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DEPO - Q2 2017 Depomed Inc Earnings Call

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

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PRESENTATION

Operator

Good afternoon, and welcome to the Depomed Second Quarter Fiscal Year 2017 Financial Results Conference Call. Please note this evening's event is being recorded. I would now like to turn the conference over to Christopher Keenan, Vice President of Investor Relations. Please go ahead.

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 second quarter 2017 financial results announced earlier today. The press release covering our earnings for this period is now available on the investor page of our website at 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 like to remind you that the 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; 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 of 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 filed today 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 June 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, August 7, 2017.

I'll now turn the call over to Arthur Higgins.



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

Thank you, Chris. Today, I will provide some context into the rapidly evolving opioid marketplace and outline why this is leading us to be more cautious in our financial outlook. I will also review the actions we are taking to adapt to the changing pain market and discuss how Depomed is fully committed to being part of the solution in combating the opioid epidemic.

For perspective, let me begin by reminding you of what I discussed in my first conference call as CEO back in May. Fundamentally, Depomed is fortunate to possess a portfolio of differentiated products that are each uniquely positioned to help patients in the management of pain. Our flagship products, NUCYNTA is a dual-mechanism opioid and NUCYNTA ER is the only opioid approved to treat diabetic peripheral neuropathy. While there are significant challenges shaping the opioid market, which I will discuss further, it is clear that when you use the proper way, opioids are and will remain important products for the treatment of pain.

With all the change taking place in the pain market, we remain committed to the physicians treating pain and the patients suffering from pain. We firmly believe that by treating patients fast and by engaging all the Depomed stakeholders to find meaningful solutions, we will emerge as a stronger company, a different type of specialty pharmaceutical company and a true leader in pain management.

It is clear we are operating in a challenging and volatile environment. You only have to turn on the television or read the newspaper to understand that opioid addiction and the resulting overdoses and deaths are a national crisis. Recently, the new FDA Commissioner, Scott Gottlieb, called the opioid epidemic the biggest crisis facing the FDA. Janet Yellen, Chairman of the Federal Reserve, called the opioid epidemic a threat to the U.S. labor force.

And the Commission on Combating Drug Addiction and Opioid Abuse, led by Governor Chris Christie, urged the President Trump last week to declare it a national emergency. Also last week, the FDA announced plans to expand the existing long-acting REMS program to include immediate-release, short-acting opioids.

We are also seeing governmental stakeholders question the role of drugmakers, wholesalers and prescribers in the space. To that end, on July 28, we received a subpoena from the Department of Justice regarding our commercialization practices for our NUCYNTA products and Lazanda. Similar inquiries have been made to other pharmaceutical companies in the opioid space, and we, as a company, look forward to cooperating with this request.

As you know, I am relatively new to Depomed and Depomed is relatively new to the opioid space, having only launched NUCYNTA IR -- relaunched NUCYNTA IR and ER in 2015. Since that time, many things have changed, but one constant is that the company has always been committed to operating according to the highest standards of compliance, ethics and patient care. And I can assure you, these standards will continue under my watch.

Not surprisingly and we feel, justifiably, this environment has significantly impacted the overall opioid market. In the second quarter, the long-acting and short-acting market showed a year-over-year decline of approximately 11% and 7%, respectively. Against this background, we were able to continue to grow our market share of our NUCYNTA franchise and deliver company-wide revenue of \$100.4 million, which was broadly in line with our expectations. However, in the past several weeks, we have experienced some softness versus our forecast in weekly prescriptions and ex-factory shipments of both IR -- NUCYNTA IR and ER. This may reflect the events that we just outlined and does coincide with recent feedback from our pain sales force that the primary care segment is becoming more conservative in their rating of opioids and that pain specialists are facing tougher roadblocks in getting prescriptions through the reimbursement system.

I had thought that given the expansion of our pain sales force earlier this year, we would see a clear separation of our performance versus the market by the year-end. And while I am not giving up on that goal, I think it's more realistic that this will not be fully apparent until sometime in 2018.

For the reasons I just described, and coupled with the associated costs required to respond to incoming legal inquiries as well as our very positive recent decision to accelerate our neurology field force build-out, we feel it's prudent to be more conservative with our full year outlook. Augie will give you more specifics on our financials for the quarter and revised guidance shortly.



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Acknowledging that we can't control the macro environment, we continue to focus our energy on what we can control, which is our strategy and execution. So let me update you on that. You will recall, after the highly disruptive changes that we made to our field force at the beginning of this year, my first priority coming in was to stabilize the field force, so we could understand what was and was not working in our go-to-market strategy. That remains our goal, and at this stage, we are making all the refinements that are aligned with the evolving opioid market and with the needs of the rest of our portfolio.

Two of the more important moves we'll make in the coming quarters are: firstly, we are reducing the number of calls on targets -- or our call targets in our pain sales force by approximately 20%. The vast majority of that target reduction comes from primary care physicians, and it's becoming clear they will play a reduced role in pain management. This move will allow our sales force to increase frequency and focus and resources to the pain specialists, who are playing an ever-increasing role in the treatment of these patients. To illustrate that point, pain specialists and their physicians, assistants and nurses currently account for approximately 70% of our NUCYNTA franchise. By focusing on the pain specialists, we will protect our base business, and by increasing our frequency and resources to the pain specialists, we will be in a position to efficiently grow the business over time.

Secondly, I am pleased to announce that we are aggressively moving forward with the expansion of our neurology sales force, which will go from 40 to 90 sales specialists. This sales focus will be on Gralise and Cambia. And we are confident this expansion, which will be completed in September, will ensure that Gralise and Cambia, which are both promotionally sensitive products, will get the resources they need to effectively compete and grow. While the cost of this expansion will mean incremental SG&A, this investment is also consistent with our stated goal to strengthen our neurology platform and create a more diversified business.

In addition to these moves, which strengthen our promotional effectiveness, I'm also excited about the steps we have taken to fortify the organization with talented, experienced individuals, who will play a critical role on my executive team. Peter Schineller joined us as Senior Vice President, Sales and Managed Care, bringing with him a professional career of more than 25 years, spanning both the diagnostic and pharmaceutical industry. Most recently, he served as Chief Commercial Officer at the diagnostic company, Skyline B.V. (sic) [SkylineDx B.V.]. Peter was brought onboard to further improve our sales force execution as well as assist us as we navigate the changing pain market dynamics.

Jeff Carrol was recently promoted to the position of Vice President and Chief Compliance Officer. Jeff has been with Depomed since 2014 as a Compliance Officer and Assistant General Counsel. Jeff's position will be reporting directly to me and reflects the continued importance we, as a company, place in operating our business ethically and appropriately.

Timothy Hermes joined us as Vice President, Government Affairs. He brings with him almost 15 years of government affairs experience, holding leading positions at Collegium, Auxilium and Sunovion Pharmaceuticals. Tim will lead our newly formed Government Affairs Group. His addition advances our commitment to an increased voice at the state and federal level. One of Tim's top priorities will be to ensure, both at the state and federal level, it is clearly known that Depomed supports the ongoing health focus to reduce the abuse of opioids.

We share the way we held good that proper patient selection and the management of these peripheral medicines is critical. Furthermore, we recognize that treatment duration for short-acting opioids should be for the shortest amount of time needed to allow the patients to effectively manage their acute pain and move on to an opioid-free recovery. We also, as a company, strongly support measures to deter and reduce abuse of these medicines.

In closing, I came to Depomed with a conviction that we were uniquely positioned to succeed. And indeed, even in the face of greater headwinds that, I think, anyone couldn't have foreseen, I remain confident in our future. Depomed's board, management and employees are resolute in the turning of business to growth and committed to being part of the solution in addressing the opioid crisis.

I would now like to turn the call over to Augie to discuss our second quarter financial performance and our updated guidance. Augie?

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

Thank you, Arthur. Today, I'll first review our second quarter results and then review our updated guidance.



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I want to mention at the offset that with respect to our second 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 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, 2017 were \$100.4 million. For the quarter, total NUCYNTA franchise sales were \$64 million, up from \$60.7 million in Q1 '17. Gralise second quarter net sales were \$18.1 million, down from the \$18.6 million in Q1 '17. Cambia had second quarter net sales of \$8.5 million, up from \$7.2 million in Q1 of '17. Lazanda had a second quarter net sales of \$5.3 million, an increase from \$3.9 million in Q1 2017. As we discussed in our first quarter call, we made the decision to halt the sales force promotion of this product. Finally, Zipsor had second quarter net sales of \$4.4 million, a decrease from \$4.7 million in Q1 2017.

As we anticipated, days on hand at wholesalers decreased approximately 4 days from the end of the first quarter of 2017, ending the quarter at approximately 19 to 20 days. Cost of goods for our portfolio in Q2 2017 was approximately 19.5% of revenue, and this is consistent with Q1 2017. As most of you on the call know, COGS for NUCYNTA is approximately 25% of net sales, and COGS for the rest of the portfolio is approximately 10%.

Turning to our expenses. GAAP selling, general and administrative expense was \$50 million for the second quarter of 2017. And non-GAAP SG&A expense, excluding stock-based comp and contingent consideration, was \$48 million for the second quarter '17. GAAP and non-GAAP R&D expenses for the second quarter 2017 were \$5.6 million and \$5.3 million, respectively. R&D expenses include the costs associated with pediatric trials of NUCYNTA.

EBITDA for the quarter was \$28.3 million, up from \$25.3 million in Q1.

Moving on to the balance sheet. As of June 30, 2017, cash, cash equivalents and marketable securities were \$117 million, a quarterly decrease of \$78 million. As we previously announced in April 2017, we prepaid \$100 million, the principal of our secured debt, along with a \$4 million prepayment fee. So when you net it out, we added \$26 million in cash to the balance sheet.

The company announced a reduction in force during the quarter ended June 30, 2017 in order to streamline operations and achieve operating efficiencies. The company recorded \$3.4 million in severance and benefit charges during the period. Restructuring and related liabilities payable as of June 30 were \$1.9 million.

I want to discuss government inquiries for a moment. Recently, Depomed and other pharmaceutical companies received subpoenas relating to opioid sales and marketing practices from the Office of the Attorney General of Maryland and, as you heard from Arthur, the United States Department of Justice. We are currently cooperating with the state of Maryland and the DOJ in their respective investigations. In addition, Depomed and other pharmaceutical companies earlier received a request for information from Senator McCaskill, the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs, relating to the company's promotion of opioid products. The company has voluntarily furnished information responsive to such requests. As a result of the activity required to respond to these requests, we will be incurring legal expenses in support of our responses, which are reflected in our updated guidance.

So turning now to guidance. We're updating our 2017 financial guidance as a result of recent developments, including an increased pressure on short-acting and long-acting opioid markets by federal and state governments, managed care and other stakeholders; July shipment and prescription demand trends; increased legal expenses associated with responding to recent government inquiries and subpoenas; and expenses associated with the increase in the neurology sales force that Arthur mentioned.

Guidance for the year is based on actual results for the first 6 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 market. For a more complete discussion on 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 filed earlier today.



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With that said, total revenues for our 6 products for 2017 are expected to be in the range of \$395 million to \$410 million. This is a reduction from our previous guidance of \$405 million to \$425 million. 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 \$195 million to \$201 million. This is an increase from our previous guidance of \$187 million to \$197 million and reflects the costs associated with responding to the government inquiries and the increase in the neurology sales force. Non-GAAP R&D expenses are expected to be \$18 million to \$23 million. This is a decrease from our previous guidance of \$22 million to \$29 million. Non-GAAP adjusted EBITDA is expected to be in the range of \$107 million to \$117 million.

Lastly, a comment on our debt refinancing. We continue to actively explore refinancing options, but given our high concentration of revenue tied to the opioid market, debt investors are requesting a risk premium in those negotiations.

I'll close with a 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.

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

Thank you, Augie. We are now open for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of David Amsellem with Piper Jaffray.

David A. Amsellem - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

So I wanted to get your high-level thoughts on spend. I know you're talking about the higher spend around the neurology-focused sales force. But given the pressures across the business and given that the product portfolio generally focuses on a relatively concentrated prescriber base, I'm just puzzled as to why you're not focusing more and trying to drive more profitability out of these franchises, and perhaps, there's a way to cut spend significantly. So if you can talk to that, that would be helpful.

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

Yes, David. I mean, David, I think I'd bring you back to when I came in. As I mentioned in my opening remarks, my first priority was to stabilize, and I also said it would take several quarters before we would see the benefit of the increased field force. I think we have to get that it's time. We believe, at this stage, we have the right size of field force and the right appropriate level of expense. But clearly, this has to be confirmed by our future performance.

David A. Amsellem - *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

Okay. And then in terms of the overall portfolio, I mean, you talked about Lazanda and halting promotion there. Are there any other products that you can envision also discontinuing active promotion?



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

No. I think we see it as [overall differences] are in our portfolio with Lazanda. We are supporting that product with nonfield force promotion. We're talking about probably less than 100 key prescribers accounting for 75% of that business. So we'd love to do that through non-promotion. But as regards to the rest of the portfolio, we have no intentions of changing our efforts behind those products.

Operator

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

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

This is Ashley Ryu on for Randall. I just want to start with NUCYNTA. So in light of the continued pressures in the opioid space, how much visibility do you feel that you have? It sounds like the market has worsened relative to your initial expectations last quarter. And how do you feel comfortable that this updated outlook kind of captures the right level?

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

Ashley, I think that's a very good question. And I think, again, in my opening remarks, we said we wanted to be more conservative and cautious. This is a highly volatile environment. It's moving rapidly, and we're doing our best to stay on top of it. So what we have presented today is our best outlook based on the information we have available. We believe it's right, but I caveat that by saying this is a very challenging and volatile marketplace.

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

Yes, that definitely makes sense. I guess switching to neurology. Of course, it looks like there was a greater investment in neurology now with the move-up to 90 reps. Is the step-up, perhaps, because you're seeing a greater opportunity there and want to invest behind it? Is it because you're seeing the need for more support since they're more promotionally sensitive products? What kind of drove that acceleration?

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

Ashley, I think it's consistent with our stated goal to try and diversify away from opioids for all the reasons we're discussing. But for us, equally importantly, we believe, historically, this has been demonstrated that both Cambia and Gralise are highly promotionally sensitive. We had reduced the sales force to a suboptimal number, and we believe, by returning that to a more optimal size, that we can get these products back on to a growth trajectory faster. And that's what we're trying to do here. So one, the products deserve it; and two, it's consistent with our strategy to diversify away from pain.

Operator

(Operator Instructions) Your next question comes from the line of Ken Trbovich with Janney.

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

I guess, Augie, just to better understand your comments about the intended plan to refinance the debt. I understand your point about the fact that they're requiring a higher premium. Does that suggest that there's no longer an opportunity to refinance it at better terms or simply that the cost savings will be less than you previously expected?



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

Ken, we will continue to negotiate to refinance the debt, and I think it's really going to go to the terms that we're able to achieve.

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

Okay. So would goal then still be to complete that in the third quarter? Or has that been pushed out?

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

We're still actively working to get this refinancing done in the quarter, which is what we had previously announced.

Operator

I would now like to turn the call back over to Arthur.

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

Hearing no more questions, let me just thank everybody for their participation today. I think you would have acknowledged that in all challenging markets, there are winners and losers. We believe that we remain focused on execution, including the needs of our patients and the physicians that treat our patients, first. So we will emerge out of this challenging market a stronger company and a true leader in the pain space. I'd like to thank you all for your attention, and I wish you all a very good evening. Thank you very much.

Operator

Ladies and gentlemen, this concludes today's conference call. You may now disconnect. Speakers, please hold.

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