
**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
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the month of September 2021

(Commission File No. 001-38215)

NUCANA PLC

(Translation of registrant's name into English)

3 Lochside Way
Edinburgh EH12 9DT
United Kingdom
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover 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):

Other Events

On September 29, 2021, NuCana plc (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration has granted Fast Track designation to Acelarin® (NUC-1031), currently being evaluated in a Phase III study (NuTide:121) for the first-line treatment of patients with advanced biliary tract cancer. The press release is attached as Exhibit 99.1 hereto.

Rafaèle Tordjman, a member of the board of directors (the “Board”) of the Company, retired from the Board effective as of September 28, 2021. There were no disagreements between Dr. Tordjman and the Company or any officer or director of the Company which led to her retirement from the Board.

The information contained herein shall be deemed to be incorporated by reference into the registration statements on Form F-3 (File Number 333-258941) and Form S-8 (File Number 333-223476 and File Number 333-248135), and related prospectuses, as such registration statements and prospectuses may be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

The information in the attached Exhibit 99.1 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

Exhibits

99.1 [Press Release, dated September 29, 2021](#)

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.

NuCana plc

By: /s/ Donald Munoz

Name: Donald Munoz

Title: Chief Financial Officer

Date: September 29, 2021

NuCana Receives Fast Track Designation from the U.S. Food and Drug Administration for Acelarin® (NUC-1031) for the Treatment of Biliary Tract Cancer

Edinburgh, United Kingdom, September 29, 2021 (GLOBE NEWSWIRE)—NuCana plc (NASDAQ: NCNA) announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Acelarin (NUC-1031), currently being evaluated in a Phase III study (NuTide:121) for the first-line treatment of patients with advanced biliary tract cancer. Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and address an unmet medical need.

“We are very pleased that the FDA recognizes the potential of Acelarin to address the significant unmet need of patients with biliary tract cancer,” said Hugh S. Griffith, NuCana’s Founder and Chief Executive Officer. “We recently announced enrollment of 418 evaluable patients in our Phase III study, which is expected to enable the first interim analysis in the first half of 2022. This has the potential to allow for an accelerated approval of a new drug application (NDA) for Acelarin in the United States. With both Fast Track and Orphan Drug designations in place, we look forward to working closely with the FDA in our efforts to gain approval for Acelarin as the first approved front-line treatment option for patients with biliary tract cancer.”

About Fast Track Designation

Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

About Biliary Tract Cancer

Biliary tract cancer, including cholangiocarcinoma, gallbladder and ampullary carcinoma, are a group of cancers originating in the biliary tract. The biliary tract is comprised of the gallbladder and interconnecting ducts responsible for the transport of bile from the liver to the gallbladder and small intestine. Approximately 178,000 new cases of biliary tract cancer are diagnosed each year worldwide, with more than 18,000 of those diagnoses in the United States. There are currently no agents approved for the first-line treatment of patients with advanced biliary tract cancer; however, the worldwide standard of care in these patients is the combination of gemcitabine and cisplatin. Patients receiving this regimen have a median overall survival of 11.7 months.

About NuCana

NuCana is a clinical-stage biopharmaceutical company focused on significantly improving treatment outcomes for patients with cancer by applying our ProTide technology to transform some of the most widely prescribed chemotherapy agents, nucleoside analogs, into more effective and safer medicines. While these conventional agents remain part of the standard of care for the treatment of many solid and hematological tumors, their efficacy is limited by cancer cell resistance mechanisms and they are often poorly tolerated. Utilizing our proprietary technology, we are developing new medicines, ProTides, designed to overcome key cancer resistance mechanisms and generate much higher concentrations of anti-cancer metabolites in cancer cells. NuCana's robust pipeline includes three ProTides in clinical development. Acelarin (NUC-1031) and NUC-3373, are new chemical entities derived from the nucleoside analogs gemcitabine and 5-fluorouracil, respectively, two widely used chemotherapy agents. Acelarin is in a Phase 3 study for patients with advanced biliary tract cancer. NUC-3373 is in a Phase 1b/2 study in patients with metastatic colorectal cancer. Our third ProTide, NUC-7738, is a transformation of a novel anti-cancer nucleoside analog (3'-deoxyadenosine) and is in a Phase 1 study for patients with advanced solid tumors.

Forward-Looking Statements

This press release may contain "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the beliefs and assumptions and on information currently available to management of NuCana plc (the "Company"). All statements other than statements of historical fact contained in this press release are forward-looking statements, including statements concerning the Company's planned and ongoing clinical studies for the Company's product candidates and the potential advantages of those product candidates, including Acelarin, NUC-3373 and NUC-7738; the initiation, enrollment, timing, progress, release of data from and results of those planned and ongoing clinical studies; the potential benefits of Fast Track designation for Acelarin; Acelarin's clinical development program continuing to meet the criteria for Fast Track designation; the Company's ability to submit an NDA for Acelarin under the FDA's accelerated approval program or at all; the Company's goals with respect to the development, regulatory pathway and potential use, if approved, of each of its product candidates; and the utility of prior non-clinical and clinical data in determining future clinical results. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the "Risk Factors" section of the Company's Annual Report on Form 20-F for the year ended December 31, 2020 filed with the Securities and Exchange Commission ("SEC") on March 4, 2021, and subsequent reports that the Company files with the SEC. Forward-looking statements represent the Company's beliefs and assumptions only as of the date of this press release. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, the Company assumes no obligation to publicly update any forward-looking statements for any reason after the date of this press release to conform any of the forward-looking statements to actual results or to changes in its expectations.

For more information, please contact:

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