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EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at Morgan Stanley Global Healthcare Conference

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OVERVIEW:

Company Summary

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Terence Flynn Morgan Stanley - Analyst

QUESTIONS AND ANSWERS

Terence Flynn - Morgan Stanley - Analyst

Great. Good morning, everybody. I'm Terence Flynn, Morgan Stanley's US biopharma analyst, and I'm very pleased to be hosting Regeneron to kick off our 23rd Annual Global Healthcare Conference this morning. For important disclosures, please see the Morgan Stanley research disclosure website at www.morganstanley.com/researchdisclosures.

If you have any questions, please reach out to your Morgan Stanley sales representative. Today from the company, we have Len Schleifer, who's the Board Co-Chair, President and CEO; Marion McCourt, Head of Commercial; and Chris Fenimore, the company's CFO. With that, I'm going to turn it over to Chris, and then go over to Len for opening remarks.

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

Thanks, Terence. Real quick. I would like to remind you that remarks made today may include forward-looking statements about Regeneron, and each forward-looking statement is subject to risks and uncertainties that could cause actual results and events to differ materially from those projected in such statements. A description of material risks and uncertainties can be found in Regeneron's SEC filings. Regeneron does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Thanks, Chris, and thanks, Terence, for having us here. It's good to be at the 23rd Morgan Stanley Conference. Chris started out with his statement about forward-looking statements. And usually, we kind of look backward, but I've decided today, we're going to really look forward and talk to you about what the future looks like.

Everybody is familiar... I think everybody is familiar with Regeneron's story about EYLEA and DUPIXENT. But I want to tell you that we think we can see the future where we can have significantly more than 10 blockbusters emerge from our trials over the coming years. And I'd like to sort of highlight what some of those might be.

If we start with our cancer program, LIBTAYO is already on its way to being a blockbuster. That's our PD-1 blocker. And -- but we have some very interesting data, that KEYTRUDA was not able to get, in the adjuvant setting of CSCC that is reviewed by the FDA, which we think has a very large market potential -- especially because KEYTRUDA failed in that setting. We also have beyond LIBTAYO as monotherapy, our combination therapy with LAG-3 in the melanoma setting. And so, we're looking forward to getting data from that.

And then we turn to our hematologic tumors. We have three really exciting drugs there, which we all think are going to be pretty special and all have blockbuster potential. Let me start with our Linvo -- LYNOZYFIC, which has been approved for the treatment of advanced multiple myeloma. We think our data there is very compelling. We think cross-study comparisons notwithstanding, we have really the best-in-class in terms of both efficacy and perhaps even safety and convenience in end-stage myeloma.

But end-stage myeloma is a relatively small indication. We're going to go for the whole enchilada, so to speak, in myeloma, where we're going all the way to the very beginning, pre-malignant MGUS, or light chain amyloidosis, sort of these pre-malignant conditions, all the way through first line, second line and so forth. We are not range bound to include DARZALEX as some of our competitors are. And we think, in fact, monotherapy may be the way to go. And we've got some pretty exciting early-stage data there that suggests that you can get dramatic, if not profound responses with monotherapy, with LYNOZYFIC, which is a BCMAxCD3 bispecific.

We also have similar compelling efficacy with our two drugs for lymphoma or two treatments for lymphoma, Odro, our CD20 bispecific is pending approval, and we're very excited about its potential, especially because we've got some very early-stage data now in frontline Follicular <Lymphoma>, where we've been able to see in the first dozen or so patients we've treated, 100% complete responses. We get that going. That's a very significant and big opportunity.

Same thing in DLBCL. We are not bound as our competitors seem to be to include Rituxan. In fact, we're looking at Rituxan-free <regimen>. The standard of care upfront for DLBCL is typically Rituxan plus a chemotherapy regimen called CHOP. R-CHOP maybe gives about a 75% complete response rate. We're looking at already, in our first preliminary dozen or so patients, a 100%.

So we're very excited about the prospects for our cancer program, once again, we've got LIBTAYO. We've got LIBTAYO plus LAG-3, we've got Lynozyfic and we've got Odro. So really big opportunities there, which we're working very hard on. Beyond that, let's take a look at some recent data we had in our complement-mediated program.

As you know, we have both an siRNA, which will decrease complement, and we can combine that with a C5 antibody. So the combination takes complement, basically completely inhibits it. And if you look in patients with PNH, we can show clearly head-to-head that we're able to treat patients better, looking at LDH, which is a measure of the complement-mediated destruction of red cells. We can completely normalize, where the Soliris (eculizumab) can't do that. In fact, the combination there is the best that's been seen. So we're pursuing that in Phase III.

In addition, we have Myasthenia Gravis data, a Phase III, that we released. This case, it seems that monotherapy with the siRNA is all you really need, which could be very important because you don't have to completely inhibit complement and therefore, you might get a safety benefit. The safety profile looked very good. The Phase III data cross-study comparisons were best-in-class for the C5 class. And I think, frankly, it can compete well. I know we're competing -- in another room, argenx is talking -- they've got a very interesting FcRn story.

But if you look at their label, you don't get complete clinical benefits. You sort of get a U-shaped <response curve>, which you have to sort of cycle through. We get complete benefit. So we're very excited that we can compete against them. We can compete certainly against the C5 antibodies. We can compete in Myasthenia. We can compete in PNH. And then, of course, the wildcard is, we think we might be able to have something special in geographic atrophy, which is another big opportunity for us.

So those -- so that's plus the cancer plus the C5. We also have opportunity in our Factor XI program, which we've already shown in total knee replacement, works very nicely and safely. We're in Phase III there. We'll be looking at all sorts of different settings where you can perhaps do better than the DOACs on safety with less bleeding and equal or better efficacy. Phase III program is going to be very large for the Factor XI opportunity.

We also, of course, have announced this morning our allergy program. We're very committed to allergy. We've got a multipronged strategy. Some stuff we haven't even talked about, we think can totally eliminate allergy. This was an example today where we could treat specific allergies, both cat allergy, which is very common, <and> birch allergy, which is very common.

We can block more than 50% <of allergy symptoms> if you put the cat dander directly in somebody's eye, and this is after a subcutaneous administration of these blocking antibodies. So that's really interesting. That might be a very important lifestyle drug. There are millions and millions of people who have both cat allergy and birch allergy.

So I won't go through the rest of the program, but we also have in, very quickly, in our metabolic area, some exciting stuff you're going to hear about in the very near future about MASH. We have, of course, our Praluent for cholesterol lowering, where we won that lawsuit against Amgen

for antitrust. We're waiting for the court to do some structural remedies, and we might be able to revive that into a fairly competitive program there as well. So lots, lots, and lots of stuff in the pipeline, while Marion keeps the fires burning bright on DUPIXENT and EYLEA.

Terence Flynn - Morgan Stanley - Analyst

Great. Well, thanks so much for framing all that, Len. I know we're going to unpack a lot of this. But I guess just big picture, I think back to DUPIXENT, we used to talk a long time ago about the size of this opportunity. You guys were always more optimistic than Wall Street. I think I remember I maybe had $2 billion in my model at some point, and you prove me wrong.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Did we do that yesterday? No.

Terence Flynn - Morgan Stanley - Analyst

So -- but as I look at kind of where the stock is now, look at these opportunities, as you go down this list, do you think the Street is missing the commercial opportunity here? Is it POS? What is the Street missing that you're enthusiastic about? Because you kind of go down this list, but I'd argue a lot of this is not reflected in the current value. So what do you think the Street is missing as you go down this list in terms of commercial opportunity?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

I think they're missing the whole pipeline. I think there's too bright of a light on what's going on with DUPIXENT and EYLEA. And then to ask somebody, we have 45 things in the clinic, we probably put another dozen or so every year into development under George Yancopoulos, who's the Chief Scientific Officer of Regeneron, the Board Co-Chair and the co-inventor of most of these programs.

It's the most prolific pipeline in the history of the industry, I would dare to say. And I think it's very hard if you were to devote your time to look at 45 programs, you'd have nothing else, no time to do anything else. And so, people have some inability, I think, to focus on the pipeline.

If you look at our cash position, which is somewhere between $15 billion and $20 billion and you look at the cash flow just from DUPIXENT, I think it's pretty clear evidence that the pipeline is being ignored. And I think the pipeline is starting to deliver. And we have more stuff coming out in the not-too-distant future. So that's what I think is going on.

Terence Flynn - Morgan Stanley - Analyst

Great. Maybe a good segue into capital allocation. I mean, it seems like based on the pipeline you have that there'd be limited interest for later-stage deals. Again, as you think about the lens through which you apply business development, maybe you and Chris can kind of tag team this, but how do you think about capital deployment here in the context of your pipeline, the investments that are required here and also external opportunities?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

So I'll let Chris dive into the details. But let me just say, we've done an analysis. And people say: “you spend a lot of money in R&D”. But if you actually look at what we spend on R&D versus what a lot of other companies spend on R&D, when you add in when they buy R&D, that's just spending on R&D, but it's hidden someplace else on your financial statements. I don't think we're actually out of line at all. We can show you evidence that, yes, we spend a lot, but we don't spend nearly as much, or we don't waste nearly as much.

There's been some analyses that people have spent $100 billion to create $60 billion in value or something like that. This external purchasing is not something we're against. But when it becomes just a crazy auction and people are buying things that are worth $5 and paying $10 for it, we don't have any interest or need for something like that. And I don't think people are being fooled, frankly, by people who do that. I mean, you can look at some of these massive purchases, and we can go through them in a more... less bright light environment, so people don't get mad at me, but some of these deals are pretty darn stupid.

Chris can comment on our...

Christopher Fenimore - Regeneron Pharmaceuticals Inc - Chief Financial Officer, Executive Vice President - Finance

I think Leonard hit all the highlights. Obviously, first and foremost, our top priority is investing in our own internal R&D capabilities, supplementing that with some business development activity and not just limited to M&A, Terence. Obviously, we do a lot on the partnership side as well. If you look at the last component of our capital allocation strategy is returning capital to shareholders, we initiated a dividend earlier this year.

And then on top of that, the primary way of returning capital to shareholders is doing buybacks. We, in Q2, bought back $1.1 billion of our shares; for the first half of the year, $2.2 billion, reduced shares outstanding by 3.2 million shares. And as of June 30, have $2.8 billion still authorized. So we're obviously, as Len said, with the amount of cash that we have, well capitalized to execute on all of our plans.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

And to be clear, Terence, we do deals. We just do -- they are less expensive because we tend to find things early that fit in nicely and adjacent to what we do. But we're not adverse to buying something, but we don't want to spend shareholders' money to decrease value.

Terence Flynn - Morgan Stanley - Analyst

Yes. Understood. I know it's something you don't want to probably talk about too much, but again, it's top of mind for everyone right now, just given where we are in the policy environment. And so, maybe you could just give us your perspective on kind of the tariff/MFN situation, where we are? And are we getting closer to a resolution in your view? And then I know the other thing that you guys have talked a lot about is Medicare co-pay assistance is an opportunity to maybe lean into. So maybe give us a view on kind of both of those and where we stand right now.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Right. So I read my “Dear Len” letter very carefully. And I'll say this. The administration has their focus on trying to lower drug prices. And we have said that the problem is that somebody has to pay for innovation, and the Europeans aren't paying for innovation. I have said that long before this administration, I've been saying this for a decade, that we have to do something about getting the Europeans to pay for innovation.

That isn't something a company -- one company -- can do. We go out there and say, we're not going to sell it for less than we sell it in the US, then there's six other companies that will step in, in front of you. And so, it's a very difficult situation. Plus, the public really doesn't understand how can it be that we sell drugs for a third outside the United States. They think we're ripping off the people in the US. What's going on actually is that Europeans are actually ripping us off. So what's the solution?

That's a structural problem that's well beyond my pay grade. It's way up there in Washington to how you figure that out. But there are some things that the administration can do with the stroke of a pen and put all this sort of chatter to bed. If you talk to people and you do surveys, people don't care about the price of drugs. That's just wrong. They don't care about the price of drugs. They care what they pay, their portion for a drug. They don't really care what their insurance company pays. They care what's the co-pay.

And seniors, it's, for example, in Part B drugs -- Part D is cut it down to $3,000, but Part B, it's sort of 20%. That's very, very, very onerous on a lot of people. And with the stroke of a pen, the administration can basically say, let's treat seniors the same way we treat people who are younger than 65 under commercial <insurance> and let the companies bear the burden of the co-pay. Now the counterargument is that, well, that will increase utilization and all that kind of stuff.

Well, maybe people actually get treated better, if they had full access to drugs. But that can be worked out. But this could all be put to bed by dealing with the co-pays, because that's the only thing patients actually really care about. I had a chance to talk to some colleagues on Martha's Vineyard, where I spent some summer vacation time. And there is an epidemic of Alpha-Gal there, Alpha-Gal is meat allergy, and it's spreading around the country. It's in North Carolina...

Anyway, they asked, well, do you guys have a treatment? I said, we do. And they said, well, when can you get it? I said, you can't, and they said, why not? I said, well, we haven't started development that soon, but I don't think we'll develop it because you guys don't want to pay for drugs and that's what pays for research. And sort of brought home the message and they all agreed, well, maybe they would pay for if it hits on.

Terence Flynn - Morgan Stanley - Analyst

All right. Maybe we'll go back to some of the key kind of growth drivers here. But I guess, one question as we think about DUPIXENT, I know there was some competitor data out recently for another OX40. Maybe, Marion, you could just give us kind of your view on kind of the key growth drivers for DUPIXENT here in the forward and how you think about this competitive landscape now we have a little bit more visibility.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Sure. Very happy to. So on DUPIXENT, 8 indications in the US marketplace. 7 of the 8, which is really impressive, are leading in both new-to-brand prescriptions and their total prescriptions. The only indication that isn't that status yet is CSU, which we only just launched but is off to a strong start. Other recent indication launches, COPD going very well, helping a lot of patients with unmet need across all of our skin indications, biologic asthma, nasal polyps, eosinophilic esophagitis, all really strong performance.

And then to your comment related to recent competitors, obviously, a number of companies have launched in the space of atopic dermatitis. The KOLs always tell me that DUPIXENT is first and best. And I would share that the data and the performance we're seeing reinforces that, that as other companies are coming into the atopic dermatitis indication, they're educating, they're bringing more consumers into the fold, but that's really translating to more first-line business for DUPIXENT based on the efficacy, the safety, the convenience of use. Indication is obviously down for children as young as six months; older populations as well.

And then also with that really remarkable dual mechanism of action, and the fact that we help across type 2 disease indications, it's not uncommon for someone who suffers, for example, from asthma to also suffer from nasal polyps, atopic dermatitis cross over with asthma as well. So I think DUPIXENT really is helping a lot of patients. We still have a lot of unmet need. Even in atopic dermatitis, we're only probably penetrated to about 20 or so percent of the patients that we could help.

So some of the recent data, and I was at a couple of conference sessions last week, kind of live time hearing updates on Sanofi's data. Obviously, Sanofi is our partner with DUPIXENT, very important to us. But I do think most thought that the OX40 data was a disappointment based on efficacy, not unlike perhaps what Amgen had seen. I think hopes were high that there might be differentiation there but probably was a bit disappointing. Not only in efficacy, safety and certainly, previously, the OX40s have shown not to be efficacious in asthma.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

And not to mention time of onset was very, very late so...

Terence Flynn - Morgan Stanley - Analyst

And then just remind us the structure of that partnership, if Sanofi launches their OX40, they have to fund that fully separately, they couldn't leverage any...

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

They cannot leverage anything related. They can't leverage the knowledge, the people, the product, no bundling or anything like that.

Terence Flynn - Morgan Stanley - Analyst

Would you be interested in the profit share if they approached you for that, so that you could leverage this across the portfolio?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

I thought you're in research, not banking.

Terence Flynn - Morgan Stanley - Analyst

No answer... all right. Well, the other focused asset in immunology that you guys have in your portfolio is Itepekimab. Maybe just talk to us about how you potentially can leverage this on your existing infrastructure.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Sure. Well, I mean, obviously, it was a disappointment that one of the trials conducted right in the middle of COVID didn't confirm the other trial, which worked exactly the way we expected. We're having conversations with the FDA. We're trying to decide.

But in the meantime, we're going forward with the nasal polyps story, which I think has a strong genetic backing, and perhaps other indications. So I think Itepekimab is far from over and should be -- that is something that's in the partnership, can be leveraged, and we will work together on.

Terence Flynn - Morgan Stanley - Analyst

And when will we get an update on the COPD side in terms of kind of go-forward strategy from you and Sanofi?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Probably before the end of the year.

Terence Flynn - Morgan Stanley - Analyst

Okay. And then remind us the -- maybe Marion could speak to this, just some of the other opportunities in terms of the commercial set for that asset. For Itepekimab, sorry...

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Thank you. No. Well, obviously, tremendous opportunity. We are working with DUPIXENT now in the space of, obviously, COPD and the understanding there, different population for Itepekimab. So it will be very complementary and certainly a major opportunity. So we look forward to the data, follow-up discussions with FDA. And certainly, the clinical data was interesting, not complete. We have more work to do, but potentially a very important opportunity.

Terence Flynn - Morgan Stanley - Analyst

Yes. All right. Maybe we'll pivot over to oncology now. You mentioned a lot of the upcoming data sets here, Len, that you're expecting. I think obviously, a lot of focus on LAG-3 in general as a target. You guys are right here behind Bristol. But as you think about the upcoming melanoma trial that we're expecting data, I think, later this year, early next year. Maybe just frame for us kind of what you want to see for success there and differentiation versus Opdualag? And then maybe, Marion, you could just speak to the commercial opportunity in that setting.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Yeah, I mean, I think we want to see a successful trial, which the primary would be against KEYTRUDA, showing that we're better than KEYTRUDA in the combination. And then we'll look cross-study comparisons of what the combination of Opdualag looks like. But first job -- job number one is -- let's win on the trial.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

And then the commercialization potential, certainly, over the last several years, we've made a lot of progress with LIBTAYO in the marketplace, both US and internationally. That footprint is important because, obviously, as we extend into hematology as we have with Lynozyfic with Ordspono as well in the future. Obviously, we've launched in Europe with Ordspono. We hope to launch Lynozyfic in Europe shortly. In the US marketplace, we're making a lot of progress against both academic and community settings for oncology, which I think is really important, as we always said, for the platform of our future portfolio.

So as we have additional clinical data following approvals, we have the commercialization footprint in the marketplace across many disease areas now and hopefully have shown you all the ability to commercialize successfully in the marketplace. As Len was talking about all of our future programs, we're always working ahead on launch readiness. So whether it's a program in obesity, cardiometabolic, oncology, hematology, we'll be at the ready to launch, often as we do today in very competitive marketplaces.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

I can't overemphasize. If you want to think about Regeneron, of course, you got to model EYLEA and you got to model DUPIXENT and think about what's happening in those settings. And that's where you guys spend about 90% of your time. But where I spend an awful lot of time is on the pipeline.

And as I said, we believe we can deliver double-digit numbers of blockbusters, and we've got line of sight already into those. I have named about six or seven of them for you, and there's more that we haven't even talked about. So we are very excited about that.

We're thinking about ways to get people to shine a light on that a little bit more. And I'm not sure why people haven't. I may blame you a little bit, Terence, not you specifically, but your ilk because you guys do have an iceberg view of the world, and it's hard to chop down into 45 programs.

Terence Flynn - Morgan Stanley - Analyst

What -- as we think about maybe just LAG-3, I know you guys have been optimistic, you have a better antibody than Opdualag. So as you think about read-through from melanoma to lung, I think that's one of the other questions people have is how broad could this LAG-3 opportunity be? And so, when we see your melanoma data, how should we think about it in the context of the lung cancer opportunity?

Because I think that's one area, checkpoint inhibition, that everyone has been focused on for a long time and just trying to understand read-through from one indication to the next. And sometimes we've seen read-through, sometimes we haven't. So as we think about extrapolating to other indications, like how excited or not should we be when we see this melanoma data?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Yes. I mean, I tend to be cautious in cancer about reading across indications. Obviously, I'm hopeful if you see strong data in one that it would lead to strong data in another, but I don't think there's a guarantee there. And we certainly aren't approaching that.

I think what you should see is we don't like to make singular bets, at least we make them, but we like them to be part of 10 bets, so that... if you think about what we're trying to do here, we've created two of the biggest drugs in the history of the industry, internally discovered, internally developed and marketed, and developed Dupi with help from Sanofi. But (both) came out of our laboratories. And to us, the way you have an evergreen company is to keep doing that.

Now we did those on shoestring budgets, okay? And so, if you want to talk about read-through, the read-through ought to be, wow, Regeneron did this EYLEA and DUPIXENT on shoestring budgets, okay? The read-through ought to be when we say that we can produce another 10 or 15 blockbusters in a reasonable period of time because we already have the data and we have the know-how and the capabilities, I think that is really the most important read-through.

And let me address some of this nonsense I think is out there that Regeneron can't get drugs approved and all that. There has been a big effort by the FDA to crack down on the filling component of manufacturing because a lot was exposed during the COVID era, how woefully inadequate the whole system might be. And so, the FDA has been cracking down. I wish we had -- we got delayed building our own during COVID because a lot of long lead items we couldn't get, but we'll get our filling online next year.

But if you think about the setbacks we've had, for the most part, first of all, we're very vocal and visible, you know with us. Now you can look at all the other CRLs that people got because the FDA published it. And with us, the big problem has been related to filling, but we think that those problems should be fixed relatively soon.

Terence Flynn - Morgan Stanley - Analyst

As you think about that filling opportunity, I know you guys have been moving this in-house, as you alluded to. Is that going to be across the portfolio? And what percentage of your filling can you ultimately accomplish as a result of this in-housing effort?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Well, we'll start with one line, which is a lot of big line, but there's a lot of capacity that we'll take back, when Sanofi has been doing most of the filling for DUPIXENT. We'll take some of that back. So that will take up a lot. But we expect to put about four lines in place. And over time, it should handle our internal filling needs.

Terence Flynn - Morgan Stanley - Analyst

Okay. Great. Maybe we'll go back to the pipeline. You mentioned your C5 effort. You've got two different assets here, several different indications. I think, again, this is one of those questions where the Street is debating the size of the -- we know the established commercial opportunity, but how do you guys come in as a later entrant, differentiate, drive share, particularly, let's say, PNH or MG. I think GA is still an open question. But again, at least in those two, maybe you could talk to us about how you come in...

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Yes, I don't think it's particularly hard. And you think about what was paid for those assets, what Alexion went for, you can get an idea of what people think the value of that is. But we did a head-to-head trial already. We know that we performed better than the other C5 antibodies. It's just clear as day in the direct part of the study and in the crossover. I don't know why none of you guys pay attention to it, but it's out there for everybody to see, and that's a big market.

The Myasthenia Gravis. We have better data in terms of the efficacy, and we are talking about a once every quarter self-administered versus once a week or once every two weeks or whatever or even once every eight weeks, intravenous, you have to go to an infusion center, et cetera. I think that efficacy and convenience in Myasthenia, potentially safety because you're not completely inhibiting the complement, I think that's going to win out. This isn't -- I don't know why one would have a hard time thinking about that. That's a well-differentiated product.

Terence Flynn - Morgan Stanley - Analyst

And then how do you think about the size of the commercial -- incremental commercial build you guys need on this? Is there anything you can leverage currently? Or do you need to build out de novo for these indications?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Yes. Marion can take that.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

I can help on that. So there are places where we do have some synergies. So now, across many therapeutic areas, for an example, we've got a very strong market access and pricing team. We might have some -- we always build very carefully in a very lean kind of model, but we certainly have the skill set there to add in many future products in the portfolio. That certainly would be one.

And then what we tend to do for the customer-facing model is we understand the program, the disease area, the customer needs and then we build that model. And you've seen us do that with Sanofi for DUPIXENT across indications. And I'll use an example, when you made the comment about launching into a highly competitive market, look at biologic asthma, where DUPIXENT came later and ultimately now with five competitors in the marketplace leads in new and total scripts.

It's the strength of the product and the science for sure, but we also have been able to attract wonderful commercial talent to the organization on my team and our medical affairs team. So very much look forward to going into neurology, another specialty audience where you would have a fairly lean type of specialized model for promotion, but we very much look forward to it. And I'm thrilled with what I'm seeing in terms of the profile of our product for Myasthenia Gravis and PNH in the future.

And then GA, obviously, tremendous unmet need and in the ophthalmology market where we have so much heritage, reputation and performance.

Terence Flynn - Morgan Stanley - Analyst

Great. Maybe just in the last couple of minutes, you guys did have a press release out this morning on some positive Phase III data in your immunology setting. Maybe, Len you can just give us the highlights there? And then I guess the question I had is, are you able to file for approval on these two data sets?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Right. So what Terence is referring to is that we showed that people who have cat allergy, and that's a huge fraction of the population. And remember, you don't have to own a cat to still get symptoms of cat allergy because cat dander is everywhere. And once there's been a cat or somebody who's had a cat comes into an environment, the dander is very sticky. So, people can be exposed even without going to cats, plus relationships break up over whether they get rid of the cat or not. And most of the time, the cat wins.

So I would say that cat allergy, what we showed there is that if you give these antibodies that block the allergen, and you give it subcutaneously… you can wait a week, you can wait months… and what happens is if you put the dander in the eye, people get itchy red teary eyes and you can have a P of less than 0.01 blockade of those effects. And we do the same thing with birch.

Now whether or not we can file, I doubt we can file on these. We need probably a second study. But I think the data was so strong. These programs have been dramatically derisked. So this needs to be -- of course, you probably won't get around to thinking about it, but it is pretty important how many people might have cat allergy.

Terence Flynn - Morgan Stanley - Analyst

How do you frame the commercial opportunity? Because that is one where there's not a lot of analogs. I mean, maybe you could say like Xolair for peanut allergy, but how do you think about the commercial opportunity?

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

The way I think about it is how many people get cat allergy shots, which cost thousands of dollars a year and take years and years and years. And they don't -- they're very burdensome and they don't work as well. I don't think, as this will work instantaneously.

I think this could be a self-pay market. I don't know. We haven't talked to the insurance, but certainly, people as I said, the cat usually wins, whether you're throwing out the fiancé or the cat, the fiancé usually goes. So I think that there's a real need for something like that.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

The early read in the market is that there certainly is payer reimbursement opportunity. But to Len's very good point, there also would be opportunity for consumer potentially in that space. But these allergies can be remarkably severe for patients and many, many patients are going for regular treatments and not getting the results they need, and these are life-threatening allergies.

Terence Flynn - Morgan Stanley - Analyst

Great. Well, I think we're up on time. But thank you so much, everyone. Really appreciate the time this morning.

Marion McCourt - Regeneron Pharmaceuticals Inc - Executive Vice President - Commercial

Thank you.

Leonard Schleifer - Regeneron Pharmaceuticals Inc - President, Chief Executive Officer, Founder, Director

Thank you, Terence. I really appreciate it.