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DEPO - Q3 2017 Depomed Inc Earnings Call

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**August J. Moretti** *Depomed, Inc. - CFO & Senior VP*

**Christopher S. Keenan** *Depomed, Inc. - VP of IR and Corporate Communications*

**Matthew M. Gosling** *Depomed, Inc. - Senior VP, General Counsel & Secretary*

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**Scott Robert Henry** *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

## PRESENTATION

### Operator

Good afternoon, and welcome to the Depomed's third quarter Fiscal Year 2017 Financial Results Conference Call. Please note that this event is being recorded.

I would now like to turn the call -- conference over to Christopher Keenan, Vice President of Investor Relations. Please go ahead.

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### Christopher S. Keenan - *Depomed, Inc. - VP of IR and Corporate Communications*

Thank you, operator. Good afternoon, and welcome to our Investor Conference Call to Discuss Depomed's third quarter 2017 Financial Results announced earlier today. A press release and slide deck covering our earnings for this period is now available on the investor page of our website at [depomed.com](http://depomed.com).

With me today are Arthur Higgins, President and Chief Executive Officer of Depomed; August Moretti, Senior Vice President and Chief Financial Officer; Matt Gosling, Senior Vice President and General Counsel; and Jack Anders, Vice President of Finance.

I would remind -- I would like to remind you that matters discussed on this call contain forward-looking statements that involve risks and uncertainties, including those relating to the commercialization of NUCYNTA, NUCYNTA ER, Gralise, Cambia, Lazanda and Zipsor; the company's financial outlook for 2017; development plans and expectations regarding governmental inquiries and investigations; expectations of the opioid markets; 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 for future performance. These and other risks are more fully described in the Risk Factors section and other sections of our Annual Report on Form 10-K for the year ended December 31, 2016, and our quarterly report on Form 10-Q that we will file this week with the SEC. 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 provide financial guidance and guidance on corporate goals for the current fiscal year and to provide update or reconfirm its guidance only by issuing a press release or filing updated guidance with the SEC in a publicly accessible document. References to current cash, cash equivalents and investments are based on balances as of September 30, 2017. 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, November 7, 2017.

With that, I'll turn the call over to Arthur Higgins.



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

Thank you, Chris, and good afternoon. We made good progress in stabilizing our business in quarter 3 despite greater-than-expected declines in both the long- and short-acting opioid markets. Indeed, we believe we have -- we would have made even more progress in the fourth quarter if not for the impact of Hurricane Irma and Maria on NUCYNTA ER supply.

Consistent with our stated goal of diversifying our revenue base, today, I'm going to share with you our go-forward strategy. You will see us grow, not based on 1, but 3 pillars. And as a result, we believe, over time, we can reduce our concentration in the opioid space. I will discuss further, in a moment, each of these pillars.

Whilst each of these pillars has different characteristics, there are 3 overarching principles that guide how we do business in each of them. First and foremost, in everything we say and in everything we do, we are committed to putting the needs of patients first. We are also focused on best-in-class productivity in everything we do and, in particular, with our largest resource, our field force. And last but not least, we are committed to achieving profitability and EBITDA margins over the next 3 years that are in line or better than our peers.

Turning to our first pillar, which is based on maintaining a strong NUCYNTA franchise. We believe NUCYNTA to be a best-in-class molecule with a unique mechanism of action and the only opioid approved for neuropathic pain. In a tough market, NUCYNTA ER and IR showed their resilience in the third quarter, with NUCYNTA ER outperforming the market by 640 basis points in Q3. And among PAIN Practices, which account for approximately 75% of our business, the growth was even stronger, with a market outperformance of over 800 basis points. In September, NUCYNTA ER prescription share reached an all-time high.

A similar picture is seen with IR, which outperformed the SEO market by 230 basis points. Again, in pain specialists which account for approximately 65% of our business, the growth was even stronger, with market outperformance close to 600 basis points.

Before I joined in April, the decision was taken to push further into primary care, which is clearly a misstep and created significant disruption in our customer relationships. In January, we intend to roll out an enhanced go-to-market strategy with an even greater focus on pain specialists. It is also designed to put patients first and enhance our commitment to appropriate prescribing of opioids. With this new strategy, we expect to improve the productivity of our sales effort and, as a result, significantly improve the profitability of our NUCYNTA franchise. We are looking forward to giving you more details of this new strategy in the coming months.

Turning to our second pillar. We are committed to growing our neurology and pain franchises. In line with our previously stated goal, as of September 1, we have completed the increase of our neurology field force, returning it to 90 representatives and, in doing so, doubling our call plan targets. This now provides the proper support to Gralise and Cambia, 2 highly promotional-sensitive products that suffered with the reduction of our salesforce early in 2017. Keeping in mind this team has just begun to ramp up, we are pleased to see some initial positive indications surrounding increased frequency and reach with our targeted physicians as well as an increased number of Gralise starter packs being prescribed in recent weeks.

In my meetings with the new team, I can tell you that they are highly energized, and we're also hearing from key opinion leaders that they are very pleased with our decision to place needed resources behind these important products.

This strong foundation provides credibility to the franchise and allows us the flexibility to add new neurology products, as we work to accelerate growth in this business; both organically and inorganically. With that in mind, we are committed to adding at least one new product to this franchise in 2018.

With today's acquisition of cosyntropin synthetic ACTH-depot, we have put in place the foundation of a new specialty Orphan Drug business and to our build strategy aimed at constructing a portfolio of high-value, high-touch products positioned to address the needs of patients, physicians and payers.

This is the third leg. With cosyntropin, we are establishing a new specialty business unit. I'm pleased to announce that Mark Booth, a 30-year biopharmaceutical executive with 30-year biopharmaceutical experience, who has been working as a consultant to Depomed for several months



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and someone I have known personally for many years and have great respect for, has agreed to take on the role of Senior VP and General Manager of this business. In a short amount of time, Mark has made a big impact, including spearheading today's Slán pharmaceutical transaction.

Cosyntropin is an exciting asset that we believe can be second-to-market behind Mallinckrodt's billion-dollar marketed product, Acthar, which is a natural ACTH-depot. Cosyntropin was acquired by Questcor from Novartis but was never launched in the U.S. It is widely available outside the U.S. with broadly the same indications as Acthar Gel. Questcor then Mallinckrodt, was forced by the FTC to divest this product to West Pharma, now a subsidiary of Slán Pharma, in July of this year. Full details of this transaction can be found in the press release that we issued shortly. But let me give you a high-level view.

The acquisition of cosyntropin provides Depomed the exclusive U.S. license to a late-stage, high-value specialty product. As I mentioned, this product will enter the market, currently served by Acthar, with estimated annual sales of \$1.2 billion. The transaction will have Slán filing an NDA for the first indication in late 2018 with a goal of an expected launch in the second half of 2019.

We are also pursuing in tandem a second indication in infantile spasms, a specific seizure-type seen in infantile epileptic syndrome. We anticipate the initiation of an investigator new drug trial in quarter 1 of 2018 by the Pediatric Epilepsy Research Foundation, or better known as PERF, led by key investigator, Dr. Kelly Knupp. Orphan drug status in this indication was granted in August of this year. Further details of this trial can be found on the PERF website.

Over the next 12 to 18 months, Mark Booth and I expect to bring additional products into this portfolio and build a strong and fast-growing Specialty Pharma Orphan Drug business.

From day one, I have taken decisive steps to strengthen multiple layers of the organization while leveraging the company's existing expertise. We have been fortunate to retain established leaders, including my CFO, Augie Moretti; and my General Counsel, Matt Gosling. We have created promoted roles for Jeff Carrol to become our Chief Compliance Officer, reporting directly to me.

We have added Mark Booth as our SVP, General Manager of our New Specialty business; Sharon Larkin, SVP of HR and Administration; and Sean McKercher, SVP of Marketing and Operations; Peter Schineller, SVP of Sales and Managed Markets; Dr. Santosh Vetticaden, Chief Medical and Scientific Officer; Tim Hermes, VP of Government Affairs; and Daniel Peisert, VP of Business Development. Each of these individuals brings decades of pharmaceutical and biotech leadership experience that, I believe, will help us in executing our 3-pillar strategy of maintain, of grow and build. And just as important, they all share my commitment to putting the patient first in everything we do at Depomed.

Looking forward to 2018, we have significant milestones that will set us up for growth in 2018 and beyond. Let me quickly review these.

In the first half of 2018, we will unveil our enhanced NUCYNTA go-to-market strategy, which, as stated earlier, is designed to put patients first, improve the productivity of our salesforce and significantly improve the profitability of our NUCYNTA franchise. We anticipate the initiation of an investigator-led new drug trial for cosyntropin in infantile spasm. We expect that a pretrial conference will be held regarding our Purdue litigation. And we hope to execute a refinancing of the Deerfield and Pharmakon secured debt.

In the second half of 2018, we anticipate the NDA filing for cosyntropin in its first indication, and our goal is to execute 1 to 2 new business development initiatives in the second half of the year. We see 2018 as a year of growth and one that will reposition us and set us up for a breakout year in 2019 and beyond.

With that, I will turn the call over to Augie, who will provide you with the financial update.

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### **August J. Moretti** - Depomed, Inc. - CFO & Senior VP

Thank you, Arthur. Let me begin by saying that with respect to our third quarter results and our revised guidance, I will be discussing certain GAAP measurements as well as certain non-GAAP measurements, which we expect to continue to present in future periods. Please refer to today's press



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release and the appendix of the slide presentation that we are using for this conference call for an explanation of our non-GAAP financial measures and tables that reconcile the company's non-GAAP measures to GAAP measures.

Total GAAP revenue for the quarter ended September 30, 2017, was \$95.4 million. For the quarter, total NUCYNTA franchise sales were \$58.7 million, down from \$63.9 million in Q2 '17.

As we mentioned in our October press release, during the quarter, NUCYNTA franchise product sales were negatively impacted by approximately \$2 million due to supply delays resulting from the impact of Hurricanes Irma and Maria at our third-party manufacturing facility based in Puerto Rico. As planned, the manufacture of NUCYNTA IR was recently transferred to a manufacturing facility in New Jersey, and we do not expect any supply issues with NUCYNTA IR.

Our NUCYNTA ER manufacturer's plant in Puerto Rico is open and operating. NUCYNTA ER has been given a high priority. Manufacture of new batches of NUCYNTA ER has begun, and we currently expect to receive some additional material before the end of Q4. However, we will experience temporary pharmacy outages of certain SKUs later in the quarter. Unfortunately, given the dynamic situation in Puerto Rico, we cannot predict with certainty when we will be fully resupplied across all SKUs. We will provide a further update when we are able.

Turning to the remainder of the portfolio. Gralise third quarter net sales were \$21.1 million, up from the \$18.1 million in Q2 '17. Cambia had third quarter net sales of \$8.2 million, down from \$8.5 million in Q2 '17. Lazanda had third quarter net sales of \$4 million, down from \$5.3 million in Q2 '17. And finally, Zipsor had third quarter net sales of \$3.2 million, down from \$4.4 million in Q2 '17.

Days on hand at wholesalers decreased approximately 5 days from the end of the second quarter of 2017 for NUCYNTA IR as a result of supply interruptions during the quarter. Days on hand at wholesalers for our other products were up 1 to 2 days during the quarter.

Cost of goods for our portfolio in Q3 2017 was approximately 18% of revenue, and this is down slightly from the second quarter. The COGS for NUCYNTA is approximately 24% of net sales. And COGS for the rest of the portfolio, approximately 9%.

Turning to our expenses. GAAP selling, general and administrative expense was \$48.9 million for the third quarter of 2017. Non-GAAP SG&A expense, excluding stock-based comp and contingent consideration, was \$46.8 million for the third quarter.

GAAP and non-GAAP R&D expenses for the third quarter were \$1.8 million and \$1.7 million, respectively. The reduction in R&D expenses relative to the second quarter is primarily the result of completion of certain portions of our ongoing pediatric trials for NUCYNTA during the second quarter and delays in the next steps of those pediatric trials. EBITDA for the quarter was \$30.1 million, up from \$28.3 million in Q2.

Moving on to the balance sheet. As of September 30, 2017, cash, cash equivalents and marketable securities were \$113.5 million, a quarterly decrease of \$3 million from Q2. In Q3, we paid both 6 months of Grünenthal royalties on NUCYNTA net sales and 6 months of interest on our convertible debt.

Turning now to guidance. We are reducing our 2017 guidance in light of our third quarter performance, the impact of supply disruption on our NUCYNTA franchise, continuing contraction in the long-acting and short-acting opioid markets that has exceeded our expectations and the transfer of Lazanda to Slán that we announced today. Guidance for the year is based on actual results for the first 9 months of the year and our current expectations for the remainder of the year. Our budget is based on a large number of assumptions, and there are significant uncertainties in estimating future product revenues. This is particularly true of our largest revenue products, NUCYNTA and NUCYNTA ER, given the rapidly evolving opioid markets and the supply issues that we discussed earlier.

For a more complete discussion of the relevant risks related to our guidance, I'll direct you to the Risk Factors section of our quarterly report on Form 10-Q that we will file later this week.

With that said, total revenues for our 6 products for 2017 are expected to be in the range of \$375 million to \$380 million. This is a reduction from our previous guidance of \$395 million to \$410 million.



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Q3 results were negatively impacted by approximately \$2 million as a result of supply disruptions to NUCYNTA, resulting from hurricanes Irma and Maria. We are uncertain that we will be resupplied with all of our demand for NUCYNTA ER during Q4. We believe the impact of supply disruption should be less than \$10 million for the year.

The opioid market continues to contract at rates that have exceeded our expectations. In Q3 2017, the short-acting opioid market contracted year-over-year by 10%. And the LAOU market contracted by 13%, again, year-over-year. The Q3 rates of contraction caused us to realize net sales below our expectations. We have reduced our Q4 estimates in light of Q3 market performance.

As a result of the Slán transaction, we will not book Lazanda revenue after today, and this will have a negative impact of \$2 million to \$3 million in Q4.

So with respect to the reduction in net sales estimates, in broad strokes, approximately \$10 million is due to supply disruption. Approximately \$2 million to \$3 million is due to the transaction with Slán that transferred to Lazanda in exchange for rights to cosyntropin. And the balance is due to our underperformance, resulting principally from the contraction in opioid markets.

Non-GAAP SG&A expenses, that is GAAP minus stock compensation, purchase accounting contingent consideration adjustments and nonrecurring costs, are expected to be in the range of \$190 million to \$194 million. This is a decrease from our previous guidance of \$195 million to \$201 million. And even though it is a decrease, it reflects the costs associated with responding to the government inquiries that we have previously disclosed and the increase in the neurology sales force in Q4.

Non-GAAP R&D expenses are expected to be \$14 million to \$16 million. This is a decrease from our previous guidance of \$18 million to \$23 million. Non-GAAP adjusted EBITDA is expected to be \$104 million to \$109 million, a decrease from our previous guidance of \$107 million to \$117 million.

A final comment on non-GAAP financial measures. The non-GAAP financial measures used by Depomed 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.

That concludes the financial discussion, and I'll now turn the call back over to Arthur.

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

Thank you, Augie. Operator, would you please open the call to questions?

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## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions)

And we do have a question from the line of Randall Stanicky.

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**Ashley Ryu** - *RBC Capital Markets, LLC, Research Division - Senior Associate*

This is Ashley Ryu, on for Randall. Arthur, you've mentioned recently that your view around adding products to your portfolio was a preference for something that was either a late-stage pipeline with -- that could meaningfully contribute to revenues in 2018, or at the latest, 2019, or a product that's already on market and accretive. It sounds like today's announced deal wouldn't contribute until probably late 2019 and start to ramp beyond. So I guess, my 2 questions are, how do you think about the contribution of this product and how you see it ramping? And also, it sounds like there



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is a continued appetite for near-term product deals; given that you saw that you can add at least one new product next year, so will these new assets be aligned with kind of 1 of those 2 criteria, either accretive or meaningfully contributing in 2018 or latest, 2019?

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

A very good question. And let me say you're exactly correct. Our focus is on identifying assets that could be immediately accretive in 2018 and '19. The situation with cosyntropin was a rather unique one. This enabled us to access a product which we believe has significant opportunity. If it can be, which is our hope, the second product into the market after Acthar, we've got access to a very large market. It also strategically provided a rationale for building-out a specialty platform where we also believe we can find assets that meet the criteria I just described. So there's no deviation from our priority when it comes to finding assets. We're looking for assets that can meaningfully impact revenues and earnings in an '18, '19 time frame. And thanks for the question.

**Operator**

And your next question comes from David Risinger.

**Onusa Chantanapongwanij** - *Morgan Stanley, Research Division - Research Associate*

This is Onusa, calling in Dave. I have a few. So regarding the corticotropin asset, what indication will be filed with the FDA in late 2018? And what percentage of the current Acthar market does that indication represent? Separately, did Lazanda's legal liability transition away or stay with Depomed with this transaction?

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

Okay. Let me answer the first question. We are not going to disclose the first indication, for competitive reasons. As for Lazanda liability, that will transfer to Slán.

**Matthew M. Gosling** - *Depomed, Inc. - Senior VP, General Counsel & Secretary*

Yes. This is Matt Gosling. It will transfer to them in a kind of our watch/their watch concept. So we hold on to liabilities associated with our promotion, and they take on liabilities associated with their own; which is typical in a deal like this.

**Operator**

And the next question comes from Scott Henry.

**Scott Robert Henry** - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

A couple questions with regards to the corticotropin asset. First, in the press release, it mentions that you will share in net sales. Can you add any color to that? How will you -- what percent will you book? How should we be modeling this?

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

At this stage, we are -- I'm not going to get into specifics, but to say that we share the majority of the profits up to a threshold.



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**Scott Robert Henry** - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

Okay. So you have the majority of the profits up to a threshold, Depomed, right?

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

Correct. Correct.

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**Scott Robert Henry** - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

Okay. That's helpful. And are there any milestones with regards to approval filing? Any of those events?

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

No. There are no milestones due to -- as a result. No.

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**Scott Robert Henry** - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

Okay. And then, I guess, a final question. When it comes to NUCYNTA ER, given the supply issues, how does that impact your ability to promote the product? And when would you expect to be at full supply such that you can promote it? And how should we think about the script trends? It looks like they kind of tailed off recently, which looks a little bit like, perhaps, the supply is becoming an issue. Just any color on how we model that in and when we should think about full strength.

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

Let me first of all remind everybody that this doesn't impact IR. So there's no confusion here. We're really talking about ER. But NUCYNTA IR is more than half of the franchise revenue. I think, as you gathered from Augie's comment, we expect the situation will improve through the quarter. As to how we are instructing a sales force, we are closely monitoring this situation, but I can tell you that everything that we do is focused on my comments and my presentation of putting interest of the patient first.

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**Scott Robert Henry** - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Head of Pharmaceuticals Research*

Okay. And I guess, you said supply is going to improve throughout the quarter. But when -- would you expect to be able to meet demand by the end of the year? Or I'm just trying to get any sense of how to model that.

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

Look, again, I think all we can say is this has our highest priority, and we are continuing to work with a supplier who is a world-class manufacturer. We're working with him around-the-clock to minimize the impact on patients and our business.

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**Operator**

(Operator Instructions)

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

Operator, if there are no more questions, let me finish with a few closing remarks. Since joining Depomed in April, my team and I have faced significant headwinds as a result of an increasingly challenging opioid market, a highly disruptive salesforce realignment that took place earlier in the year and, more recently, supply issues with NUCYNTA ER as a result of Hurricane Maria. Despite all of these challenges, we have made good progress in stabilizing the business and, as you saw in the quarter, protecting a strong EBITDA performance. We are finishing the year with a commitment to turning these headwinds into tailwinds based on our 3 growth pillars: maintaining a strong NUCYNTA franchise, growing our neurology and pain business, and building a new and exciting specialty pharma business. All of this anchored by a belief that in today's pharma market, that we can drive superior profitability while still putting the interests of the patient first.

In closing, I thank you all for your support in a difficult year and look forward to your continued support as we expect a stronger 2018 and setting ourselves up for a breakout in 2019 and beyond. Thank you very much. Operator, you may close the call.

**Operator**

This does conclude today's conference call. You may now disconnect.

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