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EDITED TRANSCRIPT

REGN.OQ - Regeneron Pharmaceuticals Inc at Sanford C Bernstein Healthcare Leaders and Disruptors Healthcare Forum

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OVERVIEW:

Company Summary

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PRESENTATION

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Good morning, everyone. My name is Will Pickering. I cover US biotech at Bernstein. Very pleased today to have Regeneron Pharmaceuticals with us.

I'm joined by CFO, Chris Fenimore; and SVP and Head of Investor Relations, Ryan Crowe. Thanks so much. And Ryan, let me hand it over to you for some forward-looking statements.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Thanks, Will, for having us at the Bernstein Conference. Always great to be here and Shana Tova to all who celebrate. I'll just read this forward-looking statement, and then we'll get straight into your questions. I'd like to remind you today that remarks made may include forward-looking statements about Regeneron. 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. Will?

QUESTIONS AND ANSWERS

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Excellent. So for the discussion today, I thought that we could start with the commercial business and then spend some time on the pipeline as well. And maybe just to kick things off with EYLEA, it would be great to know, like really what drove such strong performance of HD in the second quarter. And you've had all these sort of headwinds that you've been working to get through over the course of the year and really hadn't fixed those yet by the second quarter. So what drove that strong performance?

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

Sure. Again, thanks, Will, for having us. It's a pleasure to be here. If you look at the product, EYLEA HD in terms of how it's performed, both the first quarter, we saw growth. We saw about 5% sequential growth in demand.

We saw in the second quarter about 16% sequential growth in demand. That's really attributable to solid execution by our commercial team in terms of getting the word out with both the physician community out there in the retinal space as well as with patients and educating them about a product that they're very familiar with. If you look at EYLEA 2 mg, it's a product that both physicians and patients know brings both great efficacy as well as safety. And EYLEA HD obviously brings additional sort of dosing flexibility and durability for patients. So -- it's in the markets where we

can compete today, if you look at AMD and DME and DR, we're able to effectively compete in that landscape and the teams have done a remarkable job of really getting the word out and driving that demand.

With that being said, those headwinds still do exist, and we are working diligently in terms of trying to get those resolved, but they are important. And we do believe once we have those sort of established and approved that we will see an inflection in terms of that demand. But every four-week dosing is very important to the retinal community. It's something where there's a certain subset of their patients that they treat may not be able to get out to seven weeks, and they want to know that if they use the product, they're going to get reimbursed. So that's something that we clearly hear from the community that we are obviously working very hard to see that get approved.

Prefilled syringe is also another area where we know that physician preference is to utilize a prefilled syringe. If you look at the EYLEA 2 mg business, I think it's upward of 95%+ of utilization is in the prefilled syringe. So something, again, that's very important. And RVO is a sizable opportunity in terms of -- it's probably 20% of the market out there. So we feel that once we've got those three, obviously, buttoned up that will just bode well for EYLEA HD going forward.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Excellent. And in terms of the timing for that, I believe is it October for the prefilled syringe and the next month for the others. Is that --

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Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Yes. That's correct, Will. There's a PDUFA in late October for prefilled syringe and one in late November for the RVO and Q4 dosing sBLA. Maybe I'll take the opportunity to comment on Scholar Rock's update yesterday on their application, which is involved in Catalent and filling operation. So they received a CRL.

I think there was a bit of a misconception about what that actually means for our applications. In fact, nothing has changed. All the read-through that you can make on the FDA's decision to provide a CRL to Scholar Rock is that the Catalent facility, the remediation is not complete yet as of Monday. There was no indication that it was completed as of Monday. So the outcome was not terribly surprising to us.

There was some speculation about why we received a major amendment versus them receiving a CRL. And does that mean there was some sort of setback at Catalent? The answer to that is no. The decision on whether or not Catalent's response could be considered a major amendment is at the discretion of each division director at FDA. So in EYLEA HD's case, it's the ophthalmology division.

In the case of Scholar Rock, it's a different division. I'm not sure which. So I don't think there's any read-through into the actual action that the FDA took with Scholar Rock. And we still remain confident that these issues can be addressed in time for these upcoming EYLEA HD PDUFA dates. And we look forward to getting these into the label and hopefully accelerating uptake thereafter.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Great. Great. Are there any outstanding items that you're working through on these filings apart from CMC issues?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

I would say we feel like we're in a pretty good spot with the FDA on the prefilled syringe as well as on RVO and Q4 dosing. So we believe what we've submitted is approvable in its current form, and we are just looking forward to getting Catalent squared away so that those approvals can come.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Excellent. And coming back to 2 milligrams. So biosimilars are getting close to one year in the market. How should we think about the shape of that erosion curve and where we are on that curve?

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

So there's one biosimilar that's out there in the market today. We have seen some uptake out there in the marketplace. We would describe it as gradual at this point. With that being said, there are certain subsegments of the market, retinal practices that are financially sensitive where we would say the uptake has been a little bit, sort of, greater than in the broader marketplace. What we don't know going forward is if there will be additional biosimilar entrants that will enter the marketplace.

We have negotiated settlements with both Biocon and Sandoz. The entrance in terms of timing for those two are second half of 2026 and fourth quarter of 2026, respectively. We don't know what will happen in terms of what the uptake will look like once those two enter the marketplace. If you look at similar analogs in the past, it would suggest that there will be additional pricing pressure and make it obviously a little more competitive. But we have to wait and see in terms of what that looks like.

We will tell you, sort of, rest assured that our primary objective is to be out there getting the word out on EYLEA HD and doing all that we can to convert as many patients from 2 mg over to EYLEA HD as rapidly as possible.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Great. And in terms of the demand decline, do you feel like the rate of that decline has sort of stabilized? Or do you see that changing between now and when those other two come into the market?

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

I think we've seen -- obviously, as I said, there's been an uptake, and I think the expectation is that we should continue to expect to see additional uptake going forward. It's hard to obviously quantify what that might look like.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Moving over to Dupixent. What would you say have been the primary drivers behind continued strength this year? And just any color on the relative size of those drivers?

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

Dupixent is a remarkable drug. I mean, we've described it as literally a pipeline in a product. There's eight approved indications in the US at this point. All indications are doing exceedingly well.

I mean if you look at the established indications, those indications that have been on the market for a while, whether it's asthma or AD or some of the others, we continue to drive growth there with our collaborators at Sanofi in a joint effort. Really trying to get the word out in both patient and physician education, driving additional biologic penetration.

And then we've got, obviously, new launches in COPD, right, in CSU and Bullous Pemphigoid, where the teams are out there actively getting a word out and really trying to continue, again, on education. So we're -- as of right now, firing on all cylinders, the brand continues to do well, and we expect it to continue to be going forward.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

And on COPD, could you talk about some of the things that you've done to invest in the launch? I think that many of us have seen the commercials, but any incremental investments in the field force or just other comments on investments in the launch?

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

So I think for competitive reasons, we won't go into necessarily some of the investments that we made. Obviously, with the asthma indication, we've got a dedicated pulmonary team out there, both ourselves and our collaborators in Sanofi. That field force has been out there. They're very familiar with the pulmonologists. They've been communicating the merits of the product, obviously, for asthma, what it can do for their asthma patients.

You obviously get some leverage when you're out talking to the same physicians, now being able to talk to them about what Dupixent can do for their COPD patients. So the response thus far has been very, very positive. We've heard, obviously, feedback from the physician community, but also anecdotal stories from patients that have seen a reduction in exacerbations, have seen their quality of life improve, have seen reductions in their reliance with oxygen and things like that. So those all bode well for the launch in COPD. I think if you look at top-tier pulmonologists, I think upwards of 70% of them have already prescribed to their patients.

So our goal and objective is, as you said, you've alluded to, the commercials is to educate the consumer, get them out there, get them talking to their physicians about their condition and whether or not something like Dupixent will be applicable for them and then educating the physician community about <which> patients might be applicable for Dupixent for their COPD patients, educating them, obviously, about quantifying eos and helping them identify those patients that have type 2 applicability for COPD.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

And there's been some news recently about potential restrictions on DTC advertising from the administration. Have you had any communications with the administration on that? And do you have any comments on it from a policy lens?

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

Yes. The only thing I think we can say is that there was a broad communication that came out from the administration to probably all manufacturers. We received that generalized communication. There was nothing specific to Regeneron. It was just the standard letters that went out to all manufacturers.

We obviously read the letter. I will assure you that in preparation of our materials, whether it's for those materials that go out to physicians, to consumers or others, we have a very diligent process to ensure that everything that goes out there is fair and balanced and educates whatever target audience it is about both the risks and the benefits of whatever product that we're talking about.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Great. Great. On Dupixent exclusivity, I realize the timing of that is 2031 at the earliest. So it's obviously quite some time. But you said to expect some INDs in the next, say, six to nine months.

And I was wondering kind of what is the strategic ambition here to develop something before that patent cliff that could eventually have a similarly large place in the market as Dupixent? Or should we think of it as more of one of many pieces across your pipeline that could allow you to continue to grow through that LOE?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Yes. I mean, as Chris said, Dupixent is a remarkable drug and is one of the top -- will end up likely being one of the top-selling drugs ever. It's going to be very hard to replace that with a single magic next drug. So yes, we're working on some life cycle opportunities for Dupixent, but I don't think any will -- any in and of themselves will replace it, okay? So we're looking at longer-acting Dupixent.

We're looking at adjacent type 2 pathways that can address certain conditions that Dupixent currently treats that have longer dosing intervals. And we're looking at other novel targets in the inflammatory cascade as well. So there's many things that are coming. We still believe that they can be brought to the clinic, at least some of them in the next few months. But beyond that, obviously, the rest of the pipeline is very critical to delivering as well in hopes of bringing them to market by the end of this decade, including in hematology, and inflammation and immunology and oncology, go down the list, rare disease.

So we certainly are ambitious in replacing Dupixent, but probably not with a single opportunity, but rather a basket of opportunities.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Great. Well, maybe let's move over to that pipeline and maybe starting with oncology. You've gotten several recent approvals for your bispecifics in the relapsed/refractory setting. Initial feedback on the Lynozyfic launch in the US or your launch in Europe?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Yes, still very early. We got approved for Lynozyfic, I believe, in July. So we've only been on the market for a couple of months in the US, similar time frame in the EU. And associated with the label is a REMS program. So you need to go through the discussions with payers, you need to go to the different institutions to get them REMS certified and you need to get them added to the pathways model that a lot of these institutions use to get into the treatment algorithm.

So those are all the blocking and tackling of the launch is well underway. We've had a few patients dosed. So it's early days, but we're optimistic. We think we've got a best-in-class product. When you look cross trial in the late-line settings.

We look better than Janssen's BCMAxCD3 antibody. We look better than Pfizer's BCMAxCD3 antibody. So we look forward to competing with them in not only these fifth line plus patients, but in earlier lines. And we can talk a bit about that development program perhaps later in our chat.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Yes. Yes, that was where I was going to go next. I mean you've talked about some ambitious plans in earlier lines that would be differentiated versus competitors. Could you just say a little bit more about that and also the timelines for that?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Sure. Yes, we have very broad ambitions for linvoseltamab or Lynozyfic in earlier lines of myeloma as well as in precursor conditions. So before the end of this year, we intend to launch a study in second-line plus that will combine Lynozyfic with carfilzomib. And this would built on the data that we presented at ASCO earlier this year, where we showed a 90% plus -- 90% response rate, a 76% complete response rate in third-line plus patients. So you would expect that to improve as you go a little bit earlier into the second-line setting.

As far as I know, we're the only company pursuing a combination with carfilzomib. And that's really key to our strategy is: limited combinations or monotherapies instead of trying to just layer on top of very complex three, four and five drug treatment regimens that are currently the standard

of care today. So we will -- second line plus is going to be combined with carfilzomib. We're going to look at newly diagnosed multiple myeloma in transplant-eligible patients as well as transplant ineligible patients. Those are studies that will launch probably by end of year and early '26.

And then smoldering myeloma, where we discussed some data on our most recent earnings call, that really is compelling relative to DARZALEX monotherapy, which was recently approved in Europe with an 8.8% complete response rate versus -- in the 19 patients that we've been able to observe -- all of them responded. And of those that have been on treatment over a year, five of six reached MRD negativity. So we're very excited about it in these precursor conditions preventing – that could potentially forestall or prevent progression to myeloma. Last point is in light chain amyloidosis, which is even before smoldering, where we've seen patients reach normal levels of the biomarker for it within six weeks in patients that have been on other drugs, whereas DARZALEX in a four-drug regimen, including DARZALEX really -- was not really that competitive and it took much longer for it to reach in newly diagnosed patients.

So we're -- we think we've got a differentiated antibody. We look forward to getting this broad development program underway. And certainly, there will be more to come on that as we move forward.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Excellent. And in the near term, you've got a LAG-3 readout in melanoma that there's a lot of interest in. How would you frame what a win looks like for that trial?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Yes. We're very excited about fianlimab and Libtayo combined in advanced melanoma. So we're running a study in first-line advanced melanoma that is using pembrolizumab as the comparator arm. We're looking at the high dose of fianlimab and a low dose of fianlimab and comparing both. That's mainly to satisfy the FDA's Project Optimus dose-finding requirements in oncology studies.

But we'll see what we get with the lower dose. We think we've got a pretty good differentiated combination because of what we saw in the early first-in-human studies across three independent cohorts. We saw response rates in the low 60s to high 50s. We saw median PFS when pooled of 24 months and complete response rates around 25% in about 100 patients. So that would be very differentiated relative to PD-1 monotherapy as well as cross-trial to approved immunotherapy combinations, including the approved LAG-3 combination that's out there.

So I think for us, success is, obviously, you need to beat pembrolizumab, that's sort of table stakes here. But I think there will be immediate cross-trial comparisons made to Opdualag, where they, in their FDA label, have a 10-month median PFS and a response rate of approximately, I think it's 43%. So if we're able to replicate or even approach replicating what we were able to generate in the first-in-human studies, I think we'd be very well positioned to become the new standard of care in advanced melanoma. And while we're talking about it, I might as well throw in the rest of the upcoming readouts there. We're going to have a lung cancer data likely in the early part of 2026.

And this is a great unknown for us. We know that the tumor is a bit less immunogenic than melanoma is. But we're looking forward to seeing what an early cut of PFS and OS could look like in patients, all comers as well as in a high-expressing study as well.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

You've also got a head-to-head study with fianlimab and Libtayo against Opdualag in melanoma. Could you talk about the timeline for that trial? And also just degree to which you think that that's a gating factor for a successful launch?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Yes. I think it will be interesting to watch. This is a study that we are -- that objective response rate is the primary endpoint. And of course, we'll have progression-free survival and overall survival as key secondaries, but they may not be mature when we read out the ORR data, which we -- I think we expected the completion date on clinicaltrials.gov is in the first half of 2027. So we still have a little bit of time before that data will mature.

But I don't know that it's key to the launch. I think it really comes down to how successful are we in that pembro-controlled study, and you'll be able to compare the baseline characteristics, compare the results. But the head-to-head could certainly seal the deal for fianlimab and Libtayo to become the new standard of care.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Excellent. Moving over to complement. You had some MG data recently that – I know it's a crowded space, but at least from my standpoint, it looks very, very compelling. You probably had a bit more time to talk to some docs since then. What are you hearing about how this might fit into the treatment paradigm?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Yes. Just to refresh, we read this data out last week of August, and we generated the best data. We generated two positive data sets actually, the combination of our C5 antibody and the C5 siRNA as well as in the siRNA monotherapy. The siRNA monotherapy despite having less robust C5 blockade actually generated the better reduction in MG-ADL, the primary endpoint for the study. And that's kind of a best case scenario for us, because this siRNA monotherapy, cemdisiran, can be dosed every three months.

Quarterly dosing, we think, is a meaningful advantage over today's C5 inhibitors that are approved in generalized myasthenia gravis. There's a once-daily subcutaneous injection, zilucoplan. There's an every four-week infusion, SOLIRIS and an every eight-week infusion with ULTOMIRIS. So clearly, a dosing interval advantage, as well as an efficacy advantage when you compare cross trial. So our data stacks up pretty well in the C5 category.

But if you look beyond that in the FcRns, we also compare pretty well on an efficacy and safety standpoint. So I think our view is this is going to be a pretty big player in the C5, the MG space. And beyond that, we have a real franchise opportunity in C5 with PNH, where we're evaluating that combo I mentioned and should have data in early 2027. And even beyond that, in geographic atrophy, we're looking at, again, the monotherapy as well as the combination and could have data there in 2027. So we're moving forward pretty quickly in C5.

We think we've got great tools to use to try and treat these complement-mediated diseases.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

In geographic atrophy, you said timing was what year?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

2027, I believe, we'll have some initial data.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Great. Great. And then on Factor XI, this is another part of your pipeline that's getting a bit more focused now. You started a few trials this year on the back of the Phase II from last year. Maybe if you could just give an overview of that program?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Yes. We are very excited about Factor XI and the potential to really expand how anticoagulants are used today. They are already used quite widely, especially in indications like stroke prevention as well as in anti-clotting conditions such as following orthopedic surgery and other settings like that. So we're -- we think that the main reason this category has been somewhat limited is the bleeding risk. And we think that Factor XI will address that, and you'll get maybe as good efficacy, perhaps slightly better, but you'll have markedly lower risk of bleeding, which we think will be market expanding.

So we've launched our initial Phase III study in VTE following knee replacement surgery, and it's going to look at both of our antibodies, our catalytic domain antibody, REGN7508 and our A2 targeting antibody, REGN9933. The reason we have two is we think they're going to have distinct profiles that can address perhaps different populations with REGN7508 addressing patients that need to maximize antithrombotic activity.

We know from preclinical assays that the time to clot is significantly longer with REGN7508 versus other antibodies in the category as well as the small molecules, whereas '9933, which, as I mentioned, targets a different domain on Factor XI, could have significant safety advantages while still having competitive antithrombotic activity. So we have -- we can kind of pick and choose which antibody is right for a certain population and we're really just getting started. We began a Phase II in a stroke prevention setting that's primarily to assess safety.

And once we get some of that initial data, we'll be moving into Phase III studies. And then there's other indications that we haven't discussed yet, but will once they come to -- once we're ready to launch them, which should be within the next few months. Some of this -- another one or two this year and then a few more in early '26 is the plan.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Is the level of R&D dollars that you would want to put against Factor XI contingent on the data from milvexian that we'll see next year?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

I don't think we would ever peg our investment to someone else's drug. We also believe that, like I said, we have very different pharmacodynamic properties than the small molecules. And we'll see what we get with milvexian. I'd be probably more interested in what the safety looks like than what the efficacy looks like. But I wouldn't want to make a decision on one of our programs based on someone else's drug.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

On obesity, you recently shared the full 26-week data for the myostatin and activin trial. We've seen a lot of data across the space from those programs, including from Lilly. Like what would you say or the overall learnings from how these muscle-sparing agents could fit into the obesity landscape?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

It's a great question. I think for us, we were interested in seeing whether or not these muscle preservation assets could reduce the amount of lean mass that's lost while patients are on a GLP or GLP-GIP. And we know that, that number is somewhere around 20% to 40% of your total weight is lost in lean mass. And we saw it exactly replicate that number. I think it was 33% of your weight was lost in lean mass on the semaglutide control arm in our study.

When we combine semaglutide with trevogrumab, our myostatin blocking antibody, we saw about half of that lean mass be preserved. So we lost similar amounts of weight, but the composition of that weight loss was much more fat versus -- and less lean mass. When we layered on garetosmab to the semaglutide-trevogrumab combination, we saw an even greater preservation of lean mass, something around 80% - 85% of lean mass was

preserved. So nearly all of your weight loss was in the form of fat. That one did carry with it some safety side effect issues that we need to consider if we're going to move it forward or not.

But I think we are most interested in looking at combining weight loss assets with trevogrumab. And we have another study underway that will look at what the weight loss curve is over a longer time period over a year, as opposed to six months. So we're interested in what that looks like, and we'll make some decisions there. We also have some work that we're doing preclinically on next-gen assets that may be more effective than what we are currently looking at.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

And you also recently in-licensed the GLP-1. Could you talk about how you would fit that into your program?

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Yes. And maybe the whole philosophy for us on obesity is not so much about the weight loss, but the quality of the weight. It's not just weight loss, it's really about fat loss. We don't think that Hansoh's GLP-GIP that we in-licensed, which is known as olatorepatide, is going to be really any different than what's already out there between semaglutide and tirzepatide. But we do believe we have the assets to help improve the quality of weight loss, and we'll be looking at that as well as in combination with other agents in our pipeline in our portfolio that can address obesity comorbidities.

Of course, there's many of those -- and so we haven't divulged exactly what we're going to be doing there, but we do have several that we think would look attractive. And overall, we are going to pursue monotherapies with olatorepatide in generalized obesity as well as in type 2 diabetes. We hope to get started on our Phase III program next year, subject to regulatory feedback. And once we get underway there, I think we'll begin in earnest evaluating what some of the combinations that we have in mind look like for those certain patients that we can address.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Great. Great. Well, Chris, I think I've given you enough of a break, so I'll come back to -- maybe if you could start with just sort of laying out the overall capital allocation framework for Regeneron, and then I've got a few specific follow-ups.

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

Sure. So we've been very consistent in terms of how we describe our capital allocation priorities. First and foremost, it's in internal R&D. I think you've heard from Ryan about sort of the breadth and depth of the pipeline, and we'll continue to invest as appropriate in that pipeline. Beyond that, we also look at external opportunities.

A lot of questions we get from the investment community is about M&A. It's not the primary focus of our external investment. We also have a very active business development group that looks to in-license technologies and do collaborations, right? So I think you've seen us do deals with Alnylam. You've seen us do deals with Intellia, where we think there are opportunities to complement our core, sort of, antibody expertise with other modalities where it makes sense to target particular disease areas.

And then beyond that, we return capital to shareholders. So we've had a share repurchase program that we implemented, I believe it was in 2019. We've -- if you look at the level of repurchases, we've stepped those up in recent history. First and second quarter, on average, we repurchased about $1.1 billion of our shares in dollars, $2.2 billion through the first half of this year. And then we also implemented a dividend program this year.

So that's been in effect for all of 2025. It's in terms of yield, fairly modest, but the intent of that was to basically open up the shareholder base to those interested in Regeneron that had a dividend mandate. So this gives them the opportunity to -- if they believe in the Regeneron story – to give them an opportunity to make those investments. So those are what we call the pillars of our capital allocation, sort of, strategy.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Great. Great. And how do you think about the right pace of R&D investments when your top line is under a bit of pressure from EYLEA? Like is there a certain rate of earnings growth that is sort of a constraint on those investments? Or is it purely just an NPV-based decision?

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

Yes. I will say we don't manage the business based on short-term quarterly earnings targets. It's really about driving long-term shareholder value. We have a very robust process where the senior management team is obviously very involved in determining which programs we're going to move forward, which ones we're going to fund. And then even within programs, which studies we're going to fund.

And we're very careful about gating spend. So we look to obviously see opportunities where we can get proof of concept or get an early stage or an early look at efficacy through interims and things like that before we commit significantly to broader later-stage programs. And obviously, we look at other qualitative things that drive where we make those -- the R&D investment. And it's -- as I said, the core pillar of our capital allocation strategy is to really invest where -- in the internal capabilities of our R&D team where we think that's the best opportunity to drive long-term shareholder value.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

And on the external innovation side, you touched on this a bit, but if I could just go a little bit further on it. Is there any shift in your openness to more sizable opportunities just given the maturity of the company and the size of the balance sheet?

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

I wouldn't say there's a shift, right? I think when people describe our M&A approach, historically, it's described as being sort of bolt-on opportunities or fairly modest in size. That's just the result of those transactions where we thought it made sense for us to obviously consummate them. With that being said, we're constantly looking at various opportunities out there. The challenge is with later-stage opportunities, it's very, very competitive, right?

And we are very sort of focused on what value can we drive with some of those opportunities and where can we compete. And we're also obviously price sensitive. So we've looked at a lot of things. We have the balance sheet that has -- offers us a tremendous amount of flexibility that if the right thing came along that we thought made sense, we would obviously be in a position to execute on that. We just haven't found the right thing right now, but we're actively out there looking.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Great. Thank you so much. Just one last question would be, what would you say are the most exciting reasons to own Regeneron now and into 2026?

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

It's clearly the pipeline, right? I think if you look at the pipeline today, and I'd be curious to get Ryan's perspective, the breadth and depth of the pipeline, we think, is unprecedented in terms of what the opportunity is out there. We've got a team that is proven that if you look at what Regeneron has done historically in terms of bringing both EYLEA and Dupixent to the marketplace, two unicorns in terms of what they've done, not only for shareholders of Regeneron, but also for patients and the physician community, we are very confident that we're going to be able to -- with the pipeline we have -- to sort of drive additional opportunities, both for patients as well as shareholders.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Yes. And my old boss, Bob Landry, used to use the iceberg analogy, so I might as well too. Of our pipeline that I am -- I would agree with Chris, is the most exciting part and the reason to own Regeneron -- what's available to the outside world is a small fraction of what we're working on and what we're excited about. And there's -- I mentioned preclinical opportunities in the I&I space. I happen to also be very excited about some preclinical opportunities that should be moving in demand in ophthalmology over the next couple of months.

So some novel targets that will treat some other diseases that are highly unmet. Additionally, in rare disease, we're working on various different projects there. We just read out some positive data for garetosmab in a terrible disease, FOP, that can hopefully help a lot of patients there. We also have our otoferlin program for hearing loss, genetic hearing loss, that we're looking forward to hopefully bringing to patients very soon.

So there's a ton going on. We're very excited about all the opportunities we have, both in the clinic as well as what's to come. Genetics continue to be our compass, and we believe that will help us unlock disease and help a lot of patients.

William Pickering - Sanford C Bernstein & Co LLC - Analyst

Excellent. Thank you both so much for joining us.

Ryan Crowe - Regeneron Pharmaceuticals Inc - Senior Vice President, Head of Investor Relations

Thank you.

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

Thank you, Will.
