Cipher Pharmaceuticals, Inc.

Q3 2024 Results Conference Call

Event Date/Time: November 8, 2024 — 8:30 a.m. E.T.

Length: 37 minutes

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Andre Uddin
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Justin Keywood
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Douglas Loe
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PRESENTATION

Operator

Good morning, ladies and gentlemen. Welcome to the Cipher Pharmaceuticals Quarterly Conference Call for the Company's Q3 2024 Results.

At this time, all participants are in a listen-only mode. Following today's presentation, instructions will be given for the question-and-answer session. If anyone needs assistance at any time during the call, you may press the star followed by the zero on your touch button phone.

As a reminder, this conference is being recorded today, Friday, November 8, 2024.

On behalf of the speakers that follow, listeners are cautioned that today's presentation and the responses to questions may contain forward-looking statements within the meaning of the Safe Harbor provisions of the Canadian provincial securities laws. Forward-looking statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Certain material factors or assumptions are implied in making forward-looking statements and actual results may differ materially from those expressed or implied in such statements. For additional information about factors that could cause results to vary, please refer to the risks identified in the Company's annual information form and other filings with Canadian regulatory authorities. Except as required by Canadian securities laws, the Company does not undertake to update any forward-looking statements. Such statements speak as only of the date made.

I would like to turn the call over to Mr. Craig Mull, Interim Chief Executive Officer of the Company. Please go ahead, sir.

Craig Mull — Interim Chief Executive Officer, Cipher Pharmaceuticals, Inc.

Good morning, everyone, and thank you for joining us today. Before I begin, I would like to remind everyone that all figures discussed on today's call are based on U.S. dollars, unless otherwise specified.

I will limit my commentary on our Q3 financial results as our Chief Financial Officer, Ryan Mailling, will walk through these results in a few minutes. I would like to spend my time to provide you an update on our recent acquisition of the Natroba business in the U.S., and highlight our strategy moving forward for the combined business, which represents an exciting phase of growth for Cipher.

On Monday, July 29, Cipher Pharmaceuticals announced the acquisition of Natroba, its authorized generic Spinosad, and its U.S. based commercial infrastructure headquartered in Carmel, Indiana, from the former owner, ParaPRO. With the Natroba acquisition completed and the business having been part of Cipher's overall business for the past three months, we continue to be excited about Cipher's new phase of growth.

During the third quarter, we have been diligently integrating the business into the existing Cipher infrastructure. We have made great progress and see tremendous opportunity ahead. The combined business provides Cipher with a North American platform, whereby we have strategy to build and expand upon.

Having recently spent time engaging with our U.S. sales team, I'm highly impressed with the talent and drive of our new Cipher employees, and I'm confident in our ability to utilize the U.S. sales team's

capabilities to organically grow the Natroba business, as well as inorganically grow Cipher's U.S. business with our future strategy to acquire complementary products for the team's product portfolio. Shortly after completing the acquisition and building upon the business, we immediately put in place and began executing on plans to insource sales in certain states away from a prior co-promotion partner of ParaPRO. This transition was necessary given the end of the 2024 calendar year being the end of the term of the existing arrangement between ParaPRO and this co-promotion partner.

During the third quarter, Cipher experienced an impact on its sales and earnings in comparison to historical sales and our expectations of the business. We believe this transitionary impact with the co-promotion partner is temporary and will be completed shortly by the end of 2024. In 2025, we believe the transition will not only help grow the Natroba business sales, but also have a highly positive impact with reduced costs and higher earnings from the business moving forward.

In addition to our strategy to organically grow sales of Natroba and its authorized generic Spinosad in the U.S., Cipher intends to out license Natroba globally, particularly in warm regions where there is a high unmet need, as well as bring the product to Canada, leveraging our Canadian direct sales platform. Natroba will fit well with our dermatology product portfolio in Canada, including Epuris, the Canadian market leader for the treatment of severe acne. We have established relationships in dermatology in Canada, and we believe this will be a natural fit for Natroba. We are currently evaluating our commercial strategy to market Natroba in Canada and will progress to regulatory steps with Health Canada in the first quarter of 2025.

Earlier, I briefly touched on the addition of complementary products to the U.S. sales team product portfolio, and I'd like to expand on this portion of our strategy. There are opportunities to cross-pollinate our existing portfolio of products, as well as to in-license new products that fit well into our expertise in dermatology and infectious diseases. Cipher's business strategy includes inorganic growth through further acquisitions, and we intend to acquire complementary dermatology products to add to our North American platform. In simple terms, we believe our U.S. sales team require additional products with the same call point in order to be efficient. We are currently pursuing a number of opportunities in this area.

In order to support our business development activities, including out-licensing Natroba and acquiring complementary products, we have added to Cipher's management team to provide additional depth in the area of business development and commercial activities. On October 8 of this year, the Company announced the appointment of Dr. Hamed Ghanei as its Chief Business Officer. Dr. Ghanei brings 15 years of experience in specialty pharmaceuticals, venture funds, and healthcare investment banking. We expect his expertise in business development, including extensive experience with licensing deals and other M&A opportunities, especially pharmaceuticals and healthcare industry, to provide meaningful contributions to Cipher's next phase of substantial growth. We are thrilled that Dr. Ghanei has joined the team, and he is already hard at work evaluating and pursuing opportunities for Cipher.

I will now turn my comments to our pipeline product, MOB-015 and the update we previously provided on the product candidate during the quarter. On September 13, our partner, Moberg Pharma, issued a news release stating that it had received information about clinical cure in a subset of patients in its ongoing North American Phase 3 study for MOB-015. Moberg noted that the number of patients who

have achieved clinical cure in this blinded subset of patients is lower than its expectations, which necessitated that Moberg inform the market about this fact.

Clinical cure is one of three parameters that together make up the study's primary treatment goal, complete cure. All three parameters, clinical cure, negative fungal culture, and negative microscopy need to be met for a patient to be considered completely cured. Moberg has reported that other than clinical cure, no information has been obtained about the other study parameters included in the complete cure. Despite the setback Moberg announced related to their Phase 3 study, we believe potential for this product remains for the following reasons. Firstly, MOB-015 has already obtained European Union approvals with the existing dosing regimen and, in fact, launched earlier this year the Terclara brand in Sweden, whereby it quickly gained 30 percent market share in value and 31 percent market share in units. But more importantly, Moberg has reported that since the introduction of Terclara, the total market in Sweden has grown 52 percent compared to the same period last year.

Secondly, the ongoing North American Phase 3 study is still not completed, and if positive results over the already European product labeling are achieved, it would improve the labeling related to dosing in North America, which would serve to have positive impact on the product's commercial outlook in Canada. Thirdly, the market potential for MOB-015 in Canada is favourable, with a total prescription market for onychomycosis, or nail fungus, in Canada is approximately CAD $92 million, of which one product has over 97 percent of the market. Lastly, the terms of Cipher's licensing agreement with Moberg had an upfront payment of $500,000, with all additional payments of up to $14 million being contingent upon successful achievement of certain clinical data results, as well as development, regulatory, and commercial sales milestones. Accordingly, Cipher has no further financial obligations

related to the current licensing agreement. The applicable development and regulatory milestones outlined in the agreement are not attained. We will continue to collaborate with our partner, Moberg, as full results from the North American Phase 3 study become available.

Our second product that I would like to provide a brief update on today is piclidenoson CF101, a treatment for moderate to severe plaque psoriasis, which is being developed by our partner, Can-Fite Biopharma. As we have previously updated on, Can-Fite has successfully completed the first Phase 3 study for piclidenoson in 522 patients with moderate to severe chronic plaque psoriasis. Piclidenoson demonstrated efficiency responses that increased over time alongside favourable safety profile endpoints. The Company will start enrolling patients very shortly for the second pivotal Phase 3 clinical trial, with the topline results expected in the second half of 2026. Can-Fite had previously confirmed that upon positive conclusion of the Phase 3 program, Can-Fite plans to submit a new drug application to the U.S. FDA. Can-Fite and Cipher are in discussions regarding the expansion of their partnership for piclidenoson and other indications and territorial expansion into the U.S.

To wrap up my commentary, I will briefly summarize the main items. We are well on our way to integrating the acquired Natroba business into Cipher's existing infrastructure. In the Natroba business, there is an ongoing transition with respect to the commercial structure of the Spinosad authorized generic product, whereby the arrangement with ParaPRO’s prior co-promotion partner is coming to an end, and Cipher will be insourcing these sales. We are formulating plans and exploring opportunities to both organically and inorganically build upon our newly established North American platform. We are continuing to work with our partners on Cipher's current product pipeline. The Company has begun its

new phase of substantial growth with the acquisition of Natroba and a U.S. sales and distribution platform, which we plan to leverage and scale. Cipher will opportunistically seek to further expand our business.

I thank you for your time this morning and look forward to answering your questions after our prepared remarks. I will now pass the call over to our CFO, Ryan Mailling, for an overview of the financial results. Ryan, please go ahead.

Ryan Mailling — Chief Financial Officer, Cipher Pharmaceuticals, Inc.

Thank you, Craig. Good morning, everyone. As a reminder, all amounts provided during this call are in U.S. dollars unless otherwise noted.

Today, Cipher Pharmaceuticals is reporting results from the Company's three month and nine month periods ended September 30, 2024. Total net revenue for the three month and nine month periods ended September 30, 2024 was $10.4 million and $21.5 million, respectively. Net revenue from the third quarter increased by $4.3 million, or 71 percent, compared to the same quarter in the prior year. Net revenue for the nine month period ended September 30, 2024, increased by $5.3 million or 33 (audio interference).

Overall licensing revenue was $1.1 million for the third quarter of 2024 and $5.3 million for the year-to-date September 30, 2024, compared to $3.1 million and $6.9 million, respectively, in the prior year. This represents a decrease of 66 percent for the quarter and 24 percent for the year-to-date, respectively, compared to the same periods in prior year. Licensing revenue from Absorica in the U.S. was $600,000 in the third quarter of 2024 and $3.7 million for the year-to-date September 30, 2024,

representing a decrease of 76 percent for the quarter and 27 percent for the year-to-date, respectively, compared to the same periods in 2023. This decrease in Absorica licensing revenue was primarily attributable to significantly lower product shipments in the third quarter of 2024 compared to the same period in 2023.

The Company earns revenue from supplying product to its distribution partner, of which the volume of these shipments was higher in the third quarter of 2023 as a result of a market dynamic where a generic competitor exited the market. Market share for the overall Absorica portfolio has decreased by 0.8 percent to 6.1 percent as of September 30, 2024, compared to 6.9 percent market share at September 30, 2023, according to Symphony Health market data.

Licensing revenue from Lipofen in the Lipofen Authorized Generic was $0.4 million for the third quarter of 2024 and $1.5 million for the year-to-date September 30, 2024, a decrease of $0.1 million for the quarter and $0.2 million for the year-to-date, respectively, compared to the same periods in the prior year. The decrease for both periods was driven by lower sales volumes and net sales realized by the Company's distribution partner for these products on which Cipher earns a royalty.

Moving on to product sales. Total product revenue for the three month and nine month periods ended September 30, 2024, was $9.3 million and $6.3 million, respectively, an increase of $6.3 million or 213 percent and $7 million or 75 percent, respectively, from the comparable periods in 2023. The increase in product sales was primarily driven by the incremental revenue from Natroba and its authorized generic, Spinosad, which were acquired by Cipher in its recently completed acquisition at the end of July, 2024.

Product revenue from Natroba and its authorized generic, Spinosad, was $5.5 million for both the quarter and year-to-date September 30, 2024. Additionally, product revenue for both the quarter and year-to-date September 30, 2024, included higher Epuris sales when compared to the same periods in the prior year. Product revenue from Epuris was $3.4 million for the third quarter of 2024 and $9.5 million for the year-to-date September 30, 2024, an increase of $0.9 million or 32 percent and $1.5 million or 19 percent, respectively, compared to the same periods in 2023. The increase in revenue from Epuris for both periods was attributable to increased sales volumes. Market share for Epuris has increased by 4.2 percent to 50.3 percent at September 30, 2024, up from 46.1 percent market share at September 30, 2023, according to IQVIA market data, which contributed to an overall increase in sales volumes.

We've experienced an increase in gross margin on our product revenue of 15 percent to 79 percent gross margin for the third quarter of 2024, compared to 64 percent for the same period in the prior year. This gross margin increase results from the addition of the Natroba and Spinosad authorized generic products during the quarter, which have a combined gross margin of approximately 85 percent.

Selling, general and administrative expenses was $6.2 million for the third quarter of 2024, an increase of $4.5 million for the same period in the prior year. The increase is primarily attributable to the Natroba business, including acquisition, restructuring, and other costs incurred in connection with the acquisition of this business, as well as the incremental operating costs of this recently acquired business during the quarter, including salaries and benefits costs for the commercial sales team. Also included within acquisition, restructuring, and other costs during the third quarter of 2024 is the cost associated with the ongoing transition of the prior Spinosad authorized generic co-promotion partner expected to be completed by the end of 2024, which Craig mentioned earlier in his remarks. Further contributing to

the increase in selling, general and administrative expenses for the quarter was higher professional fees incurred in Cipher's existing business, in comparison to the same period in 2023. Given the nature of professional fees as situational, necessary, and temporary, we do not believe these to be indicative of our past history of managing the costs of our business.

Selling, general and administrative expenses for the nine months ended September 30, 2024 was $9.3 million, an increase of $4.9 million from the $4.4 million reported in the nine months ended September 30, 2023. This increase was due to a combination of the incremental costs incurred related to the Natroba acquisition, which occurred during the third quarter, and operations of the acquired business for the remainder of the quarter, as well as increased professional fees and other general expenses incurred in Cipher's existing business, partially offset by lower non-cash share-based compensation.

Adjusted EBITDA for the three months and nine months period ended September 30, 2024 was $4.1 million and $10.7 million, respectively, compared to $3.6 million and $9.9 million, respectively, for the comparative periods ended September 30, 2023.

Our business ended the quarter with $9.5 million in cash on hand after utilizing $40 million of cash that was on hand during the quarter to partially fund our acquisition of the Natroba business. Additionally, the Company drew down $40 million from its new revolving credit facility with National Bank to combine with the $40 million of cash on hand to fund the $80 million cash portion of our Natroba acquisition. National Bank has provided Cipher with a total $65 million revolving credit facility with an additional $25 million conditional accordion feature available.

As at September 30, 2024, $40 million of principal from this revolving credit facility remained outstanding. However, the credit facility terms were designed to allow for maximum flexibility both with principal repayments and interest rates. This provides Cipher the ability to actively manage its leverage while maintaining substantial additional capability to finance our future acquisitions on favorable financing terms.

Cipher's balance sheet, low leverage profile, and ongoing available liquidity places the Company in an excellent position to execute on its growth objectives. As Craig mentioned earlier, the Company is in an exciting phase of growth and we look forward to announcing our progress as new milestones are achieved.

We will now open the call up to questions. Also joining us for this question period is Bryan Jacobs, President of U.S. Operations.

Q & A

Operator

Thank you, sir. Ladies and gentlemen, if you would like to ask a question, please press star followed by one on your touchtone phone. You will then hear a prompt that your hand has been raised. Should you wish to decline from the polling process, please press star followed by two. If you're using a speakerphone, we ask that you please lift the handset before pressing any keys. Please go ahead and press star, one now if you have any questions.

First, we will hear from Andre Uddin at Research Capital. Please go ahead.

Andre Uddin – Analyst, Research Capital

Thanks, Operator. Hi, Craig, Bryan and Ryan. Just wondering, when do you think you'll add more U.S. reps for your U.S. uncovered regions?

Bryan Jacobs – President, Cipher Pharmaceuticals, Inc.

Hi, Andre, how are you doing this morning? It's Bryan Jacobs here. We just talked about how we were in the process of transitioning away from a co-promotion partner. That brought on additional sales reps and a district manager. That was already in place when we acquired the business. We're looking just to maximize the efficiency of that new team, which has grown pretty recently, before we look to expand upon and add more reps. It's really the footprint that we call it acquired when we acquired the business. For context, the number of outside sales reps we have is around 30 at the present time. We're looking for it to gain to really just train, get them efficient, up and running, and that's our near term.

Andre Uddin – Analyst, Research Capital

That's great. Based on your comments, it seems fair to say that you've identified some potential products that would fit with Natroba. Is that fair?

Craig Mull — Interim Chief Executive Officer, Cipher Pharmaceuticals, Inc.

Yes, that's fair, Andre. It's Craig here.

Andre Uddin – Analyst, Research Capital

Just in terms of, I know business development is always hard to time, but when do you think you could forge your first licensing deal for Natroba?

Craig Mull — Interim Chief Executive Officer, Cipher Pharmaceuticals, Inc.

Well, last week, Hamid Ghanei attended a conference in Europe. I think it was called Bio-Europe. He's reporting that he's received a fair amount of interest, and we'll be pursuing those leads in the coming months.

Andre Uddin – Analyst, Research Capital

That's great. Thanks.

Operator

Thank you. Next question will be from Justin Keywood at Stifel. Please go ahead.

Justin Keywood – Analyst, Stifel

Good morning. Thanks for taking my call. Some moving parts in the quarter. Should we expect Q4 to show a more normalized situation of how the business looks with Natroba, including net income and the potential use of tax loss credits as far as translating to free cash flow growth?

Bryan Jacobs – President

Hi, Justin. It's Bryan Jacobs here. Good morning. Let me break that apart into two. The first on Natroba, we are going to continue to have some transition from that co-promotion partner. Again, that

was an item that was in play that we inherited when we inherited the business. Really we believe what you're kind of seeing for run rate in 2024 is going to continue. It will be until 2025—until the first quarter of 2025, until we're fully transitioned off of that. I think that's the way to think about the Natroba business.

Then on the utilization of tax losses, that's unchanged from what we had talked about or disclosed previously. We believe that we've structured the transaction in a tax-efficient manner. We should be able to utilize tax losses efficiently from the combined business.

Justin Keywood – Analyst, Stifel

Thank you. Was there any particular elements in Q3 where those tax losses were not able to be utilized?

Ryan Mailling – Chief Financial Officer, Cipher Pharmaceuticals, Inc.

Nothing in particular. We continue to utilize those losses in the quarter. Yes, nothing has really changed from our prior quarters.

Justin Keywood – Analyst, Stifel

Okay. Then on potential M&A in utilizing that U.S. infrastructure, are you able to update us on the pipeline as far as the amount of potential transactions, the size of deals that you're looking at, and any indication on multiples as well? Thank you.

Craig Mull — Interim Chief Executive Officer, Cipher Pharmaceuticals, Inc.

Justin, Craig here. I would say that we've got two to three serious opportunities that we are currently working on. I'm not sure any of them will come to bear, just given the fact that where we're at in the negotiation, but I'm feeling quite optimistic. In addition to that, we've probably looked at six to eight other opportunities and have arrived at these three opportunities that we think would fit well with the current sales force and their call points. I think it's a little early to comment on multiples. It's likely that these arrangements will be licensing deals, where it's more of a royalty payment as opposed to a capital requirement on an acquisition. If there is acquisitions, I would say that first of all, they would have to be complementary to Natroba and fit well with our geographic distribution in the U.S.

Did I answer your question, Justin?

Justin Keywood – Analyst, Stifel

Thank you. I appreciate it. Maybe to look at these two or three acquisitions in advanced stages, how much maybe revenue or EBITDA contribution would that combined total be or any particular asset, just to give a sense of what the potential impact could be?

Ryan Mailling – Chief Financial Officer, Cipher Pharmaceuticals, Inc.

We're looking at assets that would be generating over $30 million a year in revenue. I'm yet to get to the EBITDA figure, and that's part of the modeling that we're doing currently on these deals.

Justin Keywood – Analyst, Stifel

Great. Just one more, timing of potential execution on these transactions. Is it more of a 2025 scenario?

Ryan Mailling – Chief Financial Officer, Cipher Pharmaceuticals, Inc.

Yes. I believe 2025. These deals, as you may have heard, take longer than one expects.

Justin Keywood – Analyst, Stifel

Okay. Great. Thank you for taking my questions.

Ryan Mailling – Chief Financial Officer, Cipher Pharmaceuticals, Inc.

Thanks.

Operator

Thank you. As a reminder, ladies and gentlemen, if you would like to ask a question, please press star followed by one on your touchtone phone.

Next is Doug Loe at Leede Financial. Please go ahead.

Douglas Loe – Analyst, Leede Jones Gable

Yes. Thanks, Operator. Good morning, gents. Nobody's asked an Absorica question yet, so I guess I will. The bottom fell out of your royalties in Q3 and just want to get a sense of what feedback you're getting from Sun Pharma as to how it's projecting Absorica sales to roll out over the next few quarters.

Craig Mull — Interim Chief Executive Officer, Cipher Pharmaceuticals, Inc.

Doug, Craig here. Just to reiterate, the Q3 2023 was a particularly good quarter for Absorica, where Sun had ordered a lot of product. I think that they had been short in previous periods, they were making up. I think that Q3 2023 was a bit of an outlier. We expect that things will be reasonably stable there. We're in discussions with Sun about their pricing strategy in the generic market in the U.S. I think that it's a typical generic product there. It's not likely to be growing, but we hope that the slowdown with the product is going to meet an endpoint and stabilize from here going forward.

Douglas Loe – Analyst, Leede Jones Gable

Okay. Fair enough. Just shifting gears to your existing partnered portfolio with MOB-015 and piclidenoson—thanks for the commentary there. If you have any feedback from Moberg as to what their issues were with their ongoing Phase 3 study, it smelled at the time like it was a QAQC issue with the formulation that they were testing in that trial, given that it's already approved in other markets. Any commentary there on how the train fell off the rails on that trial would be helpful.

Then with piclidenoson, it's pretty clear from looking at Can-Fite's financial results that they don't really have the existing capital to fund a well-designed Phase 3 psoriasis study; just wondering if you have any feedback from them as to the sources of capital or sources of new partnerships that might be able to drive that trial forward over a timeframe that you shared in your opening remarks. I'll leave it there. Thanks.

Craig Mull — Interim Chief Executive Officer, Cipher Pharmaceuticals, Inc.

Let me start with the Moberg question first. We haven't been given a great deal of insight as to the results that were miscommunicated to Moberg with that subset of patients I referred to. I think the concern there is that they're not getting the cosmetic cure rate that they had hoped for, and that's affecting the overall—the complete cure results.

In looking at it, and we've been out speaking with physicians a lot about—a great deal about this—is that the guidelines talk about a complete cure rate as being the endpoint that people should be looking for, but they don't really comment much on how important is the mycological cure rate, What we're hearing from dermatologists and family docs that the mycological cure rate in different sets of patients is more important. For example, the elderly or which is where nail fungus is highly prevalent, and also in diabetic patients, where their disease is causing them not to be able to get cured using the existing product. We're seeing doctors starting to segment their patients in this way. We're feeling more and more confident that the Moberg product has legs for the Canadian market, particularly with the performance that they've achieved in Sweden. I believe there's a compelling case, but we're still doing our analysis about if we will launch, and how we will launch that product in Canada.

Turning to the Can-Fite product, the piclidenoson product, yes, we're following Can-Fite, and then from what we're hearing is that they're in the process of raising additional funds for that second Phase 3 pivotal trial that they're intending to conduct in the U.S. We're keeping in touch with them. We understand that, it's a relatively small company. They've had previous success, and I believe that they're intending to raise additional money to continue with the phase three study.

Douglas Loe – Analyst, Leede Jones Gable

Yes, fair enough. Thanks, Craig.

Craig Mull — Interim Chief Executive Officer, Cipher Pharmaceuticals, Inc.

Thanks.

Operator

Thank you. At this time, I would like to turn the call back over to Mr. Mull.

Craig Mull — Interim Chief Executive Officer, Cipher Pharmaceuticals, Inc.

Before signing off, I'd like to take this opportunity to thank our team members in both our U.S. office in Carmel, Indiana, and our Canadian head office in Mississauga for their ongoing hard work and dedication towards the integration of the Natroba business into Cipher and their focus on activities that will support our future growth. We are now in the early stages of what I see being an exciting journey as we build North America's next newly successful specialty pharma company. Thank you all for joining us today.

Operator

Thank you, sir. Ladies and gentlemen, this does indeed conclude your conference call for today. Once again, thank you for attending. At this time, we ask that you please disconnect your lines..