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Skye Financing and Bird Rock Bio: On-Demand Call Transcript

Bernie Hertel, Head of Corporate Communications

Good morning. My name is Bernie Hertel. I head up Skye Bioscience's investor relations and communications. Thank you for joining our call to learn more about the strategic transaction and financing announced by Skye this morning. With me on the call today are Punit Dhillon, President and CEO of Skye, and Kaitlyn Arsenault, Chief Financial Officer of Skye.

This on-demand presentation includes forward-looking statements, which are subject to risks and uncertainties that may cause actual results to differ materially from the statements made. Factors that could cause the actual results to differ are described in the disclaimers and in our filings with the Securities and Exchange Commission, including the risk factors section of our 2022 Annual Report on Form 10-K, and the disclosures and Management's Discussion and Analysis in our most recently filed Form 10-Q for the period ended June 30, 2023.

The press release, a recording of this call, and a slide presentation regarding today's news will be available on Skye's website. Additional information about the Company, including its financial position, can be found in the Company's most recently filed 10-Q.

There will not be a Q&A associated with this call. However, we invite investors to submit questions to ir@skyebioscience.com. We also invite you to sign up for email communications at skyebioscience.com/contact.

I will now turn the call over to Punit Dhillon.

Punit Dhillon, CEO

Good morning. Thank you for your interest and time on this call.

Since I took over as CEO of Skye in August of 2020 and built the team of experienced executives that we have with us today, we have been clearly focused on our mission of developing first- and only-in-class molecules that target the endocannabinoid system with potential to address diseases with extensive, unmet needs. The

completion of the transactions we announced today is an important step toward achieving this goal.

Today Skye Bioscience announced the closing of $17 million in new funding, including investments by 5AM Ventures and Versant Ventures, which strengthens the company's financial position. It provides us with the new capital to continue development of our CB1-targeting drug, SBI-100 Ophthalmic Emulsion, or SBI-100 OE, for the treatment of glaucoma and ocular hypertension, including advancing our planned Phase 2a clinical trial.

Second, today Skye announced the acquisition of Bird Rock Bio and its complementary technology. Acquiring Bird Rock strategically expands our product portfolio with an exciting and novel molecule that fits our goal of unlocking the pharmaceutical potential of the endocannabinoid system. This step expands our pipeline with a new clinical-stage asset that has broad potential to treat multiple diseases.

Third, we have added a new base of specialist healthcare institutional investors with the experience and track record of building successful biotech companies. Together the new investment by 5AM Ventures and Versant Ventures along with the shareholdings of the existing institutional investors in Bird Rock represents over 65% ownership of Skye.

Finally, our plan to implement a reverse stock split and position the company for an uplisting is focused on expanding our access to a broader investor audience, including institutional investors.

I believe today marks an evolutionary change for the company, and I am honored to have this opportunity to share with you why.

Let me first speak about the exciting things happening with our glaucoma program. SBI-100 OE is focused on lowering intraocular pressure associated with glaucoma. We recently announced the completion of enrollment in our Phase 1 study. The purpose of this study was to evaluate the safety and pharmacokinetics of SBI-100 OE when delivered as eye drops to healthy volunteers. We are happy to report that the safety results of this study were promising, and we look forward to sharing the final data with you before the end of Q3 this year. In addition, we are preparing to initiate our Phase 2a proof-of-concept study for SBI-100 OE and expect to start

dosing patients in this study early in the fourth quarter, with a look at interim IOP data, early in 2024.

We have a well-defined clinical development plan and regulatory pathway with clear endpoints for market authorization for SBI-100 OE. Our team established this plan by using our expertise in drug development and obtaining advice from KOLs, investigators and other experts in the field that have been involved with the most recent FDA drug approvals in glaucoma.

Likewise, our team took a similar approach when evaluating and planning for the development of our newly acquired asset, nimacimab. We are focused squarely on demonstrating proof-of-concept in a meaningful clinical indication that would provide a clear development plan, along with opportunities for partnership and licensing discussions with strategic partners.

We believe nimacimab adds significant value to Skye's pipeline. Like SBI-100 OE, it is a first and only-in-class molecule that specifically targets the CB1 receptor. While SBI-100 OE activates the CB1 receptor, nimacimab is a novel peripherally-restricted, negative allosteric modulating antibody that inhibits CB1 signaling.

There is a broad but interesting parallel between SBI-100 OE and nimacimab that relates to therapeutic index and the potential ability to be safe while efficacious. While it is understood that THC and other CB1 agonists can reduce heightened intraocular pressure, ocular hypertension and associated glaucoma, these molecules have not to-date had a clinically relevant safety profile to be a useful drug. In contrast, SBI-100 OE offers a unique path to potentially overcome these safety concerns while delivering efficacy.

Similarly, we already know that certain diseases are associated with upregulated CB1 signaling. The use of CB1 inhibitors has been shown to be efficacious in models of disease including obesity, pulmonary fibrotic diseases, fibrotic liver disease, and kidney disease.

However, in the first generation of these molecules the therapeutic window between efficacy in these diseases and central nervous system liabilities was very limited. Serious adverse effects, including anxiety and depression, have been observed.

More recently, new second-generation small molecule therapeutics have been chemically modified to make them more "peripherally restricted" to limit the amount of drug that enters the brain. Some molecules in this class of peripherally restricted CB1 inhibitors may still have issues associated with potential CNS-related activity.

We believe nimacimab, which is a new and distinct class of CB1 inhibitor, has the potential to become the leader in this space.

First, nimacimab readily inhibits CB1 signaling when compared to well-established clinical and control compounds.

Second, as an antibody, which is a large molecule, nimacimab does not cross the blood brain barrier. This is highlighted in rigorous preclinical studies which demonstrated in cynomolgus and rhesus monkeys that there is no accumulation of nimacimab in the brain and cerebral spinal fluid, even at doses significantly higher than the anticipated effective doses in humans. There was also no nimacimab-related toxicity, including neurological observations, indicating nimacimab is restricted from entering the brain.

Finally, Phase 1 studies showed no impact on cognitive function or effects of anxiety or depression. In addition, clinical studies showed preferable bioavailability, limited anti-drug antibody formation, and PK of nimacimab of approximately 18-22 days.

Taken together, these data support the promise of safely and effectively targeting peripheral CB1 receptors to treat disease with nimacimab without potential central nervous system liabilities.

After due diligence, which included discussions with multiple KOLs and industry leaders, we zeroed in on chronic kidney disease, or CKD, as the first indication Skye will target as a proof-of-concept for nimacimab. Given the potential anti-inflammatory, anti-fibrotic, as well as metabolic-related mechanisms for nimacimab, we believe CKD is an ideal indication.

So, the immediate impact of nimacimab is that it gives Skye a second clinical-stage asset that has already completed a Phase 1 SAD/MAD clinical trial. Thanks to a robust nonclinical package, three active Investigational New Drug files, including

one for CKD, plus sufficient clinical drug supply to support the next planned clinical trial, we believe we can quickly progress into a Phase 2 clinical study.

What is compelling is that long term, due to its potential to treat multiple diseases, nimacimab represents a broad opportunity to expand Skye's pipeline once proof-of-concept in patients is established.

We believe the culmination of steps represented in today's announcement is truly transformative and profound for Skye and its shareholders. We have now raised a sufficient amount of capital to initiate our Phase 2a clinical study of SBI-100 OE and fund operations into 2024. But this isn't JUST capital. This is an investment by stellar specialist life science investors, specifically 5AM Ventures and Versant Ventures, who are experts in what they do, are respected by peers, and are long-term in their orientation.

Finally, we have added Andy Schwab, Managing Partner of 5AM Ventures, and Paul Grayson, a venture partner at Versant, CEO of Tentarix Biotherapeutics, and the prior CEO of Bird Rock Bio, to our board of directors. These gentlemen are highly experienced life science entrepreneurs and veterans, and we believe they will add significant value to our Board. Our team has appreciated the insight they've already shared and we look forward to our collaboration going forward.

I'll now pass it over to Skye's chief financial officer, Kaitlyn Arsenault.

Kaitlyn Arsenault, CFO

As Punit noted, this aggregate raise of $17M is a vital step for Skye to continue advancing its planned Phase 2a study of SBI-100 OE for patients with glaucoma and ocular hypertension. Conservatively, we expect that this capital will fund us through our anticipated Phase 1 data report in the current quarter and an interim data report on the Phase 2a study for SBI-100 OE in early 2024. In addition, these funds are expected to aid us in preparing for a Phase 2a study of nimacimab. Our operating runway may also be further extended based on outcomes related to our previously disclosed litigation with Wendy Cunning and our D&O insurance carrier, PartnerRe, and we are currently working to resolve such litigation through the applicable legal processes. As we have previously disclosed, we do not believe the claims alleged by the plaintiff against the prior management team are factually

accurate and we're vigorously defending our position against the current judgment in the matter of *Wendy Cunning vs. Skye Bioscience, Inc.*

In connection with the Cunning litigation, we have sought to protect the Company by posting an appellate bond with the court while we await the final order on the post-trial motions in the litigation, which could result in a reduction of the damages or a new trial. Once the post-trial motions are ruled on, we will either see through the appeal process with the Ninth District Court or work to settle the matter with the plaintiff.

To satisfy the conditions of the financing and acquisition transactions and to obtain a stay on the judgment, we posted an appeal bond of approximately $9.1 million, which represents 150% of the amount that the jury awarded the plaintiff in the Cunning litigation at trial. This amount also includes the plaintiff's legal fees recently awarded by the court. A stay means that Skye will not be required to make any payments to the plaintiff in the Cunning litigation until the appeal process is concluded. The bond is secured by an irrevocable letter of credit that is collateralized by cash and held on our balance sheet. I want to emphasize that our maximum liability on the judgment as of June 30, 2023, was $6.2 million, including the incremental interest that is accruing on the judgment.

Additionally, on June 20, 2023, in connection with a related lawsuit against our insurance carrier, Partner Re, the judge in such matter issued a final ruling in our favor denying the carrier's motion to dismiss the lawsuit that we filed regarding the denial of insurance coverage related to the Cunning litigation. Based on this outcome, the Company is pursuing up to $5,000,000 in coverage, to recover legal expenses incurred to date and damages related to the final verdict or settlement.

So, to summarize, before making any new decisions on this legal matter, we are 1) awaiting the Court's decision on our post-trial motions; and 2) we are simultaneously pursuing the maximum allowable coverage under the D&O insurance policy that was in place at the time that the suit was filed in 2021.

By taking the steps that I've just outlined, we do not anticipate any further negative impact to our forecasted cash runway, clinical development strategy, guidance on our stated milestones or core business objectives. Now, let me step back and comment further on other facets of this transaction and our business. Regarding our planned Phase 2a study for SBI-100 OE, it is noteworthy that we have already

incurred a significant amount of the cost for this trial. This financing provides the necessary capital to fund the study through the initial milestone of interim data. Our Phase 2a study has been designed to deliver data that could be the first indication of SBI-100 OE's therapeutic potential as a valuable alternative treatment for glaucoma and ocular hypertension, which could provide the basis for a revaluation of the technology and the Company.

With this acquisition, we are expanding our portfolio with a new clinical asset that is distinct from SBI-100 OE, diversifying potential technology risk and increasing the potential upside for Skye's stakeholders. Having a second Phase 2-ready program is an advantageous position for the company.

This most recent financing journey has been challenging. I'm sure most of you can see from the stock charts that the biotech indexes are trading back at levels seen in 2018. There are biotech companies that are not receiving the investment capital they need to move forward. 5AM and Versant are extremely knowledgeable about our space. We are proud to have received their endorsement and investment and greatly appreciate the support of our other investor in this transaction. We also appreciate the confidence that the shareholders of Bird Rock Bio have placed in the Skye team to pursue the further advancement of their technology.

On a separate note, the Company has also made the decision to implement a reverse stock split and has announced this intent now so that it could be considered in the context of the other key aspects of the current transactions. Here are some specific considerations regarding the need for a reverse stock split with the eventual goal to uplist to a national stock exchange. The first is that many stock clearing houses no longer handle shares that trade on the OTC. In general, institutional investors, investment banks, professional advisors and many individual investors are increasingly avoiding OTC companies, particularly ones with a large share count and a very low share price. For Skye to continue to trade on the OTC would be a growing disadvantage over time and we experienced this firsthand while searching for financing options over the last two years.

We are currently awaiting the completion of FINRA's review of our proposed reverse stock split, and intend to implement the reverse stock split promptly after completion of FINRA's review. Taking this step will help move us along the path to potentially qualify for an uplisting to a national stock exchange, which, combined

with other related accomplishments, we believe will over time serve our goal to expand our access to investors and capital.

To conclude, I will say that in the case of a reverse stock split alone, with no other concurrent transaction, the fundamental value of a company's assets before and after a reverse stock split is the same, in any event. In our case, we have just added a notable asset that we believe significantly increases the intrinsic value and development prospects of the Company. Our intention is that this strategic transaction will create value for our shareholders as we continue to advance our programs toward the key milestones.

Back to you, Punit.

Back to Punit

Thanks, Kait.

Today's announcement reflects multiple elements that move us toward the goals of our value creation plan, and we have high conviction in the steps and prospects ahead of us.

When I say "value creation plan," I am referring to something that we constantly speak about internally. We have done this since this team took over to guide the strategic direction of this company. Our aim is to build a strong company, with excellent technology, sharply focused plans in terms of our clinical trials and development programs, and effective execution, all with the goal of serving patients and creating value for our shareholders.

We have in fact moved the asset we started with in 2020 at a very quick pace and could not be more pleased to be on the verge of starting Skye's first-ever Phase 2 clinical trial. We believe there is significant upside potential in SBI-100 OE and look forward to seeing our first data from this study in early 2024.

While our key focus over the last while has been to secure funding to continue advancing the company and SBI-100 OE, the combination of our vision, experience, networking, and good fortune converged to expand our portfolio and future potential with the nimacimab technology as well. And it turned out that now was the right time for this convergence to take place.

The idea that “now” was the right time could not be more strongly exemplified than by an important industry event that took place two weeks ago. I bring this point up last because everything that we have aimed to accomplish and everything we have announced was already in motion before the event I am about to highlight. While our pertinent priority was financing, we did recognize a broader opportunity. We put the wheels in motion. Finally, we consummated an important capital raise and strategic deal - and I wanted to detail these steps based on their merit alone before highlighting a broader validating industry event.

This outside event emphasizes that we are on a compelling path – and it adds icing to the cake. On August 10th, the pharmaceutical company, Novo Nordisk, which has become a major player in weight loss with its metabolic drug, agreed to acquire a small biotech company called Inversago Pharma and its CB1 inhibitors in a deal worth up to 1.075 billion US dollars. Inversago is a developer of CB1 receptor-based therapies for the potential treatment of obesity, diabetes and complications associated with metabolic disorders. It is currently in Phase 2 clinical trials for diabetic kidney disease.

Inversago’s lead development asset is an inverse agonist, which is a different mechanism for CB1 inhibition compared to nimacimab. But like nimacimab it is designed to preferentially inhibit the receptor protein CB1 in tissues outside of the brain.

As Novo Nordisk and Inversago noted in their joint press release, and as we described earlier, the mechanistic and preclinical therapeutic effects of peripheral CB1 receptor blocking are well-studied across a range of cardiometabolic and fibrotic diseases, supporting the potential treatment of many people with current unmet needs.

As I also described earlier, we believe that nimacimab’s mechanism of action, which is distinct from the alternative mechanisms of CB1 inhibition such as Inversago’s, shares the potential for efficacy of these other approaches but has advantages in its safety profile based on its distinct, first-in-class approach.

To see the appetite of a major pharmaceutical company securing a CB1-inhibiting therapeutic is gratifying and we believe that with nimacimab we are in a unique position to unlock the value of the CB1 axis to support a successful franchise.

So here we are. There has been no lack of challenges to our progress and as is the nature of cutting-edge science and the building of entrepreneurial companies, there will be more. But I am very proud of our team's focus, effort, and accomplishment. We have and we will continue to work diligently on behalf of our shareholders to build the value of this company.

On behalf of the Skye team, I want to express the utmost appreciation to our established shareholders for their support. And I want to welcome and thank our newest shareholders for their conviction.

As a final note, following this verbal component of the call there are a set of slides highlighting key aspects of the transaction and Skye's business going forward.

That concludes our call. Thank you for your time.