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DEPO - Q2 2018 Depomed Inc Earnings Call

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PRESENTATION

Operator

Good morning, and welcome to the Depomed, Inc. Second Quarter 2018 Financial Results Call. My name is Louis, and I will be facilitating the audio portion of today's interactive broadcast. (Operator Instructions)

At this time, I would like to turn the show over to Mr. John Thomas, Senior Vice President for Investor Relations and Corporate Communications. Mr. Thomas, you may begin your conference.

John B. Thomas - *Depomed, Inc. - SVP of IR & Corporate Communications*

Thank you, Louis. Good morning, and welcome to our Investor Conference Call to discuss Depomed's Second Quarter 2018 Financial Results, which we announced this morning. The news release and investor presentation covering our earnings for this period are now available on the investor page of our website at depomed.com.

With me today are Arthur Higgins, President and Chief Executive Officer; Augie Moretti, our outgoing Senior Vice President and Chief Financial Officer; and Phil Donenberg, our current Senior Vice President and Chief Financial Officer.

I would like to remind you that the matters discussed on this call contain forward-looking statements that involve risks and uncertainties, including those related to the commercialization of Gralise, Cambia and Zipsor; our collaborative arrangements, including with Collegium Pharmaceutical; the company's financial outlook for 2018; development plans, including those for cosyntropin depot; and other statements that are not historical facts. Actual results may differ materially from the results predicted, and recorded results should not be considered an indication of future performance. These and other risks are more fully described in the Risk Factors section and other sections of our quarterly reports on Form 10-Q and our annual report on Form 10-K for the year ended December 31, 2017. Depomed disclaims any obligation to update or revise any forward-looking statements made on this call as a result of new information or future developments. Depomed's policy is to only provide financial guidance for the current fiscal year and to provide updates or reconfirm its guidance only by issuing a news release or filing updated guidance with the SEC in a public accessible document.

Reference to the current cash and cash equivalents are based on balances as of June 30, 2018. All guidance, including that related to the company's expected total product revenues, operating expenses, adjusted non-GAAP earnings and nonadjusted EBITDA are as of today. The nonfinancial -- non-GAAP financial measures Depomed uses are not based on any standardized methodology prescribed by GAAP and may be calculated differently from and, therefore, may not be comparable to non-GAAP measures used by other companies.

With that, I will turn the call over to Arthur. Arthur?



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Arthur Joseph Higgins - Depomed, Inc. - CEO, President & Director

Thank you, John. Good morning, and welcome, everyone. It's my pleasure, firstly, to introduce and welcome our new Chief Financial Officer, Phil Donenberg. Phil comes to us after a successful tenure at AveXis, the local Chicago area gene therapy biotech, where he served as CFO and played a key role in the company's almost \$9 billion purchase by Novartis. Phil brings more than 20 years of leadership in finance, M&A and operations with most of his career focused in the specialty pharmaceutical and health care arena.

I'm also joined today by Augie, our outgoing CFO, and this will be his final quarterly earnings call. On behalf of the Board of Directors, our executive leadership team and all our employees, I'd like to thank Augie for his service as CFO and his numerous contributions to our company over the last 6 years. As many of you know, Augie was instrumental in raising \$1.2 billion of capital to support our growth and transition to a commercial-stage specialty pharmaceutical company. We wish him all the best in his next engagement in the Bay Area.

I mentioned in our first quarter earnings conference call that I expected 2018 to be a very busy and productive year for our company. With more than half the year complete, I remain more confident than ever that this will indeed be the case. So I'd like to share with you some of our key achievements to date, as we continue to execute against our 3-pillar strategy of maintain, grow and build.

On maintain, we have de-risked our business through our agreement with Collegium while at the same time, significantly improving our profitability. On grow, we completed 2 new business agreements that will support future growth, our co-promotion agreement for Zipsor with Allegis and our in-licensing agreement with Applied Pharma Research for a new patient, family presentation of Cambia. And I'm pleased to report, in the second quarter, we stabilized our neurology franchise and showed the first quarter-over-quarter growth in total prescriptions for several years. On build, we remain on plan to file for cosyntropin depot by the year-end and have started patient recruitment in our infantile spasm trial, a devastating pediatric disorder.

On the corporate front, we continue to demonstrate an ability to find ways to strengthen our balance sheet and accelerate our deleveraging. We recently announced we had received \$20 million in cash from PDL BioPharma for the purchase of the remaining rights to the diabetes patents we sold to them in 2013.

We also announced that we are in confidential settlement discussions with Purdue Pharma regarding ongoing patent litigation. If a settlement is reached, as is normal and customary, the settlement value will be some percentage of what we would possibly achieve, assuming we won the case in court. The expected cash from the potential Purdue settlement along with the cash from PDL will clearly strengthen our balance sheet and give us greater flexibility when it comes to a potential refinancing of our secured debt.

Regarding adjusted EBITDA, today, we are raising our full year guidance from the previous guidance of \$125 million to \$135 million to \$145 million to \$155 million. This adjustment reflects primarily the \$20 million we received from PDL. Thus, we're encouraged by our ability to show, for the first time in the second quarter, sequential prescription growth in our neurology portfolio. We still have more work to do, particularly with respect to Galise. As a result, we are reducing our full year neurology revenue guidance from the previous guidance of \$120 million to \$125 million to \$105 to \$110 million. We see this more as a timing issue, as it is taking us slightly longer to achieve our first goal of stabilizing the business before we can return it to sustainable growth. Importantly, we have been able to offset the sale shortfall through expense reductions.

Let's look now at our progress against our 3-pillar strategy in more detail. Regarding our strategy to maintain, our Collegium agreement continues to help stabilize our business. As a reminder, under the terms of the agreement, Collegium records all revenues and assumes all responsibilities associated with the commercialization and distribution of both forms of NUCYNTA. Depomed received an upfront milestone from Collegium as well as guaranteed annual royalties of \$135 million over the next 4 years on NUCYNTA sales.

You'll recall, we began booking these royalties as revenues in the first quarter of this year. In the second quarter, we received \$33.75 million in cash and recognized \$31.2 million in royalty revenue. So this agreement is working very well and as planned.

Regarding our strategy to grow. With our neurology franchise, all 3 brands showed positive total prescription growth versus the first quarter, with both Cambia and Zipsor growing low double digits quarter-over-quarter. This is the first quarter in which all 3 products have shown sequential

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growth in total prescriptions for several years. Zipsor, in particular, stands to the benefits from our new co-promotion agreement with Allegis. However, overall, we still have more work to do and as I said, particularly with Gralise. The good news is that we believe we know what is necessary to return Gralise to growth.

First, we are reducing our total call target universe from 7,000 to 6,000 physicians, so we can increase our call frequency on our key Gralise prescribers of which there are approximately 4,000 high-quality prescribers. Second, we have strong managed care coverage for Gralise with more than 75% of commercial lives covered. We need to make sure that we better leverage this coverage and along with a simple script program, we intend to ensure that more of the scripts physicians are writing get into the physician -- get into the patient's hands. Third, we have a differentiated product in Gralise. It's combination of 2 once-daily dosing and favorable side effect profile. We need to communicate that in a more concise and proper manner.

Let me now turn to our build pillar. I am particularly excited today to discuss our work in this area, because we have several initiatives that are just now coming into focus. And these will help shape the future of our organization at a time we're also redefining our identity with a new company name and a renewed commitment to advancing patient care.

With that in mind, let me spend a few minutes discussing our lead pipeline asset, synthetic cosyntropin depot. Cosyntropin depot is a long-acting, alcohol-free synthetic ACTH analogue that, we believe, if approved, will offer patients, physicians and payers an important treatment alternative in the United States. Before I discuss a specific regulatory approval strategy for cosyntropin depot, it's important to understand the backdrop of the existing global ACTH market and the currently available products in the U.S. as well as outside of the U.S. There is only one long-acting market product available to patients in the U.S., and that is Achtar Gel, an animal-derived ACTH product marketed by Mallinckrodt that sold more than 1 billion in 2017. Achtar Gel was first approved in the U.S. in 1952. So for more than half a century, patients and physicians in the U.S. have had only one choice of a long-acting treatment. In addition, in more recent years, the cost of that treatment to the health care system has increased significantly, leading payers, patients and even the government and FDA to join the chorus of key stakeholders requesting a lower-cost alternative. We believe cosyntropin depot, which we intend to brand under the name, Synacthen depot, the same name used by Mallinckrodt in their commercialization of their synthetic cosyntropin outside of the U.S., can be that cost-effective alternative to Achtar Gel. And we're confident that U.S. physicians will consider it a viable option based on global market preference.

Outside the U.S., Synacthen depot is prescribed in many countries where physicians consider it the standard of care, given its established safety and efficacy profile. In addition, synthetic Synacthen depot has label indications that are generally recognized as similar to the animal-derived Achtar Gel. In fact, physicians well understand the similarities but appreciate the benefits of this being a synthetic product versus an animal-derived product. To that end, market research as well as analyst research shows that a significant number of physicians would prescribe a synthetic cosyntropin depot regardless of the product's label or indications, if it were priced appropriately. Our own peer research indicates a similar level of receptivity to an alternative ACTH product, regardless of indication or label.

So timeliness to the market is critical, especially as public pressure amounts for a long-acting ACTH alternative. Health care providers and payers are generally aware that Synacthen Depot sold by Mallinckrodt outside of the U.S. has similar clinical uses and a similar label to Achtar. They acknowledge this and have indicated they're opening -- open to considering using Synacthen Depot again if appropriately priced.

Also, in May, the FDA Commissioner, Scott Gottlieb, announced the list of drugs that are off-patent but without any pending application for new competition. The FDA's goal is to stimulate competition and help lower health care costs. Achtar Gel is on that list. There is clearly an emerging growing swell of demand for an alternative ACTH product in the U.S. The government wants it, peers want it, physicians want it, and most importantly, patients need it. By putting patients first, numerous stakeholders stand to benefit, and we plan to be there first. Our strategy to be first will seek us, look for approval for a diagnostic indication for suspected adrenocortical insufficiency. Pediatric and adult endocrinologists commonly use exogenous ACTH to trigger the body's cortisol response, which helps determine if a patient's adrenal and pituitary glands are functioning properly. Our goal is to demonstrate that the diagnostic performance of cosyntropin depot is comparable to the reference product, which is Cortrosyn. This will be a 505(b)(2) application that we remain on target to file by the year-end.

In addition to our near-term filing plans with cosyntropin depot, we're supporting the long-term development by evaluating issues as a treatment for important new orphan and special -- specialty indications, such as infantile spasms, a devastating and rare pediatric disorder that usually begins



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in children before the age of 1. Enrollment and dosing in new trials to evaluate cosyntropin depot for the treatment of infantile spasms began in the second quarter. The indication has already received orphan status. As with the infantile spasm program, also partnering with medical experts, academic researchers and other thought leaders in definite therapeutic areas to refine our broader clinical plans for cosyntropin depot.

So as you can see, cosyntropin depot represents a tangible near-term pipeline asset. We believe that our strategy to file first for the diagnostic indication is the most efficient and expeditious way to bring cosyntropin depot to patients in a timely manner.

The last topic I'd like to briefly cover today is our upcoming name change and new corporate identity. Depomed is officially changing its name to Assertio Therapeutics, spelled A-S-S-E-R-T-I-O, Assertio. Again, the name is Assertio Therapeutics. The ticker symbol will be ASRT. We've timed the name change to coincide with the opening of our new corporate headquarters located in Lake Forest, Illinois, where we will be staffed and operational this month. We chose the Lake Forest location because it's close in proximity to a number of pharmaceutical companies, and we believe this would make it easier to attract pharmaceutical talent. This has indeed been the case. Also, as we transformed the company, it became clear to us, the name Depomed no longer accurately reflected the business we are in today or the direction in which we're headed or for that matter, the mission, values -- and values that define us. On the other hand, Assertio reflects an aspirational mindset, consistent with our focus on advancing patient care. Our new branded entity speaks to as being assertive and decisive when it comes to our mission, vision, values and strategy and on our commitment to deliver shareholder value. It's a new name and a renewed mission to advance patient care in our core areas of neurology, orphan and specialty medicines. I'm highly confident that we have the talented experience and energy within our organization to drive Assertio forward in a way that will benefit all stakeholders, including our shareholders.

With that, I would now like to turn the call over to Augie to discuss the second quarter in greater detail. Augie?

August J. Moretti

Thank you, Arthur. This morning, I'll review financial highlights from our second quarter and then discuss guidance. My comments will primarily focus on our non-GAAP results. Please refer to today's earnings news release for an explanation of our non-GAAP financial measures and tables that reconcile the company's non-GAAP measures to GAAP measures.

Total GAAP revenues for the quarter ended June 30, 2018, were \$63.3 million. There were 3 principal elements to our revenues, net sales of our neurology products of \$25.9 million; revenue under the commercialization agreement with Collegium in the amount of \$31.2 million; and as planned, we recognized a \$5 million milestone payment from Ironwood Pharmaceuticals related to the initiation of a Phase III trial being conducted by Ironwood.

While sales of our core products were slightly lower than expected, from a profitability perspective, we were able to offset softer neurology franchise net sales by remaining vigilant in managing expenses. For perspective, total company GAAP SG&A expenses are down 37% for the quarter year-over-year and down 38% year-to-date versus 2017.

As a reminder, with respect to the Collegium agreement, collegium has the exclusive right to commercialize the NUCYNTA franchise. As planned, in the second quarter of 2018, the company received \$33.75 million in cash and recognized \$31.2 million in revenue in accordance with the revenue recognition guidance we provided on our last call.

Lastly, on revenue. In July 2011, the company entered into a collaboration and license agreement with Ironwood Pharmaceuticals, granting a license for worldwide rights to certain patents and other intellectual property rights to our Acuform drug delivery technology for an Ironwood product candidate under development for refractory GERD. The company has received \$3.4 million under the agreement previously, including a contingent milestone payment of \$1 million in March of 2014 as a result of the initiation of clinical trials.

During the second quarter of 2018, we recognized a \$5 million clinical milestone related to the initiation of a Phase III clinical trial. Going forward, we are entitled to receive additional contingent milestone payments in aggregate amount of \$18 million upon the occurrence of certain development milestones and royalties on net sales of the product, if approved.



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Turning now to the neurology portfolio. Gralise second quarter net sales were \$13.8 million, down sequentially from \$14.8 million in Q1 2018. The reduction in revenue was principally the result of a reduction of approximately 3 days on hand in the channel from the end of Q1 and increased managed care costs.

Cambia had second quarter net sales of \$8.1 million, up \$1.7 million sequentially from \$6.4 million in the first quarter of 2018. And Zipsor had second quarter net sales of \$4.0 million, down sequentially from \$4.7 million in the first quarter of 2018. The reduction in Zipsor revenue resulted principally from reduction in days on hand in the channel from the end of Q1 and favorable government rebate adjustments reflected in Q1 of 2018.

As Arthur noted previously on today's call, we've stabilized our core neurology brands and are seeing positive sequential total prescription growth for the franchise, but we have more work to do with Gralise. I'll discuss neurology net sales guidance in a moment.

Moving on. Days on hand at wholesalers at June 30, 2018, for our products were approximately 20 days versus approximately 24 days at the end of the first quarter of 2018.

Cost of goods for our neurology portfolio in the second quarter of 2018 was approximately 8% of revenue, and this is consistent with prior quarters.

Turning to our second quarter expenses. GAAP selling, general and administrative expense were \$31.3 million for the second quarter of 2018, down significantly from \$50 million in the second quarter of 2017.

Non-GAAP SG&A expense, excluding stock-based comp and contingent consideration, was \$26.2 million for the second quarter of 2018.

GAAP and non-GAAP R&D expense for the second quarter of 2018 were \$2.2 million and \$2.1 million, respectively, versus \$5.6 million and \$5.3 million in the second quarter of 2017. Second quarter 2018 R&D expense reflect certain timing delays in pediatric trial enrollment, and we expect R&D expenses to increase in future periods, in line with the lower end of our revised expense guidance for 2018.

Restructuring costs were \$5.8 million in the second quarter of 2018 and reflect costs associated with the reduction in headcount and associated move to Lake Forest, Illinois. Year-to-date restructuring costs were \$14.8 million associated with the relocation, severance and our name change. Adjusted EBITDA for the quarter was \$36.8 million, up from \$28.3 million in the second quarter of 2017.

Moving on to the balance sheet. As of June 30, 2018, cash and cash equivalents were \$57.2 million. The reduction in cash during the quarter was primarily due to a scheduled principal repayment of our secured debt of \$57.2 million paid in April, reductions in short-term liabilities and payment of restructuring charges. At quarter-end, we had \$652 million of debt outstanding, consisting of \$345 million of convertible debt and \$307.5 million of secured debt. We expect to improve our leverage ratios going forward, as we continue to pay down our secured debt.

Now moving on to guidance. This morning, we raised full year guidance for non-GAAP earnings and adjusted EBITDA and lowered full year guidance for neurology franchise net sales. We increased full year adjusted EBITDA to a range of \$145 million to \$155 million from the previous range of \$125 million to \$135 million. The increase related to the \$20 million we received from the agreement with PDL BioPharma. This non-GAAP adjusted EBITDA guidance excludes specified items, which have been set forth in the earnings release issued this morning, such as increased opioid-related litigation, investigation and regulatory costs of \$7 million to \$10 million.

We reduced guidance for the neurology franchise net sales to a range of \$105 million to \$110 million from the previous range of \$120 million to \$125 million. The lower range is primarily the result of slower Gralise prescription growth in the first half of the year. However, the majority of the earnings impact is being offset by lower SG&A expenses. As a result, we adjusted full year net loss guidance to be within the range of -- a loss of \$8 million to a loss of \$18 million due to the \$20 million of revenues from the PDL agreement and decreased expense levels, offset by the lower neurology franchise sales and increased opioid-related litigation, investigation and regulatory costs.

With respect to the PDL transaction, we filed an 8-K on August 2, 2018 announcing the company sold to PDL BioPharma in return for \$20 million in cash, the company's remaining interest in royalty and milestone payments payable under license agreements relating to the company's Acuforn



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technology in the Type 2 diabetes therapeutic area. Substantially, all of the company's interest in such payments were initially sold to PDL in October 2013. The amounts received from PDL will be reflected in third quarter revenues.

That concludes the financial discussion. And I'll now turn the call back to Arthur.

Arthur Joseph Higgins - *Depomed, Inc. - CEO, President & Director*

Thank you, Augie. So I hope you all agree, the transformation is well underway and that we have had a very busy and productive year-to-date, and we look to more progress as we close out the year.

With that, I would like to open it up for questions.

John B. Thomas - *Depomed, Inc. - SVP of IR & Corporate Communications*

Louis, we're ready for Q&A. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question comes from Irina Koffler from Mizuho.

Irina Rivkind Koffler - *Mizuho Securities USA LLC, Research Division - MD of Americas Research & Senior Analyst*

I just wanted to dig a little deeper into cosyntropin. So just wondering if you could provide a little bit more color on the payer discussions in the sense of how affirmative were payers, whether they just expressed interest in learning more about the product or actually would put it on formulary for utilization? Have you had any discussions with the government payers? And just wanted to get a little better sense of how much intent there is to really use the product.

Arthur Joseph Higgins - *Depomed, Inc. - CEO, President & Director*

Okay, thanks. Thank you, Irina. I think what I would say is, there was a receptivity with the payers. Clearly, until they get a better sense of what the price discount is going to be, Irina, they were engaged and interested, but that's about where -- how far the discussions have gone. Clearly, as we get closer to market, we will start to share with you and the payers what our pricing strategy is. But without that, I would describe it as high interest, but it's all going to depend on what the discount is.

Irina Rivkind Koffler - *Mizuho Securities USA LLC, Research Division - MD of Americas Research & Senior Analyst*

And there is no demand for additional clinical data for any indications. They are comfortable with the idea that it's Synacthen, like used in Europe. And in terms of your discussions with the FDA and promotion that you can potentially pursue, can you touch on that?

Arthur Joseph Higgins - *Depomed, Inc. - CEO, President & Director*

Yes. Again, I think, we were encouraged by the fact there was widespread knowledge of the availability of synthetic cosyntropin outside of the U.S. So we didn't have a lot of bridging to do to explain that these products have that similar use pattern. And I think, again, the issue came to -- in



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terms of clinical data, I would say, this is again more a function of, if the pricing discount is small, there'll be more pressure for that. If the pricing discount is more in line with what they're expecting, there'll be less pressure on that.

Irina Rivkind Koffler - Mizuho Securities USA LLC, Research Division - MD of Americas Research & Senior Analyst

Okay. And then I have a question on IP, just as a follow-up. So this is a 505(b2) strategy. Are you expecting 3 years of market exclusivity? Or do you have an additional IP that you can discuss?

Arthur Joseph Higgins - Depomed, Inc. - CEO, President & Director

At the moment, all we're expecting is the 3 years.

Operator

Your next question comes from the line of Ken Trbovich from Janney.

Kenneth Eugene Trbovich - Janney Montgomery Scott LLC, Research Division - MD of Specialty Pharmaceuticals

I guess, I wanted to -- we wanted to start with the discussion, again, on Synacthen. I -- just knowing that the product's available, is it sold by Novartis currently in Europe? And what's the pricing look like there? And have you contemplated any risk on the importation?

Arthur Joseph Higgins - Depomed, Inc. - CEO, President & Director

The product is actually sold by 2 people. It's sold by Mallinckrodt and a European company whose name I've forgotten. But there's 2 companies that have rights. Sandoz or Novartis gave the rights to Mallinckrodt and other European, small, midsize European company. I do not believe -- I mean, there's always a risk, but I think, again, that's something we believe we can manage.

Kenneth Eugene Trbovich - Janney Montgomery Scott LLC, Research Division - MD of Specialty Pharmaceuticals

In terms of the importation risk, is the risk that can be managed?

Arthur Joseph Higgins - Depomed, Inc. - CEO, President & Director

Yes, the other comp -- and the other comp is the Alfasigma, by the way.

Kenneth Eugene Trbovich - Janney Montgomery Scott LLC, Research Division - MD of Specialty Pharmaceuticals

Sigma?

Arthur Joseph Higgins - Depomed, Inc. - CEO, President & Director

Alfasigma.



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Kenneth Eugene Trbovich - *Janney Montgomery Scott LLC, Research Division - MD of Specialty Pharmaceuticals*

Alfasigma. In terms of revenue or guidance, I guess, in general, one of the questions that, I guess, I have has to do with the GAAP numbers. Are we certain on the accounting for the PDL milestone? Is that just a straight flow-through, all of it recognized in a single quarter? Or is there some unique accounting here that would result in a treatment of this, much the same way that we're seeing other types of agreements where you receive the cash, but the recognition's deferred over the periods?

August J. Moretti

We're comfortable, Ken, it will be recognized in Q3. And as we indicated on the call today, we've actually already received the cash. There are no future obligations on our part. It's just a clean disposition of our rights in the remainder of the future cash flow. So it'll all be recognized as revenue in Q3.

Kenneth Eugene Trbovich - *Janney Montgomery Scott LLC, Research Division - MD of Specialty Pharmaceuticals*

Okay. So part of that change in the GAAP net loss outlook is just purely a straight \$20 million adjustment as a result of that agreement?

John B. Thomas - *Depomed, Inc. - SVP of IR & Corporate Communications*

Yes.

Kenneth Eugene Trbovich - *Janney Montgomery Scott LLC, Research Division - MD of Specialty Pharmaceuticals*

Okay. And then are there any anticipated royalties from the Grünenthal agreement included in the GAAP net loss guidance?

August J. Moretti

I don't believe so, Ken. No.

Kenneth Eugene Trbovich - *Janney Montgomery Scott LLC, Research Division - MD of Specialty Pharmaceuticals*

Okay. So is that something you folks anticipate updating then when we see the third quarter results? Or when do we get a sense for how we should be thinking about the potential royalty to Grünenthal?

August J. Moretti

So what we've said, and this relates to the agreement that we made in connection with the Collegium agreement to protect Grünenthal with respect to sales of NUCYNTA above \$180 million and below \$233 million. And from an accounting perspective, we will address that as we go through the year and make a determination. Once we cross the \$180 million threshold, we will make a determination as to whether we -- estimate that we would owe any amount to Grünenthal, and we would reflect that at the time that we make that determination.

Operator

Your next question comes from the line of David Amsellem of Piper Jaffray.



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Michael Elliot Ingerman - *Piper Jaffray Companies, Research Division - Research Analyst*

This is Mickey Ingerman on for David. Regarding cosyntropin, you had previously suggested the first filing would be in a therapeutic indication. So did anything change in your thinking or perhaps, as a result of your dialogue with the FDA? And are you still looking at any therapeutic indications beyond infantile spasms? And to that extent, can you give us a sense of when we may see the start of any clinical trials?

Arthur Joseph Higgins - *Depomed, Inc. - CEO, President & Director*

Mickey, first of all, I think, we never disclosed what the first indication was. I think people bridged from the fact that we were looking at infantile spasms, so maybe a therapeutic indication. But we were very careful to say we're not going to have a discussion on that until we were ready, and we are ready today to explain our strategy. Again, it's a strategy that is designed to ensure we're first to market. As to the question of additional therapeutic indications, we are in discussions with investigators on other indications. And again, once we have determined which of those we want to pursue, we will update you on those indications.

Michael Elliot Ingerman - *Piper Jaffray Companies, Research Division - Research Analyst*

Great. And one just quick follow-up. Can you guys provide any updates regarding the pace of enrollment in infantile spasms, and when we would expect to see top line data?

Arthur Joseph Higgins - *Depomed, Inc. - CEO, President & Director*

Yes, I think, we've, again, been pretty consistent on that. Enrollment is progressing, but the trial, itself, we expect to take between 3.5 to 4 years. So you're really talking about not seeing top line data for at least 3.5 to 4 years.

Operator

Your next question comes from the line of Randall Stanicky of RBC Capital Markets.

Daniel James Busby - *RBC Capital Markets, LLC, Research Division - Senior Associate*

This is Dan Busby on for Randal. First off, welcome, Phil. Good luck out there, Augie.

August J. Moretti

Thank you.

Daniel James Busby - *RBC Capital Markets, LLC, Research Division - Senior Associate*

First question, could you elaborate on -- a little bit more on what's driven the softness in Gralise? So a couple of parts for this. What's the primary pushback you're hearing from physicians? And two, what gives you confidence that the steps you've outlined would be enough to restart growth later this year and/or next?

Arthur Joseph Higgins - *Depomed, Inc. - CEO, President & Director*

Yes, Dan, first of all, we should remind everybody what we said we were going to do. The first part was, we have -- our brand had been declining for several years. So the first step was to stabilize that brand. We've achieved that. I think it's taken us a little longer than we would've liked. But it



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has demonstrated that the brand is promotionally sensitive. As to what we need to do, I think as we indicated, I think one of the key things we got do a better job of is, we have very good managed care coverage with over 75% of commercial lives covered. But we're still seeing some leakage in the system between the prescription being written by the physician and actually getting into the hands of the patient. And we're working with our provider and our simple script program to try and reduce that leakage. I think that's one of the key steps. The other step that's clear is that frequency of calling is very important for Gralise, more so than with Cambia and Zipsor. Again, you saw Cambia and Zipsor showing pretty strong quarter-over-quarter prescription growth. We didn't see that in Gralise. And we believe that's a function of it. Just needs more call frequency and by reducing the total call universe, we're able to get our representatives more focused on the high-prescribing Gralise physicians. And finally, as I mentioned in the call, we have a pretty compelling message but we probably made it a little too complex. We've got to get that message through in a clear fashion that we are a true once-a-day product, and we have this favorable side effect profile. So it's about making that message more powerful and impactful. And we believe that combination of these 3 steps gives us a reasonable level of confidence that we can return Gralise to growth.

Daniel James Busby - *RBC Capital Markets, LLC, Research Division - Senior Associate*

Okay. Quick follow-up on the leakage in scripts. Is that a fairly new development? Or have you seen that in the past with this product?

Arthur Joseph Higgins - *Depomed, Inc. - CEO, President & Director*

We've seen it in the past. But again, I think, as we start to create demand again, we're more sensitive to it because we're trying to understand why are we not seeing the conversion of what -- you asked in the beginning, how -- what's the receptivity to physicians to Gralise. It's actually quite high, and the representatives are very motivated promoting the product. But we don't see that conversion at a level we were looking at, and as we probed into that, we validated that there is a level of leakage that we need to address.

Daniel James Busby - *RBC Capital Markets, LLC, Research Division - Senior Associate*

Okay, got it. And just one last question on business development. Broadly speaking, what are you seeing in the market? And do still expect to execute 1 or 2 deals this year?

Arthur Joseph Higgins - *Depomed, Inc. - CEO, President & Director*

We're -- we remain cautiously optimistic. The market has some attractive opportunities. Again, it's all a question of price and attractiveness. But I think, as we've demonstrated, we're pretty creative here, so we remain optimistic. We've got a few more months ago. And let's see what we can do now between now and the year-end.

Operator

(Operator Instructions)

John B. Thomas - *Depomed, Inc. - SVP of IR & Corporate Communications*

Louis, if there are no more questions, we'll wrap it up. Thanks, everybody, for listening.

Arthur Joseph Higgins - *Depomed, Inc. - CEO, President & Director*

Thanks, again.



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Operator

Yes, sir. There are no further questions at this time.

John B. Thomas - *Depomed, Inc. - SVP of IR & Corporate Communications*

All right, thanks, everyone. And obviously, we're around if you need anything else. And all the materials are posted to our website on the Investor Relations section. Thanks for joining us. Have a nice day.

Operator

And this concludes today's conference call. Thank you for your participation. You may now disconnect.

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