ALLOS THERAPEUTICS INC
Form 425
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Filed by AMAG Pharmaceuticals, Inc.

Pursuant to Rule 425 under the Securities Act of 1933, as amended

and deemed filed pursuant to Rule 14a-12

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 UBS Global Life Science Conference on September 19, 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.

AMAG Pharmaceuticals, Inc.

September 19, 2011

8:00 AM ET

Operator: Good morning, and thanks for joining us at the UBS Global Life Science Conference. My name s Matt Rodan (ph). I m a biotech analyst here at UBS. And we re very pleased to kick off the conference this morning with AMAG Pharmaceuticals. AMAG, as you know, is focused on its main product, Feraheme, for the treatment of iron-deficiency anemia. And here to speak on behalf of AMAG is its Chief Executive Officer, Brian Pereira. We also have on the podium up here with us the Chief Financial Officer, Frank Thomas. Brian?

Brian Pereira: Thank you, Matt. Good morning. A couple of slides on the forward-looking statements. For a full description of the risks, we d refer you to our quarterly and annual filings.

Well, let me start off with a brief introduction of where AMAG stands today and where we are going in terms of the future of the Company. Our lead product is Feraheme, which is an injectable IV iron for the treatment of iron-deficiency anemia. Our first indication is in chronic kidney disease, both patients on dialysis and not on dialysis, so we have largely moved away from the dialysis segment. And we have a ongoing development program for the broad iron-deficiency anemia indication.

Our partners Takeda is our ex-US partner. We received $60 million in an upfront payment in 2010 and $220 million in potential future development and commercial milestones coming down the pike. More importantly, about $33 million are due are potentially due based on European and Canadian approvals and launch, which are expected. Our partner in China is 3SBio.

Our unaudited financials at the end of 2Q showed $15.4 million in total revenues, of which $12.8 million was Feraheme net revenues. Our total operating costs for the second quarter were $35.6 million, and we ended the second quarter with $264 million in cash. We have no debt.

On the 19th of July, we announced a merger agreement with Allos. I ll talk more about this a little later in the presentation. But the Allos merger provides the combined company with a second commercial product, which is Folotyn, for the treatment of relapsing-refractory peripheral T-cell lymphoma. This leverages the commercial infrastructure in the hem-onc space. For your information, Folotyn is partnered with MundiPharma ex-US.

This the overall goal is to spread the existing commercial public company expense infrastructure on a much broader revenue base, driving the Company to break even from a cash flow point of view by the end of 2013. The shareholder votes are scheduled for October 21, and we expect to close in the fourth quarter of this year.

So, broadly speaking, how does Feraheme fare vis-à-vis the other IV irons? I think the most important thing is patient and provider convenience. Feraheme can be given in two doses of 510 milligrams while the existing IV irons require five to 10 doses of 100 to 200 milligrams each. Feraheme can be given as 17-second IV push. The other IV irons require a 15- to 60-minute infusion or a slow push. The observation period is the same for all IV irons currently. This has leveled the playing field in this quarter with the FDA changing the labels for other IV irons which in the past did not have an observation period or the requirement of resuscitative personnel and equipment. They all have it now.

A one-gram course of IV iron with Feraheme can be given in as little as two injections within a week. With the other IV irons, it takes five to 10 treatments spread over a month.

So first, let s look at the CKD market. There are about 33 million US adults with CKD, of whom half have the more advanced stages of CKD, and about 1.6 million have iron-deficiency anemia. Today, a very small fraction of these patients are treated, somewhere between 200,000 and 250,000 patients get treated for iron deficiency, and an average patient gets about 1.5 grams a year. So the math would tell you approximately 350,000 to 400,000 grams of IV iron are used today in CKD patients with iron-deficiency anemia.

Now, this market segment is growing. To put this in context, about 1.8 million grams of IV iron are sold each year, of whom about a million grams are sold in the dialysis segment. The dialysis segment is a very cost-sensitive segment, and given that we are premium priced, we have chosen not to compete in the dialysis segment.

But as you see here, the non-dialysis segment is growing consistently year-over-year, and about half of the non-dialysis segment, as I said earlier, about 400,000 grams each year, is for patients with chronic kidney disease, and the rest is for a broad swath of indications.

Now, the non-dialysis segment, the biggest piece of that is hospitals, with about 500,000 grams a year, followed by hem-onc clinics, which are about 200,000 grams a year, and then with nephrology clinics and others. Our key focus is to capture as much business as possible in these two segments. We are already the dominant player in the nephrology market.

Now, as we shared with you last quarter in the last quarter results, we have seen a 24 percent growth quarter over quarter in non-dialysis CKD provider demand. Now, the broader opportunity excuse me is iron-deficiency anemia. Iron-deficiency anemia is probably one of the most common medical conditions worldwide, but focusing more on the US market, there are approximately four and a half million patients with iron-deficiency anemia. Most of them are women with heavy menstrual bleeding and post-partum anemia, followed by GI disorders, cancer, and a broad swath of other conditions.

Now today, most of these patients are treated with oral iron, and when oral iron fails, these patients tend to be treated with IV iron. As we go back to those 800,000 grams of non-dialysis IV iron used, 400,000 is in CKD and 400,000 grams is in a broad range of

conditions. As you see here, there s only 5 percent penetration of IV iron among these four and a half million patients. And our intent is to not our intent we are in phase three trials for the broad iron-deficiency anemia indication, and we expect to complete those in short order, file our sNDA, and hopefully bring this to market in 2013 for the broad IDA indication.

So the second quarter summary would tell you that the provider demand increased by 24 percent. The momentum is building in the two large non-dialysis segments - that s hospitals and hem-onc clinics. The recent label changes for the other IV irons have leveled the playing field. In the past, Feraheme was the only IV iron which required resuscitative personnel and equipment and a 30-minute observation period. Now all of the IV irons have that requirement, and that is a very important step in favor of Feraheme.

We continue to make great progress on market expansion for Feraheme. We expect Canadian and European approval in the upcoming months. And as I said earlier, we are more than 75 percent enrolled in the broad iron-deficiency anemia global clinical development program. And finally, on in July, we announced our strategic merger with Allos Therapeutics. This provides us product diversification and operating leverage.

So let me spend a few minutes on the merger with Allos. As you probably know, this is an all-stock merger. The ownership at closing will be 61 percent AMAG, 39 percent Allos. Feraheme revenues for last year were little north of $59 million and for Folotyn were north of $35 million. At the end of June, the pro forma combined cash in the two companies was close to $375 million. Neither company has debt. Both companies have strong ex-US partners. This is subject, of course, to the customary closing conditions. As I said earlier, the shareholder votes are due on October 21. We expect to close this in the fourth quarter of this year.

Now, let s spend a few minutes on the strategic rationale of the merger. This fits with our long-term strategy of building a profitable specialty pharma company in an area of great strategic interest. There are overlapping call points. Both of us spend a lot of time in the hem-onc clinics and the hospital infusion centers, and what we really see coming out of this is increased access at accounts and penetration. Today we have a larger sales force than Allos, and the combined organization will have the same size sales force as we currently have. This provides about a 50 percent increase in face time for Folotyn.

The second is that Folotyn is an exciting therapeutic. Feraheme is the supportive care. And therefore, Folotyn is likely to provide increased attention in the hem-onc clinic and the hospital segments for our reps detailing Feraheme, as well.

On the financial front, we have modeled very conservative estimates that will tell us that show us that, in 2013, the combined companies should generate, at the very least, $125 million in revenues. That s $60 million in US Feraheme, $10 million in ex-US Feraheme, and $55 million in Folotyn. These are very conservative estimates, and as you see from our run rate, this would require single-digit growth year-over-year.

We have committed to ensuring that the total operating expenses in 2013 will be no more than $120 million. That compares to the two companies today who are spending about $215 million to $230 million combined. This provides $20 million in incremental annual cash flow by 2013, and the new Co s (ph) total cash balance is not expected to fall below $220 million at any time between now and turning cash-flow positive.

Now, that s the base case. As you see here, this deal provides a lot of call options for investors. On the revenue front, the combination of Feraheme and Folotyn in our rep s bags in new Co s rep s bag in the marketplace provides an opportunity to enhance revenues of both products. Of course, there are Feraheme sales from the US iron-deficiency anemia approval and launch, Folotyn sales from label indication, and Folotyn use derived from results of the large number of ongoing investigator-initiated trials. There are royalties that both products are due, Feraheme ex-US IDA royalties and early European royalties for Folotyn.

On the milestone front, we have up to $187 million in additional milestones related to Feraheme. That doesn t count the $33 million in near-term milestones, which we hope to achieve, and on the Folotyn front, up to $310 million in additional regulatory and commercial milestone.

Finally, as you probably know, the deal with MundiPharma expects Allos to share 60-40 the development costs, but upon European approval, that turns to 50-50, so another positive that can be achieved.

So the 2011 and 2012 milestones are listed in this slide. On the Feraheme front, we have already had our second manufacturing source approved, and we expect a regulatory decision in Canada by the end of this year for iron-deficiency anemia and CKD. On the Folotyn front, a phase three study of Folotyn in first line has begun. And the teams are working with the FDA to finalize agreement on the phase three combination study in refractory-relapsing cutaneous T-cell lymphoma.

So 2012 milestones for Feraheme, we expect to finish our phase three broad iron-deficiency anemia global program. We expect to get European approval for the CKD indication. We expect to launch in Europe. We expect to launch in Canada, both by our partner Takeda, and we expect our sNDA submission, both in the US and EU, for the broad iron-deficiency anemia indication. On the Folotyn front, a decision is expected in the EU for refractory-relapsing PTCL, and a potential launch in Europe, and the initiation of the broad phase three global registration program in CTCL.

So the Company as it stands today, and new Co, is focused on building long-term value for shareholders. We believe that the merger with Allos expands access to hematology-oncology for Feraheme in chronic kidney disease and the broad iron-deficiency anemia indication. It s very important for us, as we move towards potential approval in broad IDA, that we strengthen our presence in the hem-onc space and in the hospital infusion centers, because that is where patients with iron-deficiency anemia are treated today, and that is the focus of growth in the future.

This deal leverages the existing commercial infrastructure and cost base in the hematology-oncology space, but, more importantly, it spreads the public company costs over a larger revenue base. We literally double the revenue opportunity by combining the two products but keep the cost base pretty much the same as what a single company runs today. We have approximately 250 employees. Allos has approximately 160 employees. The new company will have approximately 250 employees. So both personnel and non-personnel costs will be eliminated.

This provides, of course, further revenue opportunities and diversification through new geographical markets and additional indications, particularly since both of us have strong ex-US partners. New Co s center of gravity will be in hem-onc. Feraheme and Folotyn share this critical call point, and this is a space which has a very high strategic interest,

and that will continue to grow. This strategically positions New Co for future growth and value generation through additional product acquisitions or licensing.

So thank you for your attention. And Matt, I don t know how you re going to hand this from here.

Matt Rodan: Yes, so the breakout is in the Carnegie Room downstairs.

Brian Pereira: So the breakout session will be in the Carnegie Room downstairs. We ll see you up (ph) there. Thank you.