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): **June 21, 2019**

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 St. **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))

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. ☐

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

Item 7.01. Regulation FD Disclosure.

On June 21, 2019, AMAG Pharmaceuticals, Inc. ("AMAG") issued a press release announcing the approval of Vyleesi™ (bremelanotide injection) granted by the U.S. Food and Drug Administration (the "FDA"). A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On June 21, 2019, AMAG announced that the FDA has approved Vyleesi™ (bremelanotide injection) to treat acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women.

Item 9.01. Financial Statement and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated June 21, 2019 (furnished herewith)

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, Quality & Corporate Secretary

Dated: June 21, 2019

AMAG PHARMACEUTICALS ANNOUNCES FDA APPROVAL OF VYLEESI™ (BREMELANOTIDE INJECTION) FOR ACQUIRED, GENERALIZED HYPOACTIVE SEXUAL DESIRE DISORDER (HSDD) IN PREMENOPAUSAL WOMEN

The First FDA-Approved As-Needed Treatment for Premenopausal Women Experiencing Distress or Interpersonal Difficulty Due to Low Sexual Desire

1 in 10 Premenopausal Women in the U.S. (Approximately 6 Million Women) Suffer From HSDD

WALTHAM, Mass. June 21, 2019 – AMAG Pharmaceuticals, Inc. (NASDAQ:AMAG) announced today that the U.S. Food and Drug Administration (FDA) has approved Vyleesi™ (bremelanotide injection), a melanocortin receptor agonist, to treat acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women. The Vyleesi autoinjector is the first treatment for this patient population that can be self-administered as needed in anticipation of sexual activity.

HSDD is characterized by low sexual desire that causes distress or interpersonal difficulty and is not due to a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.

“HSDD has been recognized as a medical condition since the 1970s, yet it has been widely underdiagnosed and undertreated,” said Anita H. Clayton, M.D., Chair, Department of Psychiatry & Neurobehavioral Sciences, University of Virginia School of Medicine, VA. “Women with HSDD often avoid situations that could lead to intimacy, the impact of which goes far beyond the bedroom and can often result in anxiety, loss of vitality, self-esteem issues and relationship stress. It is important that women suffering with this condition have a choice of treatment options available to them.”

HSDD is thought to have a neurobiologic basis which is supported by brain imaging studies. When study participants were shown visual sexual stimuli, there was a difference in the brain activation patterns between women with HSDD compared to those women without HSDD[i].

“Today's approval underscores AMAG’s commitment to women’s health and dedication to raising awareness and improving education about HSDD,” said Julie Krop, M.D., chief medical officer at AMAG. “While HSDD is the most common female sexual dysfunction condition, it is largely under-recognized. I want to thank the thousands of women who participated in the clinical trials to support the approval of Vyleesi. Their participation in the trials helped to pave the way for a novel treatment option that offers hope to the nearly six million premenopausal women who have suffered in silence from HSDD—empowering them to reclaim their sexual desire.”

The FDA approval of Vyleesi is based upon data from approximately 1,200 women in two pivotal, double-blind placebo controlled Phase 3 trials (RECONNECT). In both clinical trials, Vyleesi met the pre-specified co-primary efficacy endpoints of improvement in desire and reductions in distress as measured by validated patient-reported outcome instruments. Upon completion of the trial, women had the option to continue in a voluntary open-label safety extension study for an additional 12 months. Nearly 80 percent of patients who completed the

Phase 3 trials elected to remain in the open-label portion of the study, where all of these patients received Vyleesi.

In the pivotal trials, the most common adverse events were nausea, flushing, injection site reactions, and headache. The majority of events were reported to be transient and mild-to-moderate in intensity. In clinical trials, Vyleesi caused small, transient increases in blood pressure, and is contraindicated in women with uncontrolled high blood pressure or known cardiovascular risk.

AMAG is committed to working with payers and healthcare professionals to help ensure women with HSDD have access to Vyleesi. The product will be commercially available in September through select specialty pharmacies. To raise healthcare provider awareness of Vyleesi, AMAG will leverage its existing women's and maternal health sales force of approximately 125 sales representatives calling on U.S. obstetrics, gynecologists and sexual medicine specialists, and will also offer patients the ability to connect with a physician through a telemedicine option. Patients and providers can learn more about HSDD and Vyleesi at www.vyleesi.com and sign up to receive information about how to obtain Vyleesi as soon as it is available.

AMAG in-licensed Vyleesi from Palatin Technologies, Inc. in February 2017. Under the terms of the agreement, the approval of Vyleesi by the FDA triggers a $60 million payment obligation to Palatin. In addition, AMAG will pay Palatin tiered royalties on annual net sales of Vyleesi ranging from the high-single digits to the low double-digits. AMAG will also pay Palatin sales milestones based on escalating annual net sales thresholds, the first of which is $25 million, triggered at annual net sales of $250 million.

About Vyleesi™ (bremelanotide injection)
Vyleesi is approved for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD). The prefilled Vyleesi autoinjector pen is self-administered into a woman's abdomen or thigh at least 45 minutes before anticipated sexual activity and can be taken at any time of day. Vyleesi is thought to possess a novel mechanism of action. While the exact mechanism of action is unknown, Vyleesi is believed to bind to melanocortin receptors in the central nervous system. Vyleesi has no known alcohol restrictions.

Vyleesi (bremelanotide injection) Important Safety Information

Contraindications
VYLEESI is contraindicated in patients who have uncontrolled hypertension or known cardiovascular disease.

Warnings and Precautions
Transient Increase in Blood Pressure and Decrease in Heart Rate: VYLEESI transiently increases blood pressure and reduces heart rate after each dose. Advise patients that these changes usually resolve within 12 hours. VYLEESI is not recommended in patients at high risk for cardiovascular disease. Consider the patient's cardiovascular risk before initiating VYLEESI and periodically during treatment and ensure blood pressure is well-controlled. To minimize the risk of more pronounced blood pressure effects, patients should not take more than one VYLEESI dose within 24 hours. Patients should not use more than 8 VYLEESI doses per month.

Focal Hyperpigmentation: Reported by 1% of patients who received up to 8 doses per month, including involvement of the face, gingiva and breasts. Patients are at higher risk of developing focal hyperpigmentation if they have darker skin and with daily dosing. Resolution of the focal hyperpigmentation was not confirmed in all patients after discontinuation of VYLEESI. Consider discontinuing VYLEESI if hyperpigmentation develops.

Nausea: Reported by 40% of patients who received up to 8 monthly doses, requiring anti-emetic therapy in 13% of patients and leading to premature discontinuation for 8% of patients. Nausea improves for most patients with

the second dose. Consider discontinuing VYLEESI or initiating anti-emetic therapy for persistent or severe nausea.

Adverse Reactions
Most common adverse reactions (incidence >4%) are nausea, flushing, injection site reactions, headache, and vomiting.

Drug Interactions
VYLEESI may slow gastric emptying and impact absorption of concomitantly administered oral medications. VYLEESI may significantly decrease the systemic exposure of orally-administered naltrexone; avoid use with orally administered naltrexone-containing products intended to treat alcohol or opioid addiction.

Pregnancy
Advise patients to discontinue VYLEESI if pregnancy is suspected. Advise patients to use effective contraception while taking VYLEESI.

There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VYLEESI during pregnancy. Pregnant women exposed to VYLEESI and healthcare providers are encouraged to call the VYLEESI Pregnancy Exposure Registry at 1-877-411-2510.

For full Prescribing Information, please see package insert.

Indication
VYLEESI is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:

- A co-existing medical or psychiatric condition,
- Problems with the relationship, or
- The effects of a medication or drug substance.

Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation or partner.

<u>Limitations of Use</u>

- VYLEESI is not indicated for the treatment of HSDD in postmenopausal women or in men.
- VYLEESI is not indicated to enhance sexual performance.

Vyleesi is protected by a number of U.S. and foreign patents and applications that are owned by Palatin Technologies, Inc. Certain of the patents include claims directed to the Vyleesi drug composition and methods of use thereof with terms expiring in 2020, and other patents include claims directed to methods of treating female sexual dysfunction by subcutaneous administration of compositions that include Vyleesi with terms expiring in 2033.

About AMAG
AMAG is a pharmaceutical 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, including women's health. For additional company information, please visit www.amagpharma.com.

Forward-Looking Statements This press release contains forward-looking information about AMAG 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, the belief that HSDD is underdiagnosed and undertreated; beliefs about the size of the potential population for Vyleesi and the behaviors of such potential patients; beliefs about low sexual desire in women, including the causes; the belief that HSDD is the most common female sexual dysfunction condition; the anticipated access to Vyleesi; the timing for commercial availability and plans to leverage AMAG's sales force and provide patient access to physicians 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, the ability of AMAG to successfully execute on its commercialization plans and the level of market adoption for Vyleesi; the likelihood that healthcare providers, patients and/or healthcare payers will support the commercialization and use of Vyleesi; the risk that AMAG has over-estimated the size of the market for Vyleesi; as well as those 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, 2018, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 and subsequent filings with the U.S. Securities and Exchange Commission (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.

[i] Arnow B, et al. (2009) "Women with hypoactive sexual desire disorder compared to normal females: a functional magnetic resonance imaging study" Neuroscience; 158(2):484-502; Bianchi-Demicheli, Francesco et al. (2011) "Neural Bases of Hypoactive Sexual Desire Disorder in Women: An Event-Related fMRI Study" Journal of Sexual Medicine; 2546-2559; Bloemers J, et al. (2014) "Reduced Gray Matter Volume and Increased White Matter Fractional Anisotropy in Women with Hypoactive Sexual Desire Disorder" J Sex Med; 11:753-767; Goldstein I et al. (2017) "Hypoactive Sexual Desire Disorder: International Society for the Study of Women's Sexual Health (ISSWSH) Expert Consensus Panel Review" Mayo Clin Proc.; 92(1):114-128; Holstege G. (2016) "How the Emotional Motor System Controls the Pelvic Organs" Sex Med Rev.; 4(4):303-328; Versace, F, et al. (2013) "Brain responses to erotic and other emotional stimuli in breast cancer survivors with and without distress about low sexual desire: a preliminary fMRI study" Brain Imaging and Behavior; 7:533-542; Woodard, T., et al. (2013) "Brain activation patterns in women with acquired hypoactive sexual desire disorder and women with normal sexual function: a cross-sectional pilot study" Fertility and Sterility; 100(4):1068-1076.

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