Ensysce Biosciences, Inc.

Corporate Update Call

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CORPORATE PARTICIPANTS

Lynn Kirkpatrick, PhD, *Chief Executive Officer*

Dave Humphrey, *Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Thomas Flaten, *Lake Street Capital Markets*

PRESENTATION

Operator

Good morning and welcome to Ensysce Biosciences, Inc. Corporate Update Call.

As a reminder, this conference is being recorded.

Your hosts today are Dr. Lynn Kirkpatrick, Chief Executive Officer, and Dave Humphrey, Chief Financial Officer.

Before we begin the formal presentation, I would like to remind everyone that statements made on the call and webcast may include predictions, estimates or other information that might be considered forward-looking. While these forward-looking statements represent our current judgment on what the future holds, they are subject to risks and uncertainties that could cause actual results to differ materially. You are cautioned not to place undue reliance on these forward-looking statements, which reflect our opinions only as of the date of this presentation. Please keep in mind that we are not obligating ourselves to revise or publicly release the results of any revision to these forward-looking statements in light of new information or future events. Throughout today's discussion, we will attempt to present some important factors relating to our business that may affect our predictions. You should also review our most recent Form 10-K for a more complete discussion of these factors and other risks, particularly under the heading Risk Factors.

At this time, I'd like to turn the call over to Ensysce's Chief Executive Officer, Dr. Lynn Kirkpatrick. Lynn?

Dr. Lynn Kirkpatrick

Thank you, Operator. Good morning, everyone. I am pleased to welcome you to our corporate update conference call. Thank you for joining us.

Ensysce is a clinical stage biotech company and our focus is to advance our pipeline and initial drug candidates through commercialization. As most of you know, we are using transformative trypsin-controlled chemistry to improve drug safety and performance. This technology is designed to improve delivery and reduce abuse and overdose of prescription drugs, with a goal of creating new classes of prescription medicines that are intended to be powerful and safe. Our immediate focus is to utilize this transformative technology to address the ongoing opioid crisis. We have over 100 patents issued in 25 countries, supported by over $100 million in investment since our inception. We have been hard at work to achieve our goals and the runway for our technology is vast.

Before I continue our update, I wanted to describe our two technology platforms in detail. The first, TAAP, stands for Trypsin-Activated Abuse Protection. Trypsin is a digestive enzyme that is only active in the small intestine. TAAP is a chemical modification that inactivates the active ingredients in Ensysce's opioid products, including our lead agent PF614. This chemical modification protects from non-oral abuse, provides resistance to manipulation of our products, and is meant to reduce other forms of recreational drug abuse.

The second technology platform, MPAR, stands for Multi-Pill Abuse Resistance. MPAR is a smart overdose protection platform, designed to be combined with our TAAP products to prevent patients from overdosing. This protection from oral overdose exists only when more than the prescribed dose is taken.

Importantly, applying our technologies to opioids does not limit the ability of our products to provide a high degree of pain relief for those in severe pain.

While we will touch on our financials during this call from our earnings release last week, I wanted to take this opportunity now to speak to our accomplishments to-date, as well as the many exciting milestones we have in front of us this year. We will then answer any questions you may have.

Turning to the prior year, we started 2021 by receiving FDA allowance for an Investigational New Drug Application, or IND, for PF614-MPAR. PF614-MPAR is a combination product, bringing together our two-step extended release oxycodone prodrug PF614 and the trypsin inhibitor, nafamostat, designed to provide not only abuse deterrence, but also overdose protection.

In July '21, following our entrance into the public markets, we were honored to receive the third year of funding from our multiyear grant from the National Institute on Drug Abuse, or NIDA, providing $2.8 million to initiate a Phase 1 study of PF614-MPAR, which will be the first MPAR or oral overdose protection product in the U.S. This brings the total support from NIDA to $8 million. An additional $2.8 million award for the fourth year of the grant is pending. This financial support further confirms the importance of our TAAP and MPAR technologies.

Our public debut and our listing on the NASDAQ Capital Markets has provided the Company with the opportunity to continue the progression of our clinical programs. Additionally, and most recently, in the fourth quarter of 2021, we completed a convertible note financing of $15 million, providing additional funds to advance our clinical trials, build the nonclinical programs and the required CMC, or Chemistry Manufacturing and Controls, activity for filing our first New Drug Application, or NDA, and support our mission to apply our transformative chemistry to improve prescription drug safety and performance.

With the rapid pace of our platform timelines, during the fourth quarter of 2021, we positioned the Company for commercial success at the executive level with the appointment of Dr. Linda Pestano as Chief Development Officer. Linda has worked through her career to guide the development of novel therapeutics to improve patient outcomes and quality of life. She brings a wealth of experience in preclinical drug development that will aid in advancing our lead next generation opioid products through to commercialization. We were also pleased to welcome Lee Rauch to our Board of Directors. Lee is an experienced Chief Executive Officer and strategy advisor who has successfully built companies ranging in focus from preclinical research to advanced clinical development. Additionally, as we continue to meet significant milestones, we are in the process of adding to our management team in 2022. I look forward to providing a further update on this front in the next few weeks.

Turning to our clinical program updates, we concluded 2021 by achieving a critical company milestone as the first patients were enrolled in the Phase 1 study of PF614-MPAR, our first product designed to reduce drug oral overdose. Again, PF614-MPAR is a combination product, providing both abuse and overdose protection that we believe is unique in the industry.

MPAR is designed to prevent drug overdose by inhibiting the activity of trypsin and hence the first step of the activation process of a TAAP prodrug only when more than a prescribed dose—doses are taken.

The MPAR combination technology is the first approach that we expect may prevent all four forms of abuse: injecting, chewing, inhaling and oral overdose. Data is expected by fourth quarter that will drive additional studies for PF614-MPAR in 2023. Along with our current clinical study of PF614, our TAAP opioid with abuse protection, this additional study of PF614-MPAR with added oral overdose protection will enhance our dual-pronged approach to provide safer solutions to patients and prescribers. As I previously mentioned, the NIDA grant of $2.8 million received in 2021 supports this clinical study.

For our TAAP clinical programs and the first commercial candidate PF614, in December, we successfully completed the first part of the two-part clinical study, PF614-102. This Multi-Ascending Dose or MAD part of the trial evaluated three dose levels of PF614 delivered orally, twice daily for five days to healthy subjects. Additional study participants received OxyContin at three comparable dose levels. The second part of the study, a bioequivalence evaluation of PF614 compared to the commercial product OxyContin, was initiated in January of 2022 and recently completed clinical enrollment. Both the MAD and bioequivalence study data expected to be available at the end of the second quarter of this year will position PF614 as our first commercial candidate, fueling our ability to bring a unique pipeline of products to the market, aligned with our mission of helping millions suffering with severe pain. Additionally, we believe this bioequivalence data will support the 505(b)(2) regulatory path for clinical development of PF614, an abbreviated pathway to FDA approval.

PF614 designed using the abuse protective platform, TAAP, is a delayed onset extended-release oxycodone prodrug, similar to OxyContin. Again, we believe TAAP provides improved abuse protection to that of OxyContin, resistance to manipulation and other forms of recreational drug abuse and controls the rate of release of the active opioid. The PF614-102 MAD and bioequivalence study builds on the safety and pharmacokinetic results of our initial Phase 1 study and is designed to improve the understanding of how PF614 compares to currently available commercial products.

Additional clinical trials to evaluate PF614 are in the process of being initiated in the second and third quarters of 2022, including two human abuse liability, or HAL studies, that will be key for gaining abuse deterrent labeling. The studies will help us further understand the tendency for drug abusers to like the

effects, achieved after taking PF614 either orally or nasally, as compared to that of similar product, for example, crushed OxyContin. Finally, we are also exploring pain indications to evaluate PF614 for efficacy and safety, which we are seeking to initiate by the first quarter of 2023.

We continue to be encouraged by our progress towards bringing our lead next generation opioids to market. The completion of these studies will be a critical milestone for Ensysce and a major step toward providing safer options for doctors and patients.

I will now turn the call over to Dave Humphrey, Chief Financial Officer, to discuss the financials.

Dave Humphrey

Thank you, Lynn. I will give a brief review of our financial results and a full breakdown is available in our regulatory filings and in the press release that crossed the wire last week on March 31.

Starting with revenues, funding under federal grants was $1.6 million for the fourth quarter of 2021, a significant increase from $0.4 million in the fourth quarter of 2020. The quarterly increase is attributable to increased clinical development activity with our PF614-MPAR overdose protection product under our NIDA MPAR grant, as Lynn mentioned. For the full year, total 2021 funding under federal grants of $3.5 million represented a decrease from $3.9 million in 2020, due to higher preclinical activities in 2020.

Now, looking at operating expenses. Our research and development expenses for the fourth quarter of 2021 increased to $2.2 million from $1.3 million in the 2022 fourth quarter. The increase was primarily due to external research and development costs related to the clinical programs for PF614 and PF614-MPAR. The full year comparison showed a smaller increase in R&D expenses from $4.4 million in 2020 to $4.7 million in 2021.

General and administrative expenses for the fourth quarter of 2021 of $1.5 million represents an increase from $0.3 million in the same period of 2020, largely due to higher costs from operating as a public company in 2021. The full year increase in G&A expenses from $1.2 million in 2020 to $18.7 million in 2021 was primarily driven by a one-time $11.6 million non-cash expense related to warrants issued in July 2021 for a $60 million share subscription facility, as well as for non-cash expense for consultants and commitment fees for the share subscription facility.

Shifting to non-operating expenses, total other income expense for the fourth quarter of 2021 was $8 million of expense, compared to $1.1 million of income in the fourth quarter of 2020. This increase in net expense was primarily related to non-cash fair value adjustments for the convertible notes and warrants totaling $6.7 million in the fourth quarter. Similarly, the full year periods show other expense of $9.3 million in 2021 and other income of $1.5 million in 2020, driven by $6.3 million of non-cash fair value adjustments for the convertible notes and warrants for the full year.

Overall, our net loss for 2021 totaled $29.1 million. I want to point out that our net loss for the full year consisted of significant non-cash expenses, including $17.9 million related to fair value accounting for various warrants and convertible notes. For the fourth quarter, $6.7 million of the $10 million net loss was for these non-cash fair value adjustments related to the convertible notes issued in September and November 2021, while our loss from operations in the fourth quarter was $2 million. These non-cash fair value adjustments are impacted by changes in the Company's stock price and are therefore difficult to

project going forward. As a clinical stage biotech company, we expect to incur losses for the foreseeable future as we advance the development of our product candidates.

Turning to cash, we ended 2021 with $12.3 million in cash and cash equivalents, compared to $6.8 million as of September 30, 2021, and $0.2 million as of December 31, 2020. In November 2021, we received additional funding of $10 million under the convertible note financing on top of the initial $5 million that was received in late September. So, covering all of 2021, we raised $20.3 million of net proceeds from financing activities, and used $8.2 million in our operating activities.

We remain committed to investing in our clinical trials and development activities to support our continued path towards regulatory approval and commercialization. Our Management team, along with our Board of Directors, regularly conducts extensive reviews of our operations and development pipeline. We are carefully watching our cash, and we estimate that our cash burn will likely be approximately $4 million on a quarterly basis. Our plans reflect that our estimated runway of current cash resources takes us into the fourth quarter of this year.

As we execute upon our mission, it is also our intent to align with our shareholders and we remain committed to maximizing the value our shareholders hold as we consider our ongoing capital needs.

I will now turn the call back to Lynn for closing thoughts.

Dr. Lynn Kirkpatrick

Thanks, Dave.

In summary, we believe we are well positioned to create long-term value for our shareholders. Throughout 2021, we made significant advances for our TAAP and MPAR programs to launch the next generation opioid products to reduce abuse and overdose while relieving suffering for people in severe pain. We believe we are beginning 2022 with increased momentum, resources and enthusiasm. Our revolutionary abuse-resistant opioids are designed to combat prescription drug abuse, a problem that continues to be a major concern in the U.S.

During late 2021, more than 200 people were dying daily in the U.S. after overdosing on opioids. Beyond opioids, we believe our two distinct novel technology platforms can be applied to a large majority of prescription drugs which we believe can drive internal growth and external partnering opportunities.

Looking ahead, with our transition to a public company and the addition of new capital to accelerate our commercial path, we remain confident in our anticipated upcoming milestones. By the end of 2022, we expect to report on three major data milestones, while progressing nonclinical and other development efforts. First, we expect the Multi-Ascending Dose and bioequivalence data from the PF614-102 study to be available by the end of the second quarter. Second, the human abuse liability studies to determine labeling claims for PF614 are scheduled to initiate in the second quarter and we expect to report data from the nasal study by the end of the third quarter and the oral study in the first quarter of 2023. Third, we expect to report on the safety and pharmacokinetic data from the Phase 1 study of PF614-MPAR in the fourth quarter of this year.

Today, supply chain issues and delays are prevalent in nearly every industry and the drug development industry is no different. We are attempting to plan our activities with timelines that should progress

each program in what we see as a timely manner. We believe we're approaching our 2022 milestones from a position of strength and with an experienced team to support our goals.

I look forward to providing our shareholders with further updates in the near term as we move towards commercialization.

I thank you all for attending. I now would like to hand the call over to the Operator to begin our question-and-answer session. Operator?

Operator

Thank you. Our first question comes from the line of Thomas Flaten with Lake Street Capital Markets. Please proceed with your question.

Thomas Flaten

Good morning, guys. Thanks for taking the questions. Just a couple for me. On the HAL, human abuse liability studies, Lynn, I was wondering if you could give us some more detail on number of patients, anticipated outcomes, what measures you are using. Is it the standard stuff? Or maybe could just provide some more color there would be great.

Dr. Lynn Kirkpatrick

With respect to the HAL studies, we are just initiating these and providing the clinical protocols to the FDA for a review. Our statistical analysis plan has not been finalized at this time, but they are the typical HAL studies with the typical outcomes that have been reported. We will be reporting a little bit more on these after we initiate the studies.

Thomas Flaten

Great. And the difference in timing between the nasal and oral readout, is that just how you staggered them for logistical reasons or is there some other reason for that?

Dr. Lynn Kirkpatrick

Correct.

Thomas Flaten

Okay.

Dr. Lynn Kirkpatrick

No. You are correct. Sorry for interrupting. The nasal study is initiating in this quarter the oral study will be initiatedin the third quarter. We are doing the study sequentially at the same clinical site.

Thomas Flaten

Got it. Then just to confirm. Your discussions with FDA around 505(b)(2), have those been finalized or is there an open question there around your ability to use that pathway?

Dr. Lynn Kirkpatrick

They have not been finalized. We have, as you know, just completed the clinical portion of our bioequivalence study, which would lead to that and we'll be having discussions, an end of Phase 2 discussion with the agency we expect in early 2023 to actually finalize that.

Thomas Flaten

Excellent. Then just one final one, the MAD and BE data, you will report those together, or will they be separate disclosures?

Dr. Lynn Kirkpatrick

We expect to lock the data for that together. We are anticipating, at this time, the data will be coming together.

Thomas Flaten

Excellent. Thanks for taking the questions. Much appreciate it.

Dr. Lynn Kirkpatrick

Thanks, Thomas.

Operator

There are no further questions in the queue. I'd like to hand the call back to Dr. Kirkpatrick for closing remarks.

Dr. Lynn Kirkpatrick

Thank you, Operator. I would like to thank each of you for joining our conference call today and look forward to continuing to update you on our ongoing progress. If we are unable to answer any of your questions, please reach out to our IR firm, MZ Group, who would be more than happy to assist.

Operator

Ladies and gentlemen, this does conclude today's teleconference. Thank you for your participation. You may disconnect your lines at this time and have a wonderful day.