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# EDITED TRANSCRIPT

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## CORPORATE PARTICIPANTS

**Stephen Hoge** *Moderna, Inc. - President*

## CONFERENCE CALL PARTICIPANTS

**Tyler Martin Van Buren** *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

## PRESENTATION

**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Okay. Great. Well, let's go ahead and keep going. Good morning, everyone. Tyler Van Buren here, Senior Biotech Analyst at TD Cowen. And for this first far-side chat, it's my pleasure to introduce Stephen Hoge, President of Moderna. Thank you very much for being here Stephen.

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**Stephen Hoge** - *Moderna, Inc. - President*

Thank you, Tyler. It's exciting.

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## QUESTIONS AND ANSWERS

**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

So before I get it started, for the audience, if you guys have questions, feel free to raise your hands as well. And we'll plan to dig in most R&D questions (technical difficulty) I wanted to kick it off with the commercial one. On COVID, you guys have talked about $5 billion in deliveries for 2023, maybe around $2 billion in the first half, $3 billion in the second half. Can you just discuss your confidence in that number and then also talk about the potential levers for outside of that number.

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**Stephen Hoge** - *Moderna, Inc. - President*

Yes, for sure. So first, I want to say thank you for having us here, having me here. It's great opportunity.

So first, that $5 billion, as you just referenced, it's divided almost equally between deferrals from last year's contracts and then advanced purchase agreements for this coming second half. And so I'll talk about those 2 somewhat separately.

We expect about $2 billion of delivery, as you just said in the first half of this year to happen, really the deferrals that happened from last year's purposes. And what you is left with that is about $3 billion of advanced purchase agreements or other contracts, which are mostly with Canada, United Kingdom, Switzerland and Taiwan, a couple of other small countries. And we feel confident that, that's going to materialize. We do believe there's going to be a booster campaigns in those countries in the coming fall in the Northern Hemisphere.

What's the upside to that and the reason why I think we described that in our quarterly call as a bit before, is the United States, Japan and the European Union, we expect all to purchase vaccines, to run full booster campaigns. And really that represents even a larger portion of the market than we currently have.

Now there are obviously supply vaccines and existing contracts with some of those countries, but we do see upside from particularly those 3 large market.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

And so last year, if I recall, I think it was June 30 when they surprised you right with the proper strain, and so do you think they might be a little bit more organized this time around? What's the potential time frame for strain selection? And again, despite that, you guys are able to get the vaccine ready by September, but maybe you could just review for us how the process will play out this year.

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**Stephen Hoge** - *Moderna, Inc. - President*

Yes. So we're guided by the regulators. And I think the U.S. FDA is most clear in defining what their process is, and they actually did that at the advisory community last month. They expect to make a strain selection decision late May, early June and run through an advisory committee on VERPAC in this country that would then define what's the composition to vaccine they want to see for the fall in the United States. They lead on a very (inaudible) typically, the right one about that. It will depend a lot upon epidemiology and then the evolution of the virus and how much in the innovation we continue to see. But if you were to look today, it's clear that we've kind of moved out of the BA.4, BA.5 and into some XBB1.5 and (inaudible) as you alluded to, it's probably still little premature to say whether the dominant strain will be by -- this time last year, it was BA.1, BA.2. And by the time they made a decision in June, it was BA.4 and BA.5.

And so what we're trying to do as a company, we are prepared for all outcomes, which is that we're actively following the evolving strains. And what we're preparing to do is to be able to respond very quickly. We're trying to do as much pre-work as we can when (inaudible) happens, so that we can do what we do last year, which is ultimately, we were able to support a global boosting campaign with updated vaccines.

Now last year, we had 2, as you know, and that added complexity. Our hope is that this year, maybe it's not 2, but if is, if it does require different geographies, different countries, choose different path. We need to be ready to meet that challenge as well. We've done it once, and will do it again. We hope the second time is a little bit easier.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

That's great. And do you think there will be most likely a bivalent or monovalent.

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**Stephen Hoge** - *Moderna, Inc. - President*

Personally, I think the science supports a bivalent approach. And we've seen that in our own data, in public health officials data. We ran actually a head-to-head clinical trial of bivalent versus monovalent last year in the United Kingdom, and showed against some of the earlier Omicron strains with significant improvements and efficacy in preventing COVID-19.

Now again, it's really not our choice alone. We have to be prepared for outcomes and that's one where we will look to guidance for public (inaudible) FDA, but also CDC on which choice they make for this coming year. We will be ready whether it's a monovalent or bivalent to move forward. I think from the data I've seen so far, I think a bivalent covered more basis.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

And there's been some, I guess, uncertainty around booster uptake, right? Especially with this last fall, winter season. I think we had a lot of people last year who thought that they were still protected from Omicron. Obviously, Omicron hasn't happened this year, but maybe can you provide some bookends around what you think booster uptake might look like in the next fall and winter season..

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**Stephen Hoge** - *Moderna, Inc. - President*

Yes. I think 2023 -- 2022 is a particularly challenging year to do any prediction of -- you just alluded to it. But a year ago today, we were dealing with Omicron BA.1 and waves and shutdowns happening and that in just 12 months. And then what you went through is people receiving a fourth dose booster recommended by the CDC or (inaudible) globally in the second quarter and then a bunch of people getting infected with Omicron, probably not BA.1, probably BA.4 or 5 in the summer. That was a big wave in this country, non-seasonal wave, and then obviously uptake in the fall of the bivalence. And many people have a hard time reading as we do, as do I, but (inaudible) of what that all means because so many people, 30% of people receive the vaccine, probably more than that actually got infected. All of it happening around the same time, what happens now that we're hopefully more of a seasonal situation, where hopefully, there isn't a summer wave of an XBB or (inaudible) therefore, people are more available for a vaccination (inaudible).

I think the best predictor may not be COVID, candidly, I think that the best predictor probably is the influenza seasonal market. In this country, even this winter, COVID led to 3x the hospitalization, 3x of that of influenza. And the approach that -- and so that's just this last few months, right? And that's in the face of all the vaccines and all the prior infections that have happened. And the CDC data shows clearly you can reduce those infection.

And so if you look at the influenza market, actually closer to 50% of Americans receive booster every year over the age of 6 months, particularly above the age of 50, those over -- at higher risk, you see numbers that are 60%, 70%. And so our assumption is that, that market, the older adult portion of in particular, which looks more like 100 million doses every year of influenza vaccine, probably is the best predictor of what a seasonal COVID looks like for this year because we don't expect people -- we hope there's no summer wave, and we expect people to want to be protected against respiratory viruses that cause hospitalization death.

And as I said, as it stands right now, COVID is the bigger threat than (inaudible).

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Yes. All right. Let's move to flu, mRNA-1010. You got immunogenicity results recently, superior on A, inferior on B. You'll have a vaccine efficacy data potentially by the end of the quarter. What do you need to show with that vaccine efficacy data to obviously match the superiority that you're seeing with immunogenicity and potentially file?

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**Stephen Hoge** - *Moderna, Inc. - President*

Yes. So it's important -- the immunogenicity study was a safety and immunogenicity study. We're happy with the safety results. And I think you covered well. We've talked about -- met superiority on influenza A for 3 out of 4 endpoints and none during the fourth and then didn't make non-inferiority (inaudible).

That wasn't a huge surprise. It was -- we were always aiming higher on the As than we were on the Bs. And the reason is because the epidemiology of influenza, the disease burden in adults, which is what this vaccine being developed for in its first instance is 95% to 99% influenza A.

In fact, as we announced in that same press release, our influenza A efficacy, our influenza efficacy study, which is running in the Northern Hemisphere this year in the United States and Europe, has collected over 200 cases, and we said over 99% of them -- over 99%, if you do the math that's in one case. Because if there was 2 cases (inaudible) case of B, 199 of A and that's just further evidence that that's actually the -- that's what the cost driver is when we say people are going to be hospitalized or they're coming down with flu in this country, that's what drives it.

And that's why we thought when we moved forward a year ago with that candidate, we really want to focus on what's hit the home run on As and let's just cover what's needed to from a regulatory perspective on the Bs.

So what are we -- your question, how would we need to see to go forward with filing at this point? Well, the efficacy results are really the gold standard, right? Immunogenicity and immune bridging and surrogates are all for accelerated approvals. But if you run an efficacy study, that's what

the regulatory gold standard is. And it is against all of influenza that we're trying to achieve that outcome. And year in, year out, that influence is H1 and H3, it's influenza A with very, very small amounts of B in this population.

So I think if we see non-inferior efficacy or superior efficacy in that study, our expectation would be that, that's [medical standard] regulatory guidance, not for accelerated, but full approval, and we engage regulators around that. There is -- the regulators may say, it's tough for them to decide. They may say, great, thank you for that. You're right, but we would love to see, you increase your titers on B, even though it's not driving efficacy. And if they did, we would obviously respond to that. We think, as we announced last month, we already have ways to increase the titer on B even though we don't think that this will necessarily contribute efficacy in the (inaudible). And so that will be a conversation we have with regulators.

But I think any [non-inferior efficacy] or superior efficacy in our ongoing study would be the basis for full approval. At least that would be the approach we take into those conversations.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Okay. That's very helpful. Are you able to state what the non-inferiority margin is for the immunogenicity study so we can at least get some sense of what the minimum threshold is for superiority on A?

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**Stephen Hoge** - *Moderna, Inc. - President*

So generally, that's a discussion with regulators, different regulators have different perspectives on it. Non-inferiority, I would say, generally, rather than give you any individual regulatory position on it because again, there will be differences, is you want to exclude a lower bound of 10%, minus 10%. But again, it's fact and case-specific and it's important to note that many of the enhanced flu vaccines actually, in different ways, all of them, most of them have failed to meet immune standpoint at some point, either in the primary study or in (inaudible) they went from trivalent to quadrivalent. It's actually a not uncommon thing that vaccines receive full approval despite challenges in infulenza B. And the reason is the same, as I said upfront, which is, for the most part, people recognize that's not what's driving the disease. It's more of influenza B are included because they drive disease in young population, you want to have a single vaccine across, if you can.

But that's why generally, there have been multiple instances (inaudible) precedented of approval for that. So I think the point -- estimate point even that you raised about (inaudible), it's really going to be a totality of data conversation with the agencies, but the precedents are pretty clear that there are lots of approvals that have happened even for enhanced vaccines where they have not met all the endpoints on immunogenicity. And even in some of the enhanced vaccines, there are approved enhanced vaccines that were proved accelerated, had an obligation to demonstrate efficacy and fail to demonstrate efficacy subsequently.

Vaccines on the market from vaccines that did not -- had around 5 seasons worth of those vaccines to get there, and they were sold throughout. So my point is the influenza is uniquely complicated space from a regulatory framework and a public health perspective. And regulators will want to see the totality of that data, we'll want to see it all and decide on the path forward. And it's really hard to give an absolute (inaudible).

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Yes. Yes. Okay. That's very helpful. I guess with respect to your next-gen candidate with better potential matching against B, what are -- what can you say about the improvements you made? And when might that be able to reach the clinic and potentially get on the market?

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**Stephen Hoge** - *Moderna, Inc. - President*

So second part of that question quickly, we're actually starting that study very shortly. I think that the -- very quickly because it's really just an immunogenicity endpoint, I mean think of something that's more in line than what we've been seeing with the COVID updates, right? Not (inaudible)

and hopefully soon to see the efficacy platform. And I think it's possible. I'm not guaranteeing anything, but possible that actually that is the product that gets launched because you bundle all of that together, right? And bear in mind that these vaccines change their composition every year as a part of being flu vaccines and seasonal. So it's very normal to do that.

And in fact, the changes that we made are, just as a reference, are even much more modest than the changes we make when we update COVID vaccines that flu vaccines will be doing normally. And so we think it's well within reason that, that actually could be a product that ultimately gets launched, again, subject to discussion with the regulators and ultimately what the data sets. And I don't have the data. I don't know, and then (inaudible) them to decide.

In terms of the changes we made, there obviously, as I've alluded to, pretty minor. We haven't disclosed what they are yet. For competitive reasons we haven't done that yet. We will at the appropriate time scientifically, give some transparency (inaudible), it's a pretty straightforward exercise, increasing titers from our perspective.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Okay. Great. And I want to finish flu with a couple of general questions. So obviously, the potential advantage of your platform is that you have the rapidity of manufacturing and improved strain selection. But if you look at the data, the strain mismatch occurs, basically every 3 to 4 to 5 years, maybe correct me if I'm wrong. So how can you potentially demonstrate that post approval? Will that come from your studies or real-world data?

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**Stephen Hoge** - *Moderna, Inc. - President*

I think the answer will be a bit of all. We certainly expect to see it realize. So just to give you quickly the background on what you said, one in 6 years, maybe 1 in 5, 1 in 7 (inaudible) around, there will be a strain mismatch. There will be a bunch of different reasons. But the short version of it is, people have to pick the vaccine composition in February and March because they make it an egg. And then either the eggs evolve the virus in a way that doesn't look like the virus, which happens, (inaudible) adaptation or they take along 6 months later, 6 months earlier. We don't have that problem. We were actually, currently as we just talked about COVID, anticipating peaking in June, and we're going to set ourselves up in flu to do the same.

In a mismatch year, we'll have to partner with public health to do that, but they've never had the option. But in a mismatch year, efficacy can be terrible. We've all seen the new stories on that. Now you go to your pharmacy, your doctor's office and you get a vaccine, it's really not expected to protect you. And so the opportunity for benefit there, say it's 1 in 5 years, even if you were non-inferior in the 4 out of 5 years or even in our current studies, you just hit the same, but you were the only one that worked in the fifth year. On average, you're 20% better, right?

And from a health care system perspective, nobody is really happy with those expensive years. And obviously, nobody wants to go to their pharmacy or doctor's office, (inaudible) told they got the wrong vaccine. And so from our perspective, heavy focus on this first-generation product is, get it approved and show public health that we can update it later in the season and have better matching and avoid those mismatch years and essentially even if we're no better on efficacy, create more value to the health care system.

Now the question of where we're going to show that. I think for now, it's -- we're going to probably do a bit of both. So we are always going to have real-world effectiveness studies that look at how the vaccine performs, a CDC will do those as well. And those are going to be really important. And so every year, vaccines get rolled out, a better managed vaccine will show better effectiveness in that data as monitored by public health officials, CDC, in particular. And then that would provide obviously publication evidence.

But we will probably also take the opportunity in a mismatch year to consider looking at efficacy because, again, it will be the difference between getting a functioning vaccine and nothing and the opportunity to run an efficacy study, it's not a huge effort when you know your competitor, you improve the vaccine, the other competitor vaccines are mismanaged.

And so it'll -- we'll make that decision at that time. It will kind of also what else we got going on, but I think we will look to demonstrate that potential and then ultimately, get credit for that.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Okay. That's helpful. So some vaccine veterans I've spoken with have talked about the importance of room temperature, stability, prefilled syringes. So how close are you guys to potentially achieving that?

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**Stephen Hoge** - *Moderna, Inc. - President*

Yes. I think in refrigerated non-frozen stability or?

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Yes.

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**Stephen Hoge** - *Moderna, Inc. - President*

Yes. Refrigerated stability. There is some room temperature, but vaccines are not generally stored at room temperature unless they're (inaudible) and flu, in pre-filled syringe as I just said.

So first on the dosage form, on both points, heavy focus area. And we're trying to prepare ourselves to be -- look like that, a refrigerated pre-filled syringe across our platform. In the short term, when we're dealing with launching products, we are looking to make single dosage forms, so pre-filled syringes. We do have pre-filled syringe and single-dose vial. Some countries prefer one versus the other. And it's a bit of a dealer's choice there. But those single-dose forms are things that we expect to do in our COVID vaccines, our RSV vaccine, which launches last next year, as well as eventually influenza, again, subject to us completing the clinical trials that are ongoing, ultimately, in all cases, subject to regulators approving them.

But we think technologically, that's possible. And so the single-dose form is the first step. Refrigerated, we are also working on that's more of a second-generation improvement for all of those. It will be easier for flu and RSV than it was for COVID. COVID is an incredibly large mRNA, as we all know, making spike protein a very, very large protein, and that really dictates a lot of our job. And so it's much easier for us in some of the newer vaccines. And as I think we announced recently with our (inaudible), I think it's second generation COVID vaccine, kind (inaudible). That is targeting actually a refrigerated storage one. And even COVID, we hope to move to that space in the coming year or 2.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Okay. Great. So let's move to RSV. Do you have any high-level takeaways from the recent advisory committee with Pfizer and why so?

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**Stephen Hoge** - *Moderna, Inc. - President*

We feel really positive about it. The -- clearly, the support when you -- we've started to share our data. Our lead investigator presented some of the initial data at RSVW and we'll obviously publish that as well. But we're really pleased with our efficacy and (inaudible) profile and encouraged that the advisory committee felt really -- felt positively, I guess, voted positively for both those products. I think we believe that it's going to be a lifelong journey. This will be for decades. This is a virus that's been with us for our entire lives and be like flu. We're going to continue to need to boost people forever. And in that sense, we're playing -- we're focused on making sure that we bring forward what we hope will be the best product overall from efficacy, safety, tolerability, optionality, the ability to combine storage conditions, all those sort of things.

But what I would say from the advisory committee conversations is it's really encouraging that the path has now been (inaudible), and we hope to very quickly look through that ourselves with our own filings, which are hoping to complete in the first half of this year and then subject to the FDA reviewing this, we'll have our own chance at...

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Okay. And for the combination respiratory vaccines, obviously, you guys need to focus on getting the individual components approved first. But when could a combination respiratory vaccine become a reality, what should that progression look like for your combination franchise?

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**Stephen Hoge** - *Moderna, Inc. - President*

Yes. So the good news on combination is the pathway there is some way simpler and clearer, right? If you get the model, our strategies pretty clearly, we're going to go get the individual pathogen vaccines approved. And those are the ones where you have to run efficacy studies, like large safety and efficacy studies. Yes, costs a lot of money, it involves tens of thousands, we recruited 75,000 people last year. But then as you move out of those approvals, what you then go start doing is the combination studies.

So the combination studies are non-inferior (inaudible) safety sides. You just put them together and you pick your final or 2, and you create the combination. It's much quicker, it's again, think of it as the difference between bivalent updates or the sequence updates we did last year versus first approvals. And then -- and that will go really quickly because you don't need to go generally. We don't expect to (inaudible) run the efficacy with vaccine. We got the efficacy, we just short in combination, not (inaudible), it's good, safe and you go.

There is a contingency though, which is that you have to get the combination of the individuals approved.

And so we're obviously there with COVID. We are optimistic on RSV. We got a little bit of work to do with flu, we're going to get there, hopefully quickly. And then once those are approved, we can do those combo.

We are starting the research and development now. So we're running clinical studies on a range at for combos because we can answer some of those questions at risk, but if there are small changes to what we're doing on individuals, we want to reflect those in the final Phase III studies going forward.

So it is contingent on getting those -- are focused on getting those first-generation models approved, working our way through the victory very quickly here. And then we will go very fast, like think of what we did with the COVID updates on the combos and then roll (inaudible) thereafter. And so we're prepared most of that work in -- and I don't have an update on it today, but we're ready to go as soon as we (inaudible).

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

So let's move to oncology with PCV.

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**Unidentified Participant**

Can I ask a question. Actually, what do you think about -- what's the likely dose for the combo dosing that you're going to need? How much in each and in total? Where do you think that's going to shake out?

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**Stephen Hoge** - *Moderna, Inc. - President*

It will depend a lot on -- just depends a lot on the immunogenicity that comes from those early studies. And so as it stands right now, our primary dose that we've taken for in COVID, as you all know, is 25 micrograms, it's bivalent, that's with our (inaudible) 73 platform. But we're actually doing

a much lower dose in the second-generation product. And so I can't even tell you with a COVID, whether it's going to be 50 micrograms or that most lower dose.

Within our -- within flu and within RSV, it's 50 micrograms. And within flu, we've been evaluating 50 micrograms in the existing studies. If those are approved, then you'd add those to it. We expected that slightly additive, A+B+C (inaudible) dose. But I think we have to wait for the data to confirm that.

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**Unidentified Participant**

So you're talking about sort of at a minimum 150?

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**Stephen Hoge** - *Moderna, Inc. - President*

If it were those 3 approved dose levels, that's a reasonable estimate. But I would remind you that I think actually, our COVID vaccine is already going through an update. So I think we'll see what that looks like as we go forward. It may or may not be that. And we haven't made that decision, so at this point, speculative to sort of pick a dose all the way to see the data.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

All right. So PCV, obviously, a 0.56 hazard ratio is really impressive. Expectations are certainly going to be high going into the update of the presentation, whether that's at ACR, ASCO or both. What else should we be paying attention to that maybe is not obvious from the top line data release?

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**Stephen Hoge** - *Moderna, Inc. - President*

Yes. So we're thrilled by that data. I think we will look to at ACR and hopefully ASCO both providing updates, clinical updates. We will look to publish very shortly here and already submitted publications on the data. There is a lot of very exciting step to see and we want to make sure we get it out in a fair view context in the right form.

I think the things that I would -- we all want to be looking at, the shape of those curves, the Kaplan-Meier curves and the evolution of that hazard ratio over time. We give you a top line number, 44% reduction, 0.56 as a hazard ratio. But the question is, is that 0.56 all the way through? Or as generally has happened in immunotherapy in (inaudible) for checkpoint inhibitors like KEYTRUDA, does that improve as you look at the piece? Is it -- does the relative benefit become more superior over time? That's a stronger signal, you've really got the immune system controlling that disease.

The other thing we'll be looking for, we are studying right now is the translational biomarker there. Can we predict those responses, right? We're giving the total top line on 0.56 as a hazard ratio. That's all comers. That's randomized by nothing other than that they enrolled in the study. But obviously, you'd expect that there are going to be criteria that might allow you to show -- select those patients that are even going to more strongly respond, and that would lead to a higher benefit and improved hazard ratio.

Some of that is -- we've got to do that, and that's what we'll be sharing in successive presentations as we pull that together. But those are the kinds of signals that would suggest not only is the picture robust and strong, but there may be populations that are already really strong or importantly, if the hazard ratio is improving over time on a piecewise perspective, actually the statistics are going to continue to enrich and get stronger that all of which might suggest as we hope will be the case that at some point, this randomized 150-person Phase IIb study that we ran might be able to become the basis of an accelerated approval. And we have to follow it. It's too early to say, but we are hopeful that the data will mature that way.

It's randomized against standard control, statistically significant benefit. That's a quite reasonable place to start that.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Very interesting. So what's your level of confidence with respect to that data translating into the metastatic setting as well as other indications like lung?

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**Stephen Hoge** - *Moderna, Inc. - President*

I'm very confident -- very confident is danger for sure. I'm much more confident on translating into other adjuvant settings than I would be into metastatic settings. And that's really based on the mechanism of action of the drug, right? Our -- what we do is specifically increase the number of tumor-specific T cells that are able to see. (inaudible) tumor and go clear it. But if you went with a really -- as the immune system is finding a (inaudible) outnumbered, it's outgone. Even checkpoint inhibitors, PD-1s, don't do great if it's too late. And I think the principle behind the cancer vaccine from our perspective is, this is something that has a safety and tolerability profile that kind of looks like your COVID booster, [denied dose], but it actually prevents your cancer (inaudible) and that tolerability and safety profile is differentiated cancer.

And the idea that it's almost having your risk would going to say, not how do I use it late, how do you use it early. I don't get into a place that feels like I mean intercepting and doing more prophylaxis itself..

So what do we feel about -- how do we feel about how it's going to do with adjuvant in the Stage III space. I feel like in the non-small cell lung cancer, in other adjuvant indications where the KEYTRUDA were of general (inaudible) labels are strong, which will benefit, and they're still headroom, right? They're still -- large number of people that are not responding like they were in melanoma. We expect to give that very, very quickly. And I -- there's really no reason from a biology perspective, from a mechanism of action perspective that you wouldn't expect the benefit can be similar because we're just adding specific T cell populations in the same way.

I think metastatic is a bigger challenge. That tumor is built up defenses that are deeper and stronger. The reason why checkpoints are working there is issue. I think the more likely situation for where you will see benefit is, as I was just (inaudible) earlier, Stage IIIA, Stage 2 disease. Those are different types of studies than they've ever been run before. People haven't wanted to give checkpoints in those context, always. But I would ultimately be biologically more convinced that that's going to be a (inaudible).

Adjuvant Stage III, we're going full speed. We will keep our eye out on metastatic. We do have some early data from our Phase I and II -- Phase I, I should say. And there are some Stage 4 patients in the current side, but I'm more optimistic about the adjuvant.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Okay. That's helpful. We're getting update on time, but I have to ask you one question about the therapeutic pipeline. What's your favorite program and why? What's your favorite child?

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**Stephen Hoge** - *Moderna, Inc. - President*

Therapeutics. I -- this is a really tough one. Well, I'm very excited (inaudible) an update in September. We expect the update this year, as last year was just (inaudible) this year. The key question for us is can we get that into a pivotal study or expansion (inaudible) study, a single-arm study that would lead to prove. That will be the first time that we demonstrate with chronic dosing, we're well over a year in many of those patients, 18 months, 2 years. And where everybody on that study has chosen to stay in the open-label extension across all the doses. That kind of uniform engagement from patients and their families is, I think, a really strong signal (inaudible) physicians.

I think that program has a chance to -- if we can find that dose and expand it quickly and go very, very quickly. And I think that will be an exciting moment for us.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

Okay. So I'll end the chat as they normally do. So in closing, what aspect of the Moderna story do you believe is most underappreciated by investors?

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**Stephen Hoge** - *Moderna, Inc. - President*

I don't think people have -- I still don't think it's obvious how much we do. We have 48 development programs. We just ran very quickly through some stuff. We didn't cover everything we do. We've got cancer in a big way working. We've got rare diseases working. We're in pulmonary diseases with cystic fibrosis with Vertex and we ran (inaudible) count the number of Phase III studies last year. We're talking about RSV and flu and we're going to do some work on flu. We've got combos coming. We've got 75,000 patients last year.

What's perhaps not obvious is that we're still a pretty small company. And technologically, what we're doing pound for pound doesn't look like anybody else. And I think that, that I think that there's sometimes the desire to look at Moderna as a portfolio of individual products and say, "Well, it's good, but does it add up? And how is it going?"

I think if you ever take a step back and say, okay, but how was this company that was 800 people 3 years ago doing $35 billion of revenue and creating [1 billion] doses in [contribution to pandemic]. And at the same time, get multiple other products prove across things as range as various RSV and cancer and PA. And that ultimately comes down to our platform mindset, the network effect that we get across that, how quickly we're able to learn and leverage our infrastructure. And if we are eventually right across even just the 4 or 5 things that you and I talked about today, I think some people are going to have to realize that there's -- that kind of leverage is exceptional in terms of the efficiency of time, capital and obviously, of health care impact.

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**Tyler Martin Van Buren** - *Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst*

That's great. Well, Stephen, thank you very much for your time.

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