christian covered it very well. But I think you made the point. These are three quarters, three data points, and I would say that there's still a little bit of noise, and we've gotta get to a more steady pattern, so to speak. So to the CMS issue into the Q2 Q3 quarters that Christian talked about, the CMS really impacted the end of the Q2, early Q3. You actually saw that play through from a treatment perspective, even in some of the deferred revenue balance there. Right? So that's a difference between the finish that we have in the Q3. With Q3, that deferred revenue, we've recognized a much larger quantity. In fact, really quarter to quarter, the main difference in our gross margin was driven by the amount of deferred revenue. That we had to recognize the cost for. But that's also gonna, you know, kinda give us a nice load, so to speak, with sales and gross margin going in to Q4. We still have to play out the rest of the year and you know, again, Krishna mentioned going through the first time with the holidays in Ash So I just think that we need we need some more time and data point here to really see more of a smoothing effect in more of these quarter over quarter dynamics.

Simon Baker: Right. Thanks so much.

Christian Itin: Thanks a lot, Simon.

Operator: Thank you. We'll now turn the call back over to Dr. Christian Itin for any closing remarks.

Christian Itin: Well, thank you very much for joining us today. We're really looking forward to seeing you, either at ASH through one or the other of the many data updates, or then, at the latest early in the year in San Francisco. I hope you're doing well, and looking forward to connecting with you in one of those venues.

Operator: This concludes today's conference call. Thank you for your participation. You may now disconnect.