Adaptimmune Q2 2022 Financial and Business Update
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CORPORATE PARTICIPANTS

Juli Miller
Investor Relations

Adrian Rawcliffe
Chief Executive Officer

Dennis Williams
Senior Vice President of Late-Stage Development and Regulatory Affairs

Gavin Wood
Chief Financial Officer

Elliot Norry
Chief Medical Officer

Joanna Brewer
Chief Scientific Officer

John Lunger
Chief Patient Supply Officer

CONFERENCE CALL PARTICIPANTS

Tony Butler
Roth Capital

Anthony Rodriguez
Cowen & Company

Alex
Barclays

Jonathan Chang
SVP Leerink

Paul
Guggenheim Investments

Mara Goldstein
Mizuho Securities

Danya Ben-Hail
Jones Research

PRESENTATION

Juli Miller, Investor Relations

Good morning and welcome to Adaptimmune's conference call to (inaudible) our second quarter 2022 financial results and business update.

I would ask you to review the full text of our forward-looking statement from this morning's press release. We anticipate making projections during this call, and actual results could differ materially due to several factors, including those outlined in our latest filings with the SEC.

Adrian Rawcliffe, our Chief Executive Officer, and Gavin Wood, our Chief Financial Officer, and Dennis Williams, our Senior Vice President of Late-Stage Development and Regulatory Affairs are here with me for the prepared portion of the call. Other members of our management team will be available for Q&A.

With that, I'll turn the call over to Adrian Rawcliffe. Ad?

Adrian Rawcliffe, Chief Executive Officer

Thank you, Juli, and thank you, everyone, for joining us.

In 2022 we are focused on four things to drive value for our stakeholders. One, submitting the BLA for afami-cel, our first-generation MAGE-A4 targeted product; two, building out the MAGE-A4 franchise, three, scaling up our manufacturing capabilities; and four, progressing our allogeneic platform. We're building a Company to deliver a long-term vision of multiple marketed cell therapies for cancer, including allogeneic therapies.

In the near and mid-term, we are focused on our MAGE-A4 franchise. We're on track to submit our first BLA for afami-cel for the treatment of synovial sarcoma in Q4, and Dennis is going to update you on our progress towards submission. If approved, this will be the first commercially available engineered TCR cell therapy for solid tumours.

Adaptimmune has received tremendous support for afami-cel from healthcare providers, clinical centres of excellence, and from patient groups, for which we're incredibly grateful, as patients are at the heart of every step that we take. We're honoured to announce that in September we will accept the Vision of Hope Award from the Sarcoma Foundation of America.

In June we presented data at ASCO that further demonstrated the potential of afami-cel in synovial sarcoma, and at CTOS this fall, we plan to present another update from Cohort 1 of the Spearhead-1 trial. The recognition from the Sarcoma Foundation and the increasingly complete and compelling data presented over the last two years is a testament to the potential of afami-cel for patients with this rare and difficult-to-treat cancer.

The afami-cel BLA is only the beginning. The submission and the focused launch we are planning is an opportunity

for Adaptimmune to develop and to exercise our commercial manufacturing and logistics infrastructure. This is important to both our near- and longer-term success as we aim to commercialize multiple cell therapies for cancer with these capabilities.

Beyond afami-cel, we've designed a next gen therapy to be more potent and to deliver responses across a range of solid tumours in addition to sarcoma. We've been investigating the enhanced potency of this next gen CD8 product in our SURPASS family of trials.

At last year's ESMO, we presented clinical data from our signal-finding Phase 1 SURPASS trial with this CD8 product. In addition to sarcoma, we reported responses in ovarian, head and neck, esophagogastric junction, or EGJ, and bladder cancers from the 22 evaluable patients. Based on positive signals in certain gastroesophageal cancers, we initiated the Phase 2 trial, SURPASS-2, targeting esophageal and EGJ cancers last year. And, based on the positive signal we saw in ovarian cancer, we are planning to initiate SURPASS-3 later this year.

We're working closely with advisors and KOLs from the Gynecologic Oncology Group Foundation, or GOG, a preeminent advisory group for clinical trials in gynecologic oncology, on the design and execution of this Phase 2 trial.

This September at ESMO Dr. David Hong, of the MD Anderson Cancer Center, will present updated data from the Phase 1 signal-finding SURPASS trial in an oral presentation. Data at ESMO will include 44 patients who were treated by the time of the data cut, and 43 patients will be evaluable for efficacy.

On the first day of ESMO, September 9, we will host a live virtual event to discuss these data and our SURPASS family of trials. We're thrilled that Dr. Kathleen Moore has agreed to speak at our event. She's an Associate Professor of Gynecologic Oncology at the University of Oklahoma College of Medicine and is a member of the GOG Investigator Counsel. Dr. Moore will provide her perspective on the potential of cell therapy in solid tumours, including her experiences with patients with ovarian cancer treated in our Phase 1 SURPASS trial.

Now, I want to emphasize the measures we're taking to ensure long-term success, and Gavin will provide a more detailed update later in the call. As we've previously stated, Adaptimmune is funded into early 2024, and we will continue to prioritize our spend and ensure success across our four focus areas that I outlined earlier.

We have an experienced management team who have gone through multiple economic cycles, and we're leveraging our collective experience to continually assess and prioritize investment. We've already implemented cost containment measures, including delaying or stopping activities as part of our continuous portfolio review, as well as deferring and cutting spend, and we are carefully monitoring market conditions. Whilst we're being disciplined about spending, we also don't want to delay our progress in the critical areas. Therefore, we will continue to pragmatically invest in our four focus areas and enhancements to the operations that support these, including continuing to build our commercial and manufacturing capabilities.

We are well positioned to weather the current economic environment and emerge as one of the few cell therapy companies with commercial products and an exciting clinical pipeline against solid tumours. We're committed to maximizing the probability of near and long-term success by managing costs and prioritizing appropriately.

Now, I'd like to turn it over to Dennis for an update on the BLA for afami-cel. Dennis?

Dennis Williams, Senior Vice President of Late-Stage Development and Regulatory Affairs

Thanks, Ad. Submitting the BLA for afami-cel in the fourth quarter of this year is our top priority. We have made great progress and remain on track to meet this important milestone. We have scheduled our pre-BLA meeting with FDA, and given the timing for this meeting, we plan to provide a brief update during our third quarter earnings call.

There have been a number of important achievements in the first half of this year. First, our vector manufacturing partner, Miltenyi Biotech, notified us that their new commercial facility has been released for GMP manufacture. Miltenyi Biotech has been our external vector provider throughout Spearhead-1. The GMP release of this manufacturing facility was an important milestone, and it enabled the vector process performance qualification, or PPQ, to initiate, and vector PPQ is presently ongoing.

Second, method validation for commercial T-cell lot release assays, including potency assays, is progressing well, and the T-cell process performance qualification is planned to initiate in the near term.

Third, Spearhead-1 Cohort 1 is the primary clinical evidence supporting an efficacy claim in the BLA, and the primary analysis and reporting of Spearhead-1 Cohort 1 is complete. Supportive clinical analyses and reporting are in progress.

Finally, other key initiatives are progressing well. As discussed previously, the pre-market approval, or PMA, application for MAGE-A4 for pending diagnostic is a modular submission. Two of the four total modules of the PMA submission have now been submitted to FDA for review. Our partner, Agilent, is planning to submit the final module at the same time that we submit the BMA for afami-cel.

We are very proud of the work we've done to advance afami-cel to where it is today. Our team is dedicated to this product and is galvanized by the potential afami-cel has to impact the lives of people living with synovial sarcoma. If approved, afami-cel will be the first new therapy approved and labeled in the United States for the treatment of synovial sarcoma in nearly a decade and would be the first marketed engineered TCR T-cell therapy for a solid tumour, which would be a milestone for Adaptimmune, patients, and healthcare more broadly.

Now, I would like to turn it over to Gavin for a financial update. Gavin?

Gavin Wood, Chief Financial Officer

Thank you, Dennis. At start of the second quarter, our total liquidity was $258 million, providing us with a cash runway (phon) into early 2024. Our cash runway is the result of the successful financing and business development actions in the last 24 months, the most recent of which was an upfront payment late last year of $150 million as part of our strategic collaboration with Roche Genentech. We expect to continue to use this combination of BD and equity to finance the Company over the coming years.

This actually is going through a period of time when the capital markets are challenging. It's our responsibility to respond to these difficult markets and to (inaudible) ourselves to take advantage of the opportunities that will arise when the markets improve. We are drawing on the collective experience of our executive team, Board of Directors, and advisors who've successfully managed through multiple economic cycles as we continue to prudently evaluate and rigorously manage our cost base to enable near and long-term successes.

I'll take a moment to look at our cost base in two verticals, operating expenses and capital investments.

Turning to operating expenses first, Adaptimmune has always had a robust resource allocation methodology. We remain committed to making disciplined investments in the focus areas Ad set out earlier. For example, in submitting the BLA, as well as focusing on our SURPASS family of trials. However, as we look to extend our cash runway in the current environment, we recently undertook a detailed review of our cost base and implemented a range of cost cutting initiatives.

As part of this strategic review, we made appropriate decisions to delay certain activities. For example, as you may have seen in this morning's press release, we are postponing filing an IND for our new next generation cell therapy that we are developing in collaboration with Noile-Immune. We're continuing to assess options to reduce costs still further, and I'll update you further on these during the Q3 earnings call.

Next, let's look at the capital investments we're making to ensure our long-term success. Firstly, we're increasing the GMP manufacturing space in (inaudible) product manufacturing facility in the Navy Yard in Philadelphia to support our current clinical trials and future commercial products.

Secondly, we're nearing completion of the fit-out of the new manufacturing facility in the U.K. to support our wholly owned allogeneic therapy targeting MAGE A-4.

With that, I'll turn it over to Ad for a few closing remarks before Q&A. Ad?

Adrian Rawcliffe, Chief Executive Officer

Thanks, Gavin. I want to emphasize four key points from today's call. One, we're focused on creating value with our MAGE A-4 franchise for the near and long term. Two, the BLA for afami-cel is only the beginning. We will use this submission and the focused launch to ensure future commercial launches will be even more successful. Three, we're building a Company that can support our long-term vision of multiple marketed cell therapies for cancer, including allogeneic therapies. Four, we have an experienced management team, and we are carefully managing investments for near and long-term success.

With that, I'll turn it over for Q&A. Operator?

QUESTION AND ANSWER SESSION

Operator

Thank you. First question is from Tony Butler from Roth Capital. Please go ahead.

Tony Butler, Roth Capital

Yes, thanks very much, appreciate the colour. Two very brief questions. One is on SURPASS-2. I think clintrials.gov (phon) has about 33 sites that are enrolling patients. My question is around how well is enrollment going, because a number of those sites are not yet enrolling and a couple have dropped. If you could just frame that within the context of the current trial sites. That's question one.

Question two is, also, I think there was—at least it's in your past slide deck. This may be a big old. But there was also the notion of beginning a Phase 1 trial with one of the TIL programs. Is that also being pushed out as focus is clearly on the MAGE A-4 franchise and the completion of the BLA (inaudible)? Thanks very much.

Adrian Rawcliffe, Chief Executive Officer

Thanks, Tony. I'm going to take those questions in reverse order. I've just confirmed no, the TIL program is not being delayed, and I'll ask Dennis to talk to the SURPASS-2.

Dennis Williams, Senior Vice President of Late-Stage Development and Regulatory Affairs

Sure, thank you for the question. You're correct, not all the sites at the moment are actively open for screening. We're rolling out sites on a periodic basis. But the trial is open for recruitment. I don't think we're commenting at this point about where individual patients are in that trial, but it is recruiting at this point presently.

Tony Butler, Roth Capital

Thanks, Dennis, appreciate it.

Operator

Thank you. Our next question is from Marc Frahm from Cowen & Company. Please go ahead.

Anthony Rodriguez, Cowen & Company

Good morning, guys. It's Anthony Rodriguez (phon) on for Marc. Regarding the ESMO presentation, what are the spread of tumour types that we're likely to see there, and would there be enough patients to make additional go or no-go decisions? How many patients do you think you will need to touch (phon) within a tumour type to make those kind of decisions? Thanks.

Adrian Rawcliffe, Chief Executive Officer

I'm going to ask Elliott to take that question. Elliott?

Elliot Norry, Chief Medical Officer

Hi, thanks for the question. At ESMO you can expect for the update in the data to be across the range of tumour types that are included in the trial. As was noted by Ad and in the press release, there'll be 44 patients included in the data cut and 43 of those will be evaluable for response.

I don't think we're guiding specifically as it relates to exactly how many in each tumour type, but I think you can expect to see data across the range of the tumours that are included in the study.

Anthony Rodriguez, Cowen & Company

Okay, so—and one more question on the BLA submission. When do you expect to complete the validation of the potency assay, and can you have a pre-BLA meeting before this happens?

Adrian Rawcliffe, Chief Executive Officer

Dennis?

Dennis Williams, Senior Vice President of Late-Stage Development and Regulatory Affairs

Sure. Essentially, the T-cell potency assay that I mentioned is actually in progress of being validated, like, imminently, like within days. The pre-BLA meeting, as I mentioned, is scheduled.

We have been using—I probably should circle back. We have been using this potency assay throughout development for this product, and certainly, that assay was used all through the Spearhead-1 clinical trial. We have optimized the assay to be more appropriate for our commercial lot release assay, so this was sort of supplementary validation work that was completed in advance of T-cell PPQ, which I mentioned, is starting imminently.

Anthony Rodriguez, Cowen & Company

Great, very helpful. Thank you, guys, and congratulations on the progress.

Adrian Rawcliffe, Chief Executive Officer

Thank you.

Operator

Thank you. The next question is from Peter Lawson from Barclays. Please go ahead.

Alex, Barclays

Hi, good morning. This is Alex on for Peter and thank you for taking our question. Just on SURPASS-3, any insights you could give us around trial design and execution, how many patients you're planning to enroll, is it going to be platinum ineligible patients, and if you're planning any combination studies here as well? Thank you.

Adrian Rawcliffe, Chief Executive Officer

I'll just say that we haven't made public any details of the trial design, etc., but if you were looking for an update on the SURPASS family of trials, then I would suggest that our webcast on the 9th of September would be a good place to start.

Alex, Barclays

Okay, great. Just another question, quickly. Given the cost containment measures you mentioned, do you expect to be able to drive both SURPASS-2 and 3 programs forward in parallel, or do you expect you might need to maybe prioritize one over the other in the near to medium term?

Adrian Rawcliffe, Chief Executive Officer

We expect to be able to develop the SURPASS family of trials within the envelope that our runway guidance indicates, and that includes SURPASS-2 and SURPASS-3. I'll point you back to the update that we plan on giving on SURPASS and the data on the first day of ESMO, September 9.

Alex, Barclays

Great, thank you.

Adrian Rawcliffe, Chief Executive Officer

Thank you.

Operator

Thank you. Our next question is from Jonathan Chang from SVP Leerink. Please go ahead.

Jonathan Chang, SVP Leerink

Hi, guys, thanks for taking my questions. First question, can you discuss how we should be thinking about duration of clinical benefit with the next gen MAGE A-4 program and the SURPASS study?

Adrian Rawcliffe, Chief Executive Officer

Elliot, do you have any comments on that at this point?

Elliot Norry, Chief Medical Officer

Hi, Jonathan. What I would say is the update to the SURPASS program at ESMO will include data on durability of response. I don't think we're providing any guidance as it relates to that at this time. I would look forward to the data that's going to be presented at ESMO, which will include response rate and durability of response.

Jonathan Chang, SVP Leerink

Got it. Are you able to maybe provide some thoughts on what the reasons for confidence are that you'll be able to achieve durable clinical benefit?

Adrian Rawcliffe, Chief Executive Officer

Yes, so I'll take the first stab at that and pass to Elliot. I think the reasons to a durable clinical benefit would start with the data from the Spearhead-1 trial which clearly shows that in a solid tumour, cell therapy can deliver durable responses that of significant benefit to patients, and (inaudible) this is the basis of the BLA file later on this year.

I think the purpose of the second generation was to extend the opportunity in cell therapy to broader tumour types. That's what we're dealing with, with the SURPASS

trial and then the SURPASS family of trials. I think apart from that, I'm going to have—and all the other technical discussions that we've had over the years, I would punt you to the update in September.

Just maybe one thing to point to, though. I think the fact that we are seeing robust responses in very late-stage patients in the SURPASS-1 trial is also reason for confidence of the clinical benefit that can be achieved in the right patient populations with these therapies. With that, I will defer to September 9.

Jonathan Chang, SVP Leerink

Got it. Maybe just a couple higher level questions for you guys, and that is, how does PRAME (phon) compare to MAGE A-4 as a TCR target? Also, how do you guys think about the interplay between TCR bispecifics and TCR in cell therapies? Thank you.

Adrian Rawcliffe, Chief Executive Officer

I'm going to ask Jo, our CSO, to talk about that.

Joanna Brewer, Chief Scientific Officer

I think when it comes to PRAME and MAGE A-4, obviously we have our own thoughts about those targets, and there's obviously a significant overlap in certain tumours. The PRAME program that we have is obviously partnered with GSK, so that's something that we can't do independently from them, whereas obviously, before it was in our control.

I think they're different targets and they're different TCRs, and I think that's really—we will have to see how those play out in the clinic. We optimize our TCRs very specifically with our—we do that optimization for every single program, and I can't comment on other people's TCRs in relation to our own. But they're both well-presented targets in solid tumours, and I'm sure there will be clinical successes with both.

Then, when it comes to bispecifics versus cell therapies, I think pros and cons to both of those. It depends on the target density and how well that works with the T-cells. Having the TCR actually inside the T-cell versus having a bridge in between, I think again, we'll see how that plays out with the number of peptides on the surface of the cells. Also, I think the tumour microenvironment plays a big role there as well.

Again, I don't think there's anything I can necessarily say here because we only deal with cell therapies rather than bispecifics ourselves.

Jonathan Chang, SVP Leerink

Got it. Thanks for taking my questions.

Operator

Thank you. Our next question is from Michael Smith. Please state your company and proceed with your question.

Paul, Guggenheim Investments

Hi, this is Paul in for Michael, from Guggenheim. Thanks for taking our questions. On SURPASS, we saw that you've opened the Nevo (phon) combination arm. Has that begun recruiting, and when would there potentially be clinical data? Is there any waiting (audio interference) to that arm for patients who could be PD-1 responsive or plans to record patients by PDL-1 (phon) (inaudible) level? Thank you.

Adrian Rawcliffe, Chief Executive Officer

Elliot?

Elliot Norry, Chief Medical Officer

Yes, so thanks. I can confirm that that arm is open and enrolling patients, being rolled out to the SURPASS study sites as quickly as we can do.

We are measuring PD-1 expression at baseline, so we will be able to provide insights as it relates to baseline PD-1 expression in relation to response.

Paul, Guggenheim Investments

Great, thank you.

Operator

Thank you. Our next question is from Mara Goldstein from Mizuho Securities. Please go ahead.

Mara Goldstein, Mizuho Securities

Oh, thank you very much. Just a couple quick ones. Just with respect to the cost containment effort, I think I saw the last figure that I saw in your deck is you have about 500 FTEs across the various manufacturing facilities. Is that still the case even with these cost containment issues?

Then, just on Spearhead-1. I know you've spoken to the primary clinical support for the BLA following as Cohort 1, but can you speak to what other data you plan to submit to support the filing?

Gavin Wood, Chief Financial Officer

This is Gavin speaking. We're running a little over 500 now. We've begun to ramp up on the commercialization and also to complete the BLA submission. But that's the sort of broadly the number (inaudible).

Adrian Rawcliffe, Chief Executive Officer

Then, on the BLA, Dennis?

Dennis Williams, Senior Vice President of Late-Stage Development and Regulatory Affairs

Yes, sure. There's a lot of things that we would use to support the clinical dossier. They would include things like integrated or pooled efficacy and safety analyses, some of which we showed back at ASCO, but there are more than that. We have a number of exposure response analyses, noncompartmental analyses taken into afami-cel exposure and its relationship to efficacies, and things of this nature that help supplement the primary efficacy data that's coming out of Spearhead-1.

Mara Goldstein, Mizuho Securities

Okay, thank you.

Adrian Rawcliffe, Chief Executive Officer

Thanks, Mara.

Operator

Thank you. Our next question is from Danya Ben-Hail from Jones Research. Please go ahead.

Danya Ben-Hail, Jones Research

Hi, this is Danya (inaudible). Thank you for taking my question. I have a quick one on the GMP manufacturing space of the (inaudible). Do you have any colour on completion and plans?

Adrian Rawcliffe, Chief Executive Officer

John, would you like to comment on that?

John Lunger, Chief Patient Supply Officer

Sure, be happy to. Thanks for the question. Yes, we're looking to have that facility structurally completed later on this year and turned over to operations for us to begin to start to qualify the process and get in there early next year. With that space plus our existing space, we'll have enough capacity in terms of equipment and facility to continue our clinical trials as well as the afami-cel launch.

Mara Goldstein, Mizuho Securities

Great, thank you. So, this will be also added into the BLA submission?

John Lunger, Chief Patient Supply Officer

The new space will not, actually. Our existing space, which we've been using for the last five years for our clinical trial, that's going to be the space that will be part of the submission and will be our commercial supply. The new space ultimately will be for clinical supply only.

Mara Goldstein, Mizuho Securities

Got it. Thank you.

Adrian Rawcliffe, Chief Executive Officer

Thank you.

Operator

Thank you. There are no further questions registered at this time, so I'll turn the call over to Mr. Rawcliffe.

Adrian Rawcliffe, Chief Executive Officer

Thank you. Thanks, everyone, for your time today. I hope you heard that we are both excited about and focused on the priorities that we outlined at the beginning of this call and our progress thereon.

I look forward to updating you at conferences and our live event on September 9, the first day of ESMO. In the meantime, please feel free to reach out with any questions.

Thank you again for your time.

Operator

Thank you. Your conference has now ended. Please disconnect your lines at this time and we thank you for your participation.
