Cantor Fireside Chat

Analyst Josh Schimmer with Alpha Cognition CEO Michael McFadden

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Josh Schimmer:

All right. I'm Josh Schimmer from the Cantor Biotech Equity Research Team, we're kicking off our final day of our Global Healthcare Conference. Very pleased to introduce Michael McFadden, Chief Executive Officer of Alpha Cognition, a very unique company. A company that is actually launching a drug for Alzheimer's. I'm not sure most investors appreciate just how much progress you've made at the company. So, Michael, give us a quick snapshot of Alpha Cognition and where you're in the launch of ZUNVEYL.

Michael McFadden:

Yes, so Alpha Cognition is a company focused on neurodegenerative diseases. As you mentioned, we have an approved product for mild to moderate Alzheimer's disease, the product, ZUNVEYL. It's a product that's used to treat the symptomatology of disease, so a utility drug that has the potential to be used in most patients that are diagnosed with disease.

Josh Schimmer:

So, we have plenty of generic acetylcholinesterase inhibitors to treat Alzheimer's now. Why is there an unmet need in this space?

Michael McFadden:

It's a great question. The drugs that are available today, most practitioners would say are very difficult to use. They're difficult to dose, they're difficult for patients to tolerate, and the discontinuation rates for every drug in the class are above 50%. So, it's a very challenging class with low position expectations in the market. The tolerability issues are pronounced, diarrhea, nausea, vomiting, insomnia. The long-term utility drugs are diminished specifically with the donepezil, the leading compound that's used. So, expectations are fairly low in the class, and that's the opportunity for a disruptive drug, which we believe ZUNVEYL is.

Josh Schimmer:

Okay. And so how have you been able to address the tolerability issues of ZUNVEYL?

Michael McFadden:

Yes, so we talk about the design of our drug. It's very unique actually for any drug that's been approved for Alzheimer's disease, in that our drug has been designed to bypass active drug release in the GI tract and the small intestine where acetylcholine receptors reside. We believe this is an issue because the triggering of active drug release through the GI tract leads to GI side effects. Our drug remains inert in the GI tract and small intestine, and we have shown to date, minimization of those side effects.

Josh Schimmer:

And how do you also minimize insomnia with that approach?

Michael McFadden:

So, our drug actually has 0% insomnia in our label, that's primarily due to the alpha-seven nicotinic modulation that our drug has, which is different from donepezil or ravastigmine, the other drug used in the class. Zunveyl has an effect on GABA and glutamate, both of which are a sleep additive or can improve sleep.

Josh Schimmer:

Okay, and was that the rationale for choosing a prodrug approach of galantamine specifically?

Michael McFadden:

Partially. The other reason we chose galantamine alpha-seven nicotinic modulation is really unique in the treatment of Alzheimer's disease and other neurodegenerative diseases. And the fact that it reduces inflammation in the brain, which is a marker for Alzheimer's disease and other brain disorders, it stimulates the cholinergic pathway, which is central to improvement in Alzheimer's disease or restoring cognitive function, restoring ability to process thought. And the downstream effect on glutamate is really important for Alzheimer's disease and that affects the behaviors that commonly occur for up to 90% of patients with disease.

Josh Schimmer:

Now, given the trial design to approval, which was primarily bioequivalence and GI tolerability, you didn't run a head-to-head against one of the generic acetylcholinesterase inhibitors. I guess given the package insert and profile, give us a sense of how it resonates with practitioners on first glance.

Michael McFadden:

Yes. So, it's been beneficial actually, because in most new drugs practitioners, especially in long-term care, which is where we've launched the drug, have residents to use new compounds. They're nervous about safety or toxicity or how the drug will perform. We actually can benefit from using the galantamine data with over 20 years of studies from an efficacy perspective. So, practitioners appreciate the fact that they've got a drug that has been used for a long period of time and provides some predictability. And then we talk about the design of the drug for GI and the fact that our MOA of our drug demonstrates no insomnia, that's resonated with them.

Josh Schimmer:

So, you mentioned launching into long-term care facilities. Tell us about your commercial strategy and why you've started to focus there.

Michael McFadden:

So, we focused on long-term care, primarily because it's a highly concentrated market for Alzheimer's disease. Number two, it has the lowest payer barriers or restrictions for that patient population. And three, it's a market that we know really well, both from a practitioner, the nursing home perspective, and pharmacy perspective.

Josh Schimmer:

Okay, and then size of the sales force and how you're deploying them relative to the number of how many long-term care facilities there are to target.

Michael McFadden:

Yes, so we have about 40 salespeople in the field. We have 45 customer facing people in the field. The market is a 15,000-nursing home market in the US. We're targeting about 4,000 of those homes. Those are the large homes with high numbers of Alzheimer's patients, which makes sense. And we call on the nursing home itself, we call on the medical director who treats and manages care for the patient, and we call on the psychiatrist who manages behavior with Alzheimer's Disease when those occur with the patients.

Josh Schimmer:

And then, so roughly how many patients are you able to reach with that approach?

Michael McFadden:

Each home has about 70% of resident care with a diagnosis of Alzheimer's disease. So, we're reaching about 80% of the market opportunity with our strategy.

Josh Schimmer:

Okay, and so you'd mentioned this demographic has the lowest barriers to commercial access. Maybe you'll elaborate a little bit on how drug reimbursement does work in a long-term care facility.

Michael McFadden:

So, most of the patients in a long-term care facility are low-income subsidy patients, or they're otherwise known as Medi-Medi, Medicare Medicaid patients. The impact for a company like ours that those patients have limited/no copay and their care is managed by the treatment team. So, if the doctor writes the drug and they work through the prior authorization process that has been set by the health plan or the PBM, approximately 90% of the time the patient receives the medicine (if use is aligned with the health plan or PBM requirement). So, this strategy minimizes walk away at the counter, minimize co-pay or co-sharing that some patients would have in a retail market. It makes the market opportunity really one of care and appropriate use, and a practitioner's willingness to complete the prior authorization criteria that's set for most new branded drugs.

Josh Schimmer:

So, are there formularies you need to be on either at the long-term care facility or at the plan level?

Michael McFadden:

No, no formularies. So, it's a Medicare Part D plan that we're under which is managed by the health plan or PBM. So, if we're covered on Medicare, patients and doctors have access to the product (although the product can be prior authorized or have a step-edit in place).

Josh Schimmer:

Okay, excellent. And how have you decided to price the product?

Michael McFadden:

Yes, so we're priced at $820 per month WAC, so sub $10,000 per year.

Josh Schimmer:

You gave us a sense of who at the long-term care facilities you're targeting or have to connect with. Talk to us a little bit about that sales cycle. Do you need to get everyone on board? How long does it take? How many iterations are you finding the sales force requiring to get traction?

Michael McFadden:

It is a longer sales cycle. So the practitioner, the medical director, the director of nursing, and the pharmacy all need to be aligned that this is an appropriate product to be used in the patient. That process, as you can imagine when you're trying to align three people, takes a bit longer. The positive is that is once they use the product, the concentration of patients in a home is very high. And this is a drug that has potential applicability across wide ranges of patients in the home, so the depth (of patient use) can increase once the doctor begins to use it and get experience. But it typically takes several cycles of trial for the doctor to feel comfortable with the drug, and those cycles in this particular therapeutic area take about six to nine months of time (because the drug is titrated and it takes time to move to the therapeutic dose of 10mg BID).

Josh Schimmer:

Okay, so but your launch is underway, you've started to post some revenue.

Michael McFadden:

Yes.

Josh Schimmer:

So, where is the early success happening? And if you are finding any pockets of resistance, where and why?

Michael McFadden:

The message has been received, actually much better than we anticipated it would be. Physicians have shared very low barriers on tolerability and insomnia. Efficacy data is compelling for the doctors to consider. And we've also seen a real interest in the behavioral impact that this drug could have for behaviors that are associated with Alzheimer's disease. So from a messaging standpoint, high receptivity.

The doctors want to try the drug and we're seeing what we expected to see. The doctors are trying it on two to three patients, watching those patients, managing the patient outcomes to see how they do. They'll probably try this process again with a larger set of patients, say six to 10 patients. And we believe, and our experience shows, once they have that second trial of patients, they begin to look at the drug and how they're going to use it as a routine choice for their treatment of Alzheimer's disease.

We have over 300 nursing homes that have a prescription for ZUNVEYL, and about 20% of our doctors within one to two call points have written a prescription for ZUNVEYL. So, that's a little bit above what we expected and we expect to see those numbers grow over the coming quarter.

Josh Schimmer:

What were the trends over the first quarter? I think you posted a little under two million in your first quarter. So, was there any lumpiness to it? And obviously without too much granularity and quantification, maybe you can qualify how you envision the launch going and whether you see certain inflection points to accelerate.

Michael McFadden:

Yes, it is lumpy, it will be lumpy for the remainder of the year as doctors are trying initial patients on drug. We've framed this launch revenue curve as a hockey stick type of launch curve. So, expect modest sales in 2025 as doctors are trialing Zunveyl, monitoring the patients, getting feedback from the facility. After that occurs with that second group of initial trial patients, we anticipate the revenues will accelerate rapidly (if physicians see positive efficacy with minimal adverse events). We've seen that in other launches in this therapeutic segment, and this is playing out just as we've seen in the past.

Josh Schimmer:

Is it too soon to have any real world feedback, in terms of the tolerability profile?

Michael McFadden:

The feedback actually has been beyond our internal expectations. We have over 1,000 patients on drug. We've had two patients reporting GI, so that's far below what we anticipated. We've had 0% of patients reporting insomnia, we're not surprised by that. We have 0% insomnia in label, but it's according to label. And the feedback on behaviors is far above what we anticipated we would see. The company is not saying that there are not more adverse events, but just responding to what we have seen reported. So, we have had many dozens of reports of patients exhibiting aberrant motor behavior, agitation, anxiety, which are three of the common behaviors seen with Alzheimer's disease, respond well within first months of therapy.

Josh Schimmer:

So, you're a small company and a Canadian company. Thank you, tackling a very, very large patient population in the US. And you've decided to go alone, at least for the time being. What prompted that decision and what considerations do you have for a potential strategic partner to support?

Michael McFadden:

We decided to go alone for several reasons. Number one, our team has over 30 launches in the US market, about half of which we have experience in long-term care and/or CNS. So, we felt very comfortable in our ability to launch and execute a US commercial launch in this category. Number two, the long-term care market allows a lot of efficiencies. It's a highly concentrated market. One can launch into that market with a very small sales force, which lowers the resource needs for the company. I think those things allowed us to do it by ourselves. We do have future plans to launch into neurology, which represents another $1.5 billion opportunity for the company, and we'll evaluate whether we choose to do that by ourselves or we partner.

Josh Schimmer:

So, obviously your revenue and expenses will kind of guide timing for when you may consider a launch into neurology. So, maybe you can frame for us your cash position, your burn, and how that aligns with the launch trajectory.

Michael McFadden:

We have approximately 38 million in cash. We just shared that we will burn about 34 to 38 million over the coming 12 months. And with revenues ramping and accelerating next year, we actually believe we have enough cash to achieve profitability for the asset. We have additionally business development milestones that will add to the cash position this year. And we have a number of warrants that will be exercised all in the money, there'll be exercised over the coming 12 months, so we'll also add to cash position.

Josh Schimmer:

How much would that add?

Michael McFadden:

It could range from five to 15 million.

Josh Schimmer:

Okay. How has your confidence in the ability to get to profitability with your existing resources changed with some of the early launch metrics that you've seen?

Michael McFadden:

We're on track with early launch metrics, so we'll be looking for the inflection point in early 2026. Should that occur, we'll be on track to move to profitability in 2027.

Josh Schimmer:

Got it. And I would imagine your preferred use of capital would be a larger sales force, Yes?

Michael McFadden:

Yes, larger sales force marketing to the geriatric psychiatry community, and building upon the medical data that we know will be needed to support the product long-term. Specifically in behaviors with psychiatry, that we're looking for additional data there.

Josh Schimmer:

And how are you thinking about the rest-of-world commercial strategy?

Michael McFadden:

We've partnered in Asia, specifically China and other Asian countries with a company called CMS Pharma. They are petitioning the Chinese regulatory authorities for Zunveyl approval. And we plan to submit in four countries before end of year for marketing approval. They (CMS Pharma) have a 20-year experience in history in the Chinese market, been a great partner so far. So, Asia is covered. We have other deals that we could execute over the coming 12 months. We've made a decision as a company to

pause those to understand better some of the Trump Administration's initiatives on pricing and how that will affect the company.

Josh Schimmer:

Do you expect, ultimately, I mean, I would imagine you've got such a differentiated product for such an underserved patient population, that Ex-US over time should be very important for the product?

Michael McFadden:

It is, it's a great question, it is important. Each market opportunity, if you think Europe, Asia, Latin, South America, are equally as large as the United States in terms of Alzheimer's patient population. Obviously, pricing is different today, but they represent significant opportunity for the company.

Josh Schimmer:

So, you're developing a sublingual version as well? What's the rationale behind that and what are the timelines?

Michael McFadden:

Yes, so that's underway. We anticipate a PK study with that sublingual in Q1 2026. The company is working on tasting and formulation this quarter and next quarter with that asset. And we should have data to submit to FDA for an IND for Alzheimer's disease mid part of 2026. We also believe we'll be able to submit an IND for a condition called cognitive impairment with mild traumatic brain injury, by the end of 2026 for that asset as well.

The rationale for Alzheimer's disease with a sublingual (formulation) is 20% of patients with mild to moderate Alzheimer's disease have dysphagia or aphasia. They cannot swallow or they have difficulty swallowing. Their options for therapy today are either a patch that is put on their torso or their arms in a different location every day, very difficult to administer. Or the patients medication has to be crushed and mixed with applesauce or some type of juice and administered to them by a healthcare provider. With improved administration, we believe the sublingual has the opportunity to take over that portion of the market if it's ultimately approved.

Josh Schimmer:

And you said that the patch is difficult to wear. Why is that?

Michael McFadden:

It's difficult to wear, number one, because it's fairly large. Number two, it has to be put in a different location of the body each day. And so you can imagine elderly patients with skin issues, it's very challenging for those patients. When you pull a patch off, it has the potential to rip skin or cause skin irritation or tearing. Sometimes the patients are agitated when they're wearing the patch and they pull it off themselves. So there's a potential compliance issue for the patients. Additionally, you can't put the patch in the same location each day because there are red dots that appear after you remove the patch. So just aesthetically, these patients will have red dots all over their torso, all over their arms over the course of the month before it can be re-administered. So, it's quite challenging.

Josh Schimmer:

So, you have a program unlike any program I've heard of before, a Department of Defense Preclinical Bomb Blast Testing program. So, tell us what that was about.

Michael McFadden:

Yes, so that program was completed based on early work that we did with mild traumatic brain injury, preclinical work that demonstrated cognitive function, mobility improvements, and neurogenesis that ALPHA-1062 demonstrated in that study. The Department of Defense, one of their top five areas of focus is traumatic brain injury. And traumatic brain injury occurs in the military, either from bomb blast, or falls, or hitting of the head in some way. So we undertook with a grant, the Department of Defense, a bomb blast study. There's a model, it's a bomb blast model, and you replicate a bomb injury to an animal and then you have two groups, a placebo group and a drug group. The animal is treated to determine if there is an inflammation reduction, which ALPHA-1062 demonstrated. And to determine markers like Tau, multiple Tau markers to demonstrate reduction in inflammation. There are also several other markers that we looked at, all inflammatory markers, to determine if restoration of brain function or restoration of cognitive improvement to the animals in that study. And ALPHA-1062 demonstrated improvement in all markers.

Josh Schimmer:

So, I'm assuming that your primary resource is being deployed commercially and so for now, your R&D budget is probably fairly limited. But as your revenue profile changes, so is potentially your ability to explore new territory for ZUNVEYL. So, do you have other indications that you would consider looking to add to the label?

Michael McFadden:

Yes, we're really excited about the cognitive impairment with mild traumatic brain injury. That opportunity is a $13 billion opportunity. There's no approved drug. It (the disorder) affects our most productive population, the 26 to 50-year-old active working population in America. And the disorder is common to occur with auto accidents, violence, military, or athletics. We have demonstrated pre-clinically a statistical improvement on cognitive improvement with drug, mobility improvement with drug, with no toxicity, and then demonstrated brain repair or neurogenesis that occurred within 35 days of therapy. So, we believe we have a really interesting opportunity to potentially show cognitive improvement, which affects 50% of mild traumatic brain injury sufferers at three months to a year, and potentially have an opportunity there for regulatory advancement.

Josh Schimmer:

How are you thinking about the timelines, when you'll be in a position to explore that with clinical trials?

Michael McFadden:

So, we've completed 12 trials already that would lead to an IND. We've met with FDA in a pre-IND meeting. FDA has guided us that we need one additional Toxicity study. So we have a 12 week Toxicity study to complete with ALPHA-1062. And then we have what we believe will be sufficient to submit for an IND to advance that program.

We also have completed phase 1A and phase 1B with a different formulation of the same asset. So we believe the FDA could give us credit for our phase one program and we can move to a phase two efficacy trial.

Josh Schimmer:

What's the IP on the product?

Michael McFadden:

We have multiple patents on the product. A series of polymorph patents that have been approved by USPTO through 2042. We have a composition of matter patent on the tablet through 2044. And then we have an series of additional manufacturing, method of use, and other patents that protect the product in a range of 2029 to 2045.

Josh Schimmer:

So you said composition of matter beyond the polymorph, right?

Michael McFadden:

Correct.

Josh Schimmer:

What kind of composition of matter patent is it? Is it the molecule itself, or is it-

Michael McFadden:

It's the benzgalantamine molecule with the proprietary coating that we have that guides drug release at various pH levels with low adverse event profile. So, we had late stage novel and unexpected findings in our clinical work that allowed us to be able to file that patent.

Josh Schimmer:

So, tell us a little bit more about that formulation design, where it came from, and how it is as efficacious as it is.

Michael McFadden:

Yes. So the formulation, the history of the formulation, the lead scientist for the galantamine program, Alfred Maelicke, back in the day when galantamine loss patent exclusivity, took the molecule, which was poorly tolerated and used very seldom because of the tolerability issues. He modified the molecule in a lab in Germany and achieve partial success with the molecule via intranasal delivery. He then became terminally ill, sold the molecule to a predecessor company of ours, which they undertook seven years of trial work to advance the program and demonstrate no toxicity and a drug that actually works. They were successful, and then hired a formulation team to modify the molecule into the tablet formulation we have today. So, we have a multi-layered tablet formulation that is very unique in that it prevents active drug release where acetylcholine receptors lie throughout the GI tract, which minimizes some of the adverse events that have been derailing for previous galantamine compound.

Josh Schimmer:

Isn't that interesting?

Michael McFadden:

Yes.

Josh Schimmer:

Okay.

Michael McFadden:

So like many stories in this industry, this is a long story with multiple chapters.

Josh Schimmer:

And again, as your resources improve and increase with the product launch, are there other trials that you have in mind to help further differentiate the product?

Michael McFadden:

Yes, we're looking at two trials in the near term. One is a registry trial to look at and assess behaviors that occur with Alzheimer's disease. So, behaviors occur in 80 to 90% of Alzheimer's patient at any point in time in disease progression. These behaviors are aberrant motor behavior, agitation, anxiety and seven other behaviors that occur commonly with these patients. The behaviors can be derailing for the patient and for the family. We plan to assess patients in a nursing home environment to determine drug efficacy. So that's one trial we want to look at, which we think will give really good evidence for the practitioners who care for these patients in the long-term care facility. We think it also could be used with neurologists as we launch into neurology in several years.

And then we're looking at a sleep study for patients that have insomnia, which is common with the donepezil, and switching them to ZUNVEYL to determine if sleep quality and quantity improves. And so, we're evaluating our protocol on that particular study.

Josh Schimmer:

Maybe to close things out, what should we be watching for over the next 12 to 18 months from Alpha Cognition? Obviously the launch, probably by far the most important update, but what are the metrics around the launch we might be able to track?

Michael McFadden:

Yes, I think sales. This is a sales commercial story, so I would be looking at our sales reporting on a quarter to quarter basis. The KPIs that we think are really important to set the stage for success and long-term care or breadth and depth of nursing homes that are using product. There are 15,000 nursing homes, we're calling them 4,000. So I would be looking at a percentage of called on homes and the number of scripts per home. Number two, breadth and depth of prescribers, (HCPs, medical directors) that are managing the treatment for these patients. Those are the two key metrics I think that will set the stage for this to be a successful launch.

Josh Schimmer:

Does IQVIA capture the launch or no?

Michael McFadden:

IQVIA and Symphony captures data. I would say the data will be a little fuzzy for the first 12 months because they're using projection methodology, which is highly projected in the long-term care facilities. We'll see that normalized probably in the second quarter of 2026.

Josh Schimmer:

Michael, thank you so much for coming to share the Alpha Cognition story. We'll be keeping a close eye on the launch.

Michael McFadden:

My pleasure. Thank you.