

CEMPRA, INC.

FORM DEFA14A

(Additional Proxy Soliciting Materials (definitive))

Filed 09/12/17

Address	6320 QUADRANGLE DRIVE SUITE 360 CHAPEL HILL, NC, 27517-8149
Telephone	919-576-2306
CIK	0001461993
Symbol	CEMP
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

SCHEDULE 14A INFORMATION

**Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934**

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

- Preliminary Proxy Statement
- Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2)).**
- Definitive Proxy Statement
- Definitive Additional Materials
- Soliciting Material Pursuant to §240.14a-12.

CEMPRA, INC.

(Name of Registrant as Specified in its Charter)

N/A

(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

Payment of Filing Fee (Check the appropriate box):

- No fee required.
- Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

Fee paid previously with preliminary materials.

Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing:

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this communication regarding the proposed merger and other contemplated transactions (including statements relating to satisfaction of the conditions to and consummation of the proposed merger, the expected ownership of the combined company and the alternatives to the proposed merger) constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are usually identified by the use of words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “will,” and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control.

Risks and uncertainties for Cempra and Melinta and of the combined company include, but are not limited to: inability to complete the proposed merger and other contemplated transactions; liquidity and trading market for shares prior to and following the consummation of the proposed merger; costs and potential litigation associated with the proposed merger; failure or delay in obtaining required approvals by the SEC or any other governmental or quasi-governmental entity necessary to consummate the proposed merger, including our ability to file an effective proxy statement in connection with the proposed merger and other contemplated transactions, which may also result in unexpected additional transaction expenses and operating cash expenditures on the parties; failure to obtain the necessary stockholder approvals or to satisfy other conditions to the closing of the proposed merger and the other contemplated transactions; a superior proposal being submitted to either party; failure to issue Cempra common stock in the proposed merger and other contemplated transactions exempt from registration or qualification requirements under applicable state securities laws; risks related to the costs, timing and regulatory review of the combined company’s studies and clinical trials, including its ability to address the issues identified by the FDA in the complete response letter relating to Cempra’s new drug applications for solithromycin for community acquired bacterial pneumonia; uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; inability or the delay in obtaining required regulatory approvals for product candidates, which may result in unexpected cost expenditures; failure to realize any value of certain product candidates developed and being developed, in light of inherent risks and difficulties involved in successfully bringing product candidates to market; inability to develop new product candidates and support existing products; inability to commercialize and launch any product candidate that receives regulatory approval, including Baxdela; the combined company’s anticipated capital expenditures, its estimates regarding its capital requirements and its need for future capital; uncertainties of cash flows and inability to meet working capital needs; cost reductions that may not result in anticipated level of cost savings or cost reductions prior to or after the consummation of the proposed merger; the approval by the FDA and EMA and any other similar foreign regulatory authorities of other competing or superior products brought to market; risks resulting from unforeseen side effects; risk that the market for the combined company’s products may not be as large as expected; inability to obtain, maintain and enforce patents and other intellectual property rights or the unexpected costs associated with such enforcement or litigation; inability to obtain and maintain commercial manufacturing arrangements with third party manufacturers or establish commercial scale manufacturing capabilities; loss of or diminished demand from one or more key customers or distributors; unexpected cost increases and pricing pressures; the possibility of economic recession and its negative impact on customers, vendors or suppliers; and risks associated with the possible failure to realize certain benefits of the proposed merger, including future financial, tax, accounting treatment, and operating results. Many of these factors that will determine actual results are beyond Cempra’s, Melinta’s, or the combined company’s ability to control or predict.

Other risks and uncertainties are more fully described in our Annual Report on Form 10-K for the year ended December 31, 2016, as amended by Form 10-K/A filed with the SEC on April 13, 2017, and in other filings that Cempra makes and will make with the SEC in connection with the proposed transactions, including the proxy statement described below under “Important Information and Where to Find It.” Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The statements made in this press release or presentation speak only as of the date stated herein, and subsequent events and developments may cause our expectations and beliefs to change. While we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing our views as of any date after the date stated herein.

Important Information and Where to Find It

Cempra and Melinta and certain of their directors and executive officers may become participants in solicitation of proxies from Cempra stockholders in connection with the proposed transactions. Additional information regarding persons who may, under the rules of the SEC, be deemed to be participants in the solicitation of Cempra stockholders in connection with the proposed merger, and a description of their direct and indirect interest, whether as security holders, directors or employees of Cempra or Melinta or otherwise, which may be different from those of Cempra stockholders generally, is set forth in the preliminary proxy statement filed with the SEC on September 7, 2017 in connection with the proposed merger and will be set forth in other materials to be filed with the SEC. You can find information about Cempra’s directors and executive officers in Cempra’s Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on February 28, 2017, as amended by Form 10-K/A filed with the SEC on April 13, 2017, and in the preliminary proxy statement filed with the SEC on September 7, 2017 in connection with the proposed merger.

Each of Cempra’s directors, Garheng Kong, David Zaccardelli, Richard Kent, David Gill, Dov A. Goldstein, John H. Johnson, P. Sherrill Neff and Michael Dougherty; Cempra’s executive officers Mark W. Hahn (Executive Vice President and Chief Financial Officer), David Oldach (Chief Medical Officer) and John Bluth (Executive Vice President, Investor Relations and Corporate Communications); Melinta’s directors, Eugene Sun, Thomas Koestler, Erik Akhund, Kevin Ferro, Cecilia Gonzalo, Christopher Kiritsy, Pedro Lichtinger, Sean Murphy and John E. Sununu; and Melinta’s executive officers, John Temperato (President and Chief Operating Officer) and Paul Estrem (Chief Financial Officer); and Cempra’s proxy solicitor, Georgeson LLC; may be deemed “participants” in the solicitation of proxies from the Cempra stockholders in connection with the proposed transactions.

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval. A definitive proxy statement and a proxy card will be filed with the SEC and will be mailed to Cempra’s stockholders seeking any required stockholder approvals in connection with the proposed transactions. **BEFORE MAKING ANY VOTING OR INVESTMENT DECISION, INVESTORS AND STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND ANY OTHER RELEVANT DOCUMENTS THAT CEMPRA HAS FILED OR WILL FILE WITH THE SEC WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTIONS.** Stockholders may obtain, free of charge, copies of the proxy statement and any other documents filed by Cempra with the SEC in connection with the proposed transactions at the SEC’s website (<http://www.sec.gov>), at Cempra’s website (<http://investor.cempra.com/>), or by writing to the Secretary, Cempra, Inc. at 6320 Quadrangle Drive, Suite 360, Chapel Hill, North Carolina 27517.

Cempra
September 12, 2017
08:00 AM EDT

Jason: Hello, I am Jason Russell with the Healthcare Banking team at Morgan Stanley. Thanks for joining us this morning for the Morgan Stanley Global Healthcare Conference.

Excited to have the opportunity to be here with Dr. David Zaccardelli, acting Chief Executive Officer for Cempra. I would also like to call out the attendance of other members of the Cempra team, as well as the Melinta team, in the front row, all of whom will be available for Q&A at the end of David's remarks.

As you're likely aware, on August 9th, Cempra announced the signing of a definitive agreement with Melinta Therapeutics, a privately-held company focused on antibiotics. I would like to highlight the initial proxy statement related to the post-merger can be found in the Company's EDGAR filings at www.sec.gov. The Company has also prepared a presentation, which Dave will discuss with you shortly. And you can find the presentation at Cempra's website.

With that, Dave, I'd like to pass it over to you. We're going to go off-format a little bit to give Dave an opportunity to present the proposed combination of Cempra and Melinta. Dave?

David Zaccardelli: Well, thank you, Jason, and good morning, everyone, and everyone that's online, as well. We're very excited today to provide you an update on Cempra, and specifically the recently announced merger with Melinta, and we'll spend some time talking about that.

Before I get started, I want to remind everyone that we'll be making forward-looking statements, and I want you to rely on the SEC filings containing our language on forward-looking statements, as well as those contained in the slide deck.

I also have with me today Dr. David Oldach, our Chief Medical Officer; Mark Hahn, our CFO; and John Bluth, EVP of Investor Relations. And from Melinta, Eugene Sun, the CEO; John Temperato, the Chief Operating Officer, and Paul Estrem, the CFO. And as Jason mentioned, we'll be here to answer your questions.

We plan to review the content of a slide deck that is available at cempra.com, and it's under the Investor section, and also filed with the SEC. And as Jason mentioned, we also recently filed the proxy, preliminary proxy, such that enormous amounts of information are in there, and the detailed information, more than I'll be reviewing today.

So, over the next 15 minutes or so, I want to review four primary areas. One is the overall rationale for the merger of Cempra and Melinta, the combined Company pipeline, which we find very exciting, and, importantly, spend a fair amount of time on Baxdela, or delafloxacin, both the chemical and compound itself and its differentiation, as well as the launch strategy, and, fourth, want to review the summary of the financials that would exist upon merger of the Company related to cash and debt.

So, let me start with the rationale on slide four, for those that are following the slide deck. So, with the merger of Cempra and Melinta, we create a leading commercial-stage company focused on anti-infectives, and an initial focus on antibiotics. And as I'll review we have a substantial pipeline that is ranging from discovery platform through commercial.

Importantly, with the combination, we'll have sufficient existing cash to support a successful Baxdela launch, which is key to our path forward. We estimate that greater than \$400 million of peak Baxdela sales are possible in skin alone, keeping in mind additional indications could occur. And we're approaching this in an informed way, based on previous launches, and we'll make sure we're capital-efficient in the people and our approach to launching Baxdela.

So, the other aspect to remind ourselves is that there is significant clinical and commercial differentiation with Baxdela, and I'll be reviewing that in a bit more detail. And also, shareholders of Cempra continue to retain solithromycin and fusidic acid as advanced products in phase three and an NDA. And just as an overview, the process that went on to form the merger of Cempra and Melinta was extensive, and a process that we went through with Morgan Stanley, looking at over 90 companies during that timeframe.

So, let's take a look at the pipeline, which I think you'll find deep and extensive. So, it starts with Baxdela, which is an approved product recently this summer, and approved for skin both in IV and oral, which is going to be very important as we talk about the launch. In addition, it's currently enrolling a study in pneumonia, and expect that to progress in 2018. And we also have the opportunity to look at it in complicated UTI. So, with that, you have multiple indications that are progressing within Baxdela.

In addition, solithromycin, which has submitted NDA and is progressing in response to a CRL, and in addition, we continue to progress our ophthalmic formulation program, which we're very excited about both in conjunctivitis, but even more importantly, a potential in dry eye, as well as fusidic acid, just to remind everybody, that it has completed a phase three trial successfully, with positive results. And we have a path forward, which I'll be speaking about a little bit later. We continue to progress it in bone and joint infections, and we expect additional data later on this year. And as I referred to, we also with the merger have a proprietary discovery platform specifically looking at ESKAPE pathogens, which I think everyone will agree is a high unmet medical need.

So, now let's review the launch strategy for Baxdela and talk about Baxdela's differentiation. One thing I want to point out is that we're very familiar with previous launches of products, and most recently in the 2014 timeframe, in the skin space, and we're going to approach Baxdela launch in an informed way based on that information. We looked at why those launches were potentially less than many expected, and I think we have both a product with Baxdela, as well as an approach from a commercial launch strategy that differentiates from the previous products in this space.

So, let's take a look at why we believe that, and talk about Baxdela specifically. Baxdela has full pathogen coverage from gram-positive, including MRSA, which is unique for a fluoroquinolone, and covers gram-negative. That's going to be very important when you look at that type of coverage with a product that has intravenous and oral formulations. In addition, there is simplicity that comes with Baxdela, both in drug interactions, which are limited, and disease interactions, both kidney, liver, with no adjustments needed for treatment. And as I've referred to a couple times already, the flexibility related to having an IV and oral are critical to our strategy in the launch.

And I'll start referring now to some of the differentiation in the launch. We're looking to price Baxdela at a level that allows access both in a hospital and a community setting. And we're working in the final stages of that to ensure that there aren't pre-authorization requirements, and it is priced successfully in a hospital and a community setting such that, if a physician writes for Baxdela, that prescription can get filled. It's critical in a community setting to do that.

I'll point out just graphically on slide number 10 a pictorial of the differentiation for Baxdela. And I think that, as we talk about the launch, it'll be important to remember these attributes. And I've mentioned much of them already in the presentation.

So, when we look at the launch, just to create the framework, we're initially going to launch with 50 sales reps, and this is targeted to start in the first quarter of 2018. Because of information that's available, we are able to target very efficiently those practices, hospitals, that actually treat skin infections at a higher volume, and also those institutions and practices that allow access to new products, and also have a history of prescribing products for skin treatment.

In the slide deck, there is the typical safety language that is required. I do want to point out a few items. Clearly, the safety language covers the normal fluoroquinolone class labeling, but it is important to note that it contains no QT language; that is, there's no QT prolongation with Baxdela, and no phototoxicity issues, as well. So, I think that those are important elements to look at a differentiation on the safety language side.

So, digging in a little deeper with regard to the launch strategy on slide 14, as you're following, we're approaching this in a multi-channel approach, and I want to talk about each one of them individually and discuss how Baxdela fits into it. So, if you start with the hospital channel, we clearly see that there's a role for Baxdela in a hospital setting, because of its intravenous formulation and ability to convert to a same-drug oral formulation, we think that that's going to be very interesting and attractive for physicians.

In the hospital, there are almost three million patients treated annually, and the ability to treat those patients intravenously and convert them to oral, looking at the ease of treatment as potentially getting them discharged earlier. There's also another point of care which is very important, again related to the dual formulation of Baxdela, and that's in the emergency department. Here we have greater than 1.5 million patients treated, and we have an opportunity to treat those patients either starting with oral Baxdela or starting with intravenous and sending them out with oral treatment. So, I think it provides the emergency department the flexibility that they'd be looking for with a product that has broad coverage of the organisms that they're most interested in ensuring (ph) to cover, as well as the ability to convert the patient to oral therapy.

And then, importantly, in differentiating from previous launches, we're looking at the community setting, as well. And here we're targeting practices that have a high treatment for patients with skin infection and have prescribed previous skin drugs. And we're going to target those sites and practices very carefully. But, here you have over 11 million patients treated annually, and the ability to have an oral formulation that covers the organisms that are of greatest concern is important. And I'll talk about the patient type that we're targeting in all these settings, as well.

So, I think it's critical to understand our multi-channel approach and our over-arching philosophy of pricing related to making sure that access to Baxdela is available. And we think that the product for sure would want to be written by physicians, and we want to make sure that, when that occurs, that the actual prescription is filled. And remind everybody, we think that this is a huge opportunity, and greater than \$400 million of peak sales in skin.

Let's talk a little bit about the patients that we're targeting and why Baxdela would be preferred in a certain patient set. Here we're looking at patients that typically have maybe mixed infections, or greater concern for gram-negative while still covering gram-positive and MRSA organisms. So, here, when you look at patients that have serious skin infections, about 70% of them have comorbidities that would lead you to have concern for gram-negative mixed infections while still maintaining your gram-positive coverage. And here are patients that we're going to, again, target and discuss the applicability for Baxdela.

As I've mentioned, and it's covered really in slide 16 and 17, we're taking a very targeted approach. We're making sure that we address the need in those practices, hospitals, emergency departments that treat these patients, and also have the greatest access for influencing practicing behavior. Clearly, the drug is applicable for these patients, and now we have to make sure that we discuss and review and promote those facilities that would be most receptive. And that's covered, again, in detail in 16 and 17, in which we've already laid out where these type of practices exist, and we'll continue to refine that prior to the launch in the first quarter.

As you can imagine, there is an enormous amount of activity underway to support the launch. I won't go over all the details. John Temperato is here to do that, as well, after the meeting. But, on slide 18, all of the activity that you'd expect to be occurring to have a successful launch are well underway.

So, moving forward with the combined Company, I wanted to point out a few other attributes that we think are important to understand. First is our complementary approach to licensing the products externally in the rest of the world. And already, delafloxacin has been partnered with Menarini, and has an approach to get delafloxacin, or Baxdela, in over 68 countries, and with a filing of the MAA in 2018, a critical partnership for the expansion and opportunity for Baxdela.

In addition, Eurofarma has rights to it in Brazil and Central and South America, and we look forward to that expansion. As many of you know, we have a relationship with Toyama in which solithromycin is licensed in Japan, and currently is undergoing multiple trials, including a phase three in CABP.

So, we'll take a little deeper dive in an update on the pipeline, and specifically on solithromycin and fusidic acid. I wanted to remind everybody that progress has been made in the past few months on solithromycin since receiving the CRL. We have negotiated with the FDA successfully, keeping in mind that originally they were looking at having up to 12,000 patients in a safety study. And we've come to an agreement in a protocol to provide them 6,000 patients in response to the CRL.

An important element to that, to remind yourselves about how we're approaching it, is that we're actually studying the oral formulation only in that study, so that's done for various reasons. One is efficiency and convenience of getting the study done. There's a cost element, being more efficient from that standpoint, as well as when you look at the data, the oral formulation and the oral patients had somewhat less liver enzyme increases. And so, we think we've approached it prudently and efficiently. And we look to start that study once we receive non-dilutive funding, and we're continuing to progress that on multiple fronts.

Fusidic acid already has a positive phase three study in skin, and we've met with the agency and have a clear path forward, including conducting an essentially similar identical study phase three trial, which we'd have confidence would meet its primary endpoint, as well as additional studies of drug interaction, a thorough QT, and other elements that are required for the NDA. So, the NDA path is well sorted for fusidic acid.

I'd made reference, when I talked about the pipeline, of the earlier access that's come from Melinta, radezolid, and dermatology is partnered with a CRO and is currently progressing through phase one, and has a great opportunity to have a new treatment for acne. And we're excited about that from its progress, as well as the ability to opt back in and retain rights to that product as it progresses.

And of course, the ESKAPE pathogen and program, which is critical to continuing our diligence and making sure that we come up with new antibiotics to treat not only ESKAPE pathogens, pathogens that have resistance to current antibiotics and continue to evolve and make sure that new antibiotics are available for patients.

So, let me take a turn now on slide 22 for some of the financial information of the combined Company. I'll point you specifically to the later part in which, upon the merger, which we would expect to happen in the fourth quarter, we would expect to have approximately \$150 million of cash and debt of about \$45 million. Importantly, we expect that \$150 million to be associated with a successful Baxdela launch and to create value of the Company as that occurs, while continuing to assess and prioritize our pipeline, which is well-advanced, as well as having a discovery platform.

So, really, we're investing to build value, and we're doing that through, first, a successful Baxdela launch, critical to the continuation and insurance that the pipeline and the value increases within the combined Company. But again, the pipeline's very rich, advanced, and we have a clear path forward for both solithromycin, fusidic acid, and we'll continue to progress both of those.

I thought I'd take a minute or two just to talk about some of the details of the proposed transaction. Again, all of that detail is in the proxy. But, just to remind, upon merger, the transaction looks to have the current Melinta shareholders owning about 52% of the Company, and the current Cempra shareholders about 48%. All of this was approved by both companies already. And I also want to point out that we're in a very active search right now for a CEO that we would hope to have in place in and around near the end of the year, and we continue to work on that as providing that leadership for the Company as it goes forward.

I did mention the merger is expected to close in the fourth quarter. And with regard to Board or governance standpoint, four of the Board members will be designated by Melinta, four by Cempra, and then the CEO to make up a nine-member Board.

So, with that, I'll just summarize. Again, I think with the merger, we achieve a deep commercial and clinical and preclinical anti-infective pipeline. We create a Company that's focused on anti-infective and antibiotics. We — importantly, we have sufficient cash in order to drive a successful Baxdela launch, which we expect to have peak sales in excess of \$400 million just in the skin indication alone. And we're going to approach that in a very capital-efficient way, making sure that our progress on the launch is matching our investment.

We have significant clinical and commercial differentiation with Baxdela that we believe will allow us to have a different trajectory, a different utilization, and a different result with regard to the launch of Baxdela. Importantly, we'll continue to progress solithromycin and fusidic acid, and continue that value proposition in the combined Company.

So, with that, I'll end and take questions, or have Jason moderating.

Jason: Any questions from the audience? Thank you.

David Zaccardelli: Do you want to go?

Jason: Sure. So, maybe I'll ask a few questions you did. So, you provided some analogs of present FDA — I mean present antibiotic launches. Help us really understand what will make this and a fluoroquinolone different compared to, frankly, quite a few new antibiotics that are either currently recently approved or emerging.

David Zaccardelli: Yes, so a good question, of course. I think it starts with the differentiation of Baxdela itself. So, I think when you look at a product that has broad coverage, both in gram-positive MRSA, gram-negative, and the formulation with intravenous and oral, that combination is unique, and that all comes with a fluoroquinolone, which physicians are very familiar prescribing fluoroquinolones.

In addition, of course, on the safety labeling, besides the class label for a fluoroquinolone, it does have the advantage of having no QT or phototoxicity. So, I think you have to start with are physicians interested in prescribing it, and we think with that profile, they are. And then, you have to look at more of the tactics and strategy that we have with the launch and how we're approaching it from a multi-channel, both hospital, emergency department, and community setting, as well as the pricing to ensure access. That combination we believe will provide the advantage for Baxdela.

Jason: Okay. Thanks, Dave. Obviously Cempra has a legacy with solithromycin, still a huge opportunity. You highlighted in your remarks would be pursued but subject to non-dilutive financing. Help us understand how we should measure when you would expect to hear further news on nondilutive financing and how that might progress.

David Zaccardelli: Yes. So, as I mentioned, we have a very active program to look at nondilutive funding. We are actually putting together an application to BARDA in September for submission. That application is a request for \$50 million. And we think the study to conduct the 6,000 patient response to the CRO is approximately \$80 million, so that would be well advancing us on our way. We also have other activities in looking at business development and monetizing, for example, solithromycin in Japan. We have a relationship with Toyama that could be looked at in order to create some nondilutive funding. We also have a lot of incoming with regard to fusidic acid, and that is possible to look at different relationships and business development of fusidic acid to provide funding.

So, I think we have multiple approaches. There are also other government agencies we're looking at, but BARDA's most advanced because of our history with them. They currently finance our pediatric trial, which is important, and they're very familiar with solithromycin.

With regard to timing, I think we're hoping to get some additional traction and understanding from BARDA by the end of the year with the submission, and we've met with them multiple times on the approach and are interested in starting that study as soon as possible. They have great interest in solithromycin, so they're motivated to do that.

I think another important element of financing in a nondilutive way and blunt the risk is that this is an open-label study, safety only, and we'll actually know the results on an ongoing basis. So, as the investment occurs and results indicate continued study, the actual risk is decreasing, and it makes a greater argument for the investment.

Jason: Sure. Maybe we have time for one more. So, obviously the proposed merger and the pro forma Company would have a robust pipeline. Speaking to the current Cempra pipeline, you've read out a study, positive study in skin, positive phase three study, received FDA guidance with regards to next steps, similar design to have approval track for that drug. How does the pro forma company think about capital allocation? You obviously indicated that a large majority of the funds focused towards the Baxdela launch. So, how will the Company think about prioritizing opportunities to really progress the pipeline in the best way?

David Zaccardelli: Yes, absolutely. And we realize that, I think. Again, as I've mentioned, we want to have a successful launch with Baxdela — that's going to drive value — while understanding we have well-advanced assets that we need to take care of and progress. As we merge, we will conduct a portfolio review and staging to make sure that we utilize the cash and capital efficiently. And as you can imagine, as we're successful in our strategy, the value of the Company should be increasing, and the ability to continue to invest in advanced pipeline will make great sense.

So, we are looking at the timing now. Solithromycin, as we just talked about, stands a little bit on its own with regard to nondilutive funding, and fusidic acid, importantly, we have the plan in place, and now we'll just need to stage it correctly with the capital that we have in play and the value that we increase in the Company, we'll discuss the launch.

Jason: Great. Thanks, Dave. Think that's probably all the time we have. Thanks to the Cempra team, to the Melinta team up front. I'm sure they'll be available for questions now that we are through. Thanks.

David Zaccardelli: Thank you, great.