# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 8-K

# **CURRENT REPORT**

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): August 11, 2011

# **QUESTCOR PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in Charter)

California (State or Other Jurisdiction of Incorporation) **001-14758** (Commission File Number) 33-0476164 (I.R.S. Employer Identification No.)

1300 Kellogg Drive, Suite D, Anaheim, California (Address of Principal Executive Offices) 92807 (Zip Code)

Registrant's telephone number, including area code: (714) 786-4200

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01. Other Events.

On August 11, 2011, Questcor Pharmaceuticals, Inc. made a presentation at an investor conference. The presentation was previously noticed through a press release on July 28, 2011 and was accessible to the public via webcast. The transcript of such presentation is furnished under this Item 8.01 and is included as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

# Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Transcript of Investor Conference Presentation held on August 11, 2011.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 17, 2011

# QUESTCOR PHARMACEUTICALS, INC.

By: /s/ Michael Mulroy

Michael Mulroy, Chief Financial Officer & General Counsel

# EXHIBIT INDEX

Exhibit No. Description

99.1 Transcript of Investor Conference Presentation held on August 11, 2011.

# MANAGEMENT DISCUSSION SECTION

# **Randall Stanicky**

Good morning, everybody, and welcome to the next session. My name is Randall Stanicky. I'm the specialty pharmaceuticals analyst here at Canaccord Genuity. I'm very happy to be here and to be able to introduce our next company, Questcor Pharmaceuticals. We actually have quite a few people from Questcor here. Don Bailey, who is the president and CEO, is going to give us an overview of the company, and obviously, a lot of opportunity for Q&A in the breakout with his whole team here. Just a real quick background on the company, something that I would consider fairly unique within the pharmaceutical space, and Don's going to give us a little bit more on that and his 'pipeline in a drug' idea, here, but certainly a ton of interest in this company over the last several months, so I think it's timely that we have them here.

So I'm going to stop with that brief introduction and pass it over to Don to give us some background, and then, as I said, lots of time for Q&A.

# Don Matthew Bailey, President & Chief Executive Officer

All right. Thanks, Randall. Good morning, everybody. With me today is Mike Mulroy, our CFO, two of our Acthar specialists, or an Acthar specialist and the manager, and one of our medical science liaisons. They'll be here to answer questions in the breakout session.

Before I get started on the presentation, I wanted to just hit some highlights. Questcor had an excellent second quarter. Sales were up 62% year-over-year. We had record prescription volume. We had record vial shipments, and naturally, we had record earnings based off of that.

Our sales force has been growing, and with the expansion that we're in the middle of, we will soon have our field sales force at over 120 people strong. We also just introduced to Wall Street the fact that we're going to pursue a fourth vertical market with Acthar, so in addition to MS, nephrotic syndrome and infantile spasms, we are going to be exploring commercially the lupus market where Acthar is fortunate enough to have three indications for lupus.

And finally, just a quick update on our cash position, we just went past \$150 million, so the positive cash flow continues to pile up.

OK. So now, I'll go into the presentation. Naturally, we have the usual Safe Harbor statement, so please invest your time before you invest your money, to quote somebody. We have the usual risks that most companies have. We're always concerned about risks associated with competitors and the government and its various agencies, but we have other risks that are clearly described in this statement.

Questcor is basically a single-product company. We call it a biopharmaceutical company just to confuse Randall and Ritu so they don't know which of them or whether either of them could cover us, since one of them is biotech and the other is specialty pharma. If you both jump in here, you could have joint

# Canaccord Genuity Growth Conference Transcript - August 11, 2011

research. How about that? That would be good for you. That way, you could both take credit or blame for whatever happens.

We're focused on those medical conditions that are difficult to treat and where there are potentially serious outcomes for the patient. The name of our product is Acthar. The key chemical in Acthar, of course, is ACTH, a well-known hormone produced by the pituitary gland. This is a porcine-derived product. The product has 19 approved indications, amongst them MS, nephrotic syndrome and infantile spasms.

We have a combined market opportunity here that exceeds \$1.5 billion, and actually, it could even be that we could just move the decimal place over one. We don't really even know how big the markets are for this product. It might even by \$15 billion for all we know. As we unveil these indications to you, you start to see why we don't really know how big this product can get, but it seems to be growing very nicely.

Our strategy is extremely simple. It's just to sell more Acthar, so we're trying to grow sales in each of these three key markets, and in particular, in MS and in nephrotic syndrome, and finally, to develop, as we just announced, the on-label lupus market for Acthar, where there are very few other therapies to treat lupus patients.

Financially, we're in great shape. The company is profitable, we've got a nice cash flow, a positive feature. It says \$142 million cash, but that was a week ago; now it's \$150 million.

The history of Acthar is unusual. In fact, everything about Acthar is unusual. Everything about this company is unusual. It's rare to have a product with this many indications in this many unmet need markets. I'm not sure that's good phraseology. I'll have to work on that, but I think you get the idea. We have very little competition in the positioning of the drug, which I'll explain as we go along.

The drug was first proved 60 years ago, and yet there's a pretty good IP around the product, as we'll talk about. Acthar was acquired by Questcor in 2001, and from 1952 to 2001 whoever owned Acthar lost money. It's a difficult drug to make and it was under-priced through that time. We rationalized the strategy starting in 2007 and have done pretty well since. In 2010 the FDA, through an sNDA we filed for infantile spasms, we ended up with a cleaned up label. We have clarity on label going forward, and we have 19 indications.

I'd like to go through the barriers to entry because this is the key question most investors have with respect to the longevity of this unusual asset. The first barrier to entry is the formulation. Acthar is a biologic. Acthar is an extraction of porcine pituitaries. It's an undisclosed composition, so that's a trade secret. The manufacturing process is also a trade secret. It's complex, it's unique, and we own all elements of the manufacturing process. We have exclusive worldwide rights to Acthar, so we own it lock, stock and barrel. We have no partners. The composition of Acthar that comes out of the manufacturing process is tied to the process, so if you don't know the process you can't figure out what's actually in Acthar. Acthar is technically a polypeptide, but there are probably multiple active ingredients and there are multiple peptides within Acthar, and they're undisclosed.

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From a regulatory point of view, we think, because of the makeup of Acthar and current FDA regulations, that both generics and biosimilars are highly unlikely. Therefore, all regulatory pathways lead to a very important element, and that is that trials would be needed and that a competitive drug would have to decide which indication they wanted to go after. We have revenues from multiple indications, and that creates a business barrier.

Because ACTH, being the core chemical, is so well-known and has been sliced and diced every way possible for decades, we think it's highly unlikely that we or anybody else would be able to get patents surrounding a competitive product or a direct competitor, and without patents, that means a competitor would be stuck with Hatch-Waxman exclusivity, which isn't very much. It's not a lot of time to recover one's investment. We have revenue coming from multiple therapeutic areas, multiple indications, and IS is pretty much invulnerable until 2017.

So let's talk about the strategy now that I've covered the barriers to entry. As I've already said, our strategy is to sell Acthar within the MS, nephrotic syndrome, and infantile spasm markets, and we've just introduced systemic lupus erythematosus, which we will just call lupus for now.

Let's talk about Acthar and MS. MS is a neurodegenerative disorder. Acthar is indicated for the treatment of relapses. The only other drug approved for any of our indications just about is steroids, so typically, we're pretty much looking at using Acthar where steroids don't work.

You can see the various types of patients that might be suitable for Acthar. There are a couple hundred thousand flares a year, and only a small portion of those flare patients are fortunate enough to have a 100% response to steroids, so there's quite a large market for Acthar in the second position in the MS relapse market. Patients who have poor venous access, inadequate response to steroids or have side effects from steroids are good candidates for Acthar.

It's a short treatment. Acthar is an injectable. It comes in a multi-use vial, so typically one or two vials of Acthar are needed, which puts a cost per treatment of about \$40,000 to \$50,000.

This is a graph of our MS sales growth over the last three and a half years. We first entered the MS market in early '08. The numbers on top of the bars are the actual number of prescriptions, so in the most recent quarter, we had 751 prescriptions. You can see nice growth, here. These prescriptions are up 140% year-over-year. We've had some accelerated growth in the last two quarters. The yellow numbers on this chart across the bottom are the number of Acthar representatives we've had focused on MS during those time periods. You can see that late last year, we basically doubled our sales force, and this sales force seems to be getting traction in Q1 and then again in Q2.

So at 750 prescriptions in a quarter, if one multiplies that by four, we're talking 3,000 prescriptions a year versus an MS relapse population of probably 200,000, so the question is how many of those patients might fail steroids or need Acthar. That's kind of an unknowable number, but it's clearly substantially bigger than 3,000. Substantially bigger than 3,000.

This is the same information on a monthly basis. I provide this information because there's no other source for tracking how Acthar is doing in our various indications. This is a specialty distribution, specialty pharm drug, so you can't really get any independent data. You can see the big spike in March.

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February was a record, March was a record, then June jumped up again. I'll talk about July in just a minute. And you can see the number of reps we had.

This product is clearly promotion-sensitive. It's a very unusual selling process. If you stay around for the breakout session, Susan and Dan would be happy to tell you what it's like to try to sell Acthar, but it's not for the weak of heart. You've got to be a bulldog in order to get the sales in this area.

Let's talked about trends. We doubled the sales force not too long ago. Q2 results were very nice. MS now represents, by our best estimate, about 60% of our sales, so it's now up over \$100 million on an annualized basis. We have about 400 prescribers. We were just over 400 prescribers in Q2 out of 8,000 neurologists, there are 6,000 possible prescribers. But many of those 400 prescribers only wrote once in the quarter, and 150 of them, I think, were writing for the first time, so we're still in the very early stages, here.

June was a record month, as you can see from the prior chart. Q3, so far, looks pretty much like Q2, slightly better than Q2, but basically about the same, and that's not unusual for us to go sideways for a little, as you can see from that prior chart. Our sales jump and then they're sideways, they're down a little bit, they're up. That's just the nature of sales. We're dealing with very small numbers.

So let's move on to nephrotic syndrome. This is a kidney condition characterized by leakage of protein out of the body through the urine. This is not good for the body. Basically, a continuing condition will lead to kidney failure, end-stage renal disease, dialysis, transplant, and worse. So I think the goal of therapy is to try to slow down or reverse this process as soon as possible so the patients don't progress to end-stage renal. There's a significant unmet need. There's not only few treatment options, there's no other drug approved for nephrotic syndrome except for background therapy with ACE and ARBS, and there's a controversy about that, yesterday in the Wall Street Journal, apparently ACE and ARBS shouldn't be used together in a large doses anymore. The latest Lancet said they screwed up in 2002, so we'll see what happens.

But that's not really a competitive drug, anyway, that's background therapy. Treatment here is a longer treatment. It's still an acute treatment. Acthar, generally speaking, is not a chronic treatment, or used for chronic conditions. So the treatment here is for four to six months, which puts the value somewhere in the neighborhood of \$200,000.

Here's the first roll out, and the first thing I want to point you to is the number of sales reps here is five. We just started selling into nephrotic syndrome in March, so we hired five salespeople in February and they hit the street in March. So we were getting some scripts. We used to call them spontaneous prescriptions because it happened without any selling effort. You can see that with just a tiny bit of stimulation, we had 45 prescriptions. It's a pretty small number out on the market place, but those 45 prescriptions are worth \$30 million. So the value here of prescriptions is quite high. The return on investment, \$30 million from five reps in the first quarter was pretty unusual in the industry. Needless to say, we're pretty excited about it.

Market size here, these are the on-label indications for Acthar in the nephrotic syndrome area, so idiopathic membranous nephropathy is probably the leading place where Acthar will clearly be used. FSGS is very promising, and then there's IGA nephropathy, minimal change disease, and Lupus nephritis.

We're estimating 20,000 to 25,000 patients in this category. Now, with lupus nephritis, we're talking about the last stage of lupus nephritis, not the earlier stages, which are also on-label as I understand it.

So our plan, here, is to expand this selling effort. Based on the success of the five sales people, we are significantly expanding the selling effort. Ultimately, the number of sales will also go up by about seven times starting in Q4. So Q3 will have a little bit of a disruption. I'll talk about that in just a second. But the plan is to hire another 23 full-time, 100% nephrology sales people, so we'll go to 28 direct sales people. Then, our MS sales force, without giving up any of their MS selling effort, will switch the amount of time they were spending calling on child neurologists about infantile spasm, will replace that time with calling on a few more nephrologists so we can expand the selling effort and cover roughly 3,000 nephrologists versus the probably 300 we cover now.

So we're in the process of the hiring of the 23 additional sales people. From past experience, every time we've had a dramatic increase in the sales force, we have disruption in the selling efforts. I've highlighted that in red, here. I don't want to scare anybody, but we would expect in Q3 to witness that momentum to continue. A rep based in North Carolina that has their prime customers in Virginia, for example, would lose those customers to a new rep. There has to be a hand-off period, the new rep has to get up to speed, so you'd expect some falloff in sales in Virginia in our hypothetical example. That kind of thing just takes a little time. And we're going from 5 to 28, so the disruption could be a little more significant. But by Q4, we should see a pretty good increase in scripts over 45 would be our expectation.

In addition to our selling effort expansion, we also have initiated a phase four company sponsored study in treatment resistant idiopathic membranous nephropathy. This is a dose-response trial with two active arms and a placebo arm. That trial is technically underway as soon as the first patient is dosed, which I've been told is virtually any day. The centers are signed up, the trial structure is underway. We would expect first-look data to fall out late next year, and the trial to be finished in 2013. We think that this trial should be helpful to the selling effort, that's why we're running it.

Briefly on infantile spasms, this was the core original indication that we were looking at starting in 2007. Acthar is the gold standard for treating infantile spasms. This is an unfortunate condition that affects infants. It's a devastating condition if it's not treated adequately. It's a rare condition that affects less than 2,000 babies a year in the U.S., and is characterized by an EEG pattern called hypsarrhythmia. The physical manifestation is these spasms that freak the parents out, frankly, and should. It's a very dangerous disease.

The FDA approved Acthar for infantile spasms late last year, although Acthar had been the gold standard for infantile spasms for probably 40 years. It's a crisis therapy. Here, the treatment is just for a couple weeks. You can see from the next bullet that Acthar is highly effective in treating this disease, and a prescription here is a little bit over \$100,000. About half of the patients receive the drug for free because they are on Medicaid and because of the rules of Medicaid, basically, Medicaid patients receive the drug for free.

Our IS sales now were targeting just a few select institutions because the drug is pretty well known throughout the child neurology community. By reducing the selling effort that we had in IS, that created time our Acthar representatives to start targeting nephrotic syndrome. We see significant variability in

quarterly prescriptions just because of the small numbers involved, approximately 90 to 100 paid prescriptions per quarter, but that's \$45 million revenue base for us.

To summarize our immediate opportunities here and just to build on the sales momentum in MS, a half a billion-plus market size. We've just gotten started with nephrotic syndrome. We liked what we saw with the first five reps, so we're going to do more of that. Big market there. Infantile spasms, we're cutting back on the selling effort. That's a smaller, mature market.

In our total Acthar sales force a this point in time, we have the specialty sales force whose main focus is MS. This is 77 people spread throughout the United States and management. The nephrology sales force will be 28. When you add together all the management and sales people we end up with about 120 people. The combined forces will be calling on 7,000+ doctors across nephrology, neurology and child neurology.

Briefly on lupus, we selected Lupus as our fourth vertical market out of the other indications that are on our label, including rheumatoid arthritis, polymyositis, Stevens-Johnson, and optic neuritis. We selected lupus because of its high unmet need. There's only one approved therapy, a drug called Benlysta. It's approved for maintenance. As you can see from the chart here, Acthar is approved not only for maintenance but for treatment of exacerbations, where nothing else is approved, again, except steroids, and also lupus nephritis.

The standard of treatment for lupus right now is high dose steroids. High dose steroids do not have a good long term effect on the body. We think that there is really a good opportunity and a large patient population. Lupus is a difficult to treat disease, which again fits our criteria.

Let's take a quick look on our financials. Just in summary, we're profitable, debt free, cash flow positive. Those are all good things. Record sales in the last quarter, up 62%. Earnings were up 50%. You can see the numbers here. Sales running at just under a \$200 million run rate. Acthar is a very low-volume drug. In the second quarter, we only shipped 2,400 vials. Every vial gets tender loving care from our sales representatives, our reimbursement center. We have a dozen and a half people who do nothing but chase down reimbursement for our doctors. Medicaid reserves continue to prove adequate. There was a Barron's article on that. But, Barrons has thrown in the towel. Two weeks ago, they admitted they were wrong, which doesn't happen very often, so we like to highlight that.

We have a share repurchase program. We did not repurchase any shares in the quarter. Cash is now up over \$140 million. As I mentioned, yesterday, it totaled \$150 million. So a very nice balance sheet. Bankers don't like us.

Our share repurchase program is highlighted here, but in the past three years, we have repurchased 20% of the outstanding shares, so we have a sporadic but extremely active share repurchase program. When the opportunity presents itself, we buy in very large quantities any time the market seems to react inappropriately to what's going on within the company.

So our go-forward plan is very simple. you probably can all say it with me: Sell more Acthar. That's it. That's all we do. We're not interested in anything else. You see the bottom bullet, here, and this why bankers don't like us. We do not want to do any business development. We do not want to buy any

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other assets. We do not want to buy any other companies and our focus is on Acthar and developing the 'pipeline within the drug,' as Randall mentioned. We're going to explore lupus next and continue to grow the sales in other three that we've already got started.

And then, we're going to look at the rest of the label. There's also a lot of off-label usage for Acthar because it's a basic body hormone. Acthar is used in any place where there is severe inflammation or where the autoimmune system is not operating correctly.

So from an investment point of view, Questcor has excellent sales momentum. We believe it has some interesting barriers to entry, not impenetrable, but not easy to penetrate. We have excellent momentum in MS, starting momentum in nephrotic syndrome, new vertical market in lupus, very good financial dynamics, and we think the market sizes here are quite substantial. So with that, we'll open it up to questions.

#### **QUESTION AND ANSWER SECTION**

#### Don Matthew Bailey, President & Chief Executive Officer

That would be great idea. Can you guys come up? Let's keep webcasting because hundreds of people who will eventually tune into this webcast, either live or on replay. I think they would like to hear the answers, so why don't you guys come over here and get around me, because when you answer the question, you need to answer it into the microphones. Go ahead and introduce yourselves.

# Mike Mulroy, Chief Financial Officer

So, I'm Mike Mulroy, the CFO of the company.

#### **Christine Clemson**

I'm Christine Clemson. I'm a Medical Science Liason in the New England region.

#### Susan Zemaitis

I'm Susan Zemaitis, an Acthar specialist in New England.

#### Dan Paradis

Dan Paradis, Regional Sales Manager for New England.

# **Randall Stanicky**

(inaudible)

#### Don Matthew Bailey, President & Chief Executive Officer

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I'm going to repeat the question in case people out there in the ether world can't hear it. So his question is how long does it take for new reps in an expansion to gain traction? Dan, you've had to manage this process.

#### **Dan Paradis**

This is a really good question for Eldon.

#### Don Matthew Bailey, President & Chief Executive Officer

It's ok, Eldon is not here. Pretend that you're Eldon.

#### **Dan Paradis**

Typically, if someone has prior experience and has relationships with the physicians and the office staff, depending on demographics, it's typically three to six months. It's usually not much more than that. Some very hard to access managed care areas might be more. But for the most part three to six months.

#### **Unverified Participant**

(inaudible)

#### **Don Matthew Bailey, President & Chief Executive Officer**

The question is what's the most common off-label uses. So myasthenia gravis is a condition we see and I've heard that patients seem to respond to Acthar. We get Hashimoto's, which is an autoimmune condition of the thyroid. We've seen that quite a few times. I understand we've had some success in treating severe migraine patients. Probably the most unusual one we ever saw was arachnoditis, which is sort of what it sounds like. It sounds like a disease where you feel like you have bugs crawling on you. It's another nasty neurological condition.

So I was just told that someone might be trying to use Acthar for (inaudible) disease. (inaudible). So we see quite a few different. The most common one we see is a condition called opsoclonus myoclonus. Opsoclonus myoclonus is a neurological condition affecting toddlers three to five. Opsoclonus myoclonus, the nickname for this condition is called dancing eyes, dancing feet. Unfortunately, toddlers lose control of their arms, legs, and eyes. Mentally they are fine and a rather long treatment on Acthar can last a year, maybe longer and seems to help quite a bit. That's past ultra-rare. That's less than 100 kids a year in the U.S.

#### **Unverified Participant**

(inaudible)

# Don Matthew Bailey, President & Chief Executive Officer

Maybe could you repeat the question as best as you understand it.

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# Susan Zemaitis

The way I'm understanding the question is, essentially when you go out there and you see that initial boost to scripts, where are you getting those from initially, and then when they level out, what is your next plan of action so that bump goes back up again?

What happens initially is, I'll speak specifically to MS, is there are centers or clinicians that are treating this disease state that we sell in. As far as going in there, it's really about appropriate patient identification, and the more specific you are about where those patients would best be served by Acthar and you appropriately place it that way, that's where you're going to get the buy-in from that clinician, and then see that bump. He'll get the use and he'll get the experience, and he'll realize obviously not just that the drug works but there are some added benefits to that drug.

Once those clinicians are developed, then it is a very complex sales process, so that takes some time. You'll develop people and you'll see that there will be others that also follow along, and eventually once those people develop they're going to get the initial people on it. You might see a small plateau, but then you're going to go back up by other clinicians, low-hanging fruit, or people that— Acthar doesn't discriminate. It's not just about the people who are treating (inaudible). It pretty much serves the general population. So you see a mix between large clinical treating physicians and people that treat maybe less. Does that answer it appropriately?

# **Unverified Participant**

Can you compare selling Acthar to other drugs you've sold?

# Susan Zemaitis

Sure. That's actually a really good question. I worked for Johnson & Johnson for ten years and launched Topamax in neurology and it's a very widely used drug for epilepsy and for migraine. Going into those types of situations, obviously you're serving a large population of people who suffer from these diseases. So you go in and you're kind of swimming with the fishes, and you have to designate which pool you best swim with. That's where you do really well and it's probably easy process, just dropping samples, it becomes more like a ritual/routine than it does an actual strategic plan of where you would best see this drug fitting a certain population.

How I compare that to selling Acthar is you really have to take the time to understand, I can exemplify enough how important patient identification is, because once you get that perfect patient that we know is going to benefit from the drug, it is appropriately placed within the physician's mind. That is where, with Acthar, though the process might take a little longer—Dan's assessment of three to six months is correct. You're going to see that bump up and you're going to see clinicians buy-in, but you're also going to see physicians continuing to use the drug, because once they use it and they see that it does have a beneficial effect to this really tough to treat population, they want to use the drug again. You also have to keep in mind, to Don's question, you're serving millions with migraine versus serving thousands with MS.

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# **Unverified Participant**

What's a typical length of time for a good sales call on your Topamax case versus Acthar.

# Susan Zemaitis

I think this is important. I probably, if I speak frankly, since I can, I'm not at J&J, I probably could finish a Topamax call within five minutes. It's well-known. It's been used for a number of years. It's used across many different disease states off-label, on-label. It was a fantastic drug and served a great population.

With Acthar, it's a much longer process. It goes into such a deeper level of the complexity of the drug, in producing the drug, not only that but really the patient that it's serving and how it can best serve that patient. I would say, it's like maybe a 5 to 15 minute call that would be really quick with Topomax and get your point across. With Acthar, generally you need about initially you'd want to sit down for a physician meeting for lunch or dinner for an hour to get them to understand the general concept. From there on out, you really need to make sure you're in there with regularity and be able to answer questions as they arise.

#### **Unverified Participant**

(inaudible)

#### Susan Zemaitis

The way I understand your question is you're talking about the total office calls, not just the clinician but to support staff and people who are going to help the actual referral through to completion.

So that's the process, exactly. So, you go in, say, and you're selling a Topomax. You're going to the doctor to write the script, the script goes to CVS, the script gets filled. Everybody wins. You go in to sell Acthar, you go in, you have to go through I would say a fairly extensive clinical description of how this drug works and where to position it in order to get the physician to really understand the benefit.

Once that happens then referral process starts. We have a form that we send in and that's where the office comes in. Step one is with the clinician. Just to get them on board and get them to write it. Then step two through the end is equally if not more important because it's great if you get the clinician on board, but if you can't see the process through to the end then obviously, we don't end up hitting the numbers that we hit here.

The support staff is critically important because we have a hub called ASAP. Once that form gets there, it's really important that they can follow through with the office, the patient, verify insurance. I mean, this is a very insurance-driven drug. This is a co-pay drug. This is a drug where your insurance company has to support you and your doctor's decision. A lot of times, it's been work from the office side and the Questcor side to make sure together that the patient actually gets the drug shipped to their place.

#### **Unverified Participant**

#### (inaudible)

# Don Matthew Bailey, President & Chief Executive Officer

The question is on the selling process since the mechanism of action—there is actually a fair amount of confusion about the mechanism of action here. A lot of doctors are taught in medical school that ACTH is exactly, it's just a steroid. The mechanism of action is exactly the same as the steroid. Now, Christine is not a sales person. This is not how she would necessarily talk about (inaudible). I'm going to let Christine take a crack at answering this question. She is a medical science liaison. She is part of the group of about a dozen people we have in the company who try to answer that exact question.

#### **Christine Clemson**

I think the mechanism of action actually is an advantage to helping a prescriber choose to pick the right patient type. As Don said, it's no longer thought that Acthar is just another way to get steroids. It has direct affects which aren't related to its stereogenic properties, which may make it successful when steroids don't work. But that's solid information and so when a doctor is considering, this patient isn't responding to steroids, why would I give them another steroid? I can explain to them it's not another steroid. There's good evidence that it's got additional effects. So the way I think to answer your question is once we educate them on what we know about the mechanism of action it actually is very positive in terms of their decision to use it.

# Don Matthew Bailey, President & Chief Executive Officer

Would you like to hear what the mechanism of action is? Is that part of your question?

# **Christine Clemson**

So, ACTH is a hormone that causes corticosteroids to be produced in your body. That's one level of its effect. It's not the only effect. It's a melanocortin peptide and there are melanocortin receptors all over the body. We now know that its effects in, say, MS are really relevant to its direct effect on the immune system. So the melanocortin receptors on T-cells and ACTH potently down-regulates the immune response. So for MS, which is an immune disorder, it's really powerful. So that's really the primary, direct effect of Acthar that I discuss in an MS office. This is new information—as Don said, most of these doctors knew of ACTH years ago and thought it was another way to give steroids.

# Don Matthew Bailey, President & Chief Executive Officer

Thank you. This concept of down regulating the immune system is crucial to the value equation with Acthar, so I just want to hit it one more time. When you down regulate the autoimmune system, you're helping the body and my experience affects that the immune system acting inappropriately, which is it covers a very wide range of conditions. Obviously, lupus being one of the most infamous autoimmune medical conditions around, inappropriate autoimmune reaction. That includes MS. It includes a lot of conditions that are not on the label but that open up great expansion opportunities for us. So the more we can learn about how Acthar down regulates the immune system. We're talking about a drug used on

an acute condition or a crisis condition, so the adverse effects of down regulation which could occur probably aren't as relevant to the kind of in and out (inaudible).

# **Unverified Participant**

(inaudible)

#### Don Matthew Bailey, President & Chief Executive Officer

On the issue of guidance, I want to go back to this chart we have on monthly sales. This was chart 10. This is rather interesting because, again, I want to go to where we had this big inflection in March. So we went from 150 something on these prescriptions to almost 250 in one month. At the beginning of March, internally, we were projecting actually March to be down just a little bit because you see these months, they seem to go up and down. So we were projecting at 140 at the beginning of March.

So if we were trying to get guidance to the Street, on the 1st of March, just in March, we would have said 140 and you guys would have thought that we were sand bagging when we came in at 240. So our ability to predict the next data point here wherever this curve going to go is not very good. Unfortunately, that means it's difficult for you, too, but we apologize for that and that's just the way it is. That's the hand we're dealt and it's the nature of this market. Fortunately if you look at the overall penetration here we're still very early on. So maybe you can go on to the revenue recognition question.

#### Mike Mulroy, Chief Financial Officer

Yes, just in terms of revenue recognition, in our slide show here and our press releases, we focus a bit on prescription trends as a paid prescription is a key driver for our business. And that sets up our ultimate end-demand.

We have a single customer, a distributor that we sell through. And so we sell vials to a distributor. That distributor takes title to the goods as risk of loss transfers. There's no right of return and it's upon that sale that we recognize revenue. So the vials that we report quarterly are much closer to the revenue line. Vials times price would give a gross revenue number, with Medicaid and other reserves to get down to a net sales number. There's obvious linkage between prescriptions on the back end and vials on our actual shipments. But there's not a direct one-to-one relationship in a short period of time. Channel inventory will move from period-to-period and there's a time lag between the prescription in the doctor's office and when we're shipping vials to our distributor, so I think that covers the revenue recognition point.

And then on guidance, I think Don pointed out this has been a very tricky business to have visibility on, and it's a very dynamic business. We've been doing many things to grow the company. We have high hopes but we don't have a ton of visibility ourselves in terms of when it's going to play out.

#### **Unverified Participant**

(inaudible)

# Don Matthew Bailey, President & Chief Executive Officer

So the question is how do we see the sales force expansion playing out over a number of years and how do we see the impact on margins with respect to our cost of adding sales people and the cost of trying to do some supportive trials. And the comment was made that our margins have been hit down to 44% or 46%, which is of course a high class problem to have.

So what we have stated first several times is that our goal is to keep our operating margin over 40%. Another way we look at it is that we try to design our spending so that we're splitting the gross margin with investors. So if our gross margin is running 94%, that means we will be shooting for an operating margin of half of that or 47% and spend the rest. So it's a spend-as-you-go, pay-as-you-go kind of philosophy. Now that's depending on sales and as I said, we have a very difficult time predicting sales. So we are constantly adjusting our spending plans going forward based on that.

Separately, every time we look at spending, whether it's an increase in the sales force or doing a trial, we do an actual expected ROI calculation. We've got a fair amount of history here where we can look at ROI for MS and not as much as NS or nephrotic syndrome yet, but we would develop that. And so it's a fairly straightforward question to ask. We're currently at 77 reps and if we went to 100 reps, where do we think the return would be on that incremental 23 reps? So if we went to 120 MS representatives what do we think the return would be on that 43 additional MS reps? And we would just make that decision based on the evidence at the time, and it depends on how that penetration goes.

Another factor is we only like to do one thing at a time and we really focus on it. So last fourth quarter, third quarter, fourth quarter, we were focused on the MS expansion. Right now, we're focused on the nephrotic syndrome expansion, and selling effort. So we would probably not have another sales force expansion in this calendar year. We might have something next year if the evidence—so it's evidence-based expansion, if you will. If we look at other MS sales forces, they typically top out in 120-150 people range. We might end up higher because as Susan described the high touch selling effort very much might end up needing more MS reps. Does that answer your question?

#### **Unverified Participant**

(inaudible)

# Don Matthew Bailey, President & Chief Executive Officer

The first question related to use of cash. I'll let Mike answer that, and the second question was what should investors look to as being key value drivers and events in the future for the company, and I'll answer that question. Mike, I guess you should start with the cash question.

# Mike Mulroy, Chief Financial Officer

Thank you. I'll just set the baseline to speak to. There was a slide earlier that we have basically sworn off business development. We are a highly cash generative business, and cash has grown. Don mentioned a figure, \$150 million. On the other side of the ledger, though, our market cap has grown. So when you think about cash as a percentage of equity value, it's under 10%. So there's a lot of cash there.

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There's not a current need for all that cash. I think that's evident. And yet in terms of percentages it's not outlandish. Then, to revisit the history, we have been aggressive buying back shares, though opportunistically. It hasn't been a program like a lot of companies where they just continually buy back shares irrespective of price. We are price conscious in all of our investments, and return-on-investment conscious in all our investments. Share buyback we look at as another investment. We remain committed to returning cash to shareholders prudently and over time, but to date, I think since the implementation of the strategy change in '07 we've returned approximately 50% of free cash flow to shareholders. We look at that as a rough guide going forward. There's no commitment there of when and how to do it. But we very much remain committed to the principle of returning cash to shareholders.

#### **Don Matthew Bailey, President & Chief Executive Officer**

So on the question of what to look for in the future as the key guideposts for investors clearly our script count is the main focus. The script count for MS, the script count for nephrotic syndrome will be critical. It will take probably 12 to 24 months before we can draw any conclusions with respect to lupus so I think for the next 12 months that's going to be something interesting to follow, but the process we're heading into with lupus, there's not going to be milestones in the near term. So it's probably just as simple as MS and nephrotic syndrome.

So in the third quarter I certainly think one would expect MS sales and scripts to go up. Nephrotic syndrome could go up, might go down, but by fourth quarter it should be going up. We often caution investors that this is a difficult stock to track and have high expectations for in the very short term, in one quarter.

As Mike described, we sell vials to one distributor in large quantities. We deliver 120 or 150 at a time. That sale can move one day at the end of a quarter and dramatically affect our quarter results. So we suggest to investors they consider looking at a six-month period, for example, to see how we're doing or a nine-month period. Investors are trying to track scripts versus vial count it's really hard to do.

The other thing that's happening here is that as we build up more of our nephrotic syndrome business, we're building up a set of revenues that will happen in the future because that prescription will come in over six months, and that revenue will come in over six months in the future. So as that part of the business builds, we'll be building a forward vial wave of future revenue. So I would suggest you would just watch the script count. Everything else follows from it.

#### **Unverified Participant**

(inaudible)

#### Don Matthew Bailey, President & Chief Executive Officer

That's a good question. The question is, has Boston been a tough market, because of the characteristics of Boston? I'll let Dan Paradis answer to that.

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# Dan Paradis

The answer is yes. It's a difficult territory or section for a few reasons. Obviously, you know with Harvard they have their own way of doing things and they're excellent at doing it. With that said, it kind of closes people out, which is just the way it is. The access is really difficult. In just this area, the 128 belt we like to call it, there's very limited access, without getting into specifics, so it's difficult to get in.

But once you get in and you get to these thought leaders, what we've found is these thought leaders—it's happening as we speak—they see this product and they look at it like they've never seen it before, and Christine talks to them, and they see the different mechanisms of actions they didn't really know existed, and now they're getting excited. Now they're starting to use it and they see the potential for the product. So a market like this takes longer. Earlier the question of three to six months. This territory is a six to 12 month territory. It's one of maybe a few in the country. It's just one of those that happens. But now it's starting to break through and it's great, but it does take time. It's a great question. Did that answer it?

# Don Matthew Bailey, President & Chief Executive Officer

There are two other markets that are similar, Seattle and the Minneapolis area. Any other questions? Well thank you everybody for listening in and I appreciate the webcast and Q&A. I'm sure investors will appreciate that.

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