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Pfizer Inc.

Metsera, Inc., Pfizer Inc. - M&A Call

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Operator Operator

Good day, everyone, and welcome to Pfizer's Analyst and Investor Call to discuss proposed acquisition of Metsera. Today's call is being recorded. At this time, I would like to turn the call over to Francesca DeMartino, Chief Investor Relations Officer and Senior Vice President. Please go ahead, ma'am.

Francesca DeMartino Executive

Thank you, and good morning, everyone. I'm Francesca DeMartino, Pfizer's Chief Investor Relations Officer. On behalf of the Pfizer team, thank you for joining us. This call is being made available via audio webcast at pfizer.com. Earlier this morning, we announced our proposed acquisition of Metsera and its next-generation obesity portfolio.

The press release we issued is available on our website at pfizer.com. We will start today's call with some prepared remarks, followed by a question-and-answer session. I'm joined today by Dr. Chris Boshoff, our Chief Scientific Officer and President of Research and Development; Dr. Andrew Baum, our Chief Strategy and Innovation Officer; and Dr.

Jim List, our Chief Internal Medicine Officer.

Before we get started, I want to remind you that we will be making forward-looking statements and discussing certain non-GAAP financial measures. I encourage you to read the disclaimers in our slide presentation, the press release we issued this morning and the disclosures in our SEC filings, which are all available on the IR website on pfizer.com. Forward-looking statements on the call are subject to substantial risks and uncertainties, speak only as of the call's original date, and we undertake no obligation to update or revise any of the statements.

Today, we will discuss why Metsera is a strong strategic fit for Pfizer and provide insight into why we believe Metsera's assets have the potential to be an important therapeutic option for the

treatment of obesity and other related indications, which, in addition to oncology, have the potential to be a key driver of growth for our business.

Turning to the financial details of the transaction. Pfizer has agreed to acquire all outstanding shares of Metsera for \$47.50 per share in cash, representing a premium of 37% versus the 60-day rolling average. This results in a total transaction enterprise value of approximately \$4.9 billion. Additionally, the agreement has been structured to enable Pfizer to pay for successful development through the contingent value right or CVR. One CVR per share will entitle its holder to deferred cash payments totaling up to \$20.50 tied to 3 specific clinical and regulatory milestones for MET-097, which is a GLP-1 receptor agonist and MET-233, an injectable amylin analog.

Specifically, \$5 per CVR following the Phase III start of Metsera's monthly injectable 097 and 233 combination, \$7 per CVR following FDA approval of Metsera's monthly injectable 097 monotherapy and \$10.50 per CVR following FDA approval of Metsera's monthly injectable 097 and 233 combination, if achieved.

The transaction is expected to be financed through a combination of available cash and new debt. The proposed transaction is subject to customary closing conditions, including the receipt of required regulatory approvals and approval by Metsera shareholders and is expected to close in the fourth quarter of 2025. In terms of guidance and financial impact of Pfizer, we expect to provide an update during our quarterly earnings call. With that, I will turn the call over to Chris.

Chris Boshoff Executive

Thank you, Francesca. We are excited to be here today to share insights on our proposed acquisition of Metsera and how this opportunity seamlessly aligns with Pfizer's strategy from discovery and development through to commercial. At the start of this year, we streamlined Pfizer R&D to form a fully integrated organization spanning targeted product discovery, clinical development, global regulatory operations and medical affairs. This integrated structure provides global scale and efficiency with minimal handoffs designed to accelerate product development.

As part of streamlining our approach to R&D, we sharpened our focus to core therapeutic areas: oncology, vaccines, internal medicine and inflammation and immunology. We list key pipeline programs that represent our next wave of potential breakthroughs, many with pivotal trials already in progress. Each of these programs have the potential to provide meaningful impact to patients and to Pfizer. With today's announcement, we are reaffirming our commitment to internal medicine, which along with oncology is expected to be among the largest pharmaceutical opportunities going forward.

Today, I'm thrilled to discuss why we are eager to augment our internal medicine pipeline with Metsera's highly differentiated peptides, which can both complement and transform our internal medicine portfolio. Acquiring a portfolio of clinical stage and preclinically potential best-in-class injectables with anticipated monthly long-term dosing regimens will support our ambition to deliver substantial value to patients and to our shareholders. With that, I'll now turn the call over to Andrew, who will provide an overview of this exciting opportunity for Pfizer.

Andrew Baum Executive

Thank you, Chris. We are, and let me underline this, very excited to announce this transaction, which we believe positions Pfizer to lead in one of the most dynamic and high-growth

therapeutic areas, obesity and its comorbidities. We evaluated multiple external opportunities in the obesity space and were exhaustive in our analysis and diligence to make sure we identify the optimal opportunity that delivers compelling potential differentiation across key asset attributes. As you are all aware, obesity and its associated conditions are on track to become the largest pharmaceutical opportunities with incumbents setting a high bar for innovation.

And while there are multiple successful products on the market, significant unmet medical need remains, and there is a potential to deliver truly differentiated products that can capture market share in this rapidly growing \$100-plus billion market. Our decision to acquire Metsera is grounded in a clear thesis that we believe provides a path to leadership. Differentiated science and scalable platforms with potent and durable peptides that may enable tenfold lower doses than some approved products for a very attractive cost of goods.

We believe this portfolio offers the potential to reshape the treatment landscape, bring innovative products to patients and deliver attractive returns to our shareholders. We've taken a disciplined data-driven approach, evaluating strategic fit, product quality and potential for long-term value creation. Regarding our industry-leading commercial excellence in cardiometabolism, Pfizer has a proven track record of entering competitive markets and emerging as a leader. We did it for Eliquis, we did it for Lipitor and for Norvasc, and we plan to execute in a similar way with Metsera's unique investigational medicines.

We also plan to apply our experience pioneering and growing cardiometabolic markets gained through our VYNDAMAX franchise. Our commercial infrastructure includes one of the largest primary care field forces globally and our unique PfizerForAll platform. This infrastructure as well as our world-class R&D team are complemented by a global network of manufacturing sites, including 8 for sterile injectables, of which 4 are in the United States. As we look ahead, we are not just participating in the obesity category, we're aiming to define it.

And finally, moving to the price. We've been very conscious about our overall capital allocation strategy to ensure we are creating value for shareholders. We believe the deal terms, which include a risk-managed deal structure using CVRs, help share both the risk and upside with target shareholders. And among an evolving landscape for the industry and the overall competitive environment, we consider the full range of potential scenarios when aligning on price. With Metsera's differentiated science and Pfizer's commercial strength, we are confident in our ability to deliver for patients and for shareholders.

We look forward to additional data from Metsera's portfolio in the coming months that we believe will validate our excitement. Subject to clinical and regulatory success, we anticipate Metsera's pipeline will deliver a series of launches beginning in the 2028, '29 time frame that would accelerate our growth trajectory following our major loss of exclusivities. I'll now turn the call over to Jim List, our Chief Internal Medicine Officer. Jim joined us from J&J, where he led R&D across their cardiovascular and metabolism portfolio. Jim?

James List Executive

Thank you, Andrew. I am pleased to be at Pfizer. And since joining, I've quickly seen the depth of scientific expertise and world-class capabilities that leave us positioned to win in obesity. Bringing in the Metsera portfolio will be transformative to our work in internal medicine. The Metsera portfolio is highly differentiated, driven by proprietary peptide platforms that can bring real innovation and advances to the obesity segment with 4 programs already in the clinic and additional in preclinical development.

MET-097i Metsera's ultra-long-acting next-generation injectable GLP-1 receptor agonist currently in Phase IIb. We believe it has potential best-in-class efficacy, differentiated tolerability and it's in development for both weekly and monthly dosing. We anticipate Phase III trials for weekly and monthly MET-097i to begin by the first half of 2026 and in the second half of 2026, respectively. MET-233i is an ultra-long-acting amylin analog being evaluated in the clinic as a single agent and in combination with MET-097i. When combined, we believe these agents have the potential to deliver category-leading efficacy and competitive tolerability with monthly maintenance dosing, positioning it to be a highly competitive and convenient treatment option in the evolving obesity landscape.

The Metsera portfolio also includes earlier-stage oral peptide programs for both GLP-1 and amylin with the potential to deliver differentiated oral medicines with no food or water restrictions. An additional potential upside comes by Metsera's peptide discovery engine, which is being leveraged to advance the next-generation GIP receptor agonist and glucagon analog, along with the GLP-1 receptor agonist that could potentially be injected quarterly. The clinical and preclinical data from Metsera are compelling.

Next slide, please. There we go. Clinical and preclinical data for Metsera are compelling. Based on what we've seen, and we've done deep diligence here, we're highly confident that the Metsera portfolio has the potential to deliver peptide therapies that are highly differentiated across a number of key attributes. From a clinical perspective, we've seen encouraging results that show Metsera assets are potent with robust weight loss observed at low doses, tolerable with encouraging GI adverse event profiles that appear to be placebo-like at starting doses and durable with PK profiles that are compatible with monthly maintenance dosing.

In addition, Metsera's peptides are combinable with complementary PK profiles and solubility to enable fixed dose combinations. And finally, the Metsera peptides are scalable with attractive cost of goods due to low API and device requirements resulting from high potency and monthly dosing, respectively.

Moving now to what gets us really excited, the data. MET-097i is a fully biased injectable GLP-1 receptor agonist currently in development for both weekly and monthly dosing. Here, we see results from the Phase IIa study evaluating once-weekly dosing of MET-097i for 12 weeks, both without and with titration. On the left, we see mean percent change from baseline in body weight over time, showing dose-dependent decreases in weight continuing through day 85 with no observed plateau, suggesting the potential for additional weight loss with longer duration of dosing. On the right, we see mean placebo-adjusted percent change from baseline in body weight at day 85, with reductions ranging from approximately 6% to 11%.

After only 12 weeks of dosing, these data are compelling, and we believe they have the potential to translate into best-in-class efficacy.

Moving next to tolerability. The MET -- the Phase IIa data suggests MET-097i may have a differentiated profile. Looking across the key gastrointestinal adverse events of nausea, vomiting and diarrhea with once weekly dosing up to 12 weeks without titration, we see what would be considered an acceptable tolerability profile in the GLP-1 receptor agonist class. However, looking at the data with titration highlighted in blue at the bottom of the table, we see an extremely favorable tolerability profile with 5% of participants reporting nausea, 10% of participants reporting vomiting and no diarrhea. Also of note is that this encouraging tolerability profile was achieved with only 2 titration steps.

On this next slide are some of the data that support the potential for monthly maintenance dosing with MET-097i, which may be a key differentiator. Starting on the left, we see a PK profile showing an observed half-life of approximately 18 days, which supports monthly dosing. On the right are additional weight change data from the Phase IIa trial discussed in the prior 2 slides. In this study, participants followed their weekly -- their 12 weekly doses with a single monthly dose that was fourfold higher than the weekly dose. Notably, additional efficacy is seen after the switch from weekly to monthly while also being well tolerated with mean placebo-adjusted weight loss exceeding 14% at week 16 in the higher dose group.

MET-233i is an ultra-long-acting amylin analog injectable engineered for class-leading durability, potency and combinability with MET-097i. Here, we present data from a randomized placebo-controlled double-blind Phase I study, which evaluated the pharmacokinetics, efficacy and safety of MET-233i in participants with overweight or obesity without type 2 diabetes. On the left, are efficacy data, which demonstrate dose-dependent placebo-adjusted body weight loss of up to 8.4% after 5 weekly doses of 1.2 milligrams. These results are suggestive of class-leading efficacy.

On the right are tolerability results from the study, which further enhance the differentiation of MET-233i. Without titration, gastrointestinal events were generally mild, dose-dependent and primarily confined to the first week of dosing. Highlighted in light blue are potential starting doses for future studies, which, again, without titration, have tolerability results, which are comparable to placebo. And given the tolerability profile observed, we expect that titration may lead to further improvements in tolerability at higher doses.

A key driver of the Metsera value proposition lies in the potential to deliver what could be a first-in-category monthly GLP-1 amylin combination with potential for differentiated efficacy and tolerability shown clinically for both MET-097i and MET-233i, demonstrating the combinability of these agents as the remaining crucial element. On the left, Phase I data for MET-233i showed dose linear pharmacokinetics with an observed half-life of 19 days among the most durable PK profiles in the amylin analog class and also supporting monthly dosing.

On the right, we see the solubility of MET-097i and MET-233i peptides at different pHs, showing that both are combinable in a single formulation. Critically, the exposure profile of MET-233i after multiple doses is similar to that of MET-097i, which supports the potential of combination development of MET-097i with MET-233i as a first-in-category once-monthly GLP-1 receptor agonist amylin combination.

Here we show emerging data from a single ascending dose study evaluating the MET-097i/MET-233i combination. While early, these data provide positive signals for the development of this potentially first-in-category monthly treatment. First, they identify well-tolerated starting doses with no vomiting and relatively low levels of nausea and diarrhea seen in the first 3 dose levels on the left. Second, they demonstrate that additive weight loss can be achieved when combining MET-097i with MET-233i as can be seen from the groups highlighted in green on the right side. Taken together with a single agent, these combination results are highly encouraging and support our bold ambitions for Metsera's portfolio subject to closing of the proposed transaction.

And with that, I'll hand it back to Chris.

Chris Boshoff Executive

Thank you, Jim. As you are all aware, obesity is a complex medical condition that is associated with over 200 comorbidities that span many systems. The impacts of obesity are profound and growing, impacting over 1 billion lives globally. Our initial Phase III plans will focus on core obesity and associated morbidities with the ability to differentiate across efficacy, tolerability, combinability and monthly dosing.

However, the breadth and potential indications for GLP-1 and amylin offer significant room for expansion. This includes both weight-dependent and increasingly weight independent mechanisms with applications across multiple diseases as a backbone therapy with the potential to synergize with our broad portfolio of medicines in development. The proposed acquisition of Metsera may propel us into a new era of internal medicine at Pfizer, seamlessly integrating with our strategy, heritage and world-class capabilities. Metsera's differentiated portfolio and platform are poised to deliver potential category-leading medicines for efficacy, differentiated tolerability and monthly dosing.

The next 12 months are catalyst-rich with important data readouts expected across the MET-097 and MET-233 monotherapy and combination programs as well as an anticipated Phase III program start for MET-097 and the initiation of the oral peptide clinical programs. Taken together, the Metsera portfolio has the potential to deliver competitive efficacy with a step change in tolerability, convenience and scalability.

With the Metsera portfolio and with our internally discovered investigational medicines, we will aim to reestablish leadership in internal medicine and primary care. Together, we anticipate the Metsera portfolio has the potential to be a key growth driver for Pfizer in the late 2020s and beyond, and we look forward to a potential acquisition close in the fourth quarter of this year. With that, we'll now open the call to questions. Operator?

Operator Operator

[Operator Instructions] We'll take our first question from Mohit Bansal with Wells Fargo.

Mohit Bansal Analyst

Congrats on the deal. My question is regarding the development plan as well as VESPER-1 and 3 data. So first of all, have you seen any of those data, VESPER-1 and 3 data before making this acquisition? And number two, how do you envision the development plan for GLP-1 here given that Lilly has done extensive trial? It seems like you talk about obesity-related comorbidities.

So is diabetes in the mix as well? How are you thinking about running an extensive program here?

Chris Boshoff Executive

Thank you very much for the question. Just regarding the due diligence, as Andrew pointed out, we did very thorough due diligence and a way of data that's currently in progress and that Metsera will share in the coming weeks and months. So yes, we are very comfortable with the data we've seen and also the data, obviously, we presented today. Jim?

James List Executive

Yes, absolutely. We've done diligence across what's available right now. We are looking forward to catalysts coming in the future -- in the near future with more VESPER-1 and VESPER-3 data. And I think the second part of the question was on comorbidities, if I heard correctly. And

certainly, our initial aim is to develop these medications for obesity and overweight with comorbidities.

But we see great potential here because of their tolerability, because of the flexibility in dosing, because of the potential for monthly and combinability dosing to be able to go after some of these many, many comorbidities that plague mankind because of obesity. And so we definitely look forward to expanding our clinical trials program as we go forward.

Operator Operator

We'll go next to Dave Risinger with Leerink Partners.

David Risinger Analyst

Let me add my congratulations as well. So I wanted to ask a couple of questions, please. First, I think, Jim, you just commented that you will see more VESPER -1 and 3 data in the future. Can you just clarify exactly what you've seen to date and what you haven't seen yet that you'll see in the future, please? Second, you mentioned that you expect Metsera to disclose this data.

Could you talk about expected disclosure timing? And then third, if you could please talk about Metsera's oral peptide candidates in a little bit more detail and your level of conviction in the oral peptide opportunity?

James List Executive

Sure. So to begin with, we -- I just want to note that we still have to close the deal and undergo integration. So there's a lot of things that Metsera can answer much better than we can. What I can say is we've seen some of the data from VESPER-1 and VESPER-3, and we anticipate that further data, 28-week data will be coming out in the very near term from Metsera. With respect to the orals, that's also a place where we think it's a very differentiated set of assets because unlike the current peptide orals, which require absorption through the stomach and have food and water restrictions, what we have here are peptides that are stable enough to be at least preclinically absorbed through the gut, that means through the small bowel, the way that medicines normally are absorbed.

And because of this, we anticipate that there will not be food or water restrictions, which will make them much more convenient. But there's some additional things about the orals that are very exciting, starting with the fact that we're talking about peptides that have very long half-lives and are very potent. So we're talking about potentially a lower cost of goods and the ability to have a very tolerable profile because of the long half-life, you won't have the same sort of peaks and troughs that you might get with a small molecule or with a shorter-lived peptide. And so those are all very positive things. The orals are still in preclinical development, but we anticipate within the coming months to see orals begin to be dosed in humans, and that's when we'll really be able to talk about what we have here when we see the PK and the tolerability in single ascending dose situation.

Operator Operator

We'll go next to Evan Seigerman with BMO Capital Markets.

Evan Seigerman Analyst

Congrats on the deal. I'm sure it's been very busy on your end. Just in your due diligence, maybe could you expand a little more why you opted to go for the peptide route versus the small

molecules, especially on the heels of the enthusiasm at the [ASC] last week. Maybe characterize the challenges and issues you saw with the small molecule from your own internal experience and, of course, through your diligence.

Chris Boshoff Executive

Thanks for the question. I'm going to ask Andrew to address that.

Andrew Baum Executive

Well, look, there's -- I think for anyone to say there's not a role for small molecules in this market would be stating something that's probably untrue. However, I think this market is heavily differentiated and the peptides offer a very different set of solutions, both in terms of the dose scheduling, particularly with the ultra long-acting or ultra -- ultra long-acting within the Metsera portfolio, but also in the magnitude of the weight loss you can attain with our agents compared to what we've seen for some of the existing oral small molecules.

I would remind you, however, that we also have a portfolio of small molecules, including our oral GIPR, which is currently in a Phase II trial. And one of the things that we're also considering, and I'll let Jim and Chris talk to it, is the potential for co-formulating this with the Metsera oral peptides. And if we can do it, then that's something certainly we will look at. So over to Chris and Jim.

Chris Boshoff Executive

Jim?

James List Executive

Yes. I would add on, as I just mentioned, one of the big differentiators here for the oral peptide platform of Metsera is that the peptides are absorbed in the gut where other drugs are absorbed. And that makes it particularly amenable to combining with small molecules, which are absorbed in the same part of the gut. So we're very excited to see how we might be able to combine our small molecule GIP receptor antagonist. And of course, we've had our chemistry labs working for the past several years, developing other incretin and NuSH type analogs, both agonists and antagonists that will give us an armamentarium of possible oral molecules to combine together for solutions for patients.

Operator Operator

We'll go next to Umer Raffat with Evercore ISI.

Umer Raffat Analyst

Congrats on the deal. Two questions, if I may. And I just want to be very, very clear that this is something -- when you said you've looked at the data and you're comfortable, I just want to make sure I'm interpreting it right. Number one, there were 3 specific data points that were generated on VESPER-3 so far; a, the weight loss with titration being competitive with weight loss without titration from VESPER-1; two, they transition from weekly to monthly and that transition continued to keep the weight loss going. And number three, no major new GI issues during that monthly transition.

So could you confirm that you have a good sense around that and you're very comfortable because I think that's very relevant.

Chris Boshoff Executive

Thank you very much, Umer. Over to you, Jim.

James List Executive

Yes. I can confirm that we've seen data along those lines, and we are very comfortable. And one of the big questions, as I said, is, can you actually fourfold dose after weekly dosing. So we've seen we can titrate up. It's very well tolerated.

In fact, the tolerability suggests really class-leading tolerability. But then can you then give a fourfold dose and continue to do that month after month without having sort of reinitiation type tolerability issues. And what we're finding is because of the long life of the molecule, we're keeping the receptor agonized sufficiently that you do not lose that tolerability that you've achieved through the titration step. So that, along with continued weight loss, makes us very confident that this is going to be a super differentiated profile.

Chris Boshoff Executive

Umer, do you have an additional question? Otherwise, operator, we can move to the next.

Operator Operator

We'll go next to Kerry Holford with Berenberg.

Kerry Holford Analyst

Firstly, on the Phase III start, for MET-097. I think I heard you correctly say that you would start the weekly Phase III first half of next year and the monthly in the second half of next year. So just interested to hear why there might be a delay to starting that monthly study, more data required? Is it device related perhaps? Just any commentary you're willing to give there.

And then more broadly, I mean, clearly, there's a lot of competition coming, many of you and your peers working to bring products to market for obesity at the back end of the decade. So I would just be interested to hear what your assumptions are in terms of degree of competition, pricing, how much of the market do you expect to be funded via insured channels versus cash pay? And perhaps also what do you envisage in terms of the split between orals and injectables?

Chris Boshoff Executive

Thank you. I'll start with the -- your first question regarding timing. We're obviously going to learn more in the coming weeks between now and close and then provide more accuracy on timing. And the timing for the Phase III studies could be earlier, but we certainly do not want to overpromise at this stage. I'm going to ask Andrew to address the questions regarding market size and pricing.

Andrew Baum Executive

Well, I think just to repeat what I said in the script, and forgive me for not greater accuracy, but I called it a \$100-plus billion opportunity. And I think it's -- I think it's difficult to put an upper end on that where we are at the time. What is true that it is competitive. But hopefully, what you've heard from the comments already on this call is our excitement over the differentiation with the Metsera portfolio.

We believe it is truly foundational in defining a new standard of care for obesity and associated comorbidities because of the unique monthly scheduling, the ability to have a combination of both a best-in-class GLP-1 and amylin and an oral peptide platform, including the potential for a combination GLP-1 oral with unmatched efficacy. So we need to deliver on all of this. But if there's one thing that we want you to take away from this call is our excitement in relation to the data that we've seen, and we're looking forward to sharing that data with you in due course.

Operator Operator

We'll go next to Chris Schott with JPMorgan.

Christopher Schott Analyst

Congrats on the deal. Just 2 for me. First, can you just talk about manufacturing and capacity you'll have to make these products? Just what does the company already have in place? And how are you thinking about scaling that as you think about the commercial opportunity over time?

And the second one for me was just on the amylin space. We're obviously seeing a number of players moving assets forward here. Can you just elaborate a little bit more about the profile you're seeing with the Metsera drug and how that compares or differentiates from others in development? Is it -- just any additional color there would be appreciated.

Chris Boshoff Executive

Thank you. I'll start with that on the manufacturing. As you know, we've got extensive and existing network, both in the U.S. and abroad, specifically also for sterile injectables and oral expertise and with the proven capabilities in optimizing our COGS and we do not believe there will be any restriction on capacity or capability to deliver the portfolio and manufacturing. The second part?

James List Executive

Yes. With respect to the amylin, there's a couple of things about it that I think are differentiating. And the first one actually isn't the molecule itself, it's its combinability with the GLP-1 in a monthly format. That's really a potential first-in-class because while there are some fairly long-lived amylins, they don't have a partner GLP-1 to go with on a monthly format. But even there, this has to be one of the longest half-life amylins out there.

And we see and perhaps as a result of that, incredibly good tolerability and so when you take a well-tolerated GLP-1 combined with a well-tolerated amylin differentiated with both the tolerability and the ability to be dosed on a monthly basis with the GLP-1, I think that's where we get very excited about what this could do.

Operator Operator

We'll go next to Terence Flynn with Morgan Stanley.

Terence Flynn Analyst

Maybe 2 for me. I was just wondering if you can speak to how competitive the process might have been for the deal? And then the second one is with respect to upcoming Phase III trials. How are you thinking about the control arm in some of these studies, as I imagine the standard of care is changing across a number of these diseases as some of the other companies with

injectables receive approvals across a range of indications. So do you expect to have to do active control studies?

Or you think placebo-controlled studies will still be possible?

Chris Boshoff Executive

Thank you very much. Regarding the competitive process, we won't comment on the competitive dynamics of the process. However, Metsera's proxy statement will be filed with the SEC in the coming weeks, and that will provide information regarding the process. And I have to point out that Metsera has shown its continued confidence in us and in the portfolio by agreeing to take some of the considerations as contingent value rights. Jim?

James List Executive

Yes. With respect to the trial design, while I'm not getting into specifics about it, we believe that across the program, there will be room for both placebo-controlled trials and head-to-head trials. And in fact, one of the advantages to this portfolio is its differentiation. So we actually look forward to proving the differentiation in head-to-head studies. But the first bread-and-butter studies of overweight and obesity with and without type 2 diabetes in the monthly study, those are most likely going to be placebo-controlled, very traditional trials.

Operator Operator

We'll go next to Geoff Meacham with Citibank.

Geoffrey Meacham Analyst

Congrats on the deal. Just have a couple. The first is, just given the longer dosing interval, are there out-of-the-box indications that you guys are considering? I know you mentioned diabetes, but thinking cardio or inflammation or maybe even neuropsych. And then the second question, obviously, data dependent, but how do you guys think about the markets by the time you launch?

Are you planning for perhaps a larger consumer-driven market with out-of-pocket costs being a big component? And if so, what investments can you make to that end?

Chris Boshoff Executive

Yes. Just on your -- the first part of your question, as we stated, we'll start with the core indications around obesity and the core associated diseases. But I'm going to ask Jim to expand a little bit on potential future opportunities and then Andrew, for your second part.

James List Executive

Yes. The actual -- the dosing interval, I don't think plays so much into which particular other indications that we pursue. Rather, it's understanding the match between the indication and the amount of weight loss that's needed. The dosing interval of monthly simply makes all of these possibilities easier to take for patients, more convenient. And again, these are all going to be very well tolerated in our estimation.

So that basically gives us a large number of possibilities, and we can tailor then which particular peptide and which particular dosing interval and which particular route of administration to the patient type and disease type that needs that amount of weight loss and is willing to take that kind of an injection or pill for that amount of time.

Chris Boshoff Executive

Andrew?

Andrew Baum Executive

Yes. No, I just -- before I talk about the self-pay market, I'd add on to Jim's comments that I appreciate that the monthly is getting the bulk of the attention because that's somewhat of a scarcity. But just to remind everyone, we are offering a weekly schedule, a monthly schedule and an oral. So we are able to serve different desires and needs for the patients within our portfolio.

So moving on to the second part of the question, which is self-pay market. Look, clearly, there is already a very substantial self-pay market that exists right now, both for the approved products as well as the compounders in the U.S., in Europe or outside the U.S., more importantly, it's likely to be a very significant market given the challenges associated with reimbursement, given the size of the patient populations there. Pfizer has extensive experience, and I'd remind everyone of the PfizerForAll platform, which already supplies a number of products, both as and indeed third parties direct to patients. So we believe that we are optimally situated to take advantage of all channels to serve patients' needs.

Chris Boshoff Executive

Thank you. And just to add that across indications, we believe a well-tolerated monthly dosing could have huge advantages, not just for maintenance, but also for convenience and for compliance.

Operator Operator

We'll go next to Carter Gould with Cantor Fitzgerald.

Carter Gould Analyst

Congrats on the deal. I guess for Andrew and Jim, your response to the earlier amylin question emphasized combinability. I guess based on your due diligence and your own view of the market, is there an internal view on the importance and attractiveness of amylin as a monotherapy? Or do you see this less important commercially or more just a step is opening up the combo? Any comments would be appreciated.

Chris Boshoff Executive

Jim first.

James List Executive

Yes. I think what we have is an embarrassment of riches. We have a lot of potential ways we can take things forward, a lot of offerings here, and we're going to consider what the role of a mono amylin is versus the other offerings. Again, the reason I think for highlighting the combination is because that can lead to unprecedented amounts of weight loss that can get at some of these populations such as the patients with BMI greater than 35 who are not adequately served with current offerings.

Andrew Baum Executive

I think Jim said it well, nothing to add.

Operator Operator

We'll go next to Rajesh Kumar with HSBC.

Rajesh Kumar Analyst

The first one is, after this deal, how would the balance sheet look? And what is the remaining capacity for future deals at the end of the year, if we could get some color around that. Second is that I appreciate the color on your strategic positioning that you could get monthly, weekly, oral -- it's a platform. You went for amylin plus GLP combination, but not a double or triple G, which there were a few assets out there which could have played into that. So any color on why amylin as a mechanism one for you would be very helpful to understand.

And finally, when I look at your commentary around developing around obesity and adjacent indications, would you be also looking at an outcome study? I would imagine you would need to, but is that something on the cards eventually? Or is it something which is more near term?

James List Executive

So let me start with the amylin. We certainly, in the discovery -- peptide discovery engine, a number of other peptides are being worked on from Metsera, including glucagon agonism. Amylin, we have to remember, has been put in humans since the launch of pramlintide. So there's a lot of human experience on the safety of amylin as a therapeutic. And again, we've got some very exciting results with this peptide.

But we will continue to look at a lot of possible peptide combinations as we develop more peptides in the Discovery Labs.

Now with respect to outcomes, yes, part of the large clinical trials package will include outcomes of a number of sorts. When you're saying outcomes, I'm assuming you're referring to cardiovascular outcomes, which will be important because we understand that weight loss and GLP-1 agents lead to cardiovascular outcomes, and we'd like to certainly demonstrate that and the possibility that with better compliance with monthly dosing and with greater amounts of weight loss, those outcomes may be even better than what's been appreciated so far. But for a number of the other comorbidities that we might pursue, again, those are outcomes that we would be looking at there because after all, what we're trying to do is improve the health and life of patients. And so really looking at hard endpoints is going to be an important part of that.

Chris Boshoff Executive

Thank you very much. Just on the first part of your question specifically regarding the capacity for further business development. As Dave Denton and Albert has stated earlier this year, we can have potentially up to \$15 billion available for business development. And we've now executed so far this year the 3SBio and now the announcement for the potential close for Metsera. So there's potential for additional room for business.

Thank you. We're now going to have the last question.

Operator Operator

Our final question comes from Courtney Breen with Bernstein.

Courtney Breen Analyst

What I wanted to just dig into a little bit is as you think about advancing into Phase IIIs and demonstrating differentiation, there's now, I guess, a lot more weight placed on the tolerability and the convenience as opposed to purely the weight loss. And so as you're going to design these studies and certainly, as there's been discussion previously with 097 that perhaps titration isn't needed. Can you talk a little bit about how you're trading off those optimization factors as we head into Phase III designs?

Chris Boshoff Executive

Thank you very much. I'm going to ask Jim to please answer.

James List Executive

I think what we're anticipating doing is having a small number of steps of titration for 097 and for 233 and then getting to steady state. And the profile we've seen so far, and this needs to be borne out with more study is if you do that, you can end up with a class-leading tolerability profile. And so that's what we're aiming towards, and that's what we look forward to studying.

Chris Boshoff Executive

Thank you very much, everyone, for joining us today, and we're looking forward to update you over the coming weeks and months as this progress. Thank you very much.