Eyenovia Inc (Pipeline Update)

October 29, 2019

Corporate Speakers:

- Tram Bui; The Ruth Group, Inc.; SVP
- Tsontcho Ianchulev; Eyenovia, Inc.; CEO, President, Chief Medical Officer & Director
- Michael Rowe; Eyenovia, Inc.; VP of Marketing
- John Gandolfo; Eyenovia, Inc.; CFO & Secretary

Participants:

- Scott Henry; Roth Capital Partners, LLC; MD, Senior Research Analyst & Head of Pharmaceuticals Research
- Yi Chen; H.C. Wainwright & Co, LLC; MD of Equity Research & Senior Healthcare Analyst
- Unidentified Participant

PRESENTATION

Operator: Ladies and gentlemen, thank you for standing by. Welcome to the Eyenovia Pipeline Update Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded. (Operator Instructions)

I would now like to hand the conference over to your speaker today, Tram Bui from The Ruth Group.

Tram Bui: Good afternoon, and welcome to Eyenovia's conference call and audio webcast. With me today are Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer; John Gandolfo, Eyenovia's Chief Financial Officer; and Michael Rowe, Eyenovia's Vice President of Commercial.

Earlier this afternoon, Eyenovia issued a press release announcing the advancement of its micro line program for the treatment of presbyopia for Phase III development and the reprioritization of its late-stage ophthalmology pipeline. We encourage everyone to read today's press release as well as the supplementary materials Eyenovia filed with the SEC.

In addition, this conference call is being webcast through the company's website and will be archived there for future reference.

Please note that certain information discussed on the call today is covered under the safe harbor provisions of the Private Securities Litigation Reform Act. We caution listeners that during this call, Eyenovia's management will be making forward-looking statements. Actual results could differ materially from those stated or implied by these forward-looking statements due to risks and uncertainties associated with the company's business.

These forward-looking statements are subject to a number of risks, including risks related to, among others, the potential success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; our ability to identify new products through rate and degree of market acceptance and clinical utility of our product candidate; our estimates regarding the potential market opportunity for our product candidates; the potential advantages of our product candidates; risk to our clinical trials including but not limited to the design, initiation, timing, progress and results of such trials; the timing and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; our ability to timely develop and implement manufacturing, commercialization and marketing capabilities and strategies for existing product candidates; fluctuations in our financial results; our ability to raise money; our competitive position and others detailed in and qualified by the cautionary statements contained in Eyenovia's press releases and SEC filings, including its most annual report on Form 10-K and subsequent filings.

This conference call contains time-sensitive information that is accurate only as of the date of this live broadcast, October 29, 2019. Eyenovia undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this conference call, except as may be required by applicable securities laws.

With that, I'd now like to turn the call over to Dr. Sean Ianchulev.

Sean Ianchulev: Thank you, Tram, and thank you, everyone, for joining us this afternoon as we provide an update to our clinical development pipeline initiatives.

We're very pleased with the clinical progress we've been making this year as we continue to build a robust, late-stage pipeline in ophthalmology using our next-generation intelligent microdosing platform.

Earlier this year, we completed our MicroStat Phase III MIST-1 and MIST-2 studies using our proprietary fixed combination of phenylephrine-tropicamide for pharmacologic mydriasis. With positive results in hand, we're now focused on completing the registration and stability manufacturing lots, which will enable us to file the NDA with the FDA in 2020.

In addition, we initiated our Phase III study for MicroPine, our first-in-class, back-of-the-eye therapeutic program for the treatment of progressive myopia in June of this year. With the CHAPERONE study underway, we look forward to completing enrollment in 2020.

However, as we noted in our press release earlier today, after conducting a comprehensive strategic review of our late-stage pipeline and our recent R&D development, we have decided to reprioritize our pipeline to focus our efforts on 3 programs, which we believe represent the highest value opportunities for Eyenovia. These programs include MicroPine, MicroStat and now MicroLine for the improvement in near vision in patients with presbyopia. Combined, these programs represent areas

where there are currently no known drugs approved or where we believe we can greatly improve upon the patient experience and get our novel technology into the hands of optometrists and ophthalmologists.

Along with our reprioritization, we and our Board of Directors, have decided to defer the development activities for our MicroProst program for the treatment of glaucoma and ocular hypertension and MicroTears, our over-the-counter program for red eye and itch relief.

Before I address presbyopia, I would like to invite Michael to discuss the anticipated commercial opportunity for presbyopia as compared to glaucoma and to help elaborate on some of the reasoning behind our decision to reprioritize our pipeline. Michael?

Michael Rowe: Thank you, Sean. Taking a look at our reprioritized pipeline, MicroLine, MicroPine and Microstat represent what we believe to be our highest value opportunities. And in 2020, which is fast approaching, we will have a healthy cadence of milestones including the initiation and completion of our Phase III studies for MicroLine, the completion of patient enrollment for MicroPine and our NDA filing for MicroStat.

But more importantly, I want to touch upon the reasoning behind our decision to defer the MicroProst program in favor of MicroLine for the improvement in near vision in patients with presbyopia.

Taking a look at the direct comparison between the two, we believe that our presbyopia program has some pretty significant advantages. To start, presbyopia has a more significant anticipated market opportunity in a space that currently has no known approved pharmaceutical therapies, as opposed to MicroProst, where it would be one of dozens of IOP lowering therapies that already exist in glaucoma.

MicroLine potentially represents a more patient-friendly treatment due to our proprietary piezo-print technology platform and the Optejet dispenser. MicroLine could also potentially provide more comfortable, easier, neater application than traditional eye drops, with significant aesthetic benefits.

However, the biggest advantage of MicroLine that we see is that it would be a cash paid prescription drug. And what does this mean? It means there would be no reimbursement hurdles, no rebates, no co-pays. This provides us with a potentially straightforward commercialization strategy.

From our estimates, approximately 43 million people in the United States between the ages of 40 and 65, who have otherwise normal vision and available disposable income, could benefit from an episodic pharmacologic treatment option like MicroLine. To top things off, the MicroLine program remains consistent with the 12-month time line we had indicated for MicroProst. So overall, we believe that we have a more attractive product candidate in MicroLine that could potentially reach commercialization in the same time frame.

With that said, I would like to hand the call back to Sean to discuss presbyopia in greater depth as well as outline our MicroLine program and its upcoming Phase III VISION trials. Sean?

Sean Ianchulev: Thank you, Michael. We believe MicroLine is an immense, untapped commercial opportunity. As some of you may know, presbyopia is a nonpreventable, age-related hardening of the lens, which causes the gradual loss of the ability to focus on nearby objects, commonly known as farsightedness. Symptoms of presbyopia include blurred vision, difficulty reading materials at close range, eye strains and headaches. Presbyopia is diagnosed through a basic eye exam, though for many who have had normal vision for most of their lives, it can cause a significant shift in lifestyle.

In the United States, presbyopia affects an estimated 113 million people or 1/3 of the U.S. population, of which, like Michael mentioned earlier, an estimated 43 million people between the ages of 40 and 65, who have otherwise normal vision and available disposable income, could benefit from an episodic pharmacologic treatment option like MicroLine.

As such, we believe that presbyopia represents a very attractive opportunity for Eyenovia as there are currently no known FDA-approved drugs in this indication. Our MicroLine program is based on Eyenovia's proprietary piezo formulation of the well-known drug pilocarpine, which causes constriction of the pupil, producing a pinhole effect and temporarily correcting vision. MicroLine is designed to replace reading glasses for approximately 3 to 4 hours, while addressing the tolerability and instillation issues seen with other traditional eye drop approaches.

Combined with our novel platform technology, we believe that we could enhance the lifestyle of millions of people with a cash paid prescription drug for the improvement in near vision in those with presbyopia in the model of other steady focus products.

We're now preparing the investigational new drug application for MicroLine and expect to initiate 2 Phase III studies in 2020. We expect both studies will be double-masked, placebo-controlled crossover superiority trials and will enroll approximately 120 patients between the age of 40 and 60 with presbyopia. Subjects will be randomized to receive treatment with either of the two MicroLine concentration, 1% or 2%, or a placebo. Our primary endpoint of the studies will be binocular distance-corrected near visual acuity. We expect to complete both trials in 2020.

While there are currently no known FDA-approved therapies for presbyopia, we are aware of some companies developing their own formulations of pilocarpine or other drug combinations. As we understand, the vast majority of these are currently in Phase II development with [Biorazis] Pharmaceuticals and presbyopia therapies in Novartis. The most advanced of this program is likely Allergan, which we understand is currently in Phase III trials with its pilocarpine formulation. With our program expected to be fast paced, we think we could lead the way or be a very fast follower to Allergan.

Now before we conclude and open the call to questions, I would like to hand the call over to John to briefly discuss the expected financial impact of our reprioritization on our financials. John?

John Gandolfo: Thank you, Sean. Once again, thank you all for joining us this afternoon. As we reported in our second quarter financial results, we had approximately $9.2 million in cash and cash equivalents as of June 30, 2019, and this doesn't include the approximately $13 million in aggregate net proceeds that we raised in our underwritten public offering in July. We expect that these funds will provide us with the necessary working capital until the end of 2020.

Additionally, as a result of the reprioritization of our pipeline programs, we expect to see overall cost savings of approximately $1.5 million to $1.9 million in 2020. With that said, we are looking forward to reporting full financial details for the third quarter in a few weeks.

So now let me hand the call back over to Sean for some closing remarks.

Sean Ianchulev: Great. Thank you, John. Before I open the call to questions, I would like to conclude by saying that we believe that this reprioritization of our pipeline will allow us to maximize the value of our late-stage ophthalmology portfolio, MicroLine MicroPine and MicroStat, focus on areas where we believe there is significant gaps in treatment options or where the patient experience could be greatly improved. And with potential product launches from '22 to '24, we're very excited to press on and continue to develop our high-value therapies using our novel, microdosing approach.

With that said, I would now like to open the call to questions. Operator?

QUESTIONS AND ANSWERS

Operator: (Operator Instructions) Sean, we have this one question coming from the line of [Lynn Young] from Magna Partners.

Unidentified Participant: I think that the focus on these 3 disease states is very appropriate and seems like it's going to lead to some potentially very rewarding therapies. I was wondering two things. One is, you had previously discussed, regarding presbyopia, that a partner would be required. So I'm assuming that given the cost savings from deferring the other two programs, this would allow you to pursue this indication on your own.

And then the second thing which you mentioned, about 40 million patients with normal vision otherwise, excluding presbyopia, could benefit, does this mean if a person had some nearsightedness, that they would be contraindicated from using the therapy or not included in the study?

And then the final question is at several of the recent ophthalmic and optometry meetings, there was tremendous interest in pharmacotherapy for treating progressive myopia and comments as it relates to disadvantages of compounded atropine due to the fact it needs to be acidic and it can break down quite quickly. I was just wondering if you wouldn't mind giving us your thoughts from what you saw at those conferences in terms of the approach you're taking in progressive myopia.

Sean Ianchulev: Thank you, Lynn. Great questions. First, I think there were 3 questions that I was able to catch here. Number one, on the presbyopia. We obviously leave options open to partner, co-develop. But when we also did our own assessment, as you know, earlier this year, we had the breakthrough from the R&D on getting our own piezo formulation, and as we continue to understand presbyopia and the opportunity, we realized that it really compelled.

It compelled on many fronts, as Michael discussed. So right now, we wanted to keep that high-value opportunity internal and really focus on creating value for the company by expanding our own pipeline and loading the Phase III studies, which we expect will be fast paced, and as we mentioned, we expect both to initiate and complete the entire Phase III program for MicroLine next year.

And also, the reprioritization gave us the opportunity to really critically examine what we've learned from the past 1.5 years, not just from our own development but also from other recent launches into our common space, as we know. And then we realized that the best thing we can do now is really focus on our own pipeline, be laser blade focused on where the value is and where is the sweet spot of the technology. And again, that does not preclude all kinds of business development opportunities in the future because we now, with this reprioritization, can fund them and make sure that we take the necessary steps to immediately capture value here.

When it comes to myos, again, we're not going to specifically exclude them. Obviously, somebody who is myopic is already naturally prime for near vision. And probably some of those patients and people out there can benefit also but not to the same degree as people who are not myopic. Most myopic people do wear correction. They either wear glasses for distance or contact lenses. And for them, there will be benefits because then they would not have to remove the contact lenses or some of the other hardware they are using in order to shift their focus from far to near. So yes, this would have beneficial effects for that population as well.

And you're right, progressive myopia, shifting to our other -- I think your question was about MicroPine and our other program. Obviously, there is a ton of interest and a lot of options there. We're really continuing with the successful enrollment of our study, MicroPine study and the CHAPERONE study. We even had an investigator meeting at the AAO. We're seeing tremendous interest in that solution -- in that program. And again, we're being constantly approached by clinicians on MicroPine, and very quickly, the conversation shifts to MicroLine because we've seen also tremendous interest in presbyopia.

So our pipeline has a very interesting bandwidth. It really covers from myopia to presbyopia, which is also interesting because myopia and progressive myopia is from the youngest patients that we have in ophthalmology, the kids. Two, also the patients, the elderly and people who are adults losing their near vision. And I think that really provides a very compelling pipeline and opportunity in this space.

Operator: And our next question is coming from the line of Scott Henry with Roth Capital.

Scott Henry: Just a couple of quick questions. I guess -- I completely understand why you're prioritizing a couple of the programs. The programs deprioritizing, MicroProst and MicroTears, I would assume you looked at out-licensing those already or partnering them. Do you have any color on whether that was an option? And, as well, if you do bring them back into the mix, what is the cost to restart these programs? Is it minimal, I would think?

Sean Ianchulev: Yes. Good questions. The beautiful part about this reprioritization is that we're keeping all of the options on the table. And again, what we're saying that today, the value that we see in the 3 programs that we just discussed, tomorrow we may see value or the value can change. Or in terms of the type of opportunities we want to pick, we can definitely revisit the same opportunities because MicroProst is a definite solution for patients with glaucoma.

As we mentioned, we can provide dramatic value to patients and clinicians with the compliance monitoring, with the adherence, with the microdosing and the better tolerability profile, reducing 80% of the preservative and the ocular surface toxicity exposure. So we definitely have value there. We just feel that as a company, we have a limited amount of resources and we need to focus on the high-value opportunities.

In fact, to that point, we have -- our IND for MicroProst is open and has been submitted. It's not like we are shifting gears because there is a problem with MicroProst. And we're prepared. The team was prepared to initiate the MicroProst study according to our time line. There was absolutely no problem there. But looking forward, we realized the value is very -- the inflection of the value is very different.

And again, with the open IND and with the fact that the formulation that we have is available to us and the clinical plan is also vetted and ready to go, there is no problem to activate either MicroProst or MicroTears later in the game or with partners, and I think that will be something that we keep all the optionality. We're not terminating the programs. We're just deferring them, and we are focusing our efforts on the 3 marquee programs: MicroStat, MicroPine and MicroLine.

Scott Henry: Okay. Great. Thank you for that color. And just one question for clarity. On MicroLine and the VISION trials, those are expected to be completed in 2020. The question is, would we expect to have data in 2020 or could that lead into 2021? And to

your pre-NDA meeting, when would we expect the filing? It sounds like it would be sort of mid-2021. Just any color you can give on that would be great.

Sean Ianchulev: Yes. I mean, so far, I think it's fair to say that Eyenovia has delivered ahead of time or on time on everything that we've done in the past 1.5 years as a publicly traded company. What we've just mentioned is that we expect, if everything goes as we plan, that we will be able to initiate the MicroLine program, Phase III programs, in 2020 and complete them with data in 2020.

Scott Henry: Okay. Okay, with data. And then filing, at first half 2021. Are there any other gating factors?

Tsontcho Ianchulev: Yes. I think the filing will be subsequent to that and we're following our standard time lines. But again, the data part is something that we hope to have in 2020.

Operator: (Operator Instructions) Now our next question is coming from the line of Yi Chen from H.C. Wainwright.

Yi Chen: My question is regarding MicroTears. I thought the product was almost a ready-to-go product for OTC channels. So I mean, was there really a plan to invest heavily into this product further? Or was it really the market prospects that made you change your mind about MicroTears?

Tsontcho Ianchulev: Yes. Let me just comment on that. I think as we've said before, MicroTears was our over-the-counter. It's a nontherapeutic. It's an over-the-counter product. It was meant to be a companion product to MicroStat. As over-the-counter, it does not require clinical trials. And when we look at the time line, it was something that was positioned to be registered and ready for the time lines of MicroStat which are -- again, we said we're going to file the NDA next year, so 2021.

And it did still require the registration batches and [field] finish and other activities which are not very expensive, but they do cost resources. And when we reprioritized everything, we wanted to focus our resources on where the real value is and not distract the team operationally and not divert any resources so that we can focus and execute successfully on the 3 programs.

So MicroTears is a nice program. Obviously, ocular surface wetting is important and the microjet with the coating mechanism that we have would be a game changer there because people have a hard time putting artificial tears to the eye with eye drops. This can be a really significant game changer. But when you look at the space and when you look at the potential margins in that space and the total net present value of the opportunity in MicroTears, it's very different than everything else we have.

So we decided to really focus the company right now, for the next couple of years, on the programs that matter, that we're very excited, that we've seen great interest from our

clinicians and KOLs and also investors. And we're deferring the other two programs, which can easily -- especially MicroTears, can easily be activated when need be.

Operator: And at this time, I'm not showing any further questions. I would like to turn the conference call back over to Mr. Sean Ianchulev for closing remarks.

Tsontcho Ianchulev: Okay. Well, I'd like to thank everybody for joining us this late afternoon with this information and hopefully this articulated clearly where I know we are heading over the coming months. And we look forward to updating you on the next call for the 10-Q. Thank you.

Michael Rowe: Thanks, everyone.

John Gandolfo: Thank you.

Operator: Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may all disconnect.