

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

PROVECTUS BIOPHARMACEUTICALS, INC.

Form: 8-K

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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): **November 30, 2017**

PROVECTUS BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36457
(Commission
File Number)

90-0031917
(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 November 30, 2017, Provectus Biopharmaceuticals, Inc. (the “Company”) issued a press release (the “Press Release”) announcing results from the Company’s mechanism of action study of topical PH-10 for psoriasis were presented at the 8th International Congress of Psoriasis: from gene to clinic, held in London, England from November 30th to December 2nd. 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 November 30, 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: November 30, 2017

PROVECTUS BIOPHARMACEUTICALS, INC.

By: /s/ Timothy C. Scott

Timothy C. Scott

President



Contact:
Provectus Biopharmaceuticals, Inc.
Tim Scott, PhD
President
Phone: (866) 594-5999

FOR IMMEDIATE RELEASE

PROVECTUS ANNOUNCES RESULTS FROM MECHANISM OF ACTION STUDY OF TOPICAL PH-10 FOR THE TREATMENT OF PSORIASIS

– Responses mediated by multiple pathways, including IL-17, IL-22 and interferons –

– Down-regulation of more than 500 disease-related genes; wide range of central “psoriasis-related” genes effectively normalized –

KNOXVILLE, TN, November 30, 2017 — Provectus Biopharmaceuticals, Inc. (OTCQB: PVCT, www.provectusbio.com) (“Provectus” or the “Company”), a clinical-stage biotechnology company developing a novel therapeutic platform based on halogenated xanthenes for the treatment of multiple diseases, including cancer and inflammatory dermatoses, today announced that results from the Company’s mechanism of action (“MOA”) study of PH-10 were presented at the 8th International Congress of Psoriasis: from gene to clinic (“Psoriasis G2C”), held in London, England from November 30th to December 2nd. This MOA work was undertaken by James Krueger, MD, PhD and other members of the Laboratory for Investigative Dermatology at The Rockefeller University. PH-10 is a topical hydrogel formulation that yields selective delivery of rose bengal disodium to epithelial tissues.

The MOA work used tissue biopsy specimens collected from participants in a multicenter study of subjects with mild to moderate psoriasis (NCT02322086). Patients applied a vehicle treatment each day for 28 consecutive days to plaque psoriasis on the central part of their bodies or extremities, and then applied PH-10 each day for 28 consecutive days to these same areas. Biopsies of one target plaque were collected at baseline (at least 7 days prior to first study treatment on Day 1), and then at Days 29 and 64 (with a 7-day interval between the biopsy at Day 29 and the commencement of PH-10 application on Day 36). Study data from each subject served as an internal control (i.e., non-lesional skin and plaque skin assessment at baseline and serial biopsies at the end of the applications of the vehicle and PH-10, respectively) to assess patients’ clinical and cellular responses to PH-10.

Topical PH-10 Results from MOA Study Presented at Psoriasis G2C:

- The vehicle treatment did not significantly alter the expression of core IL-17- or IL-23-modulated genes, or the overall disease transcriptome.
- PH-10 treatment significantly down-regulated IL-17A, IL-22, IL-26, IL-36 and keratin 16 genes.
- Pathways significantly improved by PH-10 treatment included published psoriasis transcriptomes and cellular responses mediated by IL-17, IL-22 and interferons.
- PH-10 treatment also resulted in the downregulation of more than 500 disease-related genes. The expression of a wide-range of central “psoriasis-related” genes including IL-23, IL-17, IL-22, S100A7, IL-19, IL-36 and CXCL1 were effectively normalized to levels consistent with non-lesional skin.

Dominic Rodrigues, Chairman of the Company's Board of Directors, said, “This study has elucidated PH-10's novel mechanism of action for psoriasis and, combined with Provectus' prior clinical work in inflammatory dermatoses, reaffirmed our belief that the Company's therapeutic platform may now encompass psoriasis and also extend to other skin disorders. The immunologic response outcome that four weeks of topical PH-10 achieved in this study occurs with other topical or systemic drugs approved for psoriasis.”

Mr. Rodrigues added, “We believe Dr. Krueger's foundational analysis of immune and psoriasis-related gene modulation by PH-10 confirms its clinical relevancy, albeit in a brief, four-week treatment regimen. This prior regimen was studied by Provectus in multiple Phase 1 and 2 clinical studies of psoriasis and atopic dermatitis comprising more than 200 patients; minimal adverse effects were observed and efficacy was evident in all metrics, such as psoriasis severity index, plaque response assessment, pruritus self-assessment, eczema area severity index, and investigator's global assessment.”

Mr. Rodrigues concluded, “Provectus is now in the position to establish the full efficacy potential of topical PH-10. We are refining our clinical development program for dermatology to include longer administration of PH-10 that would allow for its direct comparison with both topical and systemic approved drugs.”

A copy of the poster presentation is available on Provectus' website at http://www.provectusbio.com/media/docs/publications/PVCT_PG2C2017.pdf.

About Provectus

Provectus is a clinical-stage biotechnology company leading the development of a new class of drugs based on halogenated xanthenes. Intravesicular 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 and atopic dermatitis. 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).

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