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

SCHEDULE 14A
(Rule 14a-101)

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12-Nov-2026
CORMEDIX INC.
Q3 2026 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator

Good morning, and welcome to the CorMedix Third Quarter 2026 Earnings and Corporate Update Conference Call. Today's conference call is being recorded.

[Operator Instructions]

At this time, I would like to turn the conference over to Dan Ferry from Life Science (sic) [LifeSci] Advisors. Please go ahead.

QUESTION AND ANSWER SECTION

Daniel Ferry Q
Analyst
Analyst

Good morning, and welcome to the CorMedix Third Quarter 2026 Earnings and Corporate Update Conference Call. Leading the call today is Joe Todisco, Chairman and Chief Executive Officer of CorMedix. And he is joined by Susan Blum, EVP and Chief Financial Officer. In addition, Liz Hurlburt, EVP and Chief Operating and Chief Commercial Officer; and Beth Zelnick Kaufman, EVP and Chief Legal and Compliance Officer and Corporate Secretary, will be available during the Q&A session.

Before we begin, I would like to remind everyone that during the call, management may make what are known as forward-looking statements within the meaning set forth in the Private Securities Litigation Reform Act of 1995. These statements are statements other than statements of historical fact regarding management's expectations, beliefs, goals and plans about the company's prospects and future financial position. Actual results may differ materially from the estimates and projections on which these statements are based due to a variety of important factors, including the risks and uncertainties described in greater detail in CorMedix's filings with the SEC, which are available free of charge at the SEC's website or upon request from CorMedix.

CorMedix may not actually achieve the goals or plans described in these forward-looking statements, and investors should not place undue reliance on these statements. CorMedix does not intend to update these forward-looking statements, except as required by law.

During this call, the company will discuss certain non-GAAP measures of its performance. GAAP to non-GAAP financial reconciliations and supplemental financial information are provided in CorMedix's earnings release and the current report on Form 8-K filed with the SEC. This information is also available on the Investor Relations section of CorMedix's website.

In addition, today's discussion includes statements regarding CorMedix's proposed acquisition of substantially all of the assets of Heron Therapeutics, which remains subject to approval by Heron's stockholders, regulatory clearance and other customary closing conditions. CorMedix has filed a current report on Form 8-K describing the proposed transaction in greater detail. Investors are urged to read it and any other relevant documents CorMedix files with the SEC carefully and in their entirety because they contain important information about the proposed transaction.

At this time, it is now my pleasure to turn the call over to Joe Todisco, Chairman and Chief Executive Officer of CorMedix. Joe, please go ahead.

Joseph Todisco A
Executive
CorMedix, Inc.

Thanks, Dan. Good morning, everyone, and thank you for joining us on this call.

On Monday, we announced a definitive agreement to acquire substantially all of the assets of Heron Therapeutics, encompassing both commercial and pipeline assets that we believe are highly complementary and synergistic with CorMedix's growth strategy in institutional settings of care. As we discussed on Monday, we see 4 pillars to the strategic rationale for this transaction.

First, scale and diversification. The Heron portfolio meaningfully expands our revenue base and further diversifies our revenue mix across acute care and hematology/oncology supportive care and reduces our reliance on DefenCath revenues to drive cash flow and future growth. Heron's portfolio generated approximately $150 million of net product revenue over the trailing 12 months, and we expect the acquired products to contribute approximately $125 million to $150 million of revenue for pro forma 2027, roughly doubling the revenue base for our non-DefenCath portfolio.

Second, commercial and operational leverage. We expect to deploy Heron's products through our existing infrastructure, supplemented with a subset of the Heron team, which supports the $45 million to $60 million in estimated operating cost synergies that we expect to achieve on an annualized run rate basis by the end of 2027.

Third, growth from the acute care franchise. We view ZYNRELEF in particular, as an asset with significant untapped potential as hospitals and surgery centers increasingly adopt non-opioid approaches to postsurgical pain and together with APONVIE, which serves the same perioperative call point, represents the fastest-growing parts of the Heron portfolio.

And fourth, hematology/oncology supportive care and pipeline optionality. CINVANTI and SUSTOL both bring an established presence in infusion centers and hematology/oncology clinics, which aligns directly with our planned launch of REZZAYO for the prophylaxis indication, if approved by FDA.

I also want to highlight how we structured this transaction to align payment with sales performance. Up to $55 million of the consideration is contingent on ZYNRELEF achieving net sales milestones in calendar year 2028. And there are additional contingent payments in the form of a royalty above a sales threshold for CINVANTI, SUSTOL and any products we launch under the multiproduct development agreement. To that extent, a meaningful portion of what we pay is earned only if the assets perform.

We expect the transaction to be immediately accretive to earnings and free cash flow upon closing, which we anticipate in the first quarter of 2027, subject to Heron stockholder approval, regulatory clearance and other customary closing conditions.

Turning to third quarter performance. We continue to execute on our 3 core strategic priorities: First, executing on our post-TDAPA commercial strategy for DefenCath; second, meaningfully advancing our high-value pipeline, highlighted by FDA's acceptance of the sNDA for REZZAYO for the prophylaxis of invasive fungal disease with priority review; and third, deploying our capital in a disciplined manner to fuel sustainable growth, highlighted by the Heron announcement. We believe this combination of commercial execution, pipeline progression and strategic capital allocation positions CorMedix to drive long-term value to shareholders while building an increasingly diversified and resilient business.

For the third quarter, we reported consolidated revenue of $54.5 million, above consensus and adjusted EBITDA of $3.1 million, and we ended the quarter with $355 million in cash. Importantly, our largest dialysis customers largely maintained DefenCath utilization through the quarter at the $2.37 add-on in effect for the second half of 2026. Susan will provide more granular details of third quarter financial results.

Turning to guidance. Last week, we reaffirmed our full year 2026 revenue guidance with a range of $325 million to $345 million. And today, we're also narrowing our full year adjusted EBITDA guidance to the top end of the previous range to $130 million to $140 million.

We also issued a business update last week addressing CMS' release of the ESRD PPS final rule for 2027 as well as comments made by the CFO of a large dialysis organization related to the 2027 post-TDAPA add-on payment for DefenCath. While the ESRD final rule established a post-TDAPA add-on of $8.32 for the first quarter of 2027, which is within our previously guided range, CMS also finalized a new methodology to calculate add-on payments, whereby they will be reset quarterly.

Because the quarterly add-on incorporates recent utilization and pricing data, its trajectory quarter-to-quarter depends on information that only CorMedix can report to CMS. We have not shared that data with any customer or third party, and we believe third-party projections of the quarterly path are subject to significant uncertainty. As we disclosed in our announcement, this new quarterly mechanism will result in overall average reimbursement to customers that is lower than the $8.32 over the course of the year.

However, based on our review of our own pricing and utilization data, we currently expect the add-on in each quarter of 2027 to exceed the current $2.37, and we currently estimate the full year average to be at least double that current rate. After a decline from Q1 to Q2, we expect the add-on in Q3 and/or Q4 of 2027 to be higher than the second quarter, in each case, subject to how CMS applies this methodology, including certain utilization and pricing data in its calculations.

Put simply, the lowest add-on we currently expect DefenCath to see in 2027 is higher than our current rate customers receive today. And our LDO and MDO customers have largely maintained utilization at today's current rate in the third quarter.

We are currently engaged in conversations with customers around how to structure DefenCath pricing that tracks the quarterly add-on adjustments with the goal of keeping fee-for-service patients on therapy throughout the year. We're also actively working to secure a separate payment for DefenCath from top Medicare Advantage plans.

As a result, we will not be in a position to opine on any 2027 revenue guidance for DefenCath until we have visibility into both customer pricing and expected utilization for Medicare fee-for-service patients as well as possible upside for Medicare Advantage. In that regard, we are deferring 2027 DefenCath guidance at this time and anticipate being able to update investors in early 2027.

We continue to believe that Medicare Advantage represents a meaningful long-term growth avenue for DefenCath and the best opportunity for the product to have a sustainable value following the ending of the post-TDAPA add-on in 2029. DefenCath's clinical value and its potential for meaningful downstream cost savings continue to be supported by a growing body of real-world evidence that our partners are publishing, and I'm proud of the data presentations that took place this past October at the American Society of Nephrology Kidney Week and at IDWeek.

Turning to our pipeline. We announced in October that the sNDA for REZZAYO in prophylaxis was accepted for FDA review with priority review status and a target action date from the FDA in the first quarter of 2027. As a reminder, submission was conducted by our global partner, Mundipharma, following positive clinical trial results from the ReSPECT study, a Phase III clinical study evaluating REZZAYO for the prophylaxis of invasive fungal disease in adult immunosuppressed patients undergoing allogeneic bone and marrow transplant. We're actively preparing for promotional efforts for REZZAYO in this new indication and if approved by FDA, would anticipate commencement of promotional efforts in the second half of 2027.

Finally, with respect to our Phase III TPN study for DefenCath, despite engagement of new study sites and the FDA approval of the protocol amendment that narrows certain exclusion criteria, study enrollment continues to track meaningfully behind our original estimated time lines. Given the established safety profile for DefenCath and demonstrated efficacy in its currently approved indication, we're evaluating potential alternative pathways to pursue approval with FDA should enrollment not accelerate in the next 1 to 2 months. We expect to make a decision on the strategy for TPN prior to our next quarterly update call.

I'd like to now turn the call over to Susan to discuss the company's third quarter financial results and financial position. Susan?

Susan Blum A
Executive
CorMedix, Inc.

Thank you, Joe, and good morning, everyone.

As a reminder, the Melinta acquisition closed on August 29, 2025. As a result, the third quarter of 2026 includes a full quarter of Melinta operations compared with the third quarter of 2025, which only has 1 month of Melinta's operations. This difference affects the year-over-year comparison of both revenue and expenses in a meaningful way. We also filed our Form 10-Q this morning, and I encourage investors to review it for additional information regarding our third quarter and year-to-date results, financial position and related disclosures.

Overall, our third quarter results reflect the anticipated transition of DefenCath into the post-TDAPA reimbursement environment, continued contributions from the broader product portfolio and disciplined management of our operating expense base.

Now turning to the drivers. Consolidated revenue for the third quarter of 2026 was $54.5 million compared with $104.3 million in the third quarter of 2025. Third quarter consolidated revenue consisted of $17.2 million in DefenCath net sales and $37.3 million from the remainder of the portfolio, consisting of $31.4 million of product sales and approximately $5.9 million of contract revenue and grant income under our BARDA agreement. The year-over-year decline in DefenCath revenue primarily reflects the lower net pricing associated with its transition on July 1 to the post-TDAPA reimbursement period.

Importantly, large outpatient dialysis customers largely maintained utilization during the quarter despite the reimbursement change. DefenCath net revenue included a $5 million favorable change in estimate related to certain Medicaid rebate and product return allowances. The adjustment reflects updated information regarding Medicaid utilization as well as recent DefenCath product return experience, both of which have been much lower than previously estimated.

Total operating expenses were $36.6 million in the third quarter of 2026 compared with $41.7 million in the third quarter of 2025, a decrease of approximately 12%. The reduction primarily reflects merger-related and reorganization costs incurred following the Melinta acquisition in the prior year period, which was partially offset by the inclusion of a full quarter of costs associated with the expanded organization in 2026 versus just 1 month of Melinta's costs in the third quarter of 2025.

R&D expenses were $7 million in the quarter compared with $5.1 million in the third quarter of 2025. The increase was primarily attributable to higher personnel and clinical trial costs supporting our combined company's ongoing development programs.

Selling and marketing expenses were $11.7 million in the quarter compared with $11.2 million in the prior year quarter. The modest increase reflects personnel and marketing investments supporting the expanded product portfolio, partially offset by the cost savings associated with the elimination of overlapping commercial teams that were present for a portion of the third quarter of 2025.

G&A expenses decreased to $17.9 million from $25.5 million in the third quarter of 2025. The decrease year-over-year was largely attributable to transaction, integration and reorganization expenses incurred in connection with the Melinta acquisition during the prior year period and partially offset by higher costs in 2026 of operating the combined company, including investments in personnel, IT, legal support and facilities.

On the bottom line, on a GAAP basis, CorMedix reported a net loss of $14.7 million or $0.19 per basic and diluted share compared with net income of $108.6 million or $1.42 per basic share and $1.26 per diluted share in the third quarter of 2025. A large driver of net income in the prior year period was a substantial tax benefit of $59.7 million associated with the partial reversal of the valuation allowance on deferred tax assets. Third quarter 2026 GAAP results included an $11.5 million noncash expense from the quarterly remeasurement of contingent consideration associated with the Melinta acquisition. This expense reflected changes in the discount rates applied to expected milestone and royalty payments as well as accretion of the liability from the passage of time.

On a non-GAAP basis, adjusted EBITDA was $3.1 million for the third quarter of 2026 compared with $71.9 million in the third quarter of 2025. Adjusted EBITDA excludes depreciation and amortization, stock-based compensation, interest and other income and expense, changes in contingent consideration, taxes, merger-related costs and other specified adjustments. In the third quarter of 2026, the calculation also excludes the $5 million favorable change in estimate related to sales allowances recorded during the quarter.

We ended the quarter with $355.2 million in cash and cash equivalents. For the first 9 months of 2026, net cash provided by operating activities was $218.3 million compared with $80.6 million in the first 9 months of 2025. The year-over-year increase in cash flow reflects the higher year-to-date earnings achieved during the current year relative to 2025 as well as working capital movements, including the timing of certain contractual rebate payments.

As discussed earlier, we are maintaining our full year 2026 consolidated revenue guidance of $325 million to $345 million, and we are narrowing our adjusted EBITDA guidance to $130 million to $140 million, the high end of our previous range. We have also lowered and narrowed our full year operating expense guidance, which excludes noncash items such as stock-based compensation to $140 million to $145 million.

With the integration of Melinta behind us and the financial flexibility afforded to us, we believe we are well positioned to drive significant value for shareholders in the many ways that Joe has mentioned. And now I will turn the call back to Joe for closing remarks. Joe?

Joseph Todisco A
Executive
CorMedix, Inc.

Thanks, Susan. On the heels of our recently announced agreement to acquire the Heron assets, along with a strong balance sheet and access to additional nondilutive capital from our Pharmakon term loan facility, I'm excited about the potential for the organization. CorMedix is building a leading diversified commercial platform across institutional settings of care. We have a portfolio of complementary assets utilized in hospitals, infusion clinics and hematology/oncology clinics with a commercial and medical footprint that spans across those therapeutic settings.

Our near-term priorities are clear: closing the Heron transaction and capturing synergies, navigating DefenCath through the 2027 quarterly add-on framework while pursuing Medicare Advantage and preparing for potential commercialization of REZZAYO for an expanded indication of prophylaxis. Over time, we will continue to evaluate additional assets that are synergistic with our commercial and medical footprint with the same discipline we apply to Melinta and Heron.

At this time, I'm happy to open up for questions.

Operator Q

[Operator Instructions]
Our first question comes from Les Sulewski with Oppenheimer.

Joseph Todisco A
Executive
CorMedix, Inc.

Moderator, it seems like Les is having a technical problem. Do you want to move to the next and then come back?

Operator Q

Yes.

Leszek Sulewski Q
Analyst
Analyst

I am sorry, can you hear me?

Joseph Todisco A
Executive
CorMedix, Inc.

We can now, Les.

Leszek Sulewski Q
Analyst
Analyst

Okay. I'll repeat -- sorry about that. So I have 3 questions. So Joe, you noted that CorMedix will be solely in control of providing utilization rates to CMS for the add-on calculations. Is there a factor of selectivity or subgroup or certain time frames of utilization that can be submitted by you? Or is it broad?

And then second, on Medicare Advantage, what's the main hurdle to getting the first contract signed? And how quickly could get patients utilized follow on?

And then lastly, what's driving the slow TPN enrollment?

Joseph Todisco A
Executive
CorMedix, Inc.

Okay. 3 good questions, Les. On the first one, in terms of the data that gets -- when we say we're only -- we are in control of the data that gets reported to CMS because it's our sales data. And the way that CMS calculates ASP for the purpose of calculating the add-on, it's based on the timing of when, let's say, rebates are paid as opposed to when they're accrued. So there may not necessarily be alignment between when we report net price in our earnings versus when it hits ASP. And a lot of these contracts have longer-term volume incentive rebates where perhaps you're paying those rebates on a very delayed time frame, and it ends up ultimately hitting ASP in a different period than what an outside third party might just look at financials and expect it to hit. So that's kind of the disconnect that we were -- that we wanted to highlight with how CMS calculates that add-on.

For Medicare Advantage, I am still, as I said last time, cautiously optimistic that we can get something done before the end of this year. I think I likened the example of working with the MA plan to trying to turn an aircraft carrier, which is slow. I would say that I believe that we have a contractual framework that is largely final, but for the MA plan agreeing to how this is going to be operationalized. And I think those are still the hurdles that our team is actively working at least with the largest plans through that -- through those specifics. So hopefully we'll be able to provide an update before the end of the year, and that's what our team is working on.

On TPN, I'll let Liz comment. It's not a shortage -- it's not a change in the market opportunity it's an ability for these types of patients to participate in a clinical study. Liz, do you want to add anything?

Elizabeth Masson-Hurlburt A
Executive
CorMedix, Inc.

Yes. So just to piggyback on what Joe said, there are a limited number of subjects actually eligible to participate in a study, right, not representative of the TPN market. But they're really complex patients that have a lot of underlying conditions that make it challenging to participate, right? -- intestinal failure, cancer, things like that make it difficult to adhere to a study schedule. I think we've also got a challenge that frequently antibiotics or antifungals are used prophylactically. And obviously, it's very challenging to be able to see a signal for DefenCath that patients need to be on that from a standard of care standpoint.

And so -- and lastly, there are -- we have added quite a few sites here in the U.S. as well as in Turkey. But the number of patients that are attached to an academic medical center that has the infrastructure to run a clinical trial versus those that are seen in community practices or perhaps don't live near a site is also an issue. So there's been extensive work done, I would say, extensive work done with patient advocacy groups and with all of our investigators to continue identifying subjects that are eligible, but the logistics of running a study in this patient population are proving to be rather challenging right now.

Operator Q

And the next question comes from Leo Timashev with RBC.

Unknown Analyst Q

This is [Xander] on for Leo. And I know you commented on a lot of this already, but I'm just wondering if you can expand on the outlook for '27? And what do you see as the most supportive and constructive factors for DefenCath going into this? And what areas are going to require a little bit more careful navigation?

Joseph Todisco A
Executive
CorMedix, Inc.

Thanks, Xander. I mean, as we said in the script, we're really not in a position to provide guidance right now for DefenCath for 2027. There are pushes and pulls. As we said in the script as well, we think the add-on on average is going to be lower than the $8.32. That needs to be taken into account in terms of how we essentially price the product quarter-to-quarter, specifically for fee-for-service patients. The pull we're looking for the Medicare Advantage patients to Medicare Advantage contracting to both pull up number of patients as well as pricing. And once we have better visibility of that, we can provide some -- we hope to provide guidance on where we think revenue for DefenCath can land in 2027. We'll also, at that time, provide overall guidance for the company for 2027.

Right now, what we're comfortable with is what we've put out for the Heron acquisition and what we'll update likely in the first quarter.

Operator Q

And the next question comes from Brandon Folkes with H.C. Wainwright.

Brandon Folkes Q
Analyst
Analyst

Congrats on managing through the quarter. Maybe just 2 from me. You talked about kind of uncertainty for the dialysis operators. Just given how traditionally they do take time to move, how much of a risk is that uncertainty just in terms of kind of protocols and things that they may want to put in? What can you do to provide volume certainty to the operators in 2027? Is that sort of how you're looking at it? And then ASP may be the variable in terms of CorMedix is reporting? And then that's just the one for me. Yes. I think that's it for now because I think that's probably quite...

Joseph Todisco A
Executive
CorMedix, Inc.

Sorry, Brandon. I want to clarify because I want to make sure that you understood what I had said. When I was talking about the time to move and then being slow, I was referring to the Medicare Advantage plan, which is the payer. And large organizations, we were trying to do something that's never been done before, which is take something that's traditionally inside the bundle and contract it out to be separately reimbursed. We have a compelling case for that. This is a preventative. This takes costs out of the system, right? It's a strong form of economic benefit to the MA plan to actually have payment follow the product instead of bundlizing, right? So that's largely the argument around MA.

When it comes to the dialysis operators and protocols, specifically our 3 largest customers being Fresenius, U.S. Renal Care and IRC, those protocols are already in place. And to our knowledge, nothing has been altered in the last couple of months.

Brandon Folkes Q
Analyst
Analyst

And so can they just -- just to follow on, are they in a position to dial up utilization and dial it down on a quarterly basis? Just any color in terms of that element, just so I can understand kind of the rules in '27.

Joseph Todisco A
Executive
CorMedix, Inc.

Look, I don't know if I think of it that way, right? If you have a patient that is stable on a preventative measure, I would expect that either they stay on that or if they're going to move, it's not going to be quarter-to-quarter for that patient, right? That would be -- I think that would be irresponsible to make changes quarter-to-quarter like that. The opportunity with Medicare Advantage would be they do have the ability to do a benefit verification for their patients, understand the payer dynamic and then transition certain patients longer term to that therapy.

Brandon Folkes Q
Analyst
Analyst

Great. And then maybe just 1 follow-up. Obviously, 1Q '27, there's going to be a lot going on with REZZAYO and the Heron close. Can you just talk about your expectations for Heron in terms of damping kind of what you want to do with those products? How long does that take? Just setting -- I know you can't talk too much in specifics right now, but maybe just setting the time frame in terms of when we see the CorMedix impact on the Heron products post close.

Joseph Todisco A
Executive
CorMedix, Inc.

Yes. Look, we've put out a revenue range for next year and a lot of that -- the variability in that range isn't as much related to what I think we can do immediately with kind of our fingerprint as opposed to the external dynamics certainly related to CINVANTI, the situation with Azurity and how that litigation progresses and any potential launch at risk by Azurity of a competing branded product. All of that kind of factors into that range.

Look, we're hoping to close in the first quarter. We have specifically around ZYNRELEF ideas that we think for things that based on our research that we can maybe pivot on or do a little bit differently. I don't know -- I don't want to commit today to how long that will take to either implement or see results. But certainly, we're excited about the assets and the deal that we announced.

Operator Q

And the next question comes from Jason Butler with Citizens JMP.

Jason Butler Q
Analyst
Analyst

Just a couple outside of DefenCath. First, can you talk a little bit more about what you're doing to prepare for the REZZAYO prophy launch? What is awareness of the product and the prophy data now among potential prescribers?

Second, can you just talk a little bit more about the growth potential for ZYNRELEF, 1 of the products you just got from Heron? Obviously, a large TAM, but what are your thoughts here on commercial strategy and what you guys can do to drive growth?

And then just lastly, can you just give us thoughts on the quarter for the base business for Melinta and the growth potential that's still in that portfolio?

Joseph Todisco A
Executive
CorMedix, Inc.

Okay. I'm going to actually take the second and third question first, and then Liz will comment on the REZZAYO prophylaxis launch prep.

Look, in terms of the growth opportunity for ZYNRELEF, it is -- we do see it as a large market opportunity. Even if you just look at the other non-opioid long-acting bupivacaine market that's out there, right? It's a sizable market opportunity. Where ZYNRELEF is currently being used is almost exclusively in ortho. The label is much broader than that. We do think there's an opportunity for expansion. I don't -- I'm not going to put a number today around where we think we can grow it to, but we do think there's potential upside for things that we can do there.

Like on the base business revenue, and I think you're largely talking about VABOMERE, MINOCIN, KIMYRSA/ORBACTIV those are durable-ish assets. Certainly, when you're talking about VABOMERE and MINOCIN, we do see periodically low single-digit growth on those products, but it does also kind of vary a little bit quarter-to-quarter institution to institution. ORBACTIV and KIMYRSA, which are the oritavancin products did contract this year after generic Dalvance launched last year. We're looking at somewhat of an increased promotional activity towards the back part of next year once the kind of profit arbitrage for the generics diminishes a little bit in the back part of next year. But that's how I would view the base business. And then you have TOPROL-XL and BAXDELA that are pretty much flat.

Liz, do you want to comment on REZZAYO?

Elizabeth Masson-Hurlburt A
Executive
CorMedix, Inc.

Sure. So as we prep for REZZAYO prophy launch, I'd say we have a really cross-functional approach to preparing. We're certainly leveraging a very strong commercial infrastructure, but working closely with medical and market access as well. I think right now, we're really focused on a few key priorities, refining the market segmentation and the customer targeting, really advancing the market access strategy and preparing the field for this engagement and ensuring that we've got alignment across all of our functions here. And our medical team and some of the market access team is already working on building a presence and relationships with the bone marrow transplant centers and those institutional markets.

And I would say that we are really -- the goal is to ensure that we're not just prepared for a successful launch, but that we are able to stay in the business and really maximize the long-term value that we think that prophy has.

Operator Q

The next question comes from Serge Belanger with Needham & Company.

Serge Belanger Q
Analyst
Analyst

I guess 3 questions for us, too. First, on the LDO pilot program, any update there on how much it contributed to the third quarter and whether there's plans to expand beyond a pilot?

And then secondly, on DefenCath, you reported, I think, $17.2 million in sales this quarter, $5 million of it was from a sales allowance charge. So should we think as a $12 million sales base as the level going forward for 4Q and on which you'll grow from in 2027?

And then lastly, on REZZAYO, any outlook on what the label could look like for the product now that the review is underway and the priority review has been granted?

Joseph Todisco A
Executive
CorMedix, Inc.

Thanks. Look, the LDO pilot, we're really excited to get that contract done and get that finally over the finish line and have them implement. But we have not had any kind of repeat ordering from there. We continue to engage, and we're hopeful that we can perhaps drive something next year with the engagement with Medicare Advantage. But right now, we don't have any real visibility into increased adoption or the results of that pilot.

So good question about DefenCath in the fourth quarter. I'd say tentatively, yes, I think it could be a little bit of a notch up, but that's probably the right way to look at it. From a pricing standpoint, we want the volume to stay consistent and then roll into next year with some higher pricing, at least for that kind of, we'll call base business fee-for-service patients that we're looking to preserve.

Look, on the REZZAYO label, we're not going to comment until we get feedback from FDA. The results are out there for the clinical study and Mundipharma is in control of that regulatory process, and we're providing whatever support we can to them in that regard.

Operator Q

This concludes our question-and-answer session. The conference has concluded. Thank you for attending today's presentation. You may now disconnect.