

Q4 2008 Questcor Pharmaceuticals, Inc. Earnings Conference Call - Final

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OPERATOR: Good afternoon, ladies and gentlemen. Thank you for standing by. Welcome to the Questcor Q4 earnings conference call. During today's presentation, all parties will be in a listen-only mode. (Operator Instructions). As a reminder, this conference is being recorded today, Tuesday, February 24, 2009. I would now like to turn the conference over to Mr. Doug Sherk of EVC Group.

DOUG SHERK, IR, EVC GROUP INC.: Thank you, Operator, and good afternoon, everyone. Thank you for joining us today for the Questcor Pharmaceuticals' fourth-quarter and year-end results conference call.

This afternoon at market close, Questcor issued its fourth-quarter and year-end financial results. The release is posted on the Company's website at www.Questcor.com.

In addition, we have arranged for a taped replay of this call, which will be available approximately one hour after the call's conclusion and will remain available for seven days. The Operator will provide the replay instructions at the end of the call. This call is being broadcast live and an archived replay will also be available. To access the webcast, go to Questcor's website at www.Questcor.com.

Before we get started, I would like to remind you that during the course of this conference call, the Company will make projections about forward-looking statements regarding future events, including statements about the Company's forecasted operating model for 2009. We encourage you to review the Company's past and future filings with the SEC, including, without limitation, the Company's Forms 10-Q and 10-K, which identify the specific factors that may cause actual results or events to differ materially from those described in these forward-looking statements.

Finally, during the question-and-answer period today, we would like to request that each caller limit themselves to two questions and then re-queue to ask additional questions. In advance, we appreciate everyone's cooperation with this process.

With that, let me turn the call over to Don Bailey, President and Chief Executive Officer of Questcor Pharmaceuticals.

DON BAILEY, PRESIDENT, CEO, QUESTCOR PHARMACEUTICALS INC.: Thank you and good afternoon, everyone. Thank you for joining us today to review our business and financial accomplishments for 2008, as well as our plans for 2009.

With me today is Steve Cartt, our Executive Vice President of Corporate Development; Gary Sawka, our CFO; Dave Medeiros, our Senior Vice President of Pharmaceutical Operations; and Eldon Mayer, our Vice President of Sales and Marketing.

After our opening remarks, Steve will review key business trends, Gary will cover our financial highlights for the quarter and the year, and finally, I will address future milestones and financial questions -- guidance for 2009. We will then open the call for your questions.

2008 was a banner year for Questcor. It was the first full year executing our Acthar-centric business strategy. We achieved substantial growth in sales and identified new key markets for Acthar.

Today, we are executing a plan designed to systematically build shareholder value by investing in important medical research to demonstrate the value of Acthar and, therefore, expand the number of patients who can benefit from Acthar.

While we don't provide guidance on a quarterly basis, for the full year we exceeded the guidance we provided for 2008. For that full year of 2008, net sales were \$95 million, almost double our net sales of 2007. And earnings per share were \$0.49 a share.

In addition, we generated approximately \$64 million in cash from operations. While over 75% of our sales during this year were to supply Acthar to patients with infantile spasms, we substantially grew sales of Acthar to treat multiple sclerosis flares. In addition, we have identified nephrotic syndrome as a third market for Acthar. If our initial trials show that Acthar is effective in treating nephrotic syndrome, this could be a significant growth engine for us in 2010.

We plan to continue this Acthar mining strategy and intend to select at least one additional disease area for exploratory clinical work with Acthar during 2009. In doing this, we would be looking for a fourth market focus for Acthar, adding to our existing triad of markets, IS, MS, and nephrotic syndrome.

Steve will go through these areas of market focus in more detail. But I'd like to provide some highlights for each.

In the IS market, Acthar continues to be prescribed by physicians across the country with very good results. While shipments in November and December were lower than our historical average, shipments since then have rebounded and are now trending above average for the first two months of 2009.

As discussed on previous calls, such month-to-month variation has been the norm, historically. And we believe this is principally due to the very low incidence of infantile spasm. A relatively small number of cases can create meaningful fluctuations in sales.

The usage in the IS market occurs without any selling or marketing activity on our part. Despite the extensive usage in the IS market, Acthar is not currently approved for IS.

However, we are pursuing approval from the FDA of an IS indication for Acthar. We have been working with the FDA to complete our submission of our supplemental new drug application, or sNDA, and continue to do so. The process has taken longer than we expected, due to the original format of some of the data and the overall complexity of our submission. We will keep you apprised of any milestone accomplishments regarding this effort.

A key part of our strategy is to continue to build our sales effort in the MS market. During the third and fourth quarters of 2008, we expanded our sales force into the MS market. As a result, sales increased. For example, in the fourth quarter, MS sales grew to over 20% of Questcor's net sales.

The treatment of MS flares is one of the numerous labeled indications for Acthar. We believe that the long-term market opportunity for use in this condition is considerably larger than the market potential in IS.

Because of the success in late 2008, earlier this year, we announced plans to increase our sales force from 15 to 30 sales representatives. This ramp-up will be somewhat disruptive to our sales momentum in the short run. Sales territories are being realigned around our new hires, the new sales reps are being trained, and in many cases, target doctors are being transferred to these new sales reps. We expect to regain momentum as the year progresses and the new reps become as effective as the existing sales force.

A key element of our growth strategy is to identify additional fruitful markets for Acthar, preferably ones for which Acthar is already an on-label indication. When we talked last with you in October, we discussed the opportunity for Acthar in the treatment of nephrotic syndrome, already an approved Acthar indication.

To build the foundation for a potential sales effort in nephrotic syndrome, we are funding a series of studies that will evaluate Acthar in treating this condition. Currently, there are few therapeutic alternatives for treating nephrotic syndrome.

Very importantly, recently, we have received a small number of patient -- a small number of prescriptions from nephrologists for the treatment of patients with nephrotic syndrome. While it is very early in our efforts in this new field, we are anxious to see how these few patients respond to Acthar.

Also, we will file the nephrotic syndrome trials and look forward to keeping you apprised of our progress.

Finally, over the course of the year, we strengthened our balance sheet significantly and committed \$46 million to build shareholder value through a preferred and common share buyback program. Our balance sheet is clean and strong, with over \$65 million in cash and no debt. And our ongoing business is nicely cashflow positive, even with the expanded investment in IS, MS, and nephrotic syndrome.

At this time, I would like to turn the call over to Steve Cartt.

STEVE CARTT, EVP CORPORATE DEVELOPMENT, QUESTCOR PHARMACEUTICALS INC.: Good afternoon, everyone. I'd like to begin by providing you with the competitive assessment of Acthar as a

treatment of infantile spasms. We realize that many of you have questions on this subject. At this time, there are many unknowns and many questions will likely remain, given that key variables are controlled by other parties, including decision makers at governmental agencies.

However, we can definitely tell you that, today, no drug is approved for the treatment of IS, including Acthar. However, based on guidelines published jointly by the American Academy of Neurology and the Child Neurology Society, and endorsed by the American Epilepsy Society, many physicians regularly choose to prescribe Acthar for their patients with IS.

We estimate that Acthar is used by pediatric neurologists for the treatment of infantile spasms in about 40% of all IS cases. It has been a mainstay in the treatment of IS for many years. Doctors continue to write prescriptions, payors continue to pay, and patients continue to derive significant benefit from Acthar.

Given decades of experience with both Acthar and the alternative treatments, as well as decades of published studies and review articles evaluating Acthar and these alternatives, child neurology experts continue to tell us that they view Acthar as a critically important product for the treatment of infantile spasms.

But why do they continue to do so? Let's allow the medical experts themselves to provide that answer. The IS treatment guidelines, as I mentioned earlier, which were published jointly by the American Academy of Neurology and the Child Neurology Society, and endorsed by the American Epilepsy Society, look at the available data for all IS treatment alternatives. Among other things, this pivotal paper gave ACTH, the primary pharmaceutical ingredient in Acthar, the highest rating of any IS treatment, based on an intensive, independent review of the published literature.

The paper represents the definitive guidelines endorsed by the top medical societies involved in the treatment of IS. Combined with their own practice experience, many doctors use these guidelines as the rationale behind their decision to so frequently choose Acthar for their patients with infantile spasms.

The top experts who wrote the IS treatment guidelines and, more recently, the FDA as well have focused on one particularly well-designed and well-documented randomized controlled trial for Acthar that was conducted by highly reputable independent researchers. This trial compared Acthar with oral prednisone in the treatment of IS.

The study found an 87% efficacy rate for Acthar and a 29% efficacy rate for prednisone. Efficacy was measured in terms of not only stopping the spasms, but also, importantly, resolving the underlying irregular EEG pattern, or hips arrhythmia, that commonly accompanies IS. If not addressed, hips arrhythmia is believed to be responsible for much of the damage in patients with IS.

The study, as I mentioned, found a dramatic effect in terms of stopping the spasms as well as resolving the hips arrhythmia. This study was considered highly statistically significant in favor of Acthar. In no other study, looking at these two critical treatment endpoints, has any drug been found to be as effective for IS.

It is also important to note that Acthar is a very potent drug, necessary for treating such a devastating disorder such as IS, and as such, can cause side effects, most commonly hypertension, weight gain, and irritability in the children that are treated with it. However, and very importantly, these side effects are fully reversible upon completion of treatment, which for Acthar only typically lasts from 4 to 6 weeks.

I hope that this gives all of you a better feel for how we, and also many child neurologists, view Acthar's place in the treatment of infantile spasms.

Now let's move on to our efforts in the MS market. We are pleased with the results of the test sales effort that we conducted in the third and fourth quarters of 2008. During this time, the number of new prescriptions shipped to MS patients rose steadily.

In the fourth quarter, we saw a greater than 50% increase in estimated vials shipped for use in MS patients, compared to the third quarter. This was due to an increase in new prescriptions, coupled with a higher rate of refill prescriptions than we expected. The increased usage in MS, combined with the significantly lower level of Medicaid usage among MS patients compared to IS patients, resulted in over 20% of fourth-quarter Acthar net revenues being attributable to the MS market.

As you know, we are currently in the process of expanding our sales team to 30 representatives in order to build on our success to date. We expect to have all 30 territories reconfigured and all new representatives hired and transitioned into their new territories, as well as fully trained, by the end of March. They will begin making sales calls at the very beginning of April.

As part of this restructuring, some of our top representatives have moved into sales management positions, requiring their territories to be backfilled by new hires. And some of our other salespeople are involved with

training the new hires. As a result, it is important for our investors to understand that the first quarter of 2009 is truly a transition quarter for our sales force and will largely be focused on the creation of new sales territories and the hiring and training of the new representatives.

Realistically, we do expect there to be some disruption in our sales momentum for MS during the first quarter of 2009. But, as Don mentioned, we also expect our new sales representatives to be fully productive within a six- to nine-month timeframe from their hire date, and as such, we believe we should expect to see the full sales impact from this most recent expansion later this year.

Depending on the uptake of Acthar in the MS market during the course of the year, and the possible approval and launch of the IS indication, we may consider an additional phase of expansion to approximately 40 representatives sometime in the second half of this year.

Now I think it's important to touch a bit on our patient support programs for Acthar. Our reimbursement support team continues to be very effective. We routinely get Acthar approved for insurance coverage in over 95% of IS cases. In addition, due to the significant patient assistance programs that we sponsor, we continue to be pleased to report that, to our knowledge, no patient in need of Acthar has been denied access to drug.

In fact, since the program's inception in September of 2007, the Acthar patient assistance program, which is operated by NORD, has provided free drug with commercial value of over \$20 million to uninsured and underinsured patients. Additional financial support is also provided to patients through NORD's co-pay assistance program that we sponsor.

Beyond supporting patient assistance programs, we are now also actively supporting the medical and patient communities in other important ways. We have recently accelerated our support of important new medical research in IS, MS, nephrotic syndrome, and other therapeutic areas, and expect to fund more than a dozen clinical and preclinical studies over the course of 2009. Such research is intended to better understand these disease states and Acthar's role in treatment.

Let's take a moment to briefly focus on one of these areas, nephrotic syndrome. Nephrotic syndrome is a condition which can result from a number of different disease states, such as diabetes and membranous nephropathy, where kidney function deteriorates, causing the patient to lose large amounts of protein from the kidneys into the urine. If not adequately treated, these patients will very often progress to kidney failure and dialysis, or, in some cases, will receive a kidney transplant.

Today, while there are assorted drug combinations that doctors will employ in attempt to slow the worsening of the condition, there is no well-established treatment for nephrotic syndrome. We are funding the first study evaluating Acthar in nephrotic syndrome and the first patients are expected to be enrolled shortly. Initial results of this first study are expected in the fourth quarter.

In addition to nephrotic syndrome, during 2009 we will continue to evaluate other potential new therapeutic applications, and by late 2009, we expect to have identified a fourth area of focus for Acthar. We look forward to keeping you apprised of our progress.

I will now take a moment to touch on QSC-001, our proprietary fast-melt formulation of hydrocodone plus acetaminophen for the treatment of moderate to moderately severe pain. During the fourth quarter of 2008, we completed formulation development of this product.

Ideally, the next step would be to conduct fairly costly, pivotal bioequivalent studies with the product. However, based on the intriguing growth opportunities that we have identified for Acthar over the last several months, as well as a changing regulatory environment for pain therapeutics, we have recently decided to fully focus our personnel and financial resources on Acthar and to seek a partner to complete development of the QSC-001 product.

We feel strongly that QSC-001 will have significant revenue potential if it were to be eventually granted FDA approval and marketed by a company with a pain-focused sales force. We also believe, just as strongly, that the numerous potential growth opportunities for Acthar take priority over QSC-001, with the allocation of Questcor's limited research and development and personnel resources.

Therefore, finding a partner for the QSC-001 project at this time would seem to be a prudent course to follow.

Now I like to turn the call over to Gary Sawka, our CFO, to review the financial highlights for the quarter and the year.

common shareholders for the fourth quarter was \$16.2 million, or \$0.24 per diluted common share. For the full year of 2008, net income to our common shareholders was \$35.3 million, or \$0.49 per diluted common share.

Of note, our gross margin was 93% and 92% for the quarter and year, respectively.

Our net income for the fourth quarter and full year included a onetime tax benefit of \$4.4 million and \$5.2 million, or \$0.06 and \$0.07 per diluted common share, respectively.

In addition, other ongoing tax benefits related to state income taxes and tax credits helped lower our tax rate for 2008. These state tax and credit items will also benefit us in 2009 and beyond.

As a result, our income tax expense for the fourth quarter and year ended December 31, 2008, was \$1.5 million and \$18.2 million, respectively. And our fourth quarter effective tax rate for financial reporting purposes was only 9%.

Moving to the cash-flow statement, over the course of 2008, we generated over \$64 million in cash from operations. In returning value to our shareholders, we used approximately \$46 million to repurchase all outstanding Series A preferred shares, 3.5 million shares of common stock in open market transactions under our 7 million share repurchase program, and 4 million shares of common stock in directly negotiated transactions.

We continue to have 3.5 million shares remaining in our open market repurchase program, as there were no shares repurchased during the fourth quarter of 2008.

As a note, our short-term investments are comprised of high-quality credit instruments, including U.S. government agency securities and commercial paper.

At December 31, 2008, we had approximately 66 million shares -- common shares outstanding.

With that, I'd like to turn it back to Don to discuss our outlook for 2009.

DON BAILEY: We're almost ready for questions here. 2008 has been an extremely productive year for Questcor. In summary, for 2009, we expect to continue our momentum, generating incremental increases of Acthar sales. We expect to complete the filing of our sNDA for Acthar in IS in the near future and complete expansion of the sales force during this quarter as well.

We will continue to invest in important medical research through funding of at least 12 new clinical and preclinical studies, using Acthar to treat IS, MS, nephrotic syndrome, and other on-label disease areas with significant unmet medical needs.

In order to accomplish our aggressive growth plan, we expect to significantly increase operating expenses during 2009. However, our plan calls for sales and operating income to grow as well. We have provided some specific guidance where we can in our release earlier today.

This guidance includes a target overall gross margin of 92% to 94%; SG&A expenses, including all marketing expenses, of approximately \$32 million to \$34 million; R&D expenses in the neighborhood of \$11.5 million to \$12 million; non-cash 123(R) stock-based compensation expenses of approximately \$3 million to \$4 million; our income tax rate, for financial reporting purposes, we think will be in the 36% to 40% range.

Finally, we expect fully diluted weighted average shares of 69 million to 72 million shares, absent any further repurchases by using our stock repurchase program.

With that, I'd like to turn the call back to the Operator, and we're ready for questions.

OPERATOR: (Operator Instructions). John Newman, Oppenheimer & Co..

JOHN NEWMAN, ANALYST, OPPENHEIMER & CO.: Thanks for taking the question. I actually have a couple. First, could you talk about your expectations in terms of the percentage of sales that are going to go to Medicare rebates going forward? Also, do you have any plans to expand the share repurchase program for 2009? And in terms of the additional reps, will those be added immediately?

DON BAILEY: As far as our percent of Medicaid going forward, it's really difficult to predict, especially with the expansion of various government programs. CHIP has now been passed and we expect other -- the big bill that just passed Congress has some additional healthcare provisions in it. So it's a little difficult to predict.

Absent those things, we would think that the infantile spasm rate in the 30% area would continue. MS, the Medicaid rate is under 10%. And we're really just dealing with Medicaid here. Not so much Medicare. We get a little bit of Medicare, but not too much.

On a mix basis, as we grow sales of MS, which we expect sales for MS to grow this year with the expanded sales force, we expect IS sales to stay the same or probably go down some because of -- we do expect vigabatrin to get approved and take some -- take a little market share.

As far as expanding the share buyback program, we have 3.5 million shares left on the program. And we don't need to increase that right now. If we use the 3.5 million, I would say it's certainly possible we would expand it.

The reps have all been hired. Do you want to talk about that a little bit?

STEVE CARTT: We are expanding to 30 reps at the moment. We expect to have all of them on board and fully trained and hitting the streets the first week in April. And then, there could be a future expansion. We may go up to 40 but that would not be until late in the year.

That would depend on two things, either we do see some significant MS growth, as we expect, or that the IS approval comes and we're able to launch the new indication. So that's really contingent. Going back -- going up to the 40, the full 40, it's contingent on things that happen later in the year. But we are ramping up immediately to 30 and expect to have them in place shortly.

JOHN NEWMAN: Great. Thank you.

OPERATOR: Yale Jen, Maxim Group.

YALE JEN, ANALYST, MAXIM GROUP: Good afternoon and congratulations on the good start -- outcome this quarter. Two questions I have. The first one is for the nephrotic syndrome study, do you have any sort of insight in terms of what that trial design will look like, and what was anticipated that the outcomes [done] so far in terms of this clinical information?

STEVE CARTT: There will actually be a series of different studies done during the course of the year. And the studies right now are confidential, so we really can't talk about them in any detail. But we hope to have much more information available on them during the course of the year, probably the latter part of the year.

These are going to be smaller studies. We're talking in the range of a couple dozen patients, typically, and the cost for these is generally pretty low, in the half-million dollar range.

YALE JEN: And what would be -- was there a description in the label in terms of this specific indication, given this -- I mean, from the original sort of approval --

DON BAILEY: Yes. And this is -- I do want to remind all our listeners that this nephrotic syndrome is already on label. And the specific description is actually in the press release (multiple speakers). It's in the tagline of the press release about Questcor, and it's rather a mouthful so I won't read it. But it's in there for you to take a look at.

YALE JEN: Great. That's very helpful. And secondly, that in terms of your expand the sales force, that will be the second half of this year, and -- more likely when you think that this decision might be made?

STEVE CARTT: Realistically it's probably a fourth-quarter decision. But it could, depending on what happens, it could happen earlier. But again, it's really contingent on either an IS approval and launch later in the year, or if we see significant growth from MS that's sustained.

YALE JEN: Great. And the last one, then I get back to the queue, which is that for the IS supplement NDA applications that -- was there accelerated approval across in this? In other words, there may be additional four months before that to happen or there is a different timeline we should look for once the FDA accept the application?

DON BAILEY: Our understanding is that we will receive priority review, which is six months.

YALE JEN: Great. Thanks a lot.

OPERATOR: Wayne Moore, YX Funds.

WAYNE MOORE, ANALYST, YX FUNDS: Thanks for taking my call. I wanted to spend a little bit of time on your outlook. Given the -- kind of dramatic increase in SG&A year over year, and the required kind of increase in sales to kind of cover that, one of the lines in your 2009 outlook is that you expect, essentially, operating income to be in line with 2008. Can we get a little bit of specificity in that in terms of -- are we going to see it be completely flat? I mean -- right now, kind of the street estimates are for EPS to be up 33%. So flat versus '08 would be -- 33% below what the expectations were?

DON BAILEY: First of all, I'm not sure what street estimates you're looking at, but I don't think they show quite that dramatic an increase.

WAYNE MOORE: (multiple speakers) The first call is for '09 to be \$0.56?

DON BAILEY: We did \$0.49 this year, so -- .

WAYNE MOORE: Right, but a portion of that is lower income taxes (multiple speakers) which you need to take and then, effectively, you're at a 33% increase and earnings for first-call consensus.

DON BAILEY: You also have to add back in -- there's another \$0.07 you have to add back in from Q1. So the Q1 and Q4 add in, add back, kind of cancel. You may not be aware what happened in the Q1, but when we bought back the preferred shares, we had to take the payment in excess of the book value as a deemed dividend, which hurt our earnings almost to an equal amount with this tax benefit in the fourth quarter.

So, those two things really do offset each other, and the true earnings for the year are probably pretty darn close to \$0.49.

So we've had some success in the MS market. There's nothing to push IS sales up next year, absent an approval. And in fact, we could see some IS decrease. We just don't know what's going to happen here. So it's always easier to predict cost than to predict revenues.

But what we will try to do is manage to the operating income line and we've indicated in the release that we expect operating income to be up this year. We didn't say flat, we said up, by the way. So I can't really give you numbers. If we thought we had enough visibility to give you numbers, I would've done so.

WAYNE MOORE: Maybe we can talk about -- and this is one of the questions I asked previously and maybe I could get a little more detail on it, in terms of -- it sounds like the ramp-up in SG&A is going to be -- a higher ramp-up in Q1 and Q2 and then kind of flat line after that. Is that the right way to think about it, or will it be pro-rated over the rest of the year?

STEVE CARTT: Yes, we are obviously ramping up our sales force, so there's a significant uptick there in doubling the size, plus adding some sales managers, so I think that will be the general profile.

We're also initiating plans for an IS launch, but no spending for promotion will happen until the label comes through, hopefully later in the year. So I think, overall, that there will be an uptick generally in the first couple of quarters, and then things will kind of stabilize at that point.

DON BAILEY: Unfortunately, all we can do is give you what we know. And what we know is that we have a plan, and our whole operating expenses are up approximately \$18 million from a plan perspective year over year. We expect operating income to be up more than that. Whether it's up 1%, 10%, 30%, that's really very difficult to predict.

We've got an MS market that's quite large and untapped. We've got an infantile spasm market that's actually very mature, and there's lots of competitors in that market. So it's hard for us to predict what will happen and how quickly we can get traction in the MS market. So we want to give you all the facts we have. We think it's definitely worth the investment.

We will manage the operating income line as best we can, and if sales are not picking up and we think that the marketing and sales efforts aren't working, we will slow them down or decrease them. We're unemotional about what we have to do here, but we're very emotional about -- very optimistic about the outcome.

WAYNE MOORE: Let me ask one more question and I'll get back in the queue. You mentioned in the press release that kind of MS -- was roughly, I guess, \$5 million in sales during the quarter. And you also talk about kind of that increase. Can we expect that the price per vial that it's sold at MS matches what it's sold for the IS indication?

DON BAILEY: Yes.

WAYNE MOORE: And then, on a unit basis, I guess one of my questions is, for the fourth quarter of '08, then, because it's not exactly broken out and I'm trying to work the math. Just directly speaking about the IS indication, given \$5 million in MS sales, how much -- what was the resulting vials shipped for IS during the quarter?

DON BAILEY: I wish we could give you a precise answer but we don't have precise data. We get some data. There are 55 specialty pharmacies that order Acthar, and we only get information from six of them. So the other 50 or so, we do not get any diagnosis information.

We get a little bit from referrals that start with our reimbursement center, but we learn very little about refills that are going to these 50 specialty pharmacies. So any numbers we give you, you'll always see the word approximate.

That being said, probably at the net sales line, revenues is a pretty good surrogate for the number of vials. Since we had 1,510 vials and we had a little bit over 20% of our sales in MS, we can say there were approximately 300 vials for MS, and there were -- most of the remainder, of course, would be infantile spasm. We do have some vials in there for opsoclonus myoclonus, and some vials in there for assorted other prescriptions that we get.

OPERATOR: Kevin Tang, Tang Capital.

KEVIN TANG, ANALYST, TANG CAPITAL: Thanks, guys. Congrats on a good quarter. I just want to get clarity on the regulatory situation. Did you get a refusal to file on the NDA that you filed on December 2?

DON BAILEY: I'm not sure what a refusal to file is, but (multiple speakers)

KEVIN TANG: The FDA has 60 days, after you submit, to either accept or reject your filing for review and start the PDUFA timeline.

DON BAILEY: What the FDA indicated to us that they were unable to navigate through our file due to the nature of our submission, and asked us to reformat files. So we have been reformatting files since then and communicating with them frequently and regularly to find out exactly how they want this data package submitted. So that's what's been going on.

KEVIN TANG: I'll just call that a refusal to file. So when do you plan to resubmit and start the PDUFA clock?

DON BAILEY: We plan to submit this in the very near future.

KEVIN TANG: Okay. Is that this quarter?

DON BAILEY: That's as specific as I can be.

KEVIN TANG: And the -- can you characterize the issues a little bit more? The formatting issues?

DON BAILEY: This is all -- this had nothing to do with content. It's strictly a readability, navigability. They need to be able to keyword search the document, for example. There was a lot of handwritten material in the documents because patient files, review of patient files are in the safety data, for example. It mostly relates to the nature of the data that was in the safety filing.

KEVIN TANG: Okay. So you expect to resubmit shortly. And then, in 60 days from then, you would hear whether it's acceptable for review, and that would start the clock. Is that right?

DON BAILEY: This is a good assumption. The FDA has not told us anything along the lines of that. They don't comment on that. All I know is that they're having trouble reading and we're getting the file back to them as quickly as we can.

KEVIN TANG: Okay. Thank you.

OPERATOR: Bill Strong, Strong Management Company.

BILL STRONG, ANALYST, STRONG MANAGEMENT COMPANY: I'm an old chemist, and I would like to get a little basic idea of the strategy of your company. Is Acthar the only product that you're working with and you're looking for multiple uses for it? Is that the idea?

DON BAILEY: That's very correct. Acthar is currently approved for over 50 indications. It's an old drug. It's a porcine-based drug.

BILL STRONG: I see. And so, the -- is it regarded as GRS or something like that for some of these uses? Or why do we have to get -- are you getting another FDA approval?

DON BAILEY: We're adding an indication that's not currently on the label.

BILL STRONG: Oh, I see. Okay. Thank you.

OPERATOR: Dan DiPietro, ACERAS Biomedical.

DAN DIPIETRO, ANALYST, ACERAS BIOMEDICAL: Thanks for taking the question. Regarding the use in MS, I'm just curious, what does it end up costing? I'm not sure if it's given chronically in MS or -- sort on an annualized basis, what would be the cost of a typical adult getting -- receiving Acthar for MS?

DON BAILEY: It's not used chronically in most cases. It's -- the product is indicated for the treatment of MS exacerbations, or flares, which is really a short-term condition. And it's usually in the neighborhood of two weeks to three weeks of treatment.

But then, sometimes you'll see patients get refills. They may have a further breakout of a flare. They may get a refill two, three, four months down the road. Typically, when we see a new prescription, initially it's worth about 1.5 vials of Acthar, but over time, it's worth closer to 2.5 to 3, in that range, because of the refills for some patients.

DAN DIPIETRO: Is there any weight component to how much the patient takes or anything like that?

DON BAILEY: These are all adults, so -- . Unlike IS, which is -- a dosing is based on body surface area, which is weight-based, in MS it's dosed just on a unit

DAN DIPIETRO: So what would be the -- so then, if the patient takes it, there is a potential for -- the flares come more than once a year, there is a potential for them to be taking it for multiple weeks in the year, I would imagine. What is typical?

DON BAILEY: There is a possibility of that, yes. The average time for between flares is generally more than a year.

DAN DIPIETRO: It is, okay. So, on an annualized -- so how much would it cost, then, for -- just on an annualized basis, for a patient to be treated with Acthar for MS flares?

DON BAILEY: If you figure they're having one flare per year, and they go through two vials, that's about \$46,000.

DAN DIPIETRO: As you expand, I'm just curious -- as you expand into that market, do you think ultimately there is going to be some formulary pushback?

STEVE CARTT: We see a higher rate generally of prior authorizations now than we did a year ago, but we're still getting very good coverage. We actively use our patient assistance program that's operated by NORD. So -- there's a lot of free drug that's shipped to patients.

Most of the prescriptions are covered by insurance, but we do see a few that aren't covered and those -- for those patients, they get free drugs.

DON BAILEY: I wanted to mention one thing here. **We have this drug at a very high price right now** because, really, our principal market is infantile spasms. And we only have about 800 patients a year. It's a very, very small, tiny market. There are no subsidies from the government. There are no subsidies from other companies. Unfortunately, the diseases that use a drug have to pay for it. So I just want to make sure the people on the call understand that some of these numbers sound pretty high for the course of treatment, but it's really driven by the very, very small population of patients that need the drug. It's unfortunate. We'd love to have some subsidies so we could have a lower price.

DAN DIPIETRO: Right. No, understood, I guess that was sort of the question that I had, as you push into a larger market like MS.

STEVE CARTT: I think one -- I'll piggyback on Don's comments, in that we're really not going after the entire

MS market. This is a very small subset of patients who basically they've had breakthrough flares, which in effect is a failure of the disease-modifying drug, and they've also failed first- and sometimes second-line therapies. So this is (multiple speakers)

DAN DIPIETRO: These are patients who have failed prednisone after failing the disease-modifying drugs?

STEVE CARTT: Yes, exactly, in most cases. So these are patients who are really having trouble with controlling their disease and Acthar is an effective and useful alternative for them.

DAN DIPIETRO: I had another question on the reimbursement issues. I understand you're supplying free drug for patients that can't -- that are either underinsured or uninsured. How do you handle some of the private payors that are charging more of a co-insurance than a standard sort of flat co-pay?

STEVE CARTT: We've probably set the industry standard for establishing very aggressive co-pay assistance programs with NORD. We actually fund four different co-pay assistance programs, based on disease state, through NORD, and we're actively -- most patients actually, believe it or not, have a pretty low co-pay. It's under \$100. But in those cases where they maybe -- may have a copay that's a percentage of the drug cost, then, in virtually all the cases, they're transferred over to NORD for assistance. We fund those NORD programs very, very actively.

DAN DIPIETRO: What does that end up being, like -- typically, 5%? Sort of like the Medicare equivalent?

STEVE CARTT: It can be as high as 20% as a co-pay. We see \$5,000, \$6,000, \$7,000 co-pays come through occasionally, and those are -- virtually every one of those is transferred to NORD, and NORD does their assessment of the financial capabilities of the patient. And at that co-pay level, virtually all of those patients get assistance.

DAN DIPIETRO: So you basically are picking up the tab on the co-pay.

STEVE CARTT: Yes. Through our support and our grants to NORD, we're effectively covering that co-pay.

DON BAILEY: Yes, interestingly, before we took the price increase, those uninsured and underinsured patients either went without the drug, without treatment and with some -- possibly some pretty bad outcomes, or were financially really disadvantaged.

DAN DIPIETRO: Now, do you -- and I realize that in the infantile spasm case, you don't run into this, but I'm wondering if in some cases you might, where there is a lifetime cap on insurance. I doubt you would run into -- I guess some of that is based on the family coverage of the family, which it could run into, I guess, with the infantile spasms. But do you ever run into getting that capped, and if so, how do you handle that?

STEVE CARTT: If a cap is ever hit, again, that's a situation where they're underinsured and it's transferred to NORD for free drug.

DON BAILEY: We're happy to say we don't know of any patients who've -- where a doctor has written a prescription, the patient wanted the drug, and the patient didn't get the drug.

OPERATOR: Yale Jen, Maxim Group.

YALE JEN: Thanks for taking my follow-up question. Just two things. Number one is that -- could you do a breakdown in terms of revenue of the Acthar versus the Doral for fourth quarter of '08?

DON BAILEY: Doral would've been less than \$200,000 in the fourth quarter -- about \$200,000 in the fourth quarter.

YALE JEN: That's good. The second question is in terms, again, about insurance coverage, when you're looking into the nephrotic syndrome, was that potentially could be an issue, or do you think that's basically also an area that you will have a freer [hot hand] to operation once you complete a study and present those datas?

STEVE CARTT: That's a great question. It's something we're looking into in-depth right now. But if you look conceptually at these patients, many of them, or even most of them, over time are progressing to end-stage renal disease, and they will end up on dialysis. And even in a kidney transplant, which are -- those are very unfavorable situations, cost-wise as well as health-wise.

So we feel if we're able to provide a drug that staves off either of those outcomes, it will provide a real benefit to the healthcare system.

YALE JEN: Great. Thanks a lot again.

OPERATOR: John Newman, Oppenheimer.

JOHN NEWMAN: Thanks for taking the follow-up. Do you have any idea as to the potential approval timeline for vigabatrin? I'm hearing different things in terms of the length of time that's going to be required by the FDA to put together around this program. And also, could you talk about the potential market opportunity in the future for Acthar in nephrotic syndrome? Thanks.

DON BAILEY: As far as vigabatrin, we have absolutely no information, no insight. We really can't help you there. We just don't have any source of information.

The nephrotic syndrome is very interesting because, with the exception of diabetic nephropathy causing nephrotic syndrome, the market looks quite a bit bigger than the niche market that we're looking for at MS. It may be three or four times bigger than the MS market.

The diabetic nephropathy-induced nephrotic syndrome is substantially larger, and there is, I think, 1.5 million people with kidney problems resulting from diabetes. And we're intrigued by how many of -- and I guess there's not a very good treatment for them at the moment. So we're intrigued about the size of that market, and at least some data showing efficacy of ACTH. So if we could translate that into business, then we will have a different situation.

JOHN NEWMAN: Could you briefly comment on the amount of remaining NOLs that you might utilize in 2009 and going forward?

DON BAILEY: Sure, we'll let Gary try to give you a quick --

GARY SAWKA: We have (multiple speakers)

DON BAILEY: For financial reporting purposes, we've now used them all up. We took all the remaining valuation allowance. So this would just be for cash -- cash [flurry]. We had approximately \$9 million next year.

GARY SAWKA: We have a total -- we have \$9.9 million of NOLs that we will be able to take on our tax return over the years through 2018. And for 2009 and 2010, we will be able to take \$2.2 million each.

JOHN NEWMAN: Thank you.

OPERATOR: Bill Strong, Strong Management Company.

BILL STRONG: Just a couple more general questions. Do you make your own product? What about quality control and risk with regard to problems that might come up from a manufacturing standpoint?

DON BAILEY: Our product is managed from here, and it's made by a series of contractors. We own all the equipment. We own all the processes and all the intellectual property associated with those processes. So, that's how it's made. And it's discussed in some detail in our 10-K.

BILL STRONG: I see. It's basically under your control.

DON BAILEY: Correct, completely under our control.

BILL STRONG: Secondly, what did you think about the current administration's plan? Will it be helpful or harmful with regard to the stimulus and medical stuff? I'm not asking from a political standpoint, but (multiple speakers) standpoint.

DON BAILEY: The CHIP was just passed, the Children's Health Insurance Program, and we had some analysis of that done. And that program, which will enroll an additional 4.5 million children into -- into various state programs, should, on balance, help us because it will take children from the uninsured and put them into an insurance program.

Eleven states use Medicaid, 18 states use a private system, private insurance, and the remaining states use a combined Medicaid and private. When we break that down by percentage, it looks like something in the neighborhood of 50-50, percentage-wise, will come through Medicaid and 50% will come through private insurance.

Of course, for Medicaid, we actually have rebates that are higher than the Medicaid -- than Medicaid pays, so we're actually funding the Medicaid program through its usage. And so, we think on balance we will have a net benefit of some small amount from these government programs.

BILL STRONG: So there's no real -- no bad situation that you see coming up because of it. It will be equal or better to than what you've had in the past.

DON BAILEY: With today's visibility, we're just looking at paper documents and until it is implemented, we really can't -- there as dozens of different programs running their way through Congress. And I can't tell you about all of them.

BILL STRONG: I would guess that probably with the current focus of the administration, it will be helpful rather than [hint], because that's one of their big pushes is Medicaid -- medical.

DON BAILEY: It's really hard to tell.

BILL STRONG: Thank you very much.

OPERATOR: That does conclude the question-and-answer session. I would now like turn it back to management for any closing remarks.

DON BAILEY: I want to thank everybody for listening in and asking questions. We look forward to reporting on our progress --

UNIDENTIFIED COMPANY REPRESENTATIVE: You had one more question.

DON BAILEY: Oh, I'm sorry. There's one more question?

OPERATOR: One moment, please. Gary Goggins, OFI Institutional Asset Management.

BARRY GOGGINS, ANALYST, OFI INSTITUTIONAL ASSET MANAGEMENT: It's actually Barry Goggins. How are you guys? Quick question, in the release the SG&A level was put at 33 to 36 X the FAS 123, and then, when you were going through it, I think you -- it was reported a little bit lower, like 32.5 to 34. Just more of a bookkeeping. Does that include the option expense or not?

DON BAILEY: Whatever is in the release (multiple speakers) is the most accurate.

BARRY GOGGINS: And kind of looking forward, more importantly, within 2010, if some of these programs are positive, would we expect significant operating leverage going forward?

DON BAILEY: Say that again? I'm sorry.

BARRY GOGGINS: Would you expect significant operating leverage in 2010, providing some of these programs go forward, be it the IS, the MS, and possibly the [NS]?

DON BAILEY: It's certainly possible. We already have very high margins -- operating margins, but it's certainly possible if -- it just depends on how much money we have to spend on sales and marketing to drive business. Certainly, we will be expanding -- if we're successful, we will be expanding those efforts and we will be expanding our medical affairs effort, doing more and more trials.

So in every case, with every expenditure, we make a very clear decision on -- is it better to not spend that money or make the investment? All in all, I think if we have some traction, the answer to your question should be yes.

BARRY GOGGINS: Thank you very much.

DON BAILEY: Thanks, everybody, for tuning in, and we will be talking to you pretty soon when Q1 is done.

OPERATOR: Thank you. Ladies and gentlemen, this concludes the Questcor Q4 2008 earnings conference call. If you would like to listen to a replay of today's conference, please dial 303-590-3000 or 1-800-405-2236, and enter passcode 111 24 846.

Once again, ladies and gentlemen, if you would like to listen to a replay of today's conference, please dial

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