CORPORATE PARTICIPANTS

Eric Goldstein, Managing Director, LifeSci Advisors

Robert Bestof, interim CEO, Head of Operations, Chief Commercial Officer

Ira Strassberg, Chief Financial Officer and Treasurer

PRESENTATION

Operator

Greetings, and welcome to the NRx Pharmaceuticals Full Year 2021 Earnings Call.

As a reminder, this conference is being recorded.

I would now like to turn the conference over to your host, Eric Goldstein, Managing Director, LifeSci Advisors. Thank you. You may begin.

Eric Goldstein

Thank you Operator.

Before we proceed with the call, I would like to remind everyone that certain statements made during this call are forward-looking statements under U.S. Federal securities laws. These statements are subject to risks and uncertainties that could cause actual results to differ materially from historical experience or present expectations. Additional information concerning factors that could cause actual results to differ from statements made on this call is contained in our periodic reports filed with the SEC. The forward-looking statements made during this call speak only as of the date hereof, and the Company undertakes no obligation to update or revise the forward-looking statements. Information presented on this call is contained in the press release issued earlier today, and in the Company’s Form 10K that we are filing today, which may be accessed from the investors page of the NRx Pharmaceuticals website.

Joining me on today’s call from NRx Pharma are Robert Bestof, interim Chief Executive Officer, and Ira Strassberg, Chief Financial Officer and Treasurer. Robert will provide a summary of the Company’s progress during the year, and recent weeks, before turning it over to Ira for a review of the Company’s financial results. Following their prepared remarks, the management team will address investor questions.

I will now turn the call over to Robert.

Robert Bestof

Thank you Eric. Good morning everyone, and thank you for joining us today. It is my pleasure to host today’s call as interim CEO. We appreciate your attendance and look forward to providing you with an overview of the refocused priority that will guide our activities in 2022.
Before beginning the agenda for today’s call, I want to take a few moments to speak about the leadership transition we announced on March 8 of this year. My predecessor, Dr. Jonathan Javitt, founded NRx and led the building of a Company that developed a pipeline with two Phase 3 novel therapeutics in areas of very high unmet medical needs. Under his leadership the NRx culture was and remains patient-centric, to mitigate the suffering from COVID-19 and other respiratory diseases, to providing those who have bipolar depression and suicidality a new therapeutic solution.

Recall that up to 50% of individuals with bipolar disorder attempt suicide over their lifetime or have serious thoughts about suicide. NRx went from an idea to reading out a Phase 2 study and obtaining breakthrough therapy designation and a special protocol agreement for the first drug in development for bipolar depression in patients with acute suicidal ideation and behavior.

When the COVID-19 pandemic hit two years ago, the NRx team pivoted and rapidly responded to the pandemic challenge that our country and the whole world are still facing today, by initiating an investigational new drug clinical study in critical COVID-19 with avipdatil. Our team went from concept to dosing our first patient in about 12 weeks, which included filing an investigational new drug application, filing a protocol, buying active pharmaceutical ingredients, working with manufacturers and to produce clinical supplies, engaging a contract research organization, and sites.

This is representative of the culture that defines us today, and one that Jonathan and all of us have enabled. We’re focused on patients with high unmet needs and we are very hands-on and dedicated to rapid and efficient drug development.

Today, the Company has two late-stage drug candidates that can serve as platforms for numerous indications in the psychiatry and respiratory healthcare space.

As our Phase 3 programs progress, we have to think about commercialization. Hence the Board decided that my extensive experience in pharmaceutical commercialization would best position Zyesami and NRx-101 for our next corporate phases.

I have been in the pharmaceutical industry since the early 1990s, and my career spans a series of commercial and faith leadership positions both in the U.S. and Europe, as well as strategic marketing assignments for (inaudible) franchises, specifically in the advancement of pipelines, global product launches and collaborations with partners. I have worked for global healthcare companies including Eli Lilly, Wyeth and Pfizer, and I have been part of NRx since 2016.

Our Company has a strong leadership team. Joining me in this endeavor and on today’s call is Ira Strassberg, our new Chief Financial Officer and Treasurer. Ira has been serving NRx in a financial consulting capacity since August of 2021. His career spans over 30 years, including deputy chief financial officer at Cantor Fitzgerald, various senior-level board and chief financial officer roles, as well as audit and consulting roles at KPMG.

Following my prepared remarks, Ira will join the call to provide an overview of our financial results, and then together we will address some of the questions you have kindly submitted.

So let’s begin.

As we announced in our press release earlier today, we have decided to refocus our business priorities on two core areas: the development approval of the intravenous formulation of Zyesami for treatment of critical COVID-19 and other respiratory diseases, and two, the reactivation of clinical trial development program for our psychiatric portfolio including NRx-101.
Given the complex and rapidly changing geopolitical environment we find ourselves in today, we believe it is prudent to narrow our focus on programs that are principally based in the United States, and where we can make the earliest and biggest contributions towards improving patient care.

While the COVID-19 situation has improved significantly since the early days of the pandemic, according to the CDC, we’re still losing about 500 to 1,000 individuals every day in the U.S. to this virus.

So, let me start by reviewing some of the results of our prioritization.

The most immediate change resulting from this refocusing of our priorities is our decision to not continue the pursuit of the BriLife vaccine project of the Israel Institute for Biological Research. This is one area in which geopolitical changes across the world stage have had a significant impact in our prospectus and ability to operate in certain regions. Given the rapidly changing vaccine environment and commercial expectations, we believe the best use of our resources is to focus on Zyesami and NRx-101 in the U.S. We are working with our partners in Israel on this transition.

Zyesami is our proprietary formulation of avipdatil acetate for the treatment of patients with acute respiratory failure in critical COVID-19 and potentially other respiratory diseases. Intravenous Zyesami is currently being studied in a second Phase 3 study of patients with critical COVID-19 who are experiencing respiratory failure. The Activ-3b study is sponsored and managed by the United States National Institute of Health, NIH. In our view, it is a vital study for our country in the fight against COVID-19. Zyesami is now the only new investigational treatment drug in this study focused on patients for which there are few alternative therapies, especially once patients are in respiratory failure due to COVID-19.

So, let’s briefly review where we are with Zyesami.

Recall that in 2021, we completed our Phase 2b/3 study of Zyesami in critical COVID-19 patients and submitted our first emergency use authorization or EUA to the Food and Drug Administration at the end of May 2021. The FDA declined our EUA request in early November of 2021. We also submitted a breakthrough therapy designation or BTD request. The FDA denied our request in November; one of their comments was that they were denied because remdesivir is approved for critical COVID-19. Their denial letter gave us insight to recraft our EUA application, which is the only currently pending regulatory application we have for Zyesami. We withdrew our latest BTD application to focus and submit a new EUA application in early February, focused and providing data on patients in our study that had been treated with remdesivir and continued to progress.

Some have heard about some of the recent reports of patients being treated under the right-to-try program in our earlier reports of the experiences with our expanded access program. In general, critical COVID-19 patients that are treated earlier in the course of the disease have a better chance of benefitting from Zyesami.

We thank all the physicians and families who to date have chosen to try Zyesami under right-to-try or expanded access, giving their loved ones one other alternative when there were no other options for them.

Although these experiences are encouraging, I remind us that regulatory actions are based on clinical trial data as per FDA requirements.

We also continue to closely track the safety of all patients treated with Zyesami, a key area of attention of the FDA. Recall that, in their November 2021 reply to our EUA, in a simplified way, the FDA indicated that they needed to better understand the safety profile of Zyesami. To date, about 750 patients have been treated with intravenous Zyesami across the various clinical programs, including our own study, the NIH study, and our expanded access and right-to-try programs.
We have not had any new type of serious adverse events emerge. It is our view that Zyesami is a drug that can be well used in the ICU or critical care setting.

The ongoing NIH Activ-3b trial is certainly a key study for Zyesami. It is scheduled to enroll 640 patients. NIH recently informed us that about 465 patients have been enrolled in the two avipdatil arms, avipdatil alone and avipdatil plus remdesivir, and a corresponding placebo.

Recall that patients are tracked for 90 days. We expect data by the end of the year, notwithstanding data safety monitoring board reviews, one of which is expected at the end of April.

The I-Spy study by the Quantum Leap Healthcare Collaborative is an open label rapid test platform using a Phase 2 study type approach. In this study, nebulized Zyesami was administered via mouthpiece to 51 mostly critical COVID-19 patients. As we announced this morning with Quantum Leap in a joint press release, our hope to administer Zyesami in a different form to patients may have been hindered by the challenges of administering nebulized medications to critically ill patients when they’re on high-flow oxygen of 6 liters or more.

The I-Spy DSMB recently met and recommended stopping their study of inhaled Zyesami.

Our own inhaled study in severe COVID-19, as opposed to the I-Spy study in critical COVID-19 patients, paused after having enrolled about 40% of the patients. Our DSMB informed us that the study would need to be significantly larger than the original 144 patients targeted. We are evaluating the potential options, including recrafting the enrolment criteria or ending the study to concentrate on the intravenous form of Zyesami in the severe and critical patient populations, and to explore the use of nebulized Zyesami in less severe patient populations and other pulmonary conditions.

We continue to believe that Zyesami could be a valuable therapeutic for those with COVID-19 respiratory failure who have exhausted all other therapies.

As the experience with the Omicron variant demonstrated over the last few months, COVID is likely to remain a persistent, unpredictable and ongoing health challenge. We continue to believe there will be a need for improved therapeutics to treat severe and critical COVID for some time.

To summarize, we see the following potential paths for Zyesami in 2022.

One is our ongoing EUA application for Zyesami with a narrower patient population scope which, as we said earlier, was filed with the FDA in February. There is no statutory prescribed time within which the FDA must respond.

The filing of a traditional new drug application or NDA with the FDA for Zyesami, should the NIH Activ-3b study support this. With data expected later this year, under fast track, we are allowed to initiate submission of parts of our NDA, which could accelerate the process if the NIH study is successful.

Third, we will also explore the submission for Zyesami under the accelerated approval pathway early in the second half of the year. The FDA instituted the accelerated approval program to allow for earlier approval of drugs that treat serious conditions and fill an unmet medical need, based on a surrogate endpoint. As previously disclosed, Zyesami showed a series of positive biomarker data such IL6 that correlated with positive outcomes. An NDA will still require studies that confirm that clinical benefit, such as the Activ-3b study.
As mentioned in prior communications, we have partnerships with Cardinal Health for third party logistics and distribution services, and with Iqvia for commercial and medical pharmacovigilance upon emergency use authorization or NDA approval should we receive that.

Now moving to our psychiatry franchise and the development of NRx-101. I am delighted to announce that we are reinitiating clinical development activities in our psychiatry franchise, which could result in data within the next 12 to 18 months. This franchise is the starting foundation of our Company, and we are in a unique position to help patients in areas of high unmet need.

NRx-101 is a patented medicine that should enable patients with bipolar depression and suicidality to be treated on an outpatient basis as an oral nonaddictive medicine. This could allow it to be highly differentiated for the target population.

Our NRx-101 clinical plan will have studies for the treatment of bipolar depression with acute suicidal ideation and behavior, and for bipolar depression with sub-acute suicidal ideation and behavior.

We are pleased to announce that we’re restarting our development efforts in these promising programs.

Every year, we lose about 50,000 individuals in the U.S. to suicide. The 50,000 does not include lethal drug overdoses in this population, therefore likely understating the actual number.

In the U.S., every year about 150,000 to 180,000 individuals with bipolar depression and acute suicidal ideation and behavior are hospitalized, and about two to three times as many have bipolar depression and thoughts of suicide that do not require hospitalization yet. Hence they have a subacute suicidal ideation and behavior.

This represents a very high unmet medical need. It is estimated that 50% of individuals with bipolar disorder attempt suicide in their lifetime, and 11% to 20% succumb to suicide. It is these individuals we aim to help with NRx-101.

We were awarded breakthrough therapy designation by the FDA for NRx-101 for severe bipolar depression in patients with acute suicidal ideation and behavior or ASIB, after initial stabilization with ketamine or other effective therapy.

In the NMDA space, we seem to be the only ones focusing on bipolar depression with suicidality.

Recall that antidepressants, including those recently approved for bipolar depression, carry a warning for the increased risk of suicide.

So, what is on our agenda in our psychiatry franchise for 2022, being mindful that COVID can disrupt plans?

We’re pleased to announce that we are currently initiating a Phase 2 clinical study for patients with bipolar depression and subacute suicidality. Just yesterday, on World Bipolar Day, we initiated our first study sites in this new study. We expect to enroll our first patient in the coming weeks, and aim to finish enrolment by the end of this year.

We also expect to start a new NRx-100 and NRx-101 special protocol agreement study for patients with severe bipolar depression and ASIB in the second half of 2022, and we will do so with commercial-level material. This is the study that, if successful, could lead to a new drug application or NDA for NRx-101.

Of note, restarting this study with commercial-level material will put us in a better position for a potential NDA and commercialization.
In summary, we’re now focused principally in the U.S. on our two late-stage potentially life-saving drugs: Zyesami, delivered intravenously for critical COVID-19 patients, and NRx-101, for bipolar depression in patients with acute suicidal ideation and behavior and subacute suicidal ideation and behavior. Both Phase 3 studies, if successful, could significantly change patient care in their respective areas. We also see opportunities to leverage both compounds in other populations and disease areas with high unmet need.

With that, I will turn it over to Ira for a brief overview of our financial results.

Ira Strassberg

Thank you Robert. Good morning everyone. It’s my honor to be part of the NRx team.

I would like to provide an overview of our 2021 financial results.

Research and development expenses for the year ended December 31, 2021 were $20.3 million, compared to $10.6 million for the prior year. Increased Zyesami R&D drove this increase.

General and administrative expenses for the year ended December 31, 2021 were $74.9 million, of which $60.3 million were stock-based compensation, consulting fees, and warrant expense that are not settled in cash. General and administrative expenses for the year ended December 31, 2020 totaled $11.4 million, of which $5.7 million was non-cash stock-based compensation, consulting fees, and warrant expense. The increase was primarily due to the increase in stock-based compensation expenses, consulting fees, that are not settled in cash, as well as an increase in insurance expenses, due to being a public company.

Settlement expense for the year ended December 31, 2021 was $21.4 million, compared to $39.5 million for the prior year. If you recall, the settlement expense relates to the Gem transaction, was not settled in cash, and we do not expect to recur.

Reimbursements of expenses from Relief Therapeutics were $0.8 million for the year ended December 31, 2021, compared to $10.2 million for the year ended December 31, 2020.

Other income for the year ended December 31, 2021 was $22.7 million, driven primarily by a $20.9 million decrease in the earn-out cash liability and a $1.7 million decrease in the warrant liability. Other expenses for the prior year were $0.4 million, primarily due to a loss on conversion of convertible notes payable.

Net loss for the year ended December 31, 2021 was $93.1 million or $1.98 per share, compared with a net loss of $51.8 million or $1.51 per share for the year ended December 31, 2020.

The Company used $37.7 million of cash for operating activities for the year ended December 31, 2021, compared with $2.3 million for the prior year.

As of December 31, 2021, cash was $27.6 million compared to $1.9 million as of December 31, 2020. We completed a $25 million private placement financing in February of 2022. We believe we have sufficient cash to support operations for at least the next 12 months.

With that, I will turn it back to Robert for closing remarks.

Robert Bestof

Thanks Ira.
Before addressing your questions, I want to emphasize that, even though we had a leadership transition earlier this month, I am proud to say that our strong leadership team has continued to rally around our strategic priorities and to work tirelessly with me in this effort to bring hope to life. We are thrilled to drive forward our two late-stage programs.

This Company was founded on a commitment to the application of innovative science to known molecules to address very high unmet medical needs. This continues to be our focus, and we remain confident in the opportunities before that.

Eric, we’re ready to take some of the questions that were submitted. Let’s go for those questions.

**Eric Goldstein**

Thank you. We have time for a few investor questions. First question, “What is the status with Relief?”

**Robert Bestof**

Okay. As you know, we have a commercial dispute with Relief. The parties agreed to engage in an effort to amicably resolve the dispute through mediation. We held our first mediation meeting on February 22, and we plan to hold additional mediation meeting in the coming months.

**Eric Goldstein**

Next question. “Can you provide more details on the Activ-3b NIH study?”

**Robert Bestof**

Yes. Thank you, great question.

The study has enrolled about 465 patients out of the 640. We expect data later in the year. Notwithstanding DSMB meetings that take place periodically, the next one is scheduled for the end of April. NRx is closely collaborating with the NIH. We have weekly meetings and also prepare for enrollment outside of the U.S., which could begin in Q2.

**Eric Goldstein**

Thank you. Next question. “What is the practical meaning of a pivot to U.S. medical needs?”

**Robert Bestof**

Oh, yes. Another great question.

We have two late stage Phase 3 drugs. These are the ones we believe have the potential to really make the biggest contributions towards improving patient outcomes, and perhaps even change the standard of care.

In the U.S., we understand the treatment needs and the regulatory pathway the best, and have demonstrated expertise to execute studies here. This is also where the largest commercial opportunities are for us. We also think that, given COVID-19, the need for psychiatry products such as our NRX-101 franchise is potentially higher than before.
Yesterday was World Bipolar Day, and we initiated our first clinical study site for our Phase 2 study. We are very excited for what we can do for patients in this area as well.

Thank you.

Eric Goldstein

Thank you Robert.

That is all the time we have for questions. Thank you everyone for joining us this morning. This concludes the NRx Pharma 2021 Results Conference Call. Thank you all for participating.

Operator

Thank you. This concludes today's conference. You may disconnect your lines at this time; thank you for your participation.