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PRESENTATION

Operator

Good morning, and welcome to the Aquestive Therapeutics' First Quarter 2020 Conference Call. (Operator Instructions) As a reminder, this call will be recorded. I would now like to introduce your host for today's conference, Ms. Stephanie Carrington, Westwicke, Investor Relations. You may begin.

Stephanie Carrington *ICR, LLC - SVP*

Thank you, Operator. Good morning, and welcome to today's call to review Aquestive Therapeutics' results for the first quarter of 2020 and business highlights.

On today's call I am joined by Keith Kendall, President and Chief Executive Officer; and John Maxwell, Chief Financial Officer, who are going to provide an overview of the recent business developments and performance in the first quarter. Additional members of our leadership team will be available for Q&A. In total, we expect today's call to last approximately 60 minutes.

As a reminder, our remarks today correspond with the earnings release we issued after market close yesterday. In addition, the recording of today's call will be made available on Aquestive Therapeutics' website within the Investor Relations section shortly following the conclusion of this call.

To remind you, we were discussing some non-GAAP financial measures this morning as part of a review of our first quarter 2020 results. A description of these measures along with a reconciliation of GAAP can be found in the earnings release we issued yesterday which is posted in the Investor Relations section of Aquestive Therapeutics' website.

During the call, the company will be making forward-looking statements. We remind you of the company's safe harbor language as outlined in yesterday's release, as well as the risks and uncertainty effecting the company as described in the risk factors section included in the company's annual report on Form 10-K filed with the SEC on March 11, 2020, and in our quarterly reports on Form 10-Q.

As with any pharmaceutical company with product candidates under development and products being commercialized, there are significant risks and uncertainties with respect to our business and the development, regulatory approval and commercialization of our products and other matters related to operations. Impact of COVID-19 also cannot be predicted. Given these uncertainties, you should not place undue reliance on these forward-looking statements which speak only as of the date made.

Actual results may differ materially from these statements. All forward-looking statements attributed to Aquestive Therapeutics or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement and the cautionary statements contained in the earnings release issued yesterday. The company assumes no obligation to update its forward-looking statements after the date of this conference call whether as a result of new information, future events or otherwise, except as required under applicable law.

With that, I will turn over the line to Keith.

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***

Thank you, Stephanie. And thank you to everyone on the call for joining us this morning. In our remarks, John and I will provide an update on our business for the first quarter and during April 2020. We'll be joined by additional members of the Aquestive leadership team during the Q&A session afterward.

Our key priorities as a company always start with the safety of our colleagues, the people we do business with, and the patients and caregivers who interact with our products. During this extraordinary period, as leaders and managers of our business, we have a responsibility as well to ensure that to the best of that ability, while taking all steps to keep people safe, we continue to advance the important work of the company.

Aquestive has carefully managed our business to be sure that its colleagues are safe and healthy, that all key elements of its business continue, including key R&D initiatives, FDA review processes and product manufacturing. The company's manufacturing facility continues to produce needed chronic-use medicines for patients, including the company's proprietary product, SYMPAZAN, and the company's licensee products such as Suboxone.

The company has inventory and access to our supply chain for several months of production going forward, in the event of an unforeseen shutdown of key suppliers resulting from COVID-19.

In early April, we took an important step to keep our colleagues working through this crisis by partnering with the government and accessing funds available through the CARES Act and the Paycheck Protection

Plan, or PPP, in particular. To our disappointment, however, almost 2 weeks later, the Small Business Administration issued revised guidance that we viewed as establishing a strong presumption that no public company, regardless of need, would be eligible for a PPP loan. Because of the implications of possibly not meeting ill-defined and changing criteria for qualification, we made the decision to return our PPP loan under these new conditions.

Regardless of the outcome of that program, the key areas of focus for the company include that we expect to file the IND for AQST-108, epinephrine, as planned during the second quarter 2020. AQST-108 is an oral sublingual film formulation, delivering systemic epinephrine that is in development for the treatment of anaphylaxis.

We continue to progress toward the expected start of PK trials later this year. Aquestive continues to work with the FDA in seeking approval of Libervant, diazepam buccal film for the management of seizure clusters. The company is engaging in normal course of business interactions, including responding to information requests with the FDA related to our accepted NDA for Libervant. The FDA has assigned the Prescription Drug User Fee Act, PDUFA, goal date of September 27, 2020, for Libervant.

As we have said, we are seeking to demonstrate to the FDA that Libervant will, if approved for marketing in the U.S., represent a major contribution to patient care within the meaning of FDA regulations and guidance as compared to currently available device-based treatment options. Libervant also will expand patient choices, the first orally delivered diazepam-based product available to manage seizure clusters in epilepsy patients, especially for patients who may not be able to effectively use nasal sprays due to nasal congestion, irritation, or seasonal allergies.

Concurrently, Aquestive is continuing to market SYMPAZAN, clobazam, an oral film for the treatment of seizures associated with Lennox-Gastaut syndrome or LGS to the same prescriber base for Libervant, and expanding its relationships with payers and caregivers. This product received increasing market adoption in the first quarter 2020, growing over 40% March over December of 2019.

Aquestive's lead licensee product, Suboxone, continues to hold strong market share with strong production in the first quarter of 2020 and a strong order book for the second quarter. The Aquestive team has begun the process to seek to monetize the anticipated royalties associated with APL-130277, apomorphine. The monetization would occur only after Sunovion receives approval from the FDA with an expected PDUFA goal date of May 21, 2020, and when we determine that the terms and conditions of a transaction at that time are appropriate for the company. The company expects that this monetization, if effective, along with our other capital resources and the careful management of our cash across our business, including any preapproval and prelaunch spend associated with Libervant would provide additional nondilutive capital to fund the business well into 2021 and potentially beyond.

Let's discuss in more detail each of these key areas of focus for the company. First, we expect to file the IND for AQST-108 with the FDA in the second quarter of 2020 as promised. We continue to work toward and expect to initiate PK clinical trials before the end of the year as expected. As a reminder, we had a

very constructive pre-IND meeting with the agency in early February regarding epinephrine. The FDA confirmed 2 key points for epinephrine. First, the clinical development for epinephrine will be reviewed under the 505(b)(2) regulatory approval pathway as proposed by Aquestive. And second, that no additional studies would be necessary prior to opening the proposed IND application.

The FDA also gave us clear guidance about what they are looking for in our development program. The FDA also confirmed that and understands that there is a significant unmet medical need among patients who resist the standard of care use of subcutaneous and intramuscular injections in the treatment of anaphylaxis, and that AQST-108 may potentially address some of those unmet needs.

We continue to believe that, based on the outcome from this meeting with the FDA, the development of epinephrine will be a less complex, less costly, and potentially faster path for filing than originally anticipated.

Second, as we previously communicated, the NDA filing for Libervant was accepted in January and assigned a PDUFA goal date of September 27, 2020.

Over the past few weeks, we've received a number of information requests from the FDA related to our filing, and continue to engage in the typical normal course of business correspondence with the agency.

We see no indication of delay, and have no indication that at this point there is any reason to think we are not on track for September 27, 2020, PDUFA action as scheduled.

Concurrently, we're continuing to advance the clinical development activities related to Libervant by advancing the ongoing studies that we touched on last December at the Investor R&D Day.

We've closed enrollment in the pediatric long-term safety study and in the Pediatric Epilepsy Monitoring Unit or EMU study. We are collecting the data from both studies and preparing the final analysis. We anticipate that the top-line findings from these studies will be available by the fourth quarter of 2020.

With these 2 studies nearing completion, we anticipate that we may potentially be able to expand the label for Libervant to include pediatric patients between the ages of 6 and 12. I remind everyone that neither of these studies have any impact on the NDA currently under review.

We've also closed the enrollment in our adult long-term safety study for Libervant. As a reminder, the NDA filing submitted last November included the interim analysis for this data. We're completing the data analysis and will provide the findings to the FDA to further support the NDA currently under review.

We're seeking to demonstrate to the FDA that Libervant, if approved for marketing in the U.S., would represent a major contribution to patient care within the meaning of FDA regulations and guidance as compared to the currently available device-dependent treatment options, and would further expand patient choice as the first orally administered product available for its proposed indication.

As we have shared, the FDA provided us the following criteria that it may consider when it evaluates clinical superiority for drugs demonstrating a major contribution to patient care. Convenient treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses and the potential for self-administration.

We believe that we can demonstrate to the FDA why Libervant, as an orally delivered product for this indication, has one or more of these attributes quoted by the FDA to be considered a major contribution to patient care relative to currently approved rectal and nasal products.

Currently we are also examining how nasal sprays can be used during bouts of seasonal allergies and/or common cold. A recently approved nasal spray for seizures in its pivotal study, at a clinical setting, excluded patients with, "severe seasonal or nonseasonal allergies, nasal polyps, or any nasal passage abnormality that could interfere with nasal spray administration."

We are also learning from our key opinion leaders about instances where nasal spray dosing could not occur due to seasonal allergies. According to the Asthma and Allergy Foundation of America, more than 50 million Americans have experienced various types of allergies in the last year.

According to the Centers for Disease Control and Prevention, the average American adult has 2 to 3 colds per year, and children have even more. This is a sizeable and meaningful portion of the population.

Libervant, as you know, is administered orally, and is not subject to the changing conditions of a patient's nasal passage. Therefore we believe that we could potentially show a plausible hypothesis that Libervant provides a major contribution to patient care by avoiding issues associated with seasonal allergies and/or the common cold.

Over 1 million patients in the U.S. have active uncontrolled epilepsy and a need for rescue, for rescue medication. Less than 10% of these patients are successfully treating their seizures with the current standard of care, a rectal gel application of diazepam.

A medicine is only as good as its ability to be used by patients where they need it, when they need it, and in a form they accept.

We have an accepted filing for a product with a very strong value proposition, and we believe that we can demonstrate to the FDA that Libervant is clinically superior to the currently approved alternatives.

We will continue to be thoughtful and prudent about our choices, recognizing we may not successfully overcome the orphan drug exclusivity here. And we therefore are managing appropriately our prelaunch spend on Libervant and SYMPAZAN prior to having greater clarity on any approval.

Subject to the FDA accepting our position, we are committed to launching Libervant and have the

foundational commercial capabilities to do that.

Next, we remain focused on building our CNS franchise. We are advancing the commercialization of SYMPAZAN, whose prescribers substantially overlap with potential prescribers of Libervant.

Our aim is to raise the profile of our PharmFilm technology as a commercial precursor and eventual complementary products in support of the Libervant opportunity.

SYMPAZAN continues to prove the build out of our capabilities and processes in preparation for the commercial launch of Libervant.

All of our commercialization efforts relating to SYMPAZAN provide an opportunity for direct conversations with healthcare practitioners, patients, caregivers, payors, advocacy groups and others, about the value of our PharmFilm technology that would be the basis for Libervant, if approved.

The acceptance of SYMPAZAN by those groups is an important building block, providing a meaningful value proposition for caregivers of patients suffering from LGS for SYMPAZAN to reach profitability, as we expect in 2021, its third year in the market.

SYMPAZAN's performance exceeded our internal expectations during the first quarter of 2020, as we continue to focus on growth and further market penetration. Shipment volume on a monthly basis has grown over 400% year-over-year, 40% March over December of 2019, and 25% quarter-over-quarter. March represented the highest-volume-month for SYMPAZAN since its launch.

The prescribing base also continues to grow, over 25% since the end of 2019, with over 77% of those prescribers writing multiple scripts. We now have a penetration in our core focus group of prescribers of 22%.

SYMPAZAN is strategically accomplishing what was intended when we launched the product last year. The work we do to continue to build the revenue stream and market penetration for SYMPAZAN will be an important foundation for successful launch of Libervant.

We continue to focus all of our energy and available resources on advancing the key initiatives surrounding epinephrine and Libervant. Additionally, we need to recognize and react to declining revenue from our Suboxone business and adapt our business in the face of the COVID-19 pandemic.

Our operations in Warren, New Jersey and Portage Indiana are deemed to be essential by their resident states. As such, at this time, the R&D team has continued its operations at our headquarters in New Jersey. And our manufacturing facilities in Indiana continue to produce Suboxone and the other therapeutics on PharmFilm.

We're closely monitoring the number of reported COVID-19 cases in each of these geographies. The

COVID-19 pandemic has created face-to-face access challenges with healthcare providers since mid-March for our field-based sales teams. Virtually all of our target prescribers for SYMPAZAN have limited live access to their clinics until further notice. The SYMPAZAN team has rapidly adopted digital tools and continues to engage with healthcare providers and their staff remotely on a frequent basis.

Some states have begun the discussion of reopening, and we expect prescribers to begin seeing new patients and resume checkup visits at different times in different areas of the country. At that point it is expected that we will resume some face-to-face interactions.

As such, we will continue to manage our costs and target our spending in 2020. Those plans are reflected in our guidance. We expect that our current cash resources are sufficient through 2020 based on our internal plan and assumptions. We have begun to communicate with potential investors that would buy our royalty rights to Sunovion's licensed apomorphine product subject to approval by the FDA.

We will consider market conditions, COVID-related or otherwise, structure and timing of any monetization to enable us to efficiently provide additional capital for the company. Such a potential monetization would be expected to further extend our capital horizon and provide additional capital to support our business well into 2021 and potentially beyond. We look forward to updating you with the time of the release of our second quarter financial results as we advance these initiatives throughout 2020.

With that, I'd like to turn the floor over to John, who will provide specifics of our financial performance and outlook. John?

John T. Maxwell ***Aquestive Therapeutics, Inc. - Senior VP & CFO***
Thank you, Keith. Good morning everyone.

Last night we filed our 10-Q and issued our earnings release. We will tackle most of the discussion related to the first quarter 2020 results in the Q&A. In my comments this morning I will highlight a few points from our results that are important in order to understand our reaffirmed 2020 financial guidance and our progress towards it.

Before considering additional nondilutive capital, we have worked hard to manage our capital horizon with our current cash resources which we anticipate being sufficient to last into early 2021. This was done by focusing our investments on seeking Libervant approval for U.S. marketing, continuing our development of AQST-108 epinephrine, and continuing to successfully expand SYMPAZAN's commercial footprint. Those initiatives are funded in our projections and expected to be on track. In terms of nondilutive capital, we have begun investor meetings to start our process for a potential monetization of apomorphine after the May 21 PDUFA date.

Our monetization is subject to FDA approval of apomorphine on that date. And we believe that the monetization could potentially generate nondilutive capital of $50 million to $100 million. The timing of

any such transaction will be dictated by market conditions which may be impacted by the COVID-19 pandemic. Markets have begun to stabilize. And if this trend continues, we expect to see to monetize the asset as early as late Q2. However, we will select the timing and structure of any potential transaction that we believe would represent the best overall outcome for Aquestive.

We expect that our conservative spending management and a potential apomorphine monetization would fund Aquestive's needs well into 2020 and possibly beyond. We will plan to update the market on our cash runway after such time as we complete any monetization transaction.

Our first quarter revenue was in line with our own expectations. Suboxone production was over 40 million doses in the quarter. And we are seeing a similar rate of production in our Q2 order book. We expect that Suboxone in the U.S. market combined with non-U.S. markets will continue to be a meaningful part of our revenue base while our proprietary business continues to grow. As a result, our manufacturing and supply revenue in the first quarter of 2020 was approximately flat with the 2019 first quarter driven by lower volume but higher price Suboxone revenue.

SYMPAZAN reported net revenue grew sequentially over the fourth quarter by 70%. We expect that SYMPAZAN will continue to grow throughout 2020 as our prescription volume continues to grow. Our growth in recognized net revenue will be dependent on ordering of products by wholesalers, although going forward we would expect that this will more closely align with prescription levels than we saw in the first year of launch. In addition to prescriptions filled, we continue to make solid inroads into the prescribers and support teams. And this effort will help us significantly in the launch of Libervant, if approved for access to the U.S. market.

We are very pleased with the commercial performance of SYMPAZAN and its preparations for the potential launch of Libervant in late 2020, if approved by the FDA. We are affirming our previously provided revenue guidance of $35 million to $45 million. This guidance factors in lower year-over-year Suboxone volumes with higher prices per unit, both of which we saw in the first quarter. Continued growth in SYMPAZAN, an expected $4 million milestone that would be payable for apomorphine 6 months after FDA approval, as well as co-development fees and modest licenses and royalties. Our guidance excludes any revenue for Libervant, and will not be included unless that product is approved.

Our adjusted gross margin in 2020 first quarter was 66% compared to our adjusted gross margin for the 2019 year. As our revenue base shifts towards our proprietary products, starting with SYMPAZAN and away from Suboxone, and we consider the impact of additional license fees and royalties later in the year, we expect our adjusted gross margin will rise to 70% plus as we have guided. As outlined in the earnings release issued yesterday, our first quarter 2020 non-GAAP adjusted EBITDA loss was $11.2 million, and puts our performance on target to be within our guidance range on the year of a loss of $40 million to $45 million.

The first quarter non-GAAP adjusted EBITDA reflects lower sequential expenses from the fourth quarter of 2019 to the first quarter of 2020, and we expect our level of spending to continue to moderate over

the course of 2020. Obviously, while we have managed well to-date in the face of the COVID-19 pandemic, the extent to which it may impact our ongoing and future operations and financial results and financial resources will depend on future developments which we are obviously uncertain of and cannot be predicted with any clarity.

We are focused on investing in seeking the approval of Libervant at our PDUFA goal date of for September, the continued development of AQST-108 after we open our IND, starting with PK clinical trials expected later this year, and the continued commercialization of SYMPAZAN, while focusing on seeking to drive this product to profitability in 2021.

At the same time, we are focused on being as efficient as possible across the organization. We continue to manage our variable cost structure at the plant to match the volume of production, focus on the efficiency of Libervant investments and prelaunch marketing until we have clarity on any FDA approval, and careful management of our support organizations to be aligned with the arc of the various focused initiatives of the company.

Early in 2020 we rationalized our cost, improved our adjusted EBITDA guidance range and improved our cash burn guidance by $20 million. We anticipate that this change in expenses combined with our current cash position should provide the capital necessary to get into early 2021 while maintaining the investments we need around the most important value-driving components of our business. Q1's performance is on track with our full year's expectations, and therefore we have reaffirmed our earlier guidance. To further extend our capital, we will seek to monetize apomorphine after the May 21 PDUFA, assuming approval by the FDA and acceptance of acceptable market conditions.

We anticipate that the combination of our prudent cost management and the additional nondilutive capital we would expect to see from the potential monetization of apomorphine should take our capital runway well into 2021 and possibly beyond. After the time of a potential monetization of apomorphine, we will plan to update the market on the timing of our capital runway.

In summary, our reaffirmed guidance for 2020 reflects continued cash flow from our licensee and proprietary products revenue base, careful focus of our investments into the most value-driven aspects of our future, Libervant and epinephrine, and continued focus on capital conservation so that cash is extended as far as possible.

Operator, we will now open the line for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) I show our first question comes from Gary Nachman from BMO Capital Markets.

Rafay Sardar ***BMO Capital Markets U.S. - Analyst***
It's Rafay on for Gary. So for apomorphine, can you provide a bit more color on the types of discussions you've had thus far, and the level of market interest that you're seeing relative to your expectation?

And have there been any changes to Sunovion's potential launch plans due to COVID-19? And does that impact how you're viewing the monetization opportunity at all?

John T. Maxwell ***Aquestive Therapeutics, Inc. - Senior VP & CFO***
So thank you, Rafay, for the question. Let me tackle it in reverse order. Look, I don't think we're in a position to be able to comment on Sunovion's specific launch plans. They publicly stated that they plan to launch late this year. And I believe until they tell us otherwise, that's fully their intention. I think with respect to COVID-19, it's very hard to know what the impact will be at this point, although hopefully, things will be moving in the right direction.

With respect to investor conversations, we have the market is well-prepared for the fact that this asset is coming. The market is familiar with Sunovion as a very strong commercializing organization. And so what we're waiting to see is, one, we got to get through the PDUFA date. And then, once we're through the PDUFA date and the product is approved, we would then move from there to finalizing a transaction in terms of completing it, if the markets are good. And look, COVID, the markets have stabilized, they've gotten better. And we think that'll continue. And as long as that continues, we would expect to have a transaction, hopefully late Q2 or certainly sometime in Q3.

Rafay Sardar ***BMO Capital Markets U.S. - Analyst***
Thanks. And then, regarding the NDA filing for Libervant, can you describe the types of interactions you're having with the FDA? And how much visibility do you expect to receive between now and the PDUFA on the potential to receive ODE?

Daniel Barber ***Aquestive Therapeutics, Inc. - Senior VP & COO***
Good morning, Rafay. This is Dan Barber. Nice to hear your voice. The interactions with the FDA are as you would expect with any NDA filing. We are having regular back and forth on information requests across the different parts of the NDA, all questions that we would expect and we are answering. In terms of the -- any discussion with -- you mentioned ODE orphan drug, that would be up to us. And we will seek to have those discussions, as Keith has laid out in previous comments.

Rafay Sardar ***BMO Capital Markets U.S. - Analyst***
Okay, thanks. And then, can you comment generally on how you're thinking about the market opportunity and peak sales for Libervant at this point? And has your view changed at all based on the trends for NAYZILAM since it launched around 6 months ago?

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***
Sure. Thanks for the question, Rafay. This is Keith. I think we continue to believe that there is a huge untapped and underserved patient population. This patient population has been underserved for a long

time. This patient population is looking for choice. They're looking for medications or therapeutics that they can use when they need it and where they need it, and certainly in a form that fits their life. We think NAYZILAM has demonstrated up to this point that that untapped population exists, just because of the relative split between NAYZILAM and Diastat the current rectal gel. But with the uptake of NAYZILAM and the more recently approved nasal spray would demonstrate that the patient population is not necessarily enamored with a nasal option.

We think we provide a choice, an oral choice that will be attractive to a good part of that population. We continue to guide people to we think this is a $300 million-plus peak sales product for us. And we think right now the market size is there for that. The preference is being expressed around nasal spray that we think will support an oral. And we continue to be incredibly bullish about the prospects of this product, if it's approved and granted access to the market.

Operator

Our next question comes from Randall Stanicky from RBC Capital Markets.

Randall S. Stanicky ***RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst***

Keith, I want to go and ask the prior question differently. On Libervant, has anything changed in your discussions with FDA? And I ask this because last quarter you said you don't think there's any scenario that keeps you out of the market. And now, it sounds like you're looking at various options. So I just want to gauge your level of confidence so there's no confusion around the message out of a quest of this morning on your outlook or expectation for approval. And then I have a follow up after that.

John T. Maxwell ***Aquestive Therapeutics, Inc. - Senior VP & CFO***

Thanks, Randall. It's good to good to talk to you again. I'm not sure -- let me say it differently. We're not trying to communicate any change of thinking. We continue to believe that there is no way that Libervant will be shut out of the market for the exclusivity period granted to the recently approved me nasal spray. There are multiple paths that we can choose to go down to get to that access. Some are more expedient than others. And what we're doing is attacking this in what we think are the most expedient ways while preparing, secondarily, as we always do for an eventuality of a decision perhaps that we were not anticipating.

So our level of confidence, our level of belief and expectation has not changed. We believe strongly that this represents a major contribution to patient care, that it is clinically superior to the alternatives. And we're pursuing that with all the vigor that we can.

Randall S. Stanicky ***RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst***

Great. And John, can you help us, how much have you guys built in, in terms of spend for this year around the Libervant launch?

John T. Maxwell ***Aquestive Therapeutics, Inc. - Senior VP & CFO***

So without getting into the specific dollars, Randall, the focus of our investments this year before PDUFA date are focused on making sure that we have all the materials that we need to have put into the FDA process so that we're prepared. So think of that as just making sure that we gain market access. When we reduced our spending, one of the deferrals that we made was around the timing of when we would begin to launch. And so, we pulled out any revenue associated with Libervant until we know that we're in the market. And we pulled out most of the spending. Once we understand that we're approved, hopefully on September 27, at that point we would come in and we would update likely with what we think the revenue outlook is for the rest of this year as well as any additional spending beyond where we are right now. We certainly do have some level of market presence in addition to just SYMPAZAN itself. And we are preparing the market for Libervant. But we're doing it in a prudent careful way and not a huge amount of spend prelaunch.

Randall S. Stanicky ***RBC Capital Markets, Research Division - MD of Global Equity Research & Lead Analyst***

Great. And my last question is back to Keith, the bigger-picture question. Is Aquestive a pipeline story or commercial story? And what I mean by that is, what's the -- as you talk to the Board about the 3- to 5-year strategy and outlook, what's the strategy to grow the business? Is it blocking and tackling and pushing the pipeline forward? Or is it capitalizing on this commercial footprint that you're building and bringing in assets from the outside and leveraging that? And if it's the latter, how do you do that, given the current capital structure and kind of opportunities to pursue business development?

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***

Sure. I think the answer to the question, Randall, is this, we've worked very hard for a long period of time to ensure that we were not a binary risk story, that we were not a story built on one regulatory or commercial card being overturned, that we had a combination and a flow of commercial business, which we do, of opportunities in the pipeline at different stages of development, which we do. And the ability then to on each of the individual performance platforms or segments of our business, whether its value creation, the development of products or the acquisition of products; value delivery, the ability to make and supply those products to the market; or value realization, the commercial platform that can extract value for therapeutics that we develop or acquire, we wanted to be able to put those pieces together.

I think if you look at where we are right now, we're executing against that strategy. We have products in the market that generate revenue. We've got near- and longer-term products in the pipeline that are of greater value than even the ones we've delivered up to this point. And we have a commercial platform as planned with a introductory product and a larger, more valuable complimentary product coming behind it. That's what -- that's the strategy we're pursuing. And we're going to continue to do that.

We understand that capital is an important element. We understand that things with -- that our company has to react to what happens around us, whether it's the COVID pandemic and the impact that has on the capital markets, or it is an FDA decision about a potentially competitive product and we react against that. But we're a company that has always had options for itself. And we've demonstrated that

by extending the capital horizon with the cash we have right now. And having the opportunity, at least the immediate opportunity of monetizing a substantial royalty stream. If you look into our portfolio, there's another potential royalty stream brewing behind that in our relationship with KemPharm. So we have capital options even in the face of sometimes difficult equity capital markets. That's the strategy that we're pursuing. And frankly, I think we've delivered on that up to this point.

Operator
Our next question comes from Liana Moussatos from Wedbush Securities.

Vasiliana Vireen Moussatos ***Wedbush Securities Inc., Research Division - MD of Equity Research***
I have 4 about income from apomorphine. Is the $4 million milestone part of the $35 million to $45 million revenue guidance? Or will it be part of the monetization? And what sales presumptions underlie the $50 million to $100 million expected monetization range? And the cash runway well into 2021, is that based on $50 million out of that?

John T. Maxwell ***Aquestive Therapeutics, Inc. - Senior VP & CFO***
Yes. So let me tackle those one at a time. The $4 million milestone is in our Q4 number. So it is part of the $35 million to $45 million estimate. That will happen -- that payment will occur either 6 months after approval or when they launch the product, whichever is earlier. The sales or the net sales that we use to predict the value of the asset were determined in a few different ways, but primarily with a study that we did with [LEK] that looked extensively and deeply at the market, the competition, the physician's environment, and really a complete bottoms-up view of that potential market size. We then measured that analysis against what Sunovion or the Sunovion parent company, DSP, is saying, which I believe they're in the $500 million peak revenue range, somewhere like that. You could look that up. But -- and then there are analysts that go up to $1 billion, although we're not assuming in our own thought process that.

So we've taken what we think is a reasonable view and a very thorough and thought-out view of the market. And that's how we came up with the royalties that we would be paid. And then, you discount that, that's how we get to our number. How much money we take out of that, the $50 million to $100 million is really going to be dependent upon the structure and how we do the deal. So we -- it may not be that we sell the entire asset, we may only sell part of the asset.

Vasiliana Vireen Moussatos ***Wedbush Securities Inc., Research Division - MD of Equity Research***
And cash runway is based on $50 million or another number?

John T. Maxwell ***Aquestive Therapeutics, Inc. - Senior VP & CFO***
No. The cash runway, when you think about the cash runway to 2020, that does not depend -- that does not depend upon apomorphine at all. Soâ€¦

Vasiliana Vireen Moussatos ***Wedbush Securities Inc., Research Division - MD of Equity Research***
What about well into -- yes, well into 2021?

John T. Maxwell ***Aquestive Therapeutics, Inc. - Senior VP & CFO***
Yes, yes, yes, well into 2021 or possibly beyond includes a moderate view. So sort of think of it as a haircut view of what we think the potential value of the asset is and how much we would take out. So we've not assumed that we take the entire asset out in our thought process, that gets us to that number.

Vasiliana Vireen Moussatos ***Wedbush Securities Inc., Research Division - MD of Equity Research***
Okay, so closer to $50 million.

John T. Maxwell ***Aquestive Therapeutics, Inc. - Senior VP & CFO***
Yes, I won't give you a specific number. And we will update the market once we have a view of what kind of structure of a deal that we want to do. We're going to do a deal in the market that we think represents the best economics for Aquestive. That could be a partial sale, it could be a pharma bond, it also could be an outright complete sale. It really depends on discount rates and the overall view of the market in terms of what we think it would build.

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***
Liana, this is Keith, just amplifying John's comment because you keep pushing around the quantum. We took the range of value that was given to us by the folks who are working with us around this, plus the independent view that the LEK study represented. We hair cut that and looked at that number as the starting point for our comments around being able to get well into 2021 or into 2022, potentially.

Operator
Our next question comes from Jason Butler from JMP Securities.

Jason Nicholas Butler ***JMP Securities LLC, Research Division - MD and Senior Research Analyst***
Couple for me. First, on Libervant. In your dialogue with FDA have you had any discussion around a preapproval manufacturing inspection and how FDA is thinking about that in light of COVID?

And then the second one. Just in terms of the virtual education and marketing strategies that you're thinking about for SYMPAZAN right now, how are you thinking longer term about how those tools could remain useful as you think forward to the Libervant launch?

Daniel Barber ***Aquestive Therapeutics, Inc. - Senior VP & COO***
Good morning, Jason. This is Dan again. Nice to hear your voice. On the FDA side, we have not had a specific interaction with the FDA, discussing a PAI or a preapproval inspection. However, the FDA has given guidance to industry. And that guidance does talk about you inspection history and how they will handle audits both internationally and in the U.S. So we are confident based on our audit history in our existing commercial products that we do not require a PAI during the COVID-19 era prior to launching our product. And we also do not believe that we have any international risk from any of our suppliers based on the suppliers who we've used for the product in the filing.

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***

Yes, Jason, I'm sorry. I wanted to make sure you weren't going to follow up with Dan before I jumped in on the other part of the question. So, look, we're all learning how -- I think every one of us is learning how to use technology in a way we hadn't 2 months ago. We've all had our share of dogs being introduced into conference calls and kids pulling the plugs out while a video call is going on. We have -- the truth of the matter for us is that different parts of the country are behaving very differently. We still have some small number of our sales force that are able to make face-to-face visits. And as people start -- as parts of the country start reopening, doctors are seeing new patients and doing well-care visits. We expect more of our sales force to be able to resume face-to-face. Be that as it may, we have discovered that some of the tools available to us technologically are very useful. And it is causing us to think about what sales deployment might look like and how we might be able to use a combination of those tools in our face-to-face opportunity to not only drive sales for SYMPAZAN, but to help accelerate the curve, the slope of the curve on the launch of Libervant. What those are specifically, we've not yet laid out, but we'll certainly talk about them as we do.

Operator

Our next question comes from Thomas Flaten from Lake Street Capital.

Thomas Flaten ***Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst***

Just a follow-up on the field question. In advance of the Libervant launch, do you expect any significant field force changes, territory realignments, anything like that? Upsizing of the field force. Or are you happy with the current deployment to support the initial launch of the product?

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***

Well, we are going to absolutely grow the field sales force substantially for the launch of Libervant. I think we'll determine how far in advance. We'll make a determination based on our confidence on the outcome of September 27, when to start that build. If the prudent thing to do is wait until after we have absolute conformation that the market is available to us, we will build the sales force very quickly after that. If we're confident going into that, based on the interactions we're able to have, if we're able to have the interactions with the agency, then we'll build in advance of that. Libervant as a launched product will represent a significantly larger sales force than we have now. And I would assume based on that, yes, there will be a realignment of territories and a redistribution of regions and distribution of accountabilities around Libervant and SYMPAZAN revenue targets.

Thomas Flaten ***Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst***

Switching over to epinephrine, could you provide any additional color around what you anticipate that PK study will look like and any additional studies beyond that, that you preliminarily discussed with FDA?

Daniel Barber ***Aquestive Therapeutics, Inc. - Senior VP & COO***

Sure. So as we've discussed before -- and thank you, Thomas, this is Dan again. We will be in the clinic again in the fall in a fairly standard PK study where we will compare our product against approved epinephrine products. And the PK data we'll collect will be the typical Cmax that you see, the Tmax, as

well as we also will have some blood pressure data, things like that. Once we have completed that initial PK study, we will look to ramp up to what would be typically called a true pivotal PK study, which we, the time gap between this first study and the second study will be fairly tight, we believe. In between those studies we will most likely go back to the FDA and have a conversation and ensure we are on course for the expectations we believe we heard in the pre-IND meeting.

Thomas Flaten ***Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst***
Great. And then just one final one. Regarding -- you had a -- obviously you have a fair bit of time of -- with experience of SYMPAZAN in the market. Could you share anything qualitatively around the patient experience, average time on treatment, treatment success with the first few doses and anything? I'm just curious to hear what you guys are hearing from prescribing docs.

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***
Sure. This may be a technological feat, but let's try it anyway. Ken, are you there?

Kenneth W. Marshall ***Aquestive Therapeutics, Inc. - Senior VP & Chief Commercial Officer***
Yes, I'm here, Keith.

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***
You want to take that?

Kenneth W. Marshall ***Aquestive Therapeutics, Inc. - Senior VP & Chief Commercial Officer***
Yes, sure, absolutely. Yes, we've had actually very positive feedback from physicians. As Keith noted in his remarks, we've seen a substantial growth in our prescriber base. To-date we just crossed over around 550. And if you look at those physicians, about 77% of them have written multiple times. It's a little challenging to define the absolute number of prescriptions for patients since these are schedule meds, and a lot of times they have to repeatedly come through as NRxs. But the qualitative feedback is very strong. If you look at historic analogs where you can dig into patient data, you would expect maybe 8 to 10 months on a patient. We have every reason to believe we're getting at least that with SYMPAZAN. And then qualitatively, the value proposition holds up the ability to deliver a consistent. So those seems to be ringing true with a lot of the physicians.

Operator
(Operator Instructions) I show our next question comes from Raghuram Selvaraju from H.C. Wainwright.

Blair Cohen ***H.C. Wainwright & Co, LLC, Research Division - Associate***

This is Blair Cohen] on for Ram. Just a couple of questions for you. First, what has been your worst challenge to cope with COVID-19 pandemic? And how quickly do you anticipate getting back up to speed?

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***

This is Keith. I think the worst challenge is for a lot of old people to figure out how to deal with so much technology so fast in order to be able to continue to communicate. The serious answer is this is a company built on collaboration. It's a company built on interaction, and not being able to see each other sitting in room together has been a challenge. But we have used the technology available to us to be able to continue to do that. We were a very planful and thoughtful company about very quickly making sure we protected the essential parts of our business, the R&D work to support -- to support the products in development, and the manufacturing facilities to support the production. We've approached all of this from the #1 principle that it is absolutely imperative that we protect our colleagues, their families, the people they interact with and the people who interact with our therapeutic products, right. So making sure that we took those steps early and we took those steps decisively I think has allowed us to continue to operate as well as we possibly can up to this point. At this point in time, virtually all of our sales people are interacting with prescribers virtually. No one is working in our offices other than the lab folks here in New Jersey and the manufacturing folks in Indiana, so that we are protecting everybody in the organization.

Blair Cohen ***H.C. Wainwright & Co, LLC, Research Division - Associate***

Okay, great. And do you think the demand for Suboxone has been affected by COVID-19?

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***

Suboxone. Suboxone volume is doing pretty well, I think, at this point in time. Whether or not the inability for doctors to see new potential patients for Sublocade, as Indivior has spoken about, has an impact on the Suboxone volume I think remains to be seen. It's a little early to understand that. But Suboxone, at least according to our projections for the year, is performing at the level we expect in the first quarter. And we've got a good order book for the second quarter, as John said.

Blair Cohen ***H.C. Wainwright & Co, LLC, Research Division - Associate***

Okay, and just lastly. And forgive me if you've already answered this, but do you still expect on-time approval for sublingual apomorphine?

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***

We still expect apomorphine and Sunovion to get an approval in May. I forget what the exact date is.

John T. Maxwell ***Aquestive Therapeutics, Inc. - Senior VP & CFO***

May 21.

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***

May 21. Thank you, John. We still expect that. And as we've said repeatedly in the comments today and leading up to today, we've begun the process of monetizing that royalty stream. And once it is approved, we'll -- in a transaction or series of transactions based on the market condition, structure and timing, monetize those royalties.

Operator

Thank you. I show no further questions in the queue. At this time I would like to turn the call over to Keith Kendall, President and CEO, for closing remarks.

Keith J. Kendall ***Aquestive Therapeutics, Inc. - CEO, President & Director***

Well, thank you every one for your continued interest in Aquestive. Thank you for taking the time to join us this morning. Thank you for your questions. And we look forward to keeping you up-to-date on the progress on the key value drivers for the company. Have a great day. And we look forward to talking to you again soon.

Operator

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