UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): **July 23, 2020**

AMAG PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware		
(State or other jurisdiction of incorporation)		
001-10865		**04-2742593**
(Commission File Number)		(IRS Employer Identification No.)
1100 Winter Street, Waltham, Massachusetts		**02451**
(Address of Principal Executive Offices)		(Zip Code)

(617) 498-3300
(Registrant's telephone number, including area code)

(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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	AMAG	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company 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 ☐

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 1.01 Entry into a Material Definitive Agreement

On July 23, 2020 (the "Effective Date"), AMAG Pharmaceuticals, Inc. and it subsidiary, Perosphere Pharmaceuticals Inc. (collectively, "AMAG") entered into a License and Commercialization Agreement (the "Agreement") with Norgine B.V. ("Norgine"). Under the terms of the Agreement, AMAG will grant Norgine an exclusive license, with the right to grant sublicenses, to develop and commercialize ciraparantag (the "Product") in certain countries in Europe, Australia and New Zealand (the "Norgine Territory"). Ciraparantag is in development for use in patients treated with direct oral anticoagulants and low molecular weight heparin when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding.

AMAG will oversee a Phase 3 clinical program (the "Phase 3 Program") to support regulatory approval of the Product by the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA"), and the Medicines and Healthcare Products Regulatory Agency (the "MHRA"). AMAG has agreed to use commercially reasonable efforts to conduct the activities set forth in a development plan for the Phase 3 Program to be agreed by the parties, including a pivotal clinical trial intended to be sufficient to support the filing for regulatory approval with the FDA, the EMA and the MHRA. Norgine will be responsible for the regulatory filings and any clinical trials specifically required for approval of the Product in the Norgine Territory and will hold all marketing authorizations in the Norgine Territory.
AMAG will be responsible for manufacturing and supplying the Product necessary for development and commercialization in the Norgine Territory, pursuant to a supply agreement(s) to be entered into by the parties. Norgine will have the option of assuming the responsibility for manufacturing the Product in the event of a material breach of a supply agreement, failure to enter an agreement with third party contract manufacturers to supply required quantities of the Product, the supply price of the Product exceeds certain benchmarks, or a supply disruption (as defined in the Agreement).

During the term of the Agreement, Norgine may not develop, manufacture or commercialize any agent that reverses, reduces, or otherwise inhibits the effects of one or more of the following anticoagulants as indicated on the approved label for such agent: rivaroxaban, apixaban, edoxaban and/or enoxaparin sodium injection (a "Competitive Product") anywhere in the world, and AMAG may not develop, manufacture or commercialize a Competitive Product anywhere in the Norgine Territory.

Pursuant to the terms of the Agreement, and subject to the conditions set forth therein, Norgine is required to make the following payments to AMAG: (i) $30 million of total upfront consideration on the Effective Date and (ii) one-third of the actual and reasonable out-of-pocket costs and expenses incurred by AMAG in connection with conduct of the Phase 3 Program pursuant to a mutually agreed upon budget.

In addition, pursuant to the terms of the Agreement, AMAG will be eligible to receive from Norgine: (i) up to $70 million contingent upon achieving certain regulatory milestones (of which $40 million will be paid by AMAG to the former equity holders of Perosphere Pharmaceuticals Inc. pursuant to the Agreement and Plan of Merger with Perosphere Pharmaceuticals, Inc. filed as Exhibit 2.2 to our Annual Report on Form 10-K for the year ending December 31, 2019) and (ii) up to $190 million contingent upon meeting certain sales milestones.

Norgine is also obligated to pay AMAG tiered double-digit royalties as a percentage of annual net sales of the Product in the Norgine Territory. The royalties will expire on a country-by-country basis on the latest to occur of (i) the tenth anniversary of the date of first commercial sale of the Product in such country, (ii) the expiration of the last-to-expire AMAG licensed patent having a valid claim covering the drug substance, the drug product, a method of using (including, without limitation, a dose or dosing regimen), or a method of treatment, in each case related to the Product in such country; or (iii) the expiration of the latest period during which regulatory exclusivity applies to the Product in such country. Such royalties are subject to reduction in the event that: (a) Norgine must license additional third party patents in order to develop, manufacture (as permitted in the Agreement) or commercialize the Product or (b) generic competition occurs with respect to the Product in a given country, subject to an aggregate cap on such reductions of royalties otherwise payable to AMAG. After the expiration of the applicable royalty term in a given country, the license for the Product in such country will become a fully paid-up, royalty-free, perpetual and irrevocable license, and will remain exclusive until the launch of a generic product in such country.

AMAG and Norgine have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

The Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the agreement. In addition, Norgine has the right to terminate the Agreement without cause in its entirety after the two year anniversary of the Effective Date, upon prior written notice to AMAG. Either party may terminate the Agreement for cause if the other party materially breaches, and, if curable, such material breach remains uncured for certain agreed upon time frames. Norgine has the ability to elect not to terminate the Agreement in the case of a material breach, in which case

future payments owed to AMAG would be reduced by a specified percentage. AMAG may also terminate the Agreement in the event Norgine challenges the validity of a licensed patent, and either party may terminate the Agreement if the other party is unable to perform its obligations due to a force majeure event.

The foregoing is only a summary of the material terms of the Agreement and does not purport to be a complete description of the rights and obligations of the parties under such agreement. The foregoing summary is qualified in its entirety by reference to the available text of the Agreement, a redacted copy of which AMAG expects to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter in which such agreement is entered.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of AMAG Pharmaceuticals Inc., dated July 23, 2020 (furnished herewith)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

AMAG PHARMACEUTICALS, INC.

By: /s/ *Joseph D. Vittiglio*

Joseph D. Vittiglio
Executive Vice President, General Counsel, Chief Business Officer & Corporate Secretary

Dated: July 23, 2020

FOR IMMEDIATE RELEASE

AMAG PHARMACEUTICALS AND NORGINE B.V. ENTER INTO EXCLUSIVE LICENSING AGREEMENT TO COMMERCIALIZE CIRAPARANTAG IN EUROPE, AUSTRALIA AND NEW ZEALAND

Agreement provides AMAG with $30 million upfront payment and eligibility to receive up to $260 million in development and commercial milestones in addition to sales royalties

Collaboration further advances the development of ciraparantag

WALTHAM, Mass. and AMSTERDAM, The Netherlands, July 23, 2020 — AMAG Pharmaceuticals, Inc. (NASDAQ: AMAG) and Norgine B.V., a leading European specialist pharmaceutical company, today announced they have entered into an exclusive licensing agreement to develop and commercialize ciraparantag in Europe, Australia and New Zealand. Ciraparantag is in development for use in patients treated with direct oral anticoagulants (DOACs) and low molecular weight heparin (LMWH) when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding.

Under the terms of the license agreement, AMAG will receive $30 million of total upfront consideration and up to $260 million contingent upon the achievement of certain regulatory and sales milestones together with escalating double-digit royalties. Additionally, Norgine has committed to contribute one-third of the costs of the Phase 3 clinical program, which would be conducted by AMAG to support regulatory approval of ciraparantag by the U.S. Food and Drug Administration, the European Medicines Agency, and the Medicines and Healthcare Products Regulatory Agency. AMAG will continue to oversee the Phase 3 clinical program, while working closely with Norgine. Norgine will be responsible for the regulatory filings and any subsequent clinical trials required for approval in its territory and will eventually hold all marketing authorizations in the licensed territories.

“This agreement is a significant milestone on our strategic evolution. We are looking forward to partnering with Norgine and working together to unlock the value of ciraparantag, which will further strengthen our company’s ability to continue investing in innovative therapies that address urgent unmet medical needs,” said Scott Myers, AMAG’s Chief Executive Officer. “Norgine’s infrastructure and capabilities to develop and commercialize products will help us further advance the program into Phase 3 clinical trials and work towards regulatory approval in countries where providers and patients may benefit from a reversal agent.”
There are currently approximately six million patients in the U.S. and nine million patients in certain ex-U.S. countries on DOAC and LMWH therapy.[1] A recent study found that approximately 1.5-2% of patients taking certain DOACs can be at risk for serious bleeding complications each year.[2]

“We are delighted to enter into this new collaboration with AMAG to develop and commercialize ciraparantag in Europe, Australia and New Zealand,” said Peter Stein, Chief Executive Officer of Norgine. “Patients who take anticoagulants can be at risk of serious and uncontrolled bleeding, especially in emergency situations, and we are proud to be able to support the development of a new, potentially life-saving treatment, subject to successful completion of ciraparantag’s research programme and subsequent regulatory approval.”

About Ciraparantag

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[1] Perosphere sponsored commercial assessment report conducted by a third party in May 2016.
[2] Tepper, Ping G et al. (2018) Real-world comparison of bleeding risks among non-valvular atrial fibrillation patients prescribed apixaban, dabigatran, or rivaroxaban” PLoS ONE 13(11): e0205989. https://doi.org/10.1371/journal.pone.0205989

Ciraparantag is a novel small, water-soluble molecule being investigated for reversal of anticoagulation induced by direct oral anticoagulants (DOACs) or low molecular weight heparin (LMWH). Target patient populations include patients for whom rapid reversal of anticoagulation is needed because of life-threatening or uncontrolled bleeding, or for emergency surgery or urgent procedures. It is believed that ciraparantag exerts its effects by binding to and blocking the effects of DOACs such as Xarelto® (rivaroxaban), Eliquis® (apixaban) and Savaysa® (edoxaban), as well as to the LMWH Lovenox® (enoxaparin sodium injection), which in turn reestablishes normal clot formation. Ciraparantag is administered by intravenous infusion; the anticipated clinical treatment regimen is a single dose administered over approximately 10 minutes. Ciraparantag has been studied across seven completed trials, with 277 subjects having been dosed with ciraparantag and has been well tolerated in these studies. To date, the most common adverse events related to ciraparantag have been mild transient sensations of warmth or skin flushing, skin tingling, and alterations in taste. The safety and efficacy of ciraparantag is under investigation through the ongoing clinical development program.

ABOUT AMAG
AMAG is a commercial stage biopharmaceutical company focused on bringing innovative products to patients with unmet medical needs. The company does this by leveraging its development and commercial expertise to invest in and grow its pharmaceutical products across a range of therapeutic areas. For additional company information, please visit www.amagpharma.com.

About Norgine
Norgine is a leading European specialist pharmaceutical company that has been bringing transformative medicines to patients for over a century. Our commitment to transforming people's lives drives everything we do and our European experience, fully integrated infrastructure and exceptional partnership approach enables us to quickly apply creative solutions to bring life-changing medicines to patients that they may not otherwise be able to access. Norgine is proud to have helped 22 million patients around the world in 2019 and generated €419 million in net product sales, a growth of 6% over 2018.

Norgine has a direct presence in 12 European countries, as well as Australia and New Zealand. We also have a strong global network of partnerships in non-Norgine markets. We are a flexible and fully integrated pharmaceutical business, with manufacturing (Hengoed, Wales and Dreux, France), third party supply networks and significant product development capabilities, in addition to our sales and marketing infrastructure. This enables us to acquire, develop and commercialize specialist and innovative products that make a real difference to the lives of patients around the world.

In 2012, Norgine established Norgine Ventures, a complementary business which supports innovative healthcare companies through the provision of debt-like financing in Europe and the US. For more information, please visit www.norgineventures.com.

Forward Looking Statements
This press release contains forward-looking information about AMAG Pharmaceuticals, Inc. within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein which do not describe historical facts, including, among others, expectations about the benefits of the transaction to AMAG's corporate strategy and strategic evolution, including its ability to unlock value in ciraparantag and continue investing in innovative therapies; beliefs about the benefits of the partnership on the development and regulatory approval of ciraparantag; beliefs about ciraparantag's potential benefits to patients; AMAG's expected plans related to the clinical development of ciraparantag and Phase 3 clinical program to support regulatory approval in the U.S., Europe, Australia, and New Zealand; statements regarding Norgine eventually holding all marketing authorizations in the licensed territories; statements regarding the potential market size and target patient population; statements regarding ciraparantag, including its safety and mechanism of action , are based on management's current expectations and beliefs and are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.
Such risks and uncertainties include, among others, risks and uncertainties related to the scale and scope of the COVID-19 pandemic and its impact on AMAG's revenues and , operations, and clinical development (including,

more specifically, the ciraparantag clinical development program), as well as COVID-19's impact on AMAG's business partners, healthcare providers, patients, employees and the health care industry and worldwide economies generally; uncertainties regarding AMAG's and Norgine's ability to successfully and timely complete clinical development programs and obtain regulatory approval for ciraparantag in the U.S., Europe, Australia and New Zealand, including as a result of clinical trial design or enrollment, or as a result of any safety or efficacy issues that may arise as part of such trial; the risk that the cost of the clinical development of ciraparantag will be more than planned or that the timeline will be significantly delayed; the risk that even if approved, the market for ciraparantag may be smaller than expected or AMAG and Norgine may not be successful in commercializing in such market or otherwise realize the expected benefits of the transaction; uncertainties regarding the manufacture of ciraparantag and our ability to supply Norgine; the risk that AMAG or Norgine will fail to fully perform their respective obligations under the license agreement; and those other risks identified in AMAG's filings with the U.S. Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2019, its Current Reports on Form 8-K, its Quarterly Reports on Form 10-Q, including for the quarter ended March 31, 2020, and in any subsequent filings with the SEC , which are available at the SEC's website at www.sec.gov. Any such risks and uncertainties could materially and adversely affect AMAG's results of operations, its profitability and its cash flows, which would, in turn, have a significant and adverse impact on AMAG's stock price. AMAG cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made.
AMAG disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

AMAG Contacts:
Investors:
Rushmie Nofsinger
(781) 530-6838

Media:
Stacy Nartker
(781) 430-9212

Norgine Contacts:
Clara Bentham +44 (0)1895 826654 or +44 (0)7734 367883
Eleni Fistikaki +44 (0)1895826227 or +44 (0)7825 389477

contact@norgine.com
www.norgine.com
Follow us @norgine

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