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

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the Month of June 2018

Commission File Number: 001-38217

Nightstar Therapeutics plc

(Translation of registrant's name into English)

**215 Euston Road
London NW1 2BE United Kingdom**
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Nightstar Therapeutics Receives Regenerative Medicine Advanced Therapy (RMAT) Designation for NSR-REP1 in Choroideremia

On June 14, 2018, Nightstar Therapeutics plc issued a press release announcing that it has received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration for NSR-REP1 in choroideremia. The press release is attached as Exhibit 99.1 and is incorporated by reference herein.

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated June 14, 2018.

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, thereunto duly authorized.

Date: June 14, 2018

NIGHTSTAR THERAPEUTICS PLC

By: /s/ Bryan Yoon

Name: Bryan Yoon

Title: General Counsel and Secretary



Nightstar Therapeutics Receives Regenerative Medicine Advanced Therapy (RMAT) Designation for NSR-REP1 in Choroideremia

- *First gene therapy RMAT designation for an inherited retinal disease*
- *STAR Phase 3 registrational trial ongoing and FDA interactions planned*
- *RMAT designation enables closer and more frequent multidisciplinary interaction with FDA with all of the benefits of breakthrough therapy designation*

WALTHAM, Mass. and LONDON – June 14, 2018 (GLOBE NEWSWIRE) – Nightstar Therapeutics plc (NASDAQ: NITE), a clinical-stage gene therapy company developing treatments for rare inherited retinal diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to NSR-REP1, the company’s lead product candidate currently in Phase 3 development for the treatment of choroideremia, a rare, degenerative, genetic retinal disorder that leads to blindness.

“Receiving RMAT designation for NSR-REP1 highlights the potential of this gene therapy to maintain and improve visual acuity in choroideremia,” said Dave Fellows, Chief Executive Officer. “This designation further underscores a recognition of the serious nature of choroideremia and the urgent need to develop new treatments for those affected by inherited retinal diseases that would otherwise lead to blindness. We look forward to working closely with the FDA to discuss the NSR-REP1 development program and to determine how we can accelerate the pathway for making NSR-REP1 available to choroideremia patients.”

Established under the 21st Century Cures Act, the RMAT designation is an expedited program for the advancement and approval of regenerative medicine products. A regenerative medicine is eligible for the designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT allows companies developing regenerative medicine and gene therapies to work more closely and frequently with the FDA, and grants all of the benefits of Breakthrough Therapy Designation, including eligibility for priority review, rolling review and accelerated approval. In November 2017, the FDA expanded the RMAT designation to include gene therapies.

RMAT designation for NSR-REP1 was based on clinical data supporting the maintenance and improvement of visual acuity from completed Phase 1/2 trials in choroideremia patients treated with NSR-REP1 and disease progression in untreated patients in the ongoing NIGHT natural history observational study.

About Choroideremia

CHM is a rare, degenerative, X-linked genetic retinal disorder primarily affecting males, with no treatments currently available and represents a significant unmet medical need. CHM presents in childhood as night blindness, followed by progressive constriction of the visual fields, generally leading to vision loss in early adulthood and total blindness thereafter. CHM is caused by mutations in the CHM gene, which encodes REP1, a protein that plays a key role in

intracellular protein trafficking and the elimination of waste products from retinal cells. Absence of functional REP1 leads to death of the RPE cells and degeneration of the overlying retina, which contains the retinal photoreceptors required to convert light into visual signals. Thus, the loss of REP1 function in retinal cells caused by CHM results in progressive vision loss and blindness.

About Nightstar and NSR-REP1

Nightstar is a leading clinical-stage gene therapy company focused on developing and commercializing novel one-time treatments for patients suffering from rare inherited retinal diseases that would otherwise progress to blindness. Nightstar's lead product candidate, NSR-REP1, is comprised of an AAV2 vector containing recombinant human complementary DNA, or cDNA, that is designed to produce REP1 inside the eye. NSR-REP1 is currently in Phase 3 development for the treatment of patients with choroideremia, a rare, degenerative, genetic retinal disorder that has no current treatments and affects approximately one in every 50,000 people. Positive results from Phase 1/2 trials of NSR-REP1 were published in The Lancet in 2014 and in The New England Journal of Medicine in 2016. In data from 32 patients treated with NSR-REP1 across four open-label Phase 1/2 clinical trials, over 90% of treated patients maintained their visual acuity over a two-year follow-up period. In some cases, substantial improvements in visual acuity were also observed. Nightstar's second product candidate, NSR-RPGR, is currently being evaluated in a clinical trial known as the XIRIUS trial for the treatment of patients with X-linked retinitis pigmentosa, an inherited X-linked recessive retinal disease that affects approximately one in every 40,000 people.

For more information about Nightstar or its clinical trials, please visit www.nightstartx.com.

Cautionary Language Concerning Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The words "believe," "anticipate," "intend," "estimate," "will," "may," "should," "expect" or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. All statements contained in this press release other than statements of historical facts are forward-looking statements, including, without limitation: statements about our planned and ongoing clinical trials for NSR-REP1, including our Phase 3 STAR trial in choroideremia, the continued clinical development of our pipeline, the timelines associated with our research and development programs including the timing of patient enrollment and the release of data from ongoing clinical trials and studies, whether the receipt of regenerative medicines advanced therapy designation for NSR-REP1 in choroideremia will meaningfully impact the development and review of NSR-REP1 by the FDA or the likelihood that the product candidate will be found safe and effective, the prevalence of patient populations for our targeted indications, and the utility of prior preclinical and clinical data in determining future clinical results. These forward-looking statements are based on management's current expectations of future events and are subject to a number of involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements, including the risks and uncertainties set forth in Item 3.D. "Risk Factors" section of our Annual Report on Form 20-F for the year ended December 31, 2017 and subsequent reports that we file with the U.S. Securities and Exchange Commission We may not actually

achieve the plans, intentions, estimates or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, estimates and expectations disclosed in the forward-looking statements we make. We anticipate that subsequent events and developments will cause our views to change. We are under no duty to update any of these forward-looking statements after the date of this press release to conform these statements to actual results or revised expectations, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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Investors:

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