

## **September 4, 2019 Conference Call Corporate update**

### **Call participants:**

- Matt Coffey, President & Chief Executive Officer
- Kirk Look, Chief Financial Officer
- Andrew de Guttadauro, Global Head of Business Development
- Michael Moore, Vice President of Investor Relations and Corporate Communications

### **Michael Moore, Vice President, Investor Relations & Corporate Communications**

Thank you, operator. Good morning, ladies and gentlemen and thank you for joining us on our call today to discuss our Corporate Update, including our updated catalysts and milestones. With me on the call this morning from Oncolytics are Dr. Matt Coffey, President and Chief Executive Officer, Kirk Look, Chief Financial Officer and Andrew de Guttadauro, Global Head of Business Development.

On today's call, Dr. Coffey will review our clinical and operational progress and provide an update on our clinical development plans and strategy, including our growing critical mass of catalysts and milestones. Andrew will



touch on our business development strategy and growing relationships with pharma and big biotech and Kirk will then speak to our financial position.

I'd like to point out certain statements made on this call, such as those relating to our clinical development plans and business development plans are forward-looking within the meaning of applicable security laws. Please refer to our second quarter press release and MD&A for important assumptions and cautionary statements related to forward looking information.

I will now turn the call over to Dr. Matt Coffey. Matt?

**Matt Coffey, President & CEO**

Hello and welcome to our conference call to provide a corporate update. We typically hold these calls immediately following our quarterly reporting, but we were not able to due to the ongoing financing and felt it was best to wait until after Labor Day, rather than hold the update during what seem to be the two most popular vacation weeks of the year.

I want to use the call today to remind everyone of our two main objectives at Oncolytics:

- First, to advance the breast cancer program in to our first phase 3 registration study, and
- Second, expand to additional combinations with immunotherapies.
  - It's important to note that we'll explore these combinations based on interest and financing coming from pharma and investigators.
  - I think it's also important to note that this would happen in indications where we have seen activity with pelareorep and believe there to be a faster path to approval. This also provides for a higher likelihood of success, which of course builds greater interest from pharma.

I also want to use the call to highlight a couple of key differentiators for Oncolytics, the first of which seems to be underappreciated. Pelareorep has demonstrated its ability to reach tumor tissue through intravenous delivery and treat metastatic disease. This is something for which almost no other OV has meaningful data and something we have demonstrated yet again in the first few AWARE-1 patients. Second is our biomarker, which has led to increased business development conversations and resulted in an incredibly robust set of catalysts and I look forward to highlighting a steady cadence of value inflection points between now and mid-2021.

As everyone knows, we chose metastatic breast cancer as our lead indication for three reasons: the unmet need, the sheer size of the opportunity, and of course, our strong phase 2 data from the IND-213 study that demonstrated an almost doubling of overall survival in our target patient population of HR+/HER2-.

There are more than 100 thousand women living with HR+/HER2- metastatic breast cancer and the best available therapies offer only 10 additional weeks of overall survival. Approved therapies that offer only a progression-free survival benefit are still multi-billion-dollar drugs, which highlights the value ascribed to new and effective therapies in this high-need space. In our AWARE-1 window of opportunity study in early stage breast cancer – one of two studies required to provide the data needed to enter phase 3 with greater confidence – is enrolling now with SOLTI in Spain where we are testing pelareorep in combination with Roche's Tecentriq and evaluating the utility of our biomarker measuring T cell clonality.

Our safety run-in of three patients highlighted some extremely meaningful data that I want to take a few minutes to highlight:

- First the data demonstrated the holy grail of the oncolytic virus world: viral replication in the tumor via intravenous delivery.
- The inflammation caused by pelareorep created an abundance of new T cells and Adaptive Biotechnologies, who runs our

biomarker measuring T cell repertoire, actually commented that this is some of the most robust T cell clonality they have ever seen.

- As an example, the average person in North America living in an urban or sub-urban neighborhood will create 3 to 5 new T cell clones a month. Pelareorep created over 450, including an increase in CD8+ T cells in the tumor after a single cycle.
- Importantly, the T cells are reactive to tumor, suggesting we are creating the necessary tumor environment for checkpoint blockade in the presence of Tecentriq.

In short, this is definitive clinical proof that pelareorep has trained the immune system to engage, target and kill tumor cells.

A paper was published in July in Nature Medicine highlighting the importance of the expansion of novel T cell clones that had not previously been observed in the tumor, as opposed to pre-existing tumor-infiltrating T lymphocytes. The paper states that – and I quote – “This demonstrates that pre-existing tumor-specific T cells may have limited reinvigoration capacity, and that the T cell response to checkpoint blockade derives from a distinct repertoire of T cell clones that may have just recently entered the tumor.”

The ability to expand these new T cell clones is exactly what pelareorep demonstrated in these first 3 patients from the AWARE-1 safety run-in, which is what our biomarker is measuring. We're not just reinvigorating existing tumor-associated T cells, we're creating and expanding new ones that are reactive to tumor. These results, while from only three patients, are extremely encouraging. The next cohort will confirm if this is enhanced by Tecentriq and will be part of the interim data announced before the end of the year. Importantly, the data will support our biomarker working in breast cancer and provide tumor inflammation data for the three sub-types of breast cancer we're studying.

BRACELET-1 – our other breast cancer study in metastatic breast cancer that will provide the data needed to enter phase 3 with greater confidence – came from our recently announced co-development agreement with Pfizer and Merck KGaA to develop pelareorep with their jointly owned PD-L1 checkpoint inhibitor, Bavencio. This was the culmination of considerable effort, and worth noting that Oncolytics went through full due diligence with both Pfizer and Merck KGaA. We are pleased to have entered a true co-development agreement representing meaningful payments from both parties and not just an investigator sponsored study, or IST. Those too, are crucially important to our clinical path and robust set of data catalysts, but IST's don't represent the same level of commitment or engagement, which we've already been very pleased with.



Regarding the study itself, BRACELET-1 is based on our biomarker and pelareorep's ability to treat systemically. It is being designed as a phase 2, three arm, open label study to treat second line, HR+/HER2- metastatic breast cancer patients, which is our target patient population for the phase 3 study of pelareorep. The design of the study will be finalized in the coming weeks and will then go to the FDA for approval. This keeps us well in line to be enrolling in Q1 2020. Data from these two key studies will enable us to optimize our phase 3 program for pelareorep and help us confirm patient selection for the highest chance of clinical success, as we move quickly towards registration. We believe that the totality of data from these studies, supported by additional data readouts, can lead to a phase 3 and successful business development relationships.

Beyond breast cancer – and to be VERY clear, there is more than just a breast cancer opportunity here – we also intend to build upon the body of evidence we're generating for pelareorep by exploring additional, commercially valuable new treatment areas, including other co-therapies with checkpoint inhibitors, as well as other key oncology drug classes such as CDK 4/6's and PARP inhibitors. Dr. Kevin Harrington at the Institute of Cancer Research in London has been doing some preclinical work with Pfizer's CDK 4/6 inhibitors, Ibrance, as well as their PARP inhibitor, Talzenna and this is one of the data catalysts I'll highlight later on the call.

This work was designed, developed and funded by Dr. Kevin Harrington along with his colleagues and collaborators, and is an example of the type of working relationship we will continue to develop and foster in order to advance pelareorep in multiple studies at little to no cost to the company. Dr. Harrington's preliminary findings were originally presented at a scientific conference in New York and will be updated by Dr. Harrington when presented later this year. While his work with a CDK 4/6 and a PARP inhibitor also happen to be focused on breast cancer, there are several tumor targets we consider most interesting right now, largely in the gastrointestinal space, including pancreatic cancer. This space is interesting for a variety of reasons, but most importantly because:

- we have data that suggests tumor response;
- checkpoint inhibitors have demonstrated efficacy in GI indications;
- studies could be designed and carried out at little to no cost;
- and most importantly, timelines to data would be relatively short

I touched on our breast cancer program, our recent business development progress with Pfizer and Merck KGA and the potential expansion of tumor targets. I'd now like to address one of the most important drivers of all of our clinical programs - now and in the future - our biomarker.

I can't overstate the significance of having a convenient biomarker in our studies moving forward, and this is why we are testing it in additional studies to help inform our registrational program. But let me back up a little bit to put it in context. Checkpoint inhibitors remove the brakes that tumors place on the immune system and enable inflammatory cells, primarily cytotoxic T cells, to recognize and kill cancer.

As most of our investors are aware, but it is worth noting again, even though checkpoint inhibitors are expected to generate \$25 billion in revenue in 2022, they are not without shortcomings. As little as 1 in 5 patients respond to checkpoint blockade because three pre-existing conditions must exist:

- The presence of an immunologically active, or hot tumor
- The presence of T cells to recognize and kill tumor cells, and
- The expression of the molecule PD-L1 on tumor cells

The infection process induced by pelareorep can satisfy all three of these requirements, so as you can imagine going from 1 in 5 responders, to 2 in 5 responders could be worth billions of dollars. So what if you could confidently predict who will respond to pelareorep?

This of course brings me right back to our biomarker – a simple blood draw that allows us to measure a patient's T cell repertoire – for which we have already made significant strides to confirm its utility for predicting patient



response to pelareorep, as well as its ability to confirm early responses to therapy. Being able to select and stratify patients who are likely to respond to treatment in our pivotal studies substantially improves our chances of success and enables a precision medicine approach to fighting cancer. It also enables us to be more cost-efficient and enroll the trials faster, which gets us to potential value inflection points sooner and with greater financial flexibility. To put this in context, the biomarker has transformed our business development conversations, including the conversations and diligence that led to our co-development agreement with Pfizer and Merck KGaA.

I'll now hand the call over to Andrew de Guttadauro, global head of business development to provide a brief business development review. Andrew?

**Andrew de Guttadauro, Global Head of Business Development & President, Oncolytics Biotech, U.S.**

Thank you, Matt.

Over the last two years, we've seen large pharma take a renewed interest in oncolytic viruses as a potential means of safely potentiating their immunology assets. Merck, BMS, J&J, and others have all struck deals to gain access to oncolytic viruses. Most of the companies in question have been

clinical-stage, thereby requiring that the deals be either acquisitions or licensing in nature, rather than the direct investments that you might see with pre-clinical companies.

It's important to note that the majority of these deals were preceded by clinical collaborations designed to evaluate the OV in question's potential with their own immuno-oncology assets, as we are doing now. As a company preparing for phase 3, pharma's evaluation must consider the significant downstream investment in clinical studies, registration, and commercial launch efforts. An early stage partnership might come with a small up-front of 25 million dollars and bio-bucks that can be close to a billion dollars, but the next several years are likely to require no more than another 25 million dollar investment and no meaningful bio-bucks coming for many years.

The situation is much different for Oncolytics. For perspective, in addition to an up-front payment, pharma is looking at significant real money investment – not just bio-bucks. A global oncology phase 3 trial, plus related multi-country registration costs, can easily exceed \$100 million. The related commercial costs to launch the product in major pharma markets can total an additional \$300 million or more. Given such costs are material to even the biggest pharma companies, the decision to enter into a licensing agreement goes beyond the direct licensing costs and is not taken lightly by pharma.



This is why we're running studies designed to demonstrate potential clinical synergies with Keytruda, Opdivo, Tecentriq, and Bavencio. This is the evidence required by pharma to make these licensing and investment decisions and have great confidence in a phase 3 program. We intend to leverage our forthcoming clinical data to demonstrate our potential synergies with multiple checkpoint products and across a range of tumor targets in a dynamic environment with multiple pharma's looking at combination data with pelareorep. Through this data, we plan to strike a licensing agreement with either a company with checkpoint assets or a company recognizing the significant clinical and commercial potential inherent in a therapy capable of being safely and efficaciously combined with multiple checkpoints to treat a range of targets with unmet clinical need.

With that, I will turn the call back over to Matt.

**Matt Coffey**

Thanks, Andrew. Before I hand the call to Kirk for a quick review of our financial position, let me outline our very robust catalysts and milestones which lead the oncolytic virus space over the next 2 years.

Before the end of this year we expect to report interim data in combination with Roche's Tecentriq from the AWARE-1 study, announce preclinical proof-of-concept data in combination with Pfizer's CDK 4/6 Ibrance and their PARP inhibitor Talzenna and initiate a phase 2 study of pelareorep in combination with Merck's Keytruda in multiple myeloma.

Looking into the first half of 2020, we will complete enrollment in AWARE-1, initiate BRACELET-1, report final data from AWARE-1, and report interim data from our ongoing phase 2 study of pelareorep and Keytruda in second-line pancreatic cancer. This study should also complete enrollment around mid-2020.

The second half of 2020 will include interim data from both multiple myeloma studies with Opdivo and Keytruda and final topline data from our phase 2 pancreatic study in combination with Keytruda, followed by both enrollment completion of, and interim data from, the BRACELET-1 study.

Finally, we expect final data from the BRACELET-1 study in the first half of 2021. This is without question the most robust set of data catalysts of any company in the oncolytic virus space and is why we are so excited about the future.

I also want to note that this formal guidance, meaning that it is what we fully expect to happen and what we want to be measured by. That said, we believe there will be more to come during this time period. Nothing we are ready to call formal guidance and be measured by, but there are always additional things going on behind the scenes of every company and we hope some of our activities result in more of these catalysts.

I'll now turn the call to Kirk Look, our CFO, to discuss our financial results for the quarter.

### **Kirk Look, CFO**

Thanks, Matt. Rather than going through expenses and net gains and losses, as I would typically on a quarterly call, I'd like to take this opportunity to highlight where we are today and what it means operationally and from an investment perspective.

I think everyone took note that our cash position at the end of June was 12.7 million Canadian or about 9.3 million US dollars. The addition of our recent financing, along with our additional access to capital we can maintain a 12-month financial runway. Now, as Matt discussed, we have a very robust set of catalysts and milestones. The OV world is not huge, but it is growing and

yet we are VERY comfortable saying that we have more data catalysts coming than any other OV company before the middle of 2021 and importantly, some of these come before the end of this year.

Why is that so important? It's important because there are three basic reasons to invest in biotech: There is revenue, if you are a big biotech with marketed products, but that doesn't exist for the vast majority of biotech that is focused on research and development. For the vast majority, the investment thesis revolves around data and business development and we're guiding towards 9 data catalysts that should provide the totality of data required to move into a phase 3 registrational study. I know everyone has been focused on a phase 3 and a partnership – and we don't discount the importance of those – but we have so many value inflection catalysts coming and we want to make sure our audience understands their value and that they all lead to Oncolytics achieving its objectives.

Again, several catalysts and milestones are expected before the end of this year and we expect that new data from our current studies can truly impact our valuation.

With that I'll turn it back to Matt



## **Matt Coffey – CEO**

Thanks, Kirk.

Before we wrap up, a few comments. I want to point out just how highly differentiated we are – and this is something we plan to message very strongly going forward. Almost every other OV in development – including the only approved OV in North America – is genetically modified and/or requires intratumoral delivery and therefore can not reach metastatic disease.

We are the only OV with meaningful data demonstrating systemic delivery - and to be very clear, we have the data and there are multiple scientific publications supporting this.

This data has generated multiple big pharma partnership opportunities on the back of an established clinical proof-of-concept. Pelareorep remains the only viral agent to show a survival benefit in late-stage metastatic breast cancer.

As we continued to advance our lead clinical program in breast cancer, our goal is to continue expanding our pipeline into additional, commercially valuable indications and other combination therapies with checkpoint inhibitors and potentially other drug classes in oncology. We now have the most robust set of data catalysts of any company in the oncolytic virus space



including 9 data announcements within 21 months and it is based on pelareorep's ability to synergize with chemotherapy and the entire class of checkpoint inhibitors. We look forward to achieving these milestones and building value for our company.

I'd now like to open the lines to take some of your questions. Operator?