SECURITIES & EXCHANGE COMMISSION EDGAR FILING

PROVECTUS BIOPHARMACEUTICALS, INC.

Form: 8-K

Date Filed: 2018-02-22

Corporate Issuer CIK: 315545

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): **February 22, 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, TN 37932
(Address of Principal Executive Offices)

(866) 594-5999
(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. [ ]

Item 7.01. Regulation FD Disclosure.

On February 22, 2018, Provectus Biopharmaceuticals, Inc. (the "Company") issued a press release (the "Press Release") providing an update on the Company's gastrointestinal cancer clinical development program for its lead investigational drug PV-10. A copy of the Press Release is attached to this Current Report as Exhibit 99.1 and is incorporated herein by reference.

Pursuant to the rules and regulations of the SEC, the information in this Item 7.01 disclosure, including Exhibit 99.1 and information set forth therein, is deemed to have been furnished and shall not be deemed to be "filed" under the Securities Exchange Act of 1934, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release, dated February 22, 2018

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: February 22, 2018

PROVECTUS BIOPHARMACEUTICALS, INC.

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

EX-99.1 2 ex99-1.htm

Contact:
Provectus Biomaceuticals, Inc.
Tim Scott, Ph.D.
President
Phone: (866) 594-5999

FOR IMMEDIATE RELEASE

PROVECTUS BIOPHARMACEUTICALS PROVIDES UPDATE ON GI CANCER PROGRAM FOR INVESTIGATIONAL DRUG PV-10

- **Current Phase 1 basket study continues to enroll and treat patients for HCC and liver cancer metastases (colorectal, lung, pancreatic, melanoma, ovarian, and breast); updated data presentation planned for 2018**

- **First expansion of GI cancer program, Phase 1 study of PV-10 for symptomatic NET metastatic to liver, has now treated multiple patients; preliminary data presentation planned for 2018**

- **Projected second program expansion: Phase 1b/2 study of PV-10 neoadjuvant to chemotherapy for metastatic pancreatic cancer**

KNOXVILLE, TN, February 22, 2018 — Provectus Biopharmaceuticals, Inc. (OTCQB: PVCT, www.provectusbio.com) ("Provectus" or the "Company"), a clinical-stage biotechnology company developing the first small molecule oncolytic immunotherapy for solid tumor cancers, today provided an update on the Company's gastrointestinal ("GI") cancer clinical development program for its lead investigational drug PV-10, which is administered percutaneously when targeting GI cancer tumors.

Provectus' Phase 1 study of patients with hepatic lesions (a "basket study" open to patients with different hepatic tumor types and entitled *A Study to Assess PV-10 Chemoablation of Cancer of the Liver*, NCT00986661) has treated 18 patients at four U.S. sites to date: six patients with hepatocellular carcinoma ("HCC"), six patients with metastatic colorectal cancer ("mCRC") metastatic to the liver, and six patients with breast cancer, lung cancer, melanoma, ovarian cancer or pancreatic cancer liver metastases. A fifth U.S. site is currently projected to enroll patients in the first half of 2018 and focus on uveal melanoma metastatic to the liver.

The most recent data from this basket study was presented at the 9 th Annual Symposium of Clinical Interventional Oncology ("CIO") in Hollywood, Florida on February 4-5, 2017 (a similar presentation was made at the 26th Conference of the Asian Pacific Association for the Study of the Liver in Shanghai, China on February 15-19, 2017). Results included:

- Two of six patients with HCC who remained alive for 58 and 75 months after treatment, the latter with no evidence of disease;
- Four of five patients with mCRC liver metastases who remained alive 9 to 73 months after treatment, including one patient with no evidence of disease at 73 months; and
- One patient with pancreatic cancer liver metastases who remained alive 12 months after treatment.

Evidence of tumor destruction in both target (injected) and bystander (non-injected) lesions was displayed. A copy of the CIO poster presentation is available on Provectus' website. Provectus currently plans to present updated data from this basket study at a medical conference in the second half of 2018.

In February 2017, researchers at the University of Illinois at Chicago published work elucidating PV-10's mechanism of action in colon cancer, whereby PV-10 may induce immunogenic cell death that contributes to specific antitumor immunity.[1]

In April 2017, the first patient was treated in the Company's first expansion trial of the GI cancer program (*A Phase 1 Study of PV-10 Chemoablation of Neuroendocrine Tumors Metastatic to the Liver*, NCT02693067). The patient, who had multifocal disease refractory to Lutate (^{177}Lu-DOTA-octreotate, a radio-labelled somatostatin analog; also known as LUTATHERA®, which was approved earlier this month by the U.S. Food and Drug Administration), received percutaneous PV-10 to a single neuroendocrine tumor ("NET") metastasis, and subsequently received a second injection of PV-10 to a second NET metastasis.[2] Since then, a second patient received a first injection. [2] Provectus currently plans to present preliminary data from this study at a medical conference in the second half of 2018.

Provectus is planning to initiate a second expansion of its GI cancer program focused on metastatic pancreatic cancer. This new study will be the first clinical combination use of PV-10 in GI cancer:

- The study, with the preliminary title *A Phase 1b/2 study of percutaneous PV-10 neoadjuvant to chemotherapy for metastatic pancreatic cancer*, builds on the data from the Company's hepatic basket and NET trials to address pancreatic cancer that has metastasized to the liver. Prior preclinical work by Moffitt Cancer Center established that PV-10 has therapeutic activity in pancreatic cancer murine models as both a single agent and in combination with gemcitabine, a standard chemotherapeutic agent used to treat this disease.[3]

Dominic Rodrigues, Chairman of the Company's Board of Directors, said, "GI cancers as a group are responsible for more deaths than any other disease type. Provectus and its research collaborators have independently established PV-10 as an oncolytic immunotherapy in melanoma[4], colon cancer, and pancreatic cancer. We will expand our GI cancer clinical development program by continuing to initiate trials where PV-10, either as a single agent or in combination with another class of agent, may address multiple different indications with substantial unmet need or that are rare diseases."

About Provectus

Provectus is a clinical-stage biotechnology company leading the development of a new class of drugs based on halogenated xanthenes. Intralesional PV-10, the first small molecule oncolytic immunotherapy, which can induce immunogenic cell death, is undergoing clinical study for adult solid tumor cancers like melanoma and cancers of the liver as well as preclinical study for pediatric cancers. Topical PH-10 is undergoing clinical study for inflammatory dermatoses like psoriasis; pathways significantly improved include published psoriasis transcriptomes and cellular responses mediated by IL-17, IL-22 and interferons. Information about the Company's clinical trials can be found at the NIH registry, www.clinicaltrials.gov. For additional information about Provectus, please visit the Company's website at www.provectusbio.com.

FORWARD-LOOKING STATEMENTS: This release contains "forward-looking statements" as defined under U.S. federal securities laws. These statements reflect management's current knowledge, assumptions, beliefs, estimates, and expectations and express management's current views of future performance, results, and trends and may be identified by their use of terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," and other similar terms. Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements. Readers should not place undue reliance on forward-looking statements. Such statements are made as of the date hereof, and we undertake no obligation to update such statements after this date.

Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements include those discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016).

References:

1. Qin J., Kunda N., Qiao G., Calata J.F., Pardiwala K., Prabhakar B.S., Maker A.V. (2017), Colon cancer cell treatment with rose bengal generates a protective immune response via immunogenic cell death. *Cell Death Dis*. 2017 Feb 2;8(2):e2584. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5386459/.

2 . On February 16, 2018, an article was published in the Adelaide, Australia newspaper *The Advertiser* describing the experiences of the two patients participating in the Phase 1 NET study. *DISCLAIMER: In linking to the article Provectus makes no claims about the safety or efficacy of investigational drug PV-10.*

3. Pilon-Thomas S., Weber A., Morse J., Kodumudi, K., Liu H., Mullinax J., Sarnaik A.A., (2016), Intralesional injection with Rose Bengal and systemic chemotherapy induces anti-tumor immunity in a murine model of pancreatic cancer. *Journal for ImmunoTherapy of Cancer* 2016 4(Suppl 1):73. https://jitc.biomedcentral.com/articles/10.1186/s40425-016-0173-6.

4. Liu H., Innamarato P.P., Kodumudi K., Weber A., Nemoto S., Robinson J.L., Crago G., McCardle T., Royster E., Sarnaik A.A., Pilon-Thomas S. (2016), Intralesional rose bengal in melanoma elicits tumor immunity via activation of dendritic cells by the release of high mobility group box 1. *Oncotarget*, 7:37893–37905. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5122358/.

Trademark:

###