NRx Pharmaceuticals, Inc.

Second Quarter 2022 Earnings Conference Call

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CORPORATE PARTICIPANTS

Tom Johnson, *Director Corporate Communications, LifeSci Advisors, LLC*

Stephen Willard, *Chief Executive Officer*

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Robert Besthof, *interim CEO, Head of Operations, Chief Commercial Officer*

CONFERENCE CALL PARTICIPANTS

Vernon Bernardino, *H.C. Wainwright*

PRESENTATION

Operator

Good day, and welcome to the NRx Pharmaceuticals Second Quarter 2022 Conference Call.

Please note this event is being recorded.

I would now like to turn the conference over to Tom Johnson. Please, go ahead.

Tom Johnson

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's speak only as the date hereof, and the Company undertakes no obligation to update or revise these forward-looking statements. Information presented on this call is contained in the press release issued earlier today and in the Company's Form 10-Q that we're filing today, which may be accessed from the Investor's Page of the NRx Pharmaceuticals, Inc. website.

Joining me on today's call from NRx Pharmaceuticals are Stephen Willard, Chief Executive Officer, and Seth Van Voorhees, Chief Financial Officer and Treasurer. Stephen will provide a summary of the Company's progress before turning it over to Seth for a review of the financial results. Following their

prepared remarks, Stephen and Seth will be joined by Robert Besthof, Head of Operations and Chief Commercial Officer, to address investor questions.

I will now turn the call over to Stephen.

Stephen Willard

Thank you, Tom. Good morning, everyone, and thank you for joining us today. I'm excited to host my first quarterly results call as CEO of NRx Pharmaceuticals. I spent a large portion of my career in both private industry and public service, dedicated to advancing compelling science to benefit people and to build value for shareholders.

When I decided to assume the leadership role at NRx, I saw an opportunity to do both. Joining me in this endeavor are Seth Van Voorhees, our new Chief Financial Officer, Jonathan Javitt, our Chief Scientific Officer, and Robert Besthof, Head of Operations and Chief Commercial Officer. We appreciate your attendance today and look forward to engaging with you on this and future calls as we work to realize the opportunities before us.

Before discussing our second quarter results and plans for the balance of this year, I wanted to take a few moments to highlight what attracted me to the opportunities at NRx. First, NRx has an extraordinary organization, with a strong scientific and regulatory foundation and a unique and robust intellectual property portfolio. This fact is a point of differentiation between the NRx and many of its competitors.

Second, our lead asset, NRX-101, forms the basis of a psychiatry franchise with potential applications in the array of mental health issues, such as PTSD and other major depressive disorders.

Third, our renewed development program for NRX-101 seeks to address significant unmet medical needs in bipolar depression that also represent a significant commercial opportunity.

Together with a strong team that has a track record of rapidly developing and bringing life-saving medications to market, I am delighted to be leading the effort to change the treatment paradigm for those patients and deliver value to all of us.

Let's begin. NRX-101. To our knowledge, NRX-101 is the only oral antidepressant that targets patients with bipolar depression and active suicidality, which typically is an exclusion criterion in clinical studies of depression and PTSD.

Data from one of our previously completed Phase 2 clinical trials shows a significant reduction in both depression and suicidality compared to standard therapy in patients with bipolar depression who were acutely suicidal and who were initially stabilized with ketamine.

We have also released preclinical findings demonstrating that unlike ketamine, the key component in NRX-101 is not addictive. Moreover, we have shared with you the peer-reviewed biomarker findings from Columbia University, showing that NRX-101 achieves the same chemical changes in the brain as are achieved by ketamine and that these changes are statistically correlated with improvement in depression. NRX-101 is the only psychiatry drug that has been granted the biomarker letter by FDA, which you may read on the FDA website.

The potential oral non-addictive nature of NRX-101 therapy combined with its potential therapeutic effects to reduce both depression and suicidality offer significant advantages over other commercial and developmental drugs as a new therapeutic option for bipolar patients.

During our second quarter, we met our stated milestones for advancing NRX-101 to commercialization. Let me share the catalysts we project for the rest of the year. We initiated enrolment in our new Phase 2 trial of NRX-101 patients and patients who have bipolar depression would sub-acute suicidal ideation and behavior, and has activated 10 clinical sites, which represents about two-thirds of our intended sites. Additional sites are being activated soon and enrolment is ongoing.

This 70-patient study is targeted at patients with bipolar depression and suicidality that do not require hospitalization. We expect to upgrade this trial to Phase 3 as soon as we release our newly manufactured Phase 3 drug supply and have received FDA's guidance on primary and secondary end points. This trial in sub-acute patients who were treated in the outpatient study aims to achieve a substantial enlargement of our potential indication from 150,000 to 180,000 patients with bipolar depression and acute suicidality to the significantly larger population of patients being treated in the ambulatory setting.

As I mentioned at the Annual Meeting of Shareholders, we view this as a $2 billion opportunity. The sub-acute trial also reflects the request of many of our study clinicians who voiced the desire to also treat patients who were on the verge of needing to be hospitalized due to their increased thoughts of suicide.

NRX-101 is the first drug introduced for these patients that has shown potential to decrease rather than increase risk of suicide, unlike SSRI antidepressants and perhaps even reduce the need for hospitalization. We project a readout of the data of this trial by the end of 2022 or in the first quarter of 2023 and look forward to adding it to our registration package.

During the second quarter, we also advanced preparations to restart our Phase 3 trial of NRX-101 in patients with acute suicidal ideation and behavior under a special protocol agreement awarded to us by FDA. This study will be conducted with commercial level material, and if successful, could lead to a new drug application or NDA with the FDA for NRX-101 by late 2023 or the first half of 2024.

Recall that is part of our special protocol agreement with the FDA, the agency advised in writing the successful completion of this trial would permit a regulatory filing for drug approval. Conducting this trial with commercial level of material is key to submitting clinical data on a rolling basis under our breakthrough designation by, as I said, mid-2023, the potential NDA filing by year-end 2023, and commercialization as early as 2024.

During the first half of 2022, we transferred manufacturer of NRX-101 to Alcami Corporation in North Carolina in order to enable Phase 3 readiness and preparedness for commercial stage. We have recently manufactured our first batch of medicine. Manufacturing is a crucial element to achieving submission readiness and approval for a new drug. This investment is an important piece of our overall plan to initiate our Phase 2b/3 registrational study with commercial level materials.

The psychiatry franchise is the starting foundation of our Company, and with our broad patent estate, we believe we are in a unique position to deliver a highly differentiated product, to help patients in this area of very high unmet medical need. We are also considering exploring other high unmet medical need indications such as PTSD with suicidality.

There are approximately 9 million individuals in our country that experienced PTSD. One-third of them have severe PTSD. Between 17 and 22 members of our armed forces and veterans are lost every day to suicide. We view this as another very high unmet medical need.

Our intellectual property estate offers a range of options to combine a variety of molecules and NMDA receptor antagonist, including D-cycloserine, a component of NRX-101.

Turning to ZYESAMI. As we announced in May, the NIH ACTIV-3b TESICO trial was stopped for futility. COVID-19 continues to be an unpredictable and challenging area as evidenced by another clinical trial done recently for another company by the NIH that also did not read out with the desired efficacy.

Our assessment of future options for ZYESAMI will be guided by independent analysis of NIH data. Along with data, we received from an independent assessment of chest X-ray from a sub-study that includes a subgroup of approximately 80 patients that had survived to day 10 during our Phase 3b ZYESAMI 3 study.

This sub-study showed a statistically significant improvement in chest X-rays using rail scores in patients with COVID-19 respiratory failure compared to a worsening in patients treated with placebo, and that P was less than 0.05. We expect to receive the NIH data in late—the late third quarter or early fourth quarter, and we'll conduct an independent analysis at this time.

Earlier this year, we completed manufacture of phase 3 commercial ready ZYESAMI. We are not funding additional trials at ZYESAMI at this time.

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

Seth Van Voorhees

Thank you, Stephen, and good morning, everyone. Like Stephen, I'm delighted to be part of the NRx leadership team, and I look forward to discussing our results and plans with you.

First, I'd like to comment on our recent restatement of financial results for the second and third quarter of 2021. At the time of our merger in May of last year, warrants in the private company, NeuroRx, were exchanged for warrants in the public company, Big Rock Partners Acquisition Corp which subsequently was renamed NRx Pharmaceuticals. These warrants were initially classified as equity in our financial reports.

However, in the process of preparing our financial statements for the second quarter of 2022, we concluded that the contingent features of these substitute warrants require that they be classified as a liability and not as equity. Last week, we detailed this issue in an 8-K and restated the second and third quarter reports for Fiscal Year 2021.

The change resulted in a $15.9 million reduction in net loss from $16.1 million to $0.1 million for the three months ended June 30, 2021 and a comparable offsetting increase in the net loss during the third quarter of 2021 of $16.3 million from $20.8 million to $37.0 million for the three months ended September 30, 2021. The year had no impact on our cash balance and no impact on our operating cash flows and did not have a material impact on the Company's consolidated financial statements for the full year.

Now, I'd like to discuss our financial results for the second quarter of 2022. Research and development expenses for the three months ended June 30, 2022, totaled $3.0 million, compared to $4.7 million for the same period in Fiscal of 2021. The decrease of $1.7 million related primarily to a decrease in clinical trial and developmental expenses related to ZYESAMI.

For the six-month period, R&D expenses totaled $8.4 million as compared to $7.6 million for the same period in Fiscal Year 2021. The increase of $0.9 million related primarily to an increase in regulatory and process development expenses.

General and administrative expenses for the three months ended June 30, 2022, totaled $6.6 million as compared to $12.5 million in the same period in Fiscal Year 2021. The decrease of $5.8 million was primarily

related to a decrease in stock-based compensation and consulting fees, partially offset by an increase in higher insurance-related expenses.

For the six-month period, G&A expenses totaled $16.9 million in Fiscal Year 2022 as compared to $14.6 million for the same period in Fiscal Year 2021. The increase of $2.3 million was primarily related to an increase in legal, professional and insurance expenses, partially offset by a decrease in consulting fees and stock-based compensation expenses.

For the three-month period ended June 30, 2022, our net loss was $7 million as compared to a net loss of $0.1 million for the three months ended in June 30, 2021. For the six-month period, our net loss was $20.4 million as compared with a net loss of $25.6 million for the same period in 2021.

Now, I'd like to comment on our cash resources. As of June 30, 2022, we reported a cash balance of $24.5 million. We believe that we have sufficient funds and if necessary, the ability to reduce expenditures to support our operations through August of 2023. We may consider raising capital during this year to further strengthen our balance sheet and to support our clinical trials and other operational activities.

With that, I'll turn it back to Steven for closing remarks. Stephen?

Stephen Willard

Thank you, Seth. To conclude, we are excited about restarting development work in our psychiatry franchise. The unmet medical need in bipolar depression with suicidality are enormous. Today, we estimate that U.S. annual peak sales potential for bipolar depression suicidality to be around $2 billion a year. There are only five drugs currently approved for bipolar depression and all of them carry the warning of increased suicidality.

Our Phase 2 study showed that NRX-101 has the potential to treat bipolar depression in patients with suicidality. That's why the FDA gave us breakthrough therapy designation and a special protocol agreement for registrational studies of less than 150 patients. If successful, this could lead to a commercialized product as early as 2024, and significant potential value.

We believe that NRX-101 is a potentially life-saving medicine that could change the treatment paradigm for individuals with bipolar depression that are also experiencing suicidality.

Tom, with that, we'll take some questions.

Operator

We will now begin the question-and-answer session. Our first question comes from Vernon Bernardino with H.C. Wainwright.

Vernon Bernardino

Hi, thanks for taking my question. Steve and Seth, welcome aboard. Looking forward to catching up to you in-person in the near future. Regarding the repatriated NRX-101 drug supply, just wondering if you could go to through the mechanics or perhaps a history of that process and what was the situation before that repatriation?

Tom Johnson

Vernon, thank you very much for your call and your interest in us. Robert, would you like to handle that question?

Robert Besthof

Yes, hi. Good morning, Vernon. How are you. Thank you for collaboration. So, we had initially produced clinical material at WuXi in China, and that is the material we've used to-date in our clinical studies and also the material that is being used currently in the Phase II study. As you know, CMC is a crucial part of the regulatory and submission process and we felt it was appropriate to transfer that process, which we started late last year in this first half of the year to the U.S. to Alcami, and we've now started producing material and we will be using that material in our Phase III study. We've successfully produced batches that will be released and we expect to be using that material in our Phase III study later this year.

Vernon Bernardino

As far as that was a desire to control the supply because of…

Robert Besthof

Exactly. Well, not only with shipping, but it was our desire to have that in the U.S., closer to us at that time. Recall, we also had COVID at that time, we didn't know working to deal and we felt Alcami is an excellent partner to transfer the manufacturing to.

Vernon Bernardino

Okay. Maybe this is for Seth, is there any accounting considerations as far as debt, supplies, location that needs to be considered?

Seth Van Voorhees

No. I mean, there obviously will always be things in terms of exchange rate fluctuations, but nothing material that we anticipate.

Vernon Bernardino

Okay. One more question and then that's all I have, if I could. Regarding the supply of the semis (phon), is there any accounting considerations that you're looking at there, considering there may, at least in my opinion a possible impairment if future studies aren't pursued?

Seth Van Voorhees

I'm sorry, could you repeat that question? You broke up in the middle, so I didn't quite catch it.

Vernon Bernardino

Sorry, it was probably just me mumbling, but is there any accounting consideration as far as the supply of (inaudible) that you may be considering that and like that you may not pursue further future studies with those (inaudible)?

Seth Van Voorhees

Nothing that would be material.

Vernon Bernardino

Okay. Thanks for taking my question and congrats and looking forward to seeing the whole team in the near future.

Seth Van Voorhees

Thank you for your interest.

Tom Johnson

Okay. We had two additional questions, Stephen, that were pre-submitted by investors.

Stephen Willard

Okay.

Tom Johnson

First question, there is a lot of business development going on in the pharmaceutical industry. Has NRx been a part of that in some way?

Stephen Willard

Well, our technology includes components that have not shown addiction potential, which is an important differentiator. As a result of that, our technology, our IP portfolio, have attracted strong interest, and we are in conversations with a number of potential partners.

Tom Johnson

Thank you. Second question, how do you see NRX-101 comparison to others in the industry, Axsome and Relmada compounds, those are both in late Phase 3?

Stephen Willard

Sure. I think there are interesting comparators to us. I believe that they do not study patients with suicidality. In essence, they're seeking to develop an improved agent for major depressive treatment-resistant depression. We're focusing on a much higher unmet medical need in the bipolar segment with suicidality and up to 50% of bipolar people attempting suicide. Hence, we're working on an improved antidepressant that can be used in patients where the other two medicines cannot be used. We think that while it's a comparator, is a point of differentiation where we exceed the opportunities in a fairly significant $22 billion market.

Tom Johnson

Okay. I believe those are the questions we had, Operator.

Operator

This concludes our question-and-answer session. I would like to turn the conference back over to Tom Johnson for any closing remarks. Please go ahead.

Tom Johnson

Well, thank you, everyone. That's all the time we have for questions today. I'm going to thank you for joining us this morning. This concludes NRx Pharmaceuticals second quarter 2020 results conference call. Thanks, everyone, for participating this morning.

Stephen Willard

Thank you.

Operator

The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.