UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 20, 2018

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-36728	56-2590442
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
465 State Route 17, Ramsey, New Jersey		07446
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: (201) 478-5552

(Former name or former address, if changed since last report.)

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

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

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

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ý

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

As reported in a Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission (the "SEC") on December 20, 2018, on December 19, 2018, ADMA Biologics, Inc., a Delaware corporation (the "Company"), issued a press release announcing that the U.S. Food and Drug Administration has issued a Complete Response Letter (the "CRL") for the drug substance Prior Approval Supplement ("PAS") submission for BIVIGAM® (Intravenous Immune Globulin [Human], 10%) ("BIVIGAM®") and previously approved the drug product PAS submission for BIVIGAM®.

On December 20, 2018, the Company held a conference call at 9:00am Eastern Time (the "Conference Call") to provide more detail about the CRL.

A copy of the transcript of that call is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information set forth in this Item 7.01 and contained in the transcript furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about the Company. These forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements concerning the Company's plans to develop, manufacture, market, launch and expand its commercial infrastructure, the expected timing of, and the Company's ability to, obtain and maintain regulatory approvals of its current products and product candidates and the Company's expectations for future capital requirements. Actual events or results may differ materially from those events or results that may be implied by these forward-looking statements due to a number of important factors. There can be no assurances that the forward-looking statements included will prove to be accurate. Except to the extent required by applicable laws or rules, the Company does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause our actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in the Company's filings with the SEC, including the Company's most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

Item 8.01 Other Events.

On December 20, 2018, the Company issued a press release announcing that it would be hosting the Conference Call to discuss the CRL received on December 19, 2018.

The full text of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of Conference Call held on December 20, 2018.
99.2	ADMA Biologics, Inc. Press Release, dated December 20, 2018.

SIGNATURE

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

December 20, 2018

ADMA Biologics, Inc.

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer

VIAVID
communications simplified.

ADMA Biologics, Inc.

Regulatory Update on Bivigam PAS Submissions Call

December 20, 2018

CORPORATE PARTICIPANTS

Jeremy Feffer, *Managing Director, LifeSci Advisors, LLC*

Adam Grossman, *President and Chief Executive Officer*

CONFERENCE CALL PARTICIPANTS

Jason McCarthy, *Maxim Group*

Leland Gershel, *Oppenheimer and Company*

Edward Marks, *H.C. Wainwright*

Yale Jen, *Laidlaw & Co.*

Ren Benjamin, *Raymond James*

Keay Nakae, *Chardan*

PRESENTATION

Operator:

Good day and welcome to the conference call to discuss recent regulatory updates on Bivigam PAS submission. Today's conference is being recorded. At this time I would like to turn the conference over to Jeremy Feffer. Please go ahead.

Jeremy Feffer:

Thank you, Kim, and good morning. This conference call contains forward-looking statements pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995, about ADMA Biologics Incorporated, we, our or the Company.

These forward-looking statements include without limitation any statement that may predict, forecast, indicate or imply future results, performance or achievements concerning our plans to develop, manufacture, market, launch and expand our commercial infrastructure, the expected timing of and our ability to obtain and maintain regulatory approvals of our CARD (phon) products and product candidates, and our expectations for future capital requirements. Actual events or results may differ materially from those described in this conference call due to a number of important factors. There can be no assurances that the forward-looking statements included will prove to be accurate. Except to the extent required by applicable laws or rules, ADMA does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements. Forward-looking statements are subject to many risks and uncertainties and other factors that could cause our actual results and the timing of certain events to differ materially from any future results expressed or implied by the forward-looking statements including but not limited to the risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K and any amendments thereto.

With that, I would like to turn the call to Adam Grossman, ADMA's President and Chief Executive Officer. Adam?

Adam Grossman:

Thanks, Jeremy. Good morning everybody. Thank you to our shareholders, analysts and other interested constituents in our growing company ADMA Biologics. I am Adam Grossman, the co-Founder, Director, President and CEO of the company, and I sincerely appreciate your time and attention today as we provide some further updates and details on the status of our much needed IVIG product Bivigam and its FDA review for approval.

I'd like to start today by reporting that it's been approximately 18 months since closing our acquisition on the manufacturing plant and drug product assets from Biotest Pharmaceuticals, and we have made significant and tremendous progress accomplishing tasks and objectives which the prior owners could not achieve. We are truly pleased with our progress in turning the plant and assets around as we continue to execute on our goals and corporate objectives.

We would like to specifically point out that under our leadership and guidance, the compliance status of the facility has improved from OAI, standing for Office Action Indicated, to VAI meaning Voluntary Action Indicated. This again is something the previous owners could not accomplish in four years. This improved compliance status is a necessary step in order to receive any new FDA approval under the previous compliance status which was OAI. No approvals were issued for new applications at the site during the time period that that status was in place with the previous ownership.

Subsequent to our April 2018 FDA Compliance Inspection at our Boca Raton manufacturing facility, the agency accepted our responses and plans for addressing the inspectional observations and issued the Company what's known as an Establishment Inspection Report, or EIR, which indicated that we were found to be operating within compliance. Again, this is the first time that this site has been operating in compliance and received an EIR since 2012.

Today, ADMA operates as a commercial biologics manufacturer and marketing and sales organization. We continue to produce and release commercial drug into the U.S market with Nabi-HB, our specialty hyperimmune globulin for use in patients at risk or infected with hepatitis B. We also continue to produce and release batches of rabies immune globulin paste for our contract client customer. With this as our backdrop, I'd like to turn the topic over to the topic of the day which is the receipt of a Complete Response Letter, or CRL, in regard to selected topics included in Bivigam's drug substance Prior Approval Supplement to amend it's already approved BLA.

As we reported previously, ADMA successfully produced three conformance batches of Bivigam earlier in 2018 using what we call our new, optimized IVIG manufacturing process. These conformance batches were produced after we conducted extensive evaluation and study of the old Bivigam process in our small-scale production model in which the old process frequently exhibited filter clogging and contained other undesirable impurities in its production. We then executed a comparability protocol to compare the old process to the new ADMA optimized Bivigam process. We believe these manufacturing evaluations were completed appropriately, successfully and were well documented in accordance with GMP.

The CRL ADMA received for Bivigam is mainly asking for additional clarification with regard to these topics for Bivigam. These requests and the CRL received are for Bivigam only and we want to make it clear that they do not directly affect anything for our other ongoing interactions including RI-002's ongoing FDA BLA review and potential approval.

As you may expect, ADMA provided thousands of pages of documents, data, explanations and information to the FDA in our initial PAS submission, which we made in June 2018. During the FDA's review cycle, the Company responded to multiple routine information requests from our regulatory project manager at FDA, which also included additional thousands of pages of documents and data. The data and submissions which ADMA prepared are robust and full of complex information and details. The point I'm trying to make is we gave the FDA a lot of information to review. As we previously reported, FDA extended the Bivigam PAS PDUFA Review Action Date by two months from October 2018 to December 2018 due to the volume of our submission. We believe since receiving the CRL that FDA had a few remaining questions and clarification requests and therefore they need a bit more time to complete their review of our extensive data package.

All of the questions and clarification requests including in the recently received CRL for Bivigam drug substance PAS, we feel are fully resolvable and addressable in the near term. We believe that none of the requests included in the CRL appear to require lengthy amounts of time to complete and we believe that some of the additional data FDA is requesting is currently included in other sections of the PAS submission or we have the data on file at the company, ready to go.

I want to emphasize that the questions in the CRL are strictly related to specific CMC, chemistry manufacturing and controls-related topics, and the agency has not requested any additional information for new clinical trials, data, anything to do with our compliance status. We believe there are no additional manufacturing runs required or other lengthy processing or testing studies or information which could delay our ability to respond to the CRL. Additionally, the CRL does not identify any issues with our third-party laboratories, vendors or suppliers.

It's important to note that while Bivigam and RI-002 share the same plant, share certain equipment and relatively similar production processes, both products are separate from each from a regulatory standpoint, which means they are two separate and standalone complete submissions. We continue to work with the FDA review team assigned to RI-002's review and we are routinely receiving information requests with the ongoing review of RI-002's BLA.

It's important today for me to point out how encouraging it is that our drug product Prior Approval Supplement for Bivigam's BLA was approved. For clarification, when ADMA submitted its PAS, we separated the submission into two parts. The first part is for what we do at our Boca Raton plant to manufacture the actual immunoglobulin drug substance for Bivigam. The second part of the PAS submission was for the fill finish at our contract CMO and for the final release and release testing of final drug product that's filled and packaged into vials. We are hopeful that this encouraging news will give investors confidence in that we did not receive any rejections for ADMA's Boca Raton plant's compliance status and the receipt of this approval demonstrates we do have a clear compliance check and we are able to get approvals.

All the third party labs and associated lot release tests that we used for Bivigam are in good standing and are compliant. Many of these labs and release tests are also utilized for RI-002.

We are also able to now finally receive approvals post our successful completion of the April 2018 FDA inspection, which, again, is something that the previous owners in this plant has been unable to achieve since the warning letter was issued in November of 2014.

While it is disappointing that the potential approval for Bivigam has been delayed, we are committed to responding to all of FDA's questions and clarification requests contained in the CRL in the near term. As we have previously provided updates on the manufacturing progress of our organization, we will keep the investor community apprised of any developments at the appropriate times.

We are committed to resolving these issues and will be ready to bring Bivigam to market as soon as possible post FDA's review of our response to the information contained in the CRL.

I would importantly like to note that the Company and our Board of Directors have met and we are exercising fiscal responsibility and will, to any extent necessary and warranted, implement a cost-containment strategy to slow our cash burn and reduce the planned expenditures for ramping up for the commercial inventory build and launch for Bivigam. We previously reported that cash on-hand at the end of the third quarter was approximately $43 million and disclosed in our third quarter 10-Q that we would have cash into the second quarter of 2019. By implementing these cost containment strategy measures, we believe that we will be able to manage and conserve cash to take us further into 2019 with the expectation being well through the approval for RI-002 which is scheduled for April 2, 2019.

This concludes my prepared statements. I thank you all for your attention and time. With the remaining time, Jeremy and Operator, we'd be happy to entertain a few questions from participants, and we thank you for your questions in advance.

Operator:

Thank you. If you'd like to ask a question today, please press star, one on your touch-tone telephone. If you are using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. Once again, it is star, one to ask a question. We'll pause for just a moment to give everyone an opportunity to signal.

Our first question is from Jason McCarthy from Maxim Group.

Jason McCarthy:

Hey guys, thanks for taking the question. So, you may have already answered this but relating to the CRL, can you address what some of the specific concerns were from the FDA on the drug substance side? I know you mentioned the CMCs but could you go into a bit more detail? And then … oh, go ahead.

Adam Grossman:

No, sorry. Ask your second part.

Jason McCarthy:

Just the second part, I wanted to know if you have any idea what the FDA is asking for to resubmit later on.

Adam Grossman:

I think it's all kind of in the same question. I mean to go into further details, Jason, they're asking for some specific questions about, you know, 'Please share with us your redlined batch record. Please share with us your redlined SOP for … " a certain testing asset. I think that they are really just looking at some of the additional changes and from our internal assessment it really looks like these would be questions that one would sometimes receive during the normal review cycle.

Again, we submitted a lot of data. I think FDA just ran out of time and they sent us these questions.

Your second part of the question is what's it going to take to submit or what's the FDA asking for? It's really just written responses and clarifications. I think the FDA may have some confusion over parts of our comparability protocol that we ran in the small-scale model comparing the old process to the new process. I think with just some further explanation and a realignment of say the way the data tables are presented can help resolve some of that confusion, but we feel very, very confident.

I said a couple of times in the statement that we feel very confident to be in a position to submit in the near term and we do not believe that there is going to be any significant hold-up in our ability to turn this around.

What I can say is that typically when you get information requests from FDA they usually give you somewhere between one to three weeks to respond to those information requests. While my attorneys who are probably listening do not want me to give guidance on that, I can certainly tell you that my internal timelines with our staff, I would try to be treating this just like it is a routine information request because from what's been presented to me by our staff, we have the ability to respond to all of these questions with data we have on-hand.

Jason McCarthy:

All right. Thank you very much. Extremely helpful.

Adam Grossman:

Thanks, Jason.

Operator:

Moving on, we have a question from-

Jeremy Feffer:

Other questions?

Operator:

We have a question from Leland Gershel from Oppenheimer.

Leland Gershel:

Hey, good morning. Thanks for taking my questions. Wanted to just check. Given that an extension was already implemented for the review, given the amount of material that the FDA was going through, is it the case that no further extensions were allowed and therefore given the PDUFA Date this action, absent a full approval even if there were any outstanding issues would have led to a CRL?

Adam Grossman:

You know, Leland, that's a very good point. Nice to speak with you. We've spoken with our regulatory advisors and our regulatory counsel and I guess I believe also in the press release that the Company issued when we received the major amendment classification and the PDUFA Date extension, under the CFR it is my understanding that the agency is only allowed to extend the review one time. I'm told the agency has their own prerogative; if they want to miss their PDUFA Date they can just not respond and take the time that they need, but the agency is graded and I know that they like to make their grades, just like the rest of us do.

So, I think to your point, I think that that's accurate. I think that we just ran out of time. I think with the holiday, the Thanksgiving holiday in between may have caused an issue; I have no facts, just my own personal conjecture, but at the end of the day I think that we did send them a lot of information. I mean we put together submissions that are robust, complete and thorough, and I think that that's evidenced by the fact that we had an FDA inspection and there were observations and we responded to those observations very fulsomely and we received an improvement in our compliance status.

We provide all the details, all of the information and we explain ourselves as well as we can. So, we're very hopeful and optimistic that we can turn this back around to FDA and they can take the remaining time that they need and hopefully approve the PAS for a well-needed product like IVIG which is currently ink a shortage situation in the United States.

Leland Gershel:

Thanks. Then just wanted to touch on timelines a bit further. So, obviously we're still sort of in this holiday season. Wanted to just kind of ask if we could drill further down on timelines for getting information to the FDA for the request and if you would have to have a formal, in-person meeting or if this could be handled without needing a in-person meeting with the FDA.

Adam Grossman:

Sure. They don't want me to answer that question, but candidly, Leland, look, I'm trying to get this out in the first few weeks of the New Year. Again, I don't see any reason why my teams should be delayed in preparing responses to these submissions.

It's always good to get on the phone with FDA. It's always good to get a teleconference. I love face-to-face meetings with the agency. If you're listening guys, you know I love coming down there. But in all honesty, we understand what they're looking for, or at least we believe that we understand, but we have not yet had a chance to speak with our regulatory project manager. We are currently working through all of these issues but my hope would be—and again, no assurances and I'm giving you this, this is my own personal views so please don't hold me to it. The first few weeks of the year we get this thing back on file, try to get them on the phone to clarify any questions that we have. But candidly, it seemed pretty straightforward. We have action plans for all departments that need to provide input to respond to this CRL. They're currently working on it, and for those who know me, I hold myself to a high standard, I hold my teams to a high standard. For those from the company that are listening, I want to see responses as soon as possible.

Leland Gershel:

Okay. Just one last question, if I may? Even though there may be no direct impact on RI-002 with the separate application, separate review, given that the two products are made via very much a similar if not the same process in terms of any of the steps, wanted to ask if given we time until the PDUFA for that product which is I believe early April, if we can then kind of cut off at the head any issues that could creep up like the ones that did for Bivigam for 002 by sort of submitting the same types of information for that application ahead of time versus running into a similar situation down the road?

Adam Grossman:

Sure, absolutely. Those are all great questions and we are thinking about how to navigate that. Again, don't hold me to it but I think one of the goals is that we speak with our regulator project manager and we explain to them, 'Hey, we're getting these questions on the Bivigam review. We don't know if the review team is identical. I'm sure there are some similar reviewers.' Immunoglobulin reviewers are—there are some of them at FDA but it's not an extensive group. We're hopeful that some of the reviewers are the same.

Our strategy that I would like to see our company employ would be to ask our regulatory project manager, just say, 'How would you like this handled? Are these going to be questions that may come up for 002?' Because, Leland, what we don't want to trigger, we don't want to automatically trigger a potential major amendment submission by just lobbying in the information and them getting this and saying, "Wow, there's a lot of stuff here. Let's issue a major amendment.'

If we can do it in a way where we can speak with the agency and we can say, "Hi. You asked for it in this submission. It's similar data in the other one. Would you like us to update it? Could you send us an information request?' there's still a potential that they could classify it as a major amendment. Remember, every time you resubmit something, whether you're responding to a question for FDA or you send something in on your own, whether it's one piece of paper or whether it's 3,000 pieces of paper, the FDA, it's their prerogative to classify it as a major or a minor amendment and potentially extend the PDUFA.

Our goal is to work with the agency as collegially as possible and to maintain these PDUFA dates. It's very routine and when I speak with other CEOs, not only of plasma companies but other companies, when you have a BLA or an NDA on file you routinely get information requests.

So, that's how we've looked to handle this, Leland.

Leland Gershel:

All right. Thanks very much, Adam, for the additional clarity.

Adam Grossman:

Thank you. Thanks for your time and the questions.

Operator:

Our next question comes from Raghuram Selvaraju at Wainwright.

Adam Grossman:

Hi Ram.

Edward Marks:

Hi. This is Edward Marks on for Ram. Just a couple of clarifying questions here. You mentioned, say, one to three weeks that you're trying to get some of the stuff returned, but I'm wondering what happens then, once the FDA reviews all the materials, what maybe is the timeline of a turnaround time after that?

Adam Grossman:

You know, I can't possibly speculate what the agency is going to do. What I can speak to is that in the Code of Federal Regulations when you respond to a Complete Response Letter, they can classify it I believe as a Type 1 or a Type 2. I believe a Type 1 carries a—don't hold me to this—I think it's a 60-day review, and a Type 2 is a 6-month review. Type 2 reviews usually include the need for preapproval inspections or based on the sheer volume of the submission and they need that amount of time.

With regard to the number of questions and the amount of data, we don't look at this as being a multi-thousand page response to the FDA, so our hope would be for the shortest review time possible, and it's certainly something that we will speak with our regulatory project manager about when we are preparing to resubmit and respond to the CRL.

Edward Marks:

Okay, thanks. Then just a question on the facility itself.

Adam Grossman:

Sure.

Edward Marks:

Wondering if the VAI status will be affected at all or if this will remain in place, or if there's any other warning letters that we should be aware of in terms of the facility?

Adam Grossman:

No, that's a great question. As far as I understand it, we successfully completed a FDA compliance inspection. My understanding is that we are on a two-year inspection cycle and we don't see any reason why this Complete Response Letter would have any effect on our compliance status.

Again, we have all the answers to the CRL within our four walls of our offices. We don't believe that there's any other issues. The FDA has inspected us within the last year; again, they were in our facility first two weeks of April 2018. Typically, if the FDA has done an inspection in the prior 12 months they don't reinspect, but again, anything's possible.

On the FDA website it's listed that we are Voluntary Action Indicated status. The name of the facility or I guess the plant name changed from Biotest Pharmaceuticals Corporation to ADMA Biologics. So, we have no notification that anything has changed with our status. We believe that we are in good standing. As I mentioned during this call today, we received an approval for a PAS to amend Bivigam's BLA for the drug product portion. We are receiving other approvals, routine things that you send in, CBE-0, CBE-30, regular manufacturing changes, suppliers, change parts and components and you're always updating your submissions. We are receiving routine approvals. We feel that we are in very good shape.

Edward Marks:

All right. Thanks for the clarification.

Adam Grossman:

Thank you very much.

Operator:

Moving on, our next question is Yale Jen from Laidlaw & Company.

Yale Jen:

Good morning and thanks for taking the questions. My question is in terms of the nature of the CRL for both product was in the manufacture side, but could you clarify that some of the difference between 002 and Bivigam? Would that be something possible?

Adam Grossman:

Well, some things that I can point out and just say, Yale—nice to speak with you—are that first and foremost when we produced batches at Biotest Pharmaceuticals Corporation, when they were our contract manufacturer, we never experienced filter clogging with RI-002. Biotest experienced filter clogging with their production of Bivigam. Bivigam already has an approved BLA, so they have an approved process that obviously is not or was not working well. So the reason why the product's production was voluntarily halted in December of 2016 is so that they could identify what the root cause for this filtering clogging was and then remediate that.

Some things I can say is that small-scale model that was developed was developed to show and reproduce, if you will, the old bad process for Bivigam and compare it to the new optimized process for Bivigam where the impurity profile has been improved, the filterability has been improved and the actual manufacturing steps, processing times, etc., have all been validated and qualified.

Maybe that can give you a little bit of insight into some of the differences, but with Bivigam's PAS we are amending an already existing BLA and with RI-002 we are applying for the initial BLA approval. Hopefully that answer some of your questions.

Yale Jen:

Okay. Great, that's very, very helpful. Maybe just two quick ones. The first is that the issue has been cited in the CRL for (inaudible) 002. Has those issues been—I assume the Company has addressed those issues. Is that correct?

Adam Grossman:

That's correct. In order for us to refile the BLA for RI-002 and respond to the CRL, we would have had to submitted a complete response to that information and the FDA's initial read, obviously they considered the response complete and they issued us a PDUFA Action Date of April 2.

As I noted today during this call, with regard to the Prior Approval Supplement approval for Bivigam's drug substance, I made mention that the facility passed the compliance check; our contract laboratories passed the compliance check; and our contract fill finish provider that we're using is in good standing. So, if you recall the Complete Response Letter press release from—I want to say it was July of 2016—the most notable issues in there were compliance issues noted at our third party contract laboratories and contract manufacturer. So, we feel very, very good. We are very encouraged by the fact that the drug product PAS was approved as a number of the third party labs that we use for Bivigam's lot release testing for IVIG—again, measles, diphtheria, polio, GMP tests, we also use for RI-002. So, we're feeling very good.

Even with this CRL, certainly, Yale, it's not expected, not pleasant. We are disappointed, but we think it's a minor setback. We'll get it taken care of quickly.

Yale Jen:

Maybe the last question on Bivigam is that according—with your discussion with the consultants, do you anticipate a potential refiling the BLA for that, or you think just a continued process of this as the current filing and hopefully that will be resolved later on?

Adam Grossman:

Well, so we have to file a complete response. Unfortunately, this is not under the initial review cycle, so we will have to file a complete response with the FDA. They'll take that response. I imagine—again, don't quote me on this. I didn't prep on this one. I should have. I think that they have 30 days to acknowledge the receipt and then it's either a Type 1 or a Type 2.

Yale Jen:

Okay, great. Thanks and best of luck.

Adam Grossman:

Thank you, Yale.

Operator:

Our next question is from Ren Benjamin from Raymond James.

Ren Benjamin:

How are you doing, Ren?

Operator:

Your line is open.

Adam Grossman:

Ren?

Operator:

Please go ahead with your question.

Ren Benjamin:

Hey, I'm sorry. Can you hear me now?

Adam Grossman:

I can.

Ren Benjamin:

Hello?

Adam Grossman:

How are you doing?

Ren Benjamin:

Oh great. Hey, good morning. Sorry to hear the news but thanks for taking the questions.

Just, I apologize. I jumped onto the call a little bit late and so you may have answered this. But can you just provide a little bit more color on what it means that there was a problem with the drug substance? To me, I don't necessarily know how to take that? Is it completely different substance? Is it just-

Adam Grossman:

No, no. Ren, let me explain.

Ren Benjamin:

Yes.

Adam Grossman:

When you manufacture a biologic, when you manufacture the actual API, the drug itself, that's called drug substance. When you fill it into vials, then that's called drug product. We manufacture drug substance at our site in Boca Raton. We then take that bulk drug substance and we ship it to our contract fill finish provider who then takes that product and fills it into vials, and then it's classified as drug product.

Now, because of the issues plaguing ADMA's plant from a warning letter standpoint, a compliance standpoint, all the things that we have talked about since before the acquisition of the assets and during the acquisition of the assets and after the acquisition of the assets, what we didn't want to have happen was we didn't want to submit a PAS that included everything for making the bulk drug substance and the fill finish into one, because if there was a problem with one part we would not get the approval for the other.

So as you see, our strategy, in a way, while disappointing it worked because what we were able to do is we were able to say, "Okay, these are the things that we do here. These are the things that we have others do for us, and here's all of our laboratories." So, we want to make sure that—hey, let's just play this scenario. Let's say everything we did was right. Let's just say, for example, the FDA was happy with the drug substance submission and they approved it, but let's say one of our testing labs had a problem and we had the whole PAS rejected or a Complete Response Letter because of a compliance problem with one of our third party vendors that we can't control. That's something that we were trying to stave off. It worked in the flip side. This way, now we know we've got clear compliance check at our facility, at our third-party vendors facilities and these are folks that also work with RI-002, so we're very, very pleased that we know, okay, we feel confident that we're probably not going to get issues on that side of our submission in response to the CRL for RI-002.

So, you shouldn't have any concerns that there's any problems with the drug substance. The CRL did not speak of any issue with the drug substance. In fact, and I don't know if I'm allowed to say this or not, but ADMA has received as part of the ongoing review lot release testing authorization from FDA that we passed all their lot release tests for the Bivigam conformance batches. So to the best of my knowledge there is absolutely no problem with our drug substance. The CRL is relating to documentation. They're asking for additional data. They're asking for clarification on the small-scale model, but there is no issue with our drug substance whatsoever.

Ren Benjamin:

Got it. Thanks for the clarification. Just one last one for RI-002. The comparability assays that you guys run right now—and I appreciate the nuance that this is the first time you're applying for the approval of—the entire package, right? The comparability assays that you run, are they exactly in line with what the FDA is going to run so that basically you know right now that, hey, the substance that we used when we were running our pivotal study is exactly the same substance that we are giving to you, FDA, on these batch runs as part of the submission?

Adam Grossman:

I can tell you that the assays that ADMA is running are either the same assays that we used during clinical trial testing for 002, or those assays have been improved or bridged to new assays. Ren, I just—I'm not versed enough in what the FDA does with respect to their release assays. I assume that the assays are all similar that the FDA runs, and again, don't hold me to it. That's my assumption. They're looking at total protein, they're looking at measles, polio, diphtheria potencies. They're probably looking at chromatographic purity and thrombogenicity assays. I would imagine the FDA is doing all of that testing. Look, we receive lot release authorizations from them for the conformance batches for Bivigam. We get them from Navi-HB all the time as we release commercial drugs, so hopefully that answers your question.

Operator:

Moving on, we'll take a question from Keay Nakae from Chardan.

Kay Nakae:

Yes, thanks. Just wanted to clarify one of your previous comments, and that's more of the procedure from here. As you gather the information that you think is appropriate to respond to the requests in the CRL, that then becomes its own new filing with its own new review period and PDUFA date?

Adam Grossman:

Can you ask me that again, Keay? I'm sorry.

Keay Nakae:

Well, I guess as you gather and prepare your response to the CRL, as you submit that, is that essentially the equivalent of filing a new PAS with its own review period and new PDUFA date?

Adam Grossman:

Yes, okay. Sure. I understand now. Sorry about that. It would not be a new Prior Approval Supplement. It would be responding to a Complete Response Letter that was received due to the Prior Approval Supplement filing that we submitted, so the answer is yes. It will start a new review clock. It would either be, as I mentioned, a Type 1 which I believe is a 60-day review—don't hold me. I have to check. Nobody has texted me that I was wrong. I think it's 60 days for a Type 1, and it's six month, 180 days for a Type 2.

Once we respond to that CRL and put it back on file, I mean, look, my hope and my begging is going to be for a Type 1, but I have absolutely no way to determine that. FDA determines it when they get the submission. I would hope, Keay-

Keay Nakae:

So would they-

Adam Grossman:

Go ahead, I'm sorry.

Keay Nakae:

Within 30 days of your submittal they'll let you know I guess their establishment of a new PDUFA date, whether there would be—it's a Type 1 or a Type 2.

Adam Grossman:

That's correct. They will send us a fax that will say this is classified as a Type 1 or a Type 2, and under the PDUFA User Fee Act your Action Date is X.

Keay Nakae:

Okay, very good. Thanks.

Operator:

That's all the time we have for questions today. Mr. Grossman, I'll turn it back to you for closing remarks.

Adam Grossman:

Well, thank you. Thanks, everybody, for your time. I'm disappointed again but I hope that you can hear we are confident. We've got an asset that is in good compliance status that is receiving approvals in the plasma products, immunoglobulin production space, and when you look at what's going on around the world, immunoglobulins are in short supply worldwide. We've got a seat a the table.

I was actually talking with someone the other day and they said, "You know, even the worst basketball team is still part of the NBA and it's worth a lot of money." That's how we look at this. We've got a true asset here and we are creating value there. The plant can get approvals. I want to stress that the FDA, again, has not requested any additional information for new clinical trials, new manufacturing runs or other lengthy processing or testing. The CRL questions are specific to Bivigam, and again, we have all of the answers within our four walls, and again, what's going on with Bivigam right now does not affect the regulatory review for RI-002.

We've got a track record of accomplishing our goals. This is a minor delay and setback, and we want to thank those investors who are sticking with us, and we hope that you do too because we really think that this is the start of us doing great things.

With that being said, thank you, everybody, very much for all the opportunities and we look forward to having you work with us to help make the good products that patients need because they're fighting on us to fight through this and to succeed. So, thanks, everybody, for your time today.

Operator:

That does conclude our conference today. Thank you for your participation. You may now disconnect.

ADMA to Host Conference Call to Discuss Recent Regulatory Update on BIVIGAM® PAS Submissions

Call Scheduled for 9am Eastern Time

RAMSEY, N.J. and BOCA RATON, Fla., Dec. 20, 2018 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases, will host a conference call today to discuss the FDA's Complete Response Letter ("CRL"), received on Wednesday, December 19th, in response to the Company's drug substance Prior Approval Supplement ("PAS") submission and previously approved drug product PAS submission.

Conference Call Details

Date:	Thursday, December 20, 2018
Time:	9:00 am Eastern Time
Domestic:	888-220-8474
International:	323-794-2590
Conference ID:	3968168
Webcast:	http://public.viavid.com/index.php?id=132652

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease ("PIDD") and the prevention and treatment of certain infectious diseases. ADMA's mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease, or who may be immune-compromised for other medical reasons. ADMA has received U.S. Patents 9,107,906, 9,714,283, 9,815,886 and 9,969,793 related to certain aspects of its lead product candidate, RI-002. For more information, please visit www.admabiologics.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about ADMA Biologics, Inc. ("we", "our" or the "Company"). Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "expect," "believe," "will," "is likely," "will likely," "should," "could," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements also include, but are not limited to, statements concerning our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products, the safety, efficacy and expected timing of, and our ability to, obtain and maintain regulatory approvals of our current products and product candidates, and the labeling or nature of any such approvals, the success of our work with our third party vendors and the U.S. Food and Drug Administration (the "FDA") in furtherance of and progress towards an approval of our Biologics License Application for specialty plasma-based biologics and the ability of such third parties to respond adequately or in a timely manner to the issues raised by the FDA, our ability to successfully pursue commercialization and prelaunch activities, the timeframe within which we may receive approval from the FDA for specialty plasma-based biologics, if at all, the potential of our specialty plasma-based biologics to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other indications, our ability to realize increased prices for plasma growth in the plasma collection industry and our expectations for future capital requirements. Actual events or results may differ materially from those described in this document due to a number of important factors. Current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. Except to the extent required by applicable laws or rules, ADMA does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause our actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

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