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PRESENTATION

Mark Dehring - *CSL Limited - Head of IR*

Ladies and gentlemen, good morning, and welcome to CSL's investor briefing. It's Mark Dehring speaking, and I have with me here online, Paul Perreault, CSL's Chief Executive Officer; and Andrew Cuthbertson, CSL's Chief Scientific Officer. Paul and Andrew will be speaking to a short deck of slides, which by now, you should have in front of you. If you don't, you can find them on the Investors section of the company's website, and they've also been lodged with the Australian Securities Exchange. Following the briefing, we'll then move to Q&A and be joined by David Lamont, CSL's Chief Financial Officer; and Paul McKenzie, CSL's Chief Operating Officer.

Please note, this briefing is being webcast. And lastly, before we start, I draw your attention to the forward-statement disclaimer contained in the slide deck.

I'll now pass you over to Paul Perreault.

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Thank you, Mark, and good morning, everyone, and thank you for joining us today. I hope everyone is safe, your families are safe, your friends are safe and healthy.



As you know, Slide 3 is the first slide I'll be covering on the overview. The COVID-19 pandemic is affecting all of us, and I would like to take this opportunity to provide shareholders with some insights as to how this is impacting CSL operations. What initiatives we're taking to respond to this global health conference will also be provided. I'll also update you on our employees, plasma collections, our commercial operations. And Andrew will provide that insight on CSL's R&D activities. And our capabilities as they relate to the COVID-19 as well as the company's response to support global efforts and deal with this pandemic. And then I'll finish with a brief comment on our financials.

So on Slide 3, the COVID pandemic spreads across the globe and has been, as you know, and all of us are experiencing the impact, both at work and at home. And without question, our daily lives and routines and those of our loved ones have been altered. And we are all trying to adjust very rapidly, and that's no different within CSL. And while this is a quickly evolving situation, I want to ensure you that the health and safety of our employees, our patients and our donors remain our top priority.

Over the past few weeks, I've heard numerous stories about the ways in which CSL employees are really coming together and continuing to deliver on our patients and for public health. And I would say that our employees are focused, they're remaining calm, they're productive so that they can be there for each other, for the families and the people that depend on our therapies.

CSL has always been an organization that deals with challenges head on, and I think we're proving that once again right now. I think it's also a testament to the values-based culture that we have at CSL, where everybody is banding together.

A small number of our colleagues have tested positive for COVID-19, and we're providing as much support as possible as they focus on their recovery. And whilst in the depths of COVID-19, our strategy and our mission hasn't changed, we continue to focus on delivering these innovative medicines to patients around the world, helping to save and improve their lives and, especially those living with this rare and serious diseases that our therapies address.

Our research and development team is well engaged with multiple academic partners and governments to find ways to apply our capabilities to help address the significant challenges that are posed by this COVID-19. Our well-established adjuvant technology of MF59 has been donated to the University of Queensland's COVID-19 vaccine development program. And in addition, Seqirus is working with a number of other agencies who may be able to utilize MF59 in their vaccine development efforts.

COVID-19 has also given rise to an increased demand for influenza vaccine. And unlike COVID-19, there is a vaccine available for influenza, and people are taking the precautionary measures to vaccinate. At the request of the Australian government, we will be manufacturing additional southern hemisphere influenza vaccine doses to meet the increased demand in Australia. You may have seen some headlines with Minister Hunt talking about our response to that request.

Many of CSL's products are life-saving and to safeguard our ability to deliver these medicines to patients who rely on them, we have implemented, across our business, our business continuity plans at all of our sites. And at this time, we are not experiencing any material issues with product supply. Even before COVID-19, our supply chain resilience measures ensured that critical materials are not sourced from any single supplier or country.

Turning now to Slide 4 -- there we go. Turning to Slide 4. Safeguarding the health of our people continues to be our top priority. We need to keep our staff of 26,000 across 60 countries safe. And unfortunately, some of our colleagues have tested positive. However, I'm pleased to report that many of the colleagues have already recovered or in recovery. When I say many, we've had a total of 45 employees across the organization that have tested positive. Now not all employees have been tested. And so I'm careful to say that we are monitoring the health of all of our employees at the sites and also tracking everyone that is working remotely. So if they do get tested and test positive, we try to address and help them wherever possible.

Being a global organization, we have been able to respond quickly to the needs of our staff, and we did so in China. As you know, we have a facility in Wuhan, and we were supplying additional personal protection equipment from our Swiss operations, for instance. And wherever possible, our employees who are able to perform their work remotely have been strongly encouraged to do so using available communication technologies to continue conducting business and to mitigate any business disruptions.



We do, however, need to continue producing medicines. Recognizing the importance of these products to patients, our sites are considered critical infrastructure. So we have been in countries that are locking down nonessential services as part of the containment efforts. We have been able to continue to operate as we've received the designation as critical and essential infrastructure.

Employees who need to be on-site to perform their work, such as plasma collection and manufacturing, continue to work. They're supported by the introduction of enhanced protocols on hygiene, social distancing, staggered work hours, and the list goes on. We've also had great support from many of the governments where our sites are located.

We've also accelerated the onboarding of critical roles and the implementation of succession plans for all key critical positions, both designed to improve the resilience within the organization. And as our employees are facing challenging situations at home, ranging from unexpected child care to self quarantine, we are staying abreast of pay and leave benefits arising in various countries, while we're implementing our own emergency standards to ensure employee jobs and income are protected during the crisis.

In addition, like many companies, all travel until the end of May has been restricted to business-critical, with employees observing strict adherence to the appropriate border control protocols throughout the globe.

Turning now to Slide 5 in plasma collections. Clearly, the collection of our raw material of normal plasma will be a challenge during this uncertain time. Even before COVID-19, the supply and demand status for immunoglobulins was a bit tight, as you all know, with plasma collection being a critical element of that dynamic. And we've implemented a wide range of initiatives to protect staff and donors as well as optimizing our plasma collections. Some of these initiatives can be seen in the plasma center photos that I'll show you on the following slide, and they include really responsive protocols on hygiene, greater frequency of sanitization, increased social distancing, enhanced personal hygiene practices in all of our centers and the pre-assessment of donors prior to their entry into the facility.

Consistent with our manufacturing sites, plasma collection centers are redeemed critical infrastructure. Currently, our network of centers is fully operational. And despite the challenges, we continue to expect to meet our objective of opening a total of 40 new collection centers this financial year. We opened a new center in Houston just a few weeks ago. To date, we have 32 centers that we have opened. So we have been on track this year. I have to say that the last 8 we'll continue to monitor to see if the cities and the resources that we have to open the last 8 this financial year will continue or whether we'll need to put those into next year.

And that really depends on how the plasma collections are running at our other centers as well. As medical facilities with critical infrastructure designations, we are able to provide our staff, donors and key vendors with a letter of safe passage. This provides the mobility needed to travel to the centers. Importantly, the document also extends to Mexican citizens, allowing them to continue to cross the border of the United States and donate. This is not a silver bullet, however, we still have to make sure that we're increasing our advertising, promotional programs to encourage new donors to come into a center and donate plasma. We have a process in place which redirects donors to a sister center if any problem arises with another center that we might have in the same city. And we've engaged the FDA with initiatives to release plasma earlier in the cycle, and we'll see how that progresses.

Investors may recall that plasma collection activity during the global financial crisis in 2008, and there was also a bit of a slowdown. And although this is a completely different environment and a different issue, I do expect that we will see our donors return as they're able to feel like they're safe to come out of their homes and come back. So I do think that the timing of this will have an impact on the amplitude of donors coming into the center, but also will give us some indication as to how we will recover to higher levels of plasma collection after this particular situation starts to moderate.

I do have to say though that, that doesn't mean there won't be any impact to next year's numbers, I think it will be a bit lumpy as time goes on because we just don't know yet. I can tell you that in the month of March, we started to see a dip in collections. We were still above collections from last year. But over the last 2 weeks, we've seen a dip again where collections have dropped below last year's levels for the same month. So that gives us some indication that there is clearly some decline in the plasma, and you all know the cycle. So that as we continue to operate, we'll get more and more data, and we'll be able to give you further guidance at the full year. However, we do have the plasma that's needed to continue to supply through this year, and it should not have any impact on this year's financial results.



Switching gears, it is critical to keep our centers operational. Our centers have implemented a range of protocols, including temperature checks, questionnaires, and as I mentioned, expanded hygiene measures and heightened social distancing. We'll continue to follow guidance provided by federal state and local health officials, the CDC and work collaboratively with the FDA to ensure that supply is not compromised. When this crisis does pass, there will be an opportunity, hopefully, to accelerate back our collections.

I would say that there will clearly be some bumps in the road, and we do have a number of initiatives underway. And as normal, we'll be providing investors, as I mentioned, with an update at the full year. I do have to say that each center is its own universe in this situation. So even though we have designated status in all these areas for our plasma collection and for our manufacturing sites, there are local authorities that sometimes do not get the message. So some centers have seen a bigger decline than others, individual centers. And other centers are actually collecting above their budget. So it is quite a mix, and we're monitoring it very carefully, and we'll update you in August.

Moving on to Slide 6. You can see that in the first photo, and many of you have been on our site tours to our plasma collection centers. You'll notice that there is a much wider separation of the donor chairs. And we do are looking at screens between the rows of the donor chairs. We also have physical distancing markers on the floors in tape. You've probably seen this in some areas where you've been if you've been out to the stores, et cetera. So keeping people distanced from that social distancing as they come through the center.

Moving on to Slide 7. No doubt, you have read stories about elective surgeries being suspended, hospitals being overwhelmed or prioritizing COVID-19 patients, the unavailability of some clinicians to provide diagnosis, all of which might have some effect on demand for our products in the long term, but we just haven't seen that yet in our numbers. Perhaps not unsurprising, the product CSL produces are generally life-saving and life-extending and nondiscretionary. Patients need these products.

I will say that we have had a couple of observations that we've seen in the marketplace. We have received an increase in the number of request for immunoglobulins. And obviously, the demand for influenza vaccines has also been strong. As we enter right now into the vaccination period in the southern hemisphere, the reason that the Australian government has asked for additional doses, obviously, is that the burden on the health care system could be overwhelming if we start to see high influenza disease as well as COVID accelerating at the same time. I am pleased to report there has been no interruption in our supply chain. Our logistics team has done just a terrific job in getting product to where it needs to go. Despite some of the difficulties early on in China and in Italy, products still got through. And currently, there are no stock-outs being reported of our products.

And to round out my comments on the supply chain, again, despite these challenges, we are getting what we need to manufacture our products. As you may expect from a company our size, even before COVID, we have multiple contingencies in place with primary, secondary and tertiary suppliers around the world and across our supply chain. We also had very good help across borders in Europe, where our trucks and supplies were coming through and being expedited past the lines that were at the borders. We've made sure that we had those opportunities in place to make sure that as part of the critical infrastructure, things were getting where they needed to get in the right time.

On China, our manufacturing facility in Wuhan has recommenced operations, and skeleton staff are returning to work in Shanghai in our Beijing offices. So the staff is starting to return from work at home. We did see some congestion at sea ports with the importation of albumin in China, but we addressed this with air-freighted product into the country. And so overall, our business in China is starting to return to normal.

I'm going to pass over now to Andrew Cuthberston, my Chief Scientific Officer, who will be describing CSL's core R&D capabilities and the company's response to the pandemic. So Andrew, over to you.

Andrew Cuthberston

Thanks a lot, Paul. Hello, everyone. This is not an R&D briefing, and I'll be pretty precise. But we thought it might be interesting for investors to understand how CSL and Seqirus are responding to this crisis. We've had over 100 approaches from academic colleagues, other companies to do things. So -- but we will determine to reduce that number down to a small number of projects where we really believe we could make a difference. And part of that process was to look hard at our core R&D capabilities across the whole company, CSL and Seqirus, look at our skilled people, our technologies, our facilities, manufacturing facilities, importantly, and to an extent, our geography, where our key people and facilities were clustered.

And it's interesting just to note that both CSL, originally called the Commonwealth Serum Laboratories, and our Behring operations were established over 100 years ago to respond to public health crisis with biological medicines. And that deep expertise still exists in the organization, but obviously, with very modern research and development tools.

So what do we have on Slide 8, broadly looking across the whole organization, it's a powerful mix run by Bill Mezzanotte and Russell Bassar and their teams. We have an integrated R&D network around the world. And we've got world-class expertise in immunological science, vaccinology and protein therapeutics. Extensive experience in hyperimmune product development and, importantly, manufacturing capability; scaled recombinant protein-based vaccine development expertise and manufacturing; recombinant protein monoclonal antibody therapeutics development, expertise and manufacturing. And as Paul mentioned, our proprietary MF59 adjuvant technology, which is formulated with vaccines to increase their potency. And we have the ability to manufacture, again, this adjuvant at very large scale.

So if we move to Slide 9. So what are we actually doing so far? And I'd emphasize these are R&D projects. They have risk. They won't all work, but we've chosen them because, first of all, we believe in the deep scientific foundation on which they're based. And they match our skills, technologies and facilities in R&D that we can bring to bear around the world. And as I mentioned, we're considering this as a CSL and Seqirus joint effort.

So what does the world need at the moment? Well, the very obvious thing the world needs is a safe and effective vaccine that can be manufactured at large scale. The point is, this is the way to stop the virus on a population basis post strong public health measures. It's the way to create herd immunity, but without trashing the health system. But what I would say is vaccines, of course, are hard to develop. They take time. But they are very effective in a public health sense. So we've chosen to partner with the University of Queensland and CEPI, an international epidemic preparedness organization. And we are bringing to bear our adjuvant technology, our development expertise in recombinant proteins and potentially our scaled manufacturing. So that relationship is very strong, and we're already working closely to accelerate that program, and we are in a position to manufacture at large-scale for that program, should it be successful in clinical development.

In the meantime, the other thing the world needs are treatments. And let me just mention 2 areas. First, Emil von Behring won the Nobel Prize in 1901 for describing a hyperimmune therapy for diphtheria. And CSL has the ability to make hyperimmune medicines, the basis of which is to take antibodies from subjects who have recovered from COVID-19 infection, take their antibodies from their plasma, purify them into a potent medicine and deliver that medicine to patients and subjects at high-risk of disease. And you might have seen, we were very pleased to announce an alliance in the northern hemisphere with Takeda and other plasma product development companies to a focused, powerful hyperimmune effort across sites in the northern hemisphere. And we have mounted a similar effort here in Australia with the Australian Red Cross and Department of Health.

The issue with hyperimmune, which may be life-saving, is that you need access to convalescent donors. And while our clinical colleagues around the world are very excited about us producing hyperimmune medicines, it is limited to accessing safe convalescent donors who are willing to donate their plasma. At the same time, and we very recently announced an exciting collaboration with a company called SAB Therapeutics, based in the United States. They have wonderful technology for effectively transplanting the human antibody repertoire into cattle. So in this case, it's possible to vaccinate cattle, harvest their hyperimmune serum from the cattle, which will contain human immunoglobulin.

Now the point about hyperimmunes, whether from human donors or the cattle is that they could go faster than a vaccine approach. And that's why in parallel, we're pursuing the whole hyperimmune approach. And then finally, for completeness, we have realized that a number of our biotech products in early-stage clinical development actually could be used to block the cytokine cascade, which causes vascular leakage and acute respiratory distress syndrome in desperately ill patients in intensive care. And so we are repurposing with our academic colleagues and collaborators some of our early-stage biotech projects to pivot them into clinical studies looking at ARDS in COVID-19 patients.

So look, with that, my summary would be, we're very focused on matching our strong science with our technical capabilities and facilities around the world. These are R&D projects that I've described to you. They won't all work, but our R&D teams are heavily engaged in delivering some of these projects right now. Thanks, Paul. That's it for me.



Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Thanks, Andrew. So let's move on to Slide 10, and I'll finish with a couple of key points. First of all, the COVID-19 outbreak will continue to present an extremely challenging time for the world for some time to come, I believe. And our top priority, as I mentioned at the beginning, is to safeguard our people, our patients and our donors that are really helping us to supply these life-saving, life-extending medicines to people around the globe as well as protect human health with our influenza vaccines. And I'd say now more than ever, our patients and at-risk populations need to have a continuous, reliable supply of medicines, and we're working to support them in every way that we possibly can. A lot of these patients have, as you know, obviously, other co-morbidities or diseases that could put them at higher risk if they were infected with immunodeficiencies or other disease states.

As a business, we understand the need to be agile and adapt to the evolving environment. And I think we've been able to demonstrate that, for instance, with a pivot back to southern hemisphere influenza manufacturing at the request of the government in Australia. But there's no doubt that we have some challenges with the collection of plasma, and we also have a range of initiatives underway to mitigate a lot of those challenges. So you know that we do this every single day, many, many hours a day. And so we're trying to pull all the levers that we can to ensure that we continue to have this very precious supply of raw material to take care of our patients in the future.

You heard from Andrew, a description of CSL's core R&D capabilities and how CSL is well placed to respond with a range of assets and capabilities. We do have a lot of activity underway in the development of all the areas that you spoke about in terms of vaccines, hyperimmunes and polyclonal monoclonal antibodies. It was interesting when we were discussing in this briefing, and I was looking at the core capabilities of the organization. If you actually look at everything that was on that slide, which is quite a bit, it would be hard to find another company that was touching all those areas to try to respond to COVID-19. It's almost as if you want to start a biotech company to respond to COVID, it would look very much like CSL in terms of the capabilities, the competency and the assets that we have across the organization. We haven't been blowing our horn very loudly in the public because we have been working very hard behind the scenes. This is a very complex and -- business to operate. But we are acutely aware of our responsibilities as a leader in the field, and that's why we took on a number of these projects. We could have taken it on others, but we felt that these were the ones that were closest to our capabilities.

Having said that, the COVID-19 implications, with all the work we're doing on these other areas for a number of reasons, we're able to allocate some resources because this disease and what's spreading right now does have implications for some of our capital projects and our clinical trials. We've taken a considered view and paused some of our programs, both on the capital side and in our clinical trial area. Both capital programs and clinical trials generally have a multiyear time frame. As you know, when we talk about capital and R&D, we don't manage these on a fiscal basis. So there will be opportunities to accelerate the programs once the crisis is behind us. And at this point in time, we don't anticipate any material deviation from the original plans.

So for instance, when you take a look at CSL112, people are still having heart attacks despite COVID. There's no doubt about that. However, the overwhelming responses of the hospitals to have their staff responding to the COVID crisis limits our ability to actually utilize the clinical trial protocols because the staff is overwhelmed. So the burden on the health care system to run clinical trials of that scale are difficult. We don't want to expose more patients to the hospital environment, but we also want to protect the quality of the data, especially important in 112 that if you don't get that second, third or fourth dosing, where the data collection is not appropriate, this could really set back the trial. So we've made decisions on all of our clinical trials we'll continue to run a few. But when you look at areas like 112 or transplant, for instance, these are not the trials that will be up and running at the moment. So we have put a hiatus on the recruitment in those particular trials for all of those reasons.

The group does remain in a strong financial position. Our leverage is conservative. Our liquidity is secure. And with an estimated \$1.1 billion in cash and undrawn facilities available to us, and this takes into account the dividend being paid today, which is unchanged from what was announced at our half year results.

Lastly, there's no change to our fiscal year '20 profit guidance. We continue to expect a net profit after tax at constant currency to be in the range of approximately to \$2.110 billion to \$2.170 billion. We will, as usual, provide guidance for next year's profit at our full year results in August.

And in closing, I encourage everyone to take care of yourselves, take care of your families, colleagues, the communities that we live in. These are truly unprecedented times. There's no manual how to navigate through this, but together, I'm confident that we will.



And with that, I'm going to hand it back to Mark so that he can open up for questions. And just remember that besides Andrew and myself, David Lamont and Paul McKenzie, who are also online. So, thank you.

Mark Dehring - *CSL Limited - Head of IR*

Thanks, Paul. (Operator Instructions) So operator, if you could open the lines up, please? And our first question comes from Lyanne Harrison of Bank of America.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Lyanne Harrison - *BofA Merrill Lynch, Research Division - VP*

First of all, Paul, you mentioned early on in the presentation that the request for IVIG are elevated. Can you give us some color on that, whether or not you think that it's because hospitals and clinics are stockpiling? Or is there just, in general, higher usage amongst patient grid?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

I think there's a couple of things, Lyanne. I think, one, certainly, people are concerned that there could be some stock-outs or things of that nature because they're assuming that plasma collection is going to be tight as people are trying to get to centers. So there could be some of the stockpiling. But I think it's generally people trying to respond to COVID, thinking that a boost in the immune system to try to help patients recover would be a good thing. And there has been some anecdotal reports out of China and other areas where people are using IG as supplemental to everything else that they're putting into the therapeutic areas that they're trying to use. You see combo therapy being used all over. And I think it's really people trying to save lives and thinking that this could help. So we don't have specific data around why the requests are coming in. It could be that some people are short on their current suppliers, it could be that they are doing some stockpiling in anticipation. But I think generally, it's people trying to respond to the health crisis.

Lyanne Harrison - *BofA Merrill Lynch, Research Division - VP*

Okay. And a follow-up question around, I guess, your existing immunodeficient patient base. Are you seeing anything come through around, I guess, increased interest or demand to move from IV delivery to a subcu?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Look, I think we haven't seen anything that's demonstrable in terms of additional requests for people to go on to subcu at the moment. I think that this crisis will, in the future, give a little bit more attention to home therapy. It's hard just within a couple of months to see that big shift because these patients would have to go into the health care system and the training and the -- that goes into changing a patient from IV to subcu. And the difference in how it's administered takes time. And we don't have people that are able to travel to help people get started at home, even though it's a critical essential service, and the consultation with the physicians would need to occur as well. So from a medical system perspective, I think the burden on the system is such that these people don't want to go out when they're immune-compromised, and they're worried about getting sick. Two, they don't have the resources within the medical infrastructure in many of the countries to actually adapt to this at the moment. But certainly, I would say people will be paying attention once we start to stabilize these countries from COVID. And it wouldn't surprise me that people would be more interested in trying to infuse at home.

Mark Dehring - *CSL Limited - Head of IR*

Next question comes from David Low at JPMorgan.

David A. Low - *JP Morgan Chase & Co, Research Division - Research Analyst*

Thanks, Mark. Paul, just starting with the plasma collection, you talked about initiatives with the FDA, the earlier release or change of cycle time. Can you just elaborate a little bit on what you're pushing for there or what you'd like to see, please?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Well, based on the science and the data that we have, David, in terms of our NAT testing and PCR testing, we know that we are able to reduce the window period for detection of viruses. The legislation on 60-day plasma holds has been in place for decades. And so that's one area where we would be looking to try to get some relief. And now that would release a bolus for a short period of time and then it would normalize. So it's more of a onetime effect. And then the availability would be more -- would be sooner going forward, but it would be part of the normal process at that point. So looking to try to get, with the science and the data, a reduction in the hold times for plasma release from the system. So nothing that I can point to yet. But clearly, we understand that we could probably reduce it from 60 to, say, 45 days with the data. And then depending on the availability of products, I think the FDA will be helping us to work through that.

David A. Low - *JP Morgan Chase & Co, Research Division - Research Analyst*

Great. I mean I'm thinking a lot of questions, but maybe 1 for you, David. Just FX, we've seen a few movements of late. Could you perhaps update us on what the FX impact has been in the financial year-to-date, please?

David Mark Lamont - *CSL Limited - CFO*

Yes. So David, in the slide deck, you will see we've still called out around about \$100 million headwind at this stage. I will preface that by saying rates are moving around like the rest of the market. And so volatility is back. But at this stage, that's our best estimate of where we would expect to be for the full year, David.

Mark Dehring - *CSL Limited - Head of IR*

Our next question comes from Sean Laaman at Morgan Stanley.

Sean M. Laaman - *Morgan Stanley, Research Division - Australian Healthcare Analyst*

Mark and Paul, hope you and your family are safe and well. Maybe if I could just tease out a little bit, Paul, a bit more on the plasma collection side of things. So you mentioned that I think you said that there's been a dip on last year over the last 2 weeks in terms of volume. I'm wondering if the 32 new centers are contributing to that in any material way. Are they actually adding any volume? And the second part of the question would be, you've been very clear that we'll get guidance for fiscal '21 in August. But I'm wondering if, for example, if you sort of say, a 10% or a 20% drop in plasma collections, between now and then, would we know about it? Would the market be informed about that?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Well, I think it depends on the persistence of that dip. So 2 weeks is not enough to tell me. I think that we'll be able to see when things start to open back up and people start to travel more freely within the next 3 to 4 weeks in the U.S. through the month of April, I would expect that, that decline will probably continue, would be my thoughts. But I do think that once things start to open back up, that we'll see a return to the plasma collection. So if it was maintained over that period of time, and we could see that we're going to have stock-outs or something like that, I think we would certainly want to certainly inform our physicians and patients. And then consequently, the market would know about that.

But look, I would say that it's really too early to make that call. Clearly, we have continuous disclosure guidelines that we have to follow. And so the issue is we haven't given any disclosure for next year yet. So -- and with the ratings, I know there's a lot of companies that aren't giving any guidance at the moment. I think we're doing pretty good right now to give the guidance on this year, and we'll see how it goes. But we've always been direct with you all and informed what we know, and we'll make that call if we see a need to do that.

Sean M. Laaman - *Morgan Stanley, Research Division - Australian Healthcare Analyst*

Maybe just a quick one for David. Just with respect to the slowdown or however you want to describe it on the R&D side of the equation, is that R&D savings material?

David Mark Lamont - *CSL Limited - CFO*

So the first comment is, I don't know that I would assume that there is any R&D savings because what we have been doing is redirecting our staff and activity into the COVID-19 activities. So my view and what you should take forward is that there's no change in that guidance that we've historically given, the sort of that 10% to 11% of sales as an R&D spend even for this year.

Mark Dehring - *CSL Limited - Head of IR*

Our next question comes from Andrew Goodsall at MST Marquee.

Andrew Goodsall - *MST Marquee - Healthcare analyst*

Likewise, hoping everyone's family is safe. Probably just a continuation of that previous question. Just is there a sort of cutoff point where you need to sort of step up your actions, particularly at the FDA and see that unemployment, I guess, turning to donors before we see that risk of disruption. I'm just sort of thinking, is it 3 months, is it 4 months where you need to see that take place?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Look, again, it's such a fluid situation, Andrew. It's hard to predict how long and how often. I would say that we need a lot more data points to really see because each of these centers, as I said, is an individual issue. We have some centers that are overcollecting today to their budgets, and we have some that are severely undercollecting. But net-net, I mean, we're still collecting a lot of plasma. It's just that it's not where we would like to be at the moment. I think the good thing that we were able to do over the last couple of years is opening a lot more centers. So back to -- maybe I didn't answer the original question, that's been fairly de minimis in terms of the additional plasma we've gotten from centers we've opened this year, especially in the second half of the year. But I would say that the centers we opened last year are certainly contributing. So the ability for CSL to try to stay ahead of the curve in terms of opening new centers to our fleet size now is really, I think, doing a very good job. We're doing a lot of things across the organization. And one of the things that we've recently done is plasma operates within plasma, and that's all plasma all the time. But we have now enlisted our marketing groups from our commercial teams to help the marketers in plasma and said, okay, what else are we thinking the right way? Or is there anything else we can do? We also are going to employers through our HR group to look at employers who may have had to furlough people and said, look, plasma donation is a good thing to do for patients. And especially with the initiative that we have with



the industry to try to collect as much convalescent plasma as possible, there are good reasons that people will become familiar with plasma donations in general. So we're trying to pull as many levers as we can. And I think the levers that we pulled over the last 5 years to expand our collection centers is what's helping us today. So it's going to take quite a few data points for us to give you a view on next year.

Demand is still high for these products. I don't expect demand to curtail next year for any reason that I can see. So the demand will be there. The question will be how much will we be able to supply. And we will be able to supply more product, but there will be lumpiness next year would be my expectation because what we collect in April will probably put pressure on the system as you look 4 to 5 months out from now. So again, our comments in the past about we don't manage the business half-on-half, that's clearly, clearly evident in today's environment, where we just can't predict where the ebbs and flows will be through the year at this particular point until we get a better handle on the collections.

Andrew Goodsall - *MST Marquee - Healthcare analyst*

That's very comprehensive. And just a quick follow-up. Just on sort of any delays to CapEx. Is there any, I guess, critical CapEx infrastructure, I guess, like just production that would be impacted by any delays in some of your builds?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Throw that to David or to Paul. Paul, you want to comment?

Paul F. McKenzie - *CSL Limited - COO*

Yes, sure, Paul. Thank you for the question, Andrew. No, at this point, what we're doing is we're taking all the projects and looking at their critical paths. And then by managing the critical path, we don't expect to see, as Paul said, any material impact to our plan for new production capabilities to come online. So it's really just about a focus on (inaudible) during this period.

Mark Dehring - *CSL Limited - Head of IR*

Next question comes from Saul Hadassin at UBS.

Saul Hadassin - *UBS Investment Bank, Research Division - Executive Director & Research Analyst*

Just Paul a quick question on whole blood donations and the recovered plasma you get from that or that the industry gets from that. The FDA, I think, over the last few weeks, has put out notices saying that there is a decline in whole blood donations across the U.S. How much recovered plasma do you think goes to the industry from whole blood? In other words, how much pressure is going to be across the system, do you think in 3 to 6 months' time from lack of whole blood donation? And secondly, on that question, the FDA also announced that they're going to relax some of the donation criteria, for example, people that might have been exposed to vCJD, et cetera, to allow an increase in theoretical donations. You see that assisting both on the whole blood side but also on the resource plasma side?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Yes sure, Saul. Thank you. We have obviously looked at the recommendations, and it does apply to plasma collections as well tattoos and things of that nature where they're relaxing some of the criteria and donor deferrals. So look, I think that will help. Is it going to be significant to make up for some of the downturns that we've seen and incentive checks going out from the government in the near term? I'd say probably not. But the long term, if they maintain those, I would say it certainly increases the pool of donors that we're able to access. So I think that it would be a good thing overall because we do have data around a lot of these things, and a lot of them are historical in terms of the safety profile.

In terms of the amount, it varies, as you know, by company, it's very small. It's less than 10% of our collection comes from recovered. And it's not like it's going to 0, it is less, and there are fewer donations, just as we've seen it in the source side. But again, I think people are going to respond and start to come through. The whole idea of recovered plasma from the convalescent donors through whole blood collections has increased some, but of course, that convalescent plasma is going into another patient. So it's not coming back to the manufacturers for manufacture of products. So again, I think from an industry perspective, I don't know what the numbers look like, to be honest, so I can't answer the question with any knowledge, but it will have an impact at some level. And if people were highly dependent on recovered across their donations, then they'll be impacted more. But I'm optimistic that when this starts to moderate, we'll see a return of the donors back into the system.

Mark Dehring - *CSL Limited - Head of IR*

Next question comes from Dave Stanton at Jefferies.

David Andrew Stanton - *Jefferies LLC, Research Division - Equity Analyst*

Look, I had a question regarding unemployment in the U.S., given that you're going to see an increase or you are seeing an increase in the number of people unemployed and that those people at least the lowest proportion of those are going to have health insurance, what does that mean for volume of use for your product over the medium term? I know that you've been saying you won't be curtailed in terms of demand into '21. But does it mean that potentially some of those people who use your products on a prophylactic basis might move to an acute basis? Or will there be increased time between infusions for some of these patients? Any color on that would be great.

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Yes, I wish I could give you color on that. This is the most complex health care system in the world. And so it's hard to understand how this will move out. I have seen that a lot of the insurance carriers are continuing to cover. The hospitals are continuing to move through. So with the companies that have worker layoffs, they're trying to get that gap coverage for their employees that they've had to furlough or lay off. So the infusions, the time between infusions. A lot of our patients also are on government program. So in IG, I think it's about 20% is Medicare. And those patients should still be okay. And in hemophilia, there's a lot that are on Medicaid, the state Medicaid programs, due to disabilities and the disability designation. So they also are getting coverage. But it's -- I don't have data to tell you how many of those patients are not employed, to be honest. It's one of those things where it will be a patient by patient. And because these are rare diseases, you could have 1 company that employs a lot. But as you look across the payers, not 1 payer has the bulk of these rare disease patients. So it's going to be really hard to get that data. David, and I'm not sure that we'll have that anytime soon. There's a lot of people looking at the various cities. We know where patients are located, but they're located everywhere. It's not just in New York City or other major cities. So it's going to take us time to get any of the data that I can then give you a, hopefully, better informed position than what I just did.

David Andrew Stanton - *Jefferies LLC, Research Division - Equity Analyst*

Fair enough. And I guess my second question is regarding the donors from Mexico who come across and donate in Southern United States plasma, can you give us any update on whether they are being quarantined when they come back? And perhaps, as a result, not so willing to donate their plasma?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Sure. So it's been a mix, depending on the city and the border area. There were some initial when COVID started, where donors that came across to donate we're being asked to quarantine when they return to Mexico. And so then that prevented them from coming back. Many of that has already changed again. It is a large part of our donations in terms of -- when you look at the number of centers there, it's not a large part, it's about 4% of our donations come across from the border centers in the U.S. But Arizona is different than Texas and different cities in Texas are different. But as I said at the beginning, we have letters, which are allowing people to come back and forth as an essential service. So there has been some



impact. Those are some centers that have been impacted. But they're still collecting. So there is some impact. As I said, it's a center by center, whether they're on the border or not on the border, it's a center by center issue. Some towns in Mexico have specific requirements. It's not the whole country of Mexico, some towns in the U.S. are allowing and other towns are limiting the number coming across. So it just depends on the center.

Mark Dehring - *CSL Limited - Head of IR*

Next question comes from Gretel Janu at Crédit Suisse.

Gretel Janu - *Crédit Suisse AG, Research Division - Research Analyst*

So maybe a question for David to start with. So how should we think about the cost base and margins varying over the next few months, just given the -- in case they have frightened donors and other disruptions that you have in the general supply chain?

David Mark Lamont - *CSL Limited - CFO*

Yes. So as Paul mentioned, really, when you look at where we are for the remainder of this year, there is not a large impact at all. We have had to airfreight some product into certain regions to get through some supply chains, but I would put that very much at the fringe. Really, when you get into FY '21, that's where you start to see the cost side of things for the plasma start to flow through. And as Paul mentioned earlier, it's a moving beast. We're monitoring it, and we'll give you far more clarity on that when we get to the guidance for FY '21 up on the full year result, but certainly at this stage for FY '20, we're not seeing that sort of cost pressure come through, given that we're really selling out of the inventory that we've produced in the prior months.

Gretel Janu - *Crédit Suisse AG, Research Division - Research Analyst*

Okay. And then just on CSL112. So with the hiatus there, what does that mean for the futility test that was scheduled this year? Those -- have those still gone ahead? And do you expect to update the market, I think you previously had said at the August results as to where you were on that trial?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Andrew, I'll hand that over to you. I think we're in pretty good shape. But...

Robert Andrew Cuthbertson - *CSL Limited - Chief Scientific Officer, Director of R&D and Director*

Good question. I think that the -- those milestones will move out in a controlled way by some months would be my answer. Because they're driven by the statistical powering of the study and triggered by a certain number of recruitments. So I think those milestones will move out and we'll be more precise about how long. But I think the whole approach will be to move them out in a very deliberate controlled way and preserve the power and integrity of the study.

Mark Dehring - *CSL Limited - Head of IR*

Our next question comes from Steve Wheen at Evans & Partners.



Steven David Wheen - *Evans & Partners Pty. Ltd., Research Division - Executive Director of Healthcare*

Just a question just on albumin in China. Just wondering if you could comment on how the -- you've given some guidance and pretty specific guidance around this year as you swapped over to the GSP license. I just wonder how it is panning out, particularly around the impact of Coronavirus?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Yes. Thanks, Steve. Look, I'd say that we've been mostly on track up until corona hit. We are still getting the albumin in. So there's a little bit of movement and a little bit of noise in it. But in general, I'd say and if you look at the guidance that we've given, that includes how we guided to that number, which included our work in China. I'd say we're in pretty good shape. So things are moving. There is some supply chain things we're working through. But in general, given the situation we're in, I think we're doing reasonably well..

Steven David Wheen - *Evans & Partners Pty. Ltd., Research Division - Executive Director of Healthcare*

Right. Okay. And my second question is just around specialty products, with the hospital system being overwhelmed, what does that mean for products like KCENTRA?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Look, we haven't seen a slowdown. I mean, people are still coming to the hospital when they're in car accidents or have bleeding and warfarin. And as I said, even with 112 even though the trial has been put on hold for the time being, people are still having heart attacks. So we haven't seen a decrease in the patients coming and/or the use of the product. As I said, the demand has been still coming through. We're still on guidance for the year. So we haven't seen a major slowdown in any particular product based on COVID or the hospital administration or the admissions. So right now, I'd say, really, we haven't seen an impact.

Mark Dehring - *CSL Limited - Head of IR*

Our next question comes from Chris Cooper at Goldman Sachs.

Chris Cooper - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Firstly, just on your hyperimmune programs. I don't know whether this is a question for Andrew, but Paul, you talked to the challenges of finding sufficient donors for that approach. Look, I appreciate you're probably still trying to figure this out yourselves, but just at this stage, can you give us your best guess on scalability? How many recipients would you expect to be able to treat from 1 donation from a recovered patient?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Andrew?

Andrew Cuthberston

No. Thanks, Chris. I mean, clearly, we don't know precisely, but I can give you some guidance. I mean, it depends, of course, on the titer and the titer of anti-COVID antibodies in the pool and in the batch. But it won't be 1:1. I would anticipate that you'll probably need something in the range of 5 to 10 donors to treat a patient, making a lot of assumptions, but something of that order.



Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

So I think as we've looked at this, Chris, and we've made -- sorry, Chris, as we've looked at this, we've -- this is not our first foray into hyperimmunes. So the reason that we spearheaded this arrangement with our competitors, with Takeda and BPL, LFB, Octapharma, Kedrion and Biotest is because we want to make sure that anybody that wants to donate can find a center. And that's really the key is to make sure that there's access to get the recovered patient, the patient that has recovered from COVID and get the convalescent plasma. Now we are working on the testing for the titers because it is important that we get the highest titer donors coming through the system and that the pools have the high titers that are available to make the hyperimmune. So there's a lot of work going into it. The website -- we've worked with Google and Microsoft, and the website for this initiative should be up and running now and will be fully operational this week. And we will start to get the word out of actually getting and trying to recruit patients to whichever center because then it needs to go to one manufacturer to actually manufacture the product. And that's what we've agreed to, both in the U.S. and in Europe. I can't give you all the specifics yet, but the coalition is working very closely to make sure this happens because trying to do convalescent plasma from a blood donation is completely not scalable, and you have no idea on the titer levels. And you could have activating titers -- activated nonneutralizing antibodies that can cause issues for patients, which is why we don't normally do this anymore. When people look back at the beginning, and Andrew talked about CSL at the beginning, in Spanish flu, they talk about using convalescent sera, but that's why we don't do it anymore. It can be dangerous, and it may not be effective if you don't have the right titer. So clearly, a lot of work going into this, and we'll continue to update the market as we make progress.

Chris Cooper - *Goldman Sachs Group Inc., Research Division - Research Analyst*

Okay. So I've got some follow-ups to that, but I might just take them offline. Just try to stick with my -- of Mark's request of 2 questions. So I want to get to this 1 on unemployment as well. I'm more interested from the perspective of donor fees with unemployment actually. So just thinking a couple of months ahead, I know during the last sort of major recession, you actually had to reduce donor fees to actually disincentivize people coming through the door. Certainly, it looks like we're well on track for unemployment to be the multiple of the levels we saw back there. At this stage, are you expecting to need to reduce donor fees at some point in the coming months?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Look, I don't know. Can't tell you. It depends on what happens, but I don't feel a need to reduce donor fees other than we want to make sure that donors have access to coming into the center. So I'm more concerned about -- I'm less concerned about oversupply of plasma than I am about making sure we have enough and so I don't want to do anything that would disincite people from coming in. Remembering that typically, if things return to normal, only about 20% of the people that come into our centers are unemployed, and that's been decreasing as unemployment has dropped. Most patients or most donors are underemployed. So they're part-time workers, et cetera. So look, we don't know. Is the right answer. We will see how things progress, and we'll adapt as we go.

Mark Dehring - *CSL Limited - Head of IR*

Our next question comes from David Bailey at Macquarie.

David Bailey - *Macquarie Research - Research Analyst*

Just following on from that, just given the dip in plasma donations at the moment, I mean, following on from Chris, are you seeing an increase in donor fees at the moment? Is it costing me more to collect that plasma? And then secondly, just interested in the comment on inventory levels. Do you carry enough inventory such that if there is a short from plasma now and finished product in near -- 6 months' time? Is there any ability for you to respond in terms of inventory down the track?



Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

So answer to your first question is yes. Donor fees have gone up, and they -- as you know, they were going up earlier this year as well before COVID. So yes, donor fees have gone up. Second, question do we have enough inventory? Yes, for a time, but it depends on how long this goes, right? I mean, again, we don't have the answer yet, but we clearly have inventory to get us through manufacturing for the time being, and we have some finished goods stock that we can dip into. We try to keep minimum levels to make sure that we have backup. But this is going to be a tough time, and we'll see how we can respond. We're going to do everything we possibly can to make sure we respond not only short term but long term for patients that need these products.

Mark Dehring - *CSL Limited - Head of IR*

Next question comes from John Deakin-Bell at Citigroup.

John Deakin-Bell - *Citigroup Inc, Research Division - Director and Head of Healthcare in Australia & New Zealand*

Just a question on the flu side, I'm assuming that next year in the U.S., that there'll be a reasonable increase in demand for flu given what's happened. Can you just update us about the increase in capacity? I know there was the fill and finish is kind of the bottleneck in the units, can you just tell us where you expect that capacity to be? And if you agree that the demand should increase?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Yes. Thanks, John. What we are doing is looking at our production capacity, and it is to fill, finish. So it will be the mix. We may have to do more multi-dose vials to meet if there's additional demand as opposed to single-dose syringes. So syringes is really the tightness at the moment for us. I mean, that's why the new filling line in Holly Springs has really adapted to syringe filling. That's where the bottleneck is. So we can finish in more vials. And of course, we've already started Northern Hemisphere Manufacturing in Liverpool and Holly Springs, and we have reverted back from Northern and Australia for the short-term while we fulfill some of the needs of the government. But that's really the bottleneck. But it will be a matter of presentation because we do have some vial capacity at Bar Berg and other places where we could fill more vials.

John Deakin-Bell - *Citigroup Inc, Research Division - Director and Head of Healthcare in Australia & New Zealand*

And just a follow-up, perhaps for Andrew, there's been a lot of discussion around the time frame to get a vaccine for COVID-19 and my understanding is there haven't been any vaccines for Coronavirus produced at this point. Can you just give us your -- your expert opinion, the likelihood of it being less than 12 months and what the real issues are?

Andrew Cuthberston

Look, thanks, John. And I'll just give you my opinion. I mean, given that there are quite a number of vaccine projects underway and where people are trying to go as fast as they can. You have to be clear what you mean by delivery of a vaccine. I mean, for example, there will be dose, experimental doses available for human testing in a number of the programs in the May-June time frame. Then depending on the technology, the manufacturing technology used, it's possible for manufacturers, including CSL to make a lot of doses sort of in the second half of this calendar year. But you've got to match -- there's a difference between manufacturing capacity and just the progress of the vaccine through clinical or preclinical and then clinical testing. So all that being -- so you have to have the ability to make the vaccine at scale, which CSL and a number of other companies around the world can do, you then have to test it carefully but rapidly in human clinical trials. And it's probably more the testing regime than availability of product that will determine ultimate large-scale availability for vaccinating whole populations. But I would anticipate that there will be vaccine available for human testing in the next few months, next 2 months, something of that order from different places around the world. There will be scaled production occurring in this calendar year, and there will be large-scale clinical trial testing of several candidates in places around the world.



But with a whole lot of uncertainty, I would say that if there is a successful product or product, they're liable to become available during calendar '21.

Mark Dehring - *CSL Limited - Head of IR*

And we have 1 final question, and that is from Andrew Goodsall at MST Marquee.

Andrew Goodsall - *MST Marquee - Healthcare analyst*

So just a really quick follow-up. If the situation emerged where you are -- were able to collect more, given that a few of your competitors are more heavily reliant on recovered, would you sort of go down that pathway to actually go above?

Paul R. Perreault - *CSL Limited - MD, CEO & Executive Director*

Look, Andrew, you know my feeling, I think. I think we need more plasma. So I've been saying that for a number of years and encouraging my competitors to help. So yes, absolutely, go hard.

Mark Dehring - *CSL Limited - Head of IR*

Ladies and gentlemen, we will now draw to a close. Thank you very much for your interest in CSL, and have a good morning. Stay safe, and goodbye.

Operator

Thank you. That does conclude our conference for today. Thank you for participating. You may now disconnect your lines.

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