PROVECTUS BIOPHARMACEUTICALS, INC.
Form 8-K
June 27, 2018

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): **June 27, 2018**

PROVECTUS BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in charter)

Delaware	**001-36457**	**90-0031917**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10025 Investment Drive, Suite 250, Knoxville,

Tennessee 37932

(Address of Principal Executive Offices) (Zip Code)

(866) 594-5999

(Registrant's Telephone Number, Including Area Code)

N/A

(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 (see General Instruction A.2 below):

[ ] 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 7.01. Regulation FD Disclosure.

During its annual meeting of stockholders to be held on June 27, 2018, Provectus Biopharmaceuticals, Inc. (the "Company") will discuss, among other things, the recently initiated program of single patient expanded access (compassionate use) to PV-10, the Company's lead investigational oncology drug and small molecule oncolytic immunotherapy.

Physician requests for the treatment use of PV-10 for four patients under single patient expanded access have been approved by the Company since the initiation of this program in January 2018, as follows:

- PV-10 in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 drug, for mucosal melanoma of the vagina (refractory to the combination of YERVOY® (ipilimumab) and KEYTRUDA),
- PV-10 in combination with BAVENCIO® (avelumab), an anti-PD-L1 drug, for Merkel cell carcinoma (refractory to BAVENCIO),
- PV-10 in combination with KEYTRUDA for metastatic melanoma (refractory to IMLYGIC® (talimogene laherparepvec), an oncolytic virus drug), and
- PV-10 in combination with OPDIVO® (nivolumab), an anti-PD-1 drug, for breast cancer (refractory to OPDIVO).

In each case, single patient expanded access to PV-10 was granted under 21 CFR 312.310(b)(2), which provides for individual patient expanded access (i) within a sponsor's existing investigational new drug application with the U.S. Food and Drug Administration (the "FDA") and (ii) with oversight from the respective governing institutional review board. Prior to reporting each case to the FDA, the Company reviewed eligibility in existing Provectus-sponsored clinical trials with the respective patient's treating physician and Company clinical trial personnel.

Provectus previously provided expanded access to PV-10 for cutaneous and subcutaneous malignancies under 21 CFR 312.315 (treatment of intermediate-size patient populations). This program facilitated access to PV-10 for nearly 190 melanoma and non-melanoma skin cancer patients in the U.S. and Australia from 2009 to 2016.

Pursuant to the rules and regulations of the Securities and Exchange Commission, the information in this Item 7.01 disclosure is deemed to have been furnished and shall not be deemed to be "filed" under the Securities Exchange Act of 1934, as amended.

SIGNATURE

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.

Date: June 27, 2018

PROVECTUS BIOPHARMACEUTICALS, INC.

By: */s/ Timothy C. Scott*
Timothy C. Scott
President