PFE - Pfizer Inc at RBC Global Healthcare Conference (Virtual)

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PRESENTATION
Randall S. Stanicky - RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst

Great, thanks, everybody, for joining us for our next virtual fireside chat here. We're kicking things off again with our next company. I'm Randall Stanicky, the pharmaceuticals analyst here at RBC Capital Markets.

And next up, we have Pfizer. The stock has proven resilient in the current pandemic. It's one of the names that we've been highlighting as defensive and wanting to own in this environment. And so with us to chat on the company, current dynamics and outlook here, Senior Vice President of Investor Relations, Chuck Triano.

And so Chuck, first, I just want to say thanks for joining us. It's great to have Pfizer at our conference. So thank you for that.

QUESTIONS AND ANSWERS
Randall S. Stanicky - RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst

And then to start off, let’s jump into DMD and the market opportunity. This was something that you guys sounded pretty excited about on Friday relative to the data. You’re pushing into Phase 3 early second half. To me, there seems to be more debate with investors around the competitive dynamics with Sarepta. So I have 2 questions but the first one is just, how do you think about the DMD market opportunity for Pfizer? And again, I mean, you guys talked about scaling up here on a presumption of success. So maybe touch on that and then I have a follow-up.

Charles E. Triano - Pfizer Inc. - SVP of IR

Yes, sure, sure. Yes. And thanks for hosting the conference, so a pleasure to be here.

If we look at the prevalence, we see about 40,000 individuals affected with DMD in the developed countries. So within that 40,000, there’s probably 10,000 to 12,000 affected in the U.S. markets here, so certainly a significant market, obviously very dire unmet medical need on that front.

And I'd maybe just add quickly that sometimes one of the first questions that we get is just about gene therapy in general and whether it is a focus area for Pfizer. Or is it more just a one-off? And I just want to really emphasize that the whole Rare Disease business, inclusive of gene therapy, is a very high priority for Pfizer, right? As you're probably aware, we're set up into therapeutic area business units. Rare Disease has its own business unit, right, its own chief scientific officer, chief development officer, a president. So rare disease, inclusive of gene therapy, is a very high focus area for Pfizer.

And even with DMD, we’ve talked about spending around $800 million of investment in manufacturing capacity down in North Carolina, so not just for the DMD program but for some hemophilia programs as well. So this is a big area of focus for Pfizer, an important area.

And I guess I just wanted to add that because sometimes the first question I get is why is Pfizer in gene therapy. We’re here because we think we can – we have a very comprehensive and a very competitive end-to-end capability between manufacturing, clinical trial, development and then
marketing, right? So we’ve been in rare disease for quite some time, have a lot of experience here, and this is one area where we think we are absolutely playing to one of our strengths. So I’ll stop there go on to your next questions on the topic.

Randall S. Stanicky - RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst

Yes. I mean you’re clearly committed, and so there’s a lot of focus on this program as a big driver within gene therapy and rare disease in general. So if you look at what we’ve heard coming out of Pfizer is there’s some debate around efficacy as you and Sarepta have used different study measures. You developed an LCMS method or mass spec, and Sarepta uses Western blot. But I thought you’d said Friday, you looked at both. And I also think your patient age was slightly older, which matters. How do you characterize your data versus Sarepta’s understanding, that they’re not totally comparable?

Charles E. Triano - Pfizer Inc. - SVP of IR

Yes. And right, there’s always the danger of cross-trial comparisons, right? So our mean age was a bit over 8 years old. And I think the first fact to point out is when you get into the older age group, this is where you’re going to see some natural regression, right? So you’re going to see natural decline in the boys at that age as opposed to maybe in the 4- to 6-year-old age group, you’re seeing natural improvement, right, regardless of any intervention. So as you have older boys, you are showing improvement in a cohort that you would expect to decline as opposed to showing improvement in an area where you would expect some improvement. So there’s one difference there in terms of just the bandwidth of the ages that we looked at.

For us, we have seen right now, we’ve shown the most comprehensive efficacy data for either program out there. Very encouraging consistency in the results is what we’ve seen. And that’s one big point I would stress for us, is that consistency of the results, right? We used some different measurements. We mentioned we’re using LCMS, which we view as more modern, more predictable, more accurate approach than Western blot. We did mention on the call that when we looked Western -- looked at Western blot with some of our data, in some instances, the readings exceeded 100% of the normal value that we see in our assays. So in terms of LCMS, we show it to be a much more qualitative measure of dystrophin levels, higher -- more highly sensitive with good reproducibility and a wider dynamic range.

So we mentioned that we’re talking with the agency and have been very encouraged. We’re showing them our data and how we’re measuring it, but we do see differences there. We have runs, as we pointed out in the call, we have runs on Western blot, so we’ll see what we do with that data. But that is also a difference in terms of how we’re measuring.

So a couple of apples versus oranges in a sense in terms of the comparability, but the encouraging consistency in the results is what we are happy to have. No need for high steroid use there. And when we talk about the adverse events, we’ve had 3 that we reported, right? They happened early. They all rectified. And once we saw those, we made some amendments to the protocol where the protocol now is to look for complement activation and platelet reduction in the first 2 weeks, with instructions to treat with an anti-complement drug as necessary, right? So the patients, the boys don’t need to be inpatient for this. Since they’re going to be monitored for liver function, they’re not going to be too far away from a medical center anyhow.

And then I’d note we showed data on the 9 boys where we had the 3 SAEs that resolved. We’ve dosed an additional 3, so we’ve got 12 boys dosed. We have not seen any additional SAEs at this point in the Phase 1b study.

So I think as we look at the view that this may be decades, if not a lifetime treatment versus the initial lead-in period of 14 days with adverse events that were manageable on a benefit/risk profile, that’s why we’re very encouraged, right? So again, consistency in the results, manage and understand adverse events and the benefit that we can potentially provide these boys has us very bullish on the program.

And as we mentioned, we’re looking over the next several months that we’ll start in the Phase 3 program that is planning to enroll 99 boys, so a good program. Again, this is the Phase 1b data. More to come here, but in terms of what’s out there to look at, clearly the most comprehensive efficacy data of either of the studies is the data that we just showed.
Randall S. Stanicky - RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst

So that may stay in the underappreciated pipeline bucket for now. And when I launched in January, one of the biggest pushbacks was 2026 LOE. And now 2026 in the current pandemic seems really, really far away. But one of the themes that did stick was you do have some underappreciated pipeline, and you guys have been wanting to discuss that. You pushed the analyst meeting to September for obvious reasons given the pandemic.

But as you think about some of the things that Pfizer thinks that the Street is missing, what are those? You filed tanezumab. You're about to file abrocitinib soon in atopic derm. The Street feels lukewarm on those. If you were to step back and say, "Okay, here are the programs that Pfizer is most excited about," what would those be?

Charles E. Triano - Pfizer Inc. - SVP of IR

Yes. Sure, sure. Thanks. Yes, it's interesting, right? The LOEs, which start probably second half of 2026 -- and it's not that all of the LOEs happen in 2026, right? It's spread out between '26 and really '29. Paragraph 1, sentence 1 is that if you're launching drugs on a regular basis, that's part of the business, right? So that's not a surprise. The fact that we don't have big

(technical difficulty)

For the next few years is more a reflection of underwhelming R&D productivity 12 years ago, right, because we didn't have products to launch.

So for us, having LOEs is not something that we say, well, that's really peculiar. How are we going to manage that? And I'd also add when we look at sell-side models, generally the LOE cliff in totality in the back half of the decade, it all depends on which model

(technical difficulty)

Between $18 billion and $20 billion. I think we'd probably agree with that. But I'd also say when we take a snapshot of our pipeline today -- and to your question, Randall, when we take a snapshot of the pipeline today, again, this is ignoring any future business development and just take a risk-adjusted view of our pipeline, we have significantly more in terms of revenue generation from the pipeline than what the projections are in terms of revenue lost.

And so if you look at the R&D Day, how we're -- and this goes right to your question, how we are determining what to focus with the shareholder base and investors and analysts, with -- rather than saying we've got 70, 80, 90 programs, look how many we have. This is about quality. And so we made a couple of different cuts. We looked at compounds that we thought would be of most interest because, one, in almost all cases, what we want to discuss launching by 2025 or the end of 2025 or sooner, right, so this way, you can bring in compounds that would start to ameliorate LOEs. Two, we took a look at compounds -- again, this won't be all of them but for many, where we can show some new data. Always easier to talk about why you're excited when you've got some data to show. And then the third cut, we looked at our internal risk-adjusted revenue projections for those compounds. And then we took a look at sell-side models. And we took the ones where there were the biggest gaps in terms of what we think on a risk-adjusted basis and many of the sell-side models.

And look, we fully understand that from some compounds at Analyst Day, I haven't -- I'm aware of it but I've seen no data. I haven't heard you talk about it. We don't expect that they're necessarily going to be modeling revenue. But just to run down, I mean if we've got, I don't know, 18 analysts or so, you mentioned abrocitinib, right? So Phase 3 data going to be filing. I think about 1/3 of the models have any revenue at all for abro. If I stick with the I&I, we've got our JAK3/TEC for alopecia, right? This is post proof of concept in Phase 3. Maybe 1/4 of the sell-side models have any revenue at all there. If I look at our Internal Medicine area, which is probably an area in terms of the revenue potential where we might see the biggest potential in terms of single products, we have a post proof of concept if we look at NASH, a DGAT with an ACC. Again, it's post proof of concept. Is -- are there any revenue in any models out there? No.
We have the Akcea program, right, for high triglycerides, which is going to start a phase -- moving toward Phase 3, not being modeled. If I look at gene therapy, right, our hemophilia A, hemophilia B, again, both programs that already have proof of concept, 2 or 3 models showing revenue at all there. And then looking at our RSV maternal vaccine, where on our earnings call, we mentioned we just got positive Phase 2 data there, that's not modeled at all. And then the pentavalent meningococcal vaccine, also post proof of concept, not being modeled.

So a lot of companies like to talk about everything in their pipeline. And I saw one analyst note that said, but most of the compounds companies talk about are all pre-proof of concept, highly risky. The ones I just listed are -- have proof of concept already.

So the thought is that we want to show you our work. We want to show the community why we're excited. We leave it up to the investment community to do their own homework and see if they agree, disagree. But we find it's always easier to pick a meaningful and a manageable number of compounds, show our work with some data, with some patient analytics, market sizes, and then talk about how we see ourselves fitting in. Because usually the question that you just asked, what is Pfizer excited about? What is Pfizer focused on and why? So I think when we get to the Analyst Day, we'll have a good -- a manageable number of compounds where we can deep dive and move there.

But the short answer is right now, there's a lot that we have internally with good, risk-adjusted profiles that are not yet being included in analyst models. So when people look at the "cliff", it becomes a one-sided story externally. But that's why I say internally, we don't see it at all as a one-sided story. In fact, if anything, we see it more one-sided toward we have more than enough to replace what's out there. And again, that does not include any future business development. So I'll stop there on that question.

Randall S. Stanicky - RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst

Yes. And then if we pivot to what’s probably definitely not in Street models, you can look at COVID-19 therapy or vaccine. Obviously with Moderna’s update, a lot of focus around vaccines right now. But as we step back, there’s also a lot of focus on where Pfizer is at. And I think Albert was recently quoted as saying you guys could be in a position to deliver millions of vaccine doses of BN 162 (sic) [BNT162] by October. And so just in light of some of the news over the last couple of days, how are you guys thinking about COVID-19 from either a therapy or vaccine perspective?

Charles E. Triano - Pfizer Inc. - SVP of IR

Yes. So we’ve got both. We’re in the clinic now with our partner, BioNTech, right? And so we’ve got an mRNA vaccine -- and I’ll say plural, vaccines. We’re testing 4 different variants of an mRNA vaccine. So we’re testing not just the spike protein, which we are testing but we’re not just testing that. That’s Moderna’s approach, and I’m not saying that that’s a bad approach at all. But in addition, we’re testing both the spike and the receptor binding domain. So we -- which offers a different hypothesis and allows us then to select based on clinical data, the best 1 or 2 hypotheses to move forward here, right?

So as we look at that, we are looking to dose just under 400 patients with each of the 4 variants of the vaccine. One is a self-amplifying version of that. We have 2 modified RNA and one with unmodified RNA. So we’re looking at those. And the plan would be as we move forward -- and I expect we’ll probably be in a position -- and we’ve got our partnership here, so I can’t commit to everything. But I would think by June sometime, we should be in a position to have some early antibody data there. And presuming that 1 or 2 of the programs starts to show itself and emerge as probably a best hypothesis, we’d look to move to sort of a stage 2 of testing where we’d get into now closer to 2,500 patients and continue to add on the database.

And so that would run really through the summertime. And then after that, again, presuming things continue to go well and we’re seeing a good profile emerge, we’ve said in the fall, we’d have probably close to 8,000 total participants on vaccine. We’d be manufacturing the lead candidate. We’d be manufacturing at risk. We’d be in a position to have tens of millions of doses, if successful, this year and then hundreds of millions next year. So really kind of growing the clinical study, reporting data maybe not quite real time, but more of a back and forth with the regulatory agencies in terms of, as we get data in, to supply them with data. And we can do a much, we think, quicker analysis of the data.
But I think our view having the 4 different variants of the mRNA vaccine, both the spike and the RBD, may be an advantage here as we look to move quickly toward a vaccination. We’ve got manufacturing capacity at our existing facilities there. So we’re very hopeful that 1 of the 4 programs will look good.

And then on antiviral, we have screened out a lead compound. We’ve had some antivirals in our library back from SARS. They had not been in preclinical tests at that point. But we had, with a third party, screened out and have looked to -- looked and have identified a lead candidate that we’ll start looking at that. We’re also looking at Xeljanz. There’s a study going to occur in Italy with Xeljanz, looking if there may be some impact on the cytokine storm that we’re seeing as part of the ramifications of COVID-19.

So several irons in the fire here. Pfizer, in terms of decision-making and resource allocation, moving very, very quickly. And this is led from the top down, from the CEO level down, doing everything we can to, as safely and as quickly, look for vaccines or therapies here. So the company is moving very, very quickly. The whole leadership team and clinical development team, highly, highly focused here, which is what you need, right? You need a company, in not just Pfizer, but you need other companies, large companies that can make the investment, that have the resources in terms of clinical studies, manufacturing.

And look, and if it doesn’t work, we’re not going to go out of business, right, but we’re able to put our best effort forward. And just given the experience we have, we’re very hopeful that we can get a therapy here.

Randall S. Stanicky - RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst

So good-case scenario has you in the market on a vaccine with millions of doses in October. At what point would you be in scale-up mode to supply a good part of the country?

Charles E. Triano - Pfizer Inc. - SVP of IR

So I think we thought -- we think if it’s -- we’d have tens of millions, probably more under an emergency use utilization, and then we would look to see where is the high need and exposure there. And then as we look at next year, without giving the exact numbers, we have said hundreds of millions of doses as we move into 2021. So it’s going to be interesting.

It’s also interesting. In the one version, the one variant, the self-amplified, some of the preclinical studies show that you could need up to maybe 50x less dosing material for that compound, so that would really expand the ability. But I think for us, manufacturing into hundreds of millions is clearly easily a 2021 event for us.

Randall S. Stanicky - RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst

Got it. We’re in the last couple of minutes, but I did want to ask you just on business development outlook. Look, as you get past this Upjohn closing, you’re going to have $12 billion in proceeds from Viatris. You’ll pay down debt with that. That’s going to bring debt down to net leverage of closer to, call it, 1.5 to sub-2x. And you’re generating close to $10 billion in cash flow a year.

So the argument or the support to go do deals is there. And I understand Pfizer’s messaging, right? There’s no need to run out and do a big deal that’s only going to add to the LOE issues in late 2020s when you could do mid to late-stage pipeline deals that can help you grow through that 2026 LOE.

How are you thinking, though, about deploying capital? I mean should we be looking at Pfizer getting more aggressive coming out of this pandemic? Are you seeing deals currently?
Charles E. Triano - Pfizer Inc. - SVP of IR

So I think -- I mean, we always see deals. And I guess there’s no necessarily pattern that you have to follow, meaning steady deals, one a quarter or what have you. And sometimes, they seem to come in flurries as well. We just brought in a Lyme disease vaccine that’s in Phase 2, right? So we’ve been doing -- we’ve done things in rare disease and vaccines.

So we’ve been steadily building on what we know best. So when we look at deals, we are for the most part, sticking to our key therapeutic areas because you’re less likely to make mistakes if you’ve got a real talented team in the rare disease or the vaccine or the I&I space where you really know what to look for when you’re looking to source externally. So again, less likely to make mistakes as opposed to buying into an area that you don’t know. So I think it’s when we focus on what we’re looking at.

Revenue now is not our issue, right? We’ve said at least 6% on the top line in terms of a revenue CAGR, right? We were saying about 6%. Now we’re saying at least 6% through the end of 2025.

So it’s not about bolting on revenue now, right? That was more on the Hospira or the Medivation deals. It’s really looking to what your earlier question was about supplementing the internal pipeline for this back half of the decade. So that almost lends itself more often to doing licensing deals and maybe one-off of deals for compounds that are in Phase 2 or so, that we can add a lot of value to given the expertise, if we stick with the areas that we have.

Look, we never say never, right? There’s no upside to saying we will never do something because you never know when the facts change or opportunities present themselves. But right now, our focus really is on the back half of the decade. And as a pure-play biopharma company post Upjohn, right, it’s all about the pipeline. And you really want to -- you want to carve yourself out as a real winner in a manageable number of therapeutic areas. I think the old Pfizer, way back, right, was in a lot of different therapeutic areas but didn’t really command many of them. So I think that’s how we look at BD.

When I look at the $10 billion to $11 billion in cash flow, capital allocation and dividend I’d say is very -- will remain an important part of the Pfizer story and a growing dividend, right? So that takes a big chunk of that cash flow. CapEx is probably a little less than $2 billion a year. So that leaves you, in terms of cash flow that’s not allocated to either the dividend or CapEx, it leaves you $1 billion to $2 billion left over to redeploy in the business. Now we could always borrow for opportunities, but it is a bit of a different story as opposed to having $5 billion or $6 billion or $8 billion in cash flow kind of left over after your dividend and CapEx every year. So it’s a different story.

So I think to our view, we’re always looking. I think we do see a lot of interesting -- I know we see a lot of interesting science out there that we’re pursuing. And we’ve got a reputation now as becoming a very good partner, as I’d say as opposed to a decade or 2 ago where it was a different story here. So again, we never say never to anything, but again, with our -- I would echo what we’ve been saying generally is that our main focus is to bolster the areas where we already believe we have the right people, the right platform, and we want to add more compounds into those areas.

Randall S. Stanicky - RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst

That’s helpful, helpful color and probably a good place to end as well. We’re a couple of minutes over. So I want -- Chuck, thanks for joining us. We’re glad we have Pfizer at our conference.

And for those on the line, our next session starts in 3 minutes. And that’s the keynote with Dr. Scott Gottlieb, who coincidentally, Chuck, is also on the Pfizer Board. So with that, thanks, everyone for...

Charles E. Triano - Pfizer Inc. - SVP of IR

Good. Thanks, Randall. Thanks, everybody, for your attention. So long.
Randall S. Stanicky - *RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst*

Take care.