PROVECTUS BIOPHARMACEUTICALS, INC.
Form 10-K
March 07, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

[X] **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

[ ] **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 001-36457

PROVECTUS BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**90-0031917**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

10025 Investment Drive, Suite 250, Knoxville, TN 37932

(Address of principal executive offices) (Zip Code)

866-594-5999

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None.

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.001 per share

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. [ ] Yes No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. [ ] Yes [X] No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. [X] Yes [ ] No

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). [X] Yes [ ] No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		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. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). [ ] Yes [X] No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 29, 2018 was $26,046,375 (computed on the basis of $0.071 per share).

The number of shares outstanding of the registrant's common stock, par value $.001 per share, as of February 28, 2019 was 384,714,528.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III is incorporated by reference to portions of the definitive proxy statement to be filed within 120 days after December 31, 2018, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the 2019 annual meeting of stockholders.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements regarding, among other things, our anticipated financial and operating results. Forward-looking statements reflect our management's current assumptions, beliefs, and expectations. Words such as "anticipate," "believe," "estimate," "seek," "expect," "intend," "could," "plan," and si expressions are intended to identify forward-looking statements. While we believe that the expectations reflected in our forward-looking statements are reasonable, we can give no assurance that such expectations will prove correct. Forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from the future results, performance, or achievements expressed in or implied by any forward-looking statement we make. Some of the relevant risks and uncertainties that could cause our actual performance to differ materially from the forward-looking statements contained in this report are discussed below under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. We caution investors that these discussions of important risks and uncertainties are not exclusive, and our business may be subject to other risks and uncertainties which are not detailed there. Investors are cautioned not to place undue reliance on our forward-looking statements. We make forward-looking statements as of the date on which this Annual Report on Form 10-K is filed with the Securities and Exchange Commission (SEC), and we assume no obligation to update the forward-looking statements after the date hereof whether as a result of new information or events, changed circumstances, or otherwise, except as required by law.

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PART I

ITEM 1. BUSINESS.

General

Provectus Biopharmaceuticals, Inc. (Provectus or the Company), a Delaware corporation formed in 2002, is a clinical-stage biotechnology company developing a new class of drugs based on halogenated xanthenes, which are chemical small molecules, such as Rose Bengal, which has a molecular formula of 4,5,6,7-tetrachloro-2',4',5',7'-tetraiodofluorescein. Intratumoral (IT) (aka intralesional or IL) injection of PV-10, the first small molecule oncolytic immunotherapy, can yield immunogenic cell death and stimulate tumor-specific reactivity in circulating T cells. PV-10 is undergoing clinical study for adult solid tumor cancers, like melanoma and gastrointestinal (GI) cancers, and preclinical study for pediatric cancers. Topical application of PH-10, an investigational formulation of Rose Bengal for dermatology, can modulate inflammation. PH-10 is undergoing clinical study for inflammatory dermatoses, like psoriasis and atopic dermatitis. Pathways significantly improved by PH-10 include published psoriasis transcriptomes and cellular responses mediated by IL-17, IL-22, and interferons.

Our approach to drug development comprises two related, complementary, clinical program paths based on the features of our respective investigational drugs and their clinically-rational applicability to different patient populations. In solid tumor cancers for adults, for example, we believe PV-10 has important implications as a single-agent for earlier states of disease (e.g., locally advanced disease; Stage III or earlier), while the combination of PV-10 with other classes of therapy (e.g., immunotherapy, chemotherapy, radiotherapy, targeted therapy) is more appropriate for advanced disease states (e.g., widely metastatic disease; Stage IV).

Product Pipeline

Oncology (PV-10)

Melanoma (single-agent)

Phase 3 study for locally advanced melanoma (Stage IIIB-IV M1a) (NCT02288897): In 2018, we placed a hold on enrollment pending a more thorough performance comparison analysis of PV-10 cancer combination therapy

treatment (PV-10 and KEYTRUDA) and historical single-agent PV-10 treatment for these patients.

Completed Phase 1 and 2 studies (NCT00219843 and NCT00521053, respectively).

Orphan drug designation status has been granted by the U.S. Food and Drug Administration (FDA) for metastatic melanoma (2006).

In 2018, a study of expanded access patients treated with PV-10 for in-transit melanoma by principal investigators at the Princess Alexandra Hospital in Brisbane, Australia was published: Read et al. Intralesional PV-10 for the treatment of in-transit melanoma metastases-Results of a prospective, non-randomized, single center study. *J Surg Oncol*. 2018 Mar;117(4):579-587.

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Melanoma and Non-Melanoma Cancers of the Skin (combination therapy)

With immune checkpoint inhibitor KEYTRUDA® (pembrolizumab) – Ongoing Phase 1b/2 study for checkpoint inhibition-naïve metastatic melanoma (Stage III-IV) (NCT02557321); in 2018, we:

- Completed enrollment of 23 patients in the main cohort,
- Reported interim Phase 1b overall patient-level data at the annual meeting of the Society for Melanoma Research (SMR),
- Reported preliminary Phase 1b lesion-level response data at Melanoma Bridge,
- Added an expansion cohort to the Phase 1b portion of the study of patients with metastatic melanoma (Stage III-IV) refractory to checkpoint inhibition, and
- Added an expansion cohort to the Phase 1b portion of the study of patients with satellite or in-transit disease. These patients are typically naïve to checkpoint inhibition treatment.

With KEYTRUDA – In 2018, combination therapy was provided to one patient under single-patient expanded access for mucosal melanoma of the vagina refractory to the combination of YERVOY® (ipilimumab) and KEYTRUDA.

With checkpoint inhibitor BAVENCIO® (avelumab) – In 2018, combination therapy was provided to one patient under single-patient expanded access for Merkel cell carcinoma refractory to BAVENCIO.

With KEYTRUDA – In 2018, combination therapy was provided to one patient under single-patient expanded access for metastatic melanoma refractory to IMLYGIC® (talimogene laherparepvec, which is an oncolytic virus-based drug.

With checkpoint inhibitor OPDIVO® (nivolumab) – In 2018, combination therapy was provided to one patient under single-patient expanded access for breast cancer refractory to OPDIVO.

In 2018, a study of T cell mediated immunity from the combination of PV-10 and checkpoint inhibition in murine melanoma models by researchers at Moffitt Cancer Center in Tampa, Florida was published: Liu et al. T cell mediated immunity after combination therapy with intralesional PV-10 and blockade of the PD-1/PD-L1 pathway in a murine melanoma model. *PLoS One*. 2018 Apr 25;13(4):e0196033.

Gastrointestinal Cancers (single-agent)

Ongoing Phase 1 basket study of hepatocellular carcinoma (HCC) and other solid tumors metastatic to the liver (NCT00986661); to date, patients have received PV-10 via percutaneous administration into several different hepatic

tumor types, including HCC, colorectal cancer, lung cancer, cutaneous melanoma, uveal melanoma, breast cancer, ovarian cancer, and pancreatic cancer. In 2018, we:

- Added a single-site expansion cohort metastatic of uveal melanoma patients at MD Anderson Cancer Center in Houston, Texas, and
- Reported initial uveal melanoma data on 3 patients at the SMR annual meeting.

Orphan drug designation status has been granted by the FDA for HCC (2011).

Ongoing Phase 1 study of symptomatic neuroendocrine tumors (NETs) metastatic to the liver (NCT02693067); in 2018, we:

- Completed enrollment of 6 patients in the first cohort, and are currently recruiting patients to the second cohort, and
- Presented a trials in progress poster at the annual meeting of the European Society for Medical Oncology (ESMO).

Gastrointestinal Cancers (combination therapy)

With checkpoint inhibitor combination of YERVOY and OPDIVO – Ongoing Phase 1 basket study of HCC and other solid tumors metastatic to the liver (NCT00986661); in 2018:

- The single-site expansion cohort of metastatic uveal melanoma patients at MD Anderson Cancer Center treated patients with the combination therapy of PV-10, and YERVOY and OPDIVO, and
- We reported initial uveal melanoma combination therapy data on one patient at the SMR annual meeting.

Pediatric Cancers (single-agent and combination therapy)

Ongoing non-clinical assessment of pediatric cancer tumor cell lines by the Pediatric Oncology Experimental Therapeutics Investigators' Consortium (POETIC); in 2018:

- POETIC reported non-clinical data for relapsed pediatric neuroblastoma, Ewing sarcoma, rhabdomyosarcoma, and osteosarcoma at the annual meeting of the American Society of Clinical Oncology (ASCO), and
- Non-clinical work was ongoing to investigate the immune-stimulatory effects of PV-10 and its potential in combination with checkpoint inhibitors.

In 2018, orphan drug designation status for neuroblastoma was granted by the FDA (2018).

Dermatology (PH-10)

Toxicology

In 2018, in support of extended 12-week administration, we finished two toxicology-focused, non-clinical, single-administration studies using carbon-14- (^{14}C-) labeled rose bengal to demonstrate lack of systemic uptake.

Psoriasis

Completed Phase 2c randomized study of mild-to-moderate psoriasis (NCT01247818).

Completed Phase 2d mechanism of action study of mild-to-moderate psoriasis (NCT02322086).

Atopic Dermatitis

Completed Phase 2 study of mild, moderate or severe atopic dermatitis (NCT00690807).

Oncology (PV-10)

We are developing PV-10, a formulation of Rose Bengal, for direct injection into tumors as an investigational oncolytic immunotherapy, where it can (a) destroy injected tumors (i.e., oncolytic) and (b) elicit an anti-tumor immune response via the adaptive immune system (i.e., immunotherapy).

Locally Advanced and Widely Metastatic Melanoma

Our pivotal Phase 3 randomized controlled trial of PV-10 as single-agent treatment for locally advanced cutaneous melanoma (Stage IIIB-IV M1a), compared to standard therapy (i.e., investigator's choice of oncolytic viral therapy or systemic chemotherapy), opened to enrollment in 2015. The primary outcome measure of the study is progression-free survival assessed every 12 weeks for up to 18 months. Secondary outcome measures include complete response rate and its duration, and overall survival, all also assessed every 12 weeks up to 18 months. In December 2018, we announced a hold on trial enrollment to allow for a more thorough performance comparison analysis of PV-10 combination therapy (i.e., PV-10 and checkpoint inhibition) and historical single-agent PV-10 treatment for these patients. Systemic therapy with checkpoint inhibition is now recommended in the U.S. for Stage III melanoma patients with satellite or in-transit disease.

Mechanism of action and other work previously reported by our research collaborators at Moffitt Cancer Center (Toomey et al., *PLOS ONE* 2013: 8(7); e68561, Liu et al., *Oncotarget* 2016; 7: 37893, and Pilon-Thomas et al., *Journal for ImmunoTherapy of Cancer 2016*; 4(Suppl 1): 73) and the University of Illinois at Chicago (Qin et al., *Cell Death and Disease* 2017; 8: e2584) indicate that PV-10 functions as an oncolytic immunotherapy in laboratory models of multiple tumor types, such as melanoma, breast cancer, colon cancer, and pancreatic cancer. Both groups of collaborators definitively classify PV-10 as an oncolytic immunotherapy capable of yielding immunogenic cell death, a primer for adaptive immunity, functioning via multiple immune effector cells, including CD8+ T cells, dendritic cells, and natural killer T cells. By the end of 2018, additional mechanism work was underway to assess the potential breadth of this immunotherapy capability.

In April 2018, principal investigators at the Princess Alexandra Hospital published results from an investigator-led, single-center study of patients with in-transit melanoma who received intralesional PV-10 under expanded access detailing the experience of treating 45 patients with almost exclusively Stage III disease from 2008 to 2015, including:

- Baseline characteristics: 60% men; median age of 76 years (range 51-90); 96% Stage IIIIB-C; median of 2 prior directed locoregional therapies,
- Median of 6 lesions treated with PV-10 (range 1-31); median of 2 treatments with PV-10 (range 1-4),

- Per patient best overall response: 42% complete response, 44% partial response, and 7% stable disease,
- 22% durable response rate (an objective response lasting more than 6 months from the time of first PV-10 treatment),
- Median overall survival of 25 months from the first PV-10 treatment; 12-, 24-, 36-, and 48-month overall survival rates of 90%, 85%, 68% and 65%, respectively, from the time of first PV-10 treatment, and
- At least one Grade 1 or 2 treatment-associated adverse event per patient; a total of three treatment-associated Grade 3 adverse events (treatment site ulceration, cellulitis, and photosensitivity reaction).

For those patients with more advanced melanoma that is not fully accessible to injection (Stage III-IV), we are assessing PV-10 in combination with checkpoint inhibition in a Phase 1b/2 clinical study. This study is the result of mechanism of action work on PV-10 showing that it may be complementary to checkpoint inhibition. Interim patient-level data from the fully-enrolled Phase 1b study portion of 23 patients were reported at the SMR annual meeting in October 2018, including:

- Baseline characteristics: 83% men; median age of 70 years (range 28-90) and 70% > 65 years; 91% checkpoint naïve,

- Disease characteristics: 13% Stage IIIC/IIID and 52% Stage IV M1b/M1c; median of 2 cutaneous/subcutaneous lesions (range 1-15); most subjects had substantial non-injected systemic disease burden in addition to their injectable cutaneous and/or subcutaneous lesions,
- Treatment summary: Subjects received a median of 4 cycles of PV-10 (mean 3.7, range 1-5) and a median of 5 injections of PV-10 (range 1-82); PV-10 was not administered after week 12,
- Preliminary safety: adverse events were consistent with the established patterns for single-agent use of each drug; there were no unexpected toxicities or evidence of significant overlapping toxicity,
- Preliminary target lesion efficacy (best overall response): 43% complete response and 65% objective response,
- Preliminary overall efficacy (per RECIST 1.1): 9% complete response, 65% objective response, and 70% clinical benefit; 83% objective response in M1c patients.

The interim data were consistent with preliminary data from the Phase 1b study of 12 patients reported at the SMR annual meeting in October 2017, and demonstrated no compounding of safety risk for the combination (the Phase 1b's primary endpoint) and likely synergy of efficacy (the Phase 1b's secondary endpoint).

Preliminary lesion-level data from the fully-enrolled Phase 1b study were reported at Melanoma Bridge in December 2018, including:

- Complete response of injected target lesions for the combination of PV-10 and pembrolizumab was higher than historical complete response for single-agent PV-10 (NCT00521053) across all disease stages: 77% vs 46%,
- Complete response of injected target lesions for the combination was higher than CR for single-agent PV-10 for each of these stages:

  - 73% vs 0% for Stage IV M1a
  - 71% vs 4% for Stage IV M1b
  - 100% vs 17% for Stage IV M1c,

- Although data on combination treatment of Stage III disease is currently limited, complete response of injected target lesions for the combination was higher than complete response for single-agent PV-10: 67% vs 54%, and
- 40% of injected target lesions achieved complete response after one or two injections.

We expanded the Phase 1b study in 2018 to include a first expansion cohort of up to 24 patients with advanced melanoma (Stage III-IV) who are refractory to checkpoint inhibition and a second expansion cohort of up to 24 patients who have satellite or in-transit disease. Both expansion cohorts are currently enrolling patients.

Research collaborators at Moffitt Cancer Center published results from a study investigating cancer combination therapy with PV-10 and checkpoint inhibition (anti-CTLA-4, anti-PD-1 and anti-PD-L1 antibodies) in murine melanoma models (Liu et al., PLOS ONE 2018: 13(4); e0196033), and also examined the role of specific immune cell populations in eliciting and controlling tumor-specific response. The authors showed the impact of combining

checkpoint inhibition with the tumor-specific immune response induced by PV-10. Treatment with PV-10 and anti-PD-1 antibody resulted in a delay in tumor growth and enhanced T cell activation in an M05 melanoma tumor model. Similar effects were observed with PV-10 and anti-PD-L1 antibody in a B16 tumor model. The effect of combination therapy with PV-10 and PD-1 blockade is mediated by CD8+ T cells, and depletion of either CD4+ T cells or CD4+CD25+ Tregs enhanced anti-tumor immunity in the M05 melanoma model.

Gastrointestinal Cancers

During 2018, we continued our exploratory Phase 1 study of cancers of the liver at five regional centers in the U.S. (St. Luke's University Health Network in Bethlehem, Pennsylvania, Florida Hospital Tampa in Tampa, Florida, Sharp Memorial Hospital in San Diego, California, Vanderbilt University Medical Center in Nashville, Tennessee, and MD Anderson Cancer Center in Houston, Texas). This "basket study" enrolls patients with HCC and other tumor types that have metastasized to the liver. Patients are treated using percutaneous injection of PV-10 under image guidance into a single liver lesion; patients with multiple lesions may receive additional treatment cycles after initial safety follow-up. To date patients with HCC and liver metastases, including colorectal, lung, breast, cutaneous melanoma, uveal melanoma, ovarian, and pancreatic, have been treated at the five centers. The non-clinical mechanism of action work reported by Qin et al. was consistent with clinical observations reported for patients with metastatic colorectal cancer participating in our Phase 1 basket study.

In July 2018, we announced that the Phase 1 study had expanded to include a single-site (MD Anderson Cancer Center) cohort of 10 uveal melanoma patients with hepatic metastases. Eligible metastatic uveal melanoma patients may receive either single agent PV-10 or PV-10 in combination with standard of care checkpoint inhibition. Initial data were reported at the SMR annual meeting in October 2018, including:

- A total of four patients received PV-10 to at least one uveal melanoma liver tumor; two patients received a second round of PV-10 treatment to an additional liver tumor; one patient initiated standard of care immunotherapy (YERVOY and OPDIVO) between PV-10 treatments,
- Treatment-related adverse events were consistent with established patterns, and
- Tumor reduction was observed in 5 of 6 PV-10-injected tumors.

In 2016, we initiated a Phase 1 study to assess PV-10 as an oncolytic immunotherapy for patients with symptomatic metastases of NETs metastatic to the liver. This study was open to enrollment at The Queen Elizabeth Hospital in Adelaide, Australia in 2017 and uses a treatment protocol comparable to that employed in the Phase 1 liver cancer basket study. Because the NET study is focused on a single tumor type, it includes radiologic (medical imaging), blood biomarker, and quality of life assessments specific to NETs. The study was the subject of a trials in progress poster presented at the ESMO annual meeting in October 2018. Six patients in the first cohort each received one injection of PV-10 to one target lesion per treatment cycle. Patients are currently being enrolled into the second cohort that allows for injection of up to three lesions per cycle.

Pediatric Cancers

In December 2016, we announced a joint research agreement with POETIC to investigate the potential of PV-10 for pediatric cancers. This collaboration involves National Cancer Institute-Designated Cancer Centers that are part of the POETIC group such as Memorial Sloan Kettering Cancer Center, Alberta Children's Hospital, and other cancer centers.

In June 2018, POETIC researchers presented non-clinical PV-10 data from their pediatric cancer research at ASCO annual meeting. PV-10 induced cell death in pediatric solid tumor cell lines derived from relapsed pediatric neuroblastoma, Ewing sarcoma, rhabdomyosarcoma, and osteosarcoma with a measurable therapeutic window compared to normal cells. Western blot analyses of cells treated with PV-10 indicated induction of apoptosis. Drug combination studies showed synergy with radiation and agents that target mitosis. Xenograft studies showed significant reduction of tumor burden in PV-10-treated mice compared to control animals, with a corresponding increase in overall survival.

In November 2018, the Company was granted orphan drug designation by FDA for PV-10 for the treatment of neuroblastoma. Initial non-clinical testing of PV-10 in treatment-refractory neuroblastoma has closely paralleled previous non-clinical and clinical study of PV-10 for murine and human adult solid tumors, at both the tumor (selective destruction of injected tumors) and cellular (immunogenic cell death) levels. Non-clinical investigation by POETIC has confirmed that immunogenic cell death also occurs in neuroblastoma. The FDA grants orphan drug designation status to medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US. Orphan drug designation status qualifies companies for benefits that include seven years of market exclusivity following marketing approval, tax credits on U.S. clinical trials, eligibility for orphan drug grants, and waiver of certain administrative fees.

Dermatology (PH-10)

We are developing PH-10, an aqueous hydrogel formulation of rose bengal disodium, for topical administration to the skin for inflammatory dermatoses such as psoriasis and atopic dermatitis.

In January 2015, we commenced a mechanism of action study of PH-10 to characterize its immunologic signaling aspects, safety, and efficacy. The clinical portion of this study was completed in January 2016. Advanced immunologic profiling of clinical samples obtained from that work was completed in June 2017 and data were reported at Psoriasis Gene to Clinic in London, England in November 2017. These data demonstrated downregulation of more than 500 disease-related genes, including central “psoriasis-related” genes that were normalized to levels consistent with non-lesional skin, and established that PH-10 has a novel mechanism of action in inflammatory dermatoses.

Work has begun in support of extended 12-week administration (proof-of-concept or POC) for PH-10. In 2018, we finished two toxicology-focused, non-clinical, single administration studies using ^{14}C-labeled Rose Bengal to demonstrate lack of systemic uptake. Radio-labeled Rose Bengal is easier to detect in plasma and tissues at very low levels than Rose Bengal itself. These data suggest there is minimal potential of visceral target organ effects from topical application of PH-10. The goal of a planned, non-clinical, toxicology-focused, 12-week administration study would be to demonstrate local effects in the skin from the extended use of PH-10 and identify any potential systemic toxicities. When completed, the 12-week POC program may allow for direct comparison of PH-10 to approved topical treatments for psoriasis and atopic dermatitis.

Research and Development

Our approach to drug development comprises two related, complementary, clinical program paths based on the features of our respective investigational drugs and their clinically-rational applicability to different patient populations. In solid tumor cancers for adults, for example, we believe PV-10 has important implications as a single-agent for earlier states of disease (e.g., locally advanced disease; Stage III or earlier), while the combination of PV-10 with other classes of therapy (e.g., immunotherapy, chemotherapy, radiotherapy, targeted therapy) is more appropriate for advanced disease states (e.g., widely metastatic disease; Stage IV).

Intellectual Property

U.S. Patents

We hold a number of patents covering the technologies we have developed and are continuing to develop for the production of investigational drugs and other technologies. All patents material to an understanding of the Company are included below, and a cross reference to a discussion that explains the patent technologies and products is identified for each patent in the following table:

U.S. Patent No.	Title and Cross Reference	Issue Date	Expiration Date
6,451,597	Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	September 17, 2002	April 6, 2020
6,468,777	Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	October 22, 2002	April 6, 2020
6,495,360	Method for enhanced protein stabilization for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	December 17, 2002	April 6, 2020
6,541,223	Method for enhanced protein stabilization and for production of cell lines useful production of such stabilized proteins; see discussion under Material Transfer Agreement in Description of Intellectual Property	April 1, 2003	April 6, 2020
6,986,740	Ultrasound contrast using halogenated xanthenes; see discussion under Oncology in Description of Business	January 17, 2006	August 3, 2019
7,201,914	Combination antiperspirant and antimicrobial compositions; see discussion under Over-the-Counter Pharmaceuticals in Description of Business	April 10, 2007	May 15, 2024
8,470,296	Improved intracorporeal medicaments for high energy photodynamic treatment of disease; see discussion under Dermatology in Description of Business	June 25, 2013	July 28, 2022
8,530,675	Process for the synthesis of rose bengal and related xanthenes; see discussion under Oncology in Description of Business	September 10, 2013	April 21, 2031

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8,974,363	Topical medicaments for disease; see discussion under Dermatology in Description of Business	March 10, 2015	December 2, 2019
9,107,887	Combination therapy for cancer; see discussion under Oncology in Description of Business	August 15, 2015	March 9, 2032
9,273,022	Process for the synthesis of rose bengal and related xanthenes; see discussion under Oncology in Description of Business	March 1, 2016	September 17, 2030
9,422,260	Process for the synthesis of rose bengal and related xanthenes; see discussion under Oncology in Description of Business	August 23, 2016	September 26, 2030
9,808,524	Combination of local and systematic immunomodulative therapies for melanoma and liver cancer	November 7, 2017	June 24, 2035
9,839,688	Combination of rose bengal and systemic immunomodulative Therapies for enhanced treatment of cancer	December 12, 2017	June 24, 2035
10,130,658	Method of ex vivo enhancement of immune cell activity for cancer immunotherapy with a small molecule ablative compound	November 20, 2018	November 20, 2036

New U.S. Patents

In 2018, we received U.S. patent no. 10,130,658, entitled “Method of ex vivo enhancement of immune cell activity for cancer immunotherapy with a small molecule ablative compound.” Under the patent’s treatment, PV-10 is injected into solid tumors and the resulting immune products (e.g., T cells trained via PV-10 oncolytic immunotherapy to be functional against treated tumors) are harvested, banked, and amplified. Amplified T cells may be administered via adoptive cell transfer, if needed. The patent also covers the adoptive cell transfer treatment of either the original patient or other immunologically-suitable patients.

Global, Non-U.S. Patents

In 2018, we received India patent related to “Process for the synthesis of rose bengal and related xanthenes” from U.S. patent no. 8,530,675 and European and Japanese patents related to “Combination of local and systemic immunomodulative therapies for enhanced treatment of cancer” from U.S. patent no. 9,107,887.

Competition

In general, the pharmaceutical and biotechnology industries are competitive, characterized by advances in products and technology. A number of companies have developed and continue to develop products that address the areas we have targeted. Some of these companies are pharmaceutical companies and biotechnology companies that are international in scope and very large in size, while others are small companies that have been successful in one or more areas we are targeting. Existing or future pharmaceutical, device, or other competitors may develop products that accomplish similar functions to our technologies in ways that may be less expensive, receive faster regulatory approval, or receive greater market acceptance than our products. Many of our competitors have been in existence longer than we have, have greater capital resources, broader internal structure for research, development, manufacturing and marketing, and may be further along in their respective product cycles.

Federal Regulation of Therapeutic Products

All of the prescription drug candidates we currently contemplate developing will require approval by the FDA prior to sales within the U.S. and by comparable international governmental healthcare regulatory agencies prior to sale outside the U.S. The FDA and comparable international agencies impose substantial requirements on the manufacturing and marketing of pharmaceutical products. These agencies and other entities regulate, among other things, research and development activities and the testing, manufacturing, quality control, safety and effectiveness claims, labeling, storage, record keeping, approval, advertising, and promotion of our prescription drug candidates. While we attempt to minimize and avoid significant regulatory bars when formulating our products, some degree of regulation from these regulatory agencies is unavoidable.

The regulatory process required by the FDA, through which our prescription drug candidates must successfully pass before they may be marketed in the U.S., generally involves pre-clinical laboratory and animal testing, submission of an application that must become effective before clinical trials may begin, adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication, and FDA approval to market a given product for a given indication after the appropriate application has been filed. For pharmaceutical products, pre-clinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as *in vitro* and animal studies to assess the potential safety and efficacy of the product. Where appropriate (for example, for human disease indications for which there exist inadequate animal models), we will attempt to obtain preliminary data concerning safety and efficacy of prescription drug candidates using carefully designed human pilot studies. We will require sponsored work to be conducted in compliance with pertinent local and international regulatory requirements, including those providing for Institutional Review Board approval, national governing agency approval, and patient informed consent, using protocols consistent with ethical principles stated in the Declaration of Helsinki and other internationally recognized standards and delineated by the International Council on Harmonisation (ICH) Good Clinical Practice (GCP) standards.

If the FDA is satisfied with the results and data from pre-clinical tests, it will authorize human clinical trials. Human clinical trials traditionally are conducted in three sequential phases which may overlap. Each of the three phases involves testing and study of specific aspects of the effects of the investigational product on human subjects, including testing for safety, dosage tolerance, side effects, absorption, metabolism, distribution, excretion, and clinical efficacy.

Phase 1 clinical trials include the initial introduction of an investigational new drug into humans, or via a new route of administration or new organ system if previously investigated in humans. These studies are closely monitored and may be conducted in patients but may also be conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. While the FDA can cause us to end clinical trials at any phase due to safety concerns, Phase 1 clinical trials are primarily concerned with safety issues. We also attempt to obtain sufficient information about the drug candidate’s pharmacokinetics and pharmacological effects during Phase 1 clinical trials to permit the design of well-controlled, scientifically valid, Phase 2 studies.

Phase 1 studies also evaluate drug metabolism, structure-activity relationships, and the mechanism of action in humans. These studies also determine which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects included in Phase 1 studies varies with the drug but is generally in the range of 10 to 80.

Phase 2 clinical trials include the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving up to several hundred people.

Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2 and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually include several hundred to several thousand people.

We have established a core clinical development team and have been working with external and FDA-experienced consultants to assist us in developing product-specific development and approval strategies, preparing the required submittals, guiding us through the regulatory process, and providing input into the design and site selection of human clinical studies.

The testing and approval process requires substantial time, effort, and financial resources, and we may not obtain FDA approval on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. The FDA or research institution conducting the trials may suspend clinical trials or may not permit trials to advance from one phase to another at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Once issued, the FDA may withdraw a prescription drug approval if we do not comply with pertinent regulatory requirements and standards or if problems are identified after the product reaches the market. If the FDA grants approval of a prescription drug candidate, the approval may impose limitations, including limits on the indicated uses for which we may market a drug product. In addition, the FDA may require additional testing and surveillance programs to monitor the safety and/or effectiveness of approved drug products that have been commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Further, later discovery of previously unknown problems with a drug product may result in restrictions on the product, including withdrawal from the market.

Marketing our prescription drug candidates abroad will require similar regulatory approvals by equivalent national authorities and is subject to similar risks. To expedite development, we may pursue some or all of our initial clinical testing and approval activities outside the U.S., and in particular in those countries where our prescription drug candidates may have substantial medical and commercial relevance. In some such cases, any resulting drug products may be brought to the U.S. after substantial offshore experience is gained. Accordingly, we intend to pursue any such development in a manner consistent with U.S. and ICH standards so that the resultant development data is maximally applicable for potential global approval.

Management Changes

Effective April 27, 2018, the board of directors (the “Board”) increased its number of directors from four to five, appointing Edward V. (Ed) Pershing, CPA and John W. “Jack” Lacey, III, MD to the Board, while Eric Wachter, PhD stepped down from the Board. Mr. Pershing was elected new Board chairman. Former Board chair Dominic Rodrigues was elected Board vice chairman.

On January 24, 2019, the Board of Directors provided Interim Chief Financial Officer John Glass 60-day written notice of the Company’s intent to terminate the independent contractor agreement between Mr. Glass and the Company, entered into on April 14, 2016 and amended on December 3, 2016. Mr. Glass will continue to serve in his current capacity with the Company until the effective date of the termination of the independent contractor agreement on March 25, 2019.

Employees

We currently have two full-time employees. We also currently engage independent contractors serving as interim Chief Financial Officer (CFO), chief operations consultant, director of clinical operations, several clinical research associates, project manager, information technology manager, controller, and patient advocacy manager.

On November 26, 2018, pursuant to Section 5(a) of the employment agreements between each of Timothy C. Scott, Ph.D., President, and Eric A. Wachter, Ph.D., Chief Technology Officer, and the Company, dated April 28, 2014, the Board provided notice to Drs. Scott and Wachter that the Company would not renew their employment agreements as of their April 28, 2019 expiration dates. The Company is currently evaluating potential future roles, responsibilities, duties, and compensation for Drs. Scott and Wachter. Dr. Scott and/or Dr. Wachter may or may not remain with the Company in existing or new capacities following the expiration of their respective employment agreements.

Available Information

Our website is located at www.provectusbio.com. We make available free of charge through this website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed with or furnished to the U.S. Securities and Exchange Commission (the “SEC”) pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Reference to our website does not constitute incorporation by reference of the information contained on the site and should not be considered part of this document.

The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC as we do. The website is http://www.sec.gov.

ITEM 1A. RISK FACTORS.

Our business and its future performance may be affected by various factors, the most significant of which are discussed below.

We are a clinical-stage drug company, have no prescription drug products approved for commercial sale, have incurred substantial losses, and expect to incur substantial losses and negative operating cash flow for the

foreseeable future.

We are a clinical-stage drug company that has no prescription drug products approved for commercial sale. We have never generated any substantial revenues and may never achieve substantial revenues or profitability. As of December 31, 2018, we have incurred net losses of approximately $227 million in the aggregate since inception in January 2002. We expect to incur substantial losses and negative operating cash flow for the foreseeable future. We may never achieve or maintain profitability, even if we succeed in developing and commercializing one or more of our prescription drug candidates. We also expect to continue to incur significant operating expenditures and anticipate that our operating and capital expenses may increase substantially in the foreseeable future as we continue to develop and seek regulatory approval for our prescription drug candidates PV-10 and PH-10, implement additional internal systems and infrastructure, and hire additional personnel.

We also expect to experience negative operating cash flow for the foreseeable future as we fund our operating losses and any future capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

We need additional capital to conduct our operations and commercialize and/or further develop our prescription drug candidates in 2019 and beyond, and our ability to obtain the necessary funding is uncertain.

We need additional capital in 2019 and beyond as we continue to develop and seek commercialization of our investigational drug product candidates. We intend to continue with the development of PH-10 on the basis of our expanding Phase 2 psoriasis and atopic dermatitis results.

We have based our estimate of capital needs on assumptions that may prove to be wrong, and we cannot assure you that estimates and assumptions will remain unchanged. On March 19, 2017, we entered into an exclusive Definitive Financing Commitment Term Sheet with a group of our stockholders, which was amended and restated effective as of March 19, 2017 (the Term Sheet), which sets forth the terms on which such investors will use their best efforts to provide financing to the Company in the minimum amount of $10 million up to $20 million (the 2017 Financing). As of December 31, 2018, we have raised $13,932,000 through the 2017 Financing. We intend to acquire additional funding through the 2017 Financing, and we may also seek capital from public or private equity or debt financings or other financing sources that may be available.

Such additional financing may not be available on acceptable terms, or at all. As discussed in more detail below, additional equity financing could result in significant dilution to stockholders. Further, in the event that additional funds are obtained through licensing or other arrangements, these arrangements may require us to relinquish rights to some of our products, product candidates, and technologies that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of, or eliminate one or more of our programs, any of which could have a material adverse effect on our business and may impair the value of our patents and other intangible assets.

The 2017 Financing is in the form of a secured convertible loans (the Loan) from the PRH Group or other investors in the 2017 Financing (the Investors). The Loan is evidenced by secured convertible promissory notes (individually a PRH Note and collectively, the PRH Notes) from the Company to the PRH Group or the Investors. Subsequent to December 31, 2018, the Company entered into PRH Notes with non-related party accredited investors in the aggregate principal amount of $3,475,000 in connection with Loans received by the Company for the same amount.

There is substantial doubt as to our ability to continue as a going concern.

Our cash and cash equivalents were $50,986 at December 31, 2018, compared with $105,504 at December 31, 2017. We continue to incur significant operating losses, and management expects that significant on-going operating expenditures will be necessary to successfully implement our business plan and develop and market our products.

These circumstances raise substantial doubt about our ability to continue as a going concern for a period of one year from the date that the consolidated financial statements included elsewhere in this Annual Report on Form 10-K are issued. Implementation of our plans and our ability to continue as a going concern will depend upon our ability to develop PV-10 and PH-10, and to raise additional capital.

Management believes that we have access to capital resources through possible public or private equity offerings, including the 2017 Financing, exchange offers, debt financings, corporate collaborations or other means. If we are unable to raise sufficient capital, we will not be able to pay our obligations as they become due.

Our investigational drug product candidates are at an early to late stage of development and may never obtain U.S. or international regulatory approvals required for us to commercialize our investigational drug product candidates.

We will need approval of the FDA to commercialize our investigational drug product candidates in the U.S. and approvals from FDA-equivalent regulatory authorities in international jurisdictions to commercialize our investigational drug product candidates there.

We are continuing to pursue clinical development of our most advanced investigational drug product candidates, PV-10 and PH-10, for use as treatments for specific conditions. The continued and further development of these investigational drug product candidates will require significant additional research, formulation and manufacturing development, and pre-clinical and extensive clinical testing prior to their regulatory approval and commercialization. Pre-clinical and clinical studies of our investigational drug product candidates may not demonstrate the safety and efficacy necessary to obtain regulatory approvals. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in earlier trials. Pharmaceutical products that appear to be promising at early stages of development may not reach the market or be marketed successfully for a number of reasons, including a product may be found to be ineffective or have harmful side effects during subsequent pre-clinical testing or clinical trials, a product may fail to receive necessary regulatory clearance, a product may be too difficult to manufacture on a large scale, a product may be too expensive to manufacture or market, a product may not achieve broad market acceptance, others may hold proprietary rights that will prevent a product from being marketed, and others may market equivalent or superior products.

Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may delay commercialization of, and our ability to derive revenues from, our prescription drug candidates, impose costly procedures on us, and diminish any competitive advantages that we may otherwise enjoy.

Our research and product development efforts may not be successfully completed and may not result in any successfully commercialized drug products. Further, after commercial introduction of a new drug product, discovery of problems through adverse event reporting could result in restrictions on the product, including withdrawal from the market and, in certain cases, civil or criminal penalties.

Even if we comply with all FDA requests, we cannot be sure that we will ever obtain regulatory clearance for any of our investigational drug product candidates. Failure to obtain FDA approval of any of our prescription drug candidates will severely undermine our business by reducing our number of salable drug products and, therefore, corresponding revenues.

In international jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our prescription drug candidates. International regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

We must conduct additional clinical trials to demonstrate the safety and efficacy of our investigational drug candidates, including PV-10 and PH-10, in order to obtain regulatory approval of our drug product candidates, which clinical trials are expensive, difficult to design and implement, can take many years to complete, and are uncertain as to timing and outcome.

Before obtaining regulatory approval for the sale of our investigational drug product candidates, including PV-10 and PH-10, we must conduct additional clinical trials to demonstrate the safety and efficacy of our drug product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to timing and outcome. Competition in clinical development has made it difficult to enroll patients at an acceptable rate in some of our clinical trials. Advances in medical technology could make our prescription drug candidates obsolete prior to completion of clinical testing. A failure of one or more of our clinical trials may occur at any stage of testing. The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

We are conducting (i) a Phase 1 trial of single-agent PV-10 and combination PV-10 therapy for HCC and other solid tumors metastatic to the liver, (ii) a Phase 1 trial of PV-10 for symptomatic NETs metastatic to the liver, (iii) a Phase 1b/2 combination therapy study of PV-10 and checkpoint inhibition for locally advanced and widely metastatic melanoma. We have placed an enrollment hold on our Phase 3 clinical trial of PV-10 versus investigator's choice of standard therapy in patients for melanoma confined to cutaneous and subcutaneous sites. We have completed (i) a Phase 1 clinical study of PV-10 for recurrent breast cancer, (ii) a Phase 1 trial of PV-10 in an investigator-initiated study to elucidate the adaptive immune response from injection of melanoma tumors, which led to publication of data in 2016, (iii) immunologic profiling of clinical samples obtained in a Phase 2 clinical trial for mechanism of action of PH-10 for psoriasis, and (iv) multiple Phase 2 clinical trials of PH-10 for psoriasis and atopic dermatitis. While we have experience with earlier phase clinical development, we have never completed a Phase 3 clinical trial. The positive results we have seen to date in our Phase 2 clinical trials of PV-10 for metastatic melanoma and out Phase 1 clinical trials of HCC and other solid tumors metastatic to the liver do not ensure that later phase clinical trials will demonstrate similar results. The positive results we have seen to date in our Phase 2 clinical trials of PH-10 for inflammatory dermatoses do not ensure that later phase clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed satisfactorily through pre-clinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical development, even after seeing promising results in earlier clinical trials.

We expect our research and development expenses to increase in connection with our ongoing activities to expand our clinical trials of our product candidates in existing indications and undertake additional clinical trials of our product candidates in other indications. Because successful development of our investigational drug product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development.

Negative or inconclusive results of our future clinical trials of PV-10 and PH-10, or any other clinical trial we conduct, could cause the FDA to require that we repeat or conduct additional clinical studies. Despite the results reported in earlier clinical trials for PV-10 and PH-10, we do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates, may be adversely impacted.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval.

Our planned or ongoing clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all. Events which may result in delays or unsuccessful completion of clinical trials, including our future clinical trials, include inability to raise funding, initiate or continue a trial, delays in obtaining regulatory approval to commence a trial, delays in reaching agreement with the FDA or other regulatory

authorities on final trial design, imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities, delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites, delays in obtaining required institutional review board (IRB) approval at each site, delays in recruiting suitable patients to participate in a trial, delays in having subjects complete participation in a trial or return for post-treatment follow-up, delays caused by subjects dropping out of a trial, delays caused by clinical sites dropping out of a trial, time required to add new clinical sites or to obtain regulatory approval and open sites in geographic regions beyond the sites initially planned, and delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

In addition, we may experience a number of unforeseen events during clinical trials for our prescription drug candidates, including PV-10 and PH-10, that could delay or prevent the commencement and/or completion of our clinical trials, including regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, the clinical study protocol may require one or more amendments delaying study completion, clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us to conduct additional clinical trials or abandon product development programs, the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, subjects may drop out of these clinical trials at a higher rate than we anticipate and enrollment in these clinical trials has been significantly slower than we anticipated requiring us to expand the geographic scope of enrollment of patients, clinical investigators or study subjects may fail to comply with clinical study protocols, trial conduct and data analysis errors may occur, including, but not limited to, data entry and/or processing errors, our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, we might have to suspend or terminate clinical trials of our prescription drug candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks, regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, the cost of clinical trials of our prescription drug candidates may be greater than we anticipate, the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our prescription drug candidates may be insufficient or inadequate, and our prescription drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

Moreover, we or the FDA may suspend our clinical trials at any time if it appears, we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our submissions or the conduct of these trials. If initiation or completion of any of our clinical trials for our product candidates, are delayed for any of the above reasons or other reasons, our development costs may increase, the approval process could be delayed, any periods during which we may have the exclusive right to commercialize our prescription drug candidates may be reduced and our competitors may bring drug products to market before us. Any of these events could impair our ability to generate revenues from drug product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

The results of our clinical trials may not support our claims concerning our prescription drug candidates.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support acceptable label claims concerning our investigational drug product candidates. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our prescription drug candidates are safe for humans or effective for indicated uses.

This failure would cause us to abandon a prescription drug candidate and may delay development of other prescription drug candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our prescription drug candidates and generate product revenues. In addition, we anticipate that our clinical trials will involve only a small patient population. Accordingly, the results of such trials may not be indicative of future results over a larger patient population.

Physicians and patients may not accept and use our prescription drug candidates.

Even if the FDA approves our investigational drug product candidates, physicians and patients may not accept and use them. Acceptance and use of our investigational drug products will depend upon a number of factors including perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our investigational drug products, availability of reimbursement for our investigational drug products from government or other healthcare payers, and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales or licensure of our prescription drug candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

We have no sales, marketing or distribution capabilities for our prescription drug candidates.

We currently have no sales, marketing or distribution capabilities. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships, the collaborator's strategic interest in the prescription drug products under development and such collaborator's ability to successfully market and sell any such drug products. There can be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our prescription drug candidates in the U.S. or internationally.

Competition in the prescription pharmaceutical and biotechnology industries is intense.

Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in research efforts related to treatment of cancer and dermatological conditions, which may compete with our clinical trials for patients and investigator resources, cause lower enrollment than anticipated, and could lead to the development of drug products or treatment therapies that could compete directly with our investigational drug product candidates that we are seeking to develop and market.

Many companies are also developing novel therapies to treat cancer and dermatological conditions and, in this regard, are our competitors. Many of the pharmaceutical companies developing and marketing these competing products have greater financial resources and expertise than we do in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals, and marketing.

Smaller companies may also prove to be competitors, particularly through collaborative arrangements with larger and more established companies that may compete with our efforts to establish similar collaborative arrangements. Academic institutions, government agencies, and other public and private research organizations may also conduct research, seek patent protection, and establish collaborative arrangements for research, clinical development, and marketing of prescription drug candidates similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our drug development programs.

In addition to the above factors, we expect to face competition in product efficacy and safety, the timing and scope of regulatory consents, availability of resources, reimbursement coverage, price, and patent position, including potentially dominant patent positions of others.

Since our prescription drug candidates PV-10 and PH-10 have not yet been approved by the FDA or introduced to the marketplace, we cannot estimate what competition these prescription drug candidates might face when they are finally introduced, if at all. We cannot assure you that these prescription drug candidates will not face significant competition for other drug products, investigational drug products, and generic equivalents.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property our business could be harmed.

We may not be successful in securing or maintaining proprietary patent protection for our prescription drug candidates and technologies we develop or license. In addition, our competitors may develop prescription drug candidates similar to ours using methods and technologies that are beyond the scope of our intellectual property protection, which could reduce our anticipated sales. While some of our prescription drug candidates have proprietary patent protection, a challenge to these patents can subject us to expensive litigation. Litigation concerning patents, other forms of intellectual property, and proprietary technology is becoming more widespread and can be protracted and expensive and can distract management and other personnel from performing their duties.

We also rely upon trade secrets, unpatented proprietary know-how, and continuing technological innovation to develop a competitive position. We cannot assure you that others will not independently develop substantially equivalent proprietary technology and techniques or otherwise gain access to our trade secrets and technology, or that we can adequately protect our trade secrets and technology.

If we are unable to secure or enforce patent rights, trademarks, trade secrets, or other intellectual property, our business, financial condition, results of operations and cash flows could be materially adversely affected. If we infringe on the intellectual property of others, our business could be harmed.

We could be sued for infringing patents or other intellectual property that purportedly cover prescription drug candidates and/or methods of using such prescription drug candidates held by persons other than us. Litigation arising from an alleged infringement could result in removal from the market, or a substantial delay in, or prevention of, the introduction of our prescription drug candidates, any of which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

If we do not update and enhance our technologies, they will become obsolete.

The pharmaceutical market is characterized by technological change, and our future success will depend on our ability to conduct successful research in our fields of expertise, discover new technologies as a result of that research, develop products based on our technologies, and commercialize those products. While we believe that our current technology is adequate for our present needs, if we fail to stay at the forefront of technological development, we will be unable to compete effectively. Our competitors may use greater resources to develop new pharmaceutical technologies and to commercialize products based on those technologies. Accordingly, our technologies may be rendered obsolete by advances in existing technologies or the development of different technologies by one or more of our current or future competitors.

If we lose any of our key personnel, we may be unable to successfully execute our business plan.

Our business is presently managed by key employees, independent contractors, and Board members: (i) Timothy C. Scott, Ph.D., our President, (ii) Eric A. Wachter, Ph.D., our Chief Technology Officer (CTO), (iii) Bruce Horowitz, our Chief Operations Consultant, who is an independent contractor, (iv) John R. Glass, CPA, our Interim CFO, who is an independent contractor and (v) Dominic Rodrigues, CFA, who is vice chair of the Board.

In order to successfully execute our business plan, our management and board of directors must succeed in all of the following critical areas: researching diseases and possible therapies in the areas of oncology and dermatology, developing our prescription drugs candidates, marketing and selling developed prescription drug candidates, obtaining additional capital to finance research and development production, and marketing of our drug products, and managing our business as it grows.

On November 26, 2018, pursuant to Section 5(a) of the employment agreements between each of Drs. Scott and Wachter, and the Company, dated April 28, 2014, the Board provided notice to Drs. Scott and Wachter that the Company would not renew their employment agreements as of their April 28, 2019 expiration dates. The Company is evaluating and assessing potential future roles, responsibilities, duties, and compensation for Drs. Scott and Wachter.

On January 24, 2019, the Board of Directors provided Mr. Glass 60-day written notice of the Company's intent to terminate the independent contractor agreement between Mr. Glass and the Company, entered into on April 14, 2016 and amended on December 3, 2016. Mr. Glass will continue to serve in his current capacity with the Company until the effective date of the termination of the independent contractor agreement on March 25, 2019.

Disruption resulting from management transition may have a detrimental impact on our ability to implement our strategy. The reduction in role and/or loss of key employees, contractors, and/or Board members could have a material adverse effect on our operations, and limit or constrain our ability to execute our business plan.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Among other things, these provisions will (i) permit our Board to issue up to 25,000,000 shares of preferred stock which can be created and issued by the Board without prior stockholder approval, with rights senior to those of the common stock, (ii) provide that all vacancies on our Board, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, (iii) require that any action to be taken by our stockholders must be affected at a duly called annual or special meeting of stockholders and not be taken by written consent, (iv) provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice, (v) not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, and (vi) provide that special meetings of our stockholders may be called only by the Board or by such person or persons requested by a majority of the Board to call such meetings.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our Board or initiate actions that are opposed by our then-current Board, including delaying or impeding a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our Board could cause the market price of our common stock to decline.

Our stock price is below $5.00 per share and is treated as a "penny stock," which places restrictions on broker-dealers recommending the stock for purchase.

Our common stock is defined as "penny stock" under the Exchange Act and its rules. The SEC has adopted regulations that define "penny stock" to include common stock that has a market price of less than $5.00 per share, subject to certain exceptions. These rules include the following requirements: (i) broker-dealers must deliver, prior to the transaction, a

disclosure schedule prepared by the SEC relating to the penny stock market, (ii) broker-dealers must disclose the commissions payable to the broker-dealer and its registered representative, (iii) broker-dealers must disclose current quotations for the securities, and (iv) a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer's account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. If our common stock remains subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder's ability to sell their shares.

Future sales by our stockholders may adversely affect our stock price and our ability to raise funds in new stock offerings.

Sales of our common stock in the public market following any prospective offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable.

It is our general policy to retain any earnings for use in our operation.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, for use in our business and therefore do not anticipate paying any cash dividends on our common stock in the foreseeable future, although we intend to issue shares of common stock in satisfaction of the dividend payments due on our Series B Preferred Stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

We currently lease approximately 4,500 square feet of space for operations in Century Park, Knoxville, TN. Our monthly rental charge for these offices is approximately $7,360 per month. The lease is for five years and expires on June 30, 2022.

Item 3. Legal Proceedings.

The information required by this item is incorporated by reference from Part II, Item 8. Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 12 – Litigation.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information and Holders

On May 16, 2014, our common stock ceased to be traded on the OTCQB Marketplace operated by OTC Markets Group and began trading on the NYSE MKT. On October 13, 2016, NYSE MKT suspended trading of our common stock, due to the abnormally low trading prices of our common stock, and on October 17, 2016 our common stock began trading on the OTCQB Marketplace. On April 21, 2017, the NYSE MKT filed a Form 25 with the SEC, notifying the SEC of the NYSE MKT's intention to remove our shares of common stock and class of listed warrants from listing and registration on the NYSE MKT effective May 1, 2017, pursuant to the provisions of Rule 12d2-2(b) of the Exchange Act. Our common stock and listed warrants continue to trade on the OTCQB under the trading symbols "PVCT," and "PVCTWS," respectively.

As of February 28, 2019, we had 875 active shareholders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently plan to retain future earnings, if any, to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future. We may incur indebtedness in the future which may prohibit or effectively restrict the payment of dividends, although we have no current plans to do so. Any future determination to pay cash dividends will be at the discretion of our Board of Directors.

The holders of our outstanding Series B Preferred Stock are entitled to receive cumulative dividends at the rate per share of 8% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Series B Preferred Stock. The dividends become payable, at our option, in either cash, out of any funds legally available for such purpose, or in shares of common stock, (i) upon any conversion of the Series B Preferred Stock, (ii) on each such other date as our Board of Directors may determine, subject to written consent of the holders of Series B Preferred Stock holding a majority of the then issued and outstanding Series B Preferred Stock, (iii) upon our liquidation, dissolution or winding up, and (iv) upon occurrence of a fundamental transaction, including any merger or consolidation, sale of all or substantially all of our assets, exchange or conversion of all of our common stock by

tender offer, exchange offer or reclassification, provided, however, that if Series B Preferred Stock is converted into shares of common stock at any time prior to the fifth anniversary of the date of issuance of the Series B Preferred Stock, the holder will receive a make-whole payment in an amount equal to all of the dividends that, but for the early conversion, would have otherwise accrued on the applicable shares of Series B Preferred Stock being converted for the period commencing on the conversion date and ending on the fifth anniversary of the date of issuance, less the amount of all prior dividends paid on such converted Series B Preferred Stock before the date of conversion. Make-whole payments are payable at our option in either cash, out of any funds legally available for such purpose, or in shares of common stock. With respect to any dividend payments and make-whole payments paid in shares of common stock, the number of shares of common stock to be issued to a holder of Series B Preferred Stock will be an amount equal to the quotient of (a) the amount of the dividend payable to such holder divided by (b) the conversion price then in effect.

Recent Issuances of Unregistered Securities

During the year ended December 31, 2017, we issued 372,500 shares of common stock in settlement of outstanding trade payables in lieu of cash with a value of $17,301.

During the year ended December 31, 2018, we issued 1,000,000 shares of common stock in settlement of services rendered in lieu of cash with a value of $80,000.

The issuances of the securities were exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(a)(2) and Rule 506 promulgated under Regulation D thereunder as transactions not involving a public offering.

Securities Authorized for Issuance under Equity Compensation Plans

Information about the securities authorized for issuance under our equity compensation plans will be set forth under the heading “Equity Compensation Plan Information” in the definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act, incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion is intended to assist in the understanding and assessment of significant changes and trends related to our results of operations and our financial condition together with our consolidated subsidiaries. This discussion and analysis should be read in conjunction with the consolidated financial statements and notes thereto included in this Annual Report on Form 10-K. Historical results and percentage relationships set forth in the statement of operations, including trends which might appear, are not necessarily indicative of future operations.

Overview of Core Technologies

Provectus is a clinical-stage biotechnology company developing a new class of drugs for oncology and dermatology based on halogenated xanthenes, such as Rose Bengal (4,5,6,7-tetrachloro-2’,4’,5’,7’-tetraiodofluorescein). 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 gastrointestinal cancers, and preclinical study for pediatric cancers. Topical PH-10 is undergoing clinical study for inflammatory dermatoses, like psoriasis and atopic dermatitis. For psoriasis, pathways significantly improved include published psoriasis transcriptomes and cellular responses mediated by IL-17, IL-22, and interferons.

Our approach to drug development comprises two related, complementary, clinical development program paths based on the features of our investigational drugs and their clinically rational applicability to different patient populations. In solid tumor cancers for adults, for example, we believe PV-10 has important implications as a single agent for earlier states of disease (i.e., locally advanced disease, or Stage III or earlier), while the combination of PV-10 with other classes of therapy or therapeutic agent (e.g., chemotherapy, immunotherapy, radiotherapy, targeted therapy) is more appropriate for more advanced disease states (i.e., widely metastatic disease, or Stage IV).

Recent Developments

2017 Financing

On March 23, 2017, the Company entered into an exclusive Definitive Financing Commitment Term Sheet with a group of the Company's stockholders (the PRH Group), which was amended and restated effective as of March 19,

2017 (the Term Sheet) that set forth the terms on which the PRH Group would use their best efforts to arrange for a financing of a minimum of $10,000,000 and maximum of $20,000,000 (the 2017 Financing).

As of December 31, 2018, the Company had received aggregate Loans, as defined below, of $13,932,000 in connection with the 2017 Financing.

Subsequent to December 31, 2018, the Company entered into PRH Notes with non-related party accredited investors in the aggregate principal amount of $3,475,000 in connection with Loans received by the Company for the same amount.

The 2017 Financing is in the form of a secured convertible loans (the Loan) from the PRH Group or other investors in the 2017 Financing (the Investors). The Loan is evidenced by secured convertible promissory notes (individually a PRH Note and collectively, the PRH Notes) from the Company to the PRH Group or the Investors. In addition to the customary provisions, the PRH Note contains various provisions, including (i) it is secured by a first priority security interest on the Company's intellectual property (the IP), (ii) the Loan bears interest at the rate of eight percent (8%) per annum on the outstanding principal amount of the Loan that has been funded to the Company, (iii) the Loan proceeds are held in one or more accounts (the Escrow) pending the funding of the tranches of the 2017 Financing pursuant to borrowing requests made by the Company, (iv) the PRH Notes, including interest and principal, are due and payable in full on the earlier of: (a) on such date upon which the Company defaults under the PRH Notes, (b) upon a change of control of the Company, or (c) dates ranging from May 18, 2020 to the 24-month anniversary of the funding of the Final Tranche, depending on the specific PRH Note. In the event there is a change of control of the Board as proposed by any person or group other than the Investors, the term of the PRH Notes will be accelerated and all amounts due under the PRH Notes will be immediately due and payable, plus interest at the rate of 8% per annum, plus a penalty in the amount equal to 10 times the outstanding principal amount of the Loan that has been funded to the Company, (v) the outstanding principal amount and interest payable under the Loan will be convertible at the sole discretion of the Investors into shares of the Company's Series D Preferred Stock, a new series of preferred stock to be designated by the Board, at a price per share equal to $0.2862, and (vi) notwithstanding (v) above, the principal amounts of the PRH Notes and the interest payable under the Loan will automatically convert into shares of the Company's Series D Preferred Stock at a price per share equal to $0.2862 effective on the 24-month anniversary of the funding of the final tranche of the 2017 Financing subject to certain exceptions.

As of December 31, 2018, and through the date of filing, the Series D Preferred Stock had not been designated by the Board. As a result, the PRH Notes were not convertible as of their respective dates of issuance or as of December 31, 2018.

Exercise of Warrants

In 2018, holders of 12,653,077 warrants to purchase the common stock of the Company at $0.0533 per share, have exercised these warrants. The Company has received proceeds in the aggregate amount of $674,409.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

Research and development

Research and development costs totaling $4,747,557 for 2018 included payroll of $521,969, consulting and contract labor of $3,053,753, lab supplies and pharmaceutical preparations of $83,134, conferences of $20,976, insurance of $285,853, rent and utilities of $65,989, depreciation and amortization expense of $679,767, and miscellaneous expenses of $36,116.

Research and development costs totaling $8,203,926 for 2017 included payroll of $509,615, consulting and contract labor of $6,407,863, conferences of $84,960, lab supplies and pharmaceutical preparations of $147,272, insurance of $310,432, rent and utilities of $56,799, and depreciation and amortization expense of $686,985.

The overall decrease of $3,456,369 or 42% year over year in research and development costs was due primarily to the settlement between the Company and a former clinical operations vendor whereby the Company received a credit for $1,748,010 against its overall amounts due coupled with lower consulting and contract labor cost on clinical trials of $1,606,100, decreases in lab supplies and pharmaceutical preparations of $64,138, reduced conference expense of $63,984, partially offset by other miscellaneous cost increases of $25,863.

General and administrative

General and administrative expense for 2018 totaled $3,306,668. These expenses included legal fees totaling $1,318,785, accounting and public company compliance fees of $104,020, investor relations expense of $13,392, payroll expense of $484,025, travel expenses of $96,879, financial consulting expenses of $598,761, director fees of $333,357, information technology expense of $102,000, insurance expense of $187,367, rent and utilities expense of $33,870, and office expense and other of $34,212.

General and administrative expense for 2017 totaled $5,115,978. These expenses included legal fees totaling $1,882,639, accounting and public company compliance fees of $624,773, investor relations expense of $672,009, public relations expense of $120,136, payroll expense of $509,615, travel expenses of $166,348, financial consulting expenses of $569,475, director fees of $148,333, information technology expense of $166,061, insurance expense of $167,211, payroll and other taxes of $27,366, rent and utilities expense totaling $28,400, security expenses of $24,775, office expense and other of $106,337, and partially offset by a reduction of contributions totaling $97,500.

The decrease of $1,809,310 in general and administrative expense or 35% year-over-year was the result of the Company’s continued focus on reducing costs. Legal fees were down $563,854 due to wind down of the lawsuits regarding advancement and recording of improper travel expenses, travel expense of $69,469, accounting fees of $520,753, investor relations of $658,617, other cost of $25,903, partially offset by an increase in financial expense of $29,286.

Other Income

Other income increased by $690,612 from $203,680 for the year ended December 31, 2017 to $894,292 for the year ended December 31, 2018. In the quarter ended June 30, 2018, the matter with BDO was resolved pursuant to a settlement between the Company and BDO, the terms of which are confidential.

Other Expense

Interest expense increased by $568,123 from $401,592 for the year ended December 31, 2017 to $969,715 for the year ended December 31, 2018, an increase of approximately 141% period-over-period. The increase was due to the increased number of convertible notes payable relating to the PRH Notes.

Liquidity and Going Concern

Our cash and cash equivalents were $50,986 at December 31, 2018, compared with $105,504 at December 31, 2017. The consolidated financial statements and notes thereto included in this Annual Report on Form 10-K have been prepared on a basis that contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have continuing net losses and negative cash flows from operating activities. In addition, we have an accumulated deficit of $226,894,291 as of December 31, 2018. These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date that the financial statements included elsewhere in this Annual Report on Form 10-K are issued. Our financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to obtain additional financing as may be required to fund current operations.

Management’s plans include selling our equity securities and obtaining other financing to fund our capital requirement and on-going operations, including the 2017 Financing discussed above; however, there can be no assurance we will be successful in these efforts. The financial statements do not include any adjustment that might be necessary if we are unable to continue as a going concern. Significant funds will be needed to continue and complete our ongoing and planned clinical trials.

Subsequent to December 31, 2018, the Company entered into PRH Notes with non-related party accredited investors in the aggregate principal amount of $3,475,000 in connection with the 2017 Financing and the Company received funds for the same amount.

Access to Capital

Management plans to access capital resources through possible public or private equity offerings, including the 2017 Financing, exchange offers, debt financings, corporate collaborations, or other means. If we are unable to raise sufficient capital through the 2017 Financing or otherwise, we will not be able to pay our obligations as they become due.

The primary business objective of management is to build the Company into a commercial-stage biotechnology company; however, we cannot assure you that management will be successful in implementing the Company's business plan of developing, licensing, and/or commercializing our prescription drug candidates. Moreover, even if we are successful in improving our current cash flow position, we nonetheless plan to seek additional funds to meet our current and long-term requirements in 2019 and beyond. We anticipate that these funds will otherwise come from the proceeds of private placement transactions, including the 2017 Financing, the exercise of existing warrants and outstanding stock options, or public offerings of debt or equity securities. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

During the years ended December 31, 2018 and 2017, our sources and uses of cash were as follows:

Net Cash Used in Operating Activities

We experienced negative cash flow from operating activities for the years ended December 31, 2018 and 2017 in the amounts of $5,204,926 and $10,348,322, respectively (a 50% year-over-year decrease). The net cash used in operating activities for the year ended December 31, 2018 was primarily due to cash used to fund a net loss of $8,153,055, adjusted for non-cash expenses in the aggregate amount of $765,213, plus $2,182,916 of cash used to fund changes in the levels of operating assets and liabilities. The net cash used in operating activities for the year ended December 31, 2017 was primarily due to cash used to fund a net loss of $13,517,816, adjusted for non-cash expenses in the aggregate amount of $686,984, partially offset by $2,482,510 of cash provided by changes in the levels of operating assets and liabilities.

Net Cash Used in Investing Activities

During the years ended December 31, 2018 and 2017, net cash used in investing activities was $0 and $30,400, respectively, which was used for capital expenditures.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the years ended December 31, 2018 and 2017 was $5,150,408 and $9,318,488, respectively (a 45% year-over-year decrease). During the year ended December 31, 2018, $4,476,000 were proceeds from the issuance of convertible notes payable and $674,409 were from the exercise of warrants. During the year ended December 31, 2017, $9,306,000 were proceeds from the issuance of convertible notes payable and $12,488 were from the exercise of warrants.

Critical Accounting Policies

Our critical accounting policies are included in Note 3 – Significant Accounting Policies of our consolidated financial statements included within this annual report.

Recent Accounting Pronouncements

Recently issued accounting standards are included in Note 3 – Significant Accounting Policies of our consolidated financial statements included within this annual report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

Provectus Biopharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Provectus Biopharmaceuticals, Inc. (the "Company") as of December 31, 2018 and 2017 and the related consolidated statements of operations, changes in stockholders' deficiency and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses, and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum llp

We have served as the Company's auditor since 2016.

New York, NY

March 7, 2019

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2018	2017
Assets		
Current Assets:		
Cash and cash equivalents	$50,986	$105,504
Short-term receivables - legal fees, settlement and other, net	595,326	452,376
Prepaid expenses	370,209	400,416
Total Current Assets	1,016,521	958,296
Equipment and furnishings, less accumulated depreciation of $50,538 and $36,445, respectively	72,476	86,569
Patents, net of accumulated amortization of $10,816,218 and $10,145,098, respectively	899,227	1,570,347
Long-term receivable – reimbursable legal fees, net of reserve	-	455,500
Long-term receivable – settlement, net of discount and reserve	-	365,685
Total Assets	$1,988,224	$3,436,397
Liabilities and Stockholders’ Deficiency		
Current Liabilities:		
Accounts payable - trade	$3,312,049	$3,270,505
Other accrued expenses	790,358	327,143
Total Current Liabilities	4,102,407	3,597,648
Accrued interest	659,379	172,925
Accrued interest - related parties	711,927	228,667
Convertible notes payable	7,062,000	4,456,000
Convertible notes payable - related parties	6,870,000	5,000,000
Total Liabilities	19,405,713	13,455,240
Commitments and contingencies		
Stockholders’ Deficiency:		

Preferred stock; par value $0.001 per share; 25,000,000 shares authorized; Series B Convertible Preferred Stock; 240,000 shares designated; 100 shares issued and outstanding at December 31, 2018 and December 31, 2017; aggregate liquidation preference of $3,500 at December 31, 2018 and December 31, 2017	-	-
Common stock; par value $0.001 per share; 1,000,000,000 shares authorized; 384,614,528 and 370,961,451 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	384,615	370,962
Additional paid-in capital	209,092,187	208,351,431
Accumulated deficit	(226,894,291)	(218,741,236)
Total Stockholders' Deficiency	(17,417,489)	(10,018,843)
Total Liabilities and Stockholders' Deficiency	$1,988,224	$3,436,397

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2018	2017
Operating Expenses:		
Research and development	$4,747,557	$8,203,926
General and administrative	3,306,668	5,115,978
Total Operating Expenses	(8,054,225)	(13,319,904)
Other Income/Expense:		
Gain on settlement of lawsuit	825,000	172,376
Research and development tax credit	26,325	-
Investment and interest income	19,560	31,304
Interest expense	(969,715)	(401,592)
Net Loss	(8,153,055)	(13,517,816)
Dividend paid-in kind to preferred shareholders	-	(14,107)
Net Loss Applicable to Common Shareholders	$(8,153,055)	$(13,531,923)
Basic and Diluted Loss Per Common Share	$(0.02)	$(0.04)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	382,338,471	369,231,518

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIENCY

	Preferred Stock Series B		Common Stock		**Additional** Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at January 1, 2017	8,600	$ 9	364,773,297	$364,773	$208,327,822	$(205,223,420)	$3,469,184
Preferred stock conversions into common stock	(8,500)	(9)	3,986,676	3,987	(3,978)	-	-
Dividend paid-in kind to preferred shareholders	-	-	1,594,670	1,595	(1,595)	-	-
Common stock issued upon exercise of warrant			234,308	234	12,254		12,488
Common stock issued for debt			372,500	373	16,928		17,301
Net loss	-	-	-	-	-	(13,517,816)	(13,517,816)
Balance at December 31, 2017	100	$ -	370,961,451	$370,962	$208,351,431	$(218,741,236)	$(10,018,843)
Common stock issued upon exercise of warrants			12,653,077	12,653	661,756	-	674,409
Common stock issued for services			1,000,000	1,000	79,000	-	80,000
Net loss	-	-	-	-	-	(8,153,055)	(8,153,055)
Balance at December 31, 2018	100	-	384,614,528	$384,615	$209,092,187	(226,894,291)	(17,417,489)

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2018	2017
Cash Flows From Operating Activities:		
Net loss	$(8,153,055)	$(13,517,816)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	14,093	15,864
Amortization of patents	671,120	671,120
Issuance of stock for services	80,000	-
Changes in operating assets and liabilities		
Settlement receivable	528,235	216,826
Prepaid expenses	30,207	(39,854)
Accounts payable - trade	41,544	1,798,759
Other accrued expenses	613,215	105,187
Accrued interest expense	969,715	401,592
Net Cash Used In Operating Activities	(5,204,926)	(10,348,322)
Cash Flows From Investing Activities:		
Purchase of fixed assets	-	(30,400)
Net Cash Used In Investing Activities	-	(30,400)
Cash Flows From Financing Activities:		
Proceeds from issuance of convertible notes payable	2,606,000	4,306,000
Proceeds from issuance of convertible notes payable - related parties	1,870,000	5,000,000
Proceeds from exercise of warrants	674,409	12,488
Net Cash Provided By Financing Activities	5,150,408	9,318,488
Net Decrease In Cash and Cash Equivalents	(54,518)	(1,060,234)
Cash and Cash Equivalents, Beginning of Year	105,504	1,165,738
Cash and Cash Equivalents, End of Year	$50,986	$105,504
Supplemental Disclosures of Cash Flow Information:		
Non-cash investing and financing activities:		

Conversion of preferred stock into common stock	$-	$3,987
Dividend paid-in kind to preferred shareholders	$-	$1,595
Offset of related party receivable and payable	$150,000	$280,823
Common stock issued in satisfaction of trade debt	$-	$17,301
Notes payable issued in satisfaction of trade debt	$-	$150,000

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business Organization and Nature of Operations

Provectus Biopharmaceuticals, Inc., a Delaware corporation (together with its subsidiaries, "Provectus" or the "Company"), is a clinical-stage biotechnology company developing a new class of drugs for oncology and dermatology based on halogenated xanthenes. Intralesional PV-10 is undergoing clinical study for adult solid tumor cancers, like melanoma and gastrointestinal cancers, and preclinical study for pediatric cancers. Topical PH-10 is undergoing clinical study for inflammatory dermatoses, like psoriasis and atopic dermatitis. To date, the Company has not generated any revenues from planned principal operations. The Company's activities are subject to significant risks and uncertainties, including failing to successfully develop and license or commercialize the Company's prescription drug candidates.

2. Liquidity and Going Concern

The Company's cash and cash equivalents were $50,986 at December 31, 2018, compared with $105,504 at December 31, 2017. The Company continues to incur significant operating losses and management expects that significant on-going operating expenditures will be necessary to successfully implement the Company's business plan and develop and market its products. These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. Implementation of the Company's plans and its ability to continue as a going concern will depend upon the Company's ability to develop PV-10 and PH-10 and raise additional capital.

The Company plans to access capital resources through possible public or private equity offerings, including the 2017 Financing (as defined in Note 4), exchange offers, debt financings, corporate collaborations or other means. In addition, the Company continues to explore opportunities to strategically monetize its lead drug candidates, PV-10 and PH-10, through potential co-development and licensing transactions, although there can be no assurance that the Company will be successful with such plans. The Company has historically been able to raise capital through equity offerings, although no assurance can be provided that it will continue to be successful in the future. If the Company is unable to raise sufficient capital through the 2017 Financing or otherwise, it will not be able to pay its obligations as they become due. Subsequent to December 31, 2018, the Company received aggregate Loans of $3,475,000 in connection with the 2017 Financing. See Note 13 – Subsequent Events.

The primary business objective of management is to build the Company into a commercial-stage biotechnology company; however, the Company cannot assure that it will be successful in co-developing, licensing, and/or commercializing PV-10, PH-10, and/or any other halogenated xanthene-based drug candidate developed by the Company, or entering into any financial transaction. Moreover, even if the Company is successful in improving its current cash flow position, the Company nonetheless plans to seek additional funds to meet its long-term requirements in 2019 and beyond. The Company anticipates that these funds will otherwise come from the proceeds of private placement transactions, including the 2017 Financing, the exercise of existing warrants and outstanding stock options, or public offerings of debt or equity securities. While the Company believes that it has a reasonable basis for its expectation that it will be able to raise additional funds, the Company cannot provide assurance that it will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

3. Significant Accounting Policies

Principles of Consolidation

Intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. ("GAAP") requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's significant estimates and assumptions include the collectability of long-term receivables, the recoverability and useful lives of long-lived assets, stock-based compensation, liabilities and the valuation allowance related to the Company's deferred tax assets. Certain of the Company's estimates, including the carrying amount of the intangible assets, could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and could cause actual results to differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. As of December 31, 2018, and 2017, the Company's cash equivalent consists of Treasury bills.

Cash Concentrations

Cash and cash equivalents are maintained at financial institutions and, at times, balances may exceed federally insured limits of $250,000, although the Company seeks to minimize this through treasury management. The Company has never experienced any losses related to these balances although no assurance can be provided that it will not experience any losses in the future.

Equipment and Furnishings, net

Equipment and furnishings are stated at cost less accumulated depreciation. Depreciation of equipment is provided for using the straight-line method over the estimated useful lives of the assets. Computers, leasehold improvements and office equipment are being depreciated over five years; furniture and fixtures are being depreciated over ten years. Maintenance and repairs are charged to operations as incurred. The Company capitalizes cost attributable to the betterment of property and equipment when such betterment extends the useful life of the assets.

Long-Lived Assets

The Company reviews the carrying values of its long-lived assets for possible impairment whenever an event or change in circumstances indicates that the carrying amount of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less cost to sell. Management has determined there to be no impairment during the years ended December 31, 2018 and 2017.

Patent Costs, net

Internal patent costs are expensed in the period incurred. Patents purchased are capitalized and amortized over the remaining estimated useful life of the patent.

The Company's patents were acquired as a result of the merger with Valley Pharmaceuticals, Inc. "Valley" on November 19, 2002. At the time of the merger, the majority stockholders of Provectus also owned all of the shares of Valley and therefore the assets acquired from Valley were recorded at their carry-over basis. The patents are being amortized over the remaining estimated useful lives of the patents, which range from 1 to 2 years. Annual amortization of the patents is expected to approximate $671,000 in 2019 and $228,000 in 2020. Since 2003, the Company no longer amortizes the patent cost on newly acquired patents but expenses as costs are incurred.

Related Party Receivables

Management estimates the reserve for uncollectibility based on existing economic conditions, the financial conditions of the current and former employees, and the amount and age of past due receivables. Receivables are considered past due if full payment is not received by the contractual due date. Past due amounts are generally written off against the reserve for uncollectibility only after all collection attempts have been exhausted. See Note 6 - Receivables.

Research and Development

Research and development costs are charged to expense when incurred. An allocation of payroll expenses to research and development is made based on a percentage estimate of time spent. The research and development costs include the following: payroll, consulting and contract labor, lab supplies and pharmaceutical preparations, insurance, rent and utilities, and depreciation and amortization.

Income Taxes

The Company accounts for income taxes under the liability method in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 740 "Income Taxes". Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established if it is more likely than not that all, or some portion, of deferred income tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to zero. In the event the Company were to determine that it would be able to realize some or all its deferred income tax assets in the future, an adjustment to the deferred income tax asset would increase income in the period such determination was made.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination. Any recognized income tax positions would be measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement would be reflected in the period in which the change in judgment occurs. The Company would recognize any corresponding interest and penalties associated with its income tax positions in income tax expense. There were no income taxes, interest or penalties incurred in 2018 or 2017.

Basic and Diluted Loss Per Common Share

Basic loss per common share is computed by dividing net loss by the weighted average number of vested common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock. The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	December 31, 2018	2017
Warrants	136,824,138	186,873,032
Options	3,200,000	3,350,000
Convertible preferred stock	65,663	65,663
Total potentially dilutive shares	140,089,801	190,288,695

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of ASC 820 “Fair Value Measurements and Disclosures” (“ASC 820”) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. The Company determines the estimated fair value of amounts presented in these consolidated financial statements using available market information and appropriate methodologies. However, considerable judgment is required in interpreting market data to develop the estimates of fair value. The estimates presented in the financial statements are not necessarily indicative of the amounts that could be realized in a current exchange between buyer and seller. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value amounts. These fair value estimates were based upon pertinent information available as of December 31, 2018 and 2017. The carrying amounts of the Company’s financial assets and liabilities, such as cash and cash equivalents, settlement receivable, other current assets, accounts payable, convertible notes payable, and accrued expenses approximate fair values due to the short-term nature of these instruments.

The carrying amounts of our credit obligations approximate fair value because the effective yields on these obligations, which include contractual interest rates are comparable to rates of returns for instruments of similar credit risk.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1	Inputs use quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
Level 2	Inputs use directly or indirectly observable inputs. These inputs include quoted prices for similar assets and liabilities in active markets as well as other inputs such as interest rates and yield curves that are observable at commonly quoted intervals.
Level 3	Inputs are unobservable inputs, including inputs that are available in situations where there is little, if any, market activity for the related asset or liability.

In instances where inputs used to measure fair value fall into different levels in the above fair value hierarchy, fair value measurements in their entirety are categorized based on the lowest level input that is significant to the valuation. The Company’s assessment of the significance of particular inputs to these fair value measurements requires judgment and considers factors specific to each asset or liability.

Both observable and unobservable inputs may be used to determine the fair value of positions that are classified within the Level 3 category. As a result, the unrealized gains and losses for assets within the Level 3 category may include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in historical company data) inputs. Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable.

Foreign Currency Translation

The Company's reporting currency is the United States Dollar. The functional currencies of the Company's operating subsidiaries are their local currencies (United States Dollar and Australian Dollar). Australian Dollar denominated assets and liabilities are translated into the United States Dollar at the balance sheet date ($15,049 and $336,031 at December 31, 2018 and $2,245 and $125,013 at December 31, 2017, respectively), and expense accounts are translated at a weighted average exchange rate for the years then ended ($247,947 and $122,768 for the years ended December 31, 2018 and 2017, respectively).

Resulting translation adjustments are made directly to other expense and included in net (loss) income. The Company recorded balance sheet translations through the Statement of Operations since they were immaterial. The Company engages in foreign currency denomination transactions with its Australian subsidiary.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. For employees, the fair value of the award is measured on the grant date and for non-employees, the fair value of the award is measured on the measurement date and re-measured on vesting dates and interim financial reporting dates until the service period is complete. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. The Company computes the fair value of equity-classified warrants and options granted using the Black-Scholes option pricing model. Option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of the Company's common stock which is determined by reviewing its historical public market closing prices.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)." ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This amendment will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The FASB issued ASU No. 2018-10 "Codification Improvements to Topic 842, Leases" and ASU No. 2018-11 "Leases (Topic 842) Targeted Improvements" in July 2018, and ASU No. 2018-20 "Leases (Topic 842) - Narrow Scope Improvements for Lessors" in December 2018. ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is required to adopt ASU 2016-02 effective January 1, 2019 and upon adoption it expects to recognize additional assets and corresponding liabilities pertaining to its operating leases on its consolidated balance sheet. The Company does not expect the adoption of the new standard to have a significant impact on its consolidated statements of operations and cash flows.

In May 2017, the FASB issued ASU No. 2017-09, “Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting” (“ASU 2017-09”). ASU 2017-09 provides clarity on the accounting for modifications of stock-based awards. ASU 2017-09 requires adoption on a prospective basis in the annual and interim periods beginning after December 15, 2017 for share-based payment awards modified on or after the adoption date. The adoption of this ASU did not have a material impact on the Company’s consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, “Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815) - Accounting for Certain Financial Instruments with Down Round Features” (“ASU 2017-11”). Equity-linked instruments, such as warrants and convertible instruments may contain down round features that result in the strike price being reduced on the basis of the pricing of future equity offerings. Under ASU 2017-11, a down round feature will no longer require a freestanding equity-linked instrument (or embedded conversion option) to be classified as a liability that is re-measured at fair value through the income statement (i.e. marked-to-market). However, other features of the equity-linked instrument (or embedded conversion option) must still be evaluated to determine whether liability or equity classification is appropriate. Equity classified instruments are not marked-to-market. For earnings per share (“EPS”) reporting, the ASU requires companies to recognize the effect of the down round feature only when it is triggered by treating it as a dividend and as a reduction of income available to common shareholders in basic EPS. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in any interim period. The adoption of this ASU effective January 1, 2019 did not have a material impact on the Company’s consolidated financial statements.

In March 2018, the FASB issued ASU No. 2018-05, “Income Taxes (Topic 740), Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118” (“ASU 2018-05”). ASU 2018-05 adds various “SEC” paragraphs pursuant to the issuance of the December 2017 SEC Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (“SAB 118”), which was effective immediately. The SEC issued SAB 118 to address concerns about reporting entities’ ability to timely comply with the accounting requirements to recognize all of the effects of the Tax Cuts and Jobs Act in the period of enactment. SAB 118 allows disclosure that timely determination of some or all of the income tax effects from the Tax Cuts and Jobs Act are incomplete by the due date of the financial statements and if possible, to provide a reasonable estimate. The Company has accounted for the tax effects of the Tax Cuts and Jobs Act under the guidance of SAB 118 and does not believe that the adoption of ASU 2018-05 had a material impact on the Company’s consolidated financial statements or disclosures.

In June 2018, the FASB issued ASU No. 2018-07, “Compensation — Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting” (“ASU 2018-07”). ASU 2018-07 is intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. Currently, the accounting requirements for nonemployee and employee share-based payment transactions are significantly different. ASU 2018-07 expands the scope of Topic 718, Compensation — Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. This ASU supersedes Subtopic 505-50, Equity — Equity-Based Payments to Nonemployees. The amendments in this ASU are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning

after December 15, 2018. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606, Revenue from Contracts with Customers. The adoption of this ASU effective January 1, 2019 is not expected to have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement" ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements on fair value measurements based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating ASU 2018-13 and its impact on its consolidated financial statements.

4. Convertible Notes Payable

On March 23, 2017, the Company entered into an exclusive Definitive Financing Commitment Term Sheet with a group of the Company's stockholders (the PRH Group), which was amended and restated effective as of March 19, 2017 (the Term Sheet) that set forth the terms on which the PRH Group would use their best efforts to arrange for a financing of a minimum of $10,000,000 and maximum of $20,000,000 (the 2017 Financing).

As of December 31, 2018, the Company had received aggregate Loans, as defined below, of $13,932,000 in connection with the 2017 Financing. Subsequent to December 31, 2018, the Company received aggregate Loans of $3,475,000 in connection with the 2017 Financing. See Note 13 – Subsequent Events.

The 2017 Financing is in the form of a secured convertible loan (the Loan) from the PRH Group or other investors in the 2017 Financing (the Investors). The Loan is evidenced by secured convertible promissory notes (individually a PRH Note and collectively, the PRH Notes) from the Company to the PRH Group or the Investors. In addition to the customary provisions, the PRH Note contains the following provisions:

(i) It is secured by a first priority security interest on the Company's intellectual property (the IP),

(ii) The Loan bears interest at the rate of 8% per annum on the outstanding principal amount of the Loan that has been funded to the Company,

(iii) The Loan proceeds are held in one or more accounts (the Escrow) pending the funding of the tranches of the 2017 Financing pursuant to borrowing requests made by the Company,

(iv) The PRH Notes, including interest and principal, are due and payable in full on the earlier of: (i) on such date upon which the Company defaults under the PRH Notes, (ii) upon a change of control of the Company, or (iii) dates ranging from May 18, 2020 to the 24-month anniversary of the funding of the Final Tranche. In the event there is a change of control of the Company's board of directors (the Board) as proposed by any person or group other than the Investors, the term of the PRH Notes will be accelerated and all amounts due under the PRH Notes will be immediately due and payable, plus interest at the rate of 8% per annum, plus a penalty in the amount equal to 10 times the outstanding principal amount of the Loan that has been funded to the Company,

(v) The outstanding principal amount and interest payable under the Loan would be convertible at the sole discretion of the Investors into shares of the Company's Series D Preferred Stock, a new series of preferred stock, that the Company's Board may designate in the future, at a price per share equal to $0.2862, and

(vi) Notwithstanding (v) above, the principal amount of the PRH Notes and the interest payable under the Loan would automatically convert into shares of the Company's Series D Preferred Stock at a price per share equal to $0.2862 effective on the 24th anniversary of the funding of the final tranche of the 2017 Financing subject to certain

exceptions if the Company's Board designates such series of preferred stock in the future.

As of December 31, 2018, and through the date of filing, the Series D Preferred Stock had not been designated by the Board. As a result, the Company did not analyze the Loan for a potential beneficial conversion feature as the definition of a firm commitment has not been met since the PRH Notes were not convertible as of their respective dates of issuance or as of December 31, 2018.

Convertible Notes Payable – Related Parties

On February 21, 2017, the Company issued a promissory note in favor of Eric A. Wachter, Ph.D., the Company's Chief Technology Officer ("Wachter"), evidencing an unsecured loan from Wachter to the Company in the original principal amount of up to $2,500,000 (the "Wachter Note"). Interest accrues on the outstanding balance of the Wachter Note at six percent (6%) per annum calculated on a 360-day basis. As of December 31, 2017, the Company had borrowed the entire $2,500,000 principal amount under the Wachter Note. On April 3, 2017, the Wachter Note was amended and restated in order to modify its terms to mirror the PRH Notes and to convert the Wachter Note into the 2017 Financing. The Company accounted for the amendment as a debt modification. There was no material impact as a result of applying debt modification accounting.

On April 3, 2017, the Company entered into a PRH Note with Cal Enterprises LLC, a Nevada limited liability company, an affiliate of Dominic Rodrigues, a director of the Company, in the principal amount of up to $2,500,000. As of December 31, 2017, the Company had borrowed the entire $2,500,000 under this note.

During the year ended December 31, 2018, the Company entered into additional PRH Notes with related parties in the aggregate principal amount of $1,870,000. As of December 31, 2018, the Company had borrowed $6,870,000 of PRH Notes from related parties which were outstanding.

Convertible Notes Payable – Non-Related Parties

During the year ended December 31, 2017, the Company entered into additional PRH Notes from accredited investors in the aggregate principal amount of $4,456,000, of which $150,000 was issued in satisfaction of trade debt. As of December 31, 2017, the Company had borrowed the entire $4,456,000 under these notes.

During the year ended December 31, 2018, the Company entered into additional PRH Notes with accredited investors in the aggregate principal amount of $2,606,000. As of December 31, 2018, the Company had borrowed $7,062,000 under these notes.

5. Related Party Transactions

During the years ended December 31, 2018 and 2017, the Company paid Bruce Horowitz (Capital Strategists) consulting fees of $190,000 and $180,000 for services rendered, respectively and $75,000 for director fees in 2017. Accrued director fees for Bruce Horowitz for years ended December 31, 2018 and 2017 were $56,250 and $0, respectively. Bruce Horowitz serves as both Chief Operations Officer and a Director.

See Note 4 and Note 6 for details of other related party transactions.

Also, director fees during the years ended December 31, 2018 and 2017 were $333,357 and $148,333, respectively. Accrued directors' fees during the years ended December 31, 2018 and 2017 were $407,524 and $92,917, respectively.

6. Receivables

The following table summarizes the receivables at December 31, 2018 and 2017:

	December 31, 2018		
	Legal Fees	Settlement	Total
Gross receivable	$911,000	$1,783,795	$2,694,795
Reserve for uncollectibility	(455,500)	(1,649,043)	(2,104,543)
Net receivable	455,500	134,752	590,252
Short-term receivable	455,500	134,752	590,252
Long-term receivable	$-	$-	$-

	December 31, 2017		
	Legal Fees	Settlement	Total
Gross receivable	$911,000	$2,214,728	$3,125,728
Reserve for uncollectibility	(455,500)	(1,549,043)	(2,004,543)
Net receivable	455,500	665,685	1,121,185
Short-term receivable	-	300,000	300,000
Long-term receivable	$455,500	$365,685	$821,185

During the quarter ended December 31, 2017, an officer of the Company offset his receivable and trade payable totaling $280,823. This offset reduced the amount of the settlement and was approved by the Company's Board.

In December 2017, former CFO, Peter Culpepper ("Culpepper") settled an administrative proceeding with the SEC. As a result of this settlement, Culpepper was required to disgorge himself of $140,115 along with interest of $12,261 for a total payment to the Company of $152,376. The Company recorded the settlement as an account receivable at December 2017 and received payment in January 2018. There was no change to the reserve for 2018.

During the quarter ended December 31, 2018, an officer of the Company offset his settlement amounts owed to the Company against accrued payroll owed to him totaling $150,000. This offset reduced the amount of the settlement and

was approved by the Company's Board.

7. Stockholders' Deficiency

Authorized Capital

As of December 31, 2018, the Company was authorized to issue 1,000,000,000 shares of common stock, $0.001 par value, and 25,000,000 shares of preferred stock, $0.001 par value. The holders of the Company's common stock are entitled to one vote per share. The preferred stock is designated as follows: 240,000 shares to Series B Convertible Preferred Stock and 24,760,000 shares undesignated.

Series B Convertible Preferred Stock

On August 25, 2016, the Company filed the Series B Certificate of Designation with the Delaware Secretary of State. The Series B Certificate of Designation provides for the issuance of the Series B Convertible Preferred Stock, par value $0.001 per share (the Series B Preferred Stock). In the event of the Company's liquidation, dissolution, or winding up, holders of Series B Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series B Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to any beneficial ownership limitation), subject to the preferential rights of holders of any class or series of the Company's capital stock specifically ranking by its terms senior to the Series B Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily. The Series B Preferred Stock has no voting rights.

The holders of Series B Preferred Stock will be entitled to receive cumulative dividends at the rate per share of 8% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Series B Preferred Stock. The dividends become payable, at the Company's option in either cash, out of any funds legally available for such purpose, or in shares of common stock, (i) upon any conversion of the Series B Preferred Stock, (ii) on each such other date as the Board may determine, subject to written consent of the holders of Series B Preferred Stock holding a majority of the then issued and outstanding Series B Preferred Stock, (iii) upon the Company's liquidation, dissolution or winding up, and (iv) upon occurrence of a fundamental transaction, which includes any merger or consolidation, sale of all or substantially all of the Company's assets, exchange or conversion of all of the common stock by tender offer, exchange offer or reclassification; provided, however, that if Series B Preferred Stock is converted into shares of common stock at any time prior to the fifth anniversary of the date of issuance of the Series B Preferred Stock, the holder will receive a make-whole payment in an amount equal to all of the dividends that, but for the early conversion, would have otherwise accrued on the applicable shares of Series B Preferred Stock being converted for the period commencing on the conversion date and ending on the fifth anniversary of the date of issuance, less the amount of all prior dividends paid on such converted Series B Preferred Stock before the date of conversion. Make-whole payments are payable at the Company's option in either cash, out of any funds legally available for such purpose, or in shares of common stock. With respect to any dividend payments and make-whole payments paid in shares of common stock, the number of shares of common stock to be issued to a holder of Series B Preferred Stock will be an amount equal to the quotient of (a) the amount of the dividend payable to such holder divided by (b) the conversion price then in effect.

Other Common Stock Issuances

During the year ended December 31, 2017, the Company issued 372,500 shares of common stock as payment of trade payables, with a grant date fair value of $17,301.

During the year ended December 31, 2018, the Company issued 1,000,000 shares of common stock as payment of services, with a grant date fair value of $80,000.

As the fair market of these services was not readily determinable, these services were valued based on the fair market value of stock at grant date.

Preferred Stock Conversions

During the year ended December 31, 2017, holders converted 8,500 shares of Series B Preferred Stock into 3,986,676 shares of common stock such that they were entitled to dividends, including a make-whole payment, of $14,107 that

the Company elected to pay in shares of common stock. As a result, the Company issued 1,594,670 shares of common stock related to the Series B Preferred Stock dividends during the year ended December 31, 2017. The Company recorded aggregate dividends paid in kind of $14,107 during the year ended December 31, 2017.

8. Stock Incentive Plan and Warrants

The Provectus Biopharmaceuticals, Inc. 2014 Equity Compensation Plan provides for the issuance of up to 20,000,000 shares of common stock pursuant to stock options for the benefit of eligible employees and directors of the Company. Options granted under the 2014 Equity Compensation Plan are either “incentive stock options” within the meaning of Section 422 of the Internal Revenue Code or options which are not incentive stock options. The stock options are exercisable over a period determined by the Board of Directors (through its Compensation Committee), but generally no longer than 10 years after the date they are granted. As of December 31, 2018, there were 18,900,000 shares available for issuance under the 2014 Equity Compensation Plan.

There were no stock options granted to employees during 2018 or 2017.

The following table summarizes option activity during the year ended December 31, 2018 and 2017:

	Shares	Weighted Average Exercise Price
Outstanding and exercisable at December 31, 2017	3,350,000	$ 0.90
Granted	-	-
Exercised	-	-
Forfeited	(150,000)	0.89
Outstanding and exercisable at December 31, 2018	3,200,000	$ 0.89

The following table summarizes information about stock options outstanding at December 31, 2018.

Exercise Price	Number Outstanding at December 31, 2018	Weighted Average Remaining Contractual Life	Number Exercisable at December 31, 2018
$ 0.67	200,000	4.60	200,000
$ 0.75	950,000	5.11	950,000
$ 0.84	150,000	3.50	150,000
$ 0.88	150,000	5.60	150,000
$ 0.93	575,000	2.76	575,000
$ 0.99	50,000	2.50	50,000
$ 1.00	525,000	1.60	525,000
$ 1.04	400,000	1.50	400,000
$ 1.16	200,000	1.50	200,000
	3,200,000	3.31	3,200,000

As of December 31, 2018, there was no intrinsic value of outstanding and exercisable options.

Warrants

During the year-ended December 31, 2018, holders of warrants exercised warrants to purchase 12,653,077 shares of common stock at a price of $0.053 per share. In connection with the exercises, the Company received cash proceeds of $674,409 and issued 12,653,077 shares of common stock.

The following table summarizes warrant activity during the year ended December 31, 2018 and 2017:

	Warrants	Weighted Average Exercise Price
Outstanding and exercisable at January 1, 2017	189,991,541	$ 0.44
Granted	-	-
Exercised	(234,308)	0.05
Forfeited	(2,884,201)	1.04
Outstanding and exercisable at December 31, 2017	186,873,032	$ 0.43
Granted	-	-
Exercised	(12,653,077)	0.05
Forfeited	(37,395,817)	1.00
Outstanding and exercisable at December 31, 2018	136,824,138	$ 0.27

The following table summarizes information about warrants outstanding at December 31, 2018.

Exercise Price	Number Outstanding at December 31, 2018	Weighted Average Remaining Contractual Life	Number Exercisable at December 31, 2018
$ 0.053	99,677,583	2.66	99,677,583
$ 0.85	28,482,344	1.48	28,482,344
$ 1.00	2,875,115	1.38	2,875,115
$ 1.25	4,474,520	0.93	4,474,520
$ 2.00	100,000	0.00	100,000
$ 2.50	280,276	0.33	280,276
$ 3.00	934,300	0.33	934,300
	136,824,138	1.02	136,824,138

As of December 31, 2018, there was no intrinsic value of outstanding and exercisable warrants. Holders of the outstanding warrants are not entitled to vote and the exercise prices of such warrants are subject to customary anti-dilution provisions.

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9. Income Taxes

The domestic and foreign components of loss before income taxes from operations for the years ended December 31, 2018 and 2017 are as follows:

	For the Years Ended December 31	
	2018	**2017**
Domestic	(7,954,841)	(13,395,048)
Foreign	(198,214)	(122,768)
	(8,153,055)	(13,517,816)

The income tax provision (benefit) consists of the following:

	Year ended December 31	
	2018	2017
Federal:		
Current	$-	$-
Deferred	(1,385,438)	13,026,739
State and local:		
Current	-	-
Deferred	(338,773)	1,724,127
	(1,724,211)	14,750,866
Change in valuation allowance	1,724,211	(14,750,866)
Income tax provision (benefit)	$-	$-

The reconciliations between the statutory federal income tax rate and the Company’s effective tax rate is as follows:

	Year Ended December 31	
	2018	2017
Tax benefit at federal statutory rate	(21.0)%	(34.0)%
State income taxes, net of federal benefit	(5.1)%	(4.5)%
Permanent differences	(1.7)%	(1.9)%

Effect of change in federal income tax rates on deferred taxes	0.0 %	147.4 %
Change in valuation allowance	20.8 %	(109.0)%
Prior year true-up	5.8 %	0.0 %
Miscellaneous	1.3 %	2.0 %
Effective income tax rate	0.0 %	0.0 %

The components of the Company's deferred income taxes are summarized below:

	December 31 2018	2017
Deferred Tax Assets:		
Net operating loss carryforwards	$41,114,624	$40,156,864
Stock-based compensation	2,207,465	2,207,465
Research and development credit carryovers	2,791,710	2,591,539
Contribution carryovers	10,062	10,715
Accrued liabilities	490,467	-
Gross deferred tax assets	46,614,328	44,966,584
Deferred Tax Liabilities:		
Intangible assets	(235,013)	(410,410)
Prepaid expenses	(90,881)	-
Other	(29,545)	(21,496)
Gross deferred tax liabilities	(355,439)	(431,906)
Valuation allowance	(46,258,889)	(44,534,678)
Deferred tax asset, net of valuation allowance	$-	$-
Change in valuation allowance	$(1,724,211)	$14,750,866

Under ASC 740, *Income Taxes*, the enactment of the Tax Act requires companies to recognize the effects of changes in tax laws and rates on deferred tax assets and liabilities and the retroactive effects of changes in tax laws in the period in which the new legislation is enacted. In 2017, the Company's gross deferred tax assets were revalued using the new enacted rate of 21% effective January 1, 2018 with a corresponding offset to the valuation allowance and any potential other taxes arising due to the Tax Act will result in reductions to its net operating loss carryforward and valuation allowance. Deferred tax assets of approximately $60,148,509 were revalued to approximately $44,966,584 with a corresponding decrease to the Company's valuation allowance. There was no further change to the Company's assertion on maintaining a full valuation allowance against its U.S. deferred tax assets.

A valuation allowance against deferred tax assets is required if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. The Company is in the early stages of development and realization of the deferred tax assets is not considered more likely than not. As a result, the Company has recorded a full valuation allowance for the net deferred tax asset.

Since inception of the Company on January 17, 2002, the Company has generated tax net operating losses of approximately $158 million. Under the Tax Cuts and Jobs Act, net operating loss incurred after December 31, 2017 may be carried forward indefinitely. The tax loss carry-forwards of the Company may be subject to limitation by Section 382 of the Internal Revenue Code with respect to the amount utilizable each year. This limitation reduces the Company's ability to utilize net operating loss carry-forwards.

The Company has determined that there are no uncertain tax positions as of December 31, 2018 or 2017

The Company files income tax returns in the U.S. federal jurisdiction and the state of Tennessee. The Company intends to permanently reinvest earnings in its foreign subsidiary.

To date, the Company's operations conducted by its Australian subsidiary consist primarily of research and development activities. As of December 31, 2018, there were no accumulated earnings and profits in the Company's foreign subsidiary. At current tax rates, no additional Federal income taxes (net of available tax credits) would be payable if such earnings were to be repatriated.

10. Commitments

Leases

The Company leases office space in Knoxville, Tennessee for a term of five years ending on June 30, 2022. Rent expense was $88,393 and $44,335 for the years ended December 31, 2018 and 2017, respectively. The Company's lease obligations are as follows:

Period Ending	Amount
December 31, 2019	$88,884
December 31, 2020	$90,666
December 31, 2021	$92,471
December 31, 2022	$46,687
	$318,708

11. 401(K) Profit Sharing Plan

The Company maintains a retirement plan under Section 401(k) of the Internal Revenue Code, which covers all eligible employees. All employees with U.S. source income are eligible to participate in the plan immediately upon employment. There was no contribution made by the Company in 2018 or 2017.

12. Litigation

Agreement with Clinical Operations Vendor

On October 4, 2018, the Company reached a settlement with a former clinical operations vendor whereby, the Company paid the vendor $350,000 and allowed the vendor to retain a previously paid retainer of approximately $1 million. The Company received a credit of approximately $1.7 million to be applied against amounts previously owed by the Company for services rendered by the vendor. Such credit has been included as a reduction in research and development expenses on the Company's consolidated statements of operations.

Culpepper Travel Expenses and Related Collection Efforts

On December 27, 2016, the Board unanimously voted to terminate Culpepper, effective immediately, from all positions he held with the Company and each of its subsidiaries, including interim CEO and COO of the Company, "for cause", in accordance with the terms of the Amended and Restated Executive Employment Agreement entered into by Culpepper and the Company on April 28, 2014 (the "Culpepper Employment Agreement") based on the results of the investigation conducted by the Audit Committee of the Board regarding improper expense reimbursements to Culpepper.

The Audit Committee retained independent counsel and an advisory firm with forensic accounting expertise to assist the Audit Committee in conducting the investigation. The Audit Committee found that Culpepper received $294,255 in expense reimbursements that were unsubstantiated or otherwise improper. The Company seeks to recover from Culpepper the entire $294,255 in expense reimbursements, as well as all attorney's fees and auditors'/experts' fees incurred by the Company in connection with the examination of his expense reimbursements. On December 12, 2017, Culpepper agreed to an order by the SEC to pay disgorgement of $140,115, and prejudgment interest of $12,261, for a total of $152,376, to the Company within 30 days. The Company received the payment of $152,376 in January 2018.

The Company took the position that under the terms of the Culpepper Employment Agreement, Culpepper is owed no severance payments as a result of his termination "for cause" as that term is defined in the Culpepper Employment Agreement. Furthermore, Culpepper is no longer entitled to the 2:1 credit under the Stipulated Settlement Agreement and Mutual Release in the Derivative Lawsuit Settlement such that the total $2,240,000 owed by Culpepper pursuant to the Derivative Lawsuit Settlement plus Culpepper's proportionate share of the litigation cost in the amount of $227,750, less the amount that he repaid as of December 31, 2016, is immediately due and payable. The Company sent Culpepper a notice of default in January 2017 for the total amount he owes the Company and is in the process of pursuing these claims in accordance with the alternative dispute resolution provision of the Culpepper Employment Agreement. The Company has established a reserve of $2,051,083 as of December 31, 2018 and December 31, 2017, which amount represents the amount the Company currently believes Culpepper owes to the Company under the Derivative Lawsuit Settlement (excluding the amount of attorneys' fees incurred in enforcing the terms of the Derivative Lawsuit Settlement), while the Company pursues collection of this amount.

Culpepper disputed that he was terminated "for cause" under the Culpepper Employment Agreement. Pursuant to the alternative dispute resolution provisions of that agreement, the Company and Culpepper participated in a mediation of their dispute on June 28, 2017. Having reached no resolution during the mediation, the parties participated in arbitration under the commercial rules of the American Arbitration Association, arbitrating both Culpepper's claim for severance against the Company and the Company's claims against Culpepper for improper expense reimbursements and amounts Culpepper owes the Company under the Derivative Lawsuit Settlement (the Culpepper Arbitration). The Culpepper Arbitration hearing was held from May 15 through May 18, 2018.

On July 12, 2018, the arbitrator issued an interim award in favor of the Company, the terms of which are confidential pursuant to the terms of the Culpepper Employment Agreement and instructed the parties that a final award was forthcoming. On September 12, 2018, the arbitrator issued its final award in favor of the Company. On October 4, 2018, the Company filed a petition with the Chancery Court for Davidson County, Tennessee to confirm the arbitration award. On November 7, 2018, the Company received Culpepper's answer to the petition filed on October 4, 2018. This court entered an order confirming the arbitrator's award on January 23, 2019. On February 20, 2019, Culpepper filed a motion to alter or amend this judgment. The parties are working to schedule a hearing for the motion.

The Bible Harris Smith Lawsuit

On November 17, 2016, the Company filed a lawsuit in the Circuit Court for Knox County, Tennessee (the "Tennessee Circuit Court") against Bible Harris Smith PC ("BHS") for professional negligence, common law negligence and breach of fiduciary duty arising from accounting services provided by BHS to the Company. The Company alleges that between 2013 and 2015, Dees received approximately $2.4 million in advanced or reimbursed travel and entertainment expenses from the Company and that Dees did not submit back-up documentation in support of substantially all of the advances he received purportedly for future travel and entertainment expenses. The Company further alleges that had BHS provided competent accounting and tax preparation services, it would have discovered Dees' failure to submit back-up documentation supporting the advanced travel funds at the inception of Dees' conduct, and prevented the misuse of these and future funds. The Company has made a claim for damages against BHS in an amount in excess of $3 million. The complaint against BHS has been filed and served, an answer has been received, and the parties are in the midst of discovery. BHS filed a Motion for Summary Judgment, which was denied in full by the Tennessee Circuit Court June 21, 2018. Depositions for the BHS lawsuit were taken on August 16 and 17, 2018.

The Company and BHS participated in a mediation of their dispute on October 23, 2018. Subsequent to December 31, 2018, this matter was resolved pursuant to a settlement between the parties, the terms of which are confidential, and proceeds from the settlement were received.

The RSM Lawsuit

On June 9, 2017, the Company filed a lawsuit in the Circuit Court for Mecklenburg County, North Carolina (the "North Carolina Circuit Court") against RSM USA LLP ("RSM") for 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 to the Company. The Company alleges that between 2013 and 2015, Dees received approximately $2.4 million in advanced or reimbursed travel and entertainment expenses from the Company and that Dees did not submit back-up documentation in support of substantially all of the advances he received purportedly for future travel and entertainment expenses. The Company similarly alleges that Culpepper received $294,255 in travel expense reimbursements and advances that were unsubstantiated. The Company further alleges that had RSM provided competent accounting, internal audit and consulting services, it would have discovered Dees' and Culpepper's conduct at its inception and prevented the misuse of these and future funds. The Company has made a claim for damages against RSM in an amount in excess of $10 million. The Complaint against RSM was filed by the Company and RSM moved to dismiss the Complaint. On September 28, 2018, RSM's motion to dismiss was granted in part for breach of fiduciary duty and denied in part for negligence, professional malpractice, negligent misrepresentation, gross negligence, intentional misrepresentation, and fraudulent concealment. The Company was not precluded from seeking consequential or punitive damages on its claims for gross negligence, intentional misrepresentation, and fraudulent concealment at this stage of the litigation.

The Company also was not precluded, at this time, from seeking consequential or punitive damages on its claims for breach of contract, negligence, negligent misrepresentation, or professional malpractice to the extent those claims are premised on the outsourcing engagement between the Company and RSM or the engagement between the Company and RSM under which RSM was to review the Company's financial statements. The North Carolina Circuit Court entered a Case Management Order and the Parties are in the process of beginning discovery in the case. The Company and RSM participated in a mediation on February 4, 2019, when the matter was resolved pursuant to a settlement between the parties, the terms of which are confidential. The proceeds from the settlement were received and recorded during the first quarter of 2019.

The BDO Matter

On November 16, 2017, the Company filed a demand for arbitration with the American Arbitration Association that alleged professional negligence, common law negligence, gross negligence, intentional misrepresentation, negligent misrepresentation, and breach of fiduciary duty by the Company's former external audit firm, BDO USA LLP ("BDO"),

arising from accounting, external auditing, and consulting services provided by BDO related to travel and expense advances and reimbursements received by Dees and former Company executive Culpepper. During the quarter ended June 30, 2018, this matter was resolved pursuant to a settlement between the parties, the terms of which are confidential. The proceeds from the settlement were received and recorded during the third quarter of 2018.

Other Regulatory Matters

From time to time, the Company receives subpoenas and/or requests for information from governmental agencies with respect to its business. The Company received a subpoena from the staff of the SEC related to the travel expense advancements and reimbursement received by Dees. The Company also received a subsequent subpoena from the staff of the SEC related to the travel expense advancements and reimbursements received by Culpepper. On December 12, 2017, the Company reached a settlement with the SEC in connection with these investigations. Under the terms of the SEC settlement, the Company, without admitting or denying the findings of the SEC, consented to the entry of administrative order that required the Company to cease and desist from committing or causing any violations and any future violations of Sections 13(a), 13(b)(2)(A), 13(b)(2)(B), and 14(a) of the Securities Exchange Act of 1934 and Rules 12b-20, 13a-1, 14a-3, and 14a-9 thereunder.

13. Subsequent Events

Convertible Notes Payable

Subsequent to December 31, 2018, the Company entered into PRH Notes with non-related party accredited investors in the aggregate principal amount of $3,475,000 in connection with Loans received by the Company for the same amount. None of the proceeds were received from a related party.

Exercise of Warrants

In addition, holders of 100,000 warrants to purchase the common stock of the Company at $0.0533 per share, have exercised these warrants. The Company has received proceeds in the aggregate amount of $5,330.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures by us are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of the period covered by this report based on the criteria for effective internal control described in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on the results of management's assessment and evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our principal executive officer and principal financial officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the

time periods specified in SEC rules and forms, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Inherent Limitations on Effectiveness of Controls

Even assuming the effectiveness of our controls and procedures, our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error or all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. In general, our controls and procedures are designed to provide reasonable assurance that our control system's objective will be met, and our principal executive officer and principal financial officer has concluded that our disclosure controls and procedures are effective at the reasonable assurance level. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls in future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the fourth quarter of 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 11. EXECUTIVE COMPENSATION.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

Financial Statements

All financial statements are set forth under Part II, Item 8 of this report.

Financial Statement Schedules

None

Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation of Provectus Biopharmaceuticals, Inc., as amended (incorporated by reference to Exhibit 3.1 of the Company's annual report on Form 10-K filed with the SEC on March 31, 2017).
3.2	Certificate of Designation for the Company's Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's current report on Form 8-K filed with the SEC on August 25, 2016).
3.4	Bylaws of Provectus Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 3.4 of the Company's annual report on Form 10-K filed with the SEC on March 13, 2014).
4.1	Specimen certificate for the Common Stock, par value $0.001 per share, of the Company (incorporated by reference to Exhibit 4.1 of the Company's annual report on Form 10-KSB filed with the SEC on April 15, 2003).

4.2	Specimen certificate for the Common Stock, par value $0.001 per share, of the Company (incorporated by reference to Exhibit 4.1 to the Company's registration statement on Form S-4, Commission File No. 333-208816, filed with the SEC on December 31, 2015).
4.3	Form of Warrant Agency Agreement between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.1 to the Company's current report on Form 8-K, filed with the SEC on June 19, 2015).
4.4	First Amendment to Warrant Agency Agreement between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.3 to the Company's registration statement on Form S-4, Commission File No. 333-208816, filed with the SEC on December 31, 2015).
4.5	Second Amendment to Warrant Agency Agreement between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.4 to the Company's registration statement on Form S-4, Commission File No. 333-211353, filed with the SEC on May 13, 2016).

4.6	Form of Warrant Certificate (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on June 19, 2015).
4.7	Exchange and Escrow Agent Agreement between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.5 to the Company's registration statement on Form S-4, Commission File No. 333-208816, filed with the SEC on December 31, 2015).
4.8	Exchange and Escrow Agent Agreement between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.6 to the Company's registration statement on Form S-4, Commission File No. 333-211353, filed with the SEC on May 13, 2016).
4.9	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed with the SEC on August 25, 2016).
10.1*	Provectus Pharmaceuticals, Inc. 2012 Stock Plan (incorporated herein by reference to Appendix A of the Company's definitive proxy statement filed with the SEC on April 30, 2012).
10.2*	Confidentiality, Inventions and Non-Competition Agreement dated as of November 26, 2002 between the Company and Timothy C. Scott (incorporated by reference to Exhibit 10.9 of the Company's annual report on Form 10-KSB filed with the SEC on April 15, 2003).
10.3*	Confidentiality, Inventions and Non-Competition Agreement dated as of November 26, 2002, between the Company and Eric A. Wachter (incorporated by reference to Exhibit 10.10 of the Company's annual report on Form 10-KSB filed with the SEC on April 15, 2003).
10.4	Material Transfer Agreement dated as of July 31, 2003 between Schering-Plough Animal Health Corporation and the Company (incorporated by reference to Exhibit 10.15 of the Company's quarterly report on Form 10-QSB filed with the SEC on August 14, 2003).
10.5	Securities Purchase Agreement dated as of January 13, 2011, by and between the Company and the purchasers identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on January 13, 2011).
10.6	Purchase Agreement dated as of December 22, 2010, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on December 23, 2010).
10.7	Registration Rights Agreement dated as of December 22, 2010, by and between the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 of the Company's current report on Form 8-K filed with the SEC on December 23, 2010).
10.8	Purchase Agreement dated as of July 22, 2013, by and between Provectus Pharmaceuticals, Inc. and Alpha Capital Anstalt (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on July 26, 2013).
10.9*	Amended and Restated Executive Employment Agreement by and between the Company and Timothy C. Scott, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.2 to the Company's Item current

report on Form 8-K filed with the SEC on April 30, 2014).

10.10* Amended and Restated Executive Employment Agreement by and between the Company and Eric A. Wachter, Ph.D., dated April 28, 2014 (incorporated by reference to Exhibit 10.3 to the Company's current report on Form 8-K filed with the SEC on April 30, 2014).

10.11*	Provectus Biopharmaceuticals, Inc. 2014 Equity Compensation Plan (incorporated herein by reference to Appendix A of the Company's definitive proxy statement filed with the SEC on April 30, 2014).
10.12	Controlled Equity Offering[SM] Sales Agreement, dated April 30, 2014, by and between Provectus Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 30, 2014).
10.13	Stipulated Settlement Agreement and Mutual Release, dated June 6, 2014, by and among the Company as nominal defendant, H. Craig Dees, Timothy C. Scott, Eric A. Wachter, Peter R. Culpepper, Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV, as defendants, and Glenn Kleba and Don B. Dale, as plaintiffs (Exhibits Omitted) (incorporated by reference to Exhibit 10.6 of the Company's quarterly report on Form 10-Q filed with the SEC on August 7, 2014).
10.14	Consent and Waiver of Rights, between Provectus Biopharmaceuticals, Inc. and Alpha Capital Anstalt (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on June 24, 2015).
10.15*	Independent Contractor Agreement between Provectus Biopharmaceuticals, Inc. and John R. Glass (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 22, 2016).
10.16*	Amendment No. 1 to the Independent Contractor Agreement between Provectus Biopharmaceuticals, Inc. and John R. Glass (incorporated by reference to Exhibit 10.18 of the Company's annual report on Form 10-K filed with the SEC on March 31, 2017).
10.17	Form of Securities Purchase Agreement between Provectus Biopharmaceuticals, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on August 25, 2016) (exhibits and schedules have been omitted, and the Company agrees to furnish to the Commission a copy of any omitted exhibits and schedules upon request).
10.18	Warrant Agency Agreement, dated August 30, 2016, by and between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on August 30, 2016).
10.19	Convertible Promissory Note dated February 21, 2017 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on February 21, 2017).
10.20	Definitive Financing Commitment Term Sheet dated March 19, 2017 (incorporated by reference to Exhibit 10.2 of the Company's quarterly report on Form 10-Q filed with the SEC on May 10, 2017).
10.21	Secured Convertible Promissory Note between the Company and Cal Enterprises LLC, dated April 3, 2017 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 4, 2017).
10.22	Amended and Restated Secured Convertible Promissory Note between the Company and Eric A. Wachter, dated April 3, 2017 (incorporated by reference to Exhibit 10.2 of the Company's current report on Form 8-K

filed with the SEC on April 4, 2017).

10.23 Indemnification Agreement between the Company and Dominic Rodrigues, dated April 3, 2017 (incorporated by reference to Exhibit 10.3 of the Company's current report on Form 8-K filed with the SEC on April 4, 2017).

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10.24	Indemnification Agreement between the Company and Bruce Horowitz, dated April 3, 2017 (incorporated by reference to Exhibit 10.4 of the Company's current report on Form 8-K filed with the SEC on April 4, 2017).
10.25*	Independent Contractor Agreement, dated April 19, 2017, between the Company and Bruce Horowitz (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 20, 2017).
10.26*	Amendment No. 1 to the Independent Contractor Agreement, dated May 9, 2017, between the Company and Bruce Horowitz (incorporated by reference to Exhibit 10.6 of the Company's quarterly report on Form 10-Q filed with the SEC on August 9, 2017).
10.27	Second Amendment to Amended and Restated Secured Convertible Promissory Note between the Company and Eric Wachter, Ph.D., dated January 22, 2018 (incorporated by reference to Exhibit 10.1 of the Company's quarterly report on Form 10-Q filed with the SEC on May 9, 2018).
10.28	Third Amendment to Amended and Restated Secured Convertible Promissory Note between the Company and Eric Wachter, Ph.D., dated January 22, 2018 (incorporated by reference to Exhibit 10.2 of the Company's quarterly report on Form 10-Q filed with the SEC on May 9, 2018).
10.29	Fourth Amendment to Amended and Restated Secured Convertible Promissory Note between the Company and Eric Wachter, Ph.D., dated January 22, 2018 (incorporated by reference to Exhibit 10.3 of the Company's quarterly report on Form 10-Q filed with the SEC on May 9, 2018).
10.30	First Amendment to Amended and Restated Secured Convertible Promissory Note between the Company and CAL Enterprises LLC, dated January 22, 2018 (incorporated by reference to Exhibit 10.4 of the Company's quarterly report on Form 10-Q filed with the SEC on May 9, 2018).
10.31	Secured Convertible Promissory Note between the Company and Eric A. Wachter, dated January 25, 2018 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on January 30, 2018).
10.32	Secured Convertible Promissory Note between the Company and Timothy C. Scott, dated February 23, 2018 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on February 26, 2018).
10.33	Indemnification Agreement between the Company and Ed Pershing, dated April 19, 2018 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on April 24, 2018).
10.34	Indemnification Agreement between the Company and Jack Lacey, MD, dated April 19, 2018 (incorporated by reference to Exhibit 10.2 of the Company's current report on Form 8-K filed on April 24, 2018).
10.35	Secured Convertible Promissory Note between the Company and Edward V. Pershing, dated July 26, 2018 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on July 30, 2018).
14	Code of Ethics (incorporated by reference to Exhibit 14 of the Company's annual report on Form 10-K filed with the SEC on March 16, 2011).

21	Subsidiaries of the Company (incorporated by reference to Exhibit 21 of the Company's annual report on Form 10-K filed with the SEC on March 31, 2017).
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31.1† Certification of CEO pursuant to Rules 13a-14(a) of the Securities Exchange Act of 1934.

31.2† Certification of CFO pursuant to Rules 13a-14(a) of the Securities Exchange Act of 1934.

32†† Certification Pursuant to 18 U.S.C. Section 1350.

101† The following financial information from Provectus Biopharmaceuticals, Inc.'s Annual Report on Form 10-K for the period ended December 31, 2018, filed with the SEC on February 28, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheet as of December 31, 2018 and December 31, 2017; (ii) the Consolidated Statements of Operations for the years ended December 31, 2018 and 2017; (iii) the Consolidated Statements of Equity for the years ended December 31, 2018 and 2017; (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017; and (v) Notes to Consolidated Financial Statements.

† Filed herewith.
†† Furnished herewith.
* Indicates a management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

March 7, 2019

PROVECTUS
BIOPHARMACEUTICALS, INC.

By:*/s/ Timothy C. Scott, Ph.D.*
Timothy C. Scott, Ph.D.
President (principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Timothy C. Scott, Ph.D. Timothy C. Scott, Ph.D.	President (principal executive officer)	March 7, 2019
/s/ John R. Glass John R. Glass	Interim Chief Financial Officer (principal financial officer and principal accounting officer)	March 7, 2019
/s/ Bruce Horowitz Bruce Horowitz	Director and Chief Operations Consultant	March 7, 2019
/s/ Jan E. Koe Jan E. Koe	Director	March 7, 2019
/s/ Jack Lacey, III, MD Jack Lacey, III, MD	Director	March 7, 2019
/s/ Ed Pershing Ed Pershing	Director and Chairman of the Board	March 7, 2019
/s/ Dominic Rodrigues	Director and Vice Chairman of the Board	March 7, 2019

Dominic Rodrigues

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