Pharming Group N.V. 2Q/1H 2025 Results Call

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Fabrice Chouraqui – Chief Executive Officer:
Good morning, or good afternoon, everyone. And welcome to our Q2 2025 Earnings Call.

So I'm Fabrice Chouraqui, the CEO of Pharming. And I'll be joined on this call today by Steve Toor, our Chief Commercial Officer; and Anurag Relan, our Chief Medical Officer. Next slide.

So on this call we will be making forward-looking statements that are based upon our current insights and plans. As you know these may differ from future results. Next slide.

Slide 5:
So as you saw in our press release earlier today, Pharming delivered a very strong quarter.

Total revenues grew by 26% in the second quarter of 2025 versus the same quarter last year and we delivered meaningful operating profit of US$12.9 million compared to a loss in the previous year. This number excludes about US$2 million in nonrecurring Abliva acquisition-related expenses.

Our strong top line growth was fueled by the continued significant growth of RUCONEST®, 28% year-on-year and the further acceleration of patient uptake on Joenja®, with the increase of patients on drug in the first half of 2025 already surpassing the total increase for all of 2024. The strong momentum for our two commercial assets support an upgrade to our full year 2025 revenue guidance, for which I'll provide more details later in the call. Next slide.

Slide 6:
Before we go into detail on our financial results and, obviously, on our recent regulatory and clinical development progress, I'd like to say that our results in the second quarter of 2025 are a good illustration of the solid growth foundation that we have built.

Over the past two years, Pharming has evolved from being a one-asset company to having two fast-growing commercial products and a high-value late-stage pipeline with two assets with over US$1 billion potential each.

RUCONEST® continues to grow double digits after 10 years on the market. With its unique value proposition for HAE patients, who experience more frequent and stronger attacks, and its very specialized manufacturing process, RUCONEST® is well-positioned to remain a foundational drug to finance the growth of our portfolio and pipeline.

Joenja® is only at the very beginning of its life cycle. It is the only disease modifying therapy, or DMT, for APDS. And in fact, it is the only therapy specifically approved for APDS.

Joenja® has several key short-term growth drivers in this indication with the reclassification of the U.S. patients, the pediatric expansion and the launch in key markets.

And the possible much higher prevalence of APDS as suggested by the June publication in *Cell* provides, in my opinion, a significant upside. The ongoing development of Joenja® in two larger indications for genetically defined PIDs with immune dysregulation as well as for CVID, has the opportunity to propel the brand to a whole new level.

And finally, KL1333 from the acquisition of Abliva is another high-value late-stage development asset, which has already successfully passed an interim analysis in a registrational trial.

So this unique combination of commercial and pipeline assets is very much the key reason why I joined Pharming six months ago, as I see the opportunity for significant value creation in the near term as well as in the long term. Next slide.

Slide 7: I also see great opportunity to build a leading global rare disease company by leveraging the strong rare disease capability platform that we have built over the years and that has yielded this strong performance in Q2.

I must say that I'm extremely pleased to see the excitement and the commitment of our employees to realize this vision.

So let me now turn to Steve Toor, who will provide you with more detailed information on the continued growth of RUCONEST® and the further acceleration of Joenja® patient uptake in APDS.

Over to you, Steve.

Stephen Toor – Chief Commercial Officer:
Thank you, Fabrice. Good morning, everybody. Next slide, please.

Slide 9:
So as Fabrice has said, RUCONEST® delivered a strong performance with double digit revenue growth of 28%, taking us to a revenue of US$80.4 million in Q2 of this year. And as you can see on this slide, this is being driven by the ongoing growth in prescribers.

Over the years, since launch back in 2015, we have consistently added new RUCONEST® prescribers, as they recognize the value RUCONEST® brings to patients suffering with moderate to severe hereditary angioedema.

In fact, we've added an average of 21 new prescribers in each of the past six quarters. And this leads directly to the continuing increase in new patient enrollments, which obviously translates to a volume increase over prior year, which is 27% in the U.S.

In part, the reason for this is RUCONEST® has a unique profile in the acute on-demand HAE market, which makes it an important treatment option for moderate to severe patients who experience more frequent attacks.

It is this differentiation in the acute HAE segment of the market that explains the strong momentum that RUCONEST® continues to have and the growth prospects we have for RUCONEST® over the long term. Next slide, please.

Slide 10:
Now, as I've said just now and in other calls, in RUCONEST®, we have a highly effective product that serves all patients within the HAE spectrum. That's type 1, type 2 and normal C1.

What all three groups have in common is they all suffer from moderate to severe debilitating HAE attacks and they have them frequently. They also have typically failed other single pathway specific targeted acute therapies, such as icatibant, which have either not been sufficiently effective or often the case, also leads to redosing.

In the photos on this slide, you can see an actual RUCONEST® patient at the start of the attack and then a recovery as it resolves at the 4-hour mark and then the 24-hour mark.

And this is exactly the type of patient I mean, with a more severe course of disease attacking frequently and having to re-dose on other therapies.

If you're an HAE patient with this disease profile, having RUCONEST® on hand, delivering complete resolution in a single dose for 97% of attacks with half getting complete attack resolution within 4.5 hours and the vast majority within 24 hours, RUCONEST® is both critical and reassuring.

In fact, I recently attended along with other staff members of Pharming the HAEA Summit in Baltimore, of which over 1,400 HAE patients attended.

This as regards to RUCONEST® is a sentiment I repeatedly heard.

And it's for these reasons that RUCONEST® will continue to have a strong position in the U.S. acute market and will remain an important product for our company in the years to come. Next slide, please.

Slide 11:
So switching gears now to Joenja® and the Joenja® launch back from '23. As with RUCONEST®, we've delivered a strong double digit revenue growth quarter-on-quarter of 15% with US$12.8 million in net revenue.

We also achieved a further acceleration in patients on paid therapy in Q2 with a 12-patient increase, doubling the 6 patients we increased in Q1.

Importantly, as you can see in this graph, that increase of 18 patients in the first half of this year exceeded the total increase for all of 2024 and these results reflect the excellent patient finding and conversion capabilities of our commercial team.

Importantly, we've also launched Joenja® in the U.K. in April of this year and I'm pleased to report that the first patients are now on commercial therapy.

Now this is an important step as we execute our focused geographic expansion plans, having already identified over 900 patients of whom 185 are being treated through various access programs. Next slide, please.

Slide 12:
So importantly, we expect to sustain that acceleration with a number of growth catalysts to come. We have the conversion of patients already in the funnel already found and identified. As Fabrice mentioned, we have the reclassification of the U.S. patients in the U.S. starting in the second half of this year.

Now we already know of 1,400 such cases right now and we ultimately expect 20% of those patients at least to be diagnosed with APDS.

We also have the pediatric label expansion and we expect U.S. approval in the second half of next year.

And we already have 50 patients identified between the ages of 4 and 11 who will be eligible for treatment and many of those are already on therapy in various types of access programs.

Of course, we will continue to identify more and more pediatric patients in the coming months and years. And finally, as I mentioned, we have launches in other major markets where we will achieve appropriate pricing and reimbursement with forthcoming approvals expected in Japan, the European Union and Canada over the next 12 months.

This, of course reflects the significant progress for Joenja® in the APDS indication that we've made in the past two years. Next slide, please.

Slide 13:
Now all that said, Joenja® is still in the early stage of its life cycle, as can be seen on this slide.

In APDS today we're focused on approximately 500 patients in the U.S. alone. With the VUS reclassifications I mentioned earlier, that represents an important opportunity to expand that patient pool of 500.

In fact, in the paper that Fabrice mentioned published in *Cell* and Anurag will expand upon, it suggests a much higher prevalence. So, all of this could totally change how we think about APDS.

Then as you look at this slide, in addition to APDS, we have phase II clinical programs ongoing for new primary immune deficiencies indications. The first, PID with immune dysregulation linked to

PI3K delta signaling where the patient pool is at least 2,500, so 5x that of APDS. Then CVID with immune dysregulation with a patient pool of at least 13,000.

So these U.S. patient numbers shown here highlight the significant global opportunity we actually have in our hands today to expand the Joenja® franchise in APDS and with these new indications. This will enable Pharming to deliver on its mission to serve unserved rare disease patients and to build on our existing commercial success, potentially delivering a US$1 billion Joenja® franchise.

So I'd like now to hand over to Anurag Relan, our Chief Medical Officer, to discuss these opportunities and our pipeline in more detail.

Anurag Relan – Chief Medical Officer:
Thanks, Steve. Next slide, please.

Slide 15:
As you've been hearing, we have supported work to help patients who have received a VUS, or variant of uncertain significance, lab test result. Again, these are patients who have had symptoms of a primary immune deficiency, but there was not enough information available to determine if their genetic variant in their genes related to APDS was disease-causing. Here, I'm very excited to recap the details from a new study published last month that expands this understanding of APDS.

This work published in Cell found more than 100 new variants that lead to PI3K delta hyperactivity. This has two important implications.

First, as shown on the left, the data from the study will be used by genetic testing labs to reevaluate variants that were previously thought to be of VUS. But now, with this new information, patients could be reclassified as having APDS.

In addition, we are planning to expand these studies further to generate and evaluate even more variants to help more patients in the future.

With these data, we expect that 20% of the more than 1,400 patients in the U.S. who have received a VUS test result could ultimately be reclassified as APDS.

On the right, you see the other key finding from the study that the new variants found suggest a much higher prevalence of APDS, perhaps even 100x greater. The early work from the study also implies a broader clinical phenotype or clinical symptoms for patients with such hyperactive variants.

We are now planning additional work here to understand these clinical aspects, but also to get a better sense of what this greater prevalence could be. So, much more to come on this including in the near term. Next slide, please.

Slide 16:
In addition to this exciting new science leading to growth opportunities, we continue to make progress on our pipeline, having achieved a number of key milestones during the quarter.

First, to expand the addressable population for APDS, I'm pleased to report that in June, we filed our regulatory application for Joenja® in Japan for APDS patients ages four years old and older.

In addition, in fact, today we intend to file our application with FDA for label expansion for pediatrics for children ages 4 to 11.

For the two Phase II proof-of-concept studies ongoing in primary immune deficiencies with immune dysregulation, these studies remain on track to read out in the second half of next year. Again, there's a strong scientific rationale here and we have even seen some early encouraging signs with the compassionate use in this group. These populations represent more than 20x larger group of patients, as you heard from Steve, that we have currently in APDS. So the unmet need here is significant.

Lastly, we have made significant progress with restarting the registrational study for KL1333, our new asset for primary mitochondrial disease.

As I mentioned in the past, this pivotal study has already undergone a positive futility analysis and we have reactivated now previous sites and opened new ones as well with several patients now having been randomized and dosed. We continue to expect a 2027 readout for this important program. Next slide.

Slide 17:
Let's zoom out now and look at our pipeline. Having been at Pharming for quite a number of years, it is truly impressive for me to see this dramatic transformation for the company from even just a couple of years ago.

We have two marketed products and we're bringing these to more patients with geographic expansion and pediatrics. On top of that, we have a growing pipeline with two proof-of-concept studies in the KL pivotal program, both serious diseases and significant patient populations. All in all, quite a lot to be excited about.

I'll turn it back to Fabrice now to review our financials and outlook for the rest of the year.

Fabrice Chouraqui – Chief Executive Officer:
Thank you, Anurag.

Slide 19:
So as you've seen, we had another strong quarter with revenues up 26% versus last year. Gross profit increased by 27% to US$84.2 million, mainly due to the increase in the revenue. The operating profit jumped to US$12.9 million compared to an operating loss of US$3.1 million in the second quarter of last year. This number excludes US$2.1 million of nonrecurring Abliva acquisition-related expenses.

Excluding those nonrecurring expenses only, our total operating expenses did not increase significantly. Cash and marketable securities increased from US$108.9 million at the end of the first quarter of 2025 to US$130.8 million at the end of the second quarter of 2025. This meaningful

increase was primarily driven by the net cash flows that we have generated from our operating activities. Next slide.

Slide 20:
When we look at the first six months of the year, clearly, I believe that the financials show the consistent strong execution of our strategy.

Total revenues increased by 33% and gross profit increased by 37% compared to the first half of 2024. The increase in OpEx was mostly driven by US$15 million of Abliva-related expenses, of which US$9.9 million are non-recurring in nature. The operating profit excluding non-recurring Abliva acquisition-related expenses amounted to US$13.7 million compared to a loss of US$1.2 million in 2024. Cash and marketable securities decreased by US$38.6 million to US$130.8 million, primarily driven by the US$66 million acquisition of Abliva shares and the US$9.9 million in non-recurring Abliva acquisition-related expenses. This was partially compensated by the cash flows that we have generated in Q1 and Q2. Next slide.

Slide 21:
So on the back of the strong Q2 results and the outlook for the remainder of the year, we are raising our 2025 total revenue guidance to between US$335 million to US$350 million. This is up from prior guidance between US$325 million and US$340 million. This new guidance implies full year revenue growth between 13% and 18%.

We expect total operating expenses for 2025 to be between US$304 million and US$308 million, which is slightly above the prior guidance for flat OpEx plus Abliva-related expenses, which we shared at the last quarter, which was around US$303 million.

The small variances in our expense projection is largely due to the US$5.3 million negative impact of the higher euro-dollar exchange rate. Obviously, we are striving hard to save a portion of this increase while not impacting actually the growth momentum.

On that note, we are making very good progress in the development of the plan to ensure a sustainable 15% cut of G&A expenses that I announced last quarter to optimize capital allocation to grow our business.

I'm also pleased to let you know that we are making good progress in the recruitment of our new CFO and I hope to be in a position to make an announcement in the not-too-distant future.

So finally, I think it's important to bear in mind that we continue to expect that our available cash and future cash flows will cover our current pipeline and pre-launch costs. I believe actually that is actually putting Pharming in a very unique position in the biotech environment. Next slide.

Slide 22:
So in summary, I can only say that we have delivered a very strong quarter and a first half due to the strong performance of RUCONEST® and Joenja®.

With its unique profile, strong patient experience and specialized manufacturing process, I really believe that RUCONEST® is well-positioned to remain for the foreseeable future, a treatment of choice for HAE attacks.

In APDS, we are accelerating the pace of enrollment of new patients ahead of the start of the reclassification of VUS patients in H2, ahead of the expected pediatric label expansion next year and ahead of the geographic expansion in eight countries.

As you've heard from Steve, we've already launched Joenja® in the U.K., where actually the first signals are very, very encouraging.

Our pipeline is progressing at pace with the objective to generate two blockbuster assets.

So as you can see, we are building a solid platform for sustainable growth and value creation with a series of clear catalysts in the short and near term.

With that, let me now open the line for questions.

QUESTIONS AND ANSWERS

Operator: We will now take the first question from the line of Sushila Hernandez from Van Lanschot Kempen.

Sushila Hernandez: Yes, thank you for taking my questions. Two from my side on Joenja®.

So, on the VUS patient reclassification, how do you expect to see this translate on new patients on paid therapy? So how fast will 20% of these 1,400 patients get on paid therapy? And what are the bottlenecks?

Fabrice Chouraqui: I'll start answering your question, and I'll hand over to Anurag.

So clearly, this reclassification of VUS patients into APDS will happen over time.

As we've said, we expect about 20% of all VUS patients identified to ultimately be reclassified as APDS. So it's a significant opportunity, which will clearly expand significantly the total addressable patient populations.

What's clear is that this reclassification will start in the second half now that diagnostic labs, which have already tested those patients, will be able to use the data in the *Cell* publication and see which of those the U.S. patients should now be reclassified as APDS. They'll then contact the doctors to inform of this change.

So we expect to see a number of patients in the second half of the year to be reclassified as APDS. But this opportunity, obviously, will take some time to be fully captured.

And so we should see the VUS reclassification as an additional opportunity on top of adult APDS, and tomorrow, on top of the potential label expansion to pediatric, to fuel the growth of Joenja®. Anurag?

Anurag Relan: I think there's a couple of other points. Number one, the growth in VUS patients, right? So this is an ongoing problem. You've seen that number grow consistently, as more patients get tested, the pool of VUS patients continue to increase. So I think that recognizes the scope and scale of the problem.

The second is we have some experience already here with VUS patients being reclassified.

So, of course, we're doing it now and through this work supported at Columbia, this has been done at a large scale, but we have some experience doing this one by one where patients were tested individually and they had their functional tests showing hyperactivity and that was used then to reclassify them and then eventually get them on to Joenja®.

So we know how that process works. And we know that once they're reclassified as APDS, they can be quickly reimbursed to get on to Joenja® therapy if the doctor desires.

So we do know how this process works and we have a good understanding, as Fabrice outlined, of what the next steps are in terms of the reclassification, but then also what the steps are eventually to get these patients on therapy.

Sushila Hernandez: Ok, thank you. And one more question, if I may.

So of these 185 APDS patients globally, could you break this down for the ones that are in the U.K. and Japan?

Fabrice Chouraqui: We don't actually give the breakdown in the various countries. So at this stage, Sushila.

Sushila Hernandez: Ok that's clear. Thank you.

Operator: We will now take the next question from the line of Jeff Jones from Oppenheimer.

Jeffrey Jones: Thank you, guys and congrats on a really strong quarter. Two questions from us, one on Joenja®, one on RUCONEST®, if we could.

On Joenja®, you highlighted the growth in patients on therapy in the first half of this year and really nice growth. But if we look at revenue for Joenja® in the first half of this year versus the last half of last year, revenues are actually down just slightly.

So, can you comment on the conversion of patients on therapy to revenue and that lag that we see here between the last half of '24 and the first half of '25?

Fabrice Chouraqui: Absolutely. I mean this is an excellent question. There has not been any change in the very high conversion rate. Actually, what you've highlighted is due to an increase in stock inventory in Q2 last year, which actually is making this growth lower. So it's just inventory management. That's it.

Jeffrey Jones: Okay. That's helpful.

On RUCONEST®, we've, obviously, just seen the approval of sebetralstat and it's getting ready to launch.

So, we know these are targeting somewhat different populations and you've highlighted the strong efficacy of RUCONEST® as well as its use in patients who failed other therapies. Are there segments of the RUCONEST® patient population that you feel are at risk from the sebetralstat launch? And how should we be thinking about that impact?

Fabrice Chouraqui: As Steve said, and I'll let him speak in a minute, the vast majority of RUCONEST® patients are patients who have failed other treatments. There are more severe patients who have more frequent crisis, more severe crisis, and they've not been able to be controlled appropriately with other treatments.

So that's actually why they need an IV formulation with the characteristics that you know and the efficacy level that Steve reinforced, to be controlled.

So there is really hardly any specific patients that are more prone to switch.

Those patients and again we've met many of them in Baltimore, as Steve said, actually, many of them actually know how long it took them to find the right drug.

There may be a few mild patients that are treated by RUCONEST®. These ones actually may switch.

I would be surprised to be fair because, let's not forget that RUCONEST® is an IV drug. There's been for years, subcutaneous treatments. And so, I'm sure that mild patients would have preferred to be treated with subcutaneous treatment and also generic treatment.

Steve?

Stephen Toor: Thank you, Fabrice.

I'll just build very briefly on what Fabrice said. I think he hit the key points.

But the important thing here is that the majority of our patients have experienced a pretty unpleasant course of disease that's often led to them being hospitalized, et cetera, et cetera. And they're all icatibant failures for the most part.

Now, it's important to note, Jeff, that icatibant failures were actually excluded from the sebetralstat pivotal trial. So we really are targeting quite different patient populations. And probably the key

numbers to remember here are with RUCONEST®, 97% of attacks are resolved in a single dose with half of them within 4.5 hours. So, if you're this type of patient that's experienced this course of disease, those are really key numbers.

So, I would never sit here and suggest there won't be disruption in the market. There always is some, where launches are concerned. But we're confident that our patient population is well-served by RUCONEST® and will continue to be because, as I said, these are not the same types of patients that these two drugs will be treating.

Fabrice Chouraqui: And what's interesting to note as well is that, despite actually the upcoming launch of sebetralstat, we're seeing more prescribers willing to use RUCONEST®, more RUCONEST® patients on the drug. And that's not the typical pattern.

If doctors felt that a new drug will be better for the patient, they would actually warehouse those patients. So clearly, we are very encouraged by seeing the trend and that reinforces the distinctive value proposition of RUCONEST®.

Operator: We will now take the next question from the line of Benjamin Jackson from Jefferies.

Benjamin Jackson: Thanks for taking the questions. Ben Jackson, Jefferies here. Just two on Joenja® from my side, please.

The first being, can I just push you further on this VUS uptake in the second half of the year and follow up with what the first question on the Q&A was? And specifically, what is the bottleneck here? Because I appreciate that it's kind of a little bit out of your hands with regards to reclassification, but you're talking about the fact that you've got experience with reclassification. If the doctors approve it, it's quickly reimbursed and you very rarely see rejections of reimbursement.

So what is it that's keeping you on the more cautious side of the rate of uptake? Is it down to the U.S. labs taking time to reclassify and that data being sifted through? Like what specifically is the bottleneck here that should keep us cautious?

And then secondly, on the Joenja® side, again, can we just touch on a little bit more about this additional potential clinical phenotype that you're finding for the APDS patients? And what is the path here to a potential expansion of label, for example, that would reclassify, obviously, potentially a large number of patients? Is it as simple as the genetic work gets done, the kind of the clinical phenotype is better understood and then the breadth of patients that are available to start treatment are then suddenly expanded?

Or to do this, is it going to require potentially a slightly different diagnosis that's going to require clinical studies and take a little bit longer? Just try and set our expectations for the timeline that we could get updates from this initial work that has been completed.

Fabrice Chouraqui: Thank you, Ben, for these two important questions. So let me start with the reclassification. I'll hand over to Anurag about the clinical phenotypes and related to this potentially much increased prevalence of APDS. So on the reclassification, as you said, things take time.

So, first of all, I mean the genetic labs needs actually to use the data in the *Cell* publication and identify those patients that ultimately will be reclassified. We don't know first, the number. The *Cell* publication has generated a bit more than 100 new variants that were found to activate PI3K delta, okay? There are more variants as well. So with this first batch of new variants, actually, we will not exhaust that opportunity.

So first is to understand with those 100-plus variants, how many patients will be reclassified? We cannot know that. So we need to let the labs actually to figure this out. And then they'll inform doctors. It always takes time. Some patients are being seen on a regular basis. Some patients, obviously, take more time to reconnect. So that's why it's something that's going to happen over time. On top of it, obviously, we are going to commission more studies to generate more variants.

So ultimately, all VUS patients could have a chance, actually, to be considered for reclassification. And we expect that about 20% will have a variant that may indicate a reclassification into APDS.

I hope this clarifies. Anurag, would you like to take the clinical phenotype question, which is an important one?

Anurag Relan: Sure. So when we first think about this, we need to start with the fact that what is our current label.

Our current label is Joenja® is indicated for the treatment of APDS. These new patients that have been found essentially have APDS. So, these are patients with APDS because they have a genetic abnormality, they have increased PI3K delta function or hyperactivity and they have symptoms.

And the symptoms that have been found so far, again at a very superficial level at this first stage, are consistent with many of the types of things that we see with APDS.

What we don't know yet and this is the work that needs to be done is what that clinical feature set looks like in more detail. Are they more focused on one type of symptom or another type of symptom? And so, this, again is the work that we're going to be doing now.

But because these patients have a genetic abnormality and demonstrated hyperactivity in this pathway these are all patients with APDS and potentially within the scope of our existing label.

And with that, we don't really anticipate doing new clinical trials to demonstrate something in this population. There may be some work that could be done, but again the current label includes APDS.

I hope that answers your question, Ben.

Benjamin Jackson: Yes, very useful. Thank you.

Operator: We will now take the next question from the line of Simon Scholes from First Berlin.

Simon Scholes: I've just got one. I was just wondering if the OpEx that you're forecasting for this year includes any milestones on leniolisib?

Fabrice Chouraqui: It does include a US$5 million milestone.

Simon Scholes: Ok, thanks for clarifying that.

Operator: Thank you. There are no further questions at this time. I would like to turn the conference back to Fabrice Chouraqui for closing remarks.

Fabrice Chouraqui: Thank you, so much, Operator. Thank you, all for joining our call this morning or this afternoon.

As you can see, we have built over the years a very strong growth platform.

I believe that we are in a unique situation with a drug like RUCONEST® which can be a source of sustainable cash flows in the years to come and allow us to fund the very high-value late-stage pipeline.

So I personally joined Pharming, as I saw Pharming in a sense as the best of pharma with the sustainable source of cash flow and the best of biotech with this very promising and high-value pipeline.

And, obviously, we are committed to developing the company and making Pharming a leading rare disease company in the years to come. You can see that quarter-on-quarter, we are executing this strategy. There is no long term without any short term. And we look forward to telling you more as we progress. Thank you so much for your attention today.

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