Operator

Greetings, and welcome to Arcturus Therapeutics' Fourth Quarter 2022 Financial Update and Pipeline Progress Call.

As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Neda Safarzadeh, Vice President, Head of Investor Relations, Public Relations and Marketing. Thank you. You may begin.

Neda Safarzadeh

Thank you, Operator. Good afternoon, and welcome to Arcturus Therapeutics' Fourth Quarter 2022 Financial Update and Pipeline Progress call. Today's call will be led by Joseph Payne, our President and CEO, and Andy Sassine, our CFO. Dr. Pad Chivukula, our CSO and COO, will join in for the Q&A session as well.

Before we begin, I would like to remind everyone that statements made during this call regarding matters that are not historical facts are forward-looking statements within the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties, and assumptions that may cause actual results, performance and achievements to differ materially from those expressed or implied by the statements.

Please see the forward-looking statement disclaimer on the Company's press release issued earlier today, as well as the risk factors section in our Form 10-K filed with the SEC. In addition, any forward-looking statements represent our views only as of the date such statements are made. Arcturus specifically disclaims any obligation to update such statements to reflect future information, events or circumstances.

With that, I will now turn the call over to Joe.

Joseph Payne

Hey. Thank you, Neda, and good afternoon to all. Thank you for joining us for today's call.

The recent period has been characterized by substantial operational and pipeline progress here at Arcturus. We will be highlighting four areas on today's update call.

First, we closed our strategic vaccine collaboration agreement with CSL Seqirus at the end of last year. We have received the $200 million upfront payment and invoiced $90 million in additional milestones; demonstrating the positive progress that the companies have made on our partnered COVID and seasonal flu vaccine programs.

Second, we've entered into an agreement with Meiji Pharma to evaluate the ARCT-154 as a booster vaccine for SARS-CoV-2, also known as COVID-19, and we're very happy to report significant operational progress in the ongoing Phase 3 study in Japan and we'll be providing an update there.

Third, we have continued to advance our RNA platform technology and our earlier stage clinical programs, and we will provide an update on recent progress there.

Fourth, we have strengthened our Management Team by the addition of Dr. Juergen Froehlich, as our Chief Medical Officer, overseeing mRNA therapeutics and Dr. Igor Smolenov, as our Chief Development Officer, overseeing clinical development of our vaccine franchise.

I'll begin with our recently announced strategic collaboration with CSL. We are in the initial phase of our now four-month-old collaboration and very pleased with how the teams are working together. Arcturus has achieved substantial milestones this month associated with nominating next-generation candidates for COVID and seasonal flu programs.

Mutual respect is evident between the working groups of both companies. There is a clear passion and solid work ethic behind the competent execution that has led to these important and early milestones being achieved. We remain eligible for additional development and commercial milestones as covered pipeline programs advance.

Our collaboration with CSL is focused on the development and commercialization of next generation mRNA vaccines targeting COVID, Influenza, three additional pathogens as well as pandemic preparedness. Our collaboration combines CSL's well established global vaccine, commercial and manufacturing infrastructure with Arcturus' mRNA manufacturing expertise and the innovative STAR mRNA vaccine and LUNAR delivery platform technologies.

We expect this collaboration to drive the development, manufacture and global commercialization of next generation self-amplifying mRNA vaccines over the coming years. The impact of this collaboration to our balance sheet and runway continues to be meaningful and Andy will be speaking to that shortly.

Now on to our agreement with Meiji Pharma to advance ARCT-154 development in Japan. Our contracted relationship with Meiji is focused on developing ARCT-154. This is our next generation self-amplifying mRNA booster vaccine for COVID-19. You may already appreciate that Japan has one of the world's highest rates of COVID booster vaccination.

Given the Japanese government's focus on public health and infectious disease prevention, we fully expect high levels of COVID booster utilization for many years to come. In addition, the Japanese government has been clear about their interest in establishing independence in mRNA vaccines and we're very pleased to be part of this effort with Meiji.

Meiji Group received a significant subsidy from the Japanese government in the fourth quarter of 2022 to support this effort and Meiji is responsible for all development costs related to ARCT-154 in Japan.

In December 2022, we announced that Meiji had initiated a Phase 3 booster study in Japan designed to compare ARCT-154 to Comirnaty and targeting 780 adult participants based on non-inferiority immunogenicity. Meiji moved quickly with the enrollment process, very impressed and appreciative with the productivity and progress we've seen there.

I'm very pleased to report today that the study is now fully enrolled with over 800 participants, exceeding our target enrollment and ahead of schedule. In addition, the one month follow-up visits and the one month blood draws have also been completed. This timely execution allows us to immediately

collect the pre-requisite immunogenicity data and be in a position to potentially file our first NDA in Japan.

Now moving to our earlier stage programs and I'll begin with ARCT-810.

This is our therapeutic candidate for ornithine transcarbamylase deficiency, or OTC deficiency. This investigational therapeutic aims to address the deficient OTC enzyme in the livers of individuals with this disease. ARCT-810 has the potential to restore urea cycle activity and prevent metabolic crises that cause neurological damage and potentially liberalize strict dietary protein restrictions and improve the quality of life for people living with this condition.

The program utilizes our proprietary LUNAR delivery technology and one important attribute of this technology is that the lipids administered are rapidly degraded, which we expect will contribute to a favorable safety profile. We are evaluating ARCT-810 in two ongoing clinical studies, a Phase 1b study in adults and a multi-dose Phase 2 study in adolescents and adults with OTC deficiency (audio interference). These studies build upon a completed Phase 1 study that demonstrated a favorable safety profile when dosed up to 0.4 mgs per kilogram, the highest dose evaluated in that study.

We continue to advance ARCT-810 in the Phase 2 study. The study will enroll up to 24 adolescents and adults living with OTC deficiency distributed across two dose cohorts. The study has enrolled multiple subjects. We remain on track to report ARCT-810 Phase 2 interim clinical data later this year.

Now moving on to ARCT-032. This is our inhaled messenger RNA therapeutic candidate for cystic fibrosis. With this drug, we are aiming to express fully functional CFTR protein in the lungs of individuals with cystic fibrosis. Our approach is agnostic to the underlying mutations associated with the disease and we believe that ARCT-032 could provide benefit across a very wide range of those living with CF, especially Type 1 CF and for individuals who are not well served by CFTR modulator therapies.

We're grateful to have obtained support from the CF Foundation for the advancement of this promising investigational medicine. We also benefit from invaluable scientific collaboration with the experts at the CF Foundation.

Previously, we reported encouraging preclinical data demonstrating successful delivery to the lung in four different animal species: mice, rats, ferrets and primates. Notably, our data have shown the ability to deliver mRNA to airway epithelium in the CF variant. This is a disease model that produces significant mucus in the airways, similar to patients with CF.

Finally, in-vitro treatment of bronchial epithelial cells from CF donors with ARCT-032 has demonstrated robust expression of CFTR protein and restoration of chloride current. Supported by these encouraging data, we are now evaluating ARCT-032 at four different dose levels in a Phase I study being conducted in New Zealand. We have successfully completed the enrollment of the first two cohorts with expectation to complete enrollment of the entire 32 subject study in the second quarter of this year and plan to report study results later this year.

Arcturus is excited to share our LUNAR-HBV data next month. We have been optimizing our in-vivo intravenously dosed gene editing platform for years. Our preclinical gene editing mRNA platform data for hepatitis B virus will be presented on April 27 at the 18th Annual Global Hepatitis Summit Conference in

Paris, France. This will be the first opportunity for the scientific community to evaluate the benefits of Arcturus' LUNAR delivery of systemically administered mRNA or gene editing applications.

In this past quarter, we have strengthened our Management Team. We have brought on Dr. Juergen Froehlich, to be our CMO, our Chief Medical Officer, to provide seasoned leadership over our mRNA therapeutics pipeline, and also have brought on board Dr. Igor Smirnoff to be our Chief Development Officer, who will lead our Arcturus' clinical development efforts for our promising COVID and seasonal flu self-amplifying mRNA vaccines.

Now Dr. Froehlich has broad and successful experience in the field of rare diseases, including OTC deficiency and cystic fibrosis. He will assuredly increase our likelihood of success as Arcturus initiates and navigates through late-stage clinical trials for our rare disease therapeutic programs. He has three decades of broad and late-stage therapeutic clinical development experience at Genentech, Quintiles, BMS, Ipsen, Vertex and Genevant.

Juergen completed Medical School at the University of Wartburg in Germany. He is a Diplomat of the American Board of Clinical Pharmacology and holds a dual executive MBA from Zurich, Switzerland and the State University of New York at Albany. Jurgen has been directly involved in successful global marketing authorizations of drugs in the U.S., Canada, the European Union, Switzerland and Australia.

Since 2011, he's been involved in early and late-stage development of CF therapeutics, including the approval of KALYDECO and clinical development planning for other CFTR modulators. He has seasoned experience in Phase 1, 2 and 3 trials with inhaled therapeutics in patients with CF to treat chronic lung infection. We are fortunate to have Dr. Juergen Froehlich join our Management Team as our Chief Medical Officer.

Now moving on to introduce our Chief Development Officer of Vaccines. Dr. Igor Smolenov, has a strong record of successfully developing vaccines all the way through approval. He will help our vaccine team and our partnership with CSL get our COVID and flu programs to this next level, and we're excited about that. Dr. Smolenov is a recognized leader in clinical development with a proven record of accomplishment in biotech and large pharmaceutical companies. He contributed to the successful development and licensure of several innovative vaccines.

Before joining Arcturus, Dr. Smolenov was the Executive Vice President at Clover Pharmaceuticals. That's where he built a strong team that was able to rapidly generate pivotal clinical data, leading to a COVID-19 vaccine authorization and product launch there. Before that, Dr. Smolenov served as a therapeutic area head, leading the development of several seasonal flu vaccines at CSL Seqirus. Igor was the Head of Clinical Development at Moderna, managing the initiation of the first clinical trials of messenger RNA vaccines in humans.

At Novartis Vaccines, Dr. Smolenov contributed to the development and global licensure of multiple vaccines there as well. Igor graduated from Volgograd State Medical University in Russia, where he holds an MD, a PhD and a Doctor of Science degrees from this university. He's the author of more than 50 publications in peer-reviewed journals in clinical pharmacology, infectious disease and vaccine development. We are indeed fortunate to have Dr. Igor Smolenov join our team here at Arcturus as our CDO overseeing our vaccine franchise.

I will now pass the call on to Andy Sassine, our CFO, to provide financial updates.

Andrew Sassine

Thank you, Joe, and good afternoon, everyone.

The press release issued earlier today includes financial statements for the fourth quarter and Fiscal Year 2022 and provides a summary and analysis of year-over-year and sequential financial performance. Please also reference our Form 10-K for more details on the financial performance.

I'll begin with the CSL agreement. Arcturus received a $200 million upfront payment that was received in the fourth quarter of 2022. Additionally, in March 2023, our first achieved development milestones primarily associated with nominating next-generation candidate for COVID-19 and seasonal flu programs, resulting in $90 million invoiced to CSL.

We are excited to continue working on these programs under the guidance and leadership of our partner CSL. Our CSL collaboration is a 40/60 profit sharing agreement related to COVID-19 vaccine product. With respect to program costs related to the bivalent COVID-19 vaccine, we expect that future anticipated milestones will cover all related expenses going forward.

Additionally, the program cost for the seasonal flu candidate will be reimbursed in full on an ongoing basis. CSL can apply a $37.5 million R&D credit to be used within the next five years against cost incurred on the flu and three other respiratory disease vaccines.

As you heard earlier, we are excited that Meiji completed enrollment during the first quarter of 2023 for the Phase 3 COVID-19 booster trial of ARCT-154 in Japan. Meiji is responsible for all related clinical, regulatory, development and manufacturing expenses for the ARCT-154 booster vaccine.

Our manufacturing loan with the Singapore government, which had a principal and interest balance of $50.4 million as of December 31, 2022 was renegotiated in March 2023, which resulted in Arcturus paying back $17.1 million and the remaining $33.3 million being forgiven. As a result, Arcturus has no further loan obligation payable to Singapore.

On the treasury side, in March 2023, we paid off the remaining loan with Western Alliance Bank which had a balance of $10 million as of December 31, 2022, and we entered into a new banking relationship with Wells Fargo. Based on the substantial funding provided by the CSL collaboration, we expect Arcturus to be in a very strong financial position in the next few years. Our cash runway now extends to the beginning of 2026 based on our current pipeline and assuming no milestones or revenues from any commercial product sales.

I will now provide a quick summary of our financial results for the fourth quarter of 2022.

We reported revenues of $160.3 million for the fourth quarter compared to revenues of $5.8 million in the fourth quarter of 2021. The increase in revenue was predominantly driven by the licensed portion of the upfront payment from the CSL transaction.

We reported total operating expenses of $38.8 million during the fourth quarter of 2022 compared to operating expenses of $43.4 million in the fourth quarter of '21. The decline in operating expenses was primarily due to lower COVID-19-related manufacturing and clinical-related expenses.

Finally, we reported a net income of approximately $117.3 million, or $4.43 per diluted share, during the fourth quarter of 2022, compared to a net loss of $38.7 million, or $1.47 per diluted share, during the fourth quarter of 2021.

I am happy to report for the first time in the history of the Company, we reported net income of $9.3 million for the fiscal year ended 2022.

In summary, we believe that the Company is in a strong financial position and has the resources needed to achieve multiple near-term value-creating milestones for the vaccine and therapeutic programs over the next 12 months.

I will now pass the call back to Joe.

Joseph Payne

Hey. Thanks, Andy.

It's been a productive quarter. We hit the ground running with CSL, as indicated by meaningful early milestones being achieved in the partnership. We made measurable progress in each of our clinical programs, which has put us in a position to potentially file our first NDA in Japan and collect meaningful clinical data in 2023 for each one of our pipeline programs.

This will showcase the intramuscular, intravenous and inhaled applications of our proprietary mRNA and delivery technologies. We've also strengthened our Management Team and look forward to many of you meeting them over the next—the remainder of the year.

With that, we would like to turn the time over to the Operator for questions.