

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-K

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

For the fiscal year ended December 31, 2019

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

For the transition period from _____ to _____

Commission file number 001-36457

PROVACTUS BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

90-0031917
(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	N/A	N/A

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

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 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. 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). Yes No

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 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 28, 2019 was \$23,304,507 (computed on the basis of \$0.063 per share).

The number of shares outstanding of the registrant's common stock, par value \$.001 per share, as of March 2, 2020 was 390,689,475.

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, 2019, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the 2020 annual meeting of stockholders.

TABLE OF CONTENTS

<u>PART I</u>		
ITEM 1.	<u>BUSINESS</u>	2
ITEM 1A.	<u>RISK FACTORS</u>	14
ITEM 1B.	<u>UNRESOLVED STAFF COMMENTS</u>	22
ITEM 2.	<u>PROPERTIES</u>	22
ITEM 3.	<u>LEGAL PROCEEDINGS</u>	22
ITEM 4.	<u>MINE SAFETY DISCLOSURES</u>	22
<u>PART II</u>		
ITEM 5.	<u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	23
ITEM 6.	<u>SELECTED FINANCIAL DATA</u>	24
ITEM 7.	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	24
ITEM 7A.	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	30
ITEM 8.	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	31
ITEM 9.	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	32
ITEM 9A.	<u>CONTROLS AND PROCEDURES</u>	32
ITEM 9B.	<u>OTHER INFORMATION</u>	33
<u>PART III</u>		
ITEM 10.	<u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	33
ITEM 11.	<u>EXECUTIVE COMPENSATION</u>	33
ITEM 12.	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	33
ITEM 13.	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	33
ITEM 14.	<u>PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	33
<u>PART IV</u>		
ITEM 15.	<u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	34
ITEM 16.	<u>FORM 10-K SUMMARY</u>	38
<u>SIGNATURES</u>		39

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains “forward-looking statements” as defined under U.S. federal securities laws. These statements reflect management’s current knowledge, assumptions, beliefs, estimates, and expectations. These statements also express management’s current views of future performance, results, and trends and may be identified by their use of terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “plan,” “predict,” “project,” “should,” “strategy,” “will,” and other similar terms. 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 U.S. Securities and Exchange Commission (the “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.

PART I

ITEM 1. BUSINESS.

General

Provectus Biopharmaceuticals, Inc. (“Provectus”, the “Company,” or “we”) is a clinical-stage biotechnology company developing a new class of drugs for oncology, hematology, and dermatology based on an entire, wholly-owned, family of chemical small molecules called halogenated xanthenes. Intratumoral (aka intralesional) PV-10®, the first small molecule autolytic immunotherapy, which can induce immunogenic cell death, is undergoing clinical study for adult solid tumor cancers, such as melanoma and GI tumors (e.g., hepatocellular carcinoma, metastatic colorectal cancer, metastatic neuroendocrine tumors, metastatic uveal melanoma), and preclinical study for pediatric solid tumor cancers (e.g., neuroblastoma, Ewing sarcoma, rhabdomyosarcoma, osteosarcoma) and blood cancers (e.g., acute myeloid leukemia). Topical PH-10® is undergoing clinical study for inflammatory dermatoses (e.g., psoriasis, atopic dermatitis). Provectus is a Delaware corporation formed in 2002.

Our Core Science

Oncology. PV-10 drug product is an injectable formulation of rose bengal disodium (4,5,6,7-tetrachloro-2',4',5',7'-tetraiodofluorescein disodium salt) (“RB”) drug substance (i.e., active pharmaceutical ingredient). PV-10 is a bright rose red solution containing 10% w/v RB in 0.9% saline for injection, which is supplied in single-use glass vials containing 5 mL (to deliver) of solution. PV-10 is administered directly to superficial disease (e.g., cutaneous melanoma) via injection and to visceral disease (e.g., GI tumors) via image-guided percutaneous injection. PV-10 selectively accumulates in the lysosomes of cancer cells. Cancer cells, particularly advanced cancer cells, are very dependent on effective lysosomal functioning (Piao et al., *Ann N Y Acad Sci* 2016). Cancer progression and metastasis are associated with lysosomal compartment changes (Nishimura et al., *Pathol Oncol Res* 1998; Gocheva et al., *Genes Dev* 2006), which are closely correlated with, among other things, invasive growth, angiogenesis, and drug resistance (Fahrenbacher et al., *Cancer Res* 2005). Physicochemical properties of lysosomes trap PV-10. Lumenal pH of 4.5 to 5 is ideal for the conversion of soluble rose bengal disodium into insoluble rose bengal lactone.

Lysosomes are the central organelles for intracellular degradation of biological macromolecules and organelles. Discovered by Christian de Duve, M.D. in 1955, lysosomes have been linked with a number of biological processes like cell death, inflammasome activation, and immune response. In 1959, Dr. de Duve described lysosomes as “suicide bags,” because their rupture led to cell death and tissue autolysis. Lysosomes have been shown to play a role in each of the primary pathways of cell death, which are apoptosis, autophagy, and necrosis. He was awarded the Nobel Prize in 1974 for discovering and characterizing lysosomes.

Provectus showed that PV-10 selectively accumulates in the lysosomes of cancer cells and disrupts them, causing the cancer cells to die. PV-10 (RB) has also been shown by Provectus and independent researchers to trigger each major, distinct form of lysosomal cell death; that is, apoptosis, autophagy, and necrosis.

PV-10’s lysosomal targeting comprises:

- Transiting the plasmalemma (i.e., the cell membrane) of cancer cells. PV-10 penetrates the cell membrane of cancerous cells which normally protects the cancer cell from its surrounding environment. PV-10, however, is excluded from normal cells;
- Accumulating in the lysosomes of cancer cells. As noted above, the physicochemical properties of lysosomes trap PV-10;
- Triggering the release of lysosomal contents. Acute autolysis can occur within 60 minutes. Early preclinical work by Provectus on PV-10’s lysosomal targeting showed identical responses in different disease models, such as Hepa1-6 murine hepatocellular carcinoma, HTB-133 human breast carcinoma, and H96Ar human multi-drug resistant small cell lung carcinoma;
- Inducing the rapid cell death of cancer cells. Early trypan blue exclusion work by Provectus confirmed cell death within hours; and
- Intracellular pH consistency with the release of acidic lysosomal contents. Early seminaphthorhodafluor-1 (“SNARF-1”) staining work by Provectus confirmed lower intracellular pH upon exposure to PV-10 (RB).

Dermatology. For psoriasis, pathways significantly improved include published psoriasis transcriptomes and cellular responses mediated by IL-17, IL-22, and interferons. Clinical work has shown that more than 500 disease-related genes were down-regulated after four weeks of PH-10 application and expression of a wide-range of central “psoriasis related” genes including IL-23, IL-17, IL-22, S100A7, IL-19, IL-36, and CXCL1 were effectively normalized; that is, treated lesional skin had values in the same range as baseline non-lesional skin.

Our Drug Development Strategy for Oncology

The Company’s strategy is to (i) demonstrate the independent action of single-agent PV-10; that is, safety and activity in T cell and non-T cell inflamed tumor types, in high and low tumor mutation burden tumor types, and in other tumor type categories, such as gene mutations, (ii) demonstrate the coordinated induction of multiple immune signaling pathways (i.e., functional immunogenic cell death [“ICD”]; [Snyder et al., *Sci Immunol* 2019](#)) by PV-10 treatment, (iii) demonstrate the functional T cell response generated by PV-10 treatment, and (iii) contrast and compare PV-10 treatment – safety, activity, and induced immune response – with that of immune checkpoint inhibition (“CI”) and other drug classes in single-agent and PV-10-based combination therapy settings.

This strategy may quicken the advancement of single-agent PV-10 along a pathway-to-approval in solid tumor cancer indications where there is high unmet need, limited activity from other therapies, and the opportunity to display the immune response from PV-10 treatment, such as neuroendocrine tumors (“NET”) metastatic to the liver (“mNET”) ([NCT02693067](#)). This strategy may also permit the Company to develop and advance a cancer combination therapy involving one or more CI and/or other drug classes along a pathway-to-approval in a disease indication where there is high unmet need, limited activity from standard of care (“SOC”) treatment, and the opportunity to display how PV-10 augments clinical response to existing or emerging SOC, such as uveal melanoma metastatic to the liver (“mUM”) (i.e., combination therapy with an anti-CTLA-4 agent and an anti-PD-1 agent) ([NCT00986661](#)).

Our Drug Development Strategy for Dermatology

The Company’s strategy is to (i) demonstrate 12-week single-agent administration proof-of-concept (“POC”) for PH-10 that includes (a) a preclinical safety study of extended 12-week administration (compared to, previously, four weeks), (b) a clinical mechanism of action study in atopic dermatitis, which would be a “book-end” trial to the already completed clinical mechanism study in psoriasis, (c) Phase 2 randomized controlled trials of PH-10 for the treatment of psoriasis and atopic dermatitis that may potentially utilize SOC comparators, and (d) end-of-Phase 2 meetings with the FDA upon the completion of the abovementioned Phase 2 trials, and (ii) expand POC PH-10 treatment to include dermatology combination therapy. Our goal for this POC work is to achieve Phase 3 trial-ready status for PH-10 in both psoriasis and atopic dermatitis.

Product Pipeline

Oncology (PV-10)

Melanoma (single-agent)

- Completed Phase 1 and 2 studies ([NCT00219843](#) and [NCT00521053](#), respectively).
- Orphan drug designation (“ODD”) status was granted by the U.S. Food and Drug Administration (the “FDA”) for metastatic melanoma.
- In 2019, terminated a Phase 3 study ([NCT02288897](#)).
- In 2019, results from an investigator-conceived and led, single-center study of in-transit melanoma (“ITM”) patients receiving either regionally-administered isolated limb infusion (“ILI”) or PV-10 to assess and compare the effect of these treatments on survival by principal investigators at the Princess Alexandra Hospital in Brisbane, Australia (where isolated limb infusion represents the historical standard of care for ITM and PV-10 was used to treat the disease under expanded access) was published: Read et al. Patients with in-transit melanoma metastases have comparable survival outcomes following isolated limb infusion or intralesional PV-10—A propensity score matched, single center study. *J Surg Oncol*. 2019.

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

- *With CI drug KEYTRUDA® (pembrolizumab) – Ongoing Phase 1b/2 study for metastatic melanoma (Stage III-IV) (NCT02557321); in 2019, we:*
 - Reported updated data from the Main Cohort of CI-naïve patients at the annual meetings of the American Society of Clinical Oncology (“ASCO”), including preliminary progression-free survival (PFS) and changes in T cell populations (Agarwala et al., ASCO 2019), and Society for Melanoma Research (“SMR”), including 12-month overall survival (“OS”) and disease-specific survival (“DSS”) rates, and median OS and DSS (Agarwala et al., SMR 2019),
 - Continued to enroll patients in an Expansion Cohort of CI-refractory patients,
 - Reported preliminary data from the Expansion Cohort of CI-refractory patients at SMR, including objective response and disease control rates (“ORR” and “DCR,” respectively), and changes in immune system activation biomarkers (Zager et al., SMR 2019), and
 - Continued to enroll patients in an Expansion Cohort of patients with satellite or in-transit disease. These patients are typically CI-naïve.

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.
- FDA ODD status was granted for HCC.
- In 2019, FDA ODD status was granted for ocular melanoma (including uveal melanoma).
- Ongoing Phase 1 study of symptomatic mNET (NCT02693067); in 2019, we:
 - Continued to enroll in the Second Cohort, and
 - Reported preliminary data from the First Cohort at ASCO, including lesion-level ORR and DCR, and Chromogranin A responses and quality of life scores (Price et al., ASCO 2019).

Gastrointestinal Cancers (combination therapy)

- *With CI combination of YERVOY® (ipilimumab) and OPDIVO® (nivolumab)* – Ongoing Phase 1 basket study of HCC and other solid tumors metastatic to the liver ([NCT00986661](#)); in 2019:
- Continued to enroll patients in the single-site cohort of mUM patients treated with single-agent PV-10, the combination therapies of PV-10+KEYTRUDA or PV-10+OPDIVO, or the combination therapy of PV-10, YERVOY, and OPDIVO, and
- Reported updated uveal melanoma single-agent PV-10 and PV-10 based combination therapy data at the 2019 European Society for Medical Oncology (“ESMO”) Immuno-Oncology Congress (“ESMO I-O”), including lesion-level ORR and DCR ([Patel et al., ESMO I-O 2019](#)), and patient-level ORR and PFS ([Carter et al., ESMO I-O 2019](#)).

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 2019:
- Results from POETIC’s preclinical work on *in vitro* and animal tumor model studies of PV-10 for the treatment of relapsed and refractory neuroblastoma was published: Swift et al. [Potent in vitro and xenograft antitumor activity of a novel agent, PV-10, against relapsed and refractory neuroblastoma. *Onco Targets Ther.* 2019.](#)
- FDA ODD was granted for [neuroblastoma](#).

Dermatology (PH-10)

Toxicology

- Completed non-clinical, single-administration studies to demonstrate lack of systemic uptake, as part of toxicology work to support extended 12-week administration.

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 for direct injection into tumors as an autolytic immunotherapy, where (a) cancer cells in injected tumors die from self-digestion (i.e., autolytic death), which activate the innate immune system, and (b) a tumor-specific immune response can result via downstream activation of the adaptive immune system (i.e., immunotherapy).

Locally Advanced and Widely Metastatic Melanoma

A 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 (NCT02288897). The primary outcome measure of the study was progression-free survival ("PFS") assessed every 12 weeks for up to 18 months. Secondary outcome measures include complete response ("CR") rate and its duration, and OS, all also assessed every 12 weeks up to 18 months. In October 2019, we terminated the trial due to an inadequate enrollment rate, which was due in large part to systemic therapy with CI being 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, Liu et al., *Oncotarget* 2016, and Pilon-Thomas et al., *J Immunother Cancer* 2016) and the University of Illinois at Chicago (Qin et al., *Cell Death Dis* 2017) indicate that PV-10 functions as an autolytic immunotherapy in laboratory models of multiple tumor types, such as melanoma, breast cancer, colon cancer, and pancreatic cancer. These collaborators definitively classify PV-10 as an autolytic immunotherapy capable of yielding ICD, 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 2019, additional mechanism work was underway to assess the potential breadth of this immunotherapy capability in other tumor types.

In January 2019, principal investigators at the Princess Alexandra Hospital published results from an investigator-conceived and led, single-center study of ITM patients receiving either regionally-administered ILI or intratumoral PV-10 to assess and compare the effect of these treatments on survival, including:

Baseline and disease characteristics:

- Patients matched for key covariates: Age, gender, primary disease site, and Breslow thickness,
- ILI: 36 patients; 56% men; median age of 76.5 years (interquartile range 69-83); 100% Stage IIB/IIIC, and
- PV-10: 36 patients; 56% men; median age of 74.5 years (65-81); 89% Stage IIV/IIIC (11% Stage IV).

Treatment response (patient-level best overall response ["BORR"]):

- ILI: 22% CR and 50% ORR, and
- PV-10: 25% CR and 83% ORR.

ILI survival outcomes:

- Median PFS of 5.0 months (interquartile range 2.7-10.7),
- Median disease-free survival ("DFS") of 16.5 months (8.9-48.4),
- Median OS of 29.7 months (12.3-88.5), and
- Median melanoma-specific survival ("MSS") of 74.4 months (24.3-NA); 12-,24-,36-, and 60-month MSS rates of 85%, 75%, and 60%, respectively.

PV-10 survival outcomes:

- Median PFS of 3.9 months (9.6-47.9),
- Median DFS of 14.1 months (4.5-20.9),
- Median OS of 27.1 months (14.3-48.6),
- Median MSS of 36.4 months (16.6-65.3); 12-, 24-, 36-, and 60-month MSS rates of 83%, 70%, 54%, and 36%, respectively, and
- Differences in PFS, DFS, and MSS comparing ILI with PV-10 were not statistically significant.

For those patients with more advanced melanoma that is not fully accessible to injection (Stage IV), we are assessing PV-10 in combination with CI 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 CI. Updated data from the fully-enrolled Phase 1b study portion of 21 CI-naïve patients were reported at the SMR annual meeting in November 2019, including:

- Baseline characteristic: Median age of 69 years (range 28-82),
- Disease characteristics: 52% Stage IV M1b-c; median of 2 injectable lesions (range 1-15); most patients had substantial non-injected systemic disease burden,
- Treatment summary: Patients received a median of 5 cycles of PV-10 (mean 3.8, range 1-5) and a median of 5 total injections of PV-10 (mean 11.7, range 1-82); PV-10 was not administered after week 12,
- Safety: Adverse events were consistent with the established patterns for the single-agent use of each drug; principally Grade 1-2 injection site reactions to PV-10; principally Grade 1-3 immune-mediated reactions to KEYTRUDA,
- Injected target lesion efficacy (BORR): 75% CR, 79% ORR, and 86% DCR for 28 injected lesions in 21 patients; 85% CR and 92% DCR for 13 injected lesions in 11 M1b-c patients,
- Overall patient efficacy (BORR, RECIST 1.1): 10% CR and 67% ORR for 21 patients; 9% CR and 82% ORR for M1b-c patients, and
- Durability: 95% 12-month OS rate; 100% 12-month DSS rate; median OS and DSS were not reached; median PFS of 11.7 months.

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 CI-refractory and a Second Expansion Cohort of up to 24 patients who have satellite or in-transit disease. Both expansion cohorts continue to enroll patients. Preliminary data from 10 CI-refractory patients were reported at the same SMR annual meeting, including:

- Baseline characteristic: Median age of 77 years (range 54-90); compared to the median age of 69 years (range 28-62) of the CI-naïve cohort,
- Disease characteristics: 50% Stage IV M1b-d; 50% of patients were refractory to single-agent and dual-agent checkpoint inhibition treatment (KEYTRUDA, YERVOY, or OPDIVO and YERVOY),
- Treatment summary: PV-10 was limited to 5 cycles,
- Safety: Adverse events were consistent with the established patterns for the single-agent use of each drug; 1 patient withdrew due to an adverse reaction to KEYTRUDA,
- Overall patient efficacy (BORR, RECIST 1.1): 20% ORR and 40% DCR; 2 of 10 patients were not evaluated (“NEV”),
- Durability: Median OS and DSS were not reached; median PFS of 4.9 months, and
- Changes in peripheral blood biomarkers: Initial correlative results for these highly checkpoint inhibition-refractory patients were consistent with prior evidence of immune activation by PV-10 in checkpoint inhibition-naïve patients, both as a single-agent and in combination with KEYTRUDA; PV-10-based combination therapy-treated CI-refractory patients exhibited a damage-associated molecular pattern (“DAMP”) profile similar to the DAMP profile of CI-naïve patients receiving single-agent PV-10 ([NCT01760499](#)).

Research collaborators 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](#)), 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. Similar effects were also observed with PV-10 and anti-CTLA-4 antibody in the B16 tumor model.

Gastrointestinal Cancers

During 2019, we continued our exploratory Phase 1 study of cancers of the liver. 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 one or more liver lesions. 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 2018, we announced that the Phase 1 study had expanded to include a single-site cohort of mUM patients. Eligible mUM patients may also receive standard of care checkpoint blockade during and after treatment with PV-10. Updated data from this cohort were reported at the ESMO I-O meeting in December 2019, including:

- Baseline characteristics: 46% men; median age of 61 years; 46% elevated LDH,
- Disease characteristics: 100% Stage IV M1a-b; 38% of patients were refractory to one or more prior lines of treatment, with 31% having received prior immunotherapy,
- Treatment summary: 7 patients received 1 cycle of PV-10; 6 patients received 2 cycles; 26 tumors were injected with PV-10,
- Combination therapy: 9 patients received concomitant standard of care checkpoint blockade (i.e., maintenance anti-PD-1, anti-PD-1 subsequent to PV-10 treatment, or anti-CTLA-4+anti-PD-1 subsequent to PV-10 treatment),
- Safety: 3 cases of Grade 3/4 transaminitis that resolved to Grade 1 or better within 72 hours; additional Grade 1 PV-10 related events seen in 1 patient each included pink stool, pink urine, photosensitivity, injection site pain, and hyperbilirubinemia; Additional adverse events, such as nausea, headache, myalgias, blurry vision, decreased white blood cells, and fatigue, were attributed to concomitant checkpoint blockade, and
- Preliminary injected target lesion efficacy: 32% ORR and 82% DCR.

In February 2019, the Company was granted FDA ODD for PV-10 for the treatment of for the treatment of ocular melanoma (to include all melanoma disease including that affecting the eye and orbit). The FDA grants ODD 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. ODD 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.

In 2017, we initiated clinical activity in a Phase 1 study to assess PV-10 as an autolytic immunotherapy for patients with symptomatic mNET at The Queen Elizabeth Hospital in Adelaide, Australia. This study 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 NET. Updated data were reported at the ASCO annual meeting in June 2019, including:

- Baseline characteristics: 67% men; median age of 65 years (range 47-72),
- Disease characteristics: primary tumor site – 50% small intestine, 33% pancreas, and 17% caecal; 87% Grade 2 (well differentiated, intermediate); all patients were refractory to systemic somatostatin analogues and peptide receptor radionuclide therapy,
- PV-10 treatment summary: Median of 1 cycle (mean 1.7, range 1-4) and median dose per cycle of 2.1 mL (range 1.0-5.8 mL),
- Preliminary safety: Acceptable toxicity (e.g., post-procedure pain, carcinoid flare, nausea); liver function tests have remained stable,
- Preliminary target lesion efficacy: 50% objective response and 87% disease control; response follow-up in 3 patients (50%) is ongoing, and
- Preliminary clinical and biomarker outcomes: overall quality of life scores were stable in 5 patients (87%); Chromogranin A responses were stable in 5 patients (87%).

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 February 2019, POETIC researchers published preclinical work on in vitro and animal tumor model studies of PV-10 for the treatment of relapsed and refractory neuroblastoma: Swift et al. Potent in vitro and xenograft antitumor activity of a novel agent, PV-10, against relapsed and refractory neuroblastoma. *Onco Targets Ther.* 2019. According to the POETIC authors,

“Our studies provide preclinical proof-of-concept data on the efficacy of PV-10 in neuroblastoma. Mechanistically, we have found that PV-10 acts by disrupting lysosomes, inducing cell cycle changes and initiating cell death by apoptosis. We have also identified several commonly used treatments with which PV-10 shows synergistic anti-tumor activity. Furthermore, we have validated the efficacy of PV-10 in vivo, using neuroblastoma xenograft mouse experiments. Our experiments, carried out in representative cell lines and in tumor bearing mice, provide evidence for the direct cytotoxic potential of PV-10, as well as mechanisms by which this agent may induce target modulatory effects in cancer cells. We have also identified agents that can be combined to generate treatment synergy, providing the framework for the formulation of early phase clinical trials. This, in addition to the expected immunostimulatory effect of PV-10 described previously, provides support for a potential approach where a PV-10 backbone regimen can be combined with agents such as immune checkpoint inhibitors to further enhance its activity in patients with relapsed or refractory neuroblastoma.”

Among the authors’ results, PV-10 was shown to be cytotoxic to neuroblastoma cell lines, to disrupt tumor lysosomes, to induce both apoptosis and necrosis in neuroblastoma, to be synergistic with multiple standard anticancer agents, to induce radiosensitivity in neuroblastoma cell lines, and to lead to tumor regression *in vivo*.

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 (Krueger et al.). 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 began 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 ¹⁴C-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 systemic, distant target organ effects from topical application of PH-10. The goal of a planned, non-clinical, toxicology-focused, 12-week administration study is 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 in oncology 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). In both paths, direct delivery of PV-10 to cancerous tumor (i.e., intratumoral delivery) maximizes local therapeutic potential while minimizing potential for toxicity in normal tissue.

Our approach to drug development in dermatology comprises a similar approach, where direct delivery of PH-10 to diseased tissue (i.e., topical delivery) maximizes local therapeutic potential while minimizing potential for toxicity in normal tissue.

We believe these approaches optimize potential value in the single-agent setting while providing favorable pharmacologic properties for the use of PV-10 or PH-10, respectively, in combination with other systemic therapies.

Intellectual Property (“IP”)

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 certain patents in the following table:

U.S. Patent No.	Title and Cross Reference	Issue Date	Expiration Date
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

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
10,471,144	Combination of local rose bengal and systemic immunomodulative therapies for enhanced treatment of cancer	November 12, 2019	November 12 2034

New U.S. Patents

In 2019, we received U.S. patent no. 10,471,144, entitled “Combination of local rose bengal and systemic immunomodulative therapies for enhanced treatment of cancer.”

Competition

In general, the pharmaceutical and biotechnology industries are competitive, characterized by steady and sometimes disruptive 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. 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 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 early controlled clinical studies conducted to obtain 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 often randomized controlled studies that are 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 definitive 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 submissions, 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

On March 25, 2019, the Company's Board of Directors (the "Board") named Heather Raines, CPA as Chief Financial Officer ("CFO"). On May 9, 2019, the Board named Bruce Horowitz as Chief Operating Officer ("COO").

Employees

We have two full-time employees. We also engage independent contractors, who currently serve as COO, director of clinical operations, senior scientist, clinical research associates, project manager, information technology manager, controller, patient advocacy manager, and database manager.

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 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, 2019, we have incurred net losses of approximately \$234 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 2020 and beyond, and our ability to obtain the necessary funding is uncertain.

We need additional capital in 2020 and beyond to continue developing and seeking to commercialize our drug product candidates. We intend to continue with the development of PV-10 and PH-10 on the basis of historical, ongoing, and prospective clinical study and/mechanism, of action 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 (the “PRH Group”), which was amended and restated effective as of March 19, 2017 (the “2017 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 and up to \$20 million (the “2017 Financing”). On December 20, 2019, we concluded the 2017 Financing. As of December 31, 2019, we have raised \$20,067,000 through the 2017 Financing.

On December 31, 2019, our Board approved a Definitive Financing Term Sheet (the “2020 Term Sheet”), which set forth the terms under which we will use our best efforts to arrange for financing of a maximum of \$20,000,000 (the “2020 Financing”). We intend to acquire additional funding through the 2020 Financing. 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.

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

Our cash and cash equivalents were \$590,706 at December 31, 2019, compared with \$50,986 at December 31, 2018. 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 2020 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 drug product candidates, PV-10 and PH-10, for use as treatments for specific disease indications. The continued and further development of these 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 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 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.

Before obtaining regulatory approval for the sale of our 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 currently conducting (i) a Phase 1 trial of single-agent PV-10 and PV-10-based combination therapy for HCC and other solid tumors metastatic to the liver, (ii) a Phase 1 trial of single-agent PV-10 for symptomatic mNET, and (iii) a Phase 1b/2 combination therapy study of PV-10 and CI for locally advanced and widely metastatic melanoma. 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.

Our research and development expenses may increase in connection with expanding clinical trials of our product candidates in existing indications and undertaking clinical trials of our product candidates in new indications. Because successful development of our 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 may be 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 acceptable label 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 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 could 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 drug product candidates, physicians and patients may not accept and use them. Acceptance and use of our 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 drug products, availability of reimbursement for our 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 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 approved drug products, investigational drug products, and generic equivalents.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other IP, 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 IP protection, which could reduce our anticipated sales. While some of our drug product candidates have proprietary patent protection, a challenge to these patents can subject us to expensive litigation. Litigation concerning patents, other forms of IP, and proprietary technology is becoming more widespread and can be protracted and expensive and can distract management and other personnel from performing product development 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 IP, our business, financial condition, results of operations and cash flows could be materially adversely affected. If we infringe on the IP of others, our business could be harmed.

We could be sued for infringing patents and other IP 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) Bruce Horowitz, our COO, who is an independent contractor, (ii) Heather Raines, CPA, our CFO, (iii) Dominic Rodrigues, who is vice chair of the Board, and (iv) Eric Wachter, Ph.D., our Chief Technology Officer (“CTO”).

In order to successfully execute our business plan, our management and Board 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.

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.

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.

In the event of the sale, liquidation or dissolution of the Company or any of our assets, holders of shares of a yet-to-be designated Series D Preferred Stock will be entitled to a preference of a multiple of their investment amount, which will reduce the proceeds to be received by holders of our common stock.

In connection with the 2017 Financing and 2020 Financing, we have issued convertible notes that will become convertible into shares of a yet-to-be designated Series D Preferred Stock. The Series D Preferred Stock will have a first priority right to receive proceeds from the sale, liquidation or dissolution of us or any of our assets (each, a "Company Event"). If a Company Event occurs within two (2) years of the date of issuance of the Series D Preferred Stock (the "Date of Issuance"), the holders of Series D Preferred Stock will receive a preference of four times (4x) their respective investment amount. If a Company Event occurs after the second (2nd) anniversary of the Date of Issuance, the holders of the Series D Preferred Stock will receive a preference of six times (6x) their respective investment amount. As a result, upon the occurrence of a Company Event, the holders of Series D Preferred Stock would have the right to receive proceeds from any such transaction before our common stockholders. The payment of this preference could result in our common stockholders not receiving any consideration in connection with a Company Event.

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 \$7,607 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.

PART II

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

Market Information and Holders

Our common stock and listed warrants trade on the OTCQB Marketplace under the symbols "PVCT" and "PVCTWS," respectively.

As of March 2, 2020, we had 853 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, 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.

During the year ended December 31, 2019, we issued 229,090 shares of common stock as incentive compensation with a value of \$11,538.

During the year ended December 31, 2019, we issued 387,500 five-year immediately vested warrants to a consultant to purchase an aggregate of 387,500 shares of common stock with exercise prices ranging from \$1.00 to \$2.00 per share. The warrants had an aggregate grant date fair value of \$10,113, which was recognized immediately within stock compensation in general and administrative expenses.

During the year ended December 31, 2019, we issued 37,500 three-year immediately vested warrants to a consultant to purchase an aggregate of 37,500 shares of common stock with an exercise price of \$0.2862 per share. The warrants had an aggregate grant date fair value of \$1,328, which was recognized immediately within stock compensation in general and administrative expenses.

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 2020 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

Provectus is a clinical-stage biotechnology company developing a new class of drugs for oncology, hematology, and dermatology based on an entire, wholly-owned, family of chemical small molecules called halogenated xanthenes. Intratumoral (aka intralesional) PV-10[®], the first small molecule autolytic immunotherapy, which can induce immunogenic cell death, is undergoing clinical study for adult solid tumor cancers, such as melanoma and GI tumors (e.g., hepatocellular carcinoma, metastatic colorectal cancer, metastatic neuroendocrine tumors, metastatic uveal melanoma), and preclinical study for pediatric solid tumor cancers (e.g., neuroblastoma, Ewing sarcoma, rhabdomyosarcoma, osteosarcoma) and blood cancers (e.g., acute myeloid leukemia). Topical PH-10[®] is undergoing clinical study for inflammatory dermatoses (e.g., psoriasis, atopic dermatitis).

Our Advisory Boards

The Company named a second member, Frank Akers, Ph.D., to its Strategic Advisory Board effective as of September 1, 2019. The purpose of the Strategic Advisory Board is for the Company to have formal access to a group of independent people with significant, meaningful, professional experience who provide high quality, objective advice to the Company in areas of strategic importance, including but not limited to business development, corporate development, and business operations (such as clinical operations, drug development, regulatory affairs, and manufacturing of drug substance and drug product). The Company named the first member, Harold Schmitz, Ph.D., to its Scientific Advisory Board effective as of September 1, 2019. The purpose of the Scientific Advisory Board is for the Company to have formal access to a group of independent people with significant, meaningful, professional experience who provide high quality, objective advice to the Company in areas of strategic scientific importance, such as but not limited to the Company’s science and technology, and drug development.

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 “2017 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, 2019, the Company had received aggregate Loans, as defined below, of \$20,067,000 in connection with the 2017 Financing.

The 2017 Financing is in the form of a secured convertible loan (the “1st Loan”) from the PRH Group or other investors in the 2017 Financing (the “1st Loan Investors”). The 1st Loan is evidenced by secured convertible promissory notes (individually a “2017 Note” and collectively, the “2017 Notes”) from the Company to the PRH Group or the 1st Loan Investors. In addition to the customary provisions, the 2017 Notes contains the following provisions:

- (i) It is secured by a first priority security interest on the Company’s IP,
- (ii) The 1st Loan bears interest at the rate of 8% per annum on the outstanding principal amount of the 2017 Notes that has been funded to the Company,
- (iii) The 1st 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 2017 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 2017 Notes, (ii) upon a change of control of the Company, or (iii) dates ranging from May 18, 2020 to the 18-month anniversary of the funding of the Final Tranche. In the event there is a change of control of the Company’s Board as proposed by any person or group other than the 1st Loan Investors, the term of the 2017 Notes will be accelerated and all amounts due under the 2017 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 1st Loan that has been funded to the Company,
- (v) The outstanding principal amount and interest payable under the 1st Loan will become convertible at the sole discretion of the 1st Loan 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 2017 Notes and the interest payable under the 1st 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 18-month 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.

Pursuant to the 2017 Term Sheet, the PRH Group concluded its best efforts activity to arrange for a financing of \$20,000,000, which amounts were provided in a number of tranches, between the first tranche on April 4, 2017 and the Final Tranche, on December 20, 2019. As a result, the 2017 Notes under the 1st Loan will convert into shares of Series D Preferred Stock (once designated) of the Company on or before June 20, 2021, which is the 18-month anniversary of the funding of the Final Tranche of the 2017 Financing, subject to certain exceptions.

Upon conversion of the 2017 Notes, the 1st Loan Investors will release their first lien on the Company’s IP.

2020 Financing

On December 31, 2019, the Board approved a Definitive Financing Term Sheet (the “2020 Term Sheet”), which sets forth the terms under which the Company will use its best efforts to arrange for financing of a maximum of \$20,000,000 (the “2020 Financing”).

As of December 31, 2019, the Company had received aggregate 2nd Loans, as defined below, of \$100,000 in connection with the 2020 Financing.

Pursuant to the 2020 Term Sheet, the 2020 Notes (defined below) will convert into shares of the Company's Series D Preferred Stock on or before June 20, 2021, subject to certain exceptions. As of December 31, 2019, and through the date of filing, the Series D Preferred Stock had not been designated by the Board.

The 2020 Term Sheet is similar to the 2017 Term Sheet. Subject to the terms and conditions of the 2020 Term Sheet, the Company will use its best efforts to arrange for the 2020 Financing, which amounts will be obtained in several tranches. The proceeds from the 2020 Financing will be used to fund the Company's clinical development program, as currently constituted and envisioned, and to fund the Company's general and administrative expenses.

The 2020 Financing will be in the form of a secured convertible loan (the "2nd Loan") from the Investors (the "2nd Loan Investors") that will be evidenced by convertible promissory notes (individually, a "2020 Note" and collectively, the "2020 Notes") subordinate to the 2017 Notes in right of payment and to the security interests granted to holders of the 2017 Notes. In addition to customary provisions, the 2020 Notes contains the following provisions:

(i) It will be secured by a second priority security interest on the Company's IP subordinate to the first priority security interest of the 2017 Notes;

(ii) The 2nd Loan will bear interest at the rate of eight percent (8%) per annum on the outstanding principal amount of the 2nd Loan that has been funded to the Company;

(iii) In the event there is a change of control of the Company's Board, the term of the 2020 Notes will be accelerated and all amounts due under the 2020 Notes will be immediately due and payable, plus interest at the rate of eight percent (8%) per annum, plus a penalty in the amount equal to ten times (10x) the outstanding principal amount of the 2nd Loan that has been funded to the Company;

(iv) The outstanding principal amount and interest payable under the 2nd Loan will become convertible at the sole discretion of the 2nd Loan Investors into shares of the Company's Series D Preferred Stock, a series of preferred stock to be designated by the Board, at a price per share equal to \$2.8620; and

(v) Notwithstanding (iv) above, the principal amount of the 2020 Notes and the interest payable under the 2nd Loan will automatically convert into shares of the Company's Series D Preferred Stock at a price per share equal to \$2.8620 effective on June 20, 2021 subject to certain exceptions.

Upon conversion of the 2nd Loan, the 2nd Loan Investors will release their second lien on the IP. 2nd Loan Investors in the 2020 Financing will hold Series D Preferred Stock *pari passu* with the Series D Preferred Stock of 1st Loan Investors in the 2017 Financing.

The Series D Preferred Stock

As of December 31, 2019, and through the date of filing, the Series D Preferred Stock had not been designated by the Board. Per the terms of the 2017 Notes and 2020 Notes, if the Company has not designated the Series D Preferred Stock or if an insufficient number of Series D Preferred shares exist upon a conversion by a note holder, then the outstanding loans will continue to accrue interest at a rate of 8% per annum until which time the Company has designated a sufficient number of Series D Preferred shares.

The Series D Preferred Stock will have a first priority right to receive proceeds from the sale, liquidation or dissolution of the Company or any of the Company's assets (each, a "Company Event").

If a Company Event occurs within two (2) years of the date of issuance of the Series D Preferred Stock (the "Date of Issuance"), the holders of Series D Preferred Stock will receive a preference of four times (4x) their respective investment amount. If a Company Event occurs after the second (2nd) anniversary of the Date of Issuance, the holders of the Series D Preferred Stock will receive a preference of six times (6x) their respective investment amount.

The Series D Preferred Stock will be convertible at the option of the holders thereof into shares of the Company's common stock based on a formula to achieve a one-for-ten conversion ratio. The Series D Preferred Stock will automatically convert into shares of the Company's common stock upon the fifth (5th) anniversary of the Date of Issuance.

On an as-converted basis, the Series D Preferred Stock will carry the right to ten (10) votes per share. The Series D Preferred Stock will not have any dividend preference but will be entitled to receive, on a *pari passu* basis, dividends, if any, that are declared and paid on any other class of the Company's capital stock. The holders of Series D Preferred Stock will not have anti-dilution protection.

Exercise of Warrants

In 2019, holders of 5,045,857 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 \$268,943.

Components of Operating Results

Research and Development Expenses

A large component of our total operating expenses is the Company's investment in research and development activities, including the clinical development of our product candidates. Research and development expenses represent costs incurred to conduct research and undertake clinical trials to develop our drug product candidates. These expenses consist primarily of:

- costs of conducting clinical trials, including amounts paid to clinical centers, clinical research organizations and consultants, among others;
- salaries and related expenses for personnel, including stock-based compensation expense;
- other outside service costs including cost of contract manufacturing;
- the costs of supplies and reagents;
- occupancy and depreciation charges.

We expense research and development costs as incurred.

Research and development activities are central to our business model. We expect our research and development expenses to increase in the future as we advance our existing product candidates through clinical trials and pursue their regulatory approval. Undertaking clinical development and pursuing regulatory approval are both costly and time-consuming activities. As a result of known and unknown uncertainties, we are unable to determine the duration and completion costs of our research and development activities, or if, when, and to what extent we will generate revenue from any subsequent commercialization and sale of our drug product candidates.

General and Administrative Expenses

General and administrative expense consists primarily of salaries, stock-based compensation expense and other related costs for personnel in executive, finance, accounting, business development, legal, information technology and corporate communication functions. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services.

Comparison of the Years Ended December 31, 2019 and 2018

Overview

Total operating expenses were \$6,299,696 for the year ended December 31, 2019, a decrease of \$1,754,529 or 21.8% compared to the year ended December 31, 2018. The decrease was driven primarily by our transformation and process improvement efforts within the Company. Net loss for the year ended December 31, 2019 was \$6,922,537, a decrease of \$1,230,518 or 15.1% which resulted from costs incurred in connection with our preclinical and clinical trial programs and general and administrative costs.

	For the Years Ended		Increase/ (Decrease)	% Change
	December 31,			
	2019	2018		
Operating Expenses:				
Research and development	\$ 4,002,014	\$ 4,747,557	\$ (745,543)	-15.7%
General and administrative	2,297,682	3,306,668	(1,008,986)	-30.5%
Total Operating Expenses	<u>6,299,696</u>	<u>8,054,225</u>	<u>(1,754,529)</u>	<u>-21.8%</u>
Total Operating Loss	(6,299,696)	(8,054,225)	(1,754,529)	21.8%
Other Income/(Expense):				
Gain on settlement of lawsuits	675,000	825,000	(150,000)	-18.2%
Research and development tax credit	134,081	26,325	107,756	409.3%
Investment and interest income	23,162	19,560	3,602	18.4%
Interest expense	<u>(1,455,084)</u>	<u>(969,715)</u>	<u>(485,369)</u>	<u>50.1%</u>
Net Loss	<u>\$ (6,922,537)</u>	<u>\$ (8,153,055)</u>	<u>\$ (1,230,518)</u>	<u>15.1%</u>

Research and Development

Research and development expenses were \$4,002,014 for the year ended December 31, 2019, a decrease of \$745,543 or 15.7% compared to the year ended December 31, 2018. The decrease was due to (i) lower clinical operations due to closure of Phase III study in 2019 and drug manufacturing in 2018, (ii) lower insurance costs, and (iii) lower payroll and related taxes due to a lower negotiated employment agreement.

The following table summarizes our research and development expenses incurred during the year ended December 31, 2019 and 2018:

	For the Years Ended		Increase/ (Decrease)	% Change
	December 31,			
	2019	2018		
Research and development:				
Clinical trial and research expenses	\$ 2,661,530	\$ 3,206,457	\$ (544,927)	-17.0%
Depreciation/amortization	679,767	679,767	-	0.0%
Insurance	258,067	285,853	(27,786)	-9.7%
Payroll and taxes	329,532	509,615	(180,083)	-35.3%
Rent and utilities	73,118	65,865	7,253	11.0%
Total research and development	<u>\$ 4,002,014</u>	<u>\$ 4,747,557</u>	<u>\$ (745,543)</u>	<u>-15.7%</u>

General and Administrative

General and administrative expenses were \$2,297,682 for the year ended December 31, 2019, a decrease of \$1,008,986 or 30.5% compared to the year ended December 31, 2018. The decrease was due to (i) lower legal fees as we concluded the Company's lawsuits against former accounting vendors, (ii) lower payroll and related taxes, and (iii) lower professional fees, partially offset by (vi) increased director fees (from having period-over-period, a five-member Board compared to a four-member Board in previous year).

The following table summarizes our general and administrative expenses incurred during the years ended December 31, 2019 and 2018:

	For the Years Ended		Increase/ (Decrease)	% Change
	December 31,			
	2019	2018		
General and administrative:				
Depreciation	\$ 5,445	\$ 5,445	\$ -	0.0%
Directors fees	385,000	333,357	51,643	15.5%
Insurance	170,384	187,367	(16,983)	-9.1%
Legal and litigation	509,810	1,318,785	(808,975)	-61.3%
Other general and administrative cost	118,790	115,000	3,790	3.3%
Payroll and taxes	305,074	490,386	(185,312)	-37.8%
Professional fees	765,654	822,458	(56,804)	-6.9%
Rent and utilities	37,525	33,870	3,655	10.8%
Total general and administrative	\$ 2,297,682	\$ 3,306,668	\$ (1,008,986)	-30.5%

Other Income/(Expense)

Other income decreased by \$38,642 from \$870,885 for the year ended December 31, 2018 to \$832,243 for the year ended December 31, 2019. During the year ended December 31, 2019, the matters with former accounting vendors Bible Harris Smith, PC (“BHS”) and RSM US LLP (“RSM”) were resolved pursuant to a settlement between these parties and the Company, the terms of which are confidential. During the year ended December 31, 2018, the matter with BDO USA LLP (“BDO”), the Company’s former external audit firm, was resolved pursuant to a settlement between the party and the Company, the terms of which are confidential.

Interest expense increased by \$485,369 from \$969,715 for the year ended December 31, 2018 to \$1,455,084 for the year ended December 31, 2019. The increase was due to the increased number of convertible notes payable relating to the 2017 Notes.

The following table summarizes our Other Income/(Expenses) incurred during the years ended December 31, 2019 and 2018:

	For the Years Ended		Increase/ (Decrease)	% Change
	December 31,			
	2019	2018		
Other Income/(Expense):				
Gain on settlement of lawsuits	675,000	825,000	(150,000)	-18.2%
Research and development tax credit	134,081	26,325	107,756	409.3%
Investment and interest income	23,162	19,560	3,602	18.4%
Interest expense	(1,455,084)	(969,715)	(485,369)	50.1%
Net Loss	\$ (6,922,537)	\$ (8,153,055)	\$ (1,230,518)	15.1%

Liquidity and Going Concern

Our cash and cash equivalents were \$590,706 at December 31, 2019, compared with \$50,986 at December 31, 2018. 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 \$233,816,828 as of December 31, 2019. 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 2020 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.

Access to Capital

Management plans to access capital resources through possible public or private equity offerings, including the 2020 Financing, exchange offers, debt financings, corporate collaborations, or other means. If we are unable to raise sufficient capital through the 2020 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 2020 and beyond. We anticipate that these funds will otherwise come from the proceeds of private placement transactions, including the 2020 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, 2019 and 2018, 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, 2019 and 2018 in the amounts of \$6,190,215 and \$5,204,926, respectively. The net cash used in operating activities for the year ended December 31, 2019 was primarily due to cash used to fund a net loss of \$6,922,537, adjusted for non-cash expenses in the aggregate amount of \$779,341, plus \$47,019 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, 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, partially reduced by \$2,182,916 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, 2019 and 2018, net cash used in investing activities was \$0 and \$0, respectively.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the years ended December 31, 2019 and 2018 was \$6,753,943 and \$5,150,408, respectively. During the year ended December 31, 2019, \$6,485,000 were proceeds from the issuance of convertible notes payable and \$268,943 were from the exercise of warrants. During the year ended December 31, 2018, \$4,476,000 were proceeds from the issuance of convertible notes payable and \$674,408 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.

INDEX TO FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets as of December 31, 2019 and 2018	F-2
Consolidated Statements of Operations for the Years Ended December 31, 2019 and 2018	F-3
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2019 and 2018	F-4
Consolidated Statements of Changes In Stockholders' Deficiency for the Years Ended December 31, 2019 and 2018	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2019 and 2018	F-6
Notes to Consolidated Financial Statements	F-7 – F-23

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, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in stockholders’ deficiency and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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.

Adoption of New Accounting Standard

ASU No.2016-02

As discussed in Note 3 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of ASU No. 2016-02, Leases (Topic 842), as amended, effective January 1, 2019, using the modified retrospective approach.

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 5, 2020

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	2018
Assets		
Current Assets:		
Cash and cash equivalents	\$ 590,706	\$ 50,986
Short-term receivables - legal fees, settlement and other, net	55,058	595,326
Prepaid expenses	350,249	370,209
Total Current Assets	996,013	1,016,521
Equipment and furnishings, less accumulated depreciation of \$64,630 and \$50,538, respectively	58,384	72,476
Operating lease right-of-use asset	194,400	-
Patents, net of accumulated amortization of \$11,487,338 and \$10,816,218, respectively	228,107	899,227
Total Assets	\$ 1,476,904	\$ 1,988,224
Liabilities and Stockholders' Deficiency		
Current Liabilities:		
Accounts payable - trade	\$ 1,125,890	\$ 3,312,049
Accrued interest	65,333	-
Convertible notes payable	500,000	-
Other accrued expenses	1,255,266	790,358
Current portion of operating lease liability	76,423	-
Total Current Liabilities	3,022,912	4,102,407
Accrued interest	1,501,864	659,379
Accrued interest - related parties	1,226,582	711,927
Convertible notes payable	12,997,000	7,062,000
Convertible notes payable - related parties	6,670,000	6,870,000
Non-current portion of operating lease liability	130,658	-
Total Liabilities	25,549,016	19,405,713
Commitments and contingencies (Note 10)		
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, 2019 and December 31, 2018; aggregate liquidation preference of \$3,500 at December 31, 2019 and December 31, 2018	-	-
Common stock; par value \$0.001 per share; 1,000,000,000 shares authorized; 389,889,475 and 384,614,528 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	389,889	384,615
Additional paid-in capital	209,378,835	209,092,187
Accumulated other comprehensive loss	(24,008)	-
Accumulated deficit	(233,816,828)	(226,894,291)
Total Stockholders' Deficiency	(24,072,112)	(17,417,489)
Total Liabilities and Stockholders' Deficiency	\$ 1,476,904	\$ 1,988,224

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2019	2018
Operating Expenses:		
Research and development	\$ 4,002,014	\$ 4,747,557
General and administrative	2,297,682	3,306,668
Total Operating Expenses	6,299,696	8,054,225
Total Operating Loss	(6,299,696)	(8,054,225)
Other Income/(Expense):		
Gain on settlement of lawsuits	675,000	825,000
Research and development tax credit	134,081	26,325
Investment and interest income	23,162	19,560
Interest expense	(1,455,084)	(969,715)
Net Loss	\$ (6,922,537)	\$ (8,153,055)
Basic and Diluted Loss Per Common Share	\$ (0.02)	\$ (0.02)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	386,593,634	382,338,471

See accompanying notes to consolidated financial statements.

PROVACTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	For the Years Ended December 31,	
	<u>2019</u>	<u>2018</u>
Net Loss	\$ (6,922,537)	\$ (8,153,055)
Other Comprehensive Loss:		
Foreign currency translation adjustments	(24,008)	-
Total Comprehensive Loss	<u>\$ (6,946,545)</u>	<u>\$ (8,153,055)</u>

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIENCY
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Series B Shares	Amount	Shares	Amount				
Balance at January 1, 2018	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 in lieu of accounts payable	-	-	1,000,000	1,000	79,000	-	-	80,000
Net loss	-	-	-	-	-	-	(8,153,055.00)	(8,153,055)
Balance at December 31, 2018	100	\$ -	384,614,528	\$384,615	\$209,092,187	\$ -	\$ (226,894,291)	\$(17,417,489)
Common stock issued upon exercise of warrants	-	-	5,045,857	5,045	263,898	-	-	268,943
Common stock issued for services	-	-	229,090	229	11,309	-	-	11,538
Warrants issued for services	-	-	-	-	11,441	-	-	11,441
Comprehensive loss:								
Net loss	-	-	-	-	-	-	(6,922,537)	(6,922,537)
Other comprehensive loss	-	-	-	-	-	(24,008)	-	(24,008)
Balance at December 31, 2019	100	\$ -	389,889,475	\$389,889	\$209,378,835	\$ (24,008)	\$ (233,816,828)	\$(24,072,112)

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2019	2018
Cash Flows From Operating Activities:		
Net loss	\$ (6,922,537)	\$ (8,153,055)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	22,979	80,000
Noncash lease expense	71,150	-
Depreciation	14,092	14,093
Amortization of patents	671,120	671,120
Changes in operating assets and liabilities		
Settlement receivable	4,907	528,235
Prepaid expenses	19,960	30,207
Accounts payable - trade	(2,186,159)	41,544
Other accrued expenses	731,134	613,215
Operating lease liability	(71,945)	-
Accrued interest expense	1,455,084	969,715
Net Cash Used In Operating Activities	(6,190,215)	(5,204,926)
Cash Flows From Financing Activities:		
Proceeds from issuance of convertible notes payable	6,435,000	2,606,000
Proceeds from issuance of convertible notes payable - related parties	50,000	1,870,000
Proceeds from exercise of warrants	268,943	674,408
Net Cash Provided By Financing Activities	6,753,943	5,150,408
Effect of Exchange Rate Changes on Cash	(24,008)	-
Net Increase (Decrease) In Cash and Cash Equivalents	539,720	(54,518)
Cash and Cash Equivalents, Beginning of Year	50,986	105,504
Cash and Cash Equivalents, End of Year	\$ 590,706	\$ 50,986
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
Non-cash investing and financing activities:		
Offset of related party receivable against note payable, accrued interest, and accrued expenses	\$ 535,361	\$ 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 that is developing a new class of drugs for oncology, hematology, and dermatology based on an entire, wholly-owned, family of small molecules called halogenated xanthenes:

- **Oncology:** Intralesional (aka intratumoral) PV-10, a cancer immunotherapy, is undergoing clinical study for adult solid tumor cancers, like melanoma and gastrointestinal (“GI”) tumors (including hepatocellular carcinoma, metastatic colorectal cancer, metastatic neuroendocrine tumors, and metastatic uveal melanoma, among others). Orphan drug designation status has been granted to PV-10 by the U.S. Food and Drug Administration (the “FDA”) for the treatments of metastatic melanoma in 2006, hepatocellular carcinoma in 2011, and ocular melanoma (including uveal melanoma) in 2019.

PV-10 is also undergoing preclinical study for pediatric solid tumor cancers (including neuroblastoma, Ewing sarcoma, rhabdomyosarcoma, and osteosarcoma). Orphan drug designation status has been granted to PV-10 by the FDA for neuroblastoma in 2018.

- **Hematology.** PV-10 is also undergoing preclinical study for pediatric blood cancers (including leukemia).
- **Dermatology:** Topical PH-10, an immuno-dermatology agent, 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 \$590,706 at December 31, 2019, compared with \$50,986 at December 31, 2018. 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 2020 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 2020 Financing or otherwise, it will not be able to pay its obligations as they become due. Subsequent to December 31, 2019, the Company received an aggregate \$50,000 in connection with the 2020 Financing. In addition, holders of 800,000 warrants to purchase the common stock of the Company at \$0.0533 per share, have exercised these warrants. As a result, the Company has received aggregate proceeds in the amount of \$42,640. 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 2020 and beyond. The Company anticipates that these funds will otherwise come from the proceeds of private placement transactions, including the 2020 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 United States (“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 receivables, the recoverability and useful lives of long-lived assets, stock-based compensation, accrued 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, 2019, and 2018, 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, 2019 and 2018.

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 patents are being amortized over the remaining estimated useful lives of the patents, which is approximately one year. Annual amortization of the patents is expected to approximate \$228,000 in 2020.

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.

Leases

In February 2016, the Financial Accounting Standards Board (“FASB”) issued a new standard related to leases to increase transparency and comparability among organizations by requiring the recognition of operating lease right-of-use (“ROU”) assets and lease liabilities on the balance sheet (“ASC 842”) with amendments issued in 2018. Most prominent among the changes in the standard is the recognition of ROU assets and lease liabilities by lessees for those leases classified as operating leases. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The Company is also required to recognize and measure new leases at the adoption date and recognize a cumulative-effect adjustment in the period of adoption using a modified retrospective approach, with certain practical expedients available.

The Company adopted ASC 842 effective January 1, 2019 and elected to apply the available practical expedients. The standard had an impact on the Company’s consolidated balance sheets but did not have a material impact on the Company’s consolidated statements of operations or cash flows upon adoption. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases. The adoption of ASC 842 had a material impact on the Company’s consolidated balance sheet but did not have a material impact on the Company’s consolidated statement of operations.

The impact of the adoption of ASC Topic 842 on the balance sheet as of January 1, 2019 is as follows:

	<u>As Reported</u> <u>December 31, 2018</u>		<u>Adoption of</u> <u>ASC 842</u>		<u>Balance</u> <u>January 1, 2019</u>
Operating lease right-of-use asset	\$ -	\$	265,550	\$	265,550
Total assets	\$ 1,988,224	\$	265,550	\$	2,253,774
Current liabilities	\$ 4,102,407	\$	58,469	\$	4,160,876
Non-current portion of operating lease liability	\$ -	\$	207,081	\$	207,081
Total liabilities	\$ 19,405,713	\$	265,550	\$	19,671,263

Income Taxes

The Company accounts for income taxes under the liability method in accordance with 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 2019 or 2018.

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,	
	2019	2018
Warrants	126,109,532	136,824,138
Options	3,000,000	3,200,000
Convertible preferred stock	65,663	65,663
Total potentially dilutive shares	129,175,195	140,089,801

The potential dilutive effect of the conversion of the Company's convertible notes payable has been excluded from this table since the Company's Series D Preferred Stock has yet to be designated by the Board.

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, 2019 and 2018. The carrying amounts of the Company's financial assets and liabilities, such as cash and cash equivalents, receivables, other current assets, accounts 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 (\$61,380 and \$308,915 at December 31, 2019 and \$15,049 and \$336,031 at December 31, 2018, respectively), and expense accounts are translated at a weighted average exchange rate for the years then ended (\$53,210 and \$247,947 for the years ended December 31, 2019 and 2018, respectively). Equity is translated at historical rates and the resulting foreign currency translation adjustments are included as a component of accumulated other comprehensive income ("AOCI"), which is a separate component of shareholders' equity. Therefore, the U.S. dollar value of the non-equity translated items in the Company's consolidated financial statements will fluctuate from period to period, depending on the changing value of the U.S. dollar versus these currencies.

The Company engages in foreign currency denomination transactions with its Australian subsidiary. At the date that the transaction is recognized, each asset, liability, revenue, expense, gain or loss arising from the transaction is measured and recorded in the functional currency of the recording entity using the exchange rate in effect at that date. At each balance sheet date, recorded monetary balances denominated in a currency other than the functional currency are adjusted using the exchange rate at the balance sheet date, with gains or losses recorded in other income or other expense.

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. The fair value of the award is measured on the grant date and then is 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 June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 significantly changes the impairment model for most financial assets and certain other instruments. ASU 2016-13 will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets, which will generally result in earlier recognition of allowances for credit losses on loans and other financial instruments. ASU 2016-13 is effective for the Company's fiscal year beginning December 1, 2019 and subsequent interim periods. The Company is currently evaluating the impact the adoption of ASU 2016-13 will have on its consolidated financial statements. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments—Credit Losses, ASU 2019-05, Financial Instruments—Credit Losses (Topic 326) Targeted Transition Relief, ASU 2016-13, the FASB issued ASU 2019-10 Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) and ASU 2019-11 Codification Improvements to Topic 326, Financial Instruments—Credit Losses. These ASUs do not change the core principle of the guidance in ASU 2016-13. Instead these amendments are intended to clarify and improve operability of certain topics included within the credit losses standard. These ASUs will have the same effective date and transition requirements as ASU 2016-13. The Company adopted ASU 2016-13 on January 1, 2020 and it did not have a material impact on the 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 adopted ASU effective January 1, 2020 and it did not have a material impact on the Company’s consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles in Accounting Standards Codification (“ASC”) Topic 740, *Income Taxes*. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 will be effective for the Company’s fiscal year beginning after December 15, 2020, with early adoption permitted. The transition requirements are dependent upon each amendment within this update and will be applied either prospectively or retrospectively. The Company does not expect this ASU to have a material impact on its consolidated financial statements.

In January 2020, the FASB issued ASU 2020-01, “Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815).” ASU 2020-01 states any equity security transitioning from the alternative method of accounting under Topic 321 to the equity method, or vice versa, due to an observable transaction will be remeasured immediately before the transition. In addition, the ASU clarifies the accounting for certain non-derivative forward contracts or purchased call options to acquire equity securities stating such instruments will be measured using the fair value principles of Topic 321 before settlement or exercise. The ASU is effective for fiscal years beginning after December 15, 2020, and will be applied on a prospective basis. Early adoption is permitted. The Company is still evaluating the impact this standard will have on its consolidated financial statements and related disclosures.

4. Convertible Notes Payable

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 2017 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").

The 2017 Financing was in the form of a secured convertible loan (the "1st Loan") from the PRH Group or other investors in the 2017 Financing (the "1st Loan Investors"). The Loan was evidenced by secured convertible promissory notes (individually a "2017 Note" and collectively, the "2017 Notes") from the Company to the PRH Group or the Investors. In addition to the customary provisions, the 2017 Note contained the following provisions:

- (i) It is secured by a first priority security interest on the Company's IP,
- (ii) The 1st Loan bears interest at the rate of 8% per annum on the outstanding principal amount of the 2017 Notes that has been funded to the Company,
- (iii) The 1st 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 2017 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 2017 Notes, (ii) upon a change of control of the Company, or (iii) dates ranging from May 18, 2020 to the 18-month anniversary of the funding of the Final Tranche. In the event there is a change of control of the Company's Board as proposed by any person or group other than the Investors, the term of the 2017 Notes will be accelerated and all amounts due under the 2017 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 1st Loan that has been funded to the Company,
- (v) The outstanding principal amount and interest payable under the 1st Loan will become convertible at the sole discretion of the 1st Loan 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 2017 Notes and the interest payable under the 1st 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 18-month 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.

Pursuant to the 2017 Term Sheet, the PRH Group concluded its best efforts activity to arrange for a financing of \$20,000,000, which amounts were provided in a number of tranches, between the first tranche on April 4, 2017 and the Final Tranche on December 20, 2019. As a result, the 2017 Notes under the 1st Loan will convert into shares of Series D Preferred Stock of the Company (assuming such shares have been designated) on or before June 20, 2021, which is the 18-month anniversary of the funding of the Final Tranche of the 2017 Financing, subject to certain exceptions.

Upon conversion of the 2017 Notes, the 1st Loan Investors will release their first lien on the Company's IP.

2020 Financing

On December 31, 2019, the Board approved a Definitive Financing Term Sheet (the "2020 Term Sheet"), which sets forth the terms under which the Company will use its best efforts to arrange for financing of a maximum of \$20,000,000 (the "2020 Financing").

As of December 31, 2019, the Company had received aggregate 2nd Loans, as defined below, of \$100,000 in connection with the 2020 Financing.

The 2020 Term Sheet is similar to the 2017 Term Sheet. Subject to the terms and conditions of the 2020 Term Sheet, the Company will use its best efforts to arrange for the 2020 Financing, which amounts will be obtained in several tranches. The proceeds from the 2020 Financing will be used to fund the Company's clinical development program, as currently constituted and envisioned, and to fund the Company's general and administrative expenses.

The 2020 Financing will be in the form of a secured convertible loan (the "2nd Loan") from the Investors (the "2nd Loan Investors") that will be evidenced by convertible promissory notes (individually, a "2020 Note" and collectively, the "2020 Notes") subordinate to the 2017 Notes in right of payment and to the security interests granted to holders of the 2017 Notes. In addition to customary provisions, the 2020 Notes shall contain the following provisions:

- (i) It will be secured by a second priority security interest on the Company's IP subordinate to the first priority security interest of the 2017 Notes;
- (ii) The 2nd Loan will bear interest at the rate of eight percent (8%) per annum on the outstanding principal amount of the 2nd Loan that has been funded to the Company;
- (iii) In the event there is a change of control of the Company's Board, the term of the 2020 Notes will be accelerated and all amounts due under the 2020 Notes will be immediately due and payable, plus interest at the rate of eight percent (8%) per annum, plus a penalty in the amount equal to ten times (10x) the outstanding principal amount of the 2nd Loan that has been funded to the Company;
- (iv) The outstanding principal amount and interest payable under the 2nd Loan will be convertible at the sole discretion of the 2nd Loan Investors into shares of the Company's Series D Preferred Stock, a series of preferred stock to be designated by the Board, at a price per share equal to \$2.8620; and
- (v) Notwithstanding (iv) above, the principal amount of the 2020 Notes and the interest payable under the 2nd Loan will automatically convert into shares of the Company's Series D Preferred Stock at a price per share equal to \$2.8620 effective on June 20, 2021 subject to certain exceptions.

The Series D Preferred Stock

The Series D Preferred Stock shall have a first priority right to receive proceeds from the sale, liquidation or dissolution of the Company or any of the Company's assets (each, a "Company Event").

If a Company Event occurs within two (2) years of the date of issuance of the Series D Preferred Stock (the "Date of Issuance"), the holders of Series D Preferred Stock shall receive a preference of four times (4x) their respective investment amount. If a Company Event occurs after the second (2nd) anniversary of the Date of Issuance, the holders of the Series D Preferred Stock shall receive a preference of six times (6x) their respective investment amount.

The Series D Preferred Stock will become convertible at the option of the holders thereof into shares of the Company's common stock based on a formula to achieve a one-for-ten conversion ratio. The Series D Preferred Stock shall automatically convert into shares of the Company's common stock upon the fifth (5th) anniversary of the Date of Issuance.

On an as-converted basis, the Series D Preferred Stock shall carry the right to ten (10) votes per share. The Series D Preferred Stock shall not have any dividend preference but shall be entitled to receive, on a *pari passu* basis, dividends, if any, that are declared and paid on any other class of the Company's capital stock. The holders of Series D Preferred Stock shall not have anti-dilution protection.

As of December 31, 2019, and through the date of filing, the Series D Preferred Stock had not been designated by the Board. Per the terms of the 2017 Notes and 2020 Notes, if the Company has not designated the Series D Preferred Stock or if an insufficient number of Series D Preferred shares exist upon a conversion by a note holder, then the outstanding loans will continue to accrue interest at a rate of 8% per annum until which time the Company has designated a sufficient number of Series D Preferred shares. As a result, the Company did not analyze the 2nd Loan for a potential beneficial conversion feature as the definition of a firm commitment has not been met since the 2020 Notes were not convertible as of their respective dates of issuance or as of December 31, 2019. Upon conversion of the 2nd Loan, the 2nd Loan Investors will release their second lien on the IP. 2nd Loan Investors in the 2020 Financing will hold Series D Preferred Stock *pari passu* with the Series D Preferred Stock of 1st Loan Investors in the 2017 Financing.

Convertible Notes Payable – Related Parties

During the year ended December 31, 2018, the Company entered into 2017 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 2017 Notes from related parties which were outstanding.

During the year ended December 31, 2019, the Company entered into 2017 Notes with related parties in the aggregate principal amount of \$50,000 offset by the application of the 2017 Note in the principal amount of \$250,000 that the Company entered into with Timothy Scott and Leigh Anne Scott on February 28, 2018 that was applied to Dr. Scott's Kleba Settlement agreement. As of December 31, 2019, the Company had borrowed \$6,670,000 of 2017 Notes from related parties which were outstanding.

Convertible Notes Payable – Non-Related Parties

During the year ended December 31, 2018, the Company entered into 2017 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, all of which were outstanding as of that date.

During the year ended December 31, 2019, the Company entered into 2017 Notes with accredited investors in the aggregate principal amount of \$6,335,000. As of December 31, 2019, the Company had borrowed \$13,397,000 under these notes, all of which were outstanding as of that date. During the year ended December 31, 2019, the Company entered into a 2020 Note with an accredited investor in the principal amount of \$100,000. As of December 31, 2019, the Company had borrowed \$100,000 under this note.

5. Related Party Transactions

During the years ended December 31, 2019 and 2018, the Company paid Mr. Bruce Horowitz (Capital Strategists) consulting fees of \$277,200 and \$190,000, respectively, for services rendered. Accrued director fees for Mr. Horowitz as of December 31, 2019 and 2018 were \$75,000 and \$56,250, respectively. Mr. Horowitz serves as both COO and a Director.

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

Director fees during the years ended December 31, 2019 and 2018 were \$385,000 and \$333,357, respectively. Accrued directors' fees as of December 31, 2019 and 2018 were \$792,524 and \$407,524, respectively.

6. Receivables

The following table summarizes the receivables at December 31, 2019 and 2018:

	December 31, 2019			
	<u>Tax Credit</u>	<u>Legal Fees</u>	<u>Settlement</u>	<u>Total</u>
Provectus Australia Tax Credit	\$ 55,058			\$ 55,058
Gross receivable		\$ 455,500	\$ 1,649,043	\$ 2,104,543
Reserve for uncollectibility		(455,500)	(1,649,043)	(2,104,543)
Net receivable	<u>\$ 55,058</u>	<u>-</u>	<u>-</u>	<u>55,058</u>
Short-term receivable - Tax Credit	55,058	-	-	55,058
Short-term receivable - Settlement		-	-	-
Short-term receivable - Legal		-	-	-
Long-term receivable	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

	December 31, 2018			
	<u>Tax Credit</u>	<u>Legal Fees</u>	<u>Settlement</u>	<u>Total</u>
Provectus Australia Tax Credit	\$ 5,074			\$ 5,074
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	595,326
Short-term receivable - Tax Credit				
Short-term receivable - Settlement		-	134,752	134,752
Short-term receivable - Legal		455,500	-	455,500
Long-term receivable	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

During the year 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.

During the year ended December 31, 2019, officers of the Company offset their settlement amounts owed to the Company against accrued payroll and other payables totaling \$535,361. This offset reduced the amount of the settlement and was approved by the Company's Board.

See Note 12 - Litigation for additional details.

7. Stockholders' Deficiency

Authorized Capital

As of December 31, 2019, 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 (the "Series B 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 Preferred Stock, par value \$0.001 per share. 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, 2018, the Company issued 1,000,000 shares of immediately vested restricted common stock as payment of services, with an issuance date fair value of \$80,000, which was recognized immediately.

During the year ended December 31, 2019, the Company issued 229,090 shares of immediately vested restricted common stock with an issuance date value of \$11,538, which was recognized immediately.

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, 2019, there were 18,900,000 shares available for issuance under the 2014 Equity Compensation Plan.

There were no stock options granted during the years ended December 31, 2019 or 2018.

The following table summarizes option activity during the year ended December 31, 2019 and 2018:

	<u>Options</u>	<u>Weighted Average Exercise Price</u>
Outstanding and exercisable at January 1, 2018	3,350,000	\$ 0.90
Granted	-	-
Exercised	-	-
Forfeited	<u>(150,000)</u>	<u>0.89</u>
Outstanding and exercisable at December 31, 2018	<u>3,200,000</u>	<u>\$ 0.89</u>
Granted	-	-
Exercised	-	-
Forfeited	<u>(200,000)</u>	<u>0.88</u>
Outstanding and exercisable at December 31, 2019	<u>3,000,000</u>	<u>\$ 0.88</u>

The following table summarizes information about stock options outstanding at December 31, 2019.

<u>Exercise Price</u>	<u>Number Outstanding at December 31, 2019</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Number Exercisable at December 31, 2019</u>
\$ 0.67	200,000	3.60	200,000
\$ 0.75	950,000	4.11	950,000
\$ 0.84	150,000	2.50	150,000
\$ 0.88	150,000	4.60	150,000
\$ 0.93	575,000	1.76	575,000
\$ 0.99	50,000	1.50	50,000
\$ 1.00	525,000	0.60	525,000
\$ 1.04	200,000	1.50	200,000
\$ 1.16	200,000	.50	200,000
	<u>3,000,000</u>	<u>2.50</u>	<u>3,000,000</u>

As of December 31, 2019, 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.

During the year ended December 31, 2019, holders of warrants exercised warrants to purchase 5,045,857 shares of common stock at a price of \$0.053 per share. In connection with the exercises, the Company received cash proceeds of \$268,943 and issued 5,045,857 shares of common stock.

During the year ended December 31, 2019, the Company issued 387,500 five-year immediately vested warrants to a consultant to purchase an aggregate of 387,500 shares of common stock with exercise prices ranging from \$1.00 to \$2.00 per share. The warrants had an aggregate grant date fair value of \$10,113, which was recognized immediately within stock compensation in general and administrative expenses.

During the year ended December 31, 2019, the Company issued 37,500 three-year immediately vested warrants to a consultant to purchase an aggregate of 37,500 shares of common stock with an exercise price of \$0.2862 per share. The warrants had an aggregate grant date fair value of \$1,328, which was recognized immediately within stock compensation in general and administrative expenses.

In applying the Black-Scholes option pricing model to warrants granted, the Company used the following assumptions:

	For the Years Ended December 31,	
	2019	2018
Contractual terms (years)	3.00-5.00	N/A
Expected volatility	129%-131%	N/A
Risk-free interest rate	1.82%-2.23%	N/A
Expected dividend	0.00%	n/a

The following table summarizes warrant activity during the year ended December 31, 2019 and 2018:

	Warrants	Weighted Average Exercise Price
Outstanding and exercisable at January 1, 2018	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
Granted	425,000	0.94
Exercised	(5,045,857)	0.05
Forfeited	(6,093,749)	1.20
Outstanding and exercisable at December 31, 2019	126,109,532	\$ 0.29

The following table summarizes information about warrants outstanding at December 31, 2019.

Exercise Price	Number Outstanding at December 31, 2019	Weighted Average Remaining Contractual Life	Number Exercisable at December 31, 2019	Intrinsic Value at December 31, 2019
\$ 0.053	94,631,726	1.67	94,631,726	\$ 160,874
\$ 0.290	37,500	2.66	37,500	\$ -
\$ 0.85	28,482,344	0.48	28,482,344	\$ -
\$ 1.00	1,529,202	0.88	1,529,202	\$ -
\$ 1.12	366,000	4.39	366,000	\$ -
\$ 1.25	1,059,760	0.29	1,059,760	\$ -
\$ 2.00	3,000	4.39	3,000	\$ -
	126,109,532	2.11	126,109,532	\$ 160,874

Holders of the outstanding warrants are not entitled to vote and the exercise prices of such warrants are subject to customary anti-dilution provisions.

9. Income Taxes

The domestic and foreign components of loss before income taxes from operations for the years ended December 31, 2019 and 2018 are as follows:

	Year ended December 31	
	2019	2018
Domestic	\$ (6,975,747)	\$ (7,954,841)
Foreign	53,210	(198,214)
Net Pre-Tax Loss	<u>\$ (6,922,537)</u>	<u>\$ (8,153,055)</u>

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

		Year ended December 31	
		2019	2018
Federal:			
Current		\$ -	\$ -
Deferred	21.00%	(1,361,582)	(1,385,438)
State and local:			
Current		-	-
Deferred	5.14%	(332,939)	(338,773)
	<u>26.14%</u>	<u>(1,694,521)</u>	<u>(1,724,211)</u>
Change in valuation allowance		1,694,521	1,724,211
Income tax provision (benefit)		<u>\$ -</u>	<u>\$ -</u>

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

	Year Ended December 31	
	2019	2018
Tax benefit at federal statutory rate	(21.0)%	(21.0)%
State income taxes, net of federal benefit	(5.1)%	(5.1)%
Permanent differences	(1.3)%	(1.7)%
Change in valuation allowance	24.5%	20.8%
Prior year true-up	(0.1)%	5.8%
Expiration of state net operating loss carryforwards	3.1%	1.2%
Miscellaneous	(0.0)%	0.0%
Effective income tax rate	<u>0.0%</u>	<u>0.0%</u>

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

	December 31	
	2019	2018
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 41,959,558	\$ 41,114,624
Stock-based compensation	2,215,928	2,207,465
Research and development credit carryovers	2,917,857	2,791,710
Contribution carryovers	10,062	10,062
Accrued liabilities	1,041,286	490,467
Gross deferred tax assets	48,144,691	46,614,328
Deferred Tax Liabilities:		
Intangible assets	(59,616)	(235,013)
Prepaid expenses	(91,084)	(90,881)
Other	(40,581)	(29,545)
Gross deferred tax liabilities	(191,281)	(355,439)
Valuation allowance	(47,953,410)	(46,258,889)
Deferred tax asset, net of valuation allowance	\$ -	\$ -
Change in valuation allowance	\$ (1,694,521)	\$ (1,724,211)

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 federal, state and Australian tax net operating losses of approximately \$162M, \$154M, and \$73k. 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, 2019 or 2018

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, 2019, 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 currently leases 4,500 square feet of corporate office space in Knoxville, Tennessee through an operating lease agreement for a term of five years ending on June 30, 2022. Payments range from approximately \$7,300 to \$7,800 per month.

Total expense for operating leases for the year ended December 31, 2019 was \$102,378, of which, \$68,252 was included within research and development and \$34,126 was included within general and administrative expenses on the consolidated statement of operations. Total expense for operating leases for the year ended December 31, 2018 was \$88,393, of which, \$58,928 was included within research and development and \$29,465 was included within general and administrative expenses on the consolidated statement of operations.

As of December 31, 2019, the Company had no leases that were classified as a financing lease. As of December 31, 2019, the Company did not have additional operating and financing leases that have not yet commenced.

A summary of the Company's right-of-use assets and liabilities is as follows:

	Years End December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 89,574
Right-of-use assets lease obligations recognized upon adoption:	
Operating leases	\$ 265,550
Weighted Average Remaining Lease Term	
Operating leases	2.50 Years
Weighted Average Discount Rate	
Operating leases	8.0%

Future minimum payments under non-cancellable lease as of December 31, 2019 were as follows:

<u>For the Years Ending December 31,</u>	<u>Amount</u>
2020	\$ 90,666
2021	92,471
2022	46,687
Total future minimum lease payments	229,824
Less: amount representing imputed interest	(22,743)
Total	<u>\$ 207,081</u>

Employment Agreement

On March 25, 2019, the Company entered into a one-year employment agreement with its CFO that will be renewed automatically for successive one-year periods, unless the Company or CFO provides a notice of non-renewal at least thirty (30) days prior to the end of the term. In the event that coincident with or following a Change in Control (as defined in the agreement), the CFO's employment with the Company is terminated or the employment agreement is not extended (a) by action of the CFO coincident with or following a Change in Control including the CFO's death, disability or retirement, or (b) by action of the Company not For Cause (as defined in the agreement) coincident with or following a Change in Control, the Company shall pay the CFO a severance payment equal to 50% of the base salary in the preceding calendar year, payable over six months, as well as certain other specified benefits. In connection with the employment agreement, the CFO was entitled to 50,000 shares of immediately-vested common stock. (See Note 7 Stockholder's Deficiency for additional information).

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 2019 or 2018.

12. Litigation

Culpepper Travel Expenses and Related Collection Efforts

On December 27, 2016, the then-Board of Directors (the "then-Board") unanimously voted to terminate then-interim Chief Executive Officer, then-Chief Operating Officer, and former Chief Financial Officer, Peter Culpepper ("Culpepper"), effective immediately, from all positions he held with the Company and each of its subsidiaries, "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 then-Board regarding improper expense reimbursements to Culpepper.

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 Kleba Derivative Lawsuit Settlement (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 \$2,104,543 as of December 31, 2019 and December 31, 2018, 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").

On September 12, 2018, the arbitrator issued his 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. 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. On March 22, 2019, the Chancery Court upheld the arbitration award in favor of the Company. On April 16, 2019, Culpepper filed a Notice of Appeal with the Tennessee Court of Appeals regarding the judgment confirming the arbitration award and the order denying Culpepper's motion to alter or amend the judgment (the "Culpepper Appeal"). The Company and Culpepper have submitted their respective Culpepper Appeal briefs. Oral argument of the appeal was held on January 7, 2020. The Company expects a ruling from the court of appeals in the first half of 2020, although there are no assurances of timing.

The Bible Harris Smith Lawsuit

On January 28, 2019, 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 year ended December 31, 2019.

The RSM Lawsuit

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. On February 27, 2019, 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 year ended December 31, 2019.

13. Subsequent Events

Convertible Notes Payable

Subsequent to December 31, 2019, the Company entered into a 2020 Note with a non-related party accredited investor in the aggregate principal amount of \$100,000 in connection with 2nd 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 800,000 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 \$42,640.

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, 2019.

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 2019 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 2020 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 2020 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 2020 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 2020 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 2020 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 No.	Description
3.1	<u>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).</u>
3.2	<u>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).</u>
3.4	<u>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).</u>
4.1	<u>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).</u>
4.2	<u>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).</u>
4.3	<u>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).</u>
4.4	<u>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).</u>
4.5	<u>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).</u>
4.6	<u>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).</u>

- 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 \(incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed with the SEC on August 25, 2016\).](#)
- 4.10† [Description of Securities.](#)
- 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* [Provectus Biopharmaceuticals, Inc. 2014 Equity Compensation Plan \(incorporated herein by reference to Appendix A of the Company's definitive proxy statement filed with the SEC on April 30, 2014\).](#)
- 10.11 [Controlled Equity OfferingSM Sales Agreement, dated April 30, 2014, by and between Provectus Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co. \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 30, 2014\).](#)

- 10.12 [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 \(Exhibits Omitted\) \(incorporated by reference to Exhibit 10.6 of the Company's quarterly report on Form 10-Q filed with the SEC on August 7, 2014\).](#)
- 10.13 [Consent and Waiver of Rights, between Provectus Biopharmaceuticals, Inc. and Alpha Capital Anstalt \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on June 24, 2015\).](#)
- 10.14* [Independent Contractor Agreement between Provectus Biopharmaceuticals, Inc. and John R. Glass \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 22, 2016\).](#)
- 10.15* [Amendment No. 1 to the Independent Contractor Agreement between Provectus Biopharmaceuticals, Inc. and John R. Glass \(incorporated by reference to Exhibit 10.18 of the Company's annual report on Form 10-K filed with the SEC on March 31, 2017\).](#)
- 10.16 [Form of Securities Purchase Agreement between Provectus Biopharmaceuticals, Inc. and the purchasers named therein \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on August 25, 2016\) \(exhibits and schedules have been omitted, and the Company agrees to furnish to the Commission a copy of any omitted exhibits and schedules upon request\).](#)
- 10.17 [Warrant Agency Agreement, dated August 30, 2016, by and between Provectus Biopharmaceuticals, Inc. and Broadridge Corporate Issuer Solutions, Inc. \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on August 30, 2016\).](#)
- 10.18 [Convertible Promissory Note dated February 21, 2017 \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on February 21, 2017\).](#)
- 10.19 [Definitive Financing Commitment Term Sheet dated March 19, 2017 \(incorporated by reference to Exhibit 10.2 of the Company's quarterly report on Form 10-Q filed with the SEC on May 10, 2017\).](#)
- 10.20 [Secured Convertible Promissory Note between the Company and Cal Enterprises LLC, dated April 3, 2017 \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 4, 2017\).](#)
- 10.21 [Amended and Restated Secured Convertible Promissory Note between the Company and Eric A. Wachter, dated April 3, 2017 \(incorporated by reference to Exhibit 10.2 of the Company's current report on Form 8-K filed with the SEC on April 4, 2017\).](#)
- 10.22 [Indemnification Agreement between the Company and Dominic Rodrigues, dated April 3, 2017 \(incorporated by reference to Exhibit 10.3 of the Company's current report on Form 8-K filed with the SEC on April 4, 2017\).](#)
- 10.23 [Indemnification Agreement between the Company and Bruce Horowitz, dated April 3, 2017 \(incorporated by reference to Exhibit 10.4 of the Company's current report on Form 8-K filed with the SEC on April 4, 2017\).](#)
- 10.24* [Independent Contractor Agreement, dated April 19, 2017, between the Company and Bruce Horowitz \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 20, 2017\).](#)
- 10.25* [Amendment No. 1 to the Independent Contractor Agreement, dated May 9, 2017, between the Company and Bruce Horowitz \(incorporated by reference to Exhibit 10.6 of the Company's quarterly report on Form 10-Q filed with the SEC on August 9, 2017\).](#)

- 10.26* [Amendment No. 2 to the Independent Contractor Agreement dated April 19, 2017 between the Company and Bruce Horowitz, dated May 8, 2019 \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed May 9, 2019\).](#)
- 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 \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on July 30, 2018\).](#)
- 10.36* [Employment Agreement between the Company and Heather Raines, CPA, dated March 25, 2019 \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on March 25, 2019\).](#)
- 10.37* [Executive Employment Agreement between the Company and Eric A. Wachter, Ph.D., dated May 17, 2019 \(incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed May 20, 2019\).](#)
- 10.38 [Form of PRH 2 Secured Convertible Promissory Note \(incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed January 7, 2020\).](#)
- 10.39† [2020 Definitive Financing Term Sheet.](#)
- 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 \(incorporated by reference to Exhibit 21 of the Company's annual report on Form 10-K filed with the SEC on March 31, 2017\).](#)
- 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, 2019, filed with the SEC on March 5, 2020, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheet as of December 31, 2019 and December 31, 2018; (ii) the Consolidated Statements of Operations for the years ended December 31, 2019 and 2018; (iii) the Consolidated Statements of Equity for the years ended December 31, 2019 and 2018; (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2019; 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 5, 2020

PROVECTUS BIOPHARMACEUTICALS, INC.

By: /s/ Bruce Horowitz

Bruce Horowitz

Chief Operating Officer (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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Heather Raines</u> Heather Raines, CPA	Chief Financial Officer (principal financial officer and principal accounting officer)	March 5, 2020
<u>/s/ Bruce Horowitz</u> Bruce Horowitz	Director and Chief Operating Officer (principal executive officer)	March 5, 2020
<u>/s/ Jan E. Koe</u> Jan E. Koe	Director	March 5, 2020
<u>/s/ John W. Lacey, III, MD</u> John W. Lacey, III, MD	Director	March 5, 2020
<u>/s/ Ed Pershing</u> Ed Pershing	Director and Chairman of the Board	March 5, 2020
<u>/s/ Dominic Rodrigues</u> Dominic Rodrigues	Director and Vice Chairman of the Board	March 5, 2020

Exhibit 4.10**DESCRIPTION OF SECURITIES****REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT**

Provectus Biopharmaceuticals, Inc. (“Provectus”, “we” or “our”) has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”): our Common Stock.

Description of Common Stock

The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation, as amended (the “Certificate of Incorporation”), and our Bylaws, as amended (the “Bylaws”), each of which is incorporated by reference as an exhibit to the Annual Report on Form 10-K, of which this Exhibit is a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law, for additional information.

Authorized Shares of Capital Stock

Our authorized capital stock consists of 1,000,000,000 shares of common stock, \$0.001 par value per share (“Common Stock”), and 25,000,000 shares of preferred stock, \$0.001 par value per share (“Preferred Stock”). As of December 31, 2019, 389,889,475 shares of Common Stock were issued and outstanding. The outstanding shares of our Common Stock are duly authorized, validly issued, fully paid, and nonassessable.

Voting Rights

Holders of Common Stock are entitled to one vote per share on all matters voted on by the stockholders, including the election of directors. Our Common Stock does not have cumulative voting rights.

Dividend Rights

Subject to the rights of holders of outstanding shares of Preferred Stock, if any, the holders of Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Company’s Board of Directors (the “Board”) in its discretion out of funds legally available for the payment of dividends.

Liquidation Rights

In the event of our dissolution, liquidation or winding up, holders of our Common Stock are entitled to share ratably in any assets remaining after the satisfaction in full of the prior rights of creditors and the aggregate liquidation preference of any Preferred Stock then outstanding.

Other Rights and Preferences

Holders of our Common Stock do not have any conversion, redemption, sinking fund or preemptive rights.

Certain Anti-Takeover Effects

Provisions of our Certificate of Incorporation and Bylaws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our Common Stock. Among other things, our Certificate of Incorporation and Bylaws will:

- permit our Board to issue up to 25,000,000 shares of Preferred Stock, with any rights, preferences and privileges as they may designate;
- 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;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- 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;
- 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
- 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.

Preferred Stock

The rights, preferences and privileges of the holders of our Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of Preferred Stock that we have designated and issued, or may designate and issue in the future. Under our Certificate of Incorporation, we are authorized to issue up to 25,000,000 shares of Preferred Stock, from time to time in one or more series, in any manner permitted by law, as determined from time to time by our Board, and stated in the resolution or resolutions providing for the issuance of such shares adopted by our Board. Without limiting the generality of the foregoing, shares in such series shall have voting powers, full or limited, or no voting powers, and shall have such designations, preferences and relative, participating, optional, or other special rights, and qualifications, limitations, or restrictions thereof, permitted by law, as shall be stated in the resolution or resolutions providing for the issuance of such shares adopted by our Board. The number of shares of any such series so set forth in the resolution or resolutions may be increased (but not above the total number of authorized shares of Preferred Stock) or decreased (but not below the number of shares thereof then outstanding) by further resolution or resolutions adopted by the Board. As of December 31, 2019, 100 shares of Series B Preferred Stock were issued and outstanding.

Series B Convertible Preferred Stock

The following summary of certain terms and provisions of the Series B Preferred Stock is subject to, and qualified in its entirety by reference to, the terms and provisions set forth in our certificate of designation of preferences, rights and limitations of the Series B Preferred Stock, which is incorporated by reference as an exhibit to the Annual Report on Form 10-K, of which this Exhibit is a part (the "Certificate of Designation").

Our Series B Preferred Stock is convertible into shares of our Common Stock (subject to the beneficial ownership limitations as provided in the related Certificate of Designation), at the Adjusted Conversion Price equal to \$0.0533 per share of Common Stock, subject to adjustment as provided in the Certificate of Designation, at any time at the option of the holder prior to the fifth anniversary of the date of issuance, at which time all shares of outstanding Series B Preferred Stock shall automatically and without any further action by the holder be converted into shares of our Common Stock at the then effective conversion price, provided that the holder will be prohibited from converting Series B Preferred Stock into shares of our Common Stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our Common Stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

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 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 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 (i) the amount of the dividend payable to such holder divided by (ii) the conversion price then in effect. Because the conversion price in effect on the Price Reset Date exceeded 85% of the average of the 45 lowest volume weighted average trading prices of the Common Stock during the period commencing on the date of issuance of the Series B Preferred Stock and ending on the Price Reset Date, the conversion price was reset to the Adjusted Conversion Price and shall be further subject to adjustment as provided in the Certificate of Designation. In either case, if a holder of Series B Preferred Stock converted its shares of Series B Preferred Stock prior to any such price reset event, then such holder was entitled to receive shares of Common Stock equal to the difference between the conversion price and the Adjusted Conversion Price.

In the event of our liquidation, dissolution, or winding up, holders of our 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 the 4.99% or 9.99% beneficial ownership limitation, as applicable) subject to the preferential rights of holders of any class or series of our 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 holders of the Series B Preferred Stock have no voting rights, except as required by law. Any amendment to our Certificate of Incorporation, Bylaws or Certificate of Designation that adversely affects the powers, preferences and rights of the Series B Preferred Stock requires the approval of the holders of a majority of the shares of Series B Preferred Stock then outstanding.

Series D Preferred Stock

In connection with the 2017 financing and 2020 financing, the Company has issued convertible notes that are convertible into shares of a yet-to-be designated Series D Preferred Stock. The Series D Preferred Stock will have a first priority right to receive proceeds from the sale, liquidation or dissolution of the Company or any of the Company's assets (each, a "Company Event").

If a Company Event occurs within two (2) years of the date of issuance of the Series D Preferred Stock (the “Date of Issuance”), the holders of Series D Preferred Stock will receive a preference of four times (4x) their respective investment amount. If a Company Event occurs after the second (2nd) anniversary of the Date of Issuance, the holders of the Series D Preferred Stock will receive a preference of six times (6x) their respective investment amount.

The Series D Preferred Stock will be convertible at the option of the holders thereof into shares of Common Stock based on a formula to achieve a one-for-ten conversion ratio. The Series D Preferred Stock will automatically convert into shares of Common Stock upon the fifth (5th) anniversary of the Date of Issuance.

On an as-converted basis, the Series D Preferred Stock will carry the right to ten (10) votes per share. The Series D Preferred Stock will not have any dividend preference but will be entitled to receive, on a *pari passu* basis, dividends, if any, that are declared and paid on any other class of the Company’s capital stock. The holders of Series D Preferred Stock will not have anti-dilution protection.

As of December 31, 2019, and through the date of filing of the Company’s Annual Report on Form 10-K for the year ended December 31, 2019, the Series D Preferred Stock had not been designated by the Board.

Transfer Agent and Registrar

Broadridge Financial Solutions, Inc. is the transfer agent and registrar for our Common Stock.

Listing

Our Common Stock is traded on the OTCQB Marketplace under the trading symbol “PVCT.”

Exhibit 10.39**2020 FINANCING TERM SHEET**

The following is a summary of the terms and conditions of the financing plan (the “Plan”) developed by Provectus Biopharmaceuticals, Inc. (the “Company”). The Plan was approved by the Board of Directors of the Company (the “Board”) on December 31, 2019. The 2020 Term Sheet is similar to the Definitive Financing Commitment Term Sheet entered into between the Company and a group of the Company’s stockholders (the “PRH Group”), which was amended and restated effective as of March 19, 2017 (the “2017 Term Sheet”), previously disclosed by the Company in a Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission (the “SEC”) on March 23, 2017, and completed on December 20, 2019 when the PRH Group concluded its best efforts activity to arrange for financing of \$20,000,000 (the “2017 Financing”). The PRH Group specifically disclaimed, and continues to disclaim, that it is a “Group” as defined in the Federal securities laws.

Total Financing Commitment

This Financing Term Sheet (the “2020 Term Sheet”) envisions that the Company will use its best efforts to arrange for financing of a maximum of \$20 million (the “2020 Financing”), which amounts will be provided in several tranches.

Structure of the Financing

The structure of the Financing will be in the form of a secured convertible loan (the “Loan”) from investors (which may include, but not be limited to, institutional investors, family offices and accredited investors; individually, an “Investor,” and collectively, the “Investors”). The Loan will be evidenced by one or more secured convertible promissory notes (the “2020 Notes”) from the Company to each Investor.

In addition to the customary provisions, the Note shall contain the following provisions:

(i) the 2020 Notes will be subordinate to the notes of the 2017 Financing (the “2017 Notes”) in right of payment and to the security interests granted to holders of the 2017 Notes;

(ii) that the Loan will be secured by a second lien security interest in the Company’s intellectual property and such second lien shall be evidenced in writing and recorded in the county where the Company’s principal offices are located;

(iii) that the Loan will bear interest at the rate of 8% per annum on the outstanding principal amount of the Loan that has been funded to the Company;

(iv) that in the event there is a change of control of the Company’s Board of Directors as proposed by any person or group other than the PRH Group, the term of the 2020 Note will be accelerated and all amounts due under the 2020 Note will be immediately due and payable and that any proceeds received by the Company from any financing source will be used to first repay the outstanding principal amount of the 2017 Notes that have been funded to the Company plus interest at the rate of 8% per annum, plus a penalty in the amount equal to ten times (10x) the outstanding principal amount of the Loan that has been funded to the Company, and to second first repay the outstanding principal amount of the 2020 Notes that have been funded to the Company plus interest at the rate of 8% per annum, plus a penalty in the amount equal to ten times (10x) the outstanding principal amount of the Loan that has been funded to the Company;

(v) that the principal amount of the Loan and the interest payable under the Loan will be convertible at the sole discretion of the PRH Group in to shares of the Company’s Series D Preferred Stock (with the rights and preferences set forth in this Financing Term Sheet, see “Rights and Preferences of the Series D Convertible Preferred Stock” below) at a price per share of \$2.862;

(vi) notwithstanding above, the principal amount of the Note and the interest payable under the Loan will automatically convert into shares of the Company’s Series D Preferred Stock (with the rights and preferences set forth in this Financing Term Sheet, see “Rights and Preferences of the Series D Convertible Preferred Stock” below) at a price per share of \$2.862 on June 20, 2021, subject to certain exceptions; and

(vii) upon conversion of the Loan into the Series D Preferred Stock, Investors agree to release their second lien on the Intellectual Property.

The PRH Group

The PRH Group includes Edward Pershing, Dominic Rodrigues and Bruce Horowitz.

The Rights and Preferences of the Series D Convertible Preferred Stock

In addition to the following rights and preferences, the Series D Preferred Stock shall also include Sections (i) – (vii) set forth under “Structure of the Financing” above.

No subsequently issued Senior Equity Securities: No series or class of Capital Stock shall be issued by the Company after the date of the acceptance of this Financing Term Sheet that is senior to the rights and preferences of the Series D Preferred Stock (including but not limited to voting rights, conversion, dividends, anti-dilution, etc.).

Preference on Proceeds from the Sale, Liquidation or Dissolution of the Company: The Series D Preferred stock shall have a first priority right to receive proceeds/distribution from the sale, liquidation or dissolution of the Company or any of the Company's assets before proceeds from such an event are distributed to holders of other class of the Company's Capital Stock.

If the event occurs within 2 years of the date of issuance of the Series D Preferred Stock, the Series D Preferred Stock shall receive a preference of 4 times the investment amount; if the event occurs longer than 2 years of the Closing, the Series D Preferred Stock shall receive a preference of 6 times the investment amount.

Conversion to Common Stock: The Series D Preferred Stock shall be convertible at the option of the holders into shares of the Company's Common Stock based on a formula to achieve a 1-for-10 conversion, provided the Company has sufficient number of authorized but unissued shares of Series D Preferred Stock (otherwise the pricing of the Series D Preferred Stock and the conversion formula into common stock will be revised accordingly). Any fractional shares issuable pursuant to the formula will be rounded up to the next whole share of Common Stock. The Series D Preferred Stock shall automatically convert into shares of Common Stock upon the fifth anniversary of the date of issuance of the Series D Preferred Stock.

Voting Rights: Customary, and on an as-converted basis (i.e., 10 votes per share of Series D Preferred Stock assuming a 1-for-10 conversion).

No Dividend Preference: No Dividend Preference. However, the Series D Preferred Stock shall be entitled to receive dividends when any dividends are declared and paid on the Common Stock or other series or class of Preferred Stock and on a *pari passu* basis.

Anti-dilution Protection: None

Use of Proceeds

The proceeds from the 2020 Financing will be used to fund the Company's clinical development program, as currently constituted and envisioned, and to fund the Company's general and administrative expenses.

Exhibit 31.1**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

I, Bruce Horowitz, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Provectus Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2020

By: */s/ Bruce Horowitz.*

Bruce Horowitz
Chief Operating Officer (principal executive officer)

Exhibit 31.2**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

I, Heather Raines, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Provectus Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2020

By: */s/ Heather Raines*

Heather Raines, CPA
Chief Financial Officer (principal financial officer)

Exhibit 32

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND
CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(b) UNDER
THE SECURITIES EXCHANGE ACT OF 1934 AND SECTION 1350 OF
CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE**

Each of the undersigned, Bruce Horowitz and Heather Raines, certifies, pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this Annual Report on Form 10-K for the year ended December 31, 2019 of Provectus Biopharmaceuticals, Inc. (the "Company") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act, and (2) the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This Certification is signed on March 5, 2020.

/s/ Bruce Horowitz

Bruce Horowitz
Chief Operating Officer (principal executive officer)

/s/ Heather Raines

Heather Raines, CPA
Chief Financial Officer (principal financial officer)
