# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

# PROVECTUS BIOPHARMACEUTICALS, INC.

## Form: 8-K

## Date Filed: 2017-10-18

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): **October 18, 2017**

# 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 October 18, 2017, Provectus Biopharmaceuticals, Inc. (the "Company") issued a press release (the "Press Release") announcing preliminary results from its phase 1b/2 study of the Company's drug candidate, intralesional PV-10, in combination with KEYTRUDA® (pembrolizumab), Merck's systemic anti-PD-1 (programmed death receptor-1) antibody agent, for the treatment of melanoma. 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 Commission, 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 October 18, 2017 |

**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: October 18, 2017

**PROVECTUS BIOPHARMACEUTICALS, INC.**

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

EX-99.1 2 ex99-1.htm


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

**FOR IMMEDIATE RELEASE**

**PROVECTUS ANNOUNCES PRELIMINARY RESULTS FROM PHASE 1B TRIAL OF INTRALESIONAL PV-10 IN COMBINATION WITH KEYTRUDA® (PEMBROLIZUMAB) FOR THE TREATMENT OF STAGE IV MELANOMA**

**– Adverse events consistent with established patterns for each drug; no unexpected toxicities observed –**

**– 50% overall objective response rate; 10% complete response; highest responses observed in M1c patients; assessment via RECIST 1.1 –**

KNOXVILLE, TN, October 18, 2017 — Provectus Biopharmaceuticals, Inc. (OTCQB: PVCT, www.provectusbio.com) ("Provectus" or the "Company"), a clinical-stage biotechnology company leading the development of the first small molecule oncolytic immunotherapy, intralesional ("IL") PV-10, as a single agent for locally advanced disease as well as in combination with another agent for widely metastatic disease, both for multiple cancer indications, today announced that results from the Company's ongoing Phase 1b/2 study of IL PV-10 in combination with KEYTRUDA® (pembrolizumab), Merck's systemic anti-PD-1 (programmed death receptor-1) antibody agent, were presented at the Society for Melanoma Research 2017 Congress, held in Brisbane, Australia from October 18-21. IL injection of PV-10 induces immunogenic cell death that results in tumor-specific reactivity in circulating CD8+ T cells.

The Phase 1b portion of the study continues to enroll patients with metastatic melanoma at clinical sites in the U.S. and Australia (NCT02557321); Stage IV patients with at least one injectable lesion who are candidates for KEYTRUDA are eligible. A total of up to 24 patients would receive the combination of IL PV-10 and KEYTRUDA every three weeks for five cycles (i.e., for up to 12 weeks, with no further PV-10 administered after week 12), followed by only KEYTRUDA every three weeks for up to 24 months. The primary endpoint for the Phase 1b trial is safety and tolerability; objective response rate and progression-free survival are key secondary endpoints (both assessed via RECIST 1.1 after five treatment cycles, and then every 12 weeks thereafter).

**IL PV-10 Results from the Phase 1b Trial Presented at SMR:**

- Baseline characteristics (safety population, N=12): 92% men; median age of 71.5 years (range 28-81), 67% ≥ 65 years; 67% Stage IV M1b/c.
- Subject characteristics (safety population): 2.5 median number of cutaneous/subcutaneous lesions (range 1-40); patients had substantial non-injected systemic disease burden in addition to their injectable cutaneous and/or subcutaneous lesions; patients received a median of 5 cycles of PV-10 (mean 3.8, range 1-5); PV-10 was not administered after week 12.
- Preliminary safety (safety population): adverse events were consistent with the established patterns for each drug; there were no unexpected toxicities or evidence of compounded toxicity.
- Preliminary target lesion efficacy (efficacy evaluable population, N=10): 50% complete response; 80% objective response; maximum response.
- Preliminary overall efficacy (efficacy evaluable population): 10% complete response; 50% objective response; 60% clinical benefit; highest responses observed in M1c patients; per RECIST 1.1.

Dominic Rodrigues, Chairman of the Company's Board of Directors, said, "These preliminary results highlight the safety characteristics of the combination of intralesional PV-10 and checkpoint inhibition. The data confirm an almost complete absence of correlation of adverse events between the two drugs, which we refer to as 'orthogonality.' This outcome is very different from when oncolytic viruses or other biologics are used in combination with checkpoint inhibitors."

Mr. Rodrigues added, "There also was promising clinical benefit after minimal PV-10 intervention, especially in those patients with Stage IV M1c disease. These data support the advancement of the combination of PV-10 and checkpoint inhibition in the clinical study of metastatic melanoma."

A copy of the poster presentation is currently available on Provectus' website at http://provectusbio.com/media/docs/publications/SMR-2017-Poster-P15-1_18-Oct-2017.pdf.

**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, is undergoing clinical study for adult solid tumor cancers like melanoma and cancers of the liver, and preclinical study for pediatric cancers. Topical PH-10 is undergoing clinical study for inflammatory dermatoses like psoriasis. 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," "would," "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).*

**Trademark**

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. Kenilworth, New Jersey, U.S.A.

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