

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): **September 21, 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 September 21, 2017, Provectus Biopharmaceuticals, Inc. (the “Company”) posted on its website a letter to its shareholders discussing Company developments and updates. The letter can be accessed at the following link: <http://provectusbio.com/letter-to-shareholders>. A copy of the letter 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	Letter to shareholders dated September 21, 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: September 21, 2017

PROVECTUS BIOPHARMACEUTICALS, INC.

By: /s/ Timothy C. Scott

Timothy C. Scott

President

EXHIBIT INDEX

Exhibit Number	Description
99.1	Letter to shareholders dated September 21, 2017

September 21, 2017

Dear Provectus Shareholders,

Thank you for your continued support of the Company.

As you know, on April 3, 2017, a group of shareholders – Ed Pershing, Dominic Rodrigues, and Bruce Horowitz (collectively, the “PRH Group”¹) – closed a definitive financing with Provectus Biopharmaceuticals, Inc. (“Provectus” or the “Company”).

As fellow shareholders, we are committed to maximizing stockholder value through continuing to develop Provectus’ investigational drugs for the treatment of solid tumor cancers in adults as well as pediatric cancers (i.e., intralesional PV-10), and inflammatory dermatoses for dermatology in both adults and children (i.e., topical PH-10). The Company’s mission is to deliver these and other advanced, economical, healthcare solutions around the world and, in so doing, address unmet medical needs in disease areas affecting tens of millions of patients and their caregivers.

Provectus is innovating a different approach to treating cancer by leading the development of small molecule oncolytic immunotherapy. Delivered by intralesional injection (i.e., injection into a cancerous tumor), PV-10 first acts locally, causing oncolytic destruction of injected tumors. The local immunogenic cell death then has the potential to engage the adaptive immune system for a systemic, or global, effect. By harnessing the immune system in this way, PV-10 may enable patients to achieve immunity to their cancer. PH-10, delivered topically to affected skin, shares similar mechanistic themes.

At the beginning of 2017, these exciting technologies resided within a company at a crossroads and desperately in need of change.

The PRH Group listened to our fellow shareholders and specifically conditioned the definitive financing on a change of control of the Board of Directors (the “Board”) as well as the appointment of new operational management. We accomplished both goals. Mr. Rodrigues was named Chairman of the Board. Mr. Pershing was added as a Board observer and named Chairman of Provectus’ renewed Strategic Advisory Board. Mr. Horowitz was named a member of the Board, and also appointed as the Company’s chief operations consultant to manage company operations with input and assistance from Mr. Rodrigues. The PRH Group is both mindful and very appreciative of the confidence shareholders expressed through your overwhelming support of our slate of Board directors at the Company’s annual meeting of stockholders held on May 30th.

¹ The PRH Group has specifically disclaimed it is a “group” as defined in U.S. federal securities laws.

The PRH Group determined it was in the best interest of shareholders to utilize a tranche-based financing program as an efficient and less dilutive method of providing the financial resources necessary to achieve success. The PRH Group and other investors currently have committed to invest approximately \$7.85 million into the Company, \$5.85 million of which has been invested to date.² We continue to discuss potential commitments to the definitive financing vehicle in order to secure additional operating capital as and when needed to execute our business plan.

The PRH Group has integrated itself into every facet of this business, enabling the Provectus team to achieve significant efficiencies in a very short time since Mr. Horowitz's operational appointment. Having been in control for only three months (ending June 30th), the Company's general & administrative expenses and net cash used for operating activities decreased 64% and 42% quarter-over-quarter, respectively, and decreased 70% and 52% year-over-year, respectively. Furthermore, monies directed to research & development increased 28% quarter-over-quarter and 19% year-over-year. We continue to proactively manage the Company's cash position and evaluate Provectus' portfolio of biotechnology assets.

From the moment we assumed control of the Company, the Provectus team undertook a laser-like focus to resolve the "legacy" issues discovered by the PRH Group, including but not limited to:

- We affirmed Provectus' legal action against the Company's former bookkeeping firm, Bible Harris Smith, P.C. ("BHS"), that alleges professional negligence, common law negligence, and breach of fiduciary duty arising from accounting services provided by BHS related to travel and expense advances and reimbursements received by former Company executive H. Craig Dees, Ph.D. ("Dees"). This lawsuit seeks damages in excess of \$3 million from BHS. Provectus is currently in the discovery phase with this litigation.

² As noted in the Company's Form 10-Q for the quarter ended June 30th, filed with the SEC on August 9th.

- On June 9th, the Company filed a lawsuit against Provectus' former internal audit firm, RSM US LLP ("RSM"), that alleges professional negligence, common law negligence, gross negligence, intentional misrepresentation, negligent misrepresentation, and breach of fiduciary duty arising from accounting, internal auditing, and consulting services provided by RSM related to travel and expense advances and reimbursements received by Dees and former Company executive Peter Culpepper, CPA ("Culpepper"). This lawsuit seeks damages in excess of \$10 million from RSM. Provectus' complaint has been filed and served.
- The Company continues to cooperate fully with the U.S. Securities and Exchange Commission (the "SEC") regarding ongoing investigations by SEC staff related to travel and expense advances and reimbursements received by Dees and Culpepper. Provectus is in settlement negotiations with the SEC; however, no agreement has been approved by the SEC at this time.³
- On June 28th, Provectus and Culpepper participated in a mediation of the Company's dispute with him, reaching no resolution. In accordance with the terms of his Provectus employment agreement, the Company is advancing its claims against Culpepper for improper expense reimbursements as well as amounts owed to Provectus by him under the Stipulated Settlement Agreement and Mutual Release originally entered into on June 6, 2014 (the "Derivative Lawsuit Settlement"). On September 1st, the American Arbitration Association confirmed it had received our demand for arbitration.
- On July 25th, the United States District Court for the Eastern District of Tennessee (the "Court") issued a Memorandum Opinion that found Provectus was entitled to total damages in excess of \$6 million in compensatory damages for misappropriation of travel and expense funds, compensatory damages for Dees' breach of the Derivative Lawsuit Settlement, and punitive damages, plus costs. We cannot assure you the Company will recover any or all of these awarded damages; however, the Court has entered a permanent injunction enjoining Dees from selling or dissipating assets until the judgment against him has been satisfied. On September 1st, Provectus filed a motion with the Court to appoint a receiver to sell one million shares of the Company's common stock held by Dees and pledged as security pursuant to the Derivative Lawsuit Settlement, and to remit the proceeds of this sale to Provectus.

³ As noted in the Company's Form 10-Q for the quarter ended June 30th, filed with the SEC on August 9th.

The PRH Group intends to continue to maintain a lean staff because Provectus' operational team has shown the ability to manage outsourced and contracted clinical trial, regulatory affairs, and supply chain activities. It is important that shareholders know Provectus has a dedicated team of experienced, knowledgeable, competent, and hardworking professionals who manage the Company's various clinical development programs. They quickly grasped PRH Group's business culture of accountability, and renewed their pursuit of excellence. Despite the difficulties this Company experienced in 2016, Provectus continued to make good progress with each and every clinical program.

The PRH Group has spent the last approximately five months restructuring this entire organization. The Provectus team has worked diligently to develop a more efficient operational foundation. We continue to implement the Company's intended strategic and tactical framework as well as execute Provectus' clinical development plans. The team is actively engaged with core contractor relationships integral to the success of the Company's clinical operations. We have re-engaged clinicians and medical researchers as well as key opinion leaders familiar with PV-10 and PH-10 and who themselves have exhibited a culture of excellence. Together, we are working towards executing Provectus' existing programs, and pursuing new opportunities for the Company's small molecule therapeutic technology platform.

The future of Provectus is based on the foundation of great science and technology. We are keenly focused on advancing the first small molecule oncolytic immunotherapy in PV-10, which may provide a better therapeutic option and improved quality of life for cancer patients. PV-10 represents nearly a decade of work by the Company to optimize the synthetic process for manufacturing rose bengal and its related halogenated xanthene analogs to meet modern global requirements for pharmaceutical use.

Provectus' dedicated team of professionals inside and outside of the Company all recognize the limitations of existing approved cancer drugs. We are all committed to the goal of providing potentially better options for a far greater number of patients battling cancer (as well as other possible diseases). As key opinion leaders and principal investigators recognize the potential for PV-10 to provide attractive treatment options for patients, the Provectus team continues to focus on enhancing patient enrollment in all of the Company's clinical trials. We are very aware that data generated from these trials and others will be the key to unlocking value for Provectus shareholders.

All Company stakeholders are in the midst of a special opportunity that very few biotechnology companies ever approach, which is to conduct a pivotal Phase 3 trial. In our case, we have the opportunity to demonstrate that a novel therapeutic approach may potentially provide superior benefit over existing treatment options for locally advanced melanoma patients (i.e., Stage III and early Stage IV disease). As the medical community and pharmaceutical industry continue their exploration of the tumor and its microenvironment as the nexus for better cancer treatment, intralesional PV-10, the first small molecule oncolytic immunotherapy, may have arrived at an opportune time.

Provectus' approach to drug development is centered around designing clinical studies for success based on science and medicine, rather than supporting the broadest possible label at the outset. The Company has bifurcated its overall clinical development program into two complementary and related paths based on the features of our investigational drugs and their rational applicability and relevancy to different patient populations. In cancer, for example, we believe PV-10 has important implications as a single agent for earlier stages of disease (i.e., Stage III or earlier), while combination of PV-10 with other classes of therapy or therapeutic agent is more appropriate for more advanced stages (i.e., Stage IV). Our ongoing preclinical and clinical work in melanoma, cancers of the liver, pancreatic cancer, and pediatric cancers, as well as our work in inflammatory dermatoses, follows this approach.

The opportunity to bring Provectus' lead investigational drugs for cancer (PV-10) and dermatology (PH-10) to market, and deliver advanced healthcare solutions around the world for unmet medical needs in disease areas affecting tens of millions of patients and their caregivers are exactly why the PRH Group was drawn to the significant challenges of reorganizing, restructuring, and financing this Company. There are no shortcuts to success in biotechnology drug development. The road to regulatory approval and commercial acceptance is long and expensive, and success is never assured. Nevertheless, we are confident that our current Provectus team, together with additions over time, possesses the expertise, technical know-how, experience, and commitment to excellence needed to maximize the value of the Company for the benefit of our shareholders.

Thank you again for your continued support of Provectus.

Dominic Rodrigues
Chairman,
Provectus Biopharmaceuticals, Inc.

Special Note Regarding Forward-Looking Statements: This Letter to Shareholders includes "forward-looking statements" within the meanings of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this Letter to Shareholders other than statements of historical fact, are "forward-looking statements." For example, statements relating to our beliefs, expectations, plans, projections, forecasts, and estimates are forward-looking statements, as are statements that specified actions, conditions, or circumstances will continue or change. Forward-looking statements involve risks and uncertainties. In some cases, forward-looking statements can be identified by the inclusion of words such as "believe," "could," "expect," "plan," "anticipate," "estimate," "may," "should," "will," "continue," "intend," and similar words. Our actual results could differ materially from those projected or assumed in our forward-looking statements because forward-looking statements by their nature are subject to risks and uncertainties. Factors that could contribute to these differences include the factors described in "Risk Factors" in Item 1A of the Company's Annual Report on Form 10-K for the year ended December 31, 2016. 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.
