

# ABEO Earnings Call Transcript

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**Quarter: 3**

Operator: Good morning, everyone. And welcome to the Abeona Therapeutics third quarter 2025 conference call. At this time, all participants are in a listen-only mode. The floor will be opened for questions following the presentation. If anyone should require operator assistance during this conference, please press 0 on your phone keypad. Please note this conference is being recorded. I will now turn the conference over to your host, Gregory Gin, VP of Investor Relations and Corporate Communications at Abeona Therapeutics. Greg, the floor is yours. Thank you, Jenny.

Gregory Gin: Good morning, and thank you for joining us on our third quarter 2025 results conference call. During this call, we will refer to the press release issued this morning, announcing the financial results, which is available on our corporate website at [www.abeonatherapeutics.com](http://www.abeonatherapeutics.com). We anticipate making projections and forward-looking statements during today's call, which are made pursuant to the Safe Harbor provisions of the federal securities laws. Forward-looking statements are based on current expectations and are subject to change. Actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those outlined in our Form 10-Ks and periodic reports filed with the Securities and Exchange Commission. These documents are available on our website at [www.abeonatherapeutics.com](http://www.abeonatherapeutics.com). Now joining me today with prepared remarks are Dr. Vishwas Seshadri, Chief Executive Officer; Dr. Brian Kevany, Chief Technical Officer; Dr. Madhav Vasanthavada, Chief Commercial Officer; and Joseph Walter Vazzano, Chief Financial Officer. After the prepared remarks, we will conduct a Q&A session. With that, I will now turn the call over to Vishwas Seshadri to lead us off.

Vishwas Seshadri: Thank you, Greg. The 2025 was marked by significant operational progress as we continue to scale the ZivaSkin commercial launch to meet growing patient demand. While our first patient treated has shifted to 2025 due to optimization of a product release assay, our conviction in our ability to achieve our 2026 launch goals remains steadfast based on trends in patient demand, treatment center expansion, and market access. We are seeing growing patient demand for ZivaSkin, the first and only autologous cell-based gene therapy for the treatment of adult and pediatric patients with recessive dystrophic EB or RDEB. We also continue to strategically expand our qualified treatment center or QTC network. The activation of a highly recognized EB center, Children's Hospital Colorado, brings our total activated centers to three. Furthermore, we've established a strong foundation with broad market access, which is essential for sustained commercial success. In summary, despite the temporary delay in the first patient treatment, we are well-positioned for launch success in 2026. Before we dive deeper into our commercial launch progress and momentum, I now hand the call to our Chief Technical and Scientific Officer, Dr. Brian Kevany, to briefly highlight the release assay optimization.

Brian Kevany: Thanks, Vish. And hello, everyone. As we continue the ZivaSkin launch, we remain dedicated to maintaining the highest standards of quality in the manufacturing of personalized drug products for each patient. During the third quarter, a full batch of drug product was manufactured following a patient biopsy but could not be released due to a performance issue in one of our release assays. Assay retesting using established gold standard USP sterility methods confirmed the sterility of the product, but unfortunately, those test results were not available until after the lot's expiration date, so they could not be used to release the lot. As a proactive measure to ensure product quality, we temporarily paused collecting additional patient biopsies so that we could conduct a thorough

investigation, run additional tests, and further optimize the new release assay. Following successful completion of optimization, validation, and the necessary regulatory submissions, we resumed biopsy collection in November 2025. We now anticipate patient treatment starting in 2025. I will now hand the call over to Chief Commercial Officer, Madhav Vasanthavada, to discuss our commercial launch progress.

Madhav Vasanthavada: Thanks, Brian. Hello, everyone. Our launch momentum continues to accelerate on multiple fronts. Patient demand continues to build, our relationships and trust with qualified treatment centers have grown stronger, and patient access to ZivaSkin across all payer types has continued to broaden. On our second quarter call, we mentioned more than a dozen initial patients were identified at the first two qualified treatment centers. Of these patients, we have already received ZivaSkin product order forms, or ZPOFs, for 12 patients. A ZPOF is an informed consent generated by the QTC physician after the patient has been consulted, a treatment decision has been made, and the patient and their families have decided to move forward. Insurance prior authorizations have been obtained for several patients already, and we expect these patients to be biopsied over the coming months as and when full financial clearance is in place. We are happy to also report that demand for ZivaSkin continues to grow. The number of identified eligible patients at our QTCs who are motivated to initiate the treatment process has now more than doubled to approximately 30 patients, up from the 12 plus mentioned on the second quarter call. At the same time, the broader pool of potential ZivaSkin candidates at non-QTC referral sites continues to increase as our field force and promotional activities generate more ZivaSkin awareness in the marketplace, and many of these referral sites have initiated patient referrals to the qualified treatment centers, which is exactly what we were hoping for. Regarding QTC activation, we are delighted that Children's Hospital Colorado is our newest ZivaSkin qualified treatment center. Children's Hospital Colorado has an expert multidisciplinary team with years of EB experience, and their commitment to onboarding ZivaSkin speaks to their belief in the benefits this therapy can bring to RDEB patients. Activation of Children's Colorado brings the number of ZivaSkin qualified treatment centers to three, alongside Lurie Children's Hospital of Chicago and Lucile Packard Children's Hospital of Stanford. We are also in active discussions with several EB centers across the US to strategically expand the geographic footprint of ZivaSkin even further. These centers are advancing through the various stages of site onboarding, and we'll continue to announce new centers as they are activated. Finally, regarding market access, we have seen a steady cadence of positive coverage decisions from both national and regional commercial health plans in the six months since approval. Importantly, policies covering ZivaSkin have been published by all major commercial payers, including UnitedHealthcare, Cigna, Aetna, Anthem, and the majority of Blue Cross Blue Shield plans, all collectively covering more than 80% of all commercially insured lives. Now on the government payer front, for Medicaid, we are happy to report that ZivaSkin now has received baseline coverage across all 51 state Medicaid programs in Puerto Rico, effective 10/01/2025. Moreover, multiple state Medicaid programs have already published policies covering ZivaSkin, signaling that payers recognize the value ZivaSkin brings to their patients and the healthcare system. As another major highlight, CMS has established a permanent product J code for ZivaSkin that will go into effect on 01/01/2026. We believe that this product code will simplify claims and reimbursement processing between our QTCs and all payer types and will further support hospital adoption for ZivaSkin. In summary, we are very encouraged by the growing patient demand, patients actively progressing toward treatment, continued growth of the QTC site network, and a favorable market access landscape for ZivaSkin. And we are looking forward to a strong start in 2026. With that, I'll now pass the call over to our Chief Financial Officer, Joseph Walter Vazzano, to discuss our financial results.

Joseph Walter Vazzano: Thanks, Madhav. I would like to remind everyone you could find additional details on our financial results for the three and nine months ended 09/30/2025, in our most recent Form 10-Q. Starting with our financial resources, we had cash, cash equivalents, restricted cash, and short-term investments totaling \$207.5 million as of 09/30/2025. This robust cash position provides us with significant financial flexibility as we execute on the ZivaSkin commercial launch. The current cash position, without accounting for anticipated revenue from ZivaSkin, is expected to be sufficient to fund current and planned operations for over two years. Turning to the statements of operations, research and development, or R&D; spending, for the three months ended 09/30/2025 was \$4.2 million

compared to \$8.9 million for the same period of 2024. This reduction was primarily due to cost capitalized into inventory and the reclassification of selected costs, such as engineering runs and other production costs, to selling, general, and administrative expense, or SG&A; following ZivaSkin's FDA approval. SG&A; expenses were \$19.3 million for the three months ended 09/30/2025 compared to \$6.4 million for the same period of 2024. This increase reflects the reclassification of R&D; expenses as noted, along with increased headcount and professional costs associated with the commercial launch of ZivaSkin. Our net loss was \$5.2 million for 2025, or negative 10¢ per basic and diluted common share, compared to a net loss of \$30.3 million in 2024, or negative \$0.603 per basic and diluted common share. In terms of upcoming investor relations activities, we plan to participate in the Stifel 2025 healthcare conference tomorrow. With that, I'll pass the call back to Vish for additional remarks before opening the call for Q&A.;

Vishwas Seshadri: Thank you, Joe. Turning briefly to our pipeline, we have two key updates. First, our gene therapy program for X-linked retinoschisis, ABO503, has been selected to participate in the FDA Rare Disease Endpoint Advancement (RDEA) pilot program. This selection will provide opportunities for enhanced communication with the FDA to accelerate the development and validation of product-specific novel efficacy endpoints for the program. Second, we have strengthened our management team with the appointment of Dr. James A. Gao as the Senior Vice President, Head of Clinical Development and Medical Affairs. Dr. Gao brings over twenty years of industry experience and is a recognized expert in gene therapy, especially in ophthalmology, which will be valuable as we advance our pipeline. In closing, while the first patient treatment has shifted to 2025, we are encouraged by the doubling of identified patients from 12 product order forms, the expansion to a third QTC, and the broad and rapid payer coverage across commercial and government plans. This progress underscores the high value proposition of ZivaSkin for the RDEB community. With that, I will now open the call for Q&A.; Jenny, please open the Q&A; session.

Operator: Thank you very much. At this time, we will be conducting our question and answer session. If you would like to ask a question, please press star 1 on your phone keypad. A confirmation tone will indicate that your line is in the queue. You may press star 2 if you would like to remove your question from the queue. For anyone using speaker equipment, it might be necessary to pick up your handset before you press the key. Please wait a moment whilst we poll for questions.

Vishwas Seshadri: Thank you.

Operator: Our first question is coming from Maury Raycroft of Jefferies. Maury, your line is live.

Amin: Hi. Thank you for taking our questions. This is Amin on for Maury. A couple of questions from us. You mentioned receiving ZivaSkin product order forms for 12 patients. What's the expected timeline for these patients to receive treatment at this point? And I have a follow-up.

Vishwas Seshadri: Yeah. Thank you for that question, Amin. I'll request Madhav to take that one.

Madhav Vasanthavada: Hey. Thanks, Amin, for the question. So these patients, as I mentioned, the product order form is the first step. And after that, there are insurance discussions that have been ongoing between the qualified centers and the payers. For many of these patients already, we have a prior authorization. Some of them have already been scheduled for biopsy in November as well as in 2026. So we expect that if all paperwork goes through the administrative process in the coming months, we will treat these patients.

Vishwas Seshadri: Okay. Helpful.

Amin: Thanks. So thanks, Madhav. The only point I want to add there, Amin, is that as Madhav mentioned, these 12 patients are at various points in their journey. To generalize how much time it'll take for these 12 patients to come all the way through the funnel into treatment, it's a hard thing to do at this point in time. But what we believe is as we start to treat patients, this is going to normalize. So metrics in terms of time taken from a ZPOF to various time points in the journey, we'll have a better idea having been through that process for a bunch of patients, which we should have in the first quarter of 2026.

Amin: Okay. Thanks. And of the 12 ZivaSkin product order forms, how many are from patients who were referred to QTCs versus patients already being treated in these sites? And what's your timeline estimate for achieving profitability at this point? Is that bumped by a quarter based on the current delay?

Madhav Vasanthavada: Yeah. On the topic of the first question, the vast majority are at the QTCs, Amin, and there are patient referrals that already have been initiated. And those patients will go through the consult process as well. But for the 12 patients that we've talked about, the vast majority are homegrown, you know, the patients at the QTCs. Yeah. And also, Amin, to your second part question, which is how does it impact the time to profitability? We don't see a significant impact. I think in the past, we have guided that in the first half of 2026, we should be a profitable business, and that continues to be our projection. So we do not see the first patient treatment shifting to quarter four significantly impacting that time frame. Thanks.

Operator: Okay. Thank you very much. Our next question is coming from Kristen Kluska of Cantor Fitzgerald. Kristen, your line is live.

Rick Miller: Hi. This is Rick on for Kristen. Thanks for taking our questions. To start out, are you still planning on shutting the plant down in December for the routine maintenance? And if so, what's the timeline around reopening there?

Vishwas Seshadri: Yeah. No. Thanks for that question, and it's a great question. Yes. We do have a shutdown which starts approximately, you know, the second week or mid-December and takes about a month. Brian, you can add some color if I missed the timing or anything else to add there?

Brian Kevany: No. That's accurate. Yeah. And this is really a mandated FDA requirement to have this type of shutdown at the end of the year for general maintenance and recalibration of equipment. But, yeah, mid-December to early January is the current schedule for the shutdown.

Rick Miller: Okay. And on the temporary pause while you were working on the optimization, were there any biopsies that were collected but not yet sent to manufacturing before the temporary pause and reoptimization? And if so, will you be able to just sort of move into manufacturing with these, or will you need to re-biopsy any patients?

Vishwas Seshadri: Yeah. The answer is no. We paused on collecting any further biopsies when this happened. Not from any regulatory action or anything, but our own abundance of caution to avoid patients, you know, giving their biopsies and especially until we solved this problem, we were not we didn't know what exactly the problem was, how long it'll take for us to resolve it. So we didn't take any chances there.

Rick Miller: Okay. Thank you.

Operator: Thank you very much. Our next question is coming from Stephen Willey of Stifel. Stephen, your line is live.

Josh: Hey, good morning. Thanks for taking our question. This is Josh on for Steve. Is there maybe any color you can share related to the current lead time between receiving these ZivaSkin product order forms following initial patient identification efforts, and do you anticipate this to maybe come down over time as patient demand continues to increase?

Madhav Vasanthavada: Yeah. I can take that, Josh. So, yes, we do expect this will reduce over a period of time. Like I mentioned earlier, some of these patients, even though the ZPOFs, we received a couple of months ago, they're already scheduled for biopsy collection starting next year. And we have resumed biopsies already. So as more and more patients come through and the processes at the qualified centers, and the payer policies with payer policies coming through nicely, we expect this overall time to reduce. At this point, when we mentioned on our second quarter call, it's about a three-month process is what it takes, you know, from the time that you have a patient identified, consulted, prior authorization, you know, from a clinical standpoint and any agreements that take place. And as more and more patients go through the queue, we should expect that process to come down, and we'll guide more in terms of what we are seeing over a period of the next quarter or so.

Vishwas Seshadri: Yeah. And the only other thing I would add there, Josh, is that the very first few patients at the time when their prior authorization and letters of agreements were going through, the policies were not published by some of these payers. They have come in more recently. So that's the basis why we believe that for the future patients coming through the funnel, that time should reduce because the policy is already in place and we don't need exceptions for the patients.

Madhav Vasanthavada: Right. I'll just say that this is nothing new about ZivaSkin. I mean, right, I mean, any cell and gene therapy that has launched goes through these kinds of processes. And the centers

that we are working with are super experienced about working with cell and gene therapies. So we got a good team in place. We've got a good market access team on our side in place. And the receptivity that we're getting from insurance companies and the willingness for the payers to work with centers to expedite this process is there. So as more and more patients go through for a given payer, that time for agreements will also we expect that to come down.

Josh: Okay. Appreciate the color. Thank you.

Operator: Thank you very much. Our next question is coming from Ram Selvaraju of HC Wainwright. Ram, your line is live.

Ram Selvaraju: Thanks so much for taking my question. Firstly, I was wondering if you could give us some additional granularity on what you the attrition rate, if any, to be among those patients for whom ZPOFs have been received. You know, before you go through the entire biopsy, cell graft engineer, and subsequently administration of the graft. You know, just give us a sense of, you know, of those initial 12 patients. Just taking that number as an example. How many do you anticipate are going to go successfully through the entire treatment process?

Madhav Vasanthavada: I would say it's a pretty high level of conversion, Ram. These patients, because these are the patients that the physicians obviously, you know, these are motivated patients, they want to move forward, which is why we have the ZPOF already come through. And insurance clearances and those processes are work we are working through those. So we expect now with this release assay optimization also behind us, we expect as biopsies come through to be able to treat these patients. Of course, these are engineered cell therapies, right, that we are talking about. But our success rate has been, from a clinical trials perspective, has been pretty high. So for those reasons, we expect that these patients will have a pretty high level of conversion rate now that we have these ZPOFs already in place for these patients. And the fact that when we mentioned a little over a dozen patients identified at these 12 ZPOFs already shows that none of the patients that were identified, almost none of the patients that were identified early on actually said that, no, I'm not interested in getting ZPOF. I think that to me is a pretty, pretty strong metric. And as more patients get into this funnel, and as patients get treated, you can already see the word-of-mouth and the data percolating, which only motivates additional patients to come through the process.

Vishwas Seshadri: And I just wanted to add one more color to that, Ram. If you look at the number of patients that have been identified just organically within the QTC that Madhav mentioned has more than doubled to about 30 patients or so. We're not even adding the referred patients. So if you add that, the last call we had mentioned close to 50. That number has gone way north, and we are not even talking about that right now. And in some ways, from that big pool of identified patients, the QTCs are acting as kind of gatekeepers and giving us the ZPOFs because they also want to regulate how much they can treat and, you know, the first 12 patients are earmarked as the highest priority. And so we do not anticipate attrition because it's for them it's not easy to get the flood either. So this is going to be just a matter of conversion.

Ram Selvaraju: Okay. That's very helpful. And then with respect to the prior authorization process or prior authorization protocol that you are seeing with respect to payers. Can you maybe describe for us what that looks like? And I'm in particular in situations involving RDEB patients with large chronic open wounds that have persisted for an extended period of time. What is the prior authorization requirement, if any, specifically in those types of patients that's being mandated by payers at this time? Thank you.

Madhav Vasanthavada: Yeah. So the prior authorization process, Ram, essentially it's I can break it into two steps. One is a clinical prior authorization, and then the other is the financial, you know, discussion that takes place after a patient is clinically given a green signal from the insurance company. The prior authorization most payers, especially for these types of therapies, tend to follow the inclusion exclusion criteria of the clinical trials. And then there are some payers who also cover it, you know, to the label. Right? So in terms of the requirements, it's often pretty straightforward. Make sure that the patient has recessive dystrophic EB, which means the genetic testing or confirmation of the mutation of the collagen seven a one gene that they have recessive dystrophic EB. In our clinical trial, there were certain wound size requirements. We are seeing most of the insurance companies now, for example, UnitedHealthcare, covering the label, meaning no real requirement on the size of the wound for these patients. Some payers have age six years and above, but our FDA label is broader, right from birth. So

certain payers have those policies in place. But when you do have a payer that, let's say, it's a five-year-old patient that requires a treatment, we are seeing that with the letter of medical necessity, you're able to overturn that. Because you're able to explain as to what the impact ZivaSkin is bringing, and we are successfully overturning those initial PA denials that typically happen. So that's the process that takes place. And once you have that clearance, then the next step is the financial agreement between the payer and the qualified center.

Ram Selvaraju: And no meaningful step edits? Correct?

Madhav Vasanthavada: No. We have not seen any step edits. Thank you.

Operator: Thank you very much. Just a reminder there, if you have any remaining questions, you can still join the queue by pressing star 1 on your keypad now. Our next question is coming from Jeffrey Michael Jones of Oppenheimer. Jeff, your line is live.

Jeffrey Michael Jones: Good morning, guys, and thanks for taking the questions. Can you comment on, of the 12 patients in process, how many have had their biopsies done today? And have any of those doses passed the revised sterility release criteria? Or with the new assay rather?

Vishwas Seshadri: Which you want me to take that?

Jeffrey Michael Jones: Sure. Yeah. I think as of this point, we announced that we have resumed biopsy. Right? We have biopsied a patient. But we're not guiding how many are going to be biopsied within the time window for this year versus how many will spill over because that's an ongoing process that hasn't settled down. So it's too early. We're gonna be talking about that in our next quarterly call.

Jeffrey Michael Jones: Okay. Can you remind us then in terms of revenue recognition from the time that you dose these patients, how long until revenue recognition?

Vishwas Seshadri: The revenue is recognized when the product is applied on the patient from an accounting standpoint. Obviously, the cash flow has these two accounts payable that's involved. That's different for different, you know, it's governed more by trade policies with each site. But for reporting purposes, the revenue is recognized the day of administration.

Jeffrey Michael Jones: Great. Appreciate it, guys. Thank you.

Operator: Thank you very much. Our next question is coming from James Francis Molloy of Alliance Global Partners. James, your line is live.

Matt: Hi, guys. Thank you for taking our questions. Matt on for Jim today. Just one from us. Of the 30 patients that are slated to receive ZivaSkin, how many are on background VYJUVEC currently or have failed VYJUVEC?

Madhav Vasanthavada: We don't have visibility into that, Matt. I don't we would never have visibility into that, but we expect the vast majority would be on VYJUVEC and or on FILZOVEST. Because that's what we hear from the patient community. That these patients require, you know, there's an unmet need for multiple, you know, treatment options. We hear that from patients as well as from physicians across the board. So we would expect those patients and from an access standpoint, that only helps us, right, because these patients have their copies of genetic records and other letters and background already in place. So that physicians can provide that information to the payer because they have received prior other gene therapies. But we don't know the actual, you know, exact count.

Matt: Got it. Thank you guys for taking our question.

Operator: Thank you very much. And our next question is coming from David Bautz of Zacks Small Cap Research. David, your line is live.

David Bautz: Hey. Good morning, everyone. Just one for me this morning. So UMass was a center in the phase three study and, of course, noticed that they are not signed up as a QTC yet. I'm curious if there's any hold up there or why they are not listed as a QTC or if they haven't signed on yet.

Vishwas Seshadri: Yeah. I can take that question. Good morning, David. Different sites have different reasons. I don't want to call out specific reasons for specific sites. Sometimes sites would intend to onboard and activate with us, but there could be financial constraints on how the site is faring. Sometimes, you know, the types of trade policies that we're willing to accept may not be fitting within their framework. Right? So there's multiple different reasons why a given site may not be onboarded yet with us as a ZivaSkin site, but we're not going to be discussing specific sites' hurdles on why they haven't been activated despite the fact that they've got experience with handling ZivaSkin. I hope that gives some color to the types of reasons.

David Bautz: Yeah. Actually, that's great. I appreciate it.

Operator: Thank you very much. Well, we appear to have reached the end of our question and answer session. So I will now like to turn the call back over to Vish for closing comments.

Vishwas Seshadri: Thank you very much, Jenny, and I really appreciate everyone joining us today for the call. And we look forward to talking to you soon. Bye-bye.

Operator: Thank you very much. This does conclude today's call. You may disconnect your phone lines at this time, and have a wonderful day. We thank you for your participation. Goodbye.