ALLOS THERAPEUTICS INC Form 425 September 16, 2011

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of the Securities Exchange Act of 1934, as amended

Subject Company: Allos Therapeutics, Inc.

(Commission File No. 000-29815)

This filing relates to the proposed merger of Allos Therapeutics, Inc., a Delaware corporation (Allos) with Alamo Acquisition Sub, Inc. (Merger Sub), a Delaware corporation and subsidiary of AMAG Pharmaceuticals, Inc., a Delaware corporation (AMAG), pursuant to the terms of that certain Agreement and Plan of Merger and Reorganization, dated as of July 19, 2011, as amended, by and among Allos, AMAG and Merger Sub.

Below is the transcript from an AMAG presentation at the Morgan Stanley Global Healthcare Conference on September 14, 2011.

Additional Information and Where You Can Find It

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. The proposed merger between AMAG and Allos will be submitted to the respective stockholders of AMAG and Allos for their consideration.

AMAG has filed a Registration Statement on Form S-4 containing a joint proxy statement/prospectus of Allos and AMAG and other documents concerning the proposed acquisition with the Securities and Exchange Commission (the SEC). The SEC declared the Registration Statement on Form S-4 effective on September 14, 2011. Investors are urged to read the joint proxy statement/prospectus and other relevant documents filed with the SEC because they contain important information. Security holders may obtain a free copy of the proxy statement/prospectus and other documents filed by Allos and AMAG with the SEC at the SEC s website at www.sec.gov. The joint proxy statement/prospectus and other documents may also be obtained for free by contacting Allos Investor Relations by e-mail at investorrelations@allos.com, by telephone at (303) 426-6262 or by mail at Investor Relations, Allos Therapeutics, Inc., 11080 CirclePoint Road, Suite 200, Westminster, CO 80020 or by contacting AMAG s Investor Relations by e-mail at asullivan@amagpharma.com, by telephone at (617) 498-3303 or by mail at Investor Relations, AMAG Pharmaceuticals, Inc., 100 Hayden Avenue, Lexington, MA 02421.

Allos, AMAG, certain of their respective directors, executive officers, members of management and employees may, under the rules of the SEC, be deemed to be participants in the solicitation of proxies in connection with the proposed merger. Information regarding Allos directors and executive officers and their beneficial ownership of Allos common stock is also set forth in Allos annual proxy statement on Schedule 14A filed

with the SEC on April 29, 2011. This document is available free of charge at the SEC s website at www.sec.gov or by going to Allos Investors page on its corporate website at www.allos.com. Information concerning AMAG s directors and executive officers and their beneficial ownership of AMAG s common stock is set forth in AMAG s annual proxy statement on Schedule 14A filed with the SEC on April 18, 2011. This document is available free of charge at the SEC s website at www.sec.gov or by going to AMAG s Investors page on its corporate website at www.amagpharma.com. Additional information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of proxies in connection with the proposed merger, and a description of their direct and indirect interests in the proposed merger, which may differ from the interests of Allos investors or AMAG s investors generally, are set forth in the joint proxy statement/prospectus filed with the SEC.

Forward-Looking Statements

This communication contains forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Terminology such as may, will, should, expects, intends, plans, anticipates, believes, estimates, predicts potential, continue, and other similar terminology or the negative of these terms, are intended to identify such forward-looking statements, but their absence does not mean that a particular statement is not forward-looking. Such forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ

materially from those anticipated by the forward-looking statements. These statements are not guarantees of future performance, involve risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. For example, if Allos or AMAG does not receive its respective required stockholder approval or the parties fail to satisfy other conditions to closing, the transaction may not be consummated. In any forward-looking statement in which AMAG or Allos expresses an expectation or belief as to future results, such expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: failure of Allos or AMAG stockholders to approve the proposed transaction; the challenges and costs of closing, integrating, restructuring and achieving anticipated synergies; disruptions to the businesses of Allos and AMAG during the pendency of the merger and during the realization of the cost synergies, including diminished performance by the commercial organizations due to planned reductions in the size of the sales and marketing organization at the combined company; the ability to retain key employees; and other economic, business, competitive, and/or regulatory factors affecting the businesses of Allos and AMAG generally, including those set forth in the filings of Allos and AMAG with the SEC, especially in the Risk Factors section of Allos Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed with the SEC on August 4, 2011, the Risk Factors section of AMAG s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed with the SEC on August 5, 2011, and in Allos and AMAG s other periodic reports and filings with the SEC. Allos cautions investors not to place undue reliance on the forward-looking statements contained herein. All forward-looking statements are based on information currently available to Allos on the date hereof, and Allos undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this presentation, except as required by law.

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AMAG - AMAG Pharmaceuticals Inc at Morgan Stanley Global Healthcare Conference

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CORPORATE PARTICIPANTS
Brian Pereira AMAG Pharmaceuticals, Inc CEO
Frank Thomas AMAG Pharmaceuticals, Inc CFO
PRESENTATION
Unidentified Company Representative
Thanks, everyone, for joining us. And we have representatives from AMAG Pharmaceuticals up here. So, the far side, Frank Thomas, CFO and to my near left, Brian Pereira, CEO and I have two disclosures to read. The first is that all important disclosures, including personal holdings disclosures and Morgan Stanley disclosures, appear on the Morgan Stanley website MorganStanley.com/researchdisclosures.
And then second one is Morgan Stanley, their acting as financial advisor to AMAG Pharmaceuticals in relation to its proposed definitive merger agreement with Allos Therapeutics, as announced on July 20th, 2011. The proposed transaction is subject to the approval of AMAG and Allos shareholders, regulatory approvals and other customary closing conditions. AMAG has agreed to pay fees to Morgan Stanley for its financial services, including transaction fees that are subject to the consummation of the proposed transaction.
So, with all of that being said, thank you very much, both of you, for joining us. And maybe we can just kick it off if you can give an overview of the Company and what you think are sort of the most important things for people to be focused on right now.
Brian Pereira - AMAG Pharmaceuticals, Inc CEO
Sure. Good afternoon. For those of you who are new to the story, AMAG Pharmaceuticals is located in Lexington, Massachusetts. Our lead product is Feraheme, which is an intravenous iron for the treatment of iron deficiency anemia. Iron deficiency is probably the most common medical condition, bar none. Unfortunately, most of the people who suffer from iron deficiency are in the developing world. In the US, there are probably about five million plus people with iron deficiency anemia and the vast majority of people are treated with oral lines, which are most often ineffective or can cause side effects which makes continuation of therapy tough.

The existing IV irons on the market, the therapeutic doses is about a gram. They re given at five to ten doses over a period of a month. And each of these doses has to be given as a 15 to 30 minute infusion or a slow push. The quantum advantage of Feraheme is that it can be given as two doses of 510 milligrams each and each dose can be given as a simple push over under a minute.

So, this causes a huge amount of patient convenience, office convenience, logistics in the office, and it completes therapy in less than a week.

We launched the drug commercially in July of 2009, so we are entering the third year of commercial launch. Initially, this was positioned as mainly in dialysis and non-dialysis chronic kidney disease patients because the label is for iron deficiency anemia in chronic kidney disease, both dialysis and non-dialysis. But with the advent of the prospective payment system, we changed course and positioned it mainly for non-dialysis CKD patients because this is a premium priced product and in dialysis, it is a cost constrain environment.

In terms of where we sell the drug, we sell it in nephrology offices, hematology-oncology offices, and hospital outpatient infusion centers. Over time, the hematology-oncology space has become the most important place where we sell the drug. In fact, more

1

than half of our business today is in hematology-oncology settings. We ve seen steady quarter-over-quarter growth, particularly in hematology-oncology clinics where in the last quarter we saw a quarter-over-quarter growth of more than 85%.

On the clinical development front, as I said, our label was for chronic kidney disease. Late last year, the FDA changed the label to increase the observation period post-dosing from 30 to 60 minutes, added some bolded warnings based on adverse events seen in the post-marketing environment. But the good news is that as of June this year, the agency went back to 30 minute observation period for us. And over the last couple of months has added all of the restrictions that we have in our label to the labels of all the other IV irons in the marketplace. So, the playing field has been leveled.

The other important things you need to know is that our application for chronic kidney disease is under review in Europe and in Canada, and we expect regulatory decisions by the first quarter of next year.

We also have ongoing clinical trials in phase three for the broad iron deficiency anemia indications. That includes all comers, cancer, women with heavy menstrual bleeding, post-partum anemia, GI bleeders, and so on. We are expecting to finish enrollment of the patients by the end of this year, submit our SNDA somewhere around the middle or latter part of next year, and hoping for approval and launch in the latter part of 2013. So, that s largely on the AMAG front.

As you know, we recently announced an all-stock merger with Allos Therapeutics, which is headquartered in Colorado. Allos Therapeutics lead product is Folotyn, which is a folic antagonist for patients with relapsing peripheral T-cell lymphoma. This drug was approved, roughly, about two years ago and has been launched about two years ago. We see this as a very important therapeutic tool in what is a deadly disease, that s peripheral T-cell lymphoma.

Folotyn received conditional approval based on requiring two phase three trials done. One phase three trial is in first line therapy with patients who receive CHOP, and subsequently randomized to Folotyn or no Folotyn, and phase three program in patients with CTCL, which is cutaneous T-cell lymphoma, which is in discussions with the agency.

This is an all stock merger. The final construct will be Allos shareholders will own 39% of the Company, and AMAG shareholders 61% of the Company. The draft S-4 was out somewhere around the middle of August, and as of today, the final S-4 has been published. The record date is September 9th. Shareholder vote will be the 21st of October. One of Allos largest shareholders, Warburg Pincus, has signed a working agreement. They have 25% roughly 25% ownership of Allos.

So, that s where we stand. We think that this is very good for both AMAG and Allos shareholders. It allows two publicly traded single-product companies to pool their revenues and eliminated duplicative infrastructures. We believe that we can essentially put two companies together, preserve and grow the revenue base and run it with the cost base of one company. And we think that this will drive us to cash flow positivity sooner than either company alone. And then continue growth over the years ahead.

This is not a one-time issue. This is the first step in what s been a thoughtful strategy to build a multi-product specialty company. We look at the Allos merger as the first step, and we intend to build on the success of this. So, those are brief introductory comments. I ll be happy to take any questions.

QUESTIONS AND ANSWERS

Unidentified Company Representative

So, I would love for this to be interactive and people should feel free, obviously, to ask anything they want. Before we go right ahead.

Unidentified Audience Member

Hi, can you comment on the stock reaction post-your announcement with at the merger with Allos and what your shareholders that you ve been speaking with are thinking, as well as your rationale for rejection on the \$18 offer from MSMB Capital? And where the stock is trading at \$14 what how does the board think about the offers?

Brian Pereira - AMAG Pharmaceuticals, Inc. - CEO

Okay, so, there are many questions. First is what s the stock response like? As you see, we were trading in the \$18 before. We re trading in the \$14 since. The reality is my guess is that most stockholders of small to mid-CAP companies expect these companies to be acquired and not merged with one another. So, the initial response was why did the former occur?

As we have clearly outlined in the S-4, we have explored those possibilities. So has Allos. And there wasn t a clear path forward on that option. With respect to the \$18 offer that came from MSMB, we evaluated it. And looking at the totality of the offer, our board felt that it was unlikely to evolve into a superior proposal compared to the one that we had on the table, and, therefore, rejected it.

In terms of what s the path forward with our existing shareholders? As you know with the publication of the final S-4 today, today is literally day one when we begin the process of candidly and openly discussing the merits of the merger and soliciting votes from our shareholders. And we intend to do just that.

Unidentified Audience Member

So, I guess your final comment in the prepared remarks was around basically will amount to some sort of a roll-up of the industry, whether it s sort of single product unprofitable entities that you could then leverage Are you proposing to do those with stock issuance, just like the Allos deal? Or what kind of capital commitment abilities do you have in the market to pursue that because absent that, it does sort of fall back on you don t have enough right now?

Brian Pereira - AMAG Pharmaceuticals, Inc. - CEO

Yes, I think that s a good question, which probably should be addressed up front. The first deal had to be an all stock deal because we can t use our entire cash, which is one of our strengths today, in pursuing the Allos offer because that would give us very little [arm and mutadium] for the next phases. And you don t want to go into [Nuco] with a financing overhang, particularly if some of your assets are still in the development stage for additional indications.

So, in addition, for the Allos shareholders receiving stock in Nuco was a more attractive option because now there is an opportunity to partake in the upside in growth of Nuco.

Going out, the two companies had pro forma cash of \$375 million as of 30th of June. Our AMAG sclinical development program for Feraheme is coming to an end so our burn on R&D is going to drop off exponentially beginning the end of this year. Allos still has Nuco would still have for Folotyn, its obligatory expenses for several more years but there is a 60-40 split in sharing expenses with Mundipharma, which is the European partner for Folotyn, which becomes 50-50 once it gets European approval.

So, we believe we Il have enough cash to pursue cash offers for subsequent end licensing or acquisitions. And, you know, we re looking at products which are not quite in the target range for big pharma. We re looking at the \$30 million, \$40 million, \$50 million, up to \$100 million revenue products which we think there are a few out there. And we Il carefully evaluate how much is the right offer and build it. But first, we need to get Nuco on the road. Get cost synergies out as promised, or sooner, and build the revenue.

I must say that and Frank may want to talk a little more about this. As we have said on our last call, we have committed to taking out the cost within the first year most of them within the first year of post-merger. And what is exciting is that even if you look at a very, very conservative scenario of just \$60 million in Feraheme US revenues, which is roughly flat to modestly increased in 2013, add about \$10 million in Feraheme revenues for Europe.

And roughly \$55 million in Folotyn revenues in 2013, you get a revenue base of about \$125 million. And we can bring our costs to about our cash cost to about \$120 million so that by the end of 2013 we are at cash flow break even. Everything else is up-side. If Folotyn gets European approval, it gets the milestones and the royalties flowing in, the cost structure moves to 30-30 sorry 50-50. Once it gets first-line therapy, that is an up-side. Once, if the CTCL study reads positive, that is an up-side.

With the fact that now there Il be more reps promoting Folotyn and Feraheme, there are revenue up-sides. On the Feraheme front, there s the European approval for chronic kidney disease. There is the IDA approval both in the US and ex-US. And so, there are many up-sides for this very conservative scenario which have not baked in to our commitment to drive the Nuco to cash flow positive by the end of 2013.

Unidentified Audience Member

What would your cash position look like in this very conservative scenario? And at what point would you trigger the next yield? What should we be thinking about?

Brian Pereira - AMAG Pharmaceuticals, Inc. - CEO

So, as we have said that the minimum cash balance without any additional acquisitions or M&A deals, would be \$220 million, under this very conservative scenario.

Frank Thomas - AMAG Pharmaceuticals, Inc. - CFO

So, as Brian articulated, the pro forma cash balance for the two companies as of June 30th was \$375 million. And we think that over the next two plus years, by the end of 2013, that we can drive the Company to cash flow positive. And the trough in the cash balance becomes about \$220 million. So, we think that provides the Company with a great asset that we currently have. We preserve that asset and it gives us more flexibility to go out and be acquisitive for other products.

So, the financial metrics for the deal, number one, is we think that Folotyn can provide at least \$20 million in EBIT in 2013, that our cash balance doesn t dip below \$220 million in cash, and that we can drive the Company to profitability by the end of 2013. Or at least cash flow positive.

Unidentified Company Representative

Any other questions on this before we move on to just some of the details around Feraheme and ? No? Okay.

So maybe we can talk a little bit about Feraheme. And you highlighted how the Hem/Onc segment is becoming more important. And so maybe if you can just describe your recent inroads into that market versus where you were a year ago? And are there—are you noticing any sort of subtle or large differences between that segment and the nephrology segment where you were able to pretty quickly penetrate fairly deeply?

4

Brian Pereira - AMAG Pharmaceuticals, Inc. - CEO

What really happened is that immediately after launch, as you would expect, existing IV iron market was dialysis. But as we know, the dialysis sector was already getting prepared for the bundle. So coming out of the gate, we got a good chunk of dialysis business. And that was always our plan to get as much dialysis as we can and hold it for as long as we can without compromising price and build it on dialysis market. Over the last two years since launch, dialysis market has steadily declined as part of our business, and today it contributes to almost zero.

Now, in the non-dialysis market, naturally our first point of call was the nephrology offices. Our initial hope was to try and get nephrologists to build the IV iron therapy in their offices. That happened and in almost no time we had 60% share of the IV business in the nephrology offices. But the problem is that the nephrology office business is very small. The total amount of iron sold in the nephrology offices is about 20,000 to 30,000 grams.

So, in Feraheme dollars, let s say \$500 a gram, you re looking at a \$10 million to \$15 million book of business. So it became clear that we had to treat patients with chronic kidney disease in other places. And try and grow the nephrology office business.

The nephrology office business has limitations in how much you can grow because with all the bad publicity around ESAs in chronic kidney disease, the CHOIR study, the CREAT study and the then the TREAT study. Nephrologists started backing off from treating chronic kidney disease patients with ESAs, and they also started moving away from injectables in the office, in general. And so for us to maintain patient access and optimum patient treatment, we had to focus on the sites of care where patients do get treated. And that s the hematology-oncology clinics and the hospitals.

Now, as we know, hospital formulary approval and purchasing take a life of their own. It s a long cycle and it takes time. So the fastest access was Hem/Onc. And working with the pre-GTOs that play in the Hem/Onc space we have achieved what we say is very gratifying success in Hem/Onc. In literally now a year since we started focusing on Hem/Onc, more than 50% of our sales are in Hem/Onc, and we have 25% market share. And that s the fastest growing segment.

But that segment is important to us not just for today s business, but as we get the broad iron deficiency anemia market, that s the place. Because right now, of the approximately 700,000 grams each year which are sold outside of dialysis, about 300,000 grams is for chronic kidney disease sold in different settings Hem/Onc, hospitals, nephrology clinics. But there s 400,000 grams which are sold for other indications. And that is in a field where there d be no promotion for 30 years because iron dextran have been the IV iron in use. None of the others have labels.

So, our hope is by establishing ourselves in the Hem/Onc space, getting to know them, we will be able to have a well-prepared bed to launch Feraheme for the broad iron deficiency anemia indications.

But I hate to go back to my earlier point regarding the merger with Allos. But this, again, shows you the importance of the deal with Allos because this is for both companies, for Folotyn provides an enhanced share of voice because we have 70 plus reps, they have about 50. So, there s a 50% increase.

But, more importantly, Folotyn is an exciting therapeutic tool for a difficult to treat disease. And that Folotyn provides direct access to the Hem/Onc. When our reps go to detail Hem/Onc with Feraheme, oftentimes they get to see the nurse because this is supportive care, it s one of six IV irons on the market. Hem/Onc are not jumping out to meet with our reps as they are for Folotyn because, you know, it s an exciting product for difficult to treat disease. They want to be ahead of the game. So, both products really benefit from this.

Unidentified Company Representative

So, I guess two questions come from that. Number one is when we talk about the Hem/Onc segment, are we really talking about infusion centers in a Hem/Onc office or infusion centers where the Hem/Onc controls the center, meaning they re the medical

director or pharmacy director? And then the second question, in the broader iron deficiency anemia world, where is most of the iron given? Is it given as an inpatient, as part of an inpatient stay, or is it given as an outpatient?
Brian Pereira - AMAG Pharmaceuticals, Inc CEO
All important market dynamics. We go after every site of care where injectable IV iron is administered. So, whether the Hem/Onc owns the office, is the medical director of the office, or the medical director of the hospital infusion center, those are all our points of call. Those are our points of call, those are our points of contracting. So, we don't discriminate. Our reps and our account managers call on all of them.
Unidentified Company Representative
And all of those are possible?
Brian Pereira - AMAG Pharmaceuticals, Inc CEO
Correct. All of those are possible for today and for our broad iron deficiency anemia indication in the future. Now, the hospitals - it s a little hard to track exactly how much iron is used in the inpatient versus the outpatient. But, philosophically, it s safe to assume that hospitals would try to limit any therapeutic use inpatient if they can provide it outpatient because the inpatient use of therapeutic is either under the DRG of case rate, of per diem, and so on and so forth.
So, it s a cost. In the outpatient, it is a revenue source. So, hospitals try their best. But then, they are compliance or their ability to control that isn t correct. So, we think roughly between a third to half of IV use in hospitals could be inpatient. But the majority is outpatient. And the share of outpatient hospital is going, that hospital makes financially savvy decisions to administer care in the outpatient settings.
Unidentified Company Representative
Any questions?
Unidentified Audience Member

Since you re on the board of AMAG, I m curious what led you to your decision of determine that MSMB s office was inadequate?

Brian Pereira - AMAG Pharmaceuticals, Inc CEO
It was the totality of the picture [Martin].
Unidentified Audience Member
Okay. Can you be more specific? It s an \$18 price. Your shareholders don t seem to be too enamored with your proposed transaction with Allos, and our offer s bona fide, and you never reached out to us to determine whether or not it was bona fide. And how can you treat your shareholders like this if you clearly, your shareholders aren t happy with you. We gave you an offer for \$18 to acquire the whole company. Your stock is still

at \$14. You re pressing forward with the merger. You didn t even give us a chance to evaluate the transaction.

Brian Pereira - AMAG Pharmaceuticals, Inc. - CEO

Look Martin, the reality is that the offer that you sent to me was via an email and that was concurrently sent out to the press. You know, in general, we look at the totality of the picture. The value of the offer, the source of the offer, and many other factors. We spent a lot of time as a board deliberating on this. We take every advance seriously. And at that point in time, we realized the offer as it stood would not result in a superior offer to the transaction. If things change, that s different.

Unidentified Company Representative

Well. Okay. So, maybe if we can just wrap up in terms of the iron deficiency anemia trials. You said you think you Il finish by the end of this year, data next year. Is there anything about the design of those trials that will lead you to want to run other ones, either head-to-head versus a suite of different irons, or oral iron? Or do you think that this study that you have are going to be sufficient to get you where you need to be commercially.

Brian Pereira - AMAG Pharmaceuticals, Inc. - CEO

Since we are running out of time, it s fairly simple. IV irons are effective so there s no doubt about that. The question is safety. And the big determining factor is what the safety profile of the IV iron Feraheme? The reality is there isn t much to compare because none of the other IV irons have run a registration of trials in iron deficiency anemia.

We ve had a very robust discussion with the agency in developing this program. And after two to two-and-a-half years of deliberations, we have come to the program that we launched. The results will speak for themselves. The agency will look at it and see if the safety profile and the efficacy profile commensurate with what they think is good for patients. And so we think that some time by the middle of next year, we ll know.

Unidentified Company Representative

That s great. I think we re out of time, so maybe we can unless you want to ask one quick question.

Unidentified Audience Member

Is there a backup plan if your acquisition of Allos is not consummated?

Brian Pereira - AMAG Pharmaceuticals, Inc. - CEO

Well, we have a vibrant franchise. We are looking at many expanded indications which is the waterfront of iron deficiency anemia. We have a very strong cash balance. We have \$265 million. So while we re going to drive towards consummating this merger, and we are confident about that, like every prudent organization we have all other options well thought through.
Unidentified Audience Member
Thank you.
Unidentified Company Representative
I think we re out of time. So, thank you very much

Brian Pereira - AMAG Pharmaceuticals, Inc CEO
Thank you.
Unidentified Company Representative
both of you, for joining us. Thank you, everyone.
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8