XERS Xeris Pharmaceuticals / 8 May 20 / 2020 Q1 Earnings call transcript

Allison Wey – Senior Vice President-Investor Relations and Corporate Communication
Paul Edick – Chairman and Chief Executive Officer
Barry Deutsch – Chief Financial Officer
Randall Stanicky – RBC Capital Markets
Dan Clark – Mizuho Securities
David Amsellem – Piper Sandler

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Xeris Pharmaceuticals First Quarter 2020 Financial Results Conference Call. [Operator Instructions] As a reminder, this conference call is being recorded.

I would now like to turn the conference over to your host, Ms. Allison Wey, Senior Vice President of Investor Relations and Corporate Communication. Ma'am, you may begin.

Allison Wey

Good morning, and welcome to Xeris' First Quarter 2020 Financial Results Corporate Update Conference Call. I hope that everyone is doing well and staying safe. Safety is our top priority.

We are conducting this call virtually with speakers in different locations, [indiscernible] to social distancing guidelines, so please bear with us.

A press release [indiscernible] results was issued this morning and can be found on our website.

We are joined today by Paul Edick, Chairman and CEO; and Barry Deutsch, CFO. Paul will provide opening remarks, and Barry will review the financial results, then we'll open the line for questions.

Before we begin, I would like to remind you that this call will contain forward-looking statements [indiscernible] Xeris' [indiscernible] Xeris' future expectations, plans, prospects, clinical approvals, commercialization, corporate strategy performance, which constitute forward-looking statements for the purposes of the safe harbor provision under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including the effect of uncertainties related to the COVID-19 pandemic on U.S. and global markets, Xeris' business, financial condition, operations, clinical trials and our third-party suppliers and manufacturers and other risks including those discussed in our filings with the SEC.

In addition, any forward-looking statements represent our views only as of the date of this call and should not be relied upon as representing our views as of any subsequent date. We specifically disclaim any obligations to update such statements.

I'll turn the call over to Paul now.

Paul Edick

Thank you, Allison, and thank you, everyone, for joining us today as we provide an update on the first quarter and 2020 to date.

It's clear to everyone that we're living in unprecedented and challenging times. In early March, we, along with the industry, the country and the rest of the world for that matter, were thrust into uncharted waters.

First, let me say that I'm incredibly proud of how the Xeris team has responded to the crisis, recognizing the seriousness of COVID-19 and acting early and decisively.

Like so many companies, we've had to make adjustments to address the dynamics of the ongoing pandemic.

Our primary focus has been to ensure the safety and health of our employees, continuity of service to our patient community and continuity of service to our health care professional customers. Thanks to our agile structure, we adapted very quickly to minimize disruption.

In mid-March, we implement – we immediately implemented a plan to safeguard the health and safety of our employees by beginning sheltering in place and working from home. We swiftly moved to virtual customer engagement model and implemented several programs to ensure that the diabetes community will continue to have easy and convenient ways to access our Gvoke Pre-Filled Syringe. Especially important in our actions is the fact that our ultimate customer, people with diabetes, are at increased risk for severe hypoglycemia during times of high stress and erratic schedules.

Let me briefly touch upon some of those initiatives. In late March, we started a $0 co-pay offer to help relieve the financial burden for the commercially insured patients. And recently, we extended that $0 co-pay through the end of May.

We also initiated the Xeris Support Program, which is a non dispensing pharmacy or HUB that you may be familiar with, which offers patients and providers – health care providers support for everything from benefits verification and prior authorization managemen, all the way to free home delivery of Gvoke.

Additionally, we reminded the diabetes community of our partnership with PillPack and clarified the simplicity of the home delivery process.

Our rapid pivot to virtual customer engagement has been critical to maintaining and recently gaining momentum in Gvoke PFS prescriptions. We converted all of our traditional speaker dinner programs to virtual webinars, conducting 38 programs through April with almost 250 health care professional attendees.

Our sales representatives moved to digital and virtual meetings, including Zoom, FaceTime, also using text and e-mail and fax to stay engaged with their customers and assist as needed to help them serve their patients. Especially important as they, the physicians themselves were figuring out the virtual world of telemedicine.

Now, I'd like to back up a bit to talk about the first quarter, which was our first real quarter of Gvoke PFS launch. I say that because from the time of our FDA approval in mid-September through the end of 2019, our focus was on building the foundation for a successful launch, hiring and training our field force, securing wholesale distribution, ensuring retail access to Gvoke, securing – importantly, securing payer contracts and product reimbursements through formulary approvals.

During that time, we also distributed over 5,500 sample units to our physician customers. And confirming Gvoke was in all of the electronic health record systems that our physicians use.

Getting all of this in place in the fourth quarter of 2019 and through January this year was critical to setting us up to drive true demand-based sales in 2020. Also, achieving very high levels of payer coverage in the first quarter was key to the start of good prescription growth. By the end of February, approximately 70% of covered lives – we have approximately 70% of commercial lives recovered without restrictions. And we are experiencing continued improvement in Medicare and Medicaid coverage throughout the quarter.

In addition, we received units per prescription of Gvoke PFS in the 2.2 to 2.3 range in the quarter, and the overall market was growing at 25% to 30%. We, in fact, had very good momentum prior to the COVID-19 disruption. And we're even outpacing the market four weeks to five weeks prior to this disruption.

During late March and into April, the glucagon market as a result of the COVID-19 disruption, market growth slowed and Gvoke prescriptions dipped slightly.

However, over the past four weeks, Gvoke continued to gain market share. We believe this is due to the fast actions we took to immediately go virtual and the tireless work of our commercial teams to implement programs that allow health care professionals and patients to access Gvoke during the pandemic. We've seen Gvoke in the most recent weeks gain some additional momentum, with the most recent week at a launch high of 439 prescriptions in the week. Unit sales have also maintained solid momentum, and we continue to average more than two units per prescription compared to the traditional mix gifts at still around 1.4 units per prescription.

Importantly, we are prepared for the Gvoke HypoPen launch as well. Gvoke HypoPen has been included in all of the drug listing compendia, all physician electronic health record systems, all payer formulary contracts.

So the HypoPen remains on track for a July launch.

As a result of the foundation we established with the launch of Gvoke PFS, the HypoPen will launch into a much more hospitable environment, a growing market with units per prescription on the rise.

In addition, we are preparing our commercial teams for a July launch with a significant virtual component and face-to-face customer engagement depending on the degree to which physicians' offices are open for business, and in what parts of the country that may be taking place. Gvoke HypoPen will be the ultimate simple solution [indiscernible] treatment treating low blood sugar emergencies. Gvoke HypoPen is the first and only auto-injector for severe hypoglycemia, and we believe will be very well received by the diabetes community. Regardless of the degree to which the country has returned to some form of a new normal, we will be prepared for the successful launch of Gvoke HypoPen, both virtually and in person in July.

Now let me turn briefly to our pipeline.

First, our Marketing Authorization Application for our ready-to-use glucagon rescue is currently under review with EMA.

Assuming a typical EMA review time frame, we could have a CHMP opinion late this year or early next year.

So that remains on track.

We recently reported positive results from our weight-based dosing study of our IM formulation of diazepam. We believe that the pharmacokinetic properties displayed by our IM diazepam suggest it could be particularly effective in reducing the number of follow-on seizures that so often occur in this epilepsy patient population.

Our next step is to request a meeting with the FDA to agree on a path forward to this program.

This quarter, we also have top line results for each of the outpatient portions of the Exercise-Induced Hypoglycemia, the EIH study and the Post-Bariatric Hypoglycemia, the PBH study. Recall, we have already reported positive results for the in-clinic portion of each of those studies. If we see similar results in the outpatient portion of each, we will also propose Phase III study designs and a path to approval with the FDA.

As you know, our goal with these glucagon programs is to advance the use of ready-to-use glucagon for patients that will ultimately get a non rescue mini dose indication to the market.

In addition, our XeriSol pramlintide insulin will also have clinical study results this quarter. If we – again, if we see positive results, we will assess the next steps and discuss the clinical and regulatory path forward with the FDA later in 2020.

We're wrapping up current clinical studies this quarter.

We will spend the next few quarters having those discussions with the FDA on the best path forward for each program. In the meantime, we continue to pursue other applications of our technology, as well as other uses of our approved liquid glucagon outside of its current specialty indication.

For example, we are evaluating another new market opportunity for Gvoke for use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the GI tract. The current U.S. market for this indication is significant at approximately $100 million in annual sales. And Xeris liquid glucagon could provide a convenient, no reconstitution required alternative to current presentations.

As always, and especially now at this time of uncertainty, we need to also be both strategic and prudent about our capital allocation.

We have looked across the entire organization to tighten our belts, yet ensure we maintain a viable enterprise.

For example, in April, we implemented a deferred compensation plan that the whole executive team and Board of Directors are participating in by deferring a significant portion of their 2020 and 2021 compensation until 2022 to significantly reduce cash burn, including my personal potential two-year deferral of approximately 85% of my cash compensation.

We also received a PPP loan to help retain employees, maintain payroll, and pay rent and utilities, all in accordance with the terms of the CARES Act, which Barry will cover with more specifics.

So let me provide a few comments on the PPP. On April 23, we received approximately $5.09 million in PPP funding. We believe these funds were necessary to support our ongoing operations, particularly given this critical stage that we find ourselves in, where we are facing the impact of COVID-19 as we work to drive Gvoke PFS prescription growth, prepare for July launch of Gvoke HypoPen and report top line results from 3 additional clinical studies.

Nevertheless, on May 1, after due consideration in light of SBA guidance that has continued to evolve and change in the days and weeks since PPP almost approved and funded, we determined that it was advisable and in the public interest to return approximately $900,000 of the PPP funding to make additional government funding available to other small businesses.

We will use the remaining funds to retain employees, maintain payroll and for rent and utilities, all in accordance with terms of the CARES Act.

Let me provide a – now what I'd like to do is turn the remainder of the presentation over to Barry to go over our financial results, and then I'll return and summarize at the end.

Barry Deutsch

Thanks, Paul. Net sales of Gvoke PFS were $1.7 million for the first quarter of 2020. Net sales represent gross product sales, less estimated allowances for our co-pay assistance program, prompt pay discounts, payer rebates and chargebacks, distributor service fees and product returns.

Gross profit for the first quarter of 2020 was negative $2,000. The reason for the negative gross profit is that we had $1.8 million in cost of goods sold for the quarter, which included $1.2 million related to the establishment of a reserve for excess and obsolete inventory. Manufacturing costs for Gvoke incurred prior to approval and initial commercialization were previously expensed as research and development expenses.

As such, our cost of goods sold will not reflect fully-loaded standard cost of goods sold per unit until those materials have been consumed.

Total operating expenses were $28.3 million for the first quarter of 2020 compared to $25.7 million for the first quarter of 2019.

As a reminder, our total operating expenses for Q4 2019 were $33.1 million.

R&D expenses for the 3 months ended March 31, 2020, were $6.6 million compared to $13.2 million for the same time period in 2019. The decrease was driven by decreased CMC costs due to reduction of manufacturing batches and supplies needed for preclinical and clinical trials as well as the previously mentioned expenses incurred in the prior year for the manufacturing of Gvoke prior to commercialization. A second contributor to the decrease was lower expenses associated with clinical and preclinical trials. Both of these impacts were partially offset by increases in personnel costs.

Selling, general and administrative expenses were $21.6 million for the three months ended March 31, 2020 compared to $12.5 million for the same period in 2019. The increase was primarily driven by increases in marketing expenses and the addition of Xeris' commercial salesforce in the fourth quarter of 2019.

Net loss for the three months ended March 31, 2020, was $29.2 million or $0.89 per share compared to $25.3 million or $1.07 per share for the same period in 2019.

As of March 31, 2020, we held approximately $100 million in cash, cash equivalents and investments.

During the quarter, the company sold in a follow-on equity offering approximately 10.3 million shares of common stock at a price of $4.15 per share. Net proceeds from the offering were $39.9 million after deducting underwriting discounts and commissions and other public offering expenses. Total current shares outstanding as of March 31, 2020, were 37,541,037 shares.

In April, as Paul mentioned, Xeris implemented a deferred compensation plan under which members of our executive management team and Board of Directors are deferring a significant portion of their cash compensation until 2022 to minimize our cash burn. Also in April, as Paul has mentioned, the company entered into a U.S. Small Business Administration Paycheck Protection Program, otherwise known as PPP loan with Silicon Valley Bank in the amount of $5.1 million, enabled by the Coronavirus Aid, Relief and Economic Security Act of 2020, otherwise known as the CARES Act. We received the full amount of the PPP loan in April. And as Paul mentioned, on May 4, we repaid $900,000 of the loan. The company plans to use the remaining proceeds to retain employees, maintain payroll and make lease and utility payments in accordance with the relevant terms and conditions of the CARES Act.

The PPP loan matures in two years and bears interest at the rate of 1% per annum. No payments are due on the loan for the first 6 months. We believe that we have sufficient cash to fund our operations and capital expenditures for at least the next 12 months. With regard to controllable expenses, we have and continue to implement spending reductions, there are no planned significant clinical trial expenses and the executive team and board are deferring a significant portion of their cash compensation. Revenue from Gvoke will determine when we will be cash flow breakeven.

I now will turn the call back to Paul.

Paul Edick Thanks, Barry. In summary, we believe we will weather the COVID-19 storms effectively because we have an improved product generating revenue, we have aptly pivoted to a virtual customer engagement model, we are on track for July launch of Gvoke HypoPen, we're seeing momentum recently in prescriptions for Gvoke PFS, we're being prudent and strategic with our spend, we have several important data readouts upcoming, and we are continuing to add new opportunities to our development pipeline.

With that, operator, if you could please open the line for questions.

Operator [Operator Instructions] Your first question is from Randall Stanicky from RBC Capital Markets.

Randall Stanicky I've got just a few questions around the July HypoPen launch.

First, could you just walk through the final gating items before that launch? What's left to do? Second, how would you characterize the level of physician awareness around Gvoke HypoPen? If you look at your call universe, are most physicians generally aware that this launch is coming or do you have more work to do there? And lastly, to what degree does sampling factor into those launch plans?

Paul Edick Thanks, Randall.

So in terms of final gating items, I think there are two really critical ones. One, we're currently manufacturing commercial supply, and we fully expect that will be done and we'll be able to distribute in early July.

The second one is continuing to get extremely good or extremely effective with our commercial organization and all of the programs that we will be implementing that we're currently working through with Gvoke PFS in terms of virtual as well as face-to-face selling. We need to be prepared for an environment where there's a significant virtual component still.

And a lot of the programs, a lot of the activities that are currently ongoing with the prefilled syringe are really getting our people much more skilled at interacting with physicians and offices, virtually through all of the various media, e-mail, fax, Zoom meetings, et cetera.

So, I think that's going to be critically important, and that's a big part of what we're doing right now to be prepared.

Then from a sampling perspective, if you will recall, we provided a considerable number of samples into the marketplace for the prefilled syringe early in the process to avoid prescriptions going to the pharmacy and being rejected because we weren't on managed care formularies.

We will be – we're already on all the formularies, both for PFS and for the HypoPen.

So we don't anticipate that there will be a significant component at all of sampling with the HypoPen. We do consider there are some pockets of physicians that may require some and in some situations, physicians have asked if they could have samples for office use in case of in-office emergencies. And we will be providing some modest numbers potentially for that.

In terms of awareness, it's – I'd say it's modest right now. Physicians are – we're focusing physicians on expanding the use of Gvoke PFS and Gvoke in general, to a broader audience of their patient population. They're engaging more and more in discussions of why people need to have Gvoke instead of the old traditional kits. And I'd say that the level of awareness of the coming HypoPen is modest, not high yet.

Randall Stanicky Okay. That's helpful. And if I could ask just one follow-up. Do you have any data you can share on the prescription fill rate for Gvoke PFS? And how that's trended since launch?

Paul Edick Yes. Great question. The fill rates early on was relatively low. We were seeing a trend where we were losing prescriptions if they were not being filled at retail. And we saw some substitution of the traditional kits for the Gvoke PFS. We've identified that, that was – there were a few causative factors. One was the prescription written Gvoke injection – for injection, and that caused some confusion at retail.

We also – some of it was early on with less managed care coverage. What we – and then the third piece was the prior authorizations. What we've done since then is we've gone to a HUB format and 90% of the prescriptions are going through the HUB from physicians.

So instead of going into their electronic health records and doing a drop-down to pick a pharmacy, they just send it to the HUB. The HUB will deal with prior authorizations, they'll deal with reimbursement, and they will send the product to the patients by whatever means they prefer. If they want to pick it up in a local pharmacy, they'll send it there.

We're seeing a high rate of home delivery through the HUB as well.

So that gives us much greater control, and the fill rate has dramatically increased.

Randall Stanicky Okay, great. Thank you.

Operator Your next question comes from Difei Yang from Mizuho Securities.

Dan Clark Hi, thanks. This is Dan Clark on for Difei. I guess, to start, and you just mentioned, your mail-based Rx has been up over the past couple of weeks due to COVID. Do you expect that to continue once pharmacies reopen and social distancing measures relax? And then as a quick follow-up to that, are there any mail-based sources that don't show up in IQVIA data that we should be aware of?

Paul Edick So Dan, thanks for the question. The mail-based prescriptions, I think, are – have a lot to do – the percentage, I don't have it on my fingertips.

I think it's close to 75% of prescriptions going to the HUB right now are being delivered overnight for home delivery. One would expect – we would expect that once pharmacies are back open and people feel comfortable going back into pharmacies, that, that will decrease and people will go more to the traditional picking up from the pharmacy. Keep in mind, however, this is a very at-risk population.

So I think what you're going to see is, I think you're going to see that the diabetes – people with diabetes will be more cautious in their return to whatever their new normal is.

So the rate of overnight delivery or mail delivery may remain high. Those prescriptions are still showing up in IQVIA, so that's not an issue.

There are a few.

We have a few that go through PillPack. It's not hundreds, it's tens.

So if you – on an average basis, if you add 5%-ish to the – what you see in IQVIA, you'll have covered what's going through PillPack as well.

Dan Clark And then just quickly on the gross margin front, roughly like how many quarters do you expect to have sort of a higher cost of goods?

Paul Edick Yes. I don't – go ahead, Barry.

Barry Deutsch Yes.

Sorry, Paul.

So the quarter this year, as I mentioned, was impacted by the E&O reserve.

Over the next – near-term time period moving forward here, our COGS were erratic for a number of reasons. One is product launch and just inventory uncertainties, so you're seeing that reserve this quarter. But also, as we've mentioned in our 10-K and as I mentioned in my comment here, costs involved with manufacturing products prior to the approval last September, and our commercialization were expensed already as R&D expenses, so that's not going to flow through COGS.

So you're going to have sort of different factors up and down until we get to a steady state.

Dan Clark Okay, thanks. I'll pass the line.

Operator Our next question comes from David Amsellem from Piper Sandler. David your line is open. David your line is open, are you on mute.

David Amsellem Yes. Can you hear me, sorry about that, I was on mute.

So just a couple of quick ones. I wanted to get your thoughts, Paul, on how you think the overall glucagon rescue market is going to be impacted to the extent that the COVID landscape is maybe creating more, I guess, diligent patients or diligent practices in terms of patients making sure they have rescue therapy available? I mean, are you seeing what I would call more diligent or conscientious behavior in terms of patients, making sure they absolutely have rescue available. That's number one. And I guess, do you think that endures? And then second question is on the diazepam product. Can you just talk about the path forward there? I know you're resource constrained, but talk about how much of that is a priority and then the extent to which you're going to try to push that forward?

Paul Edick David, thank you very much. The – from a market perspective, the overall glucagon market, all products in, was really accelerating, growing up to 25% to 30%. The COVID-19 situation has taken a little bit of the steam out of the total market growth. But in terms of the patient population, what we're seeing is physicians are more concerned and reaching out to their patients to make sure that they have rescue glucagon. And like I said in my comments, our most recent week of data is an all-time high for us during the pandemic, during the crisis.

Now some of that is due to the fact that we're actually probably more engaged with physicians than others and really talking to our customers about the fact that their patients are at considerably increased risk right now and that they should be reaching out to them and making sure they have Gvoke PFS. And I think that's really got us a little bit of traction.

Over time, I think that will endure.

I think physicians are becoming more attuned to making sure that they're talking to patients about glucagon, especially Gvoke.

I think with the advent of the HypoPen, it's going to be even more significant.

You have to remember that this is a category where physicians were being talked to about glucagon for decades.

So they're reengaging with their patients, they're beginning to recognize the new, more convenient uses. And I think the next stage is actually going to be physicians understanding and talking to their patients about the ability to self administer. Historically, it hasn't been a self administration.

So, I think all of that combined will help for patients at-risk to have a more enduring belief that they should have something just in place. Hopefully, that answers the question.

In terms of diazepam, we think we have a great product. When you look at the pharmacokinetics of our products, both in the original Phase I study and the second study, which was a weight-based dosing, we've got more than adequate time to onset and more than adequate drug getting into the system. What's really beautiful is it hangs around for quite a while. And that is critically important to blunting follow-on seizures. The question is going to be what the FDA is going to require that we do going forward in a Phase III program.

So we're going to go to the FDA later this year.

We're going to put forward what we believe is the appropriate approach and see where we go.

In terms of resource constraints, it would be resource constrained, if they ask us to do more than is reasonable. Keep in mind, we're investigating this drug in an orphan designated population. And the kind of study that we would propose would be consistent with what is usually required. We'll see what the FDA says and then we'll decide on our path forward going – after that meeting.

David Amsellem So if I may just sneak in a follow-up, do you feel reasonably confident that you can move directly to a Phase III or that there's a rapid path to a Phase III, given that this is a 505(b)(2)? Or that is sort of to be determined based on your dialogue with the FDA?

Paul Edick Yes.

We will propose a Phase III program. There's plenty of examples in the marketplace where that's been the path forward.

So that's going to be our approach. We think it's a 505(b)(2), it's diazepam, is very well studied. There's other products that have proposed similar weeks and we think we'll have a very cogent argument, very solid argument, especially based on the data.

David Amsellem Okay, great. Thanks for taking my question.

Paul Edick Thanks, David.

Operator I am showing no further questions at this time.

Paul Edick Okay. Thank you very much. We appreciate everybody joining us today. Be safe and healthy.

Operator Ladies and gentlemen, this concludes today's conference. Thank you for your participation, and have a wonderful day.

You may all disconnect.