UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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): **September 26, 2017**

Asterias Biotherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36646**	**46-1047971**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

6300 Dumbarton Circle
Fremont, CA 94555
(Address of principal executive offices)

(510) 456-3800
(Registrant's telephone number, including area code)

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. ☐

Item 8.01 Other Events.

Recent Updates on AST-VAC Programs

VAC2 – Non-Small Cell Lung Cancer

On September 26, 2017, Asterias Biotherapeutics, Inc. (the " Company ") announced that the Medicines and Healthcare Products Regulatory Agency and the NHS Research Ethics Committee have provided the necessary approvals to initiate the first-in-human clinical trial of AST-VAC2 in the United Kingdom (UK). A copy of the Company's press release relating to the announcement is filed herewith as exhibit 99.1.

VAC1 – Acute Myeloid Leukemia (AML)

On August 3, 2016, the Company entered into a Development and Manufacturing Services Agreement (the "Services Agreement") with Cognate BioServices, Inc. ("Cognate"), a fully-integrated contract bioservices organization providing development and current Good Manufacturing Practice ("cGMP") manufacturing services to companies and institutions engaged in the development of cell-based products. Under the Services Agreement, Cognate has been performing under a Statement of Work 1 ("SOW 1") process development studies in support of the Company's clinical and commercial development activities of AST-VAC1 and production and manufacturing services of AST-VAC1 under cGMP under Statement of Work 2.

On August 16, 2017, the Company amended SOW 1 ("Amended SOW 1") and entered into a Statement of Work 1.5 ("SOW 1.5") with Cognate to modify the timing of certain process development studies being performed by Cognate under the Services Agreement. Under Amended SOW 1 and SOW 1.5, Cognate will perform certain process development studies initially contemplated by SOW 1 under SOW 1.5 after Cognate has completed the activities under Amended SOW 1 and the Company provides written notice to commence the activities under SOW 1.5.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits .

Exhibit No.	Description
99.1	Press Release

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.

ASTERIAS BIOTHERAPEUTICS, INC.

Date: September 26, 2017

By:/s/ Ryan D. Chavez
Chief Financial Officer and General Counsel

Exhibit 99.1

Asterias Receives Regulatory Clearance to Initiate Clinical Study of AST-VAC2 in Subjects with Early and Late Stage Non-Small Cell Lung Cancer

Industry News Substantiates Development of First-in-Class Allogeneic Cancer Immunotherapy

FREMONT, Calif. September 26, 2017 – Asterias Biotherapeutics, Inc. (NYSE MKT: AST), a biotechnology company pioneering the field of regenerative medicine, today announced that the Medicines and Healthcare Products Regulatory Agency (MHRA) and the NHS Research Ethics Committee (REC) have provided the necessary approvals to initiate the first-in-human (FIH) clinical trial of AST-VAC2 in the United Kingdom (UK). The trial, which is being sponsored and managed by Cancer Research UK, will examine the safety, tolerability, immunogenicity and activity of AST-VAC2 in non-small cell lung cancer (NSCLC) patients and is expected to be initiated later this year.

AST-VAC2 is a "first-in-class" allogeneic cancer immunotherapy that is composed of mature dendritic cells which are designed to kill tumor cells by stimulating immune responses to telomerase, a tumor antigen expressed by over 85% of malignant tumor cells. AST-VAC2 is available for "on demand" patient use because it is produced from allogeneic pluripotent stem cells that can be manufactured in scale and then cryopreserved. The AST-VAC2 to be used in this trial has been manufactured by Cancer Research UK's Biotherapeutics Development Unit.

AST-VAC2 is a platform cancer immunotherapy that could be investigated as a potential therapeutic for many cancer indications and for targeting of many antigens. The results from the clinical trial sponsored by Cancer Research UK could be used to support advanced clinical studies in one or more of the following areas:

- Non-small cell lung cancer
- Other indications showing high levels of telomerase activity and susceptibility to immunotherapy
- In combination with check point or immune pathway inhibitors
- In combination with additional antigens, including those arising from the exciting new field of tumor neoantigens

"The recently announced acquisition of Kite Pharma by Gilead for $11.9 billion provides strong validation for the cell therapy industry generally and especially in oncology," said Mike Mulroy, President and Chief Executive Officer. "With its potential as a ready-to-administer, off-the-shelf cancer immunotherapy, AST-VAC2 represents an exciting opportunity for Asterias in the rapidly evolving immuno-oncology sector and the approvals received from MHRA and REC to commence clinical testing represent an important milestone in the development of AST-VAC2."

The clinical trial will administer AST-VAC2 in up to twenty-four patients in two cohorts. In the first cohort, up to 12 patients with advanced non-small cell lung cancer and a specific immunological marker called HLA-A2 will receive AST-VAC2, and will be followed for safety, immune responses to telomerase, and overall clinical survival. The second cohort will evaluate AST-VAC2 in up to 12 patients with the HLA-A2 marker who have had successful resection of their tumor with no evidence of metastasis and each patient will be followed for safety, immune responses to telomerase, overall clinical survival and time to relapse. Both cohorts will have a control group consisting of patients that meet all inclusion/exclusion criteria for the study except those patients do not have the HLA-A2 marker.

"The design of the trial will allow us to assess many features of AST-VAC2 and how to best position its use in future trials," said Jane Lebkowski, Chief Scientific Officer. "We will be testing immune responses invoked by AST-VAC2 in the settings of advanced disease and resected disease and perform intermediate assessments of immune response during the course of AST-VAC2 dosing. Clinical outcome and immune response data will help confirm whether AST-VAC2 is most beneficial for patients in an active or minimal residual disease setting and inform determination of the optimal dosing regimen for future trials. The trial will also have a concurrent control group to provide real-time assessment of the safety and activity of the product. We are very excited to begin the clinical development of AST-VAC2 which could become a cornerstone agent in the immunotherapy of cancer."

"The AST-VAC2 study is an exciting step towards improving our tools in cancer immunotherapy," said Professor Christian Ottensmeier, the study's principal investigator. "Not only does the Asterias approach already have a track record in Acute Myeloid Leukemia (AML), but an 'off the shelf' dendritic cell vaccine opens the path towards making dendritic cell vaccination easily deliverable in the clinic. We are very excited to be working towards opening this study in the second half of 2017."

The partnership between Asterias and Cancer Research UK is being conducted under Cancer Research UK's Clinical Development Partnerships (CDP) scheme, which allows the first clinical trial of AST-VAC2 to be initiated without significant Asterias resources being allocated to the trial and the manufacturing of the product. On completion of the clinical trial, Asterias will have an exclusive first option to acquire the data from the trial.

About AST-VAC2

AST-VAC2 is an innovative immunotherapy product that contains mature dendritic cells derived from pluripotent stem cells. These non-patient specific (allogeneic) AST-VAC2 cells are engineered to express a modified form of telomerase, a protein widely expressed in tumor cells, but rarely found in normal cells. The modified form of telomerase invokes enhanced stimulation of immune responses to the protein. Similar to an earlier, Asterias-sponsored , hematological cancer program which provided proof-of-concept data, the AST-VAC2 dendritic cells instruct the immune system to generate responses against telomerase which will target tumor cells. AST-VAC2 is based on a specific mode of action that is complementary to and potentially synergistic with other immune therapies such as checkpoint inhibitors or other immune pathway inhibitors.

About Non-Small Cell Lung Cancer and the AST-VAC2 Trial

Lung cancer (both small cell and non-small cell) is the leading cause of cancer-related death, accounting for about one-quarter of all cancer deaths and more than colorectal, breast, and prostate cancers combined. Non-small cell lung cancer (NSCLC) accounts for about 80% to 85% of lung cancers, according to the American Cancer Society. The three main types of NSCLC are adenocarcinoma, squamous cell carcinoma, and large cell carcinoma. The American Cancer Society's estimates for lung cancer in the United States for 2017 are: about 222,500 new cases of lung cancer, and about 155,870 deaths from lung cancer. Despite the large number of people afflicted by non-small cell lung cancer, patients remain vastly underserved due to a scarcity of effective treatments. According to statistics published by Cancer Research UK, the five year survival rate for lung cancer patients in England and Wales is less than 10%.

The AST-VAC2 clinical trial will enroll up to twenty-four patients into one of two cohorts, depending on the stage of their non-small cell lung cancer. The first cohort will evaluate AST-VAC2 in up to 12 patients with advanced non-small cell lung cancer for whom only palliative treatments are available. Subjects in this cohort, who carry the major histocompatibility gene, HLA-A2, will receive six weekly injections of AST-VAC2 and will be followed for safety, immune responses to telomerase, impact on tumor burden and overall clinical survival. These safety and activity results will be compared directly to a control group who meet all of the other inclusion/exclusion criteria but do not possess the HLA-A2 gene. Assuming safety is demonstrated in the first cohort, enrollment will advance to a second cohort. In the second cohort, early stage patients who have had successful resection of their tumor with no evidence of metastasis will be enrolled. Up to 12 subjects in this second cohort who carry the major histocompatibility allele HLA-A2 will receive six, weekly injections of AST-VAC2 and will be followed for safety, immune responses to telomerase, and relapse. These safety and activity results will again be compared directly to a control group who meet all of the inclusion/exclusion criteria of cohort 2 but are not HLA-A2+. For their key endpoints, patients will be followed for one year.

About Asterias Biotherapeutics

Asterias Biotherapeutics, Inc. is a biotechnology company pioneering the field of regenerative medicine. The company's proprietary cell therapy programs are based on its pluripotent stem cell and immunotherapy platform technologies. Asterias is presently focused on advancing three clinical-stage programs which have the potential to address areas of very high unmet medical need in the fields of oncology and neurology. AST-VAC2 (antigen-presenting allogeneic dendritic cells) represents a second generation, allogeneic cancer immunotherapy. The company's research partner, Cancer Research UK, is in the process of commencing a clinical trial of AST-VAC2 in non-small cell lung cancer. AST-VAC1 (antigen-presenting autologous dendritic cells) is undergoing continuing development by Asterias based on promising efficacy and safety data from a Phase 2 study in Acute Myeloid Leukemia (AML), with current efforts focused on streamlining and modernizing the manufacturing process. AST-OPC1 (oligodendrocyte progenitor cells) is currently in a Phase 1/2a dose escalation clinical trial in spinal cord injury. Additional information about Asterias can be found at www.asteriasbiotherapeutics.com.

About Cancer Research UK

Cancer Research UK is the world’s leading cancer charity dedicated to saving lives through research. Cancer Research UK’s pioneering work into the prevention, diagnosis and treatment of cancer has helped save millions of lives. Cancer Research UK receives no government funding for its life-saving research. Every step it makes towards beating cancer relies on vital donations from the public. Cancer Research UK supports research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses.

FORWARD-LOOKING STATEMENTS

Statements pertaining to future financial and/or operating and/or clinical research results, future growth in research, technology, clinical development, and potential opportunities for Asterias, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the businesses of Asterias, particularly those mentioned in the cautionary statements found in Asterias' filings with the Securities and Exchange Commission. Asterias disclaims any intent or obligation to update these forward-looking statements.

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