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Pelthos Q3 2026 Earnings Call Transcript

Mike Moyer

Good morning everyone and welcome to Pelthos Therapeutics' 2026 Third Quarter Financial Results Conference Call.

Pelthos issued a press release today announcing its financial results for the quarter ended September 30, 2026. A copy can be found in the Investor Relations tab on the Company's corporate website, www.pelthos.com.

Before we begin, I'd like to remind you that during today's call statements about the Company's future expectations, projections, plans, and prospects are forward-looking statements. These forward-looking statements are based on Management's current expectations. These statements are neither promises nor guarantees and involve known and unknown risks, uncertainties, and other important factors that may cause the Company's actual results, performance, or achievements to be materially different from the Company's current expectations expressed or implied by the forward-looking statements.

Any such forward-looking statements represent Management's estimates as of the date of this conference call. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change. As a reminder, this conference call is being recorded and will remain available for 90 days.

I'd now like to turn the call over to Scott Plesha, Chief Executive Officer. Scott, you may begin.

Scott Plesha

Thank you, Mike, and good morning, everyone.

We're pleased to be here with you today to share our third quarter 2026 financial and operational results and highlights. I'm joined today by Peter Greenleaf, our Executive Chairman, John Gay, Chief Financial Officer, and Sai Rangarao, our Chief Commercial Officer.

The third quarter of 2026 was a successful one for Pelthos with progress made in several key areas. During Q3, we generated Zelsuvmi net revenue of $15.2 million, which represents a year-over-year increase of 114% from Q3 of 2025.

In five quarters since commercial launch, we have dispensed over 40,000 units of Zelsuvmi and treated over 31,000 patients.

In early October, we announced that we had signed an agreement with a major PBM to open access to Zelsuvmi covering 24 million commercial covered lives and received a formulary update enhancing access to Zelsuvmi with a regional health plan that covers approximately 3 million lives. We believe that these improvements in formulary access will be important to the continued growth of Zelsuvmi.

With these improvements, Zelsuvmi now has formulary coverage across 127 million or approximately 70% of commercially covered lives and strong Medicaid coverage of more than 70 million or 100% of covered lives.

We continue to make progress in establishing the manufacturing of our two other highly complementary products, Xepi and Xeglyze. We are currently building launch inventory for Xepi for the treatment of impetigo and expect to begin promoting it to our current customer base by the end of Q1 2027. With Xeglyze for head lice, we have initiated the manufacturing of API and expect to commercially launch it by the end of Q3 2027.

We are excited about the impending launches of Xepi and Xeglyze, as we expect they'll have a meaningful call overlap for our existing field force, which we expect will provide the Company with greater operational and financial leverage from our existing team and infrastructure.

Before we cover our commercial and financial results, I'm going to spend a few minutes on an exciting Castle Creek Biosciences transaction we announced on October 30. While I'm limited in what I can say given that the S-4 has not yet been filed, I believe it's important to comment on why we have such strong conviction in this acquisition and in the long-term opportunity it creates for Pelthos and our shareholders.

Since our formation in July of last year, our strategy has been focused on building a strong commercial organization in dermatology with the physician relationships, commercial infrastructure, and manufacturing expertise necessary to succeed in bringing innovative therapies to market. Having made substantial investments in establishing that foundation, we see great synergy and an opportunity to leverage these capabilities across a broader portfolio, expanding our potential future revenue base and generating greater revenue on the investments we've already made.

Castle Creek represents a particularly strong fit with that strategy. Its lead candidate is D-Fi, an investigational, redosable, gene-modified cell therapy being developed for dystrophic epidermolysis bullosa, or DEB, a rare lifelong disease characterized by extremely fragile skin, chronic wounds, and serious complications. D-Fi has been granted Orphan Drug designation, and once the transaction closes, we expect to continue development of its Phase 3 clinical trials.

Patients who suffer from DEB live with intense wound burden, frequently accompanied by serious complications, including a greatly increased risk of developing squamous cell carcinoma, which is a leading cause of death in DEB patients. The wound burden never goes away, creating sustained demand for multiple therapies that can close wounds and keep them closed.

The market for DEB therapies has already proven its commercial potential. The first gene therapy approved for DEB, a weekly topical treatment launched in 2023, generated $127 million in global net revenue in the third quarter this year, up 30% from a year ago, and more than $1.1 billion since launch, with over 760 U.S. reimbursement approvals to date. The pace of this launch demonstrates that payers recognize the severity of this rare disease. Coverage has been broad, revenue per patient is high, and gross-to-net adjustments have been modest relative to many specialty markets.

We also believe there remains significant unmet need in this disease state, and so far, our conversations with KOLs and healthcare providers who treat DEB have consistently highlighted the need for further treatment options. We believe D-Fi, upon approval, can leverage this need and capture a meaningful share of the market because it offers a differentiated approach.

It uses the patient's own skin cells, engineered to produce type VII collagen, and delivered by intradermal injection directly into the wound. It is designed to be redosed, with treatment sessions every eight weeks in the planned Phase 3 trial.

We expect the treatment paradigm with DEB to increasingly involve more than one therapy across different wounds and stages of the disease. We see a clear role for D-Fi as a standalone, first-line treatment, as well as being used alongside existing treatment options.

This opportunity is also not limited to the U.S. We believe that approximately one-half of the market for DEB treatments is outside the U.S., and our agreement with Castle Creek includes the Rest of the World rights to D-Fi as well.

This is exactly the kind of high-value, specialist-driven market where we believe our commercial model provides a great deal of synergy. It is concentrated, it is served by dermatologists we already have relationships with, particularly in pediatric dermatology, and the economics per patient support an efficient, focused launch.

Beyond D-Fi, Castle Creek's proprietary fibroblast-based technology has a cell and gene therapy capability to Pelthos' existing NITRICIL manufacturing platform. Together with our three FDA-approved products, Zelsuvmi, Xepi and Xeglyze, the combined company will offer a more diversified portfolio spanning marketed, launch stage, and late-stage assets across multiple therapeutic modalities.

This combination of complementary capabilities is central to the strategic rationale of the transaction. By leveraging our existing manufacturing expertise and commercial infrastructure, we believe we may be able to accelerate the development and, if approved, launch of this product candidate. If successful, we believe this program has the potential to expand our revenue base and create long-term value for our shareholders.

But the potential of this transaction extends beyond the addition of a single development asset, no matter how great D-Fi's potential. This transaction positions Pelthos to be a stronger, more diversified biotech company, poised to pursue additional pipeline opportunities, build a broader commercial portfolio, and expand its long-term earnings potential.

A disciplined capital allocation approach remains central to this strategy, and we intend to focus on translating these opportunities into sustainable revenue while maintaining the financial discipline necessary to generate attractive long-term returns.

In short, we are extremely enthusiastic about the potential of D-Fi and are confident that the Castle Creek transaction can be a foundational pillar of the next phase of Pelthos' growth.

I'll now turn it over to Sai to provide more specifics on the results of our commercial performance. Sai?

Sai Rangarao

Thank you, Scott. Good morning everyone.

I'm pleased to provide an update on our Q3 2026 Zelsuvmi performance and our progress to date.

Zelsuvmi continues to deliver strong utilization and adoption among HCPs and patients. We continue to receive very positive feedback from prescribers regarding Zelsuvmi's clinical profile and ease of use. According to our latest data, we now have more than 10,000 unique HCP prescribers. This reinforces our confidence that Zelsuvmi is transforming the treatment of molluscum, or MC, as evidenced by its strong HCP adoption.

Since our commercial launch in July 2025 to date, more than 34,000 patients have received Zelsuvmi. This milestone is a testament to the strong demand among HCPs and patients for Zelsuvmi as an optimal treatment option for MC.

Turning to prescription details for Q3 2026, the number of prescriptions increased by 4% from 11,925 in Q2 to 12,384 in Q3. This represents 365% year-over-year growth. The number of unique prescribers also increased from 4,571 in the second quarter to 4,942 by the end of the third quarter. Both metrics are reported in Symphony (Inaudible) data.

Prescribed units in October totaled an estimated 4,231 compared with 4,063 in September. Despite seasonal trends and summer scheduling dynamics among HCPs and patients, performance between July and August remained stable and in line with expectations. In fact, we surpassed 1,000 weekly TRx units in early October, further affirming HCP and patient demand for utilization of Zelsuvmi, even during a quarter that historically experiences lower MC claims volume.

Our coverage for Zelsuvmi has continued to grow. Most notably, we executed a contract with a large PBM to help patients gain access to Zelsuvmi. This formulary agreement, effective October 1, 2026, provides open access to approximately 24 million covered lives without a prior authorization requirement. This agreement has already helped many patients gain rapid and seamless access to Zelsuvmi. We also announced that Pelthos received a formulary update from a regional health plan covering approximately 3 million lives, further enhancing access to Zelsuvmi.

As of October 2026, Zelsuvmi has formulary coverage across 127 million commercially covered lives, representing approximately 70% of the market, along with strong Medicaid coverage of more than 70 million lives, representing 100% of covered lives.

Zelsuvmi continues to gain adoption as a first-line treatment option and is being well received by coverage providers. A large number of states still do not require a prior authorization for Medicaid coverage. In other states where a prior authorization is required, Medicaid only requires a PA written in accordance with the product label. This means that patients over one year of age presenting with MC qualify for coverage.

We continue to maintain very favorable gross-to-net performance. As a reminder, our GTNs are driven by distribution costs, Medicaid discounts, payer contracts, and our co-pay voucher program. Our goal is to offset the prescription costs through the co-pay card program so that the out-of-pocket costs to patients is zero or close to zero for the majority of prescriptions.

For the third quarter of 2026, our GTNs were 31.5%. Going forward, we expect our GTNs to move into the mid-30 range in line with our expectations considering additional formulary coverage.

Our hardworking sales teams continue to ramp up their efforts to educate HCPs across the nation. Despite expected seasonal fluctuations, the team's efforts have continued to drive increased utilization of Zelsuvmi along with growth in the number of new prescribers.

Awareness and utilization of Zelsuvmi as the first and only at-home prescription treatment option for MC are further supported by our comprehensive promotional strategy. We believe our Zelsuvmi YouTube commercial and patient testimonial videos continue to serve as highly educational resources, encouraging caregivers and patients to ask their HCPs about Zelsuvmi. With more than 9.2 million total views of our Zelsuvmi YouTube commercial and more than 1.7 million views of our patient testimonial videos, our continued awareness and conversion initiatives have developed momentum.

Throughout Q3 into early Q4, we participated in several key conferences, including the American Academy of Pediatrics Meeting and one of the largest clinical dermatology meetings in the country. Our participation in these meetings generated numerous leads and helped HCPs initiate treatment for new patients through education provided at these venues. These engagements translated into meaningful interest in both continued and new use of Zelsuvmi, reinforcing its utilization among HCPs. We continue to strengthen our differentiated commercial platform, leveraging its strong foundation and the outstanding execution capabilities of our sales team to drive continued growth of Zelsuvmi.

Lastly, here in Q4, our commercial leadership team has begun planning for the March 2027 launch of Xepi. Extensive strategic brand and tactical planning is underway to align our go-to-market strategy to meet our customers' needs and position us for a successful launch of Xepi for the treatment of impetigo.

I am proud of the strong performance we have delivered to date, which reflects the passion, commitment and outstanding execution of our exceptional commercial team.

With that, I'd like to turn the call over to John to walk us through our financials. John?

John Gay

Thank you, Sai. Good morning everyone, and thank you for joining us on today's call.

As Scott and Sai have already touched on, we continue to focus on driving growth for our lead product, Zelsuvmi, and look forward to launching Xepi in the first quarter of next year.

With today's filing of our quarterly report on Form 10-Q for the period ending September 30, 2026, we have now completed and reported five fiscal quarters of commercialization efforts for Zelsuvmi. While these quarters straddle two fiscal years, we have reported in aggregate $57.5 million of net product revenue since the commercial launch of Zelsuvmi.

Turning to the operating results of our business, please note that my comments will focus on our third quarter 2026 results as compared to the second quarter of 2026.

For the third quarter of 2026, we reported $15.2 million of net product revenue as compared to $15.4 million in the second quarter of 2026.

Our gross-to-net for the third quarter of 2026 was 31.5% as compared to 29.6% in the second quarter of 2026. As Scott and Sai mentioned, we signed a major PBM agreement to unlock access for patients seeking Zelsuvmi with no prior authorization. While overall gross revenue increased, the gross-to-net increase in Q3 reflects the formulary agreement, which we believe will contribute to future incremental revenue growth.

Cost of goods sold was $1.7 million for the third quarter of 2026 as compared to $3.6 million in the second quarter of 2026. As discussed in our last quarterly earnings call, cost of goods sold for the second quarter of 2026 also included a $900,000 write-off of commercial API inventory identified through the Company's quality control process. We had no such write-offs of inventory during the third quarter of 2026.

Absent the impact of inventory write-offs in the second quarter of 2026, the key driver of the quarter-over-quarter reduction in COGS was primarily due to an approximate 39% reduction in the U.S. GAAP per unit cost of goods sold during the third quarter of 2026 as compared to the second quarter of 2026.

As we have previously discussed, a component of our cost of goods sold includes fair value adjustments associated with the July 2025 merger. At the time of the merger, all finished goods and active pharmaceutical ingredient inventory on hand was fair valued as prescribed under U.S. GAAP. At the end of the second quarter of 2026, we had sold through all of these stepped-up finished goods inventory and we expect to consume the remaining stepped-up API inventory within the next 12 to 15 months. Once we have sold all inventory with a basis step-up, we expect to have a normalized per unit cost of goods of approximately a mid- to high single digit of our WAC price.

For the third quarter of 2026, we reported $18.8 million of SG&A expenses, representing a 25% decrease from the second quarter of 2026 at $25 million. Excluding the $5.3 million of one-time, non-recurring sales-based milestones related to our Zelsuvmi license recorded in the second quarter of 2026, SG&A decreased 5% during the third quarter of 2026.

One additional point I would like to call out with respect to SG&A. Beginning this quarter, we have presented royalty expense associated with our licensing partners as a separate line item within operating expenses on our income statement. We've made the slight change in presentation to provide a more disaggregated level of detail for OpEx on the face of our P&L.

Please note that we provide a detailed breakdown of the components of SG&A within the MD&A section of our quarterly report on Form 10-Q for the period ending September 30, 2026 filed this morning. But in total, cash basis SG&A, defined as SG&A less milestones and stock-based compensation, was approximately $16.9 million for the third quarter of 2026 as compared to $17 million for the second quarter of 2026.

Net loss for the third quarter of 2026 was $7.9 million as compared to $23.4 million for the second quarter of 2026.

Adjusted EBITDA for the third quarter of 2026 was a negative $5.6 million as compared to a negative $5.7 million for the second quarter of 2026.

Turning now to our balance sheet, as of September 30, 2026, we had $17.7 million of cash and $13.4 million in accounts receivable. Our working capital at the end of the third quarter of 2026 was $24.6 million as compared to $31.4 million at the end of the second quarter of 2026.

As previously discussed, in January of this year, we entered into a $50 million senior secured term loan facility with Horizon, of which we drew $30 million at close. On October 30 of this year, we executed an amendment to this facility and borrowed an additional $10 million. In addition, this lending facility also provides for an additional $10 million in funding prior to December 31, 2027, subject to the lender's discretion and certain conditions, including the Company achieving trailing 12-month net revenue of at least $70 million. Based on our current projections, including forecasted cash flows related to net product sales of Zelsuvmi and Xepi and proceeds drawn from the Horizon facility to date, we believe we have the flexibility to advance our business plan.

In summary, while we are pleased with our performance since the launch of Zelsuvmi in July of 2025, generating $57.5 million in net revenue, we look forward to continued growth. Furthermore, since launch, we have strengthened our balance sheet and believe we're well positioned to continue our commercial execution story, bringing a much-needed treatment to molluscum patients.

With that, I'll now turn it back over to Scott. Scott?

Scott Plesha

Thank you, John.

In closing, while we're pleased with the success of Zelsuvmi, our financial results and commercial reach since we launched in July of last year, we continue to focus on accelerating the growth of Zelsuvmi, preparing Xepi for launch and continuing to expand our reach to help patients.

Before we move to our Q&A session, I did want to remind those on the call that while we are excited with the announcement of the Castle Creek Biosciences transaction, we are limited in what we can say or discuss at this time. As you're aware, we are in the quiet period between the signing of our merger agreement and the expected close of the deal, expected in the first quarter of next year. During this time, we must limit public commentary, forecasts, promotional statements involving the transaction to only that information that is publicly available. That being said, we plan to be as transparent as we are able to be while abiding by the rules and regulations associated with a transaction such as this. However, we do expect to be able to provide more information once we file our S-4 in due course. In the meantime, I'd like to direct you to our Form 8-K that was filed on October 30 for additional information until we are able to provide additional information.

I want to thank you for joining us today to learn more about the Pelthos story.

We'll now turn the call over to the operator for any questions.

Operator

Thank you. We'll now be conducting a question-and-answer session. If you would like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two to remove yourself from the queue. For participants using speaker equipment, it may be necessary to pick up the handset before pressing these star keys.

We also ask those who are in the queue to please limit themselves to one question and one follow-up to allow others a chance to ask their questions.

Our first question comes from the line of David Amsellem with Piper Sandler. Please proceed with your question.

David Amsellem

Hey, thanks. Just a couple for me. I know you can't say all that much just yet on the transaction, but nonetheless, wanted to get your thoughts on how you see D-Fi's points of differentiation versus Vyjuvek. That's number one.

Then in terms of the base business, on Zelsuvmi, can you talk through how you're thinking about the direction of the gross-to-net in 2027?

Then a question on Xepi. This, in terms of volumes, seems like a fairly large market, particularly with a lot of usage of mupirocin ointment. I guess my question here is, with that in mind and bearing in mind that mupirocin is fairly inexpensive, how do you see usage paradigms evolving here and how do you see the payer landscape for Xepi evolving? Thanks.

Scott Plesha

Okay, David, I'll kick it off. I'll talk about Zelsuvmi first and Xepi, and maybe we can transition to the Castle Creek transaction.

First off, a little bit of a background here a bit. On the GTN side of things, we've always said that we would be strategic about our contracting going forward with the different plans. We had the opportunity in this situation to unlock a PBM, remove PA process there. If you look at the quarter, we would have been up modestly if we decided not to do that, but it's a long-term investment in the brand and long-term growth. We still have very reasonable gross-to-net rate for a newly launched product at 31.5%, especially in the derm space. The rebate that we were able to get this win at was very reasonable. Did not trip our best price with the government – really important. For the quarter, we are up 4% on units, prescribers were up 8%. Really, and other underlying metrics, increase in prescribers, new prescribers coming in.

We were strategic in being willing to take this hit on the GTNs, a very modest hit. We would have had actually a positive revenue growth quarter if we hadn't done it, but we believe it's going to accelerate growth going forward, not only next quarter, but into 2027 and beyond.

On the Xepi front, one of the things we really like about the market besides just the synergy with the call point there is that it is a large market, to your point. A little bit more skewed to pediatrician, just slightly more, maybe 60% versus 40% derm, ped-derm, and to your point, there are products in the market like mupirocin. We are already having payer conversations. They're going quite well.

One of the things we keep hearing is that there's a need for this product in the market, mostly due to the resistance you're seeing with mupirocin. It's been used at a very high level over many years. As you know, with antibiotics, a lot of times when you put that pressure on it, you end up with resistance, and in fact, that's been seen. We've actually pulled some data and done additional research and you're seeing multiple therapies being used a lot of times in impetigo because of that.

Next, the question you had asked, transitioning to Castle Creek, you had mentioned about the differentiation between the products. I think that's something right now that we're not really able to discuss, what we will be doing. I think once the S-4 is filed, we can start talking a little bit more about the profile of the products and how they compare in the marketplace.

But just high level. We feel very comfortable based on the research we've done, diligence, that it's going to fit very well in that treatment space and be sometimes complementary to Vyjuvek and maybe used in places it's not.

David Amsellem

Okay, looking forward to the S-4. Thanks.

Scott Plesha

Thank you.

Operator

Thank you. Our next question comes from the line of Jeff Jones with Oppenheimer. Please proceed with your question.

Jeff Jones

Good morning, guys. Thanks for taking the question. Just, if I could, ask for a little more color around the revenue trajectory on Zelsuvmi.

We've talked in the past about the colder months and quarters trajectory being reduced, reduced prescriptions and diagnosis for molluscum, but revenues flattened somewhat noticeably over the spring as well. Just thinking about what you're seeing in the market with your sales force, what you're learning, how you're adapting your strategy? And then in the context of SG&A spend, how that might change as you adapt your strategy to increase penetration there, and also in preparation for the Xepi launch.

Maybe just one quick follow-up on the Xepi question. Do you have numbers around the resistance levels to mupirocin at this point? Thank you.

Scott Plesha

Okay, a lot to unpack there. First off, on the revenue trajectory, we're just getting around to one year and going back, being able to see since launch, just through the fifth quarter, and we're learning a lot about the market.

We do know that during the summer months, we saw a lot of the physicians out of office. We have people obviously taking vacation. Patients are taking vacations. They just weren't in the office as much. There was typically, if you look at claims, about a 7% to 10% decline in Q3 from Q2, as far as the claims go.

But Jeff, we're really confident if we go forward in time that our base business is very strong here. Toward next year in Q3, we look back, we'll have very meaningful growth revenue. We do anticipate acceleration as we go into 2027, Q1, Q2, just based on what we've learned this last year.

Sai, I don't know if you want to comment a little bit more on the dynamics with the HCPs.

Sai Rangarao

Sure. Thanks, Scott. Hi, Jeff. This is Sai.

Just in terms of the qualitative feedback, we consistently hear the Zelsuvmi profile and the clinical profile amongst our data across efficacy and safety is still considered very, very high, very valuable to those respective practitioners. Even as we saw in our Q2 results and the overall growth that we had, which we were hitting our all-time highs, as expected, some of the fluctuations, as Scott mentioned, are tied to seasonality and some of the points that you made around colder months, but we still see a high level of utilization, a high level of adoption across several tiers of our prescribers, which again instills our belief going forward.

Scott Plesha

I'll just add, I think one of the important concepts and one of the things we're seeing, we're continually adding new prescribers, and I think that will serve us well as we go forward in the future. Really, we've seen—that's been very strong, just the number of new prescribers from week to week, month to month basis.

On the Xepi front, specifically around resistance, we've actually worked with thought leaders to try to identify that and some of the really foremost leaders there. The data is a little bit all over the board right now. The issue we have is a lot of hospitals and organizations are not really testing to actually draw real numbers there. I do think there's an interest in the physician community to mine that and also to start sharing their thoughts on that and in the literature, so I think you might see some of that here in the near future.

Regarding SG&A and Xepi, I'll let John maybe chime in on that.

John Gay

Good morning, Jeff.

As it relates to that, if you look at our financials, we've been preparing for that both from a manufacturing perspective and also from a commercialization. If you look at our run rate of SG&A, as I've touched on in my prepared remarks, that includes preparing the market and preparing for launch for next quarter for Xepi. I think it's fair to say that that spend level is not going to change materially specifically for Xepi going forward.

Jeff Jones

Great. Thank you, guys.

Scott Plesha

That's one of the powers of that launch, obviously, is that we can leverage our infrastructure there.

Jeff Jones

Thank you.

Operator

Thank you. Our next question comes from the line of Thomas Flaten with Lake Street Capital. You may proceed with your question.

Thomas Flaten

Hey, good morning. Thanks for taking the questions. I'll gamble a little bit on a Castle Creek question.

Scott, I was curious if you could maybe peel back the curtains a little bit on the thinking that pushed you to evolve from a traditional spec pharma model into more of a biotech model. What were the discussions that precipitated that?

Scott Plesha

Thomas, I think we've been very open about being aggressive on acquisitions. We've seen that—we formed a company back in July of 2025 and already acquired two other assets. As we were looking out in the marketplace, what else would make sense, we wanted first off for it to fit our current model. When we started looking at D-Fi, it's just a perfect overlay with our thought leaders, especially in the pediatric derm space, a lot of synergy. We have this base business that we're building that can actually help fund this pivot also as well as we go forward, so two more launches next year supporting this. But for us, it was also making the pivot to this biotech company that unleashes and uncaps the value of the company going forward. Just a whole different profile on the product.

I have Peter Greenleaf here also, who's our Executive Chairman, and I'll let him weigh in as well on that.

Peter Greenleaf

Hey, Thomas.

Listen, I think Scott did a really nice job of covering this strategic rationale, but just a few things to add.

One, this pivot from a classic specialty pharma company into more of a research and development-oriented diversification of a biotech was critically important.

Castle Creek brought to us a late-stage asset, the diversification and pipeline orientation, a rare disease asset, but completely aligned with our therapeutic area, solid data in the early stages of development, a large, still unmet medical need market. When I say large, this is a rare disease market, but in terms of the potential opportunity of the Company and the opportunity for the Company to make an impact on the disease, there still is an unmet medical need.

We think this is differentiated, and to go backwards a little bit into the question that was asked about how D-Fi potentially differentiates, the one thing we can say that's out there publicly is, one, that the current methods of treatment that are out there are more oriented around either skin graft or live virus orientation with somewhat of a burdened administration. What we do know from the early data is that we do not have a live virus orientation. And two, that there could be potentially better benefits to dosing this product, but we have to complete the Phase 3 trial. So there are points of differentiation.

I guess I would say, lastly, this gives us yet another shot on goal. We think we did it for the right value. To get a late-stage asset for the amount that we paid up front and the milestones that we've seen, at least as we've benchmarked it through other deals, we actually believe we got a good value in terms of the acquisition and the merger.

I'll leave it there. Thomas, have you got another question?

Thomas Flaten

Thank you for that insight.

Just a question for Sai. Any commercial realignment, mostly in the sales footprint side, that you need to undertake ahead of the Xepi launch, and then obviously just two quarters later with Xeglyze, are you pretty confident that the current alignment will allow you to launch both of those equally safely and successfully?

Sai Rangarao

Thanks for the question, Thomas. I think what we've said previously is right now, we feel like our alignment and our overall footprint is poised for growth amongst our Zelsuvmi targets and as we go into the Xepi model. However, what Scott and I have talked about extensively is we'll always take a closer look at specific territories where we might be able to get a little bit more breadth and also continue our depth strategy across our targets.

As we go into the Xepi launch, there might be the opportunity that we might add some territories, and that might be more in the single-digit range there, Thomas. Then the evaluation for Xeglyze will continue as we get closer to that launch, probably within the spring, summer of next year. But again, we're always looking at the opportunities in front of us to ensure we have the optimal field force to cover our targets.

Scott Plesha

Thomas, this is Scott. I'll just weigh in a little bit more.

We always use the word optimization, and I think we've been thoughtful and earned the right to expand previously. We did 14 in the beginning of the year, and then another 3 mid-year. Each time we've done that, they've paid for themselves in a very short period of time, actually brought in incremental revenue.

Sai mentioned we could add more reps. We're always going to probably say we could add a handful of reps here or there, just to make sure we're maximizing our growth and opportunity. So, we'll do analysis. If we feel we can bring in incremental revenue above the cost of a rep that's meaningful, we'll consider it. But we want to make sure we pay for that very quickly if we do it.

Thomas Flaten

Thank you all. Thank you.

Sai Rangarao

Thank you.

Scott Plesha

Thanks, Thomas.

Operator

Thank you. Our next question comes from the line of Brandon Folkes with H.C. Wainwright. You may proceed with your question.

Brandon Folkes

Hi. Thanks for taking my question and congrats on the quarter.

I'll stick to Zelsuvmi for two. I think we've asked a few on the acquisition.

Maybe just if we think about the current Zelsuvmi script trend, how do we think about growth in 2027? Is that just a continuation of the momentum we're seeing today? Or as you see these increased formulary coverage, do you expect any sort of stepwise function?

I'll ask a second because it sort of follows on to that, if I may. Any update on the pediatrician penetration? Does the call frequency to pediatricians change as you add these two additional products in 2027? Thank you.

Scott Plesha

Maybe we'll let Sai talk to the peds space and then I can talk about trajectory. Quickly, Sai.

Sai Rangarao

Sure. Thanks, Brandon, for the question.

From a pediatric coverage perspective, I think as we've mentioned, we have almost equal coverage amongst the dermatology specialty, which is inclusive of pediatric dermatology. But specifically the general peds category, we have equal coverage and equal footing there, and we see the growth there continue. We have some regions across the country that are doing exceptionally well within that specialty category, and that continues again because they're a big part of our coverage. They're also the first line of defense for all the disease states that we are going into market with even in the future, so that will continue as our focus.

As we get into the Xepi planning, that is a bigger part of our calibrated efforts of just the hyper-targeting efforts, which may potentially allow us to concentrate even further as, again, they are the true first line of defense for these disease states. But as we do see ourselves today, the coverage, the overall approach, again, has been optimal for where we're going forward, and I think dovetails nicely into what we expect for growth, even out of Zelsuvmi going forward.

Scott Plesha

I'll comment on the growth concept. Really what we expect is consistent growth going forward.

To your point on the market access, we really haven't seen the impact of that yet fully. Those take time. Those take multiple quarters to really recognize the benefit of that.

We made an investment. That's why our gross-to-net, I would say went up modestly. It was very minimal. That was a PBM that we decided to contract with that also has the opportunity to unlock additional lives in the future also, we have work to do there—we'll see if that happens—but at a very reasonable rate. To your point, as we add those additional plans, we could see additional uptake over time as well there.

But I think I said it earlier, we're confident that we're going to see growth in this product going forward. You look at October, it was our second highest month ever. It actually was up 4% from September, which is, I think, a good sign of the market recovering. We're seeing good early signs also in November here. We are coming up against some holidays, which people aren't in practice. People aren't being seen by doctors. But then we believe Q1/Q2, we'll see very strong growth again once we get through that holiday period.

Peter Greenleaf

I guess the one thing I would just add to Scott's comments, as we look at this at the Board level and for the Company, there are very few companies out there that have complete strategic alignment towards the peds, peds derm target, so we have a leveraged OpEx base and sales force.

We have a current in-market product that's continuing to show robust growth. Then we have two products that we're launching and a diversified pipeline down the road that's in late-stage development that will be a contributor to that.

So, a base operation that can produce cash flows to be able to fund a pipeline into the long term, I think, is a message that, at least in the early coverage of the Castle Creek deal, that's been missed, that there are very few comps out there that you can find of companies like ours that are trading at the level that we're currently trading with the level of revenue, future commercial diversification and now pipeline diversification.

Brandon Folkes

All right. Thanks very much. Thanks for taking my questions.

Scott Plesha

Thanks, Brandon.

Operator

Thank you. Our next question comes from the line of James Molloy with Alliance Global Partners. Your line is now live.

James Molloy

Hey, guys. Thank you very much for taking my questions.

I wanted to follow up on the Castle Creek. Again, noting there's not too much you can talk about, but there is the public data out there that Castle Creek put out on their Phase 1/2 and their wound healing. I'd love to get your thoughts on what you saw in there that you liked in particular as it relates to what's out there with Zevaskyn and Vyjuvek. Could you talk a little bit about the relative positioning, again, should D-Fi ultimately get approved, versus those other two assets that are already out there on the space?

I'll hold for a couple of follow-ups.

Peter Greenleaf

I'm happy to start. Listen, we've got to conduct a Phase 3 trial, so all of this is with the caveat that this is a super rare disease. The data even for Vyjuvek and as another company out there, Abeona, has been a limited number of patients, but in a small rare disease, obviously, that limited number of patients have been what has driven approvals.

As I mentioned earlier, as we look at the comparable set of potential newly launched products, first, we don't see this as anywhere near comparable to Abeona's product. Abeona's product is a skin graft. It has more intensive in terms of its application, etc. As we look at this, it's more akin to a Vyjuvek. It doesn't have the live virus orientation. It potentially has better dosing and administration benefits that we have to prove through the Phase 3.

As you mentioned, you've seen the data that's out there in the earlier stages of development. We're encouraged by it. We think the patients that have seen impact with the drug have seen pretty solid wound closure and healing that we think was a big part of, when we did diligence on the product, what we believe it'll actually show through in the Phase 3 study. But obviously there's more to come. We've got to do the study. We'll have more disclosure in the upcoming S-4 and as we roll this out, when we hope the deal closes in the near future.

Scott Plesha

The one thing I'll add here just quickly, Jim, is that we did a lot of diligence. We're very fortunate to have very strong relationships with KOLs in the derm and ped-derm space. A lot of them were involved with development in these areas of the other products. They know it very well. They speak about it. We got a lot of validation from them based on that data that you just referenced early on. We spoke to the top tier people around this and ultimately they kept coming back and saying there's a need in the market. This will be used first line and/or in combination because there's just such a wound burden here that the current products in the market are just not meeting all the needs.

We felt very good about these individuals. I mean, these are worldwide experts. These are the top of the top tier KOLs. That gave us even more confidence as we looked at it.

James Molloy

Great. Thank you. A quick follow-up on Zelsuvmi. Obviously, as you said, it's the first year of launch. There's still a lot of learnings. What learnings do you guys think you'll take into next year's back to school from this year's to drive growth? What's the counter-detail from YCANTH? Do you guys talk about it or they talk about you? What anecdotal stories are you guys hearing from the field, if any?

Sai Rangarao

Jim, I'll answer both those questions. This is Sai.

From a learnings approach and how we're going into next year, I think the back-to-school category at times, while we feel like that's, let's call it, "opportunistic" for disease manifestation or growth, at the same time, as we've discussed here, a lot of the vacation scheduling, the HCPs in and out of office has that level of disruption. A lot of what we believe we can control are still our educational methods via conferences, via digital mediums. We do intend on actually launching even more awareness campaigns next year that will target maybe even the teens category and other categories that we know are affected by molluscum. Those will actually truly help us grow more notoriety, more connection, and ultimately conversion. I think as you've seen throughout this first year, all those efforts have proven to be incredibly helpful and incredibly beneficial for our patients and ultimately the business as well.

Just the other point on the counter-detailing pieces, I think we have visited this question a few times in this forum. I'll repeat that again, we never counter-detail against any other product. We stay true to our clinical profile on efficacy and safety. At all times, our field force is trained to be compliant on those messages and to share them very informatively and confidently amongst our HCP customers across the board. We affirm to that, and we really stay true to our profile as the first and only at-home prescription treatment for molluscum for which we feel incredibly confident with, and again, affirms our confidence and our consistent approach to growth as we go forward into next year.

James Molloy

Thank you very much for taking questions.

Sai Rangarao

Thank you.

Operator

Thank you. Our next question comes from the line of Olivia Brayer with Cantor Fitzgerald. You may proceed with your question.

Olivia Brayer

Hi. Good morning. Thank you for the questions. I have a couple of follow-ups.

First one on Zelsuvmi launch dynamics. Are you guys seeing an increase in prescriptions that are being written that maybe just aren't yet translating into filled prescriptions? Or has prescribing activity itself been relatively flat?

Among physicians who are already starting to use Zelsuvmi, are you seeing them prescribe it maybe more frequently over time or getting more patients on drug? Then I've got a follow-up on Castle Creek.

Sai Rangarao

Hey, hi, Olivia. This is Sai. I'll take those questions.

From an overall prescription to fulfillment standpoint, we don't see much change from a granted approval rate to then pick up. Those are typical dynamics in an acute market, and I think those have remained stable. I think from what we've seen throughout the summer months and obviously as we talked about the fluctuation as it pertains to MC claims, we still grew in the quarter and we are seeing really promising growth here in October over September, as we've mentioned.

The overall cohort of clinicians that have a strong level of adoption continues. We have several physicians that have reached these higher tiers of consistent prescribing. Also, our refills quarter over quarter exceeded close to 22%, which really speaks to the consistency and continuity of therapy, which again is our message. It's what we really go out there educating the field force on literally every day. Those measures have helped, and I think those are also elements that, again, affirm our confidence going forward.

Scott Plesha

Olivia, if I can add just a couple of things.

I'm trying to peel back your question a little bit here, but it sounds like you're trying to understand if there's some kind of prescription fulfillment issue.

Honestly, what we're seeing, number one, is a higher approval rate over time, and adding the plan we just did, it will only help for that as well. Then also the time to fulfillment, so some of the metrics that are really important. When a prescription gets submitted, those have increased. I'm sorry, the days to get it filled actually has improved, so it's gone down, the amount of time. Some of the dynamics, I think, that are important that we track monthly have actually gotten better.

Sai mentioned the refills. We have seen a little bit of a lift in the number of units per patient also, slightly. It's gone from just over 1.2 to just over 1.3 in the last couple of months. We see that as a good sign as well.

Olivia Brayer

Okay, that's helpful.

Then on Castle Creek, I'm sorry to ask another follow-up, but how are you guys thinking about value creation as an opportunity, just relative to the level of dilution that does come with this deal? I think most people were surprised to see this deal, especially just given how early you are into Zelsuvmi's launch still. Anything that you can say about maybe how the transaction came about or why now was the right time, I think would be helpful.

Peter Greenleaf

I guess just to go back to this strategic rationale, I think if you look at—and at least at what I've seen printed so far, I haven't seen many pick up the benefits. I have seen some pushback on, sort of behind what your question is here, Olivia, but let me go into first benefit, then I'll get into where we see the near-term or future value creation.

One, we took a very strong and growing, strategically aligned commercial organization that's got a capability that's launched one product, is growing one product. We have the benefit of being able to launch two new products in the next, call it, 12-month time period to continue to grow our revenue base. And as we're doing that, we want to always continually think about how we're growing and diversifying.

We had the opportunity come along both through relationship and through doing an external scan to bring in this potential late-stage asset that takes our commercial organization and capability, completely aligns with it, gives us the ability to work the cash flows that will eventually generate from that commercial business and put them towards the development of a pipeline, so there's less dilution in that. We could have gone out and done a deal, had it be a license or had it been a cash-based transaction, where we would have had to raise money if we didn't have this commercial business, so we look at that as a potential huge benefit.

It brings us into the rare disease space. It gets us out of just a value orientation and puts us into a growth biotech orientation and puts us into what is a very large market opportunity still with unmet medical need.

All for the price of—and again, I haven't seen many people do comps of what late-stage asset deals cost today—but for an upfront consideration of equity and, if successful, milestone payments upon data and approval of the drug. If you add those three up, the amount that we paid was, I believe, our Board believes, a huge value to the organization.

Olivia Brayer

Okay. Thank you, Peter. Appreciate that color.

Operator

Thank you. We have reached the end of the question-and-answer session. I'll now turn the call back to Scott Plesha, Pelthos' CEO, for closing remarks.

Scott Plesha

Thank you, Operator. I want to thank everyone for joining today's call. I'd also like to thank the Pelthos employees for their continued focus, execution, hard work and dedication to supporting patients, caregivers, and healthcare providers.

Thank you again for joining our call and we look forward to updating you on our progress in the future. Have a great day.

Operator

Thank you. This concludes today's conference and you may disconnect your line at this time. We thank you for your participation.

Cautionary Note Regarding Forward-Looking Statements

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- the risk of any litigation relating to the proposed transaction;
- the risk that the proposed transaction and the related announcement could have an adverse effect on the ability of Pelthos and/or Castle Creek to retain and hire key personnel;
- the risk that problems may arise in successfully integrating the businesses of the companies, which may result in the combined company not operating as effectively and efficiently as expected;
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- the limited operating history of each company and their significant net losses incurred since inception;
- the need to raise additional capital to finance operations;
- uncertainties related to commercialization or market acceptance of FDA-approved products;
- the ability to advance product candidates through preclinical and clinical development;
- the ability to obtain regulatory approval for, and ultimately commercialize, the combined company's product candidates;
- the outcome of early clinical trials for product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements;
- the ability of Pelthos, Castle Creek and the combined company to protect their respective intellectual property and proprietary technologies;
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