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

FORM 10-K

☒ **Annual Report under Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2024

or

☐ **Transitional Report under Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number 001-39531

Processa Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**45-1539785**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

7380 Coca Cola Drive, Suite 106,
Hanover, Maryland 21076
(443) 776-3133

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

Title of Each Class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	PCSA	The Nasdaq Stock Market LLC

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 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 emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its managements' assessment of the effectiveness of its internal controls over financial reporting under Section 404(b) of the Sarbanes Oxley Act (15 U.S.C 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 28, 2024, the last business day of the most recently completed second quarter, based upon the closing price of Common Stock on such date as reported on Nasdaq Capital Market, was approximately $5.8 million.

The number of outstanding shares of the registrant's common stock as of March 12, 2025 was 5,269,240.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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GLOSSARY OF CERTAIN SCIENTIFIC TERMS

The medical and scientific terms used in this Annual Report on Form 10-K have the following meanings:

“Active Metabolite” means a drug that is processed by the body into an altered form which effects the body.

“Agonist” means a chemical/drug that binds to a receptor in the body and activates that receptor to produce a biological response.

“Analog” means a compound having a structure similar to that of an approved drug but differing from it with respect to a certain component of the molecule which may cause it to have similar or different effects on the body.

“cGCP” means current Good Clinical Practices. The FDA and other regulatory agencies promulgate regulations and standards, commonly referred to as current Good Clinical Practices, for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the rights and welfare of trial participants are adequately protected.

“cGMP” means current Good Manufacturing Practices. The FDA and other regulatory agencies promulgate regulations and standards, commonly referred to as current Good Manufacturing Practices, which include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation.

“CMO” means Contract Manufacturing Organization.

“CRO” means Contract Research Organization.

“Deuterated analog” means a small molecule in which one or more of the hydrogen atoms are replaced by deuterium.

“EMA” means the European Medicines Agency.

“FDA” means the Food and Drug Administration.

“IND” means an Investigational New Drug Application. Before testing a new drug on human subjects, the company must file an IND with the FDA. Information must be produced on the absorption, distribution, metabolism, and excretion properties of the drug and detailed protocols for testing on human subjects must be submitted.

“Indication” means a condition which makes a particular treatment or procedure advisable.

“Moiety” means an active or functional part of a molecule.

“NDA” means a New Drug Application submitted to the FDA. Under the Food, Drug, and Cosmetic Act of 1938, an NDA is submitted to the FDA enumerating the uses of the drug and providing evidence of its safety.

“NGC” means Next Generation Cancer therapy, referring to the drugs in our pipeline that change the metabolism or distribution of existing cancer drugs to increase potency and reduce toxicity.

“NL” means Necrobiosis Lipoidica, a rare chronic and granulomatous disorder.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Form 10-K may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These risks are discussed more fully in the "Risk Factors" section of this Annual Report on Form 10-K and are summarized below under the "Summary Risk Factors" section. These risks include, but are not limited to, the following:

- our ability to obtain funding for our future clinical trials, preclinical activities and our operations;
- our ability to meet obligations under our license agreements;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- our ability to obtain and maintain regulatory approval of our product;
- the potential market size, opportunity and growth potential for our product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize our product candidates, if approved;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the initiation, timing, progress and results of clinical trials and pre-clinical studies for our NGC drugs;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory filings and approvals and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates by physicians, patients, third-party payors and others in the medical community, if approved;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our financial performance; and
- other risks and uncertainties, including those described under part I, Item 1A. Risk Factors of this Annual Report.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable as of the date of this Form 10-K, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Form 10-K to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this Form 10-K and the documents that we reference in this Form 10-K and have filed with the SEC as exhibits with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

In this Form 10-K, "we," "us", "our", "Processa" and "the Company" refer to Processa Pharmaceuticals, Inc. and its subsidiary.

Part I

Item 1. Business

Corporate Information

We were incorporated under the laws of the State of Delaware on March 29, 2011. Our principal executive office is located at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076. Our telephone number is (443) 776-3133.

We make available free of charge on or through our Internet website (*http://www.processapharmaceuticals.com*) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as well as our Code of Ethics and Code of Conduct, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). The SEC also maintains a website which provides online access to reports and other information regarding registrants that file electronically with the SEC at: www.sec.gov.

The information contained on our website and social media channels is not included as a part of, or incorporated by reference into, this report.

Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of Next Generation Cancer therapy ("NGC") small molecules, two of which are in, or have completed, Phase 2 trials, and one is in pre-clinical development.

We believe our strategy reduces clinical risk, regulatory risk and commercial risk. Our risk-mitigated strategy is to identify existing cancer therapies where the mechanism of action is well understood and that are cornerstones of current treatment regimens, but are highly toxic, with side effects that are often treatment limiting (see Our Strategy below). We devise technologies to change the way the body metabolizes them, or the way they are distributed within the body, to improve the therapeutic effect and reduce toxicity. We then efficiently develop our pipeline of Next Generation Cancer therapies utilizing our proprietary Regulatory Science Approach (see Regulatory Science Approach below), which we believe will further increase the likelihood of regulatory approval. Since the underlying drugs are already commonly used in cancer therapy, we believe, that if our clinical trials are successful, and are showing better efficacy and tolerability than the currently used drugs, the commercial adoption for our NGC therapies will be rapid and broad.

The NGC treatments in our pipeline are as follows (see Our Drug Pipeline below for a more detailed discussion of each):

- PCS6422, also referred to as NGC-Cap, is a combination of PCS6422 and a lower dose of capecitabine.

  Capecitabine is an oral prodrug of the cancer drug 5-fluorouracil ("5-FU"), which is further metabolized into cancer-killing metabolites. It is used in many solid tumor treatment regimens, like breast cancer and colon cancer. Millions of doses of capecitabine are used annually. In 2021 Medicare Part B alone reports over 9.2 million dosing units used. Significant side effects, such as Hand-Foot Syndrome ("HFS") and cardiotoxicity, typically occur in up to 70% of patients treated with capecitabine. These side effects frequently result in decreased or interrupted doses, or discontinuation of treatment with capecitabine, which undermines its effectiveness to the patient.

  PCS6422, without having any clinically meaningful anti-cancer effect itself, alters the metabolism of 5-FU within the body, reducing interpatient and intrapatient variability in DPD, raising plasma levels of bioavailable 5-FU, and lengthening the time of pharmacologic exposure to the drug. This results in increased 5-FU distribution to the cancer cells. NGC-Cap has been found to be up to 50 times more potent than capecitabine alone, based on the systemic exposure of the capecitabine metabolite 5-FU.

  In clinical trials, NGC-Cap has shown a better safety profile than capecitabine alone. Since a much smaller amount of these metabolites are formed with NGC-Cap, the side effects appear in fewer patients and are less severe. Like capecitabine, NGC-Cap could potentially be used to treat patients with various cancers, such as breast, colorectal, gastrointestinal, and pancreatic.

  In 2024, we started our Phase 2 trial of NGC-Cap in advanced or metastatic breast cancer patients. After 20 patients have been treated, an interim analysis will be conducted.

- PCS3117, also referred to as NGC-Gem, is a cytidine analog similar to gemcitabine (Gemzar®), but different enough in chemical structure that some patients are more likely to respond to NGC-Gem than gemcitabine. In addition, we believe those patients that are inherently resistant, or who acquire resistance, to gemcitabine are likely to not be resistant to NGC-Gem. The difference in response occurs because NGC-Gem is metabolized to its Active Metabolite through a different enzyme system than gemcitabine.

- PCS11T, also referred to as NGC-Iri, is an analog of SN38 (SN38 is the active metabolite of irinotecan). The chemical structure of NGC-Iri is designed to influence the uptake of the drug into cancer cells, resulting in more NGC-Iri entering cancer cells than normal cells.

  Irinotecan is widely used in lung, pancreatic, ovarian, cervical & other solid tumor cancers. Onivyde® is irinotecan in a liposomal formulation. Approximately 15-35% of patients respond to irinotecan across the solid tumor cancers. Major drawbacks are the side-effect profile, including black box warnings for diarrhea and myelosuppression. Dose limiting side effects result in fewer patients being able to benefit from treatment. Despite the black box warning for severe side effects, Medicare reported a total of more than 1.8 million doses of irinotecan and Onivyde® in 2021.

  Our preclinical study in mouse xenograft models showed that after NGC-Iri administration, there was greater accumulation of SN-38 in the tumor compared with other tissues than after irinotecan or Onivyde® administration. Additionally, less SN-38 accumulated in non-cancer tissues, such as muscle, after NGC-Iri administration than after irinotecan or Onivyde® administration, supporting the potential for a better NGC-Iri safety profile.

We are currently evaluating options to monetize two non-oncology drug assets, which may include out-licensing or partnering these assets with one or more third parties.

- PCS12852 is a highly specific and potent 5HT4 agonist that is Phase 2B ready as potentially the first meaningful treatment for diabetic gastroparesis patients. Gastroparesis is a chronic digestive disorder characterized by delayed gastric emptying of solid food without obstruction. Gastroparesis symptoms include: nausea, vomiting, postprandial fullness, early satiety, abdominal pain, heartburn and poor appetite. Global prevalence of gastroparesis is over 30 million, with a diabetic population of over 8 million.

  We have completed a Phase 2A trial for PCS12852 in gastroparesis patients with positive results.

- PCS499 is a drug that can be used to treat unmet medical need conditions caused by multiple pathophysiological changes. We are presently defining the development plan for the use of PCS499 in a primary glomerular disease. We believe that PCS499 could be successfully developed in a primary glomerular disease such as focal segmental glomerulosclerosis, or FSGS, and IgA. We intend to design a development program with the next study being an adaptive designed Phase 3 trial, meet with the FDA, and then find a partner to take the drug to approval.

Our Strategy

We believe our strategy reduces clinical risk, regulatory risk and commercial risk, while addressing a critical need in fighting cancer.

Historically, cancer therapies targeted rapidly dividing cells because cancer cells tend to divide and grow more quickly than normal cells. Unfortunately, most of these drugs do not distinguish between cancer cells and normal cells that also divide rapidly, such as those in the bone marrow, digestive tract, and hair follicles. Prior to FDA's Project Optimus Initiative, oncology drug developers would begin human clinical trials with dose-escalating studies meant to identify a Maximum Tolerated Dose ("MTD"), which they hoped would be high enough to impact the cancer. If approved by the FDA, the recommended dose would be at or near the MTD, resulting in many patients suffering from severe side effects from treatment. Developers were defining the "optimal" treatment dose by the highest dose that may potentially be tolerated and then assumed that the highest dose would also provide the greatest efficacy, which may not have been correct.

Our risk-mitigated strategy is to identify existing effective cancer therapies where the active cancer-killing ingredients are well understood and that are foundations of current treatment regimens, but are highly toxic, with side effects that are often treatment limiting. We then devise technologies to change the way the body metabolizes the drugs, or the way they are distributed within the body, to increase potency and reduce toxicity. By modifying the drugs in this manner, we believe our treatments will provide improved safety and efficacy profiles when compared to their currently marketed counterparts. We believe our approach will extend survival and improve quality of life for many patients fighting cancer. We also believe that we can develop these drug candidates at a lower cost with a higher success rate than is common in the industry. We call our drug candidates Next Generation Cancer (NGC) therapies.

Clinical Risk

We already know these drugs work. They have been used in cancer treatment for decades, and there are hundreds, if not thousands, of scientific publications looking at all aspects of the drugs. In many ways, these drugs are better understood now than when they were first approved. This improved knowledge, added to the data from prior human clinical trials, leads us to believe clinical risk is significantly reduced when compared to a potential drug that is focusing on a new mechanism of action or new target. By modifying how an existing anti-cancer drug is metabolized or distributed within the body, thereby making the existing drug less toxic and more effective, we do not rely on finding an MTD that exceeds what is safe for many patients. Instead, we seek to merely increase the amount of the proven anti-cancer ingredients in the cancer cells, while reducing those ingredients in healthy cells, often with a lower dose of the approved drug, which we believe results in less clinical risk.

Regulatory Risk

Our strategy is to efficiently develop our pipeline of Next Generation Cancer therapies utilizing our proprietary Regulatory Science Approach (described more fully in "Regulatory Science Approach" below), including the principles associated with FDA's Project Optimus oncology initiative and the related FDA draft guidance (Optimus, 2025). Part of the development includes determining the optimal dosage regimen, rather than an MTD, based on the dose-response relationship. By changing either the metabolism, distribution, and/or elimination of already FDA-approved cancer drugs (e.g., capecitabine, gemcitabine, and irinotecan) or their Active Metabolites, we believe that our oncology drugs represent the next generation of cancer therapy with an improved safety and efficacy profile, thereby potentially benefiting more patients while maintaining the mechanism of how the drug kills cancer cells. By combining these modified, approved cancer treatments with our Regulatory Science Approach and our experience using the principles of FDA's Project Optimus initiative, we anticipate that we will be able to increase the probability of FDA approval, improve the safety-efficacy profile over the existing counterparts of our NGC drugs, and more efficiently develop each drug.

Commercial Risk

Since the underlying drugs are already heavily used in cancer therapy, we believe that, if our clinical trials are successful in demonstrating greater efficacy with better tolerability, our NGC therapies will be rapidly and broadly adopted. Why would an oncologist use the older, more toxic drug?

Summary

To date, we have data that we believe suggests our NGC treatments are likely to have a better safety-efficacy profile than the current widely used marketed counterpart drugs, not only potentially making the development and approval process more efficient, but also differentiating our NGC treatments from the existing treatment in the market.

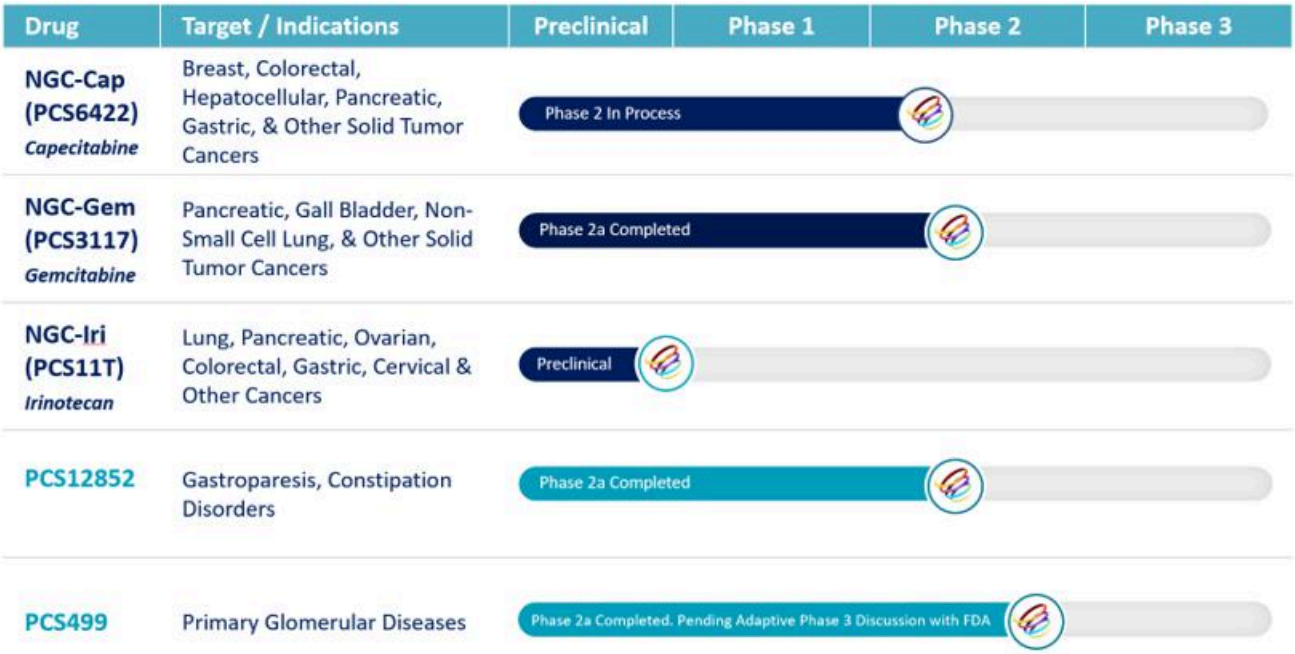
Regulatory Science Approach

Our Regulatory Science Approach was conceived in the early 1990s when the founders of Processa and other faculty at the University of Maryland worked with the FDA to develop multiple FDA Guidances. Regulatory science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products. Two of our founders, Dr. David Young and Dr. Sian Bigora, developed trade secrets and know-how developed from the regulatory science research initially developed in collaboration with FDA and later refined by Drs. Young and Bigora over the last 30+ years. They also expanded the original regulatory science concept by including it in pre-clinical and clinical studies to justify the benefit-risk assessment required for FDA approval when designing the development programs of new drug products. Our regulatory science approach defines the scientific information that the FDA requires to determine if the benefit outweighs the risk of a drug in a specific population of patients and at a specific dosage regimen for a specific drug product. The studies are designed to obtain the necessary scientific information to support the regulatory decision.

Recently, the FDA took steps to define some of the regulatory science required for the FDA approval of oncology products. Historically, most cancer drugs were dosed at the MTD, which lead to many patients experiencing significant side effects and lower quality of life. What was ignored was that a lower dose may result in the same efficacy as a higher dose while providing fewer side effects and/or less severe side effects. Through the FDA's Project Optimus Oncology Initiative (Optimus, 2025) and the related Draft Guidance on determining the "optimal" dosage regimen for an oncology drug, the FDA chose to make the development of oncology drugs more science-based than in the past. Since the principles of the FDA's Project Optimus and the related Draft Guidance have been used by our regulatory science approach in a number of non-oncology drugs, our experience with the principles of Project Optimus differentiates us from other biotechnology companies by focusing us, not only on the clinical science, but also on the equally important regulatory process. We believe utilizing our Regulatory Science Approach provides us with three distinct advantages:

- Greater efficiencies (e.g., the right trial design and trial readouts);
- Greater possibility of drug approval by the FDA or other regulatory authorities; and
- Greater ability to evaluate the benefit-risk of a drug compared to existing therapy, which allows prescribers to provide better treatment options for each patient.

Our Drug Pipeline



Our oncology pipeline currently consists of NGC-Cap, NGC-Gem and NGC-Iri (also identified as PCS6422, PCS3117, and PCS11T, respectively) and two non-oncology drugs (PCS12852 and PCS499). We are exploring options for our non-oncology drugs, which may include out-licensing or partnership opportunities. A summary of each drug is provided below.

NGC-Cap

- NGC-Cap is a combination of PCS6422 and a lower dose of the FDA-approved cancer drug capecitabine.

  Capecitabine (NCI, 2025), as presently prescribed and FDA-approved, is an oral prodrug of the cancer drug 5-fluorouracil ("5-FU") (Casale J, 2024), which is itself widely used as an intravenous anticancer agent in many types of cancer. Capecitabine is metabolized into 5-FU where it is then further metabolized to anabolites (which kill both cancer cells and normal duplicating cells) and catabolites (have no cancer killing properties and may cause side effects) (Yen-Revollo, 2008). In 2021, Medicare Part B alone reports over 9.2 million dosing units of capecitabine used.

  Dihydropyrimidine dehydrogenase ("DPD") is an enzyme that helps the body break down thymine and uracil, and inactivates 80–90% 5-FU (Yen-Revollo, 2008). This means the dose of capecitabine must be high enough to account for the DPD effect. However, DPD enzyme activity has been shown to vary among individuals in a Gaussian pattern (i.e. normal distribution or bell-shaped curve), with as much as a sixfold variation from the lowest to the highest values. This wide variation in DPD activity is likely responsible for the wide variation in the half-life observed in patients in population studies (Diasio, 1998). This may suggest a source of the high incidence of moderate to severe side effects experienced by people taking capecitabine.

  Adverse side effects occur in up to 70% of patients treated with capecitabine (Yen-Revollo, 2008) (Xeloda Package Insert, 2015), including myelosuppression, cardiac toxicity, mucositis, diarrhea, and hand-foot syndrome ("HFS"). These side effects frequently result in decreased doses, interrupted doses, or discontinuation of treatment with capecitabine, which limits its effectiveness to the patient. Approximately 30% of patients will experience toxicities above grade 3, and approximately 10% to 20% will require hospitalization to treat these toxicities (Meulendijks D, 2016).

HFS occurs in 15.5% to 68.3% (median, 53.5%) of patients treated with capecitabine (Yen-Revollo, 2008). The molecular pathophysiology of 5-FU-induced HFS remains unclear, but since combination therapy of 5-FU with a DPD inhibitor significantly reduces the occurrence of HFS, it suggests that the toxicity may be due to a byproduct of DPD catabolism of the drug (Yen-Revollo, 2008).

PCS6422 is an orally administered irreversible inhibitor of the enzyme DPD. When capecitabine is given in combination with PCS6422 ("NGC-Cap"), PCS6422 significantly changes the metabolism of 5-FU, which results in a change in the distribution of 5-FU within the body. Due to this change in metabolism, and the overall metabolite profile of anabolites and catabolites, the side effect and efficacy profile of NGC-Cap has been found to be different from capecitabine given without PCS6422. Since the potency of NGC-Cap is greater than FDA-approved capecitabine, the amount of capecitabine anabolites formed from 1mg of capecitabine administered in NGC-Cap will, therefore, be much greater than would be formed from the administration of 1mg of existing capecitabine. Therefore, a lower dose of capecitabine would be expected to accomplish the same, or greater, cancer-killing activity. Importantly, chemically inhibiting DPD activity also reduces interpatient and intrapatient variability, raises plasma levels of bioavailable 5-FU, and lengthens the time of pharmacologic exposure to the drug (Yen-Revollo, 2008), meaning that there should be less variability in response and side effects.

On August 2, 2021, we enrolled the first patient in our Phase 1B trial in patients with advanced refractory gastrointestinal (GI) tract tumors. Our interim analysis of Cohorts 1 and 2A found no dose-limiting toxicities (DLTs), no drug-related adverse events greater than Grade 1, and no adverse events associated with the catabolites of 5-FU such as HFS. In this Phase 1B trial, it was demonstrated that the irreversible inhibition of DPD by PCS6422 could alter the metabolism, distribution and elimination of 5-FU, making NGC-Cap significantly (up to 50 times) more potent than capecitabine alone and potentially leading to higher levels of anabolites which can kill replicating cancer and normal cells. By administering NGC-Cap to cancer patients, the balance between anabolites and catabolites changes depending on the dosage regimens of PCS6422 and capecitabine used, making the efficacy-safety profile of NGC-Cap different than that of FDA-approved capecitabine and requiring further evaluation of the PCS6422 and capecitabine regimens to determine the optimal NGC-Cap regimens for patients.

In an effort to better estimate the timeline of DPD inhibition and formation of new DPD, we modified the protocol for the Phase 1B trial and began enrolling patients in the amended Phase 1B trial in April 2022. On November 1, 2022, we announced that data from the Phase 1B trial identified multiple dosage regimens with potentially better safety and efficacy profiles than currently existing capecitabine regimens. Since 5-FU exposure is dependent on both the PCS6422 regimen and the capecitabine regimen, safe regimens were identified as well as regimens that cause DLTs. One of the regimens in the Phase 1B trial did cause DLTs in two patients, one of whom died from complications of his condition in conjunction with the treatment. The Phase 1B trial completed enrollment in early 2024 and the last subject completed the study in July 2024. Data from the Phase 1B showed, that although 5-FU exposure at therapeutic doses was 5 to 10 fold greater than for monotherapy, adverse events from 5-FU catabolites were minimal while anabolite associated adverse events for the highest dose cohorts were similar to those reported for monotherapy. In these evaluable subjects with refractory or intolerant cancer, the combination of PCS6422 and capecitabine showed an efficacy with a partial response rate of 11%, stable disease rate of 44%, and a median progression free survival of 93 days. This safety and efficacy data supports the inclusion of the 2 dosage regimens of PCS6422 in combination with capecitabine (from Cohort 3 [75 mg BID] and Cohort 4 [225 mg BID]) in the Phase 2 study. The safety review committee determined the MTD and RP2D as (capecitabine 450 mg/day; 225 mg BID), the Cohort 4 dosing regimen.

In parallel with the Phase 1B trial, we had discussions with the FDA which clarified that the major goal for the next Phase 2 trial would be to evaluate and understand the dose- and exposure-response relationship for anti-tumor activity and safety. The specific dosage regimens for the trial were defined following the determination of the MTD from Phase 1B trial. Following the FDA meeting on December 11, 2023, we determined the next NGC-Cap trial would be a Phase 2 trial in breast cancer. This decision was supported through discussions with the FDA, where we agreed with the FDA that the development of NGC-Cap in breast cancer would be a more efficient development program than metastatic colorectal cancer and improve the likelihood of FDA approval. The FDA agreed that the data generated from past and existing studies could be used to directly support the Phase 2 trial in breast cancer. Capecitabine is already approved as both monotherapy and combination therapy in breast cancer, which contributes to the logic and efficiency of our current direction. In addition, the FDA's agreement that our present data would support a Phase 2 trial in breast cancer makes the expansion seamless. The objective for the Phase 2 trial is to provide safety-efficacy data to preliminarily demonstrate the benefit of NGC-Cap over monotherapy capecitabine. Based on this expansion to breast cancer, we expanded our Oncology Advisory Board to include key breast cancer oncologists.

The IND for the evaluation of NGC-Cap for the treatment of breast cancer was cleared by the FDA on July 24, 2024, and allowed for the Phase 2 trial to be initiated. The Phase 2 study (NCT06568692) is a global multicenter, open-label, adaptive designed safety-efficacy trial comparing two different doses of NGC-Cap to FDA-approved monotherapy capecitabine in approximately 60 to 90 patients with advanced or metastatic breast cancer. The trial is designed to evaluate the safety-efficacy profile of NGC-Cap versus monotherapy capecitabine, to determine the potential optimal dosage regimens of NGC-Cap as required by the FDA Project Optimus Initiative and to evaluate the possibility of personalizing NGC-Cap therapy. The first patient in the trial was dosed on October 2, 2024, and the trial is currently enrolling additional patients. After 20 patients have been treated, an interim analysis will be conducted.

Breast cancer is the most diagnosed cancer, representing approximately 15% of all new cancer patients in 2023. It has a prevalence of more than 3.8 million patients, with nearly 300,000 new diagnoses last year. Over 150,000 women are currently living with advanced or metastatic breast cancer. The NGC-Cap annual newly diagnosed incidence rate for breast, colorectal and other cancers is greater than 250,000 patients per year.

NGC-Gem

- PCS3117, also referred to as NGC-Gem, is a cytidine analog similar to gemcitabine (Gemzar®), but different enough in chemical structure that some patients are more likely to respond to NGC-Gem than gemcitabine. In addition, we believe those patients that are inherently resistant, or who acquire resistance, to gemcitabine may not be resistant to NGC-Gem. The difference in response occurs because NGC-Gem is metabolized to its Active Metabolite through a different enzyme system than gemcitabine.

  Gemcitabine is widely used in pancreatic, gall bladder, lung, and other solid tumor cancers. Approximately 20%-40% of patients respond to gemcitabine across solid tumor cancers. Resistance to gemcitabine is a key problem with 55%-85% of patients are inherently resistant or acquire resistance (Gemzar PI, 2019). In 2021, Medicare Part B alone reports over 840,000 dosing units used.

  PCS3117 has completed a Phase 2A trial in patients with progressive metastatic pancreatic cancer after previous chemotherapy treatments, including 93% refractory to gemcitabine, with the following results:

  - 31% (14 patients) had progression-free survival for 8 weeks or more
  - 12% (5 patients) had stable disease for more than 4 months
  - One patient had a tumor reduction of 40% after 28 days of treatment
  - Mild to moderate adverse events were reported with a better overall safety profile than gemcitabine.

  Like gemcitabine, NGC-Gem could be used to treat patients with various cancers such as pancreatic, biliary tract, lung, ovarian, and breast. We estimate more than 275,000 patients in the United States were newly diagnosed in 2022 with pancreatic, biliary tract, lung, ovarian, and breast cancer.

NGC-Iri

- PCS11T, also referred to as NGC-Iri, is an analog of SN38 (SN38 is the active metabolite of irinotecan). The chemical structure of NGC-Iri is designed to influence the uptake of the drug into cancer cells, resulting in more NGC-Iri entering cancer cells than normal cells.

  Irinotecan is widely used in lung, pancreatic, ovarian, cervical & other solid tumor cancers. Onivyde® is irinotecan in a liposomal formulation. Approximately 15-35% of patients respond to irinotecan across the solid tumor cancers. Major drawbacks are the side-effect profile, including black box warnings for diarrhea and myelosuppression (Camptosar PI, 1996) (Onivyde PI, 1996). Dose limiting side effects result in less patients being able to benefit from treatment. Despite the black box warning for severe side effects, Medicare reported a total of more than 1.8 million doses of irinotecan and Onivyde® in 2021.

  Our preclinical study in mouse xenograft models showed that after NGC-Iri administration, there was greater accumulation of SN-38 in the tumor compared with other tissues than after irinotecan or Onivyde® administration. Additionally, less SN-38 accumulated in non-cancer tissues, such as muscle, after NGC-Iri administration than after irinotecan or Onivyde® administration, supporting the potential for a better NGC-Iri safety profile.

  Accumulation of SN-38 in the tumor compared with other tissues was greater after NGC-Iri administration than after irinotecan or Onivyde® administration:

  - Tumor-to-muscle ratio of approximately 200 for NGC-Iri and less than 15 for irinotecan and Onivyde®
  - Tumor-to-plasma ratio approximately 10 for NGC-Iri and less than 7 for irinotecan and Onivyde®

  The muscle-to-plasma ratio was less than 0.10 for NGC-Iri and greater than 0.4 for irinotecan and Onivyde®

  We are defining the potential paths to approval, which include defining the targeted patient population and the type of cancer. In 2025, subject to available funding, we plan to expand the preclinical analysis, including additional preclinical efficacy and toxicity studies; evaluate manufacturing options for NGC-Iri; and conduct chemistry, manufacturing and control (CMC) activities and pre-IND enabling studies.

  Like irinotecan, NGC-Iri could be used to treat patients with various cancers such as lung, colorectal, gastrointestinal, and pancreatic cancer. We estimate at least 200,000 patients in the United States were newly diagnosed in 2022 with lung, colorectal, gastrointestinal, and pancreatic cancer.

Non-Oncology Pipeline for Out-licensing or Partnership

- PCS12852 is a highly specific and potent 5HT4 agonist that that is Phase 2B ready as potentially the first meaningful treatment for diabetic gastroparesis patients.

  The target indication for PCS12852 is the treatment of moderate to severe gastroparesis in diabetic patients. Gastroparesis is a chronic digestive disorder characterized by delayed gastric emptying of solid food without obstruction. Gastroparesis symptoms include: nausea, vomiting, postprandial fullness, early satiety, abdominal pain, heartburn and poor appetite. Global prevalence of gastroparesis is over 30 million, with a diabetic population of over 8 million (Delveinsight), with 60% experiencing moderate to severe symptoms. Eighty percent of patients are female.

  PCS12852 was initially evaluated in clinical studies in South Korea for gastric emptying and gastrointestinal motility in healthy volunteers and volunteers with a history of constipation. In October 2021, the FDA cleared our IND application to proceed with a Phase 2A trial for the treatment of gastroparesis. We enrolled our first patient on April 5, 2022 and completed enrollment of the trial on September 2, 2022. Results from this Phase 2A trial, which included 25 patients with moderate to severe gastroparesis, demonstrated improvements in gastric emptying in patients receiving 0.5 mg of PCS12852 as compared to placebo. The results indicated that for the patients in the PCS12852 group, the mean time for 50% of the gastric contents to empty (t50) compared to their baseline value (±SD) decreased by -31.90 min (±50.53) (compared to the change seen in the placebo group of only -9.36 min (±42.43). Significant gastric emptying differences were not observed between the placebo and the 0.1 mg dose. Adverse events associated with the administration of PCS12852 were generally mild to moderate as expected, limited in duration, and quickly resolved without any sequelae. There were no cardiovascular safety events or serious adverse events reported during the trial. Additionally, the 0.5 mg of PCS12852 showed a greater improvement than placebo in the gastroparesis symptomology scales used in the trial, including both total scores in the scales, as well as sub-scores such as nausea, vomiting and abdominal pain. With the trial now complete, we have the data necessary to finalize the development plan for the treatment of diabetic gastroparesis patients.

  We are exploring options for PCS12852, which may include licensing, partnering and/or collaborating opportunities.

- PCS499 is an oral tablet of the deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). PCS499 is a drug that can be used to treat unmet medical need conditions caused by multiple pathophysiological changes. We are presently defining the development plan for the use of PCS499 in a primary glomerular disease.

  PCS499 was previously evaluated in a Phase 2 trial for the treatment of diabetic nephropathy and successfully demonstrated a positive change in proteinuria. Unfortunately, the primary endpoint for diabetic nephropathy was not proteinuria, so the development was discontinued. We do not believe that ulcerative and non-ulcerative necrobiosis lipoidica (uNL and NL, respectively) are potential target indications and do not expect to find a partner to develop PCS499 in these indications.

  However, within the last couple of years, FDA has approved drugs based on the change in proteinuria for the primary endpoint in glomerular disease IgA. Since diabetic nephropathy is not a primary glomerular disease, diabetic nephropathy is still not a viable indication given the endpoint required and the potential size/cost of a study. In evaluating the previous data, we believe that PCS499 could be successfully developed in a primary glomerular disease such as focal segmental glomerulosclerosis, or FSGS, and IgA. We intend to design a development program with the next study being an adaptive designed Phase 3 trial, meet with the FDA, and then find a partner to take the drug to approval.

Market Overview

Capecitabine

Market Drivers:

- Increasing Cancer Prevalence: The rising incidence of cancers such as breast and colorectal cancers in the U.S. is a significant driver. The American Cancer Society estimated that over 313,000 new cases of breast cancer would be diagnosed and over 42,000 deaths in 2024. They also estimated over 152,000 new cases of colorectal cancer would be diagnosed and over 53,000 deaths.
- Aging Population: The growing elderly population, particularly the baby boomer generation, contributes to a higher incidence of cancer, thereby increasing the demand for capecitabine.

Market Size and Growth:

- 2022: The U.S. capecitabine market was valued at approximately USD 408.2 million (GMI Insights, 2023).
- 2032 Projection: The market is expected to reach USD 652.9 million, reflecting a compound annual growth rate (CAGR) of 4.9% from 2023 to 2032 (GMI Insights, 2023).
- In 2021 more than 9,200,000 dosing units of capecitabine were reported by Medicare Part B, suggesting a total that may exceed 17,000,000 when considering non-Medicare patients.

Gemcitabine

Market Size and Growth:

- 2023: The U.S. gemcitabine market was valued at approximately USD 727.5 million (Fact.MR, 2023).
- 2033 Projection: The market is expected to reach USD 1.43 billion, reflecting a compound annual growth rate (CAGR) of 7% from 2023 to 2033 (Fact.MR, 2023).
- In 2021 more than 840,000 dosing units of capecitabine were reported by Medicare Part B, suggesting a total that may exceed 1,700,000 when considering non-Medicare patients.

Market Drivers:

- Increasing Cancer Prevalence: The rising incidence of cancers such as pancreatic and non-small cell lung cancers in the U.S. is a significant driver.
- Aging Population: The growing elderly population contributes to a higher incidence of cancer, thereby increasing the demand for gemcitabine.

Market Segmentation:

- By Indication: The market is segmented into pancreatic cancer, non-small cell lung cancer, breast cancer, ovarian cancer, and others.

Irinotecan / SN-38

Market Size and Growth:

- The global irinotecan market is experiencing significant growth, primarily driven by the increasing prevalence of colorectal cancer and advancements in cancer therapeutics. In 2023, the market was valued at approximately USD 9.2 billion and is projected to reach around USD 14.7 billion by 2032, reflecting a compound annual growth rate (CAGR) of 6.5% during this period (Dataintelo, 2024).
- In 2021 more than 1,800,000 dosing units of capecitabine were reported by Medicare Part B, suggesting a total that may exceed 3,000,000 when considering non-Medicare patients.

Market Segmentation:

- Colon Cancer: Irinotecan is a cornerstone in the treatment regimen for metastatic colon cancer, often used in combination therapies.
- Rectal Cancer: Employed in cases where the disease has advanced or recurred, enhancing patient survival rates.
- Other: Includes applications in treating small cell lung cancer and other malignancies where irinotecan has shown efficacy.

Key Market Drivers:

- Rising Cancer Prevalence: The global increase in colorectal and other cancers necessitates effective treatments like irinotecan.
- Adverse Effects: Common side effects, such as neutropenia and diarrhea, can limit patient compliance and pose challenges in treatment management.

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Our Team

Our drug development efforts are guided by our knowledge and experience in applying our regulatory science approach to decrease manageable risks, costs, and time toward achieving marketing authorization from regulatory authorities including the FDA. We have assembled a seasoned management team and development team with extensive experience in developing therapies, including advancing product candidates from preclinical research through clinical development and ultimately regulatory approval and commercialization. Our team is led by our President of Research and Development and Founder David Young, Pharm.D., Ph.D. who has extensive experience in research, regulatory approval and business development and who served at Questcor Pharmaceuticals for eight years, initially as an independent director on its Board of Directors and, subsequently, as its Chief Scientific Officer.

To execute our strategy, we assembled an experienced and development team with a successful track record of drug approvals and successful exits. Our team is experienced in developing drug products through all principal regulatory tiers from IND-enabling studies to New Drug Application (NDA) submission. Throughout their careers, the combined scientific, development and regulatory experiences of our team members have resulted in more than 30 drug approvals in indications reviewed by almost every division of the FDA including the oncology divisions, over 100 meetings with the FDA and involvement with more than 50 drug development programs, including drug products targeted to patients who have an unmet medical need and cancer patients. In addition, the FDA Project Optimus Oncology initiative and recent FDA Oncology Guidance applies our regulatory science approach and principles used and refined by our Founders over the last 30 years.

Intellectual Property

Our success will depend in large part on our ability and that of our licensors to:

- obtain and maintain international and domestic patent and other legal protections for the proprietary technology, inventions and improvements we consider important to our business;
- prosecute and defend our existing and future patents, once obtained;
- preserve confidentiality of our own and our licensed methods, processes and know-how; and
- operate without infringing the patents and proprietary rights of other parties.

Although we rely extensively on licensing patents from third parties, we intend to seek appropriate patent protection for product candidates in our research and development programs, where applicable, and their uses by filing patent applications in the United States and other selected countries. We intend for these patent applications to cover, where possible, claims for compositions of matter, medical uses, processes for preparation and formulations.

Our current patent portfolio consists of the number of patents related to our drug candidates licensed from each third-party licensor. In addition to the international patents and/or international and U.S. patent applications licensed from our third-party licensors, we have licensed at least the following number of U.S. patents:

	CoNCERT	Yuhan	Aposense	Elion	Ocuphire	Total
U.S. patents	9	6	3	2	6	25

A provisional patent for NGC-Cap has been filed.

Besides relying on patents, we may also rely on trade secrets, proprietary know-how and continuing innovation to develop and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. In addition, we continuously evaluate opportunities to obtain exclusivity through our regulatory filings with the FDA. We seek protection of these trade secrets, proprietary know-how and any continuing innovation, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide meaningful protection for, or adequate remedies to protect, our technology in the event of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors.

License Agreements

The following descriptions of our license agreements are only summaries. You should also refer to the copies of such agreements which have been filed as exhibits to this Annual Report.

License Agreement with Elion Oncology, Inc.

On August 23, 2020, we entered into a condition precedent License Agreement with Elion Oncology ("Elion License Agreement"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS6422 globally. The license grant was conditioned on the following being satisfied by October 30, 2020: (i) our closing on an equity financing of at least $15 million in gross proceeds and (ii) successful up-listing to Nasdaq.

On October 6, 2020, all conditions were satisfied, resulting in the addition of PCS6422 to our portfolio, and we paid $100,000 cash and issued 41,250 shares of our common stock to Elion. As part of the Elion License Agreement, we agreed to issue to Elion 5,000 shares of our common stock on each of the first and second anniversary dates of the Elion License Agreement.

As additional consideration, we will pay Elion development and regulatory milestone payments (a portion of which are payable in shares of our common stock and a portion of which are payable in cash) upon the achievement of certain milestones, which include FDA or other regulatory approval and dosing a patient. In addition, we must pay Elion one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments received with Elion based on any sub-license agreement we may enter.

On May 17, 2022, we amended the third Milestone Event of Section 6.4 of our License Agreement with Elion Oncology, Inc. changing the third Milestone Event from "1st Patient in Dose Confirmation Study" to (a) determination of the maximum tolerated dose (MTD) or (b) determination of the recommended Phase 2 Dose. Prior to this amendment, the third milestone was not considered probable since it was unknown when, or if a dose confirmation study was going to be conducted. As a result of the modification, we consider it probable that the recommended Phase 2 dosage regimen could be determined in connection with our current Phase 1B trial for NGC-Cap. We recorded an expense and related liability of $189,000 representing the value of the shares we anticipate issuing to Elion at the fair value on the date of modification. No other terms or conditions of the License Agreement were modified. We determined the dosage for our Phase 2 study on January 25, 2024 and issued 5,000 shares of common stock to Elion for meeting this milestone.

We are required to use commercially reasonable efforts, at our sole cost and expense to research, develop and commercialize products in one or more countries, including dosing a first patient with a product in a Phase 2 or 3 clinical trial by October 6, 2024. We dosed our first patient in a Phase 2 clinical trial on October 2, 2024. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 90-day opportunity to cure such breach (which is shortened to 15 days for a payment breach). See Item 3 – Legal Proceedings herein for additional information regarding the status of the Elion License Agreement.

License Agreement with Ocuphire Pharma, Inc.

On June 16, 2021, we executed a License Agreement with Ocuphire Pharma, Inc. ("Ocuphire Agreement") under which we received a license to research, develop and commercialize PCS3117 globally, excluding the Republic of Singapore, China, Hong Kong, Macau and Taiwan.

As consideration for the Ocuphire Agreement, we issued 2,235 shares of our common stock to Ocuphire, a cash payment of $200,000 and assumed $66,583 in certain liabilities. Additional consideration includes future development and regulatory milestones payments to Ocuphire upon our achievement of certain defined clinical milestones, such as dosing a patient in pivotal trials and receiving marketing authorization by a regulatory authority in the United States or another country. In addition, we are required to pay Ocuphire one-time sales milestone payments based on the achievement during a calendar year of the highest annual Net Sales for products made and pay royalties based on annual Net Sales, as defined in the Ocuphire Agreement.

We are required to use commercially reasonable efforts, at our sole cost and expense to oversee such commercialization efforts, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) first patient administered drug in a Clinical Trial of a Product prior to June 16, 2024 and (ii) first patient administered drug in a Pivotal Clinical Trial of a Product or first patient administered drug in a Clinical Trial for a Second Indication of a Product prior to June 16, 2026. We are currently in discussions with Ocuphire to extend these deadlines. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 120-day opportunity to cure such breach.

License Agreement with Aposense, Ltd.

On May 24, 2020, we entered into a condition precedent License Agreement with Aposense, Ltd. ("Aposense License Agreement"), pursuant to which we were granted Aposense's patent rights and Know-How to develop and commercialize their next generation irinotecan cancer drug, PCS11T. The Aposense License Agreement provides us with an exclusive worldwide license (excluding China), to research, develop and commercialize products comprising or containing PCS11T. The license grant was conditioned on the following being satisfied within nine months of May 24, 2020 (or the Aposense License Agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the Aposense License Agreement.

On October 6, 2020, all conditions were satisfied, resulting in the addition of PCS11T to our portfolio, and we issued 31,250 shares of our common stock to Aposense. As additional consideration, we will pay Aposense development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we will pay Aposense one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any sales milestone payments or royalties we receive with Aposense based on any sub-license agreement we may enter.

License Agreement with Yuhan Corporation

On August 19, 2020, we entered into a License Agreement with Yuhan Corporation ("Yuhan License Agreement"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 globally, excluding South Korea.

As consideration for the Yuhan License Agreement and related Share Issuance Agreement, we issued to Yuhan 25,000 shares of common stock. As additional consideration, we will pay Yuhan development and regulatory milestone payments (a portion of which are payable in shares of our common stock based on the volume weighted average trading price during the period prior to such achievement and a portion of which are payable in cash) upon the achievement of certain milestones, based on a Yuhan affiliate purchasing 37,500 shares of common stock for $3,000,000 in our October 2020 underwritten public offering. The milestones primarily consist of dosing a patient in pivotal trials or having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Yuhan one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments received with Yuhan based on any sub-license agreement we may enter.

We are required to use commercially reasonable efforts, at our sole cost and expense, in conjunction with a joint Processa-Yuhan Board to oversee such commercialization efforts, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) preparing a first draft of the product development plan within 90 days; (ii) requesting an FDA pre-IND meeting for a product within 6 months; (iii) dosing a first patient in a Phase 2A clinical trial with a product within 24 months; and (iv) dosing a first patient with a product in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial with a product by August 19, 2024. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 60-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

License Agreement with CoNCERT Pharmaceuticals, Inc.

On October 4, 2017, Promet entered into a License Agreement with CoNCERT ("CoNCERT License Agreement"). On March 19, 2018, we, Promet, and CoNCERT entered into an Amended Option Licensing Agreement ("March Amendment") that, among other things, assigned the CoNCERT Agreement from Promet to us and we exercised the exclusive commercial license option for the PCS499 compound from CoNCERT.

The CoNCERT License Agreement provides us with an exclusive (including as to CoNCERT) royalty-bearing license to CoNCERT's patent rights and Know-How to develop, manufacture, use, sub-license and commercialize compounds (PCS499 and each metabolite thereof) and pharmaceutical products with such compounds worldwide. We are required to pay CoNCERT royalties, on a product–by-product basis, on future worldwide net sales, or pay a percentage of any sublicense revenue.

We will incur royalty obligations to CoNCERT on a country-by-country and product-by-product basis that expire on a country-by-country and product-by-product basis on the later of (i) expiration or invalidation of the last patent rights covering such product in such country or (ii) the tenth anniversary of the date of the first commercial sale to a non-sublicensee third party of such product in such country.

We are required to use commercially reasonable efforts, at our sole cost and expense, to develop and obtain regulatory approval for one product in the U.S. and at least one other major market and, subject to obtaining regulatory approval in the applicable major market, commercialize one product in the U.S. and at least one other major market. CoNCERT may terminate the agreement if, following written notice and a 60-day opportunity to demonstrate a plan to cure, it believes that we are not using commercially reasonable efforts to develop and obtain regulatory approval for one product in the U.S. and in at least one other major market for any consecutive nine-month period.

The term of the CoNCERT License Agreement continues in full force and effect until the expiration of the last royalty term. On a country-by-country and product-by-product basis, upon the expiration of the royalty term in such country with respect to such product, we shall have a fully paid-up, perpetual, irrevocable license to such intellectual property with respect to such product in such country. In the event of a material breach of the CoNCERT Agreement, either party may terminate the agreement provided such breach is not cured in the 90 days following written notice of the breach (which is shortened to 15 days for a payment breach). In addition, either party may terminate the agreement upon an assignment for the benefit of creditors or the filing of an insolvency proceeding by or against the other party that is not dismissed within 90 days of such filing.

Manufacturing and Clinical Supplies

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on multiple third-party contract manufacturing organizations (CMOs) for the supply of current Good Manufacturing Practices (cGMP)-grade clinical trial materials and commercial quantities of our product candidates and products, if approved. We require all our CMOs to conduct manufacturing activities in compliance with cGMP. We have assembled a team of experienced employees and consultants to provide the necessary technical, quality and regulatory oversight of our CMOs.

We anticipate that these CMOs will have the capacity to support both clinical supply and commercial-scale production, but we do not have any formal agreements at this time with any of these CMOs to cover commercial production. We also may elect to pursue additional CMOs for manufacturing supplies of drug substance and finished drug product in the future. We believe that our standardized manufacturing process can be transferred to a number of other CMOs for the production of clinical and commercial supplies of our product candidates in the ordinary course of business.

Competition

Many of our potential competitors may have significantly greater financial resources, a more established presence in the market, and more expertise in research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and reimbursement, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These potential competitors may also compete with us in recruiting and retaining top qualified scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting each of our products, if approved, are likely to include the efficacy, safety, convenience and price of the products relative to other approved products used on- or off-label for each unmet medical need condition. Although preliminary clinical data exists to support the possibility of improved efficacy and safety profiles for our drugs, more in-depth randomized, controlled studies are required for our products to determine if our preliminary findings will support the approval in the designated unmet medical need indication.

For NGC-Cap, the competitive factors will be related to the efficacy and safety of the product when compared to capecitabine. The market penetration will depend on how much improvement will occur in the efficacy and/or safety profiles when administered in combination with PCS6422. Currently, there are no other reversible or irreversible enzyme inhibitor products approved in the US and no irreversible enzyme inhibitors approved ex-US, which may make PCS6422 the first DPD irreversible inhibitor available.

For NGC-Gem, the competitive factors will include establishing market penetration against other cytidine analogues, such as gemcitabine, which is currently used as first or second line chemotherapy either alone or in combination with other chemotherapy agents. The market penetration will depend on the potential for an improved efficacy profile in patients who have developed tolerance to other agents.

For NGC-Iri, the competitive factors will include establishing marketing penetration against the existing irinotecan product (Camptosar®) and the newer liposomal irinotecan product (Onivyde®). The establishment of that market will be based upon improved efficacy and/or safety of NGC-Iri.

For PCS12852, the competitive factors will include establishing marketing penetration against the metoclopramide products (the only approved drug to treat gastroparesis) and other 5-HT4 receptor agonists used off label. The market penetration will depend on the potential for an improved safety profile due to the very selective 5-HT4 receptor binding by PCS12852 and similar or greater efficacy in the treatment of gastroparesis.

For PCS499, there are currently no FDA-approved drugs for the treatment of patients with NL, and few drugs are used off-label for NL given the lack of efficacy and/or side effect concerns.

Our commercial opportunity for any of our product candidates could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects, than any products that we may develop. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our product candidates.

U.S. Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice (GLP) regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (IRB), at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices (GCP) requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to commercial marketing or sale of the drug in the United States; and

- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS) or to conduct a post-approval study.

Pre-clinical studies

Before testing any biological product candidate in humans, including our product candidates, the product candidate must undergo rigorous pre-clinical testing. The pre-clinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, to assess the potential for adverse events and, in some cases, to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the pre-clinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND.

An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions before that time related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by, or under control of, the trial sponsor, in accordance with GCPs, which include the requirement that all research patients provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about most clinical trials must be submitted within specific timeframes for publication on www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use the publicly available information to gain knowledge regarding the progress of development programs.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted. The goal of the Phase 2 trial is to also determine the “best” dosage regimen(s) to evaluate in the Phase 3 trial. The “best” regimen(s) means the regimen(s) that is(are) most likely to provide a safe-efficacious regimen that appropriately balances the risk-benefit analysis that the FDA is required to evaluate in each drug approval. The ideal way to define this “best” regimen for FDA is to evaluate the adverse event-drug exposure and efficacy-drug exposure relationships, which has also been previously called dose-response relationships or studies, and which has now become the foundation for both the FDA’s Project Optimus Oncology initiative and the draft Guidance to determine the optimal dose for an oncology drug.

- Phase 3 clinical trials generally involve a larger number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow up. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a biologics license application (BLA).

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time, or the FDA may impose other sanctions on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can refuse, suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional pre-clinical studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee.

The review process typically takes twelve months from the date the NDA is submitted to the FDA. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission to determine whether they are sufficiently complete to permit substantive review before accepting them for "filing." The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the current guidelines in effect in the Prescription Drug User Fee Act (PDUFA), the FDA has a goal to review and act on the submission within ten months from the completion of the preliminary review of a standard NDA for a new molecular entity.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical trials or pre-clinical studies in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product in the United States. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, by providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication that could be used "off-label" by physicians in the orphan indication, even though the competitor's product is not approved in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do of the same product, as defined by the FDA, for the same indication we are seeking, or if our product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union, or EU, has similar, but not identical, requirements and benefits.

Expedited review and approval

The FDA has various programs, including fast track designation, accelerated approval, priority review and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six- and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, priority review and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. We may explore some of these opportunities for our product candidates as appropriate.

Post-approval requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are also continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product;
- complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals; product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Healthcare Reform

The United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, the ACA was passed in March 2010 and substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, at the federal level, there is a "Blueprint" to lower prescription drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the current administration will impact the Affordable Care Act and our business.

Moreover, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates.

Other Regulatory Matters

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Manufacturing, sales, promotion and other activities following product approval are subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including Centers for Medicare and Medicaid Services (CMS), other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments.

For example, in the United States, sales, marketing and scientific and educational programs also must comply with state and federal fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws. These laws include the following:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act that can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the federal Physician Payments Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require biotechnology companies to report information on the pricing of certain drug products; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, including damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND or the issue date of the patent, whichever is later, and the submission date of an NDA plus the time between the submission date of an NDA or the issue date of the patent, whichever is later, and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

European Union Drug Development

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the European Union Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority (NCA) and one or more Ethics Committees (ECs). Under the current regime, all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation is currently undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

European Union Drug Review and Approval

In the European Economic Area (EEA), which is comprised of the 26 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of marketing authorizations:

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the European Union, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State (RMS). The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics (SmPC), and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above-described procedures, before granting the MA, EMA or the competent authorities of the Member States of the European Union make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. Similar to the U.S. patent term-restoration, Supplementary Protection Certificates (SPCs) serve as an extension to a patent right in Europe for up to five years. SPCs apply to specific pharmaceutical products to offset the loss of patent protection due to the lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance, and managed healthcare organizations. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Human Capital

As of March 12, 2024, we had 10 full- and part-time employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union and we believe our relationships with our employees are good.

We are highly dependent upon the principal members of our small management team and staff, including our Chief Executive Officer, George Ng; President of Research and Development, David Young, Pharm.D., Ph.D; and our Chief Development and Regulatory Officer, Sian Bigora, Pharm.D. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements may still allow these employees to leave our employment at any time, for or without cause. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical and scientific personnel.

Item 1A. Risk Factors

An investment in our common stock involves a high degree of risk. If any of the following risks actually occur, our business, financial condition, or results of operations could be materially adversely affected, the trading price of our common stock could decline, and you may lose all or part of your investment. You should also refer to the other information contained in this Form 10-K, including our consolidated financial statements and the notes to those statements, and the information set forth under the caption "Special Note Regarding Forward-Looking Statements and Risk Factor Summary." The risks described below and contained in our other periodic reports are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations.

SUMMARY RISK FACTORS

We are providing the following summary of the risk factors contained in our Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage our stockholders to carefully review the full risk factors contained in this Form 10-K in their entirety for additional information regarding the risks and uncertainties that could cause our actual results to vary materially from our recent results or from our anticipated future results.

Risks Related to Our Financial Position and Need for Additional Capital

- We need to raise additional capital to fund our operations.
- We have incurred a history of operating losses and expect to continue to incur substantial costs for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability. Our financial situation creates doubt whether we will continue as a going concern.
- We have limited cash resources and will require additional financing.
- We will need to raise additional capital to complete the development efforts for NGC-Cap, NGC-Gem, and/or NGC-Iri. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- Our financial statements contain a statement regarding a substantial doubt about our ability to continue as a going concern.
- Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

- Our licenses are subject to termination by the licensor in certain circumstances and any termination of a license agreement would result in a loss of important rights and have a material adverse impact on our business and prospects.
- We currently do not have, and may never develop, any FDA-approved, licensed or commercialized products.
- We depend entirely on the successful development of our product candidates, which have not yet demonstrated efficacy for their target indications in clinical trials. We may never be able to demonstrate efficacy for our product candidates, thus preventing us from licensing, obtaining marketing approval by any regulatory agency, and/or commercializing our product(s).
- We must successfully complete clinical trials for our product candidates before we can apply for marketing approval.
- We have little corporate history of conducting clinical trials. Our planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- Disruptions at the FDA and other government agencies could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

- Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully license or commercialize the product and the revenue that we generate from its sales, if any, may be limited.
- We are completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.
- Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expenses.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.
- Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.
- We could face competition from other biotechnology and pharmaceutical companies, and our operating results would suffer if we fail to innovate and compete effectively.
- We rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize any of our product candidates and our business would be substantially harmed.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- Even though we may apply for orphan drug designation for a product candidate, we may not be able to obtain orphan drug marketing exclusivity.
- Although we may pursue expedited regulatory approval pathways for a product candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development, regulatory review or approval process.
- Third-party coverage and reimbursement, health care cost containment initiatives and treatment guidelines may constrain our future revenues.
- Legal, regulatory and legislative changes with respect to reimbursement, pricing and contracting may adversely affect our business and future prospects.
- We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.
- If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.
- We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.
- Changes in U.S. and international trade policies, particularly with respect to China, Europe and India may adversely impact our business and operating results.

Risks Relating to Our Intellectual Property Rights

- We cannot ensure protection of our licensed intellectual property rights.
- Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

General Company-Related Risks

- Litigation or legal proceedings could expose us to significant liabilities and have a negative impact on our business.
- If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.
- If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, interruptions or disruptions to operations or clinical trials, reputational harm, litigation, fines and penalties.
- We are exposed to cyber-attacks and data breaches, including the risks and costs associated with protecting our systems and maintaining integrity and security of our business information, as well as personal data of our guests, employees and business partners.

Risks Related to Ownership of Our Common Stock

- Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our Common Stock.
- Future equity offerings, license transactions or acquisitions may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.
- Our common stock price is expected to be volatile.
- We are a "smaller reporting company," and the reduced disclosure requirements applicable to us as such may make our common stock less attractive to our stockholders and investors.
- We do not currently intend to pay dividends to our stockholders in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in our value.
- If securities or industry analysts do not publish research or reports about our business, or if they publish negative evaluations of our stock or negative reports about our business, our stock price and trading volume could decline.
- Provisions in our corporate documents and Delaware law could have the effect of delaying, deferring, or preventing a change in control of us, even if that change may be considered beneficial by some of our stockholders.
- Provisions in our bylaws provide for indemnification of officers and directors, which could require us to direct funds away from our business and the development of our product candidates.

Risks Related to Our Financial Position and Need for Additional Capital

We need to raise additional capital to fund our operations.

We have incurred recurring losses since inception and had an accumulated deficit of approximately $87.2 million at December 31, 2024. At December 31, 2024, we had cash and cash equivalents totaling $1.2 million and prepaid expenses with the clinical research organizations of our Phase 1B and Phase 2 trials of $1.7 million. Following our January public offering, we believe that our cash on hand will allow us to continue our Phase 2 trial of NGC-Cap and satisfy our capital needs into mid-2025 under our current business plan. In 2025, we will need to raise additional capital to fund our operations and continue our planned development of our NGC drugs.

We have incurred a history of operating losses and expect to continue to incur substantial costs for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability. Our financial situation creates doubt whether we will continue as a going concern.

We are a clinical stage biopharmaceutical company. Processa itself as an organization has never had a drug approved by the FDA or any regulatory agency. The likelihood of success of our business plan must be considered in light of the challenges, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk, and is a capital-intensive business. If we cannot successfully execute our plan to develop our drug pipeline, our business may not succeed.

We will incur additional losses as we continue our research and development activities, seek regulatory approvals for our product candidates and engage in clinical trials. These losses will cause, among other things, our stockholders' equity and working capital to decrease. Any future earnings and cash flow from the operations of our business are dependent on our ability to further develop our products and on revenues and profitability from sales of products or successful joint venture relationships.

There can be no assurance that we will be able to generate sufficient product revenue to become profitable at all or on a sustained basis. Even if we generate revenues, we expect to have quarter-to-quarter fluctuations in revenues and expenses, some of which could be significant, due to research, development, clinical trial, and marketing and manufacturing expenses and activities. We also expect to incur substantial expenses without corresponding revenues, unless and until we are able to obtain regulatory approval and successfully license or commercialize our product candidates. If our product candidates fail in clinical trials or do not gain regulatory approval, or if our products do not achieve market acceptance, we may never become profitable.

We may never be able to obtain regulatory approval for the marketing of our product candidates in any indication in the United States or internationally. As we commercialize and market products, we will need to incur expenses for product marketing and brand awareness and conduct significant research, development, testing and regulatory compliance activities that, together with general and administrative expenses, could result in substantial operating losses for the foreseeable future. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our stock price may decline, and you may lose all or a substantial part of your investment in us.

We have limited cash resources and will require additional financing.

Since inception, we have not generated any revenue, have incurred net losses, have used net cash in our operations and have funded our business and operations primarily through proceeds from the sale of our securities. We expect to continue to require significant future financing to fund our operating activities and to use cash in operating activities for the foreseeable future as we continue our research and development activities to develop products that can be commercialized to generate revenue. Our ability to obtain additional financing will be subject to many factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us.

We will need to raise additional capital to complete the development efforts for NGC-Cap, NGC-Gem and/or NGC-Iri. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

We will need to raise additional capital to fund our operations and continue to support our planned development of our next generation cancer therapy drugs. Our estimates of the amount of cash necessary to fund our activities may prove to be wrong and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, rate of progress and cost of any clinical trials and other manufacturing/product development activities for our current and any future product candidates that we develop, in-license or acquire;
- the results of the clinical trials for our product candidates;
- the timing of, and the costs involved in, FDA approval and any foreign regulatory approval of our product candidates, if at all;
- the number and characteristics of any additional future product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing, co-promotion or other arrangements and the terms and timing of such arrangements;
- the degree and rate of market acceptance of any approved products;
- costs under our third-party manufacturing and supply arrangements for our current and any future product candidates and any products we commercialize;
- costs and timing of completion of any additional outsourced commercial manufacturing or supply arrangements that we may establish;
- costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation;
- costs of operating as a public company;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- costs associated with any acquisition or in-license of products and product candidates, technologies or businesses; and
- personnel, facilities and equipment requirements.

We cannot be certain that additional funding will be available on acceptable terms, or at all. In addition, future debt financing into which we may enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our security holders losing some or all of their investment in us. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

In addition, if we are unable to secure sufficient capital to fund our operations, we may have to enter into strategic collaborations that could require us to share license rights with third parties in ways that we currently do not intend or on terms that may not be favorable to us or our security holders.

Our financial statements contain a statement regarding a substantial doubt about our ability to continue as a going concern.

We had no revenue during the year ended December 31, 2024 or in prior years, and do not have any revenue under contract or any immediate sales prospects. Our primary uses of cash are to fund our planned clinical trials, research and development expenditures and for operating expenses. Cash used to fund operating expenses is impacted by the timing of when we incur and pay these expenses. Our consolidated financial statements have been prepared using U.S. GAAP, and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging pharmaceutical companies regarding product development, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities. We currently have no customers or pharmaceutical products to sell or distribute. These risks and other factors raise substantial doubt about our ability to continue as a going concern.

Our ability to continue as a going concern is dependent on our ability to obtain the necessary financing to meet our obligations and repay our liabilities arising from the ordinary course of business operations when they become due. The substantial doubt about our ability to continue as a going concern may affect the price of our common stock, may impact our relationship with third parties with whom we do business, may impact our ability to raise additional capital and may impact our ability to comply going forward with covenants in our debt agreements.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of December 31, 2024, we had net operating loss (NOL) carryforwards of approximately $36.0 million for federal and state income tax available to offset future taxable income, and federal and state research and development tax credits of approximately $1.2 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended (Section 382). NOL carryforwards prior to 2018 will expire in 2037 if not utilized.

Our NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under Section 382, and corresponding provisions of state law, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research and development tax credits, to offset its post-change income may be limited. We have not completed a Section 382 study and as such our net operating loss carryforwards may be subject to such limitation.

In addition, we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, including through completed or contemplated financings, some of which may be outside of our control. If we determine that a future ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

Our licenses are subject to termination by the licensor in certain circumstances and any termination of a license agreement would result in a loss of important rights and have a material adverse impact on our business and prospects.

Our rights to practice the inventions claimed in the licensed patents and patent applications are subject to our licensors abiding by the terms of those licenses and not terminating them. Our licenses may be terminated by the licensor if we are in material breach of certain terms or conditions of the license agreement or in certain other circumstances. Our license agreements each include provisions that allow the licensor to terminate the license if (i) we breach any payment obligation or other material provision under the agreement and fail to cure the breach within a fixed time following written notice of termination; (ii) we or any of our affiliates, licensees or sublicensees directly or indirectly challenge the validity, enforceability, or extension of any of the licensed patents; or (iii) we declare bankruptcy or dissolve. The majority of license agreements require us to satisfy due diligence milestones that relate to the development of new products containing the licensed drug or the agreement may be terminated by such counterparty. Our rights under these licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the licenses. Termination of any of these licenses could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents we have licensed, determining the scope of the license and related royalty obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

As previously disclosed, on May 7, 2024, the Company received notification from Elion purporting to terminate the license agreement by and between us and Elion as a result of the Company's alleged breach thereof. The Company believes that Elion's claims are without merit and disputes that the license agreement has been validly terminated. We are now in litigation regarding our license agreement. The Company intends to enforce its rights under the license agreement and will pursue such other remedies as it determines are appropriate. Any termination of the Elion license would have a material adverse impact on our business and prospects.

Additionally, we have not met certain specific diligence milestones under our license agreements with Ocuphire and Yuhan. Although we are working to extend the deadlines, there can be no assurance that we will be successful and that such agreements will not be terminated, resulting in a loss of important rights.

If we are unable to maintain our license agreements, our business and results of operations will be adversely affected.

We currently do not have, and may never develop, any FDA-approved, licensed or commercialized products.

We have not yet sought to obtain any regulatory approvals for any product candidates in the United States or in any foreign market. For us to develop any products that might be licensed or commercialized, we will have to invest further time and capital in research and product development, regulatory compliance and market development. Therefore, we and our licensors, prospective business partners and other collaborators may never develop any products that can be licensed or commercialized. All our development efforts will require substantial additional funding, none of which may result in any revenue.

We depend entirely on the successful development of our product candidates, which have not yet demonstrated efficacy for their target indications in clinical trials. We may never be able to demonstrate efficacy for our product candidates, thus preventing us from licensing, obtaining marketing approval by any regulatory agency, and/or commercializing our product(s).

Our product candidates are either in the early stages of clinical development or late stages of preclinical development. Significant additional research and development activity and clinical testing are required before we will have a chance to achieve a viable product for licensing or commercialization from such candidates. Our research and development efforts remain subject to all the risks associated with the development of new biopharmaceutical products and treatments. Development of the underlying technology may be affected by unanticipated technical or other problems, among other research and development issues, and the possible insufficiency of funds needed in order to complete development of these product candidates. Safety, regulatory and efficacy issues, clinical hurdles or other challenges may result in delays and cause us to incur additional expenses that would increase our losses. If we and our collaborators cannot complete, or if we experience significant delays in developing, our potential therapeutics or products for use in potential commercial applications, particularly after incurring significant expenditures, our business may fail, and investors may lose the entirety of their investment.

When we submit an IND or foreign equivalent to the FDA or international regulatory authorities seeking approval to initiate clinical trials in the United States and other countries, we may not be successful in obtaining acceptance from the FDA or comparable foreign regulatory authorities to start our clinical trials. If we do not obtain such acceptance, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses and increase our need for additional capital. Moreover, there is no guarantee that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most drug candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval, and licensing or commercialization of our product candidates, which may never occur.

We must successfully complete clinical trials for our product candidates before we can apply for marketing approval.

Even if we complete our clinical trials, it does not assure marketing approval. Our clinical trials may be unsuccessful, which would materially harm our business. Even if our initial clinical trials are successful, we are required to conduct additional clinical trials to establish our product candidates' safety and efficacy before submitting an NDA. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country.

We are not permitted to market our product candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries.

We have little corporate history of conducting clinical trials. Our planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Our operations to date have been limited to financing and staffing, conducting research and developing our core technologies, identifying and optimizing our lead product clinical candidates, performing due diligence on other potential drug in-licensing opportunities and further moving the clinical product candidates through the development programs identified. Some of the activities in the development programs include receiving FDA IND clearance on one indication for two product candidates, completing a Phase 2A trial for PCS12852 in gastroparesis patients, conducting a Phase 1B trial for NGC-Cap in patients with advanced gastrointestinal tumors, completing a Phase 1 healthy human volunteer trial, completing a Phase 2A clinical trial and conducting a Phase 2 clinical trial in patients with NL and receiving FDA orphan designation on PCS499 in NL. Other activities include improving the manufacturing of PCS499, PCS6422 and NGC-Iri final products and developing regulatory strategy plans for each of the products including expedited review plans, as applicable. Although we have recruited a team that has experience with clinical trials in the United States and outside the United States, as a company, we have only conducted four clinical trials in any jurisdiction and have not had previous experience commercializing product candidates through the FDA or similar submissions to initiate clinical trials or obtain marketing authorization to foreign regulatory authorities. We cannot be certain that other planned clinical trials will begin or be completed on time, if at all; that our development program and studies would be acceptable to the FDA or other regulatory authorities; or that, if regulatory approval is obtained, our product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third-party clinical investigators, CROs, consultants and collaborators. Relying on third-party clinical investigators, CROs or collaborators may result in delays that are outside of our control.

Furthermore, we may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates.

Some preclinical studies and early clinical studies of our product candidates have been completed, but we do not know the predictive value of these studies for our targeted population of patients, and we cannot guarantee that any positive results in these studies will translate successfully to the larger targeted population of patients. It is not uncommon to observe results in human clinical trials that are unexpected based on preclinical testing or early clinical studies, and many product candidates fail in clinical trials despite promising preclinical or early clinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Human patients in clinical trials may suffer significant adverse events or other side effects not observed in our preclinical studies, including, but not limited to, immunogenic responses, organ toxicities such as liver, heart or kidney or other tolerability issues or possibly even death. The observed potency and kinetics of our planned product candidates in preclinical studies may not be observed in human clinical trials. If clinical trials of our planned product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our planned product candidates which may result in complete loss of expenditures which we devote to those products.

We may have difficulty recruiting patients to the clinical trial, patients may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA, an Institutional Review Board ("IRB"), or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical testing. However, any such event, were it to occur, would cause substantial harm to our business and financial condition and would result in the diversion of our management's attention.

Disruptions at the FDA and other government agencies could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, staffing cuts, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions and could greatly impact healthcare and the drug industry. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If disruptions at the FDA or other agencies occurs, such as those resulting from a restructuring of these agencies, a prolonged government shutdown, or uncertainty regarding U.S. federal government funding, could significantly affect the ability of the FDA to review and process our regulatory submissions in a timely manner, or other factors prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In addition, a reduction or delay in government funding of research and development may adversely affect our business. Government funding of research and development is subject to the political process, which is inherently fluid and unpredictable. For example, the NIH announced on February 7, 2025, a policy significantly reducing research grants by limiting payments for indirect overhead. While, as of the date of this filing, the order has been temporarily stayed, there can be no assurance that it will not take effect or that other adverse actions will not be taken. Government proposals to reduce or eliminate budgetary deficits have sometimes included reduced allocations to the NIH and other government agencies that fund research and development activities, or NIH funding may not be directed towards our products and studies, both of which could adversely affect our business and our financial results.

Further, in June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies, including the FDA. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA.

Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully license or commercialize the product and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of our product candidates will depend upon each product's acceptance by the medical community (including physicians, patients and health care payors) and the potential competitive products available to the patients upon commercialization. The degree of market acceptance for any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in treatment guidelines;

- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable.

We are completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, or API, in our product candidates for use in our clinical trials or for commercial products. In addition, we do not have the capability to formulate any of our product candidates into a finished drug product for commercial distribution. As a result, we will be obligated to rely on contract manufacturers, if and when any of our product candidates are approved for commercialization. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of any of our product candidates on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMPs to manufacture both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our product candidates.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of any of our product candidates might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply any of our product candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our product candidates if we decided to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems with suppliers could delay shipment of any of our product candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any of our product candidates over time. If the commercial-scale manufacturing costs of any of our product candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions to regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expenses.

Even if we obtain regulatory approval for any of our product candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices (cGCPs) for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. Compliance with such regulations may result in significant costs and expenses.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

In the United States, the Medicare Modernization Act (MMA) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states. The law also imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA), into law which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We could face competition from other biotechnology and pharmaceutical companies, and our operating results would suffer if we fail to innovate and compete effectively.

Our products are used for indications where we believe that there is an unmet medical need. If existing or newly approved drug products, whether approved by the FDA for the indication or not, are able to successfully treat the same patients, it may be more difficult to perform clinical studies, to develop our product and/or to commercialize our product, adversely affecting our business. Since the biopharmaceutical industry is characterized by intense competition and rapid innovation, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results than our product candidates. Our competitors may include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as a larger research and development staff and experienced marketing and manufacturing organizations, established relationships with CROs and other collaborators, as well as established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates, or may develop proprietary technologies or secure patent protection and, in turn, exclude us from technologies that we may need for the development of our technologies and potential products.

Even if we obtain regulatory approval of any of our product candidates, we may not be the first to market and that may negatively affect the price or demand for our product candidates. Additionally, we may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Furthermore, for drugs that receive orphan drug designation at the FDA, a competitor could obtain orphan product approval from the FDA with respect to such competitor's drug product. If such competitor drug product is determined to be the same product as one of our product candidates, we may be prevented from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances, and we may be subject to similar restrictions under non-U.S. regulations.

We rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize any of our product candidates and our business would be substantially harmed.

We have entered into agreements with third-party CROs to conduct and manage our clinical programs including contracting with clinical sites to perform our clinical studies. We rely heavily on these parties to execute clinical studies for our product candidates and will control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA and its foreign equivalents enforce these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or other regulatory authorities will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we design clinical trials for our product candidates in consultation with CROs, the CROs will manage all of the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of any of our product candidates for the subject indication may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or any of our product candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for any of our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing of drug product candidates is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA or comparable foreign regulatory authorities will view the results as we do or that any future trials of any of our product candidates will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our product candidates may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for any of our product candidates. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics including demographic factors and health status.

Even though we may apply for orphan drug designation for a product candidate, we may not be able to obtain orphan drug marketing exclusivity.

There is no guarantee that the FDA, EMA or their foreign equivalents will grant any future application for orphan drug designation for any of our product candidates, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Even where orphan drug designation or equivalent status is granted, there is no guarantee of orphan drug marketing exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. While the FDA granted orphan-drug designation to PCS499 for the treatment of NL and to NGC-Gem for the treatment of pancreatic cancer, there can be no assurance that we will receive orphan drug designation for any additional product candidates in the indications for which we think they might qualify, if we elect to seek such applications.

Although we may pursue expedited regulatory approval pathways for a product candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development, regulatory review or approval process.

Although we believe there may be an opportunity to accelerate the development of certain of our product candidates through one or more of the FDA's expedited programs, such as fast track, breakthrough therapy, accelerated approval or priority review, we cannot be assured that any of our product candidates will qualify for such programs.

For example, a drug may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for an expedited program for our product candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. Even if we are successful in obtaining access to an expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate.

Third-party coverage and reimbursement, health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market our product candidates will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which any of our product candidates may be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our product candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope.

Legal, regulatory and legislative changes with respect to reimbursement, pricing and contracting may adversely affect our business and future prospects.

Federal and state governments may adopt policies affecting drug pricing and contracting practices outside of the context of federal programs such as Medicare and Medicaid, which may adversely affect our business. For example, several states have adopted laws that require drug manufacturers to provide advance notice of certain price increases and to report information relating to those price increases. There can be no assurances that future changes to Medicare and/or Medicaid prescription drug reimbursement policies, drug pricing and contracting practices, or government drug price regulation programs such as the Medicaid Drug Rebate Program or 340B Drug Pricing Program will not have an adverse impact on our business and future prospects.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or even death. We cannot offer any assurance that we will not face product liability suits in the future, or that our insurance coverage will be sufficient to cover our liability in any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputations;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distractions of management's attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of revenue.

We have obtained product liability insurance coverage for our clinical trials. However, large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects and our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms, or at all. A successful product liability claim, or series of claims, brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects.

If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. If we are found to have promoted off-label uses of any of our product candidates, we may become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our brand and reputation could be damaged.

The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates outside of those indications for use when the physician's independent professional medical judgment deems appropriate. Physicians may also misuse our product candidates or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by physicians or their patients. Furthermore, the use of our product candidates for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation among physicians and patients.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates or not to continue commercializing one or more of our approved product candidates for a variety of reasons, including changes in our internal product, technology or indication focus, the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment, and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

Changes in U.S. and international trade policies, particularly with respect to China, Europe and India may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China. Both China and the United States have each imposed tariffs indicating the potential for further trade barriers, including the U.S. Commerce Department adding numerous Chinese entities to its "unverified list," which requires U.S. exporters to go through more procedures before exporting goods to such entities. Further, the current administration has imposed tariffs on foreign imports into the United States from China, signaled intent to negotiate and enter into a new trade agreement with India by the end of calendar 2025, and is expected to issue a plan for reciprocal tariffs broadly. It is unknown whether and to what extent new tariffs, export controls, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect our ability to commercialize our product candidates if approved, the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

Risks Relating to Our Intellectual Property Rights

We cannot ensure protection of our licensed intellectual property rights.

Our commercial success will depend, in part, on the ability of our licensors to obtain and maintain patent protection for our licensed technologies, products and processes, successfully defend these licensed patents against third-party challenges and successfully enforce these patents against third-party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our licensed intellectual property rights. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents. The existing patents and patent applications relating to our drug product candidates may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection for our proprietary rights is uncertain. We may not be able to adequately protect our rights, gain or keep our competitive advantage, or provide any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to any of our product candidates, or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications licensed or filed by us, or that our licensed intellectual property or intellectual property that we develop in the future will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices.

In the future, we may rely on know-how and trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, know-how and trade secrets are difficult to protect. While we intend to require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may also have rights. If we cannot maintain the confidentiality of our licensed or owned proprietary technology and other confidential information, our ability to protect valuable information licensed or owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our licensed or owned know-how and trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent or trade secret protection for our product candidates or our technologies, third parties could use our licensed or owned intellectual property, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by our licensors, us, or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we, our licensors, or business partners will have adequate resources to enforce these trademarks.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our licensed technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our licensed product candidates or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may divert the time and attention of our technical personnel and management.

Third parties may hold proprietary rights that could prevent any of our licensed product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to any of our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license and pay royalties to continue to manufacture or market any of our product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidates or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing any of our product candidates or a future product candidate, which could harm our business, financial condition and operating results.

A number of companies, including several major pharmaceutical companies, have conducted, or are conducting, research within the licensed fields in which we intend to operate, which has resulted, or may result, in the filing of many patent applications related to this research. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the United States Patent and Trademark Office (USPTO), we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

General Company-Related Risks

Litigation or legal proceedings could expose us to significant liabilities and have a negative impact on our business.

The per share price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation, including class action litigation. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations. In addition, from time to time, we may be party to other various claims and litigation proceedings. We evaluate these claims and litigation proceedings to assess the likelihood of unfavorable outcomes and to estimate, if possible, the amount of potential losses. Based on these assessments and estimates, we may establish reserves, as appropriate. These assessments and estimates are based on the information available to management at the time and involve a significant amount of management judgment. Actual outcomes or losses may differ materially from its assessments and estimates.

On December 3, 2024, two of the investors in our February 2021 private offering filed a lawsuit alleging fraud and negligent misrepresentation in connection therewith and seeking monetary damages. In addition, on May 10, 2024, we filed a lawsuit against Elion Oncology, Inc. disputing the purported termination of a license agreement, which lawsuit is subject to counterclaims by Elion. We intend to vigorously defend ourselves in these lawsuits and cannot at this time predict the likely outcome of any litigation, reasonably determine either the probability of a material adverse result or any estimated range of potential exposure, or reasonably determine how these matters or any future matters might impact our business, our financial condition, or our results of operations, although such impact, including the costs of defense, as well as any judgments or indemnification obligations, among other things, could be materially adverse to us.

Lawsuits may divert our management's attention, and we may incur significant expenses in defending any lawsuits. The results of litigation and other legal proceedings are inherently uncertain, and adverse judgments or settlements in any legal dispute may result in monetary damages, penalties or injunctive relief, or the termination of license agreements, which could have a material adverse effect on our financial position, cash flows or results of operations. While we maintain insurance for certain potential liabilities, such insurance does not cover all types of potential liabilities and is subject to various exclusions, as well as limits on amounts recoverable.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

We are highly dependent upon the principal members of our small management team and staff, including George Ng, our Chief Executive Officer; David Young, Pharm.D., Ph.D, our President of Research and Development; and Sian Bigora, Pharm.D., our Chief Development and Regulatory Officer. The employment of Drs. Young and Bigora may be terminated at any time by either us or Dr. Young or Dr. Bigora. The loss of any current or future team member could impair our ability to design, identify, and develop new intellectual property and product candidates and new scientific or product ideas. Additionally, if we lose the services of any of these persons, we would likely be forced to expend significant time and money in the pursuit of replacements, which may result in a delay in the development of our product candidates and the implementation of our business plan and plan of operations and diversion of our management's attention. We can give no assurance that we can find satisfactory replacements for our current and future key scientific and management employees on terms that would not be unduly expensive or burdensome to us.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we expect to have employment agreements with our key employees, these employment agreements may still allow these employees to leave our employment at any time, for or without cause. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical and scientific personnel.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, interruptions or disruptions to operations or clinical trials, reputational harm, litigation, fines and penalties.

In the ordinary course of our business, we, or the third parties upon which we rely, process, collect, receive, store, use, transmit, transfer, make accessible, protect, secure, dispose of, disclose and share proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets.

Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to, social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fire, flood, and other similar threats.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, drug suppliers, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to perform our research and development activities.

We are exposed to cyber-attacks and data breaches, including the risks and costs associated with protecting our systems and maintaining integrity and security of our business information, as well as personal data of our guests, employees and business partners.

We are subject to cyber-attacks. These cyber-attacks can vary in scope and intent from attacks with the objective of compromising our systems, networks and communications for economic gain to attacks with the objective of disrupting, disabling or otherwise compromising our operations. The attacks can encompass a wide range of methods and intent, including phishing attacks, illegitimate requests for payment, theft of intellectual property, theft of confidential or non-public information, installation of malware, installation of ransomware and theft of personal or business information. The breadth and scope of these attacks, as well as the techniques and sophistication used to conduct these attacks, have grown over time.

A successful cyber-attack may target us directly, or it may be the result of a third party's inadequate care. In either scenario, we may suffer damage to our systems and data that could interrupt our operations, adversely impact our reputation and brand and expose us to increased risks of governmental investigation, litigation and other liability, any of which could adversely affect our business. Furthermore, responding to such an attack and mitigating the risk of future attacks could result in additional operating and capital costs in systems technology, personnel, monitoring and other investments.

In addition, we are also subject to various risks associated with the collection, handling, storage and transmission of sensitive information. In the course of doing business, we collect employee, customer and other third-party data, including personally identifiable information and individual credit data, for various business purposes. These laws continue to develop and may be inconsistent from jurisdiction to jurisdiction. If we fail to comply with the various applicable data collection and privacy laws, we could be exposed to fines, penalties, restrictions, litigation or other expenses, and our business could be adversely impacted.

Any breach, theft, loss, or fraudulent use of employee, third-party or company data, could adversely impact our reputation and expose us to risks of data loss, business disruption, governmental investigation, litigation and other liability, any of which could adversely affect our business. Significant capital investments and other expenditures could be required to remedy the problem and prevent future breaches, including costs associated with additional security technologies, personnel, experts and credit monitoring services for those whose data has been breached. Further, if we or our vendors experience significant data security breaches or fail to detect and appropriately respond to significant data security breaches, we could be exposed to government enforcement actions and private litigation.

Risks Related to Ownership of Our Common Stock

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our Common Stock.

Our common stock is currently listed for trading on The Nasdaq Capital Market. We must satisfy The Nasdaq Capital Market's continued listing requirements risk delisting, which would have a material adverse effect on our business.

On February 4, 2025, we received notice from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq as set forth in Nasdaq Listing Rule 5550(a)(2). We will have 180 days from February 4, 2025, or through August 4, 2025, to regain compliance. If we do not regain compliance during the compliance period ending August 4, 2025, then Nasdaq may grant us a second 180 calendar day period to regain compliance, provided we meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for The Nasdaq Capital Market, other than the minimum closing bid price requirement, and notify Nasdaq of our intent to cure the deficiency. If we do not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, we may be subject to delisting. In order to satisfy the bid price requirement, we may be required to complete a reverse stock split.

If our common stock were delisted from Nasdaq, trading of our common stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB or the Pink Market maintained by OTC Markets Group Inc. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors would likely not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules as a "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and to raise capital.

Future equity offerings, license transactions or acquisitions may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be higher or lower than what our existing stockholders paid and other securities in the future could have rights superior to existing stockholders.

In addition, we may engage in one or more potential license transactions or acquisitions in the future, which could involve issuing our common stock as some or all of the consideration payable by us to complete such transactions. If we issue common stock or securities linked to our common stock, the newly issued securities may have a dilutive effect on the interests of the holders of our common stock. Additionally, future sales of newly issued shares used to effect a transaction could depress the market price of our common stock and have a dilutive effect on our existing stockholders.

We may also issue equity securities that provide rights, preferences and privileges senior to those of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

Our common stock price is expected to be volatile.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- relatively low trading volume, which can result in significant volatility in the market price of our common stock based on a relatively smaller number of trades and dollar amount of transactions;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- our ability to remain listed on The NASDAQ Capital Market;
- the timing and results of our current and any future preclinical or clinical trials of our product candidates;
- the entry into or termination of key agreements, including, among others, key collaboration and license agreements;
- the results and timing of regulatory reviews relating to the approval of our product candidates;
- the initiation of, material developments in, or conclusion of, litigation to enforce or defend any of our intellectual property rights;
- failure of any of our product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the results of clinical trials conducted by others on products that would compete with our product candidates;
- issues in manufacturing our product candidates or any approved products;
- the introduction of technological innovations or new commercial products by our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- future sales of our common stock by us, our insiders or our other stockholders;

- a negative outcome in any litigation or potential legal proceeding;
- additions and departures of key personnel;
- negative publicity or announcements regarding regulatory developments relating to our products;
- actual or anticipated fluctuations in our financial condition and operating results, including our cash and cash equivalents balance, operating expenses, cash burn rate or revenue levels;
- our filing for protection under federal bankruptcy laws; or
- the other factors described in this "Risk Factors" section.

The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to us as such may make our common stock less attractive to our stockholders and investors.

We are a "smaller reporting company" under the federal securities laws and, as such, are subject to scaled disclosure requirements afforded to such companies. For example, as a smaller reporting company, we are subject to reduced executive compensation disclosure requirements. Our stockholders and investors may find our common stock less attractive as a result of our status as a "smaller reporting company" and our reliance on the reduced disclosure requirements afforded to these companies. If some of our stockholders or investors find our common stock less attractive, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

We do not currently intend to pay dividends to our stockholders in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in our value.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that our valuation will appreciate in value or even maintain the valuation at which our stockholders have purchased their shares.

If securities or industry analysts do not publish research or reports about our business, or if they publish negative evaluations of our stock or negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, there can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrades our stock or changes his or her opinion of our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

Provisions in our corporate documents and Delaware law could have the effect of delaying, deferring, or preventing a change in control of us, even if that change may be considered beneficial by some of our stockholders.

The existence of some provisions of our certificate of incorporation or our bylaws or Delaware law could have the effect of delaying, deferring, or preventing a change in control of us that a stockholder may consider favorable. These provisions include:

- providing that the number of members of our Board is limited to a range fixed by our bylaws;
- establishing advance notice requirements for nominations of candidates for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings; and
- authorizing the issuance of "blank check" preferred stock, which could be issued by our Board of Directors to issue securities with voting rights and thwart a takeover attempt.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the General Corporation Law of the State of Delaware. Section 203 prevents some stockholders holding more than 15% of our voting stock from engaging in certain business combinations unless the business combination or the transaction that resulted in the stockholder becoming an interested stockholder was approved in advance by our Board of Directors, results in the stockholder holding more than 85% of our voting stock (subject to certain restrictions), or is approved at an annual or special meeting of stockholders by the holders of at least 66 2/3% of our voting stock not held by the stockholder engaging in the transaction. Any provision of our certificate of incorporation or our bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and affect the price that some investors are willing to pay for our common stock.

Provisions in our bylaws provide for indemnification of officers and directors, which could require us to direct funds away from our business and the development of our product candidates.

Our bylaws provide for the indemnification of our officers and directors. We may in the future be required to advance costs incurred by an officer or director and to pay judgments, fines and expenses incurred by an officer or director, including reasonable attorneys' fees, as a result of actions or proceedings in which our officers and directors are involved by reason of being or having been an officer or director of our company. Funds paid in satisfaction of judgments, fines and expenses may be funds we need for the operation of our business and the development of our product candidates, thereby affecting our ability to attain profitability.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have established processes to assess, identify, and manage cybersecurity risks. These processes are integrated into our overall risk management program and are designed to protect our information assets from internal and external cyber threats and include:

- implementing physical, procedural, and technical safeguards;
- developing and maintaining comprehensive response plans;
- engaging with external cybersecurity experts to enhance our oversight and keep pace with evolving threats; and
- considering the cybersecurity capabilities of partners and third-party service providers, both prior to engaging them and on an ongoing basis.

Cybersecurity Governance and Oversight

Our Board of Directors provides direct oversight of cybersecurity risk and has delegated to its audit committee the responsibility of reviewing and discussing with management our risk exposures relating to cybersecurity. The Board of Directors and the audit committee will receive regular updates from management on cybersecurity matters and are promptly informed by management about any significant new threats or incidents. In the future, management and our third-party service providers will conduct reviews at least once annually of our cybersecurity readiness to ensure continuous improvement in our cybersecurity strategies.

We have implemented mechanisms to monitor and manage cybersecurity threats and incidents, including utilization of tools for continuous monitoring of our IT environment to detect and mitigate threats, a fundamental plan for responding to cyber incidents and training for employees to recognize and report potential cybersecurity incidents and to foster a culture of cybersecurity awareness and vigilance. Our Chief Administrative Officer, along with a third-party service provider, are responsible for operational oversight of our cybersecurity strategy and policies. Any identified cybersecurity incident is reported to our Chief Administrative Officer who evaluates the severity of the incident. Based on this assessment, further steps are taken involving other members of management and, depending on the severity, the audit committee and the Board of Directors. We believe this structured approach allows us to effectively manage and mitigate cybersecurity risks, safeguarding our systems and data against various digital threats. Additionally, our proactive stance is supported by cybersecurity insurance, which further reinforces our preparedness against potential cyber threats.

Cybersecurity Incident Reporting and Management

During the years ended December 31, 2023 and 2024, we have not identified any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, we remain vigilant and prepared to respond effectively to any incidents, should they arise.

Item 2. Properties.

Our principal executive office is located at 7380 Coca Cola Drive, Suite 106, Hanover, MD 21076. We currently lease approximately 6,500 square feet of office space at this location until September 2025.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings. Regardless of outcome, any litigation that we may become involved in can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

On May 7, 2024, the Company received notification from Elion purporting to terminate the license agreement by and between the Company and Elion as a result of the Company's alleged breach thereof. The Company believes that Elion's claims are without merit and disputes that the license agreement has been validly terminated. On July 5, 2024, the Company filed a complaint in the Commercial Division of the Supreme Court of the State of New York, New York County seeking monetary damages, declaratory judgement and injunctive relief. On August 14, 2024, the Company received Elion's answer and counterclaims. On October 10, 2024, the Company filed its response to Elion's counterclaims. The Company intends to enforce its rights under the license agreement and will pursue such other remedies as it determines are appropriate.

On December 3, 2024, Jason Assad and Marc Gyimesi, two of the investors in our February 2021 private offering, filed a lawsuit in the Supreme Court of the State of New York, New York County alleging fraud and negligent misrepresentation in connection therewith regarding alleged company communication and statements and are seeking monetary damages. In addition to being an investor, Mr. Assad was a former investor relations and communications consultant to the Company from September 1, 2021 through June 30, 2024.

We intend to vigorously defend ourselves in these lawsuits and cannot at this time predict the likely outcome of any litigation, reasonably determine either the probability of a material adverse result or any estimated range of potential exposure, or reasonably determine how these matters or any future matters might impact our business, our financial condition, or our results of operations, although such impact, including the costs of defense, as well as any judgments or indemnification obligations, among other things, could be materially adverse to us.

Item 4. Mine Safety Disclosures.

None.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and issuer Purchases of Equity Securities.

Our common stock is traded on the Nasdaq Capital Market under the symbol "PCSA."

On January 22, 2024, we effected a 1-for-20 reverse stock split, reducing the number of our common shares issued on that date from 24,706,474 shares to 1,291,000 shares. There was no corresponding reduction in the number of authorized shares of common stock and no change in the par value per share. All share and per share amounts and conversion and exercise prices presented herein have been adjusted retroactively to reflect this change.

Holders

As of March 12, 2025, there were 5,269,240 shares of common stock outstanding and 184 shareholders of record. One of these holders of record is Cede & Co, a nominee for Depository Trust Company ("DTC"). All of the shares of common stock held by brokerage firms and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder. The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

Dividend Policy

We have not previously declared or paid any dividends on our common stock and do not intend to do so in the near future. We intend to retain any future earnings to fund ongoing operations and future capital requirements of our business. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

Securities Authorized for Issuance under Equity Compensation Plans

The table below provides information as to our 2019 Omnibus Incentive Plan as of December 31, 2024.

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	507,185(1)	$ 462.07	353,641
Equity compensation plans not approved by security holders	2,389	397.60	-
Total	509,574		27,326(2)

(1) Includes stock options to purchase 358 shares of our common stock issued under the prior equity compensation plan.
(2) Consists of shares available for issuance under the 2019 Omnibus Incentive Plan.

Recent Sales of Unregistered Securities

During the quarter ended December 31, 2024, we issued a total 7,986 shares of common stock to Berg Capital Markets, LLC in connection with a consulting agreement. The shares were issued pursuant to exemptions from the registration requirements of the Securities Act of 1933, as amended, in reliance on Section 4(a)(2) of the Securities Act, Rule 701 promulgated under the Securities Act or Regulation D promulgated under the Securities Act, relating to transactions by an issuer not involving a public offering. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

Repurchases of Equity Securities

We did not repurchase any shares of our common stock in 2024.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of the Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described below.

Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of Next Generation Cancer therapy ("NGC") small molecules, two of which are in, or have completed, Phase 2 trials, and one is in pre-clinical development. Our risk-mitigated strategy is to identify existing cancer therapies where the mechanism of action is well understood and that are cornerstones of current treatment regimens, but are highly toxic, with side effects that are often treatment limiting (see Our Strategy above). We devise technologies to change the way the body metabolizes them, or the way they are distributed within the body, to improve the therapeutic effect and reduce toxicity. We then efficiently develop our pipeline of Next Generation Cancer therapies utilizing our proprietary Regulatory Science Approach (see Regulatory Science Approach above), which we believe will further increase the likelihood of regulatory approval. Since the underlying drugs are already commonly used in cancer therapy, we believe that if our clinical trials are successful and are showing better efficacy and tolerability than the currently used drugs, the commercial adoption for our NGC therapies will be rapid and broad.

Next Generation Cancer Therapy Pipeline
(see Our Drug Pipeline above for a more detailed discussion of our NGC programs)

- PCS6422, also referred to as NGC-Cap, is a combination of PCS6422 and a lower dose of capecitabine. Capecitabine is used in many solid tumor treatment regimens, like breast cancer and colon cancer. Significant side effects, such as Hand-Foot Syndrome ("HFS") and cardiotoxicity, typically occur in up to 70% of patients treated with capecitabine. PCS6422, without having any clinically meaningful anti-cancer effect itself, when used with capecitabine, has been found to be up to 50 times more potent than capecitabine alone. NGC-Cap has shown a better safety profile than capecitabine alone. Since a much smaller amount of these metabolites are formed with NGC-Cap, the side effects appear in fewer patients and are less severe.

- PCS3117, also referred to as NGC-Gem, is a cytidine analog similar to gemcitabine (Gemzar®), but different enough in chemical structure that some patients are more likely to respond to NGC-Gem than gemcitabine. In addition, we believe those patients that are inherently resistant, or who acquire resistance, to gemcitabine may not be resistant to NGC-Gem. The difference in response occurs because NGC-Gem is metabolized to its Active Metabolite through a different enzyme system than gemcitabine.

- PCS11T, also referred to as NGC-Iri, is an analog of SN38 (SN38 is the active metabolite of irinotecan). The chemical structure of NGC-Iri is designed to influence the uptake of the drug into cancer cells, resulting in more NGC-Iri entering cancer cells than normal cells. Irinotecan is widely used in lung, pancreatic, ovarian, cervical & other solid tumor cancers. Major drawbacks are the side-effect profile, including black box warnings for diarrhea and myelosuppression. Our preclinical study in mouse xenograft models showed that after NGC-Iri administration, there was greater accumulation of SN-38 in the tumor compared with other tissues than after irinotecan or Onivyde® administration. Additionally, less SN-38 accumulated in non-cancer tissues, such as muscle, after NGC-Iri administration than after irinotecan administration, supporting the potential for a better NGC-Iri safety profile.

We are focused on drug products that improve the survival and/or quality of life for patients by improving the safety and/or efficacy of the drug in a targeted patient population, while providing a more efficient and probable path to FDA approval and differentiating our drugs from those on the market or are currently being developed.

Other Drugs in Our Pipeline

PCS12852 is a highly specific and potent 5HT4 agonist that is Phase 2B ready as potentially the first meaningful treatment for diabetic gastroparesis patients. Gastroparesis is a chronic digestive disorder characterized by delayed gastric emptying of solid food without obstruction. Gastroparesis symptoms include: nausea, vomiting, postprandial fullness, early satiety, abdominal pain, heartburn and poor appetite. Global prevalence of gastroparesis is over 30 million, with a diabetic population of over 8 million. We have completed a Phase 2A trial for PCS12852 in gastroparesis patients with positive results. We are exploring options for PCS12852, which may include licensing, partnering and/or collaborating opportunities.

PCS499 is a drug that can be used to treat unmet medical need conditions caused by multiple pathophysiological changes. We are presently defining the development plan for the use of PCS499 in a primary glomerular disease. We believe that PCS499 could be successfully developed in a primary glomerular disease such as focal segmental glomerulosclerosis, or FSGS, and IgA. We intend to design a development program with the next study being an adaptive designed Phase 3 trial, meet with the FDA, and then find a partner to take the drug to approval.

Recent Developments

Public Offering

On January 27, 2025, we raised gross proceeds in a public offering of $5.0 million (net proceeds of $4.5 million) from the sale of 1,030,972 shares of our common stock, pre-funded warrants to purchase up to 7,019,700 shares of our common stock, accompanying Series A warrants to purchase up to 8,050,672 shares of our common stock and Series B warrants to purchase up to 4,025,336 shares of common stock, as described in Note 14. Since the offering closed, pre-funded warrants were exercised in exchange for 525,700 shares of our common stock and, as of March 12, 2025, pre-funded warrants to purchase up to 6,494,000 shares of our common stock remain available to be exercised. We plan to use the net proceeds from this financing for continued research and development for NCG-Cap, and for working capital and general corporate purposes.

ATM Offering

In May 2024, we filed with the SEC a registration statement on Form S-3 (Registration No. 333-279588) (the "Registration Statement"), including a base prospectus relating to the offering of up to $50,000,000 in the aggregate of the securities identified in the base prospectus from time to time in one or more offerings; and a prospectus supplement relating to the shares of our common stock that may be issued and sold under a sales agreement dated May 21, 2024 (the "Sales Agreement") between us and A.G.P./Alliance Global Partners (the "Sales Agent"), through which we may issue and sell in a registered "at the market offering" shares of our common stock having an aggregate offering price of up to $2.4 million (subject to adjustment) from time to time through or to our Sales Agent (the "ATM Offering"). We expect to use net proceeds, if any, from the ATM Offering over time for continued research and development for our portfolio of drug candidates, especially our oncology products, and working capital and general corporate purposes. The shares under the ATM Offering will be sold and issued pursuant to the Registration Statement. During the year ended December 31, 2024, we received $1.5 million in net proceeds from the sale of 800,994 shares of common stock under the ATM Offering, of which 426,804 shares of common stock were sold during the quarter ended December 31, 2024 for net proceeds of approximately $575,000.

Results of Operations

Comparison of the year ended December 31, 2024 and 2023

The following table summarizes our operations loss during the periods indicated:

	Year Ended December 31,		
	2024	2023	Change
Operating Expenses			
Research and development costs	$ 7,269,146	$ 5,799,518	$ 1,469,628
General and administrative expenses	4,782,060	5,657,543	(875,483)
Operating Loss	(12,051,206)	(11,457,061)	
Other Income (Expense)			
Interest income, net	201,088	335,541	(134,453)
Net Loss	$ (11,850,118)	$ (11,121,520)	

Revenues.

We had no revenue during the years ended December 31, 2024 and 2023. We do not currently have any revenue under contract or any immediate sales prospects.

Research and Development Expenses.

Our research and development costs are expensed as incurred. Research and development expenses include (i) program and testing related expenses including external consulting and professional fees related to the product testing and our development activities and (ii) internal research and development staff related salaries and other payroll costs including stock-based compensation, payroll taxes and employee benefits.

Research and development costs for the years ended December 31, 2024 and 2023 were as follows:

	Year ended December 31,	
	2024	2023
Preclinical, clinical trial and other costs	$ 5,450,963	$ 3,817,669
Research and development salaries and benefits	1,818,183	1,981,849
Total	$ 7,269,146	$ 5,799,518

During the year ended December 31, 2024, our research and development expenses increased by $1.5 million to $7.3 million when compared to $5.8 million for the year ended December 31, 2023. This was primarily attributable to an increase of approximately $2.0 million for ongoing testing and related expenses related to our Phase 1B trial for NGC-Cap and the IND/initiation of our Phase 2 trial for NGC-Cap. Expenses include costs related to contract research organizations, regulatory filing and maintenance fees, drug product testing and stability, consulting, and other clinical fees. The increase was offset by a $352,000 decrease in professional fees and in employee stock-based compensation of $195,000. While we have increased salary rates for some personnel, we had fewer full-time R&D employees in 2024 than 2023.

The funding necessary to bring a drug candidate to market is subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate may be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Some programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. We anticipate our research and development costs to increase in the future, subject to obtaining sufficient financing, as we finalize our clinical trials; plan/conduct future clinical trials, including the cost of having drug product manufactured; continue our evaluation of the remaining drugs in our portfolio; and expand our development team.

Our clinical trial cost accruals are based on estimates of patient enrollment and related costs at clinical investigator sites, as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf.

In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related series are recorded as prepaid expenses until the services are rendered. At December 31, 2024, we have recorded $1.3 million in prepaid expenses for advanced payments made to our CRO and other vendors for our NGC-Cap Phase 2 clinical trial.

General and Administrative Expenses.

Our general and administrative expenses for the year ended December 31, 2024 decreased by approximately $875,000 to $4.8 million when compared to $5.7 million for the same period in 2023. This was mostly due to a $1.2 million decrease in professional fees and approximately $201,000 decrease in employee stock-based compensation. The decreases were primarily offset by increases in salaries and other payroll-related costs of approximately $443,000 and net increases in taxes, travel, and other office expenses of approximately $50,000. We share office space with CorLyst, a related party, and during the years ended December 31, 2024 and 2023, they reimbursed us approximately $110,000 and $112,000, respectively, for rent and other costs we incurred on their behalf.

Other Income.

Net other income consisting primarily of interest income was $207,567 and $335,541 for the years ended December 31, 2024 and 2023, respectively.

Income Tax Benefit.

We did not recognize any income tax benefit for the year ended December 31, 2024 or 2023. At December 31, 2024, we recorded deferred tax assets totaling $19.9 million, including $9.6 million of net operating losses that are fully offset by a valuation allowance.

Liquidity

Sources of Liquidity

At December 31, 2024, we had $1.2 million in cash and cash equivalents. On January 27, 2025, we closed a public offering where we sold 1,030,972 shares of our common stock, and/or pre-funded warrants to purchase up to 7,019,700 shares of our common stock, accompanying Series A warrants to purchase up to 8,050,672 shares of our common stock (the “Series A Warrants”) and Series B warrants to purchase up to 4,025,336 shares of our common stock (the “Series B Warrants” and collectively with the Series A Warrants, the “Common Warrants”) for net proceeds of $4.5 million, after deducting placement agent fees and offering-related expenses (see Note 14 to the Consolidated Financial Statements for additional details). On January 30, 2025, pre-funded warrants to purchase 525,700 shares of our common stock were exercised. As of March 12, 2025, pre-funded warrants for the purchase of 6,494,000 remain outstanding.

We have incurred losses and net cash used in our operating activities during the year ended December 31, 2024, which we expect to continue for the foreseeable future. We have incurred losses since our inception, devoting substantially all of our efforts toward research and development, and have an accumulated deficit of approximately $87.2 million at December 31, 2024. During the year ended December 31, 2024, we generated a net loss of approximately $11.9 million. Based on our current business plans, we believe these funds will satisfy our capital needs into mid-2025. Our ability to execute our longer-term operating plans, including unplanned future clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions. We plan to continue to actively pursue financing alternatives, but there can be no assurance that we will obtain the necessary funding in the future when needed.

Our estimate of future cash needs is based on assumptions that may prove to be wrong, and we could utilize our available cash sooner than we currently expect. Our ultimate success depends on the outcome of our planned clinical trials and our research and development activities, as disclosed above. We expect to incur additional losses in the future, and we will need to raise additional capital to fully implement our business plan if the costs of our clinical trials are greater than we expect or they take longer than anticipated. We also expect to incur increased general and administrative expenses in the future. In addition, there may be costs we incur as we develop these drug products that we do not currently anticipate, requiring us to need additional capital sooner than currently expected.

Our future capital requirements will depend on many factors, including but not limited to:

- the cost of our current and future clinical trials of NGC-Cap and the cost of third-party manufacturing;
- the initiation, progress, timing, costs and results of drug manufacturing, pre-clinical studies, and clinical trials of NGC-Gem and NGC-Iri, as well as any other future product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing, and costs of seeking regulatory approvals;
- the costs associated with hiring additional personnel and consultants for our pre-clinical and clinical activities;
- the emergence of competing therapies and other adverse market developments;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending, and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

Until such time as we can generate substantial product revenues to support our capital requirements, if ever, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. We currently have an effective shelf registration statement on Form S-3 on file with the SEC, which provides us flexibility and optionality to raise capital, including pursuant to a future at-the-market offering, but there can be no assurance that capital will continue to be available to us on acceptable terms, won't be limited, or be available at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the years ended December 31, 2024 and 2023:

	For the Year Ended December 31,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	$ (11,245,042)	$ (8,063,346)
Investing activities	(3,244)	(2,776)
Financing activities	7,733,414	6,268,724
Net decrease in cash and cash equivalents	$ (3,514,872)	$ (1,797,398)

Net cash used in operating activities

We used net cash in our operating activities of $11,245,042 and $8,063,346 during the years ended December 31, 2024 and 2023, respectively. The increase in cash used in operating activities was primarily attributable to increased costs related to closing our Phase 1B and commencing our Phase 2 trial for NGC-Cap, including the prepayment of expenses to our CRO for the Phase 2 trial; increased salaries and other payroll-related expenses; and professional fees during the year ended December 31, 2024. As we continue our Phase 2 trial for NGC-Cap and evaluate the other NGC drugs in our portfolio, we anticipate our research and development efforts and ongoing general and administrative costs will continue to generate negative cash flows from operating activities for the foreseeable future.

At December 31, 2024, our prepaid expense and other consisted primarily of $1.8 million for advanced payments we made to the CRO and other vendors related to our Phase 1B and Phase 2 trials of NGC-Cap that have not yet been applied and approximately $85,000 in various insurance policies, such as directors' and officers' insurance and product liability insurance for conducting our clinical trials.

Net cash used in investing activities

We used net cash in our investing activities of $3,244 and $2,776 during year ended December 31, 2024 and 2023 to purchase property and equipment.

Net cash provided by (used in) financing activities

During the year ended December 31, 2024, we sold 476,000 shares of common stock, pre-funded warrants to purchase up to 1,079,555 shares of common stock in lieu of shares of common stock, all of which were exercised into shares of our common stock, and warrants to purchase up to 1,555,555 shares of our common stock pursuant to a public offering for net proceeds of $6.3 million. We also sold 800,994 shares of common stock under our ATM Offering for net proceeds of approximately $1.5 million. We used cash, classified as financing activities, of approximately $16,000 to pay income taxes owed on stock-based compensation, approximately $9,000 for the settlement of a stock award, and approximately $5,000 for payments owed under a financing lease obligation. During the year ended December 31, 2023, we raised net proceeds of $6.4 million from the sale of 421,611 shares of our common stock and used $31,000 in legal expenses related to our January 2024 raise and $53,000 for the settlement of a stock award.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2024:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	$ 77,432	$ 76,861	$ 571	$ -	$ -
Total	$ 77,432	$ 76,861	$ 571	$ -	$ -

We enter into contracts in the normal course of business with CROs, clinical supply manufacturers and vendors for pre-clinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

We have also entered into license and collaboration agreements with third parties, which are in the normal course of business. We have not included future payments under these agreements in the table above since obligations under these agreements are contingent upon future events such as our achievement of specified development, regulatory, and commercial milestones, or royalties on net product sales.

Off Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies and estimates are most critical to aid in understanding and evaluating our financial results reported in our consolidated financial statements.

Clinical Trial Accruals / Research and Development

As part of the process of preparing our consolidated financial statements, we are required to estimate expenses resulting from our obligations under contracts with vendors, CROs and consultants and under clinical site agreements related to conducting our clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the period over which materials or services are provided under such contracts.

Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. During a clinical trial, we will adjust the clinical expense recognition if actual results differ from estimates. We make estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accruals are partially dependent on the accurate reporting by the CRO and other third-party vendors. Although we do not expect estimates to differ materially from actual amounts, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that may be too high or too low for any reporting period.

Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered. We expense research and development costs as they are incurred.

Stock-Based Compensation

Stock-based compensation expense is based on the grant-date fair value estimated in accordance with the provisions of ASC 718, *Compensation-Stock Compensation*. We expense stock-based compensation over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. No expense is recognized for stock-based awards with performance-vesting conditions until management believes it is probable the performance-vesting condition will be met. We value restricted stock awards (RSAs) and restricted stock units (RSUs) based on the closing share price on the date of grant. We estimate the fair value of stock option and warrant grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. We account for forfeitures in the period in which they occur, rather than estimate expected forfeitures.

See Note 3 – Stock-Based Compensation for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of warrants granted during the year ended December 31, 2023.

All stock-based compensation costs are recorded in general and administrative or research and development costs in the consolidated statements of operations based upon the underlying individual's or entity's role.

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. We have recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets since it was more-likely-than-not that benefits from our deferred tax assets would not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal. As part of an evaluation of our tax attributes in 2022, we recharacterized approximately $7.4 million of startup costs previously capitalized as an IRC Section 195 asset as net operating losses. The recharacterization has no impact on total deferred tax assets since we had previously and will continue to provide a full valuation allowance on our unutilized net deferred tax assets. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect of changes in tax rates on deferred tax assets and liabilities is recognized in income in the period such changes are enacted. No income tax benefit or expense was recorded for any periods presented nor is expected in the foreseeable future since we expect to generate future taxable net operating losses.

We recognize the impact of an uncertain tax position if the position will more likely than not be sustained upon examination by a taxing authority, based on the technical merits of the position. Our policy is to record interest and penalties related to income taxes as part of its income tax provision. At December 31, 2024, we had no unrecognized tax benefits and as such, no liability, interest or penalties were required to be recorded. We do not expect this to change significantly in the next twelve months.

Recently Issued Accounting Pronouncements

See Note 2 of our consolidated financial statements for new accounting pronouncements or changes to the recent accounting pronouncements during the year ended December 31, 2024.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Item 7A is not applicable to us as a smaller reporting company and has been omitted.

Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Processa Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Processa Pharmaceuticals, Inc. (the "Company") as of December 31, 2024, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Prior Period Financial Statements

The financial statements of the Company as of and for the year ended December 31, 2023 were audited by other auditors whose report dated March 29, 2024 expressed an unqualified opinion on those statements.

Substantial Doubt of the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred net losses since its inception which has resulted in a cumulative deficit as of December 31, 2024 that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1.

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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit 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 audit, 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 audit 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 audit 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 our audit provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgements. We determined that there were no critical audit matters.

Emphasis of Matter

We also have audited the adjustments to the 2023 financial statements to retrospectively apply the change due to the adoption of Accounting Standards Update 2023-07, *Segment Reporting*, described in Note 2. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2023 financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2023 financial statements taken as a whole.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2024.

Tampa, Florida
March 20, 2025

Processa Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31, 2024	December 31, 2023
ASSETS		
Current Assets		
Cash and cash equivalents	$ 1,191,325	$ 4,706,197
Prepaid expenses and other	682,294	926,300
Total Current Assets	1,873,619	5,632,497
Property and Equipment, net	5,016	2,554
Non-current Assets		
Prepaid expenses	1,274,442	-
Total Non-current Assets	1,274,442	-
Other Assets		
Operating lease right-of-use assets, net	70,677	146,057
Other	5,535	5,535
Total Other Assets	76,212	151,592
Total Assets	$ 3,229,289	$ 5,786,643
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of lease liability	$ 73,020	$ 83,649
Accounts payable	880,880	311,617
Due to licensor	-	189,000
Due to related parties	-	39
Accrued expenses	578,731	146,274
Total Current Liabilities	1,532,631	730,579
Non-current Liabilities		
Non-current lease liability	487	66,905
Total Liabilities	1,533,118	797,484
Commitments and Contingencies	-	-
Stockholders' Equity		
Preferred stock, par value $0.0001, 1,000,000 shares authorized; no shares issued or outstanding at December 31, 2024 or December 31, 2023	-	-
Common stock, par value $0.0001, 100,000,000 shares authorized; 3,707,628 issued and 3,702,628 outstanding at December 31, 2024 and 1,291,000 issued and 1,286,000 outstanding at December 31, 2023	371	129
Additional paid-in capital	89,214,999	80,658,111
Treasury stock, 5,000 shares	(300,000)	(300,000)
Accumulated deficit	(87,219,199)	(75,369,081)
Total Stockholders' Equity	1,696,171	4,989,159
Total Liabilities and Stockholders' Equity	$ 3,229,289	$ 5,786,643

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2024	2023
Operating Expenses		
Research and development expenses	$ 7,269,146	$ 5,799,518
General and administrative expenses	4,782,060	5,657,543
Operating Loss	(12,051,206)	(11,457,061)
Other Income (Expense)		
Interest income, net	201,088	335,541
Net Operating Loss Before Income Tax Benefit	(11,850,118)	(11,121,520)
Income Tax Benefit		-
Net Loss	$ (11,850,118)	$ (11,121,520)
Net Loss Per Common Share - Basic and Diluted	$ (3.87)	$ (8.48)
Weighted Average Common Shares Used to Compute Net Loss Per Common Shares - Basic and Diluted	3,059,906	1,311,572

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2023 and 2024

	Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance, January 1, 2023	806,774	80	72,018,222	(5,000)	(300,000)	(64,247,561)	7,470,741
Stock-based compensation	6,945	1	1,060,338	-	-	-	1,060,339
Shares issued in connection with capital raises, net of transaction costs	421,611	42	6,352,035	-	-	-	6,352,077
Warrant granted in connection with a consulting agreement	-	-	1,310,875	-	-	-	1,310,875
Settlement of stock award	-	-	(52,746)	-	-	-	(52,746)
Other	55,670	6	(30,613)	-	-	-	(30,607)
Net loss	-	-	-	-	-	(11,121,520)	(11,121,520)
Balance, December 31, 2023	1,291,000	129	80,658,111	(5,000)	(300,000)	(75,369,081)	4,989,159
Stock-based compensation	62,502	6	629,508	-	-	-	629,514
Shares issued in connection with capital raises, net of transaction costs	2,356,549	236	7,762,843	-	-	-	7,763,079
Shares issued in connection with license agreement	5,000	1	188,999	-	-	-	189,000
Settlement of stock award	-	-	(8,561)	-	-	-	(8,561)
Shares withheld to pay income taxes on stock-based compensation	(7,423)	(1)	(15,901)	-	-	-	(15,902)
Net loss	-	-	-	-	-	(11,850,118)	(11,850,118)
Balance, December 31, 2024	3,707,628	$ 371	$ 89,214,999	(5,000)	$ (300,000)	$ (87,219,199)	$ 1,696,171

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2024	2023
Cash Flows From Operating Activities		
Net Loss	$ (11,850,118)	$ (11,121,520)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	782	222
Non-cash lease expense for right-of-use assets	87,184	81,530
Stock-based compensation	629,514	1,060,339
Warrants issued for consulting services	-	1,310,875
Net changes in operating assets and liabilities:		
Prepaid expenses and other	(1,030,436)	956,834
Operating lease liability	(83,649)	(78,896)
Accounts payable	569,263	(15,931)
Due from related parties	(39)	(12)
Accrued expenses	432,457	(256,787)
Net cash used in operating activities	(11,245,042)	(8,063,346)
Cash Flows From Investing Activities		
Purchase of property and equipment	(3,244)	(2,776)
Net cash used in investing activities	(3,244)	(2,776)
Cash Flows From Financing Activities		
Net proceeds from issuance of stock	7,763,079	6,321,470
Shares withheld to pay taxes on stock-based compensation	(15,902)	-
Settlement of stock award	(8,561)	(52,746)
Payment of finance lease obligation	(5,202)	-
Net cash provided by financing activities	7,733,414	6,268,724
Net Decrease in Cash and Cash Equivalents	(3,514,872)	(1,797,398)
Cash and Cash Equivalents - Beginning of Year	4,706,197	6,503,595
Cash and Cash Equivalents - End of Year	$ 1,191,325	$ 4,706,197

The accompanying notes are an integral part of these consolidated financial statements.

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows (continued)

	Years Ended December 31,	
	2024	2023
Supplemental Cash Flow Information:		
Cash paid for interest	$ 1,204	$ -
Cash paid for income taxes	-	-
Non-Cash Financing Activities		
Issuance of 5,000 shares of common stock in connection with a licensing agreement which had previously been recorded as a due to licensor	$ 189,000	$ -
Right-of-use asset obtained in exchange for financing lease liability	$ 11,804	$ -
Financing lease liability	(11,804)	-
Net	$ -	$ -

The accompanying notes are an integral part of these consolidated financial statements.

Note 1 – Organization

Organization

We are a clinical-stage biopharmaceutical company focused on incorporating our Regulatory Science Approach into the development of our Next Generation Cancer therapy ("NGC") drugs to improve the safety and efficacy of cancer treatment. Our NGC drugs are modifications of existing FDA-approved oncology drugs resulting in an alteration of the metabolism and/or distribution while maintaining the well-known and established existing mechanisms of killing the cancer cells. By modifying the NGC drugs in this manner, we believe our NGC treatments will provide improved safety-efficacy profiles when compared to their currently marketed counterparts.

On January 22, 2024, we filed a Certificate of Amendment to our Certificate of Incorporation, as amended with the Secretary of State of Delaware that effected a 1-for-20 reverse stock split of our common stock, par value $0.0001 per share (the "Reverse Stock Split"). Pursuant to the Certificate of Amendment, our issued common stock decreased from 24,706,474 shares to 1,291,000 shares and our outstanding common stock decreased from 24,606,474 to 1,286,000. The Reverse Stock Split did not affect our authorized common stock of 100,000,000 shares or our common stock par value. All shares of common stock, including common stock underlying warrants, stock options, and restricted stock units, as well as exercise prices and per share information in these consolidated financial statements give retroactive effect to the Reverse Stock Split.

Liquidity

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. We have incurred losses since inception, currently devoting substantially all of our efforts toward research and development of our NGC drug product candidates, including conducting clinical trials and providing general and administrative support for these operations, and have an accumulated deficit of $87.2 million at December 31, 2024. During the year ended December 31, 2024, we generated a net loss of $11.9 million and used $11.2 million in net cash for operating activities from continuing operations. To date, none of our drug candidates have been approved for sale, and therefore we have not generated any product revenue and do not expect positive cash flow from operations in the foreseeable future.

We have financed our operations primarily through public equity issuances, including an offering we sold on January 27, 2025 where we sold 1,030,972 shares of our common stock, pre-funded warrants to purchase up to 7,019,700 shares of our common stock, and accompanying Series A warrants to purchase up to 8,050,672 shares of our common stock (the "Series A Warrants") and Series B warrants to purchase up to 4,025,336 shares of our common stock (the "Series B Warrants" and collectively with the Series A Warrants, the "Common Warrants") for net proceeds of $4.5 million, after deducting placement agent fees and offering-related expenses (see Note 14 for additional details). On January 30, 2025, pre-funded warrants to purchase 525,700 shares of our common stock were exercised and, as of March 12, 2025, pre-funded warrants for the purchase of 6,494,000 remain outstanding. We will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from its operations.

At December 31, 2024, we had cash and cash equivalents totaling $1.2 million. Together with the $4.5 million net proceeds we raised in January 2025, and based on our current business plans, we believe these funds will satisfy our capital needs into mid-2025. Our ability to execute our longer-term operating plans, including future preclinical studies and clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions.

We plan to raise additional funds in the future through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, but will only do so if the terms are acceptable to us. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend our current or planned future clinical trial plans, or research and development programs. This may also cause us to not meet obligations contained in certain of our license agreements and put these assets at risk. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. There can be no assurance that future funding will be available when needed.

Absent additional funding, we believe that our cash and cash equivalents will not be sufficient to fund our operations for a period of one year or more after the date that these consolidated financial statements are available to be issued based on the timing and amount of our projected net loss from continuing operations and cash to be used in operating activities during that period of time. As a result, substantial doubt exists about our ability to continue as a going concern within one year after the date that these consolidated financial statements are available to be issued. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be different should we be unable to continue as a going concern based on the outcome of these uncertainties described above.

Note 2 – Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission (the "SEC"), and reflect all of our activities, including those of our wholly-owned subsidiary. All material intercompany accounts and transactions have been eliminated in consolidation. Operating results for the year ended December 31, 2024 are not necessarily indicative of future results.

Use of Estimates

In preparing our consolidated financial statements and related disclosures in conformity with GAAP and pursuant to the rules and regulations of the SEC, we make estimates and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates are used for, but not limited to stock-based compensation, intangible assets, future milestone payments and income taxes. These estimates and assumptions are continuously evaluated and are based on management's experience and knowledge of the relevant facts and circumstances. While we believe the estimates to be reasonable, actual results could differ materially from those estimates and could impact future results of operations and cash flows.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and money market funds. We consider all highly liquid investments maturing within three months from the date of purchase as cash equivalents.

Prepaid Expenses

Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered. The majority of our prepaid expenses relate to advanced payments made to CROs and other vendors for our ongoing clinical trials. We allocate the prepaid expenses between current and non-current assets based on the anticipated timing of utilizing the advances. At December 31, 2024, we determined that $1.3 million would not be applied until after December 31, 2025.

Property and Equipment

Property is stated at cost, less accumulated depreciation. Costs of renewals and improvements that extend the useful lives of the assets are capitalized. Expenditures for maintenance and routine repairs are charged to expense as incurred. Depreciation is recognized on a straight-line basis over the estimated useful lives of the assets, which generally range from 3 to 5 years. We amortize leasehold improvements over the shorter of the estimated useful life of the asset or the term of the related lease. Upon retirement or disposition of assets, the costs and related accumulated depreciation are removed from the accounts with the resulting net gain or loss, if any, reflected in the consolidated statement of operations.

Impairment of Long-Lived Assets and Intangibles Other Than Goodwill

We account for the impairment of long-lived assets in accordance with ASC 360*, Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other,* which require that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

Fair Value Measurements and Disclosure

We apply ASC 820, *Fair Value Measurements and Disclosures*, which expands disclosures for assets and liabilities that are measured and reported at fair value on a recurring basis. Fair value is defined as an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants.

Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

Level 1 – Quoted market prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.

Level 2 – Quoted market prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly. Fair value determined using models or other valuation methodologies.

Level 3 – Significant unobservable inputs for assets or liabilities that cannot be corroborated by market data. Fair value is determined by the reporting entity's own assumptions utilizing the best information available and includes situations where there is little market activity for the asset or liability.

The asset's or liability's fair value measurement within the fair value hierarchy is based upon the lowest level of any input that is significant to the fair value measurement. Our policy is to recognize transfers between levels of the fair value hierarchy in the period the event or change in circumstances that caused the transfer. There were no transfers into or out of Level 1, 2, or 3 during the periods presented.

Stock-based Compensation

We measure compensation expense for stock options and other stock awards in accordance with ASC 718, *Compensation—Stock Compensation*. Stock-based compensation is measured at fair value on grant date and recognized as compensation expense over the requisite service period. Generally, we issue stock options and other stock awards with service-based and/or performance-based vesting conditions. For awards with only service-based vesting conditions, we record compensation cost for these awards using the straight-line method over the service period. For awards that contain performance vesting conditions, we do not recognize compensation expense until achieving the performance condition is probable. We estimate the fair value of stock option and warrant grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. We value restricted stock awards (RSAs) and restricted stock units (RSUs) based on the closing share price of our common stock on the date of grant. Stock-based compensation costs are recorded as general and administrative or research and development costs in the statements of operations based upon the underlying individual's or entity's role.

Estimates of fair value are not intended to predict actual future events or the value ultimately realized by employees or consultants who receive these awards, and subsequent events are not indicative of the reasonableness of our original estimates of fair value. We account for forfeitures in the period in which they occur, rather than estimate expected forfeitures.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average common stock outstanding (which excludes unvested RSAs) and vested, but unissued RSUs. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock outstanding during the period. Since we have experienced a net loss for all periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the years ended December 31, 2024 and 2023 excludes the impact of potentially dilutive common shares related to outstanding stock options, unvested restricted stock awards (RSAs), unvested RSUs and common stock purchase warrants.

Our diluted net loss per share for the years ended December 31, 2024 and 2023 excluded 2,013,154 and 296,326 of potentially dilutive common shares, respectively, related to outstanding stock options, unvested RSAs, unvested RSUs and warrants since those shares would have had an anti-dilutive effect on loss per share during the years then ended.

Segments

We have one reportable segment, which is focused on discovering and developing a pipeline of Next Generation Cancer therapy drugs. Our Chief Executive Officer, who is the chief operating decision maker (CODM), assesses segment performance and decides how to allocate resources based on net loss that is also reported on the Consolidated Statements of Operations and Comprehensive Loss. See Note 11 for additional information.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable and accounts payable approximate their fair value because of the short-term maturity of these instruments.

Research and Development

Research and development costs are expensed as incurred and consist of direct and overhead-related expenses related primarily to clinical trials, including development personnel salaries and related costs. Expenditures to acquire technologies, including licenses, which are utilized in research and development and that have no alternative future use are expensed as the acquisition of in-process research and development when incurred. Technology we develop for use in our products is expensed as incurred until technological feasibility has been established after which it is capitalized and depreciated. No research and development costs were capitalized during the years ended December 31, 2024 and 2023.

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. As of December 31, 2024 and 2023, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets since it is more-likely-than-not that benefits from our deferred tax assets will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

We recognize the impact of an uncertain tax position if the position will more likely than not be sustained upon examination by a taxing authority, based on the technical merits of the position. Our policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2024, we had no unrecognized tax benefits and as such, no liability, interest or penalties were required to be recorded. We do not expect this to change significantly in the next twelve months.

Recently Adopted Accounting Standard

In November 2023, the FASB issued ASU 2023-07 – Segment Reporting (Topic 280) – Improvements to Reportable Segment Disclosures, which improves segment disclosure requirements, primarily through enhanced disclosure requirements for significant segment expenses. The improved disclosure requirements apply to all public entities that are required to report segment information, including those with only one reportable segment. We adopted this standard effective for the year ending December 31, 2024 and the primary impact of which was the additional segment disclosures included in Note 11.

Recent Accounting Pronouncements

From time to time, the Financial Accounting Standards Board (“FASB”) or other standard setting bodies issue new accounting pronouncements. Updates to the FASB Accounting Standards Codification are communicated through issuance of an Accounting Standards Update (“ASU”). We have implemented all new accounting pronouncements that are in effect and that may impact our financial statements. We have considered all recent accounting pronouncements issued since the last audit of our consolidated financial statements. We believe that these recent pronouncements will not have a material effect on our consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to provide enhancements to annual income tax disclosures. The standard will require more detailed information in the rate reconciliation table and for income taxes paid, among other enhancements. The standard is effective for years beginning after December 15, 2024 and early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40), which requires disclosure, in the notes to the financial statements, of specified information about certain costs and expenses. This ASU is effective for public entities for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. We are currently evaluating the impact ASU 2024-03 will have on our consolidated financial statements.

Note 3 - Stock-based Compensation

The Processa Pharmaceuticals Inc. 2019 Omnibus Equity Incentive Plan (the "2019 Plan") allows us to make grants of stock options, restricted and unrestricted stock and other stock-based awards to employees, including our executive officers, consultants and directors. The 2019 Plan originally provided for the aggregate issuance of 150,000 shares of our common stock. On June 28, 2024, our shareholders approved an increase of shares available under the 2019 Plan, which now provides for the aggregate issuance of 800,000 shares of our common stock. At December 31, 2024, we have 353,641 shares available for future grants.

Stock Compensation Expense

We recorded stock-based compensation expense for the years ended December 31, 2024 and 2023 as follows:

	Year Ended December 31,	
	2024	2023
Research and development	$ 169,414	$ 363,956
General and administrative	460,100	2,007,258
Total	$ 629,514	$ 2,371,214

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for all net deferred tax assets relating to this expense.

Stock Options

The following table summarizes our stock option activity during the years ended December 31, 2023 and 2024:

	Total options Outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2023	8,943	$ 341.34	
Options granted	-		
Forfeited or expired	(1,951)	257.28	
Outstanding as of December 31, 2023	6,992	364.72	2.1
Options granted	-		
Forfeited or expired	(4,245)	336.00	
Outstanding and exercisable as of December 31, 2024	2,747	$ 409.09	3.7

No forfeiture rate was applied to these stock options. The aggregate intrinsic value of outstanding options, all of which are exercisable, was $0 at both December 31, 2023 and 2024. No stock options were exercised during the years ended December 31, 2023 or 2024 and there is no unamortized expense at December 31, 2024 since the options are fully vested.

Restricted Stock Awards

The following table summarizes our restricted stock award (RSA) activity during the years ended December 31, 2023 and 2024:

	Number of shares	Weighted-average grant-date fair value per share
Unvested as of January 1, 2023	3,095	$ 94.44
Granted	10,750	14.59
Forfeited	(1,250)	133.00
Cancelled	(2,555)	22.13
Vested and issued	(8,790)	24.44
Unvested as of December 31, 2023	1,250	9.26
Granted	-	-
Forfeited	-	-
Cancelled	-	-
Vested and issued	(1,250)	9.26
Unvested as of December 31, 2024	-	$ -

Restricted Stock Units

The following table summarizes our restricted stock unit (RSU) activity during the years ended December 31, 2023 and 2024:

	Number of shares	Weighted-average grant-date fair value per share
Outstanding at January 1, 2023	135,741	$ 73.81
Granted	116,078	14.18
Forfeited	(12,296)	21.69
Cancelled	(16,801)	71.36
Outstanding at December 31, 2023	222,722	45.82
Granted	192,026	1.63
Forfeited	(14,019)	71.68
Issued	(17,093)	110.59
Outstanding at December 31, 2024	383,636	19.87
Vested and unissued	(149,013)	43.10
Unvested at December 31, 2024	234,623	$ 5.11

During the year ended December 31, 2024, we granted the following RSUs:

- On June 28, 2024, we granted RSUs for the future issuance of 39,202 shares of common stock to our employees which vest accordingly: RSUs for the future issuance of 14,969 shares of common stock vest on January 1, 2025; RSUs for the future issuance of 18,173 shares of common stock vest over a three-year period upon meeting service requirements; RSUs for the future issuance of 3,030 shares of common stock vested upon grant due to regaining Nasdaq compliance; and RSUs for the future issuance of 3,030 shares of common stock vested on October 2, 2024 when we dosed the first patient in our Phase 2 study in NGC-Cap.

- On July 16, 2024, Russell Skibsted was appointed as our Chief Financial Officer (“CFO”). In addition to cash compensation, the Compensation Committee awarded RSUs for the future issuance of 28,000 shares of common stock to Mr. Skibsted, which vest accordingly: 14,000 vest on July 16, 2025; 7,000 vest upon reaching a market capitalization (i.e. total value of Processa’s outstanding shares of stock at the then current market price) of at least $30 million; and 7,000 vest upon receipt of cumulative financing(s) of at least $15 million.

- On September 3, 2024, RSUs for the future issuance of 124,824 shares of common stock were granted to our independent directors and vest on the earlier of June 28, 2025 or the next annual shareholder meeting.

- At December 31, 2024, unrecognized stock-based compensation expense for RSUs of approximately $613,000 is expected to be fully recognized over a weighted average period of 0.7 years. The unrecognized expense excludes $432,060 related to certain RSUs with a performance milestone that is not currently probable of occurring.

Holders of our vested RSUs will be issued shares of our common stock upon the satisfaction of the distribution restrictions contained in their Restricted Stock Unit Award Agreement. The distribution restrictions are typically different (longer) than the vesting schedule, imposing an additional restriction on the holder. Unlike RSAs, while employees may hold fully vested RSUs, the individual does not hold any shares or have any rights of a shareholder until the distribution restrictions are met. Upon distribution to the employee, each RSU converts into one share of our common stock. The RSUs contain dividend equivalent rights.

Warrants

The following table summarizes our warrant activity during the years ended December 31, 2023 and 2024.

	Total warrants outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2023	14,283	$ 205.01	
Granted	173,007	19.27	
Expired	(6,783)	266.96	
Not exercisable	(7,500)	7.40	
Outstanding and exercisable as of December 31, 2023	173,007	25.41	2.2
Exercisable	7,500	7.40	
Granted	1,617,777	4.54	
Expired or cancelled	(22,500)	54.62	
Outstanding and exercisable as of December 31, 2024	1,775,784	$ 5.95	3.8

During the year ended December 31, 2024, we did not grant any warrants to purchase shares of our common stock other than warrants to purchase 1,617,777 shares of common stock as part of the Offering (see Note 4). Warrants to purchase 7,500 shares of our common stock expired unexercised. We also repurchased a warrant issued to a consultant in 2023 for the purchase of 15,000 shares of our common stock in exchange for a payment of $10,000.

In February 2023, we amended our financial consulting agreement with Spartan Capital Securities, LLC (“Spartan”), our placement agent for our registered direct offering in February 2023, by extending the term until February 10, 2024. We compensated Spartan for financial consulting services provided under the amendment by granting warrants to purchase 158,007 shares of our common stock on April 17, 2023, with an exercise price of $20.40. The warrants expire on April 17, 2026, and contain both call and cashless exercise provision. We also granted warrants to purchase 15,000 shares of our common stock to a consultant on November 18, 2023, of which warrants to purchase 7,500 shares of our common stock were exercisable, with an exercise price of $7.40. These warrants expire on November 18, 2025.

We used the Black-Scholes option pricing model to calculate the grant date fair value of the two warrants granted in 2023 with the following assumptions:

Average risk-free rate of interest	4.32-4.88%
Expected term (years)	2.00–3.00
Expected stock price volatility	82.85-108.47%
Dividend yield	0%

Note 4 – Stockholders' Equity

Common Stock

Financings

During the year ended December 31, 2024, we issued 2,356,549 shares of our common stock through several fundraising efforts described below:

- *Public Offering* – On January 30, 2024, we closed a public offering (the "Offering") for the sale of 476,000 shares of common stock, Pre-Funded Warrants to purchase up to 1,079,555 shares of common stock in lieu of shares of common stock, and Common Warrants to purchase up to 1,555,555 shares of our common stock. The Common Warrants have an exercise price of $4.50, are immediately exercisable and expire on January 30, 2029. The shares of common stock were offered at a combined public offering price of $4.50 per share and accompanying Common Warrant and $4.4999 per Pre-Funded Warrant and accompanying Common Warrant. The Pre-Funded Warrants had an exercise price of $0.0001 and were exercised in full simultaneously with the closing of the Offering in exchange for 1,079,555 shares of our common stock. Gross proceeds in connection with the Offering were $7.0 million. We received $6.3 million in net proceeds from the Offering, after deducting the fees of the placement agent and other offering-related expenses.

- *ATM Offering* – We sold 800,994 shares at an average price of $1.93 per share for aggregate net proceeds of $1.5 million.

We also issued to the placement agent warrants to purchase 62,222 shares of common stock, exercisable at $5.625 per share that expire on February 1, 2027.

During the year ended December 31, 2023, we issued 421,611 shares of our common stock through several fundraising efforts described below:

- *ATM Offering* – On February 5, 2023, in connection with our Registered Direct Offering discussed below, we terminated our ATM and suspended the Sales Agreement with Oppenheimer & Co. Inc., but we may reinstate it in the future. During the year ended December 31, 2023, we sold 28,483 shares at an average price of $24.40 per share for aggregate gross proceeds of $693,000 (net proceeds of $672,000) prior to deducting sales commissions.

- *Lincoln Park Capital Fund, LLC Purchase Agreement* – During the year ended December 31, 2023, we sold 2,500 shares at an average price of $21.60 per share for aggregate gross proceeds of $54,000 under the purchase agreement with Lincoln Park.

- *Registered Direct Offering* – On February 14, 2023, we closed a registered direct offering (the "Offering") for the sale of 390,628 shares of common stock at a purchase price of $16.00 per share for gross proceeds of $6.3 million (net proceeds of $5.6 million).

We paid Spartan a cash fee of 8.0% of the gross proceeds from the Offering, excluding proceeds received from our insiders, and reimbursed Spartan for legal fees of $60,000. The engagement agreement with Spartan required us to indemnify Spartan and certain of its affiliates against certain customary liabilities. On February 14, 2023, we amended the consulting agreement with Spartan originally entered into on August 24, 2022, extending the term of the consulting agreement until February 10, 2024. As compensation for services under the agreement, on April 17, 2023, we granted Spartan warrants to purchase 158,007 shares of our common stock with an exercise price of $20.40. The warrants will expire April 17, 2026 and contain both call and cashless exercise provisions.

Note 5 – Net Loss per Share of Common Stock

Basic net loss per share is computed by dividing net loss by the weighted average common stock outstanding (which excludes unvested RSAs) and vested, but unissued RSUs. Diluted net loss per share is computed by dividing net loss by the diluted weighted average common stock outstanding, which includes potentially dilutive effect of stock options, unvested RSAs, unvested RSUs and warrants. The treasury-stock method is used to determine the dilutive effect of our stock options and warrants grants. Since we experienced a loss for both periods presented, basic and diluted net loss per share are the same and, as they would have an anti-dilutive impact on diluted net loss per share, any dilutive common shares outstanding were excluded from the computation shown below.

The computation of net loss per share for the year ended December 31, 2024 and 2023 was as follows:

	2024	2023
Basic and diluted net loss per share:		
Net loss available to common shareholders	$ (11,850,118)	$ (11,121,520)
Weighted-average number of common shares-basic and diluted	3,059,906	1,311,572
Basic and diluted net loss per share	$ (3.87)	$ (8.48)

	2024	2023
Weighted-average number of common shares outstanding – basic and diluted	2,912,539	1,186,952
Weighted-average number of vested RSUs– basic and diluted	147,367	124,619
Weighted-average number of common shares-basic and diluted	3,059,906	1,311,572

As described in Note 3, we issued various equity instruments during the years ended December 31, 2024 and 2023 which impact our EPS calculation. All granted RSAs are considered issued and outstanding for purposes of our financial statements. Unvested RSAs are included as dilutive securities, but are excluded from our denominator of basic EPS. At December 31, 2023, 1,250 RSAs were not vested and were excluded from the EPS calculation. We had no unvested RSAs at December 31, 2024. Vested RSUs are included in our computation of the weighted average shares for basic EPS and unvested RSUs are included as dilutive securities. At December 31, 2024 and 2023, 234,623 and 102,623 unvested RSUs were excluded from the EPS calculation.

The outstanding stock options, unvested RSAs, unvested RSUs and warrants to purchase common stock were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive for the periods presented below:

	2024	2023
Stock options, unvested RSAs, unvested RSUs and purchase warrants	2,013,154	296,326

Note 6 – Leases

We lease our office space under an operating lease agreement. This lease does not have significant rent escalation, concessions, leasehold improvement incentives, or other build-out clauses. Further, the lease does not contain contingent rent provisions. Our office space lease includes both lease (e.g., fixed payments including rent, taxes, and insurance costs) and non-lease components (e.g., common-area or other maintenance costs), which are accounted for as a single lease component as we have elected the practical expedient to group lease and non-lease components for all leases. We also lease office equipment under an operating lease. Our leases do not provide an implicit rate and, as such, we have used our incremental borrowing rate of 8% to determine the present value of the lease payments based on the information available at the lease commencement date.

Lease costs included in our consolidated statements of operations totaled approximately $90,000 and $97,000 for the years ended December 31, 2024 and 2023, respectively. The weighted average remaining lease terms and discount rate for our operating leases at December 31, 2024 were as follows:

	Year Ended December 31,	
	2024	2023
Remaining lease term (years) for our office lease	0.8	1.8
Remaining lease term (years) for our equipment lease	1.1	0.3
Weighted average discount rate for our facility and equipment leases	8.0%	8.0%

Annual lease liabilities for the operating lease were as follows at December 31, 2024:

2025	$ 70,040
Total lease payments	70,040
Less: Interest	(3,135)
Present value of lease liabilities	66,905
Less: current maturities	(66,905)
Non-current lease liability	$ -

Annual lease liabilities for the financing lease were as follows at December 31, 2024:

2025	$ 6,821
2026	571
Total lease payments	7,392
Less: Interest	(790)
Present value of lease liabilities	6,602
Less: current maturities	(6,115)
Non-current lease liability	$ 487

Note 7 – License Agreements

We have entered into license agreements which allow us to develop, manufacture, and/or commercialize the following drug assets:

Licensor	Drug Asset	Agreement Date	Amendment Date
Elion Oncology, Inc.	NGC-Cap (PCS6422)	August 23, 2020	May 17, 2022
Ocuphire Pharma, Inc.	NGC-Gem (PCS3117)	June 16, 2021	N/A
Aposense, Ltd.	NGC-Iri (PCS11T)	May 24, 2020	N/A
Yuhan Corporation	PCS12852	August 19, 2020	N/A
CoNCERT Pharmaceuticals, Inc.	PCS499	March 19, 2018	N/A

For more information, you should refer to the summaries described in the Business section of this Annual Report and the copies of such agreements, which have been filed as exhibits to this Annual Report.

Note 8 - Income Taxes

We have incurred net operating losses since inception. At December 31, 2024 and 2023, we had available federal and state net operating loss carryforwards of $36.0 million and $28.6 million, respectively. The federal net operating losses generated in 2018 and later of $29.3 million will carry forward indefinitely. Net operating losses generated prior to 2018 will expire 2037. We have not recognized any deferred tax assets related to the federal orphan drug or other research and development tax credits as of December 31, 2024 or 2023. The federal research and development tax credits have a 20-year carryforward period.

Pursuant to Code Sec. 382 of the Internal Revenue Code ("the Code"), the utilization of our net operating loss carryforwards could be limited as a result of a cumulative change in stock ownership of more than 50% over a three-year period. We have not completed a Sec. 382 study and as such our net operating loss carryforwards may be subject to such limitation.

A reconciliation of our effective income tax rate and statutory income tax rate for the years ended December 31, 2024 and 2023 is as follows:

	Year Ended December 31,	
	2024	2023
Federal statutory income tax rate	21.00%	21.00%
State tax rate, net	5.58%	5.77%
Permanent differences	(0.04)%	(0.25)%
Federal orphan drug tax credit	0.05%	1.41%
Deferred tax asset valuation allowance	(26.59)%	(27.93)%
Effective income tax rate	0.00%	0.00%

The significant components of our deferred tax assets and liabilities for Federal and state income taxes consisted of the following:

	December 31,	
	2024	2023
Deferred tax assets:		
Non-current:		
Net operating loss carry forward – Federal	$ 7,566,071	$ 6,012,941
Net operating loss carry forward – State	2,074,542	1,672,436
Stock compensation expense	2,794,226	3,453,799
Depreciation and other	238	999
Purchased in-process R&D	2,477,193	2,500,562
Federal orphan drug credits	1,209,202	1,202,955
Capitalized research and development costs	3,781,193	2,795,379
Start-up expenditures and amortization	-	-
Total non-current deferred tax assets	19,902,665	17,639,071
Valuation allowance for deferred tax assets	(19,902,665)	(17,639,071)
Total deferred tax assets	-	-
Deferred Tax Liabilities:		
Non-current:		
Intangible asset	-	-
Total non-current deferred tax liabilities	-	-
Total deferred tax asset (liability)	$ -	$ -

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 (TCJA) eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to amortize them over five or fifteen years pursuant to IRC Section 174. During 2024 and 2023, for income tax purposes, we capitalized approximately $3.8 million and $3.2 million of research and development expenditures, net of amortization of these costs in each year.

The valuation allowance generally reflects limitations on our ability to use the tax attributes and reduces the value of such attributes to the more-likely-than-not realizable amount. We assessed the available positive and negative evidence to estimate if sufficient taxable income will be generated to use the existing net deferred tax assets. Based on a weighing of the objectively verifiable negative evidence primarily in the form of cumulative operating losses, we believe that it is not more-likely-than-not that the deferred tax assets will be realized and, accordingly, a full valuation allowance has been established. The valuation allowance increased by $2.3 million and $3.1 million for the years ended December 31, 2024 and 2023, respectively.

We recognize potential liabilities for uncertain tax positions using a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more-likely-than-not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon settlement. We have not recorded any uncertain tax positions. As of December 31, 2024 and 2023, we had no accrued penalties or interest related to uncertain tax positions.

We file U.S. Federal income tax returns, as well as state tax returns for California, Florida and Maryland. There are currently no income tax examinations underway for these jurisdictions. However, tax years from and including 2017 remain open for examination by federal and state income tax authorities.

Note 9 – Related Party Transactions

CorLyst, LLC ("CorLyst") reimburses us for shared costs related to payroll, health insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses in our consolidated statements of operations. We recorded approximately $110,000 and $112,000 in reimbursements during the years ended December 31, 2024 and 2023, respectively. At December 31, 2024, $47 was due from CorLyst and no amounts were due at December 31, 2023. Our President, Research and Development is the CEO of CorLyst, and CorLyst is a shareholder.

Note 10 – Litigation

On May 7, 2024, the Company received notification from Elion purporting to terminate the license agreement by and between the Company and Elion as a result of the Company's alleged breach thereof. The Company believes that Elion's claims are without merit and disputes that the license agreement has been validly terminated. On July 5, 2024, the Company filed a complaint in New York State Court seeking monetary damages, declaratory judgement and injunctive relief. On August 14, 2024, the Company received Elion's answer and counterclaims. On October 10, 2024, the Company filed its response to Elion's counterclaims. The Company intends to enforce its rights under the license agreement and will pursue such other remedies as it determines are appropriate.

On December 3, 2024, Jason Assad and Marc Gyimesi, two of the investors in our February 2021 private offering, filed a lawsuit in New York County Court alleging fraud and negligent misrepresentation in connection therewith and seeking monetary damages.

We intend to vigorously defend ourselves in these lawsuits and cannot at this time predict the likely outcome of any litigation, reasonably determine either the probability of a material adverse result or any estimated range of potential exposure, or reasonably determine how these matters or any future matters might impact our business, our financial condition, or our results of operations, although such impact, including the costs of defense, as well as any judgments or indemnification obligations, among other things, could be materially adverse to us.

Note 11 – Segment Reporting

We manage our operations as a single segment, focused on developing the next generation of cancer therapy drugs. As our CODM, our CEO manages and allocates resources at a consolidated level. He assesses performance, monitors budget versus actual results, and decides how to allocate resources based on net loss that also is reported on the consolidated statement of operations and comprehensive loss as consolidated net loss.

The accounting policies of our single operating segment are the same as those described in the summary of significant accounting policies in Note 2. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. In 2024 and 2023, all our long-lived assets were held in the United States. Expenditures for the addition of long-lived assets are reported on the consolidated statements of cash flows as purchases of property and equipment. We do not have intra-entity sales or transfers since our only subsidiary is currently dormant.

The following table presents reportable segment profit and loss, including significant expense categories, attributable to our reportable segment for the years ended December 31, 2024 and 2023:

	Year ended December 31,	
	2024	2023
Preclinical, clinical trial and other costs	$ 5,450,963	$ 3,817,669
Research and development personnel expense[(1)]	1,818,183	1,981,849
General and administrative personnel expense[(2)]	1,981,756	1,737,792
Administrative and facilities expense[(3)]	2,800,304	3,919,751
Interest income, net	(201,088)	(335,541)
Total	$ 11,850,118	$ 11,121,520

(1) Research and development personnel costs include employee stock-based compensation expense of $169,414 and $363,956 for the year ended December 31, 2024, and 2023, respectively.

(2) General and administrative personnel costs include employee stock-based compensation expense of $186,925 and $387,854 for the year ended December 31, 2024, and 2023, respectively, and are net of reimbursements received from CorLyst, LLC.

(3) Administrative & facilities expense primarily consists of facilities expenses, office expenses, legal costs, insurance, consulting, travel, and other administrative costs.

Note 12 – Commitments and Contingencies

Purchase Obligations

We enter contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If we terminated a cancellable contract with a specific vendor, we would only be obligated for products or services that we received as of the effective date of the termination and any applicable cancellation fees. As of December 31, 2024, we are contractually obligated to pay up to approximately $12.2 million for future services under the agreements with the CROs for our clinical trials in NGC-Cap. Our actual contractual obligations will also vary depending on the progress and results of the remaining clinical trials.

Note 13 – Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of our cash and cash equivalents. We utilize only well-established banks and financial institutions with high credit ratings. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by our banks at December 31, 2024, exceeded FDIC limits.

Note 14 – Subsequent Events

Public Offering

On January 27, 2025, we sold, pursuant to securities purchase agreements (the "Purchase Agreement"), 1,030,972 shares of our common stock and accompanying Series A warrants to purchase up to 8,050,672 shares of our common stock (the "Series A Warrants") and Series B warrants to purchase up to 4,025,336 shares of our common stock (the "Series B Warrants" and collectively with the Series A Warrants, the "Common Warrants") at a combined purchase price of $0.615 for institutional investors and $0.7975 for the Company's Chief Executive Officer and certain board members. The Series A and Series B Warrants both have an exercise price of $0.65 per share of common stock, and will be exercisable beginning on the effective date of stockholder approval of the issuance of the shares upon exercise of the warrants ("Warrant Stockholder Approval"). The Series A Warrants will expire on the five-year anniversary date of stockholder approval and the Series B Warrants will expire on the eighteen-month anniversary date of stockholder approval.

We also sold pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 7,019,700 shares of our common stock to a purchaser whose purchase of shares of common stock in the public offering would have resulted in the purchaser beneficially owning more than 9.99% of our outstanding common stock immediately following the consummation of the public offering. Each Pre-Funded Warrant is exercisable for one share of common stock at an exercise price of $0.0001 per share of common stock. The public offering price per Pre-Funded Warrant, is equal to the public offering price per share and Common Warrants less $0.0001. Each Pre-Funded Warrant will be exercisable upon issuance and will expire when exercised in full. On January 30, 2025, Pre-Funded Warrants to purchase 525,700 shares of our common stock were exercised and, as of March 12, 2025, Pre-Funded Warrants for the purchase of 6,494,000 remain outstanding.

Gross proceeds in connection with this offering were $5.0 million and we received $4.5 million in net proceeds from the offering, after deducting the fees of the placement agent and other offering-related expenses.

Amended and Restated Bylaws

On March 18, 2025, the Board of Directors (the "Board") of the Company adopted the Amended and Restated Bylaws (as amended, the "Bylaws"). The Bylaws, which became effective immediately, amended Section 2.4 to change the quorum requirements for a stockholders meeting to be the holders of shares of outstanding capital stock of the Company representing one third (1/3) of the voting power of all outstanding shares of capital stock of the Company except if business is to be voted on by a class or series of stock voting as a class, then the holders of shares representing one third (1/3) of the voting power of the outstanding shares of such class or series shall constitute a quorum.

Executive Employment Agreements

On March 19, 2025, we entered into new or amended employment agreements with all members of our executive team that continue until terminated or modified pursuant to the terms of the employment agreements. The agreements establish their base salaries, target bonuses, eligibility to participate in our 2019 Omnibus Incentive Plan, and severance benefits, among other things.

Item 9. Changes in and Disagreements with Accountants

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as our controls are designed to do, and management was required to apply its judgment in evaluating the risks related to controls and procedures.

In connection with the preparation of this Annual Report on Form 10-K, as of December 31, 2024, an evaluation was performed by management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2024 to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) 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

Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles ("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 our receipts and expenditures 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 financial statements.

Management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, 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. Because of the inherent limitations in all control systems, no evaluation of internal controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Also, any evaluation of the effectiveness of controls in future periods is subject to the risk that those internal controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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 Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP.

Management assessed our internal control over financial reporting as of December 31, 2024. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that, as of December 31, 2024, our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with GAAP.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm, Cherry Bekaert, LLP, regarding internal controls over financial reporting. Management's report was not subject to attestation by our registered public accounting firm as we are a smaller reporting company. We are not currently subject to Section 404(b) of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control Over Financial Reporting

There were no changes to our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Trading Plans

During the quarter ended December 31, 2024, none of our directors or executive officers adopted or terminated a Rule 10b5-1 trading plan or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

Amended and Restated Bylaws

On March 18, 2025, the Board of Directors (the "Board") of the Company adopted the Amended and Restated Bylaws (as amended, the "Bylaws"). The Bylaws, which became effective immediately, amended Section 2.4 to change the quorum requirements for a stockholders meeting to be the holders of shares of outstanding capital stock of the Company representing one third (1/3) of the voting power of all outstanding shares of capital stock of the Company except if business is to be voted on by a class or series of stock voting as a class, then the holders of shares representing one third (1/3) of the voting power of the outstanding shares of such class or series shall constitute a quorum.

The preceding description of the Bylaws is qualified in its entirety by reference to the full text of the Bylaws dated March 18, 2025, which is filed herewith as Exhibit 3.2.

Executive Employment Agreements

On March 19, 2025, we entered into new or amended employment agreements with each of George Ng, Russell Skibsted, Sian Bigora, Wendy Guy, Patrick Lin and David Young. See Item 11 Executive Compensation – Employment Agreements herein for a summary of the employment agreements. The description of the employment agreements is qualified in its entirety by reference to the full text of the agreements, which are filed herewith as Exhibits 10.11, 10.12, 10.13, 10.14, 10.15 and 10.16.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors and Executive Officers of the Registrant

The following table sets forth information concerning our executive officers, as of March 12, 2025.

Name	Age	Position
Executive Officers:		
George Ng	51	Chief Executive Officer
Dr. Sian Bigora	64	Chief Development and Regulatory Officer
Wendy Guy	60	Chief Administrative Officer
Patrick Lin	59	Chief Business and Strategy Officer
Russell Skibsted	66	Chief Financial Officer
Dr. David Young	72	President of Research and Development
Non-Employee Directors:		
Khoso Baluch	67	Director
James Neal	69	Director
Geraldine Pannu	55	Director
Justin Yorke	58	Director

George Ng – Mr. Ng has served as our Chief Executive Officer and as a director since August 8, 2023. He has served as a member of the board of directors of Calidi Biotherapeutics Inc. (NYSE:CLDI) ("Calidi") from October 2019 to September 2024, and was Calidi's President and Chief Operating Officer from February 1, 2022 until June 23, 2023. He has been a partner at PENG Life Science Ventures since September 2013; a member of the board of directors and co-founder at IACTA Pharmaceuticals, Inc. since January 2020; and member of the board of directors of TuHURA Biosciences, Inc. (formerly, Morphogenesis, Inc.) since February 2020 . His experience further includes serving in various executive-level or board of director positions for multiple publicly-traded and private global biotechnology and pharmaceutical firms. Mr. Ng previously served as a member of the board of directors of Inflammatory Response Research, Inc. from May 2019 to April 2020; Invent Medical Corp from July 2019 to January 2020; ImmuneOncia Therapeutics Inc. from June 2016 to 2019; and Virttu Biologics Limited from April 2017 to April 2019. He was also the Executive Vice President and Chief Administrative Officer of Sorrento Therapeutics, Inc. (Nasdaq: SRNE) from March 2015 to April 2019; the Co-Founder and President, Business of Scilex Pharmaceuticals Inc. from September 2012 to April 2019; and the Senior Vice President and General Counsel of BioDelivery Sciences International Inc. (Nasdaq: BDSI) from December 2012 to March 2015. Mr. Ng holds a JD degree from the University of Notre Dame School of Law, as well as a B.A.S. (B.A. and B.S.) dual degree in Biochemistry and Economics from the University of California, Davis. We believe that Mr. Ng is qualified to serve on our Board due to his experience with pharmaceutical companies.

Sian Bigora, Pharm.D. - Dr. Bigora has served as our Chief Development and Regulatory Officer since October 4, 2017 and has over 30 years of pharmaceutical research, regulatory strategy and drug development experience. From 2009 to 2015 Dr. Bigora was Vice President of Regulatory Affairs at Questcor Pharmaceuticals (acquired by Mallinckrodt Pharmaceuticals in 2014), including leading efforts on modernizing the Acthar Gel label and in obtaining FDA approval in Infantile Spasms, events of material importance to Questcor's subsequent success. During her time at Questcor, she assisted in building an expert regulatory group to address both commercial and development needs for complex products such as Acthar. Dr. Bigora's role at Questcor included heading up the development of a safety pharmacovigilance group and a clinical quality group. Prior to her position at Questcor, Dr. Bigora was Vice President of Clinical and Regulatory Affairs, U.S. Operations of AGI Therapeutics, plc. In this role, she was responsible for the development and implementation of Global Phase 3 studies and interactions with regulatory authorities. Previously, she operated her own consulting company, serving as the regulatory and drug development expert team member for multiple small and mid-sized pharmaceutical companies. Dr. Bigora held multiple positions in regulatory affairs, operations and project management ending as VP of Regulatory Affairs at the Strategic Drug Development Division of ICON, plc, an international CRO, and at GloboMax LLC, a CRO specializing in FDA drug development, purchased by ICON plc in 2003. Prior to GloboMax, she worked in the Pharmacokinetics and Biopharmaceutics Laboratory at the School of Pharmacy, University of Maryland on the FDA funded Clinical Pharmacology contract and UMAB-FDA contract as a clinical scientist and instructor for FDA reviewers. Dr. Bigora received a Pharm.D. from the School of Pharmacy at the University of Maryland at Baltimore. She also completed a Fellowship in Pharmacokinetics and Pediatric Infectious Diseases at the University of Maryland at Baltimore.

Wendy Guy - Ms. Guy has served as our Chief Administrative Officer since October 4, 2017. She has over 20 years of experience in business operations, management, contracts, human resources recruiting, and finance roles. From 2009 to 2014, Ms. Guy was employed at Questcor Pharmaceuticals (acquired by Mallinckrodt Pharmaceuticals in 2014) as Senior Manager, Business Operations in charge of the Maryland Office for Questcor. During the five years she spent at Questcor, she built a dynamic administrative and contracts team, grew the Maryland Office from two employees to just under 100, and expanded the facility from 1,200 sq. ft. to 15,000 sq. ft. Prior to her position at Questcor, Ms. Guy was Senior Manager, U.S. Operations of AGI Therapeutics, plc. In this role, she was responsible for the day-to-day business and administrative operations of the company. Previously, she held multiple senior level positions with the Strategic Drug Development Division of ICON, GloboMax, and Mercer Management Consulting. Ms. Guy received an A.A. from Mount Wachusett Community College.

Patrick Lin - Mr. Lin has served as our Chief Business & Strategy Officer since October 4, 2017 and has over 30 years of financing and investing experience in the Biopharm Sector. He is founder and, for more than 15 years, Managing Partner of Primarius Capital, a family office that manages public and private investments focused on small capitalization companies. For 10 years prior to forming Primarius Capital, Mr. Lin worked at several Wall Street banking and brokerage firms including Robertson Stephens & Co., E*Offering, and Goldman Sachs & Co. Mr. Lin was Co-Founding Partner of E*Offering. Mr. Lin received an MBA from Kellogg Graduate School of Management, an M.S. in Engineering Management, and a BS from the University of Southern California.

Russell Skibsted – Mr. Skibsted has served as our Chief Financial Officer since July 16, 2024. He has nearly 30 years of experience in the pharmaceutical industry including expertise in financial management, global business development, capital raises, investor relations and operations. He has worked with public and private life sciences companies at all stages of development. Most recently, he served as Senior Vice President and CFO of Alimera Sciences, a publicly traded global ophthalmic pharmaceuticals company that was acquired by ANI Pharmaceuticals from January 2023 to December 2023. Prior to that, he was Executive Vice President, CFO and Chief Business Officer at Rockwell Medical, a public company providing hemodialysis products from September 2020 to November 2022. From July 2017 to May 2020, Mr. Skibsted served as CFO of BioTime, a publicly traded biotechnology company now named Lineage Cell Therapeutics, where he also was CFO at various times for several of BioTime's public and private subsidiaries, including Agex Therapeutics, OncoCyte Corporation and Asterias Biotherapeutics. Prior to BioTime, Mr. Skibsted served as CFO or Chief Business Officer for several public and private life science companies, including Aeolus Pharmaceuticals, Spectrum Pharmaceuticals and Hana Biosciences. Mr. Skibsted holds a BA in economics from Claremont McKenna College and an MBA from the Stanford Graduate School of Business.

David Young, Pharm.D., Ph.D. - Dr. Young has served as our President, Research and Development and a director since August 8, 2023. He also served as our Chief Executive Officer from October 4, 2017 until August 7, 2023, as the Chairman of our Board until July 11, 2022, and as our President from July 11, 2022 until August 8, 2023. He has over 35 years of drug development experience serving as CEO, President and VP in different drug development companies. He served as our interim CFO from October 4, 2017 to September 1, 2018. From 2006 to 2014, Dr. Young served as a Questcor Pharmaceuticals Board Member and later as CSO, where he worked with FDA on the sNDA approval of Acthar for infantile spasms, an ultra-rare orphan indication, and other indications. In 2014, Questcor was acquired for $5.7 billion. Dr. Young was previously an Associate Professor at the University of Maryland, has served on FDA Advisory Committees, and was involved with two FDA-funded contracts as co-principal investigator and investigator. Research from these contracts resulted in multiple FDA Guidances, which became the basis of our regulatory science approach to drug development. Dr. Young has served on NIH grant review committees and was Co-Principal Investigator on an NCI contract to evaluate new oncology drugs. He has met with the FDA over one hundred times and has been a key member on more than thirty FDA indication approvals. Dr. Young received a B.S. in Physiology, M.S. in Medical Physics, and Pharm.D.-Ph.D. specializing in pharmacokinetics-pharmacodynamics. We believe Dr. Young is qualified to serve on our Board due to his pharmaceutical experience.

Khoso Baluch – Mr. Baluch has served as a director since over July 2022. He has over 36 years of experience across global geographies in the biopharmaceutical industry. He serves on Relevant Bio, a private US company, as a member of the board of directors since February 2024 and Longeveron, a US public company, as a member of the board of directors since June 2023. Since 2012, he has served as an independent director of Poxel S.A. (OTC: PXXLF), a French publicly traded biotech company, and chairs its compensation committee and as of March 2023 became Chairman. He also served as the Chairman of the Board for Da Volterra, a French privately held company, from December 2021 until November 2022. From 2016 to 2021, Mr. Baluch served as the Chief Executive Officer and a member of the board of directors of CorMedix, Inc. (Nasdaq: CRMD), a publicly traded pharmaceutical company in the United States. Mr. Baluch also held various senior positions at UCB, S.A. between January 2008 to April 2016, including Senior Vice President and President Europe, Middle East & Africa. Prior to joining UCB, Mr. Baluch worked for Eli Lilly and Company (NYSE: LLY) for 24 years, holding international positions spanning Europe, the Middle East and the United States in general management, business development, market access and product leadership. Mr. Baluch holds a B.S. in Aeronautical Engineering from City University London and an MBA from Cranfield School of Management. We believe Mr. Baluch is qualified to serve as on our Board due to his business expertise and significant executive management experience in the pharmaceutical industry.

James Neal – Mr. Neal has served as a director since July 2022. He brings more than 25 years of experience forming and maximizing business and technology collaborations globally and in bringing novel products and technologies to market. Mr. Neal served as the Chief Executive Officer and member of the board of directors of XOMA Corporation (Nasdaq: XOMA) ("XOMA") from December 2016 until his retirement in January 2023. Mr. Neal joined XOMA in 2009 as its Vice President, Business Development. Prior to joining XOMA, Mr. Neal was Acting Chief Executive Officer of Entelos, Inc. a leading biosimulation company. Previously, in 2007, Entelos acquired Iconix Biosciences, a privately held company where Mr. Neal served as Chief Executive Officer and established multi-year collaborations with Bristol-Myers Squibb, Abbott Labs, Eli Lilly and the U.S. Food and Drug Administration. While Executive Vice President of Incyte Genomics from 1999 to 2002, he led the global commercial activities with pharmaceutical company collaborators and partners including Pfizer, Aventis and Schering-Plough, as well as sales, marketing and business development activities for the company. Earlier, he was associated with Monsanto Company in positions of increasing responsibility. Mr. Neal also serves on the Board of Directors of Akari Therapeutics, a pre-clinical stage biopharmaceutical company. Mr. Neal earned his B.S. in Biology and his M.S. in Genetics and Plant Breeding from the University of Manitoba, Canada, and holds an Executive MBA degree from Washington University in St. Louis, Missouri. We believe Mr. Neal is qualified to serve on our Board because of his business expertise and significant executive management experience in the pharmaceutical industry.

Geraldine Liu Pannu – Ms. Pannu has served as a Director since February 13, 2020. Since May 2022, she has also served as an independent director on the Board of Royal Business Bank (Nasdaq: RBB). Ms. Pannu has over 25 years of experience in investment and financial management, fund operations, consulting and marketing. Since January 2020, she has been the Founding and Managing Partner of GLTJ Pioneer Capital, a firm that specializes in land acquisition, entitlement and vertical development of multifamily, student and senior housing in the San Francisco Bay Area. From September 2018 to September 2019, Geraldine was the Managing Director of Business Development for Golden Gate Global (GGG), a leading investment fund company in the Bay Area, CA. During this time, she was also the President of Golden Wealth Management Group (GWMG), an affiliated company of GGG that provides professional wealth management services to high net worth individuals and families. From March 2007 to December 2016 , Ms. Pannu was the COO and Managing Partner for ChinaRock Capital Management, a leading hedge and venture capital fund company. She previously worked at McKinsey & Co., Monitor Company as a management consultant. She has successfully raised capital for several hedge, venture capital and real estate funds. She also helped start-up companies expand and diversify business categories and client verticals and grow revenue. Ms. Pannu was born in Shanghai and grew up in Hong Kong. She received her BBA from the Chinese University of Hong Kong and an MBA from Harvard Business School. She is fluent in English, Mandarin, Cantonese and Shanghainese. We believe Ms. Pannu is qualified to serve on our Board because of her extensive investment experience.

Justin Yorke – Mr. Yorke is currently the Chairman of the Board, a position he has held since July 11, 2022, and has served as a director since August 2017. Mr. Yorke has over 25 years of experience as an institutional equity fund manager and senior financial analyst for investment funds and investment banks. For more than 20 years, he has been a partner at Arroyo Capital Management which manages the Richland Fund whose primary activity is investing in public and private companies in the United States. Since March 2020, Mr. Yorke has served as a director and Corporate Secretary of Splash Beverage Group, Inc (NYSE:SBEV). From 2006 to 2007, Mr. Yorke served as non-executive Chairman of Jed Oil and a director/CEO at JMG Exploration. From 2000 to 2004, he was a partner at Asiatic Investment Management, based in San Francisco. From 1997 to 2000, Mr. Yorke was a Fund Manager and Senior Financial Analyst, based in Hong Kong, for Darier Henstch, S.A., a private Swiss bank, where he managed their $400 million Asian investment portfolio. From 1995 to 1997, Mr. Yorke was an Assistant Director and Senior Financial Analyst with Peregrine Asset Management, which was a unit of Peregrine Securities, a regional Asian investment bank. From 1990 to 1995, Mr. Yorke was a Vice President and Senior Financial Analyst with Unifund Global Ltd., a private Swiss Bank, as a manager of its $150 million Asian investment portfolio. Mr. Yorke has a B.A. from University of California, Los Angeles. We believe Mr. Yorke is qualified to serve on our Board because of his extensive investment experience.

Policy Statement on Insider Trading

We have adopted an Insider Trading Policy that governs the purchase, sale, and/or other dispositions of our securities by directors, officers, employees, and consultants that is reasonably designed to promote compliance with insider trading laws, rules and regulations and NASDAQ listing standards. A copy of our Policy Statement on Insider Trading is included as Exhibit 19 to this report.

Board Composition

Currently, our Board of Directors is comprised of six members. Each director has been elected to hold office until the next annual meeting of shareholders or special meeting in lieu of such annual meeting or until his or her successor has been duly elected and qualified, or until his or her earlier death, resignation or removal.

Our Board of Directors may consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity, which is not only limited to race, gender or national origin. We have no formal policy regarding Board diversity. Our Board of Directors' priority in selecting Board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among Board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy.

Director Independence

The Nasdaq Marketplace Rules require a majority of a listed company's Board of Directors to be comprised of independent directors. In addition, the Nasdaq Marketplace Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act.

Under Rule 5605(a)(2) of the Nasdaq Marketplace Rules, a director will only qualify as an "independent director" if, in the opinion of our Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 of the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the Board of Directors, or any other Board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

Our Board of Directors has reviewed the composition of our Board of Directors and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that each of Khoso Baluch, James Neal, Geraldine Pannu, and Justin Yorke is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. Our Board of Directors also determined that the directors who serve on our audit committee, our compensation committee, and our nominating and corporate governance committee satisfy the independence standards for such committees established by the SEC and the Nasdaq Marketplace Rules, as applicable. In making such determinations, our Board of Directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our Board of Directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

There are no family relationships among any of our directors or executive officers.

Committees of the Board of Directors

Each of the below committees has a written charter approved by our Board of Directors located at our website: www.processapharmaceuticals.com. Each of the committees' report to our Board of Directors as such committee deems appropriate and as our Board of Directors may request. Copies of each charter are posted on the investor relations section of our website. Members serve on these committees until their resignation or until otherwise determined by our Board of Directors. In addition, from time to time, special committees may be established under the direction of our Board of Directors when necessary to address specific issues.

The Board of Directors met 20 times during 2024. All directors attended each meeting, with the following exceptions: Khoso Baluch missed three meetings, James Neal missed one meeting, Geraldine Pannu missed three meetings, Justin Yorke missed one meeting, and David Young missed two meetings.

Audit Committee

Our audit committee is comprised of Khoso Baluch, Geraldine Pannu, and Justin Yorke, with Justin Yorke serving as chairman of the committee. Our Board of Directors has determined that each member of the audit committee meets the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq Listing Rules, and has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our Board of Directors has determined that Justin Yorke is an "audit committee financial expert" within the meaning of the SEC regulations and the applicable Nasdaq Listing Rules. The audit committee's responsibilities include:

- selecting a firm to serve as the independent registered public accounting firm to audit our financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- considering the effectiveness of our internal controls and internal audit function;
- reviewing material related-party transactions or those that require disclosure; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

The audit committee met four times during 2024. All the committee members attended each meeting, with the exception of Khoso Baluch who did not attend one meeting.

Compensation Committee

Our compensation committee is comprised of Khoso Baluch, James Neal and Geraldine Pannu, with Geraldine Pannu serving as chairman of the committee. Each member of this committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"). Our Board of Directors has determined that each member of the compensation committee is "independent" as defined in the Nasdaq Listing Rules. The composition of our compensation committee meets the requirements for independence under the Nasdaq Listing Rules, including the applicable transition rules. The compensation committee's responsibilities include:

- reviewing and approving, or recommending that our Board of Directors approve, the compensation of our executive officers;
- reviewing and recommending to our Board of Directors the compensation of our directors;
- reviewing and recommending to our Board of Directors the terms of any compensatory agreements with our executive officers;
- administering our stock and equity incentive plans;
- reviewing and approving, or making recommendations to our Board of Directors with respect to incentive compensation and equity plans; and
- reviewing all overall compensation policies and practices.

The compensation committee met one time during 2024. All the committee members attended the meeting.

Nominating and Governance Committee

Our nominating and governance committee is comprised of James Neal, Geraldine Pannu and Justin Yorke, with Justin Yorke as the chairman of the committee. Our Board of Directors has determined that each member of the nominating and corporate governance committee is "independent" as defined in the applicable Nasdaq Listing Rules. The nominating and corporate governance committee's responsibilities include:

- identifying and recommending candidates for membership on our Board of Directors;
- recommending directors to serve on Board committees;
- reviewing and recommending our corporate governance guidelines and policies;
- reviewing proposed waivers of the code of conduct for directors and executive officers;
- evaluating, and overseeing the process of evaluating, the performance of our Board of Directors and individual directors; and
- assisting our Board of Directors on corporate governance matters.

The nominating and governance committee did not meet in 2024.

Leadership Structure and Risk Oversight

On July 11, 2022, Justin Yorke became the Chairman of the Board of Directors. Prior to that time, Dr. David Young, our former Chief Executive Officer (now President, Research and Development) also served as Chairman of the Board. Our Board of Directors does not have a policy regarding the separation of the roles of Chief Executive Officer and Chairman of the Board of Directors, as our Board of Directors believes it is in our best interest to make that determination based on our position and direction and the membership of the Board of Directors.

Our Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board of Directors performs this oversight role by using several different levels of review. In connection with its reviews of our operations and corporate functions, our Board of Directors addresses the primary risks associated with those operations and corporate functions. In addition, our Board of Directors reviews the risks associated with our business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our Board committees also oversees the management of our risks that fall within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Financial Officer reports to the audit committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its risk management role, our audit committee meets privately with representatives from our independent registered public accounting firm and our Chief Financial Officer. The audit committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks, and reports to our Board of Directors regarding these activities.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the Board of Directors or compensation committee of any entity that has one or more executive officers serving on our Board of Directors or compensation committee.

Code of Business Conduct and Ethics

We maintain a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on our website at www.processapharmaceuticals.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website or in a Current Report on Form 8-K.

Involvement in Certain Legal Proceedings

To our knowledge, none of our current directors or executive officers has, during the past ten years:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding;
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he or she was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the SEC to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated; or
- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of any federal or state securities or commodities law or regulation or any law or regulation respecting financial institutions or insurance companies.

Except as set forth above and in our discussion below in "*Certain Relationships and Related Transactions*," none of our directors or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates or associates which are required to be disclosed pursuant to the rules and regulations of the SEC.

Item 11. Executive Compensation

Summary Compensation Table for 2024 and 2023

The following table sets forth the compensation awarded to or earned by our Chief Executive Officer and our two other highest paid executive officers for the years ended December 31, 2024 and 2023. George Ng joined as our CEO and a director on August 8, 2023. Up until that time, Dr. David Young served as our CEO. Dr. Young, who continues as a director, is now President, Research and Development to focus on drug development.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)[2]	Option Awards ($)	All Other Compensation ($)[3]	Total ($)
George Ng[1]	2024	400,000[5]	100,000[4]	-	-	21,033	521,033
Chief Executive Officer	2023	159,091	-	312,000	-	-	471,091
David Young	2024	290,940[6]	-	14,484	-	-	305,424
President, Research and Development and former Chief Executive Officer	2023	160,200	-	26,433	-	-	186,633
Sian Bigora	2024	290,940[7]	-	14,484	-	22,827	328,251
Chief Development and Regulatory Officer	2023	160,200	-	136,837	-	24,665	321,702

(1) Mr. Ng joined the Company on August 8, 2023.
(2) Reflects the aggregate grant date fair value of RSUs granted calculated in accordance with FASB ASC Topic 718. Assumptions applicable to these valuations and other information can be found in Note 3 of the Notes to Consolidated Financial Statements — Stock-Based Compensation contained in the Processa Pharmaceuticals, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 and Annual Report on Form 10-K for the year ended December 31, 2023.
(3) Amounts reflect the dollar value of group health insurance premiums for the named executive officer.
(4) $100,000 discretionary bonus received during the year ended December 31, 2024.
(5) Includes$16,259 of salary that was voluntarily deferred by the executive.
(6) Includes $181,733 of salary that was voluntarily deferred by the executive.
(7) Includes $11,664 of salary that was voluntarily deferred by the executive.

Narrative to the Summary Compensation Table

Overview of Our Executive Compensation Philosophy and Design

We believe that a skilled, experienced and dedicated executive and senior management team is essential to the future performance of our Company and to building stockholder value. We have sought to establish competitive compensation programs that enable us to attract and retain executive officers with these qualities. The other objectives of our compensation programs for our executive officers are the following:

- to motivate our executive officers to achieve strong financial performance;
- to attract and retain executive officers who we believe have the experience, temperament, talents and convictions to contribute significantly to our future success; and
- to align the economic interests of our executive officers with the interests of our stockholders.

Our executive compensation philosophy in 2023 and 2024 centered on providing the majority of each executive officers compensation in common stock. This allowed us to conserve our cash and utilize it in our clinical and other operating activities.

Setting Executive Compensation

Our compensation committee has primary responsibility for, among other things, determining our compensation philosophy, evaluating the performance of our named executive officers, setting the compensation and other benefits of our named executive officers and administering our equity compensation plan.

It is our CEO's responsibility to provide recommendations to the compensation committee for most compensation matters related to executive compensation. The recommendations are based on a general analysis of market standards and trends and an evaluation of the contribution of each executive officer to our performance. Our compensation committee considers, but retains the right to accept, reject or modify such recommendations and has the right to obtain independent compensation advice. Neither the CEO nor any other members of management is present during executive sessions of the compensation committee. The CEO is not present when decisions with respect to his compensation are made. Our Board of Directors appoints the members of our compensation committee and delegates to the compensation committee the direct responsibility for overseeing the design and administration of our executive compensation program.

We have not historically utilized a compensation consultant to set the compensation of our named executive officers.

Elements of Executive Compensation

We believe the most effective compensation package for our named executive officers is one designed to reward achievement of individual and corporate objectives; provide for short-, medium- and long-term financial and strategic goals; and align the interest of management with those of the stockholders by providing incentives for improving stockholder value. To accomplish that objective, our named executive officers have, and it is anticipated will continue to receive a significant portion of their annual compensation in the form of RSUs.

Base Compensation – We pay our named executive officers base compensation to compensate them for services rendered and to provide them with a steady source of income for living expenses throughout the year. In 2024, our named executive officers received base salaries ranging between $298,000 and $400,000, depending on their position and responsibilities. With the exception of Mr. Ng, our named executive officers received $290,940 in cash and the remainder was paid in salary shortfall RSUs that cliff vested on January 1, 2025. During 2024, the named executive officers voluntarily deferred a portion of their base salary for the benefit of the Company: Mr. Ng deferred $16,259, Dr. Young deferred $181,733 and Dr. Bigora deferred $11,644.

For 2023, with the exception of Mr. Ng, our named executive officers received base compensation ranging between $160,200 to $244,000, depending on their position and responsibilities. These two named executive officers received $160,200 in cash and with the remainder paid in salary shortfall RSUs that cliff vested on January 1, 2024.

Adjustments to base salaries are expected to be determined annually and may be increased based on the executive officer's success in meeting or exceeding individual objectives, as well as to maintain market competitiveness. Additionally, base salaries can be adjusted as warranted throughout the year to reflect promotions or other changes in the scope of breadth of an executive officer's role or responsibilities.

Bonuses – During 2024, Mr. Ng received $100,000 in bonus compensation for meeting the following conditions: (i) $50,000 was earned on February 2, 2024 when the Company's closing stock price was about $1.00 per share for at least ten consecutive trading days, thus regaining Nasdaq compliance; and (ii) $50,000 was earned on October 2, 2024 upon enrolling the first patient in the Phase 2 trial of NGC-Cap.

Equity Awards – In addition to the salary shortfall RSUs awarded to our named executive officer's for the difference between their base compensation and cash compensation paid, we have used equity awards to align the interest of our named executive officers with those of our stockholders, as the value of the awards granted thereunder is linked to the value of our common stock, which, in turn, is indirectly attributable to the performance of our executive officers.

We have traditionally made an annual equity grant to our employees, which include our named executive officers. In 2024, with the exception of Mr. Ng, we granted RSUs other than the salary shortfall RSUs for 6,466 shares of our common stock to our named executive officers totalling a grant date fair value of approximately $14,000, which vest accordingly: RSUs for 4,850 shares of our common stock vest over a three-year period upon meeting service requirements; RSUs for 808 shares of our common stock vested upon grant for regaining Nasdaq compliance; and RSUs for 808 shares of common stock vested upon dosing the first patient in our Phase 2 study in NGC-Cap, which occurred on October 2, 2024. In 2023, we granted RSUs other than the salary shortfall RSUs for 3,627 shares of our common stock to our named executive officers totalling a grant date fair value of $80,000, which vest over the subsequent three years from the grant date. Upon joining the Company, we granted Mr. Ng 40,000 RSUs, as described below, with a grant date fair value of $312,000.

We measure compensation expense for RSUs in accordance with ASC 718, *Compensation—Stock Compensation*. Stock-based compensation is measured at fair value on grant date and recognized as compensation expense over the requisite service period. For awards with only service-based vesting conditions, we record their fair value as compensation cost using the straight-line method over the service period. For awards that contain performance vesting conditions, we do not recognize the fair value of the awards as compensation expense until achieving the performance condition is considered probable.

Retirement and Other Benefits – We maintain a defined contribution employee retirement plan for our employees, including our named executive officers. The plan is intended to qualify as a tax-qualified 401(k) plan so that contributions to the 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan (except in the case of contributions under the 401(k) plan designated as Roth contributions). Under the 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee as directed by participants. The 401(k) plan provides us with the discretion to match employee contributions. We currently do not match employee contributions.

Employment Agreements

George Ng Employment Agreement. On March 19, 2025, we entered into an amended employment agreement with Mr. Ng that continues until terminated or modified pursuant to the terms of the employment agreement.

Mr. Ng's employment agreement entitled him to, among other benefits, the following compensation: (i) an annual base salary of at least $400,000, reviewed annually after December 31, 2024; (ii) RSUs previously granted under our 2019 Omnibus Incentive Plan along with additional grants made at the discretion of the Compensation Committee of the Board; and (iii) participation in welfare benefit plans, practices, policies and programs (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) made available to other executive officers of the Company.

Russell Skibsted Employment Agreement. On March 19, 2025, we entered into an amended employment agreement with Mr. Skibsted that continues until terminated or modified pursuant to the terms of the employment agreement.

Mr. Skibsted's employment agreement entitled him to, among other benefits, the following compensation: (i) an annual base salary of $400,000; (ii) a $50,000 base salary increase upon a cumulative (one or multiple) financing of at least $15 million that he leads and substantially participates in; (iii) RSUs previously granted under our 2019 Omnibus Incentive Plan along with additional grants made at the discretion of the Compensation Committee of the Board; and (iv) participation in welfare benefit plans, practices, policies and programs (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) made available to other executive officers of the Company. He is also eligible to participate in an executive bonus pool with a target bonus of 40% of his base compensation.

Sian Bigora Employment Agreement. On March 19, 2025, we entered into an employment agreement with Dr. Bigora that continues until terminated or modified pursuant to the terms of the employment agreement.

Dr. Bigora's employment agreement entitled her to, among other benefits, the following compensation: (i) an annual base salary of $387,920; (ii) RSUs previously granted under our 2019 Omnibus Incentive Plan along with additional grants made at the discretion of the Compensation Committee of the Board; and (iii) participation in welfare benefit plans, practices, policies and programs (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) made available to other executive officers of the Company. She is also eligible to participate in an executive bonus pool with a target bonus of 40% of her base compensation.

Wendy Guy Employment Agreement. On March 19, 2025, we entered into an employment agreement with Ms. Guy that continues until terminated or modified pursuant to the terms of the employment agreement.

Ms. Guy's employment agreement entitled her to, among other benefits, the following compensation: (i) an annual base salary of $325,520; (ii) RSUs previously granted under our 2019 Omnibus Incentive Plan along with additional grants made at the discretion of the Compensation Committee of the Board; and (iii) participation in welfare benefit plans, practices, policies and programs (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) made available to other executive officers of the Company. She is also eligible to participate in an executive bonus pool with a target bonus of 30% of her base compensation.

Patrick Lin Employment Agreement. On March 19, 2025, we entered into an employment agreement with Mr. Lin that continues until terminated or modified pursuant to the terms of the employment agreement.

Mr. Lin's employment agreement entitled her to, among other benefits, the following compensation: (i) an annual base salary of $325,520; (ii) RSUs previously granted under our 2019 Omnibus Incentive Plan along with additional grants made at the discretion of the Compensation Committee of the Board; and (iii) participation in welfare benefit plans, practices, policies and programs (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) made available to other executive officers of the Company. He is also eligible to participate in an executive bonus pool with a target bonus of 30% of his base compensation.

David Young Employment Agreement. On March 19, 2025, we entered into an employment agreement with Dr. Young that continues until terminated or modified pursuant to the terms of the employment agreement.

Dr. Young's employment agreement entitled her to, among other benefits, the following compensation: (i) an annual base salary of $387,920; (ii) RSUs previously granted under our 2019 Omnibus Incentive Plan along with additional grants made at the discretion of the Compensation Committee of the Board; and (iii) participation in welfare benefit plans, practices, policies and programs (including, without limitation, medical, prescription, dental, disability, employee life, group life, accidental death and travel accident insurance plans and programs) made available to other executive officers of the Company. He is also eligible to participate in an executive bonus pool with a target bonus of 40% of his base compensation.

Potential Payments Upon Termination or Change in Control

All executive employment agreements provide that either party may terminate the agreement at-will, and regardless of the manner in which such executive's service terminates, the executive is entitled to receive amounts earned during his or her term of service, including salary and other benefits. In addition, the agreement provides that in the event of the executive's termination for good reason or if Processa exercises its right to terminate the executive, the executive will be eligible to receive the following severance benefits: (i) an amount equal to one-year's annual base salary; (ii) 12 months of continued health coverage; and (iii) the vesting in full of all RSUs or other equity awards then outstanding and subject to time-based vesting.

The following definition is contained in the employment agreements:

- "termination for cause" means a termination of the executive's employment by Processa due to (i) refusal or inability of executive to perform or observe any of the material duties, responsibilities or obligations set forth in the employment agreement following the Company giving written notice that the specified conduct has occurred and the executive fails to cure the conduct within thirty (30) days after receipt of such notice; (ii) any act of the executive involving fraud, theft, misappropriation of funds, or embezzlement; (iii) the executive's commission of, or being charged with, a felony and/or convicted of any felony or misdemeanor involving dishonesty, violence or moral turpitude, or which in the reasonable judgment of the Company, reflects materially and adversely on the reputation of the Company; (iv) failure to comply with any of the Company's policies, including but not limited to by engaging in the illegal use of controlled substances, the knowing abuse of prescribed medications, or the misuse of alcohol; or (v) breach of fiduciary duty.

All severance benefits payable to the executive under the employment agreement are subject to the executive signing, not revoking and complying with a release of claims in favor of Processa.

Employee Non-Competition, Non-Solicitation, Invention and Non-Disclosure Agreements

Each of our named executive officers has entered into standard form agreements with respect to non-competition, non-solicitation, invention and non-disclosure. Under these agreements, each of our named executive officers has agreed not to compete with us during his or her employment and for a period of one year after the termination of his or her employment, not to solicit our employees, consultants, customers, business or prospective customers during his or her employment and for a period of one year after the termination of his or her employment, and to protect our confidential and proprietary information indefinitely. In addition, under these agreements, each named executive officer has agreed that we own all inventions that are developed by such named executive officer during his or her employment with us that (i) are related to our business or our customers or suppliers or any of our products or services being researched, developed, manufactured or sold by us or which may be used with such products or services; (ii) result from tasks assigned to the executive officer by us; or (iii) result from the use of our premises or personal property (whether tangible or intangible) owned, leased or contracted for by us.

Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan

We maintain an Omnibus Plan that currently provides us with the authority to issue up to 800,000 shares of our common stock to eligible participants. The two complementary goals of the Omnibus Plan are to attract and retain outstanding individuals to serve as our officers, directors, employees and consultants, and to increase stockholder value by providing participants incentives to increase stockholder value by offering the opportunity to acquire shares of our common stock, receive monetary payments based on the value of our common stock and receive other incentive compensation on the potentially favorable terms that the Plan provides. The following is a summary of the material provisions of the Omnibus Plan:

Administration. The Omnibus Plan is administered by our Board of Directors, the compensation committee of the Board of Directors, any other committee of the Board, any subcommittee of the compensation committee or one or more of our officers to whom the Board or compensation committee has delegated authority, which are collectively referred to as the "Administrator." The Administrator has the authority to interpret the Omnibus Plan or award agreements entered into with respect to the Omnibus Plan; make, change, and rescind rules and regulations relating to the Omnibus Plan; make changes to, or reconcile any inconsistency in, the Omnibus Plan or any award or agreement covering an award; and take any other action needed to administer the Omnibus Plan.

Eligibility; Participant Award Limits. The Administrator may designate any of the following as a participant under the Omnibus Plan: any officer or employee, or individuals engaged to become an officer or employee, of our company or our affiliates; consultants of our company or our affiliates; and our directors, including our non-employee directors.

Types of Awards. The Omnibus Plan permits the Administrator to grant stock options, stock appreciation rights (SARs), performance units, shares of common stock, restricted stock, restricted stock units, cash incentive awards, dividend equivalent units, or any other type of award permitted under the Omnibus Plan. The Administrator may grant any type of award to any participant it selects, but only our employees or our subsidiaries' employees may receive grants of incentive stock options within the meaning of Section 422 of the Code. Awards may be granted alone or in addition to, in tandem with, or (subject to the repricing prohibition described below) in substitution for any other award (or any other award granted under another plan of our company or any affiliate, including the plan of an acquired entity).

Shares Reserved under the Omnibus Plan. We have reserved an aggregate of 800,000 shares of our common stock available for issuance under the Omnibus Plan. We may issue all reserved shares pursuant to the exercise of incentive stock options. The number of shares reserved for issuance under the Omnibus Plan will be reduced on the date of the grant of any award by the maximum number of shares, if any, that may become payable with respect to which such award is granted. However, an award that may be settled solely in cash will not deplete the Omnibus Plan's share reserve at the time the award is granted. If (a) an award lapses, expires, is canceled, or terminates without issuance of shares or is settled in cash, (b) the Administrator determines that the shares granted under an award will not be issuable because the conditions for issuance will not be satisfied, (c) shares are forfeited under an award, or (d) shares are issued under any award and we reacquire them pursuant to our reserved rights upon the issuance of the shares, then those shares are added back to the reserve and may again be used for new awards under the Omnibus Plan. Shares that are tendered or withheld in payment of the exercise price of a stock option or as a result of the net settlement of an outstanding SAR, shares we purchase using proceeds from stock option exercises and shares tendered or withheld to satisfy any federal, state, or local tax withholding obligations may not be made available for re-issuance under the Omnibus Plan.

Transferability. Awards are not transferable other than by will or the laws of descent and distribution, unless the Administrator allows a participant to (i) designate in writing a beneficiary to exercise the award or receive payment under the award after the participant's death, (ii) transfer an award to a former spouse as required by a domestic relations order incident to a divorce, or (iii) otherwise transfer an award without receiving any consideration.

Adjustments. If (i) we are involved in a merger or other transaction in which our shares of common stock are changed or exchanged; (ii) we subdivide or combine shares of common stock or declare a dividend payable in shares of common stock, other securities, or other property (other than stock purchase rights issued pursuant to a stockholder rights agreement); (iii) we effect a cash dividend that exceeds 10% of the fair market value of a share of common stock or any other dividend or distribution in the form of cash or a repurchase of shares of common stock that our Board determines is special or extraordinary, or that is in connection with a recapitalization or reorganization; or (iv) any other event occurs that in the Administrator's judgment requires an adjustment to prevent dilution or enlargement of the benefits intended to be made available under the Omnibus Plan, then the Administrator will, in a manner it deems equitable, adjust any or all of (A) the number and type of shares subject to the Omnibus Plan and which may, after the event, be made the subject of awards; (B) the number and type of shares of common stock subject to outstanding awards; (C) the grant, purchase, or exercise price with respect to any award; and (D) the performance goals of an award.

In any such case, the Administrator may also provide for a cash payment to the holder of an outstanding award in exchange for the cancellation of all or a portion of the award, subject to the terms of the Omnibus Plan.

The Administrator may, in connection with any merger, consolidation, acquisition of property or stock, or reorganization, authorize the issuance or assumption of awards upon terms and conditions we deem appropriate without affecting the number of shares of common stock otherwise reserved or available under the Omnibus Plan.

Change of Control. To the extent a participant has an employment, retention, change of control, severance, or similar agreement with us or any of our affiliates that discusses the effect of a change of control (as defined in the Omnibus Plan) on the participant's awards, such agreement will control. Otherwise, unless otherwise provided in an award agreement or by the Administrator prior to the change of control, in the event of a change of control, if the purchaser, successor or surviving entity (or parent thereof) (the "Successor") agrees, then some or all outstanding awards will be assumed or replaced with the same type of award with similar terms and conditions. If applicable, each award that is assumed must be appropriately adjusted, immediately after such change of control, to apply to the number and class of securities that would have been issuable to a participant upon the consummation of such change of control had the award been exercised, vested, or earned immediately prior to such change of control, and other appropriate adjustment to the terms and conditions of the award may be made.

If a participant is terminated from employment without cause (as defined in the Omnibus Plan) or the participant resigns employment for good reason (as defined in the Omnibus Plan) within 24 months following the change of control, then upon such termination, all of the participant's awards in effect on the date of such termination will vest in full or be deemed earned in full.

Term of Omnibus Plan. Unless earlier terminated by our Board of Directors, the Omnibus Plan will remain in effect until the date all shares reserved for issuance have been issued, except that no incentive stock options may be issued if the term of the Omnibus Plan extends beyond 10 years from the effective date without stockholder approval of such extension.

Outstanding Equity Awards at Fiscal Year-End

The following table lists the outstanding equity awards held by each of our named executive officers as of December 31, 2024:

		Stock Option Awards			Restricted Stock Units	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Number of Shares of Stock (#) Not Vested[1]	Market Value of Shares Not Vested ($)[2]
George Ng	08/08/23	-	-	-	31,109	27,500
David Young	06/28/24(3)	-	-	-	3,233	2,858
	06/28/24(3)	-	-	-	2,425	2,144
	01/01/23(4)	-	-	-	801	708
	07/01/21(5)	-	-	-	215	190
Sian Bigora	06/28/24(3)	-	-	-	3,233	2,858
	06/28/24(3)	-	-	-	2,425	2,144
	01/01/23(4)	-	-	-	1,616	1,429
	07/01/21(5)	-	-	-	215	190

(1) Not included in the above table are RSUs representing 47,844 shares of our common stock that have vested but have not met the distribution requirements as of December 31, 2024.

(2) Market value is based on $0.88 per share, which was the closing market price of our common stock on December 31, 2024, the last trading day of the year.

(3) Stock awards in the form of RSUs for 6,466 shares of our common stock granted to each of Dr. Young and Dr. Bigora on June 28, 2024 contained either service or performance vesting conditions and must meet distribution requirements before any shares of common stock will be issued. These stock awards had the following vesting conditions: (i) RSUs representing 3,233 shares of our common stock vest on January 1, 2025; (ii) RSUs representing 2,425 shares of our common stock vest one-third on January 1, 2025, and the remaining vest monthly afterward; (iii) RSUs representing 404 shares of our common stock vested upon grant for regaining Nasdaq's minimum price requirement; and (iv) RSUs representing 404 shares of our common stock vested when we dosed the first patient in the Phase 2 trial of NGC-Cap, which occurred on October 2, 2024.

(4) On January 1, 2023, stock awards in the form of RSUs were granted to Dr. Young and Dr. Bigora. One-third of these stock awards vested on January 1, 2024 and the remaining vest annually on January 1, 2025 and 2026.

(5) Stock awards in the form of RSUs for 215 shares of our common stock granted to each of Dr. Young and Dr. Bigora on July 1, 2021 vest when we cumulatively raise at least $30 million.

Director Compensation

On September 3, 2024, our compensation committee recommended, and our Board of Directors approved, an amendment to our compensation plan for non-employee directors effective July 1, 2024. Each non-employee director will receive annual compensation for serving as a director totaling $100,000, consisting of an annual cash retainer of $56,000, payable in quarterly installments and an annual RSU award representing 31,206 shares of our common stock equal to $44,000 total value, which was based on the closing price of our common stock on the date of award. These RSUs vest on the earlier of June 28, 2025 or the date of our 2025 annual meeting.

Our directors are also reimbursed for any reasonable out-of-pocket expenses incurred in connection with service as a director.

The table below shows all compensation paid or earned to our non-employee directors during the year ended December 31, 2024.

Name	Fees Earned or Paid in	Stock Awards($)[1]	Total ($)

	Cash ($)		
Khoso Baluch	49,000	44,000	93,000
Jim Neal	49,000	44,000	93,000
Geraldine Pannu	49,000	44,000	93,000
Justin Yorke	49,000	44,000	93,000

(1) Reflects the aggregate grant date fair value of RSUs granted in 2024 calculated in accordance with FASB ASC Topic 718.

Outstanding Equity Awards at Fiscal Year-End

The following table lists the outstanding equity awards held by each of our directors as of December 31, 2024:

		Stock Option Awards			Restricted Stock Units	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Number of Shares of Stock (#) Not Vested[1]	Market Value of Shares Not Vested ($) [2]
Khoso Baluch	09/03/24[3]	-	-	-	31,206	27,586
James Neal	09/03/24[3]	-	-	-	31,206	27,586
Geraldine Pannu	09/03/24[3]	-	-	-	31,206	27,586
Justin Yorke	09/03/24[3]	-	-	-	31,206	27,586

(1) Not included in the above table for each of our non-employee directors are RSUs representing 5,069 shares of our common stock that have vested but have not met the distribution requirements as of December 31, 2024.

(2) Market value is based on $0.88 per share, which was the closing market price of our common stock on December 31, 2024, the last trading day of the year.

(3) On September 3, 2024, RSU awards were granted to each director. These RSU awards vest on the earlier of June 28, 2025 or the next annual shareholder meeting. These RSUs also have distribution requirements, such that they will be distributed on the earlier of: the end of their appointment or reappointment as a director; the third anniversary of the grant date; a change of control; or their death.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

BENEFICIAL OWNERSHIP OF COMMON STOCK

The following table sets forth certain information with respect to the beneficial ownership of our common stock at March 12, 2025 for:

- Each of our directors;
- Each of our named executive officers;
- All of our current directors and executive officers as a group; and
- Each person, or group of affiliated persons, who beneficially owned more than 5% of our common stock.

The number of shares of our common stock beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of March 12, 2025, through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The percentage of shares beneficially owned is computed on the basis of 5,269,240 shares of our common stock outstanding as of March 12, 2025. Shares of our common stock that a person has the right to acquire within 60 days of March 12, 2025, are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group.

	Shares beneficially owned	
	Shares	Percent
Name and address of beneficial owner [1]		
Officers and Directors		
Sian Bigora [2]	54,141	1.0%
Wendy Guy [3]	43,086	*%
Patrick Lin [4]	160,703	3.0%
George Ng [5]	259,671	4.8%
Russell Skibsted	-	*
David Young [6]	475,666	8.7%
Khoso Baluch [7]	6,467	*
James Neal [8]	5,790	*
Geraldine Pannu [9]	7,951	*
Justin Yorke [10]	71,038	1.3%
Total for all Officers and Directors	1,084,513	18.7%

* represents less than 1%

(1) Unless otherwise indicated, the address for each beneficial owner listed is c/o Processa Pharmaceuticals, Inc., 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076.

(2) Consists of (i) 21,878 shares of common stock held directly by Dr. Bigora; (ii) 6,668 shares held by CorLyst; and (iii) restricted stock units representing 25,595 shares of common stock issuable within 60 days of March 12, 2025.

(3) Consists of (i) 11,857 shares of common stock held directly by Ms. Guy; (ii) 8,335 shares held by CorLyst; and (iii) restricted stock units representing 22,894 shares of common stock issuable within 60 days of March 12, 2025.

(4) Consists of (i) 29,059 shares of common stock held directly by Mr. Lin; (ii) 43,500 shares and warrants to purchase 65,250 shares of common stock held by Lin Family Trust Feb 4, 2024, of which Mr. Lin is a trustee and has investment and disposition power over the shares and warrants; and (iii) restricted stock units representing 22,894 shares of common stock issuable within 60 days of March 12, 2025.

(5) Consists of (i) 20,000 shares of common stock held by Ng Cha Family Trust, of which Mr. Ng is a trustee and has investment and disposition power over the shares of common stock; (ii) 87,200 shares of common stock and warrants to purchase 130,800 shares of common stock held by George Ng IRRA FOB George Ng, of which Mr. Ng is a beneficiary and has investment and disposition power over the shares and warrants; and (iii) restricted stock units representing 21,671 shares of common stock issuable within 60 days of March 12, 2025.

(6) Consists of (i) 205,405 shares of common stock held directly by Dr. Young; (ii) warrants to purchase 186,750 shares of common stock; (iii) 18,851 shares held by family entities; (iv) 41,464 shares held by CorLyst, LLC ("CorLyst") (22,920 shares held on behalf of entities controlled by Dr. Young and 18,544 shares held on behalf of other stockholders); and (v) restricted stock units for 23,196 shares of our common stock issuable within 60 days of March 12, 2025. Dr. Young is the Chief Executive Officer and Managing Member of CorLyst. Dr. Young disclaims beneficial ownership of a portion of CorLyst shares.

(7) Consists of (i) 1,398 shares of common stock held directly by Mr. Baluch and (ii) restricted stock units representing 5,069 shares of common stock issuable within 60 days of March 12, 2025.

(8) Consists of (i) 721 shares of common stock held directly by Mr. Neal and (ii) restricted stock units representing 5,069 shares of common stock issuable within 60 days of March 12, 2025.

(9) Consists of (i) 2,882 shares of common stock held directly by Ms. Pannu and (ii) restricted stock units representing 5,069 shares of common stock issuable within 60 days of March 12, 2025.

(10) Justin Yorke is a manager of the Richland Fund, LLC. The shares of common stock reported for Mr. Yorke include (i) 3,737 shares of common stock held directly by Mr. Yorke; (ii) 12,400 shares and warrants to purchase 18,600 shares of common stock held by Directed Trust Company FBO Justin Yorke IRA, of which Mr. Yorke is a beneficiary and has investment and disposition power over the shares and warrants; (iii) restricted stock units representing 5,069 shares of common stock issuable within 60 days of March 12, 2025; and (iv) the shares held by the Richland Fund, LLC which total 31,232 shares.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers, directors, and persons who beneficially own more than ten percent of our common stock to file reports of their beneficial ownership and changes in ownership (Forms 3, 4, and 5, and any amendment thereto) with the SEC.

Based solely on our review of the copies of such forms furnished to us and written representations from the directors and executive officers, we believe that all Section 16(a) filing requirements were timely met in fiscal year 2024, except three late Forms 4 were filed on April 12, 2024 and August 2, 2024 for each of Sian Bigora, Wendy Guy, Patrick Lin, and David Young.

Item 13. Certain Relationships and Related Transactions

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Related Person Policy

The audit committee has adopted written policies and procedures for the committee to review and approve, or ratify related party transactions. These transactions include:

- transactions that must be disclosed in proxy statements under SEC rules, and
- transactions that potentially could cause a non-employee director to cease to qualify as an independent director under Nasdaq Stock Market listing requirements.

Transactions that are deemed immaterial under applicable disclosure requirements are generally deemed pre-approved under these written policies and procedures, including transactions with an entity with which a director's sole relationship is as a non-employee director and the total amount involved does not exceed 1% of the entity's total annual revenues.

Criteria for committee approval or ratification of a related party transaction, in addition to factors that the committee otherwise deems appropriate under the circumstances, include:

- whether terms of the transaction are no less favorable than terms generally available from an unaffiliated third party, and
- in the case of a non-employee director, whether the transaction would disqualify the director from (1) being independent under Nasdaq Stock Market listing requirements, or (2) from serving on the audit committee, compensation committee or nominating and governance committee under Nasdaq Stock Market and other regulatory requirements.

With the exception of the transactions set forth below, we were not a party to any transaction (in which the amount involved exceeded the lesser of $120,000 or one percent of the average of our assets for the last two fiscal years) in which a director, executive officer, holder of more than five percent of our common stock, or any member of the immediate family of any such person has or will have a direct or indirect material interest and no such transactions are currently proposed.

CorLyst, LLC

CorLyst, LLC ("CorLyst") reimburses us for shared costs related to payroll, health insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses in our consolidated statement of operations. We recorded approximately $110,000 and $112,000 in reimbursements during the years ended December 31, 2024 and 2023, respectively. At December 31, 2024, $47 was due from CorLyst and no amounts were due at December 31, 2023. Our President, Research and Development is the CEO of CorLyst, and CorLyst is a shareholder. Dr. Young spends a nominal amount of effort related to CorLyst activities. As of March 12, 2025, CorLyst beneficially owns 56,467 shares of our common stock.

Item 14. Principal Accounting Fees and Services

Audit and Non-Audit Fees Billed to the Company by Independent Registered Public Accounting Firm

The following table sets forth the aggregate fees billed to Processa for the years ended December 31, 2024 and 2023 by Cherry Bekaert, LLP, our auditors as of October 31, 2024; and BD & Company, Inc., our auditors from January 1, 2023 to October 31, 2024:

Service Type	2024	2023
Audit Fees	$ 128,750 (1)	$ 94,000
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	42,461	1,657
Total	$ 171,211	$ 95,657

Audit Fees. These fees were for professional services rendered for 2024 and 2023 in connection with the audit of our annual financial statements on Form 10-K and review of the financial statements included in our Quarterly Reports on Form 10-Q. The amounts also include fees for services that are normally provided by Cherry Bekaert, LLP and BD & Company, Inc. in connection with statutory and regulatory filings and engagements for the years identified.

All Other Fees. These fees were primarily for services related to our Registration Statements and related comfort letters in 2024 and 2023.

(1) Audit fees incurred in 2024 were billed accordingly: $39,500 by BD & Company, Inc. and $89,250 by Cherry Bekaert, LLP.

Audit Committee Policies and Procedures for Pre-Approval of Independent Auditor Services

The following describes the Audit Committee's policies and procedures regarding pre-approval of the engagement of the Company's independent auditor to perform audit as well as permissible non-audit services for the Company.

For audit services and audit-related fees, the independent auditor will provide the Committee with an engagement letter during the first quarter of each year outlining the scope of the audit services proposed to be performed in connection with the audit of the current fiscal year. If agreed to by the Committee, the engagement letter will be formally accepted by the Committee at an Audit Committee meeting held as soon as practicable following receipt of the engagement letter. The independent auditor will submit to the Committee for approval an audit services fee proposal after acceptance of the engagement letter.

For non-audit services and other fees, Company management may submit to the Committee for approval (during May through September of each fiscal year) the list of non-audit services that it recommends the Committee engage the independent auditor to provide for the fiscal year. The list of services must be detailed as to the particular service and may not call for broad categorical approvals. Company management and the independent auditor will each confirm to the Audit Committee that each non-audit service on the list is permissible under all applicable legal requirements. In addition to the list of planned non-audit services, a budget estimating non-audit service spending for the fiscal year may be provided. The Committee will consider for approval both the list of permissible non-audit services and the budget for such services. The Committee will be informed routinely as to the non-audit services actually provided by the independent auditor pursuant to this pre-approval process.

To ensure prompt handling of unexpected matters, the Audit Committee delegates to its Chairman the authority to amend or modify the list of approved permissible non-audit services and fees. The Chairman will report any action taken pursuant to this delegation to the Committee at its next meeting.

All audit and non-audit services provided to the Company are required to be pre-approved by the Committee.

Part IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) and (2) Financial Statements and Schedules:

See Part II, Item 8, of this Annual Report on Form 10-K.

(3) Exhibits

Exhibit Number	Description of the Exhibit
1.1	Sales Agreement, dated May 21, 2024, by and among Processa Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 1.2 to Form S-3 filed on May 21, 2024)
3.1	Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1 to Form S-1 filed on September 17, 2020)
3.1.1	Amendment to Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1.1 to Form S-1 filed on September 17, 2020)
3.1.2	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation dated August 8, 2019 (incorporated by reference to Exhibit 3 to Form 10-Q filed on August 14, 2019)
3.1.3	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. dated June 25, 2020 (incorporated by reference to Exhibit 3.1.4 to Form S-1 filed on September 17, 2020)
3.1.4	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation dated January 1, 2022 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 6, 2022)
3.1.5	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 29, 2023)
3.1.6	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 18, 2024)
3.2*	Amended and Restated Bylaws of Processa Pharmaceuticals, Inc., dated March 18, 2025
4.1	Specimen of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form S-1 filed on September 17, 2020)
4.2	Form of Series A Common Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed January 30, 2025)
4.3	Form of Series B Common Warrant (incorporated by reference to Exhibit 4.2 to Form 8-K filed January 30, 2025)
4.4	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.3 to Form 8-K filed January 30, 2025)
4.5	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.5 to Form 10-K filed March 29, 2024)
10.1+	Amended and Restated 2011 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Form S-1 filed on September 17, 2020)
10.2	License Option Agreement with CoNCERT (incorporated by reference to Exhibit 10.2 to Form S-1 filed on September 17, 2020)
10.3	Amendment to License Agreement and Securities Purchase Agreement with CoNCERT Pharmaceuticals (incorporated by reference to Exhibit 10.3 to Form S-1 filed on September 17, 2020)
10.4+	Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.5 to Form S-1 filed on September 17, 2020)
10.5+	Amended and Restated Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 4.1 to From S-8 filed on July 22, 2024).
10.6	License Agreement with Aposense, Ltd. dated May 24, 2020 (incorporated by reference to Exhibit 10.9 to Form S-1 filed on September 17, 2020)
10.7	License Agreement with Yuhan Corporation (incorporated by reference to Exhibit 10.11 to Form S-1 filed on September 17, 2020)
10.8	License Agreement with Elion Oncology, Inc. (incorporated by reference to Exhibit 10.13 to Form S-1 filed on September 17, 2020)
10.9	Addendum No. 1 to the Aposense Ltd. License Agreement (incorporated by reference to Exhibit 10.15 to Form 10-K filed on March 25, 2021)
10.10	License Agreement with Ocuphire Pharma, Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed June 17, 2021)
10.11*+	Employment Agreement dated March 19, 2025 by and between George Ng and Processa Pharmaceuticals, Inc.
10.12*+	Employment Agreement dated March 19, 2025, by and between Russell Skibsted and Processa Pharmaceuticals, Inc.
10.13*+	Employment Agreement dated March 19, 2025, by and between Sian Bigora and Processa Pharmaceuticals, Inc.
10.14*+	Employment Agreement dated March 19, 2025, by and between Wendy Guy and Processa Pharmaceuticals, Inc.
10.15*+	Employment Agreement dated March 19, 2025, by and between Patrick Lin and Processa Pharmaceuticals, Inc.
10.16*+	Employment Agreement dated March 19, 2025, by and between David Young and Processa Pharmaceuticals, Inc.
10.17	Form of Securities Purchase Agreement, dated January 27, 2025, by and between Processa Pharmaceuticals, Inc. and each of the Purchasers (as defined therein) (incorporated by reference to Exhibit 10.1 to Form 8-K filed January 30, 2025)
10.18	Placement Agency Agreement, dated January 27, 2025, by and between Processa Pharmaceueticals, Inc. and A.G.P. (incorporated by reference to Exhibit 10.2 to Form 8-K filed January 30, 2025)
19*	Insider Trading Policy
21.1*	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm, BD & Co. Inc.
23.2*	Consent of Independent Registered Public Accounting Firm, Cherry Bekaert, LLP
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Processa Pharmaceuticals, Inc. Restatement Clawback Policy (incorporated by reference to Exhibit 97.1 to Form 10-K filed on March 29, 2024)
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

\+ Indicates a management contract or compensatory plan or arrangement.
* Filed herewith

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

PROCESSA PHARMACEUTICALS, INC.

By: */s/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Dated: March 20, 2025

By: */s/ Russell Skibsted*
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: March 20, 2025

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

Name	Capacity	Date
/s/ George Ng George Ng	Chief Executive Officer	March 20, 2025
/s/ Russell Skibsted Russell Skibsted	Chief Financial Officer	March 20, 2025
/s/ David Young David Young	President of Research and Development and Director	March 20, 2025
/s/ Khoso Baluch Khoso Baluch	Director	March 20, 2025
/s/ James Neal James Neal	Director	March 20, 2025
/s/ Geraldine Pannu Geraldine Pannu	Director	March 20, 2025
/s/ Justin Yorke Justin Yorke	Director	March 20, 2025

Exhibit 3.2

AMENDED AND RESTATED
BYLAWS
OF
PROCESSA PHARMACEUTICALS, INC.
(THE "CORPORATION")

ARTICLE I
OFFICES

Section 1.1. Registered Office. The registered office of Processa Pharmaceuticals, Inc. (the "***Corporation***") within the State of Delaware shall be located at either (a) the principal place of business of the Corporation in the State of Delaware or (b) the office of the Corporation or individual acting as the Corporation's registered agent in Delaware.

Section 1.2. Additional Offices. The Corporation may, in addition to its registered office in the State of Delaware, have such other offices and places of business, both within and outside the State of Delaware, as the Board of Directors of the Corporation (the "***Board***") may from time to time determine or as the business and affairs of the Corporation may require.

ARTICLE II
STOCKHOLDERS MEETINGS

Section 2.1. Annual Meetings. The annual meeting of stockholders shall be held at such place, either within or without the State of Delaware, and time and on such date as shall be determined by the Board and stated in the notice of the meeting, provided that the Board may in its sole discretion determine that the meeting shall not be held at any place, but may instead be held solely by means of remote communication pursuant to Section 9.5(a). At each annual meeting, the stockholders entitled to vote on such matters shall elect those directors of the Corporation to fill any term of a directorship that expires on the date of such annual meeting and may transact any other business as may properly be brought before the meeting in accordance with these Bylaws.

Section 2.2. Special Meetings. Subject to the rights of the holders of any outstanding series of the preferred stock of the Corporation ("***Preferred Stock***"), and to the requirements of applicable law, special meetings of stockholders, for any purpose or purposes, may be called only by the Chair of the Board, Chief Executive Officer, or the Board pursuant to a resolution adopted by a majority of the Board, and may not be called by any other person. Special meetings of stockholders shall be held at such place, either within or without the State of Delaware, and at such time and on such date as shall be determined by the Board and stated in the Corporation's notice of the meeting, provided that the Board may in its sole discretion determine that the meeting shall not be held at any place, but may instead be held solely by means of remote communication pursuant to Section 9.5(a).

Section 2.3. Notices. Notice of each stockholders meeting stating the place, if any, date, and time of the meeting, and the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting and the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, shall be given in the manner permitted by Section 9.3 to each stockholder entitled to vote thereat as of the record date for determining the stockholders entitled to notice of the meeting, by the Corporation not less than 10 nor more than 60 days before the date of the meeting unless otherwise required by the General Corporation Law of the State of Delaware (the "***DGCL***"). If said notice is for a stockholder meeting other than an annual meeting, it shall in addition state the purpose or purposes for which the meeting is called, and the business transacted at such meeting shall be limited to the matters so stated in the Corporation's notice of meeting (or any supplement thereto). Notices of meetings to stockholders may be given by mailing the same, addressed to the stockholder entitled thereto, at such stockholder's mailing address as it appears on the records of the Corporation and such notice shall be deemed to be given when deposited in the U.S. mail, postage prepaid. Without limiting the manner by which notices of meetings otherwise may be given effectively to stockholders, any such notice may be given by electronic transmission in accordance with applicable law. Notice of any meeting need not be given to any stockholder who shall, either before or after the meeting, submit a waiver of notice or who shall attend such meeting, except when the stockholder attends for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of the meeting shall be bound by the proceedings of the meeting in all respects as if due notice thereof had been given. Any meeting of stockholders as to which notice has been given may be postponed, and any meeting of stockholders as to which notice has been given may be cancelled, by the Board upon Public Disclosure (as defined in Section 2.7(a)(ii)) given before the date previously scheduled for such meeting.

Section 2.4. Quorum. Except as otherwise provided by applicable law, the Corporation's Certificate of Incorporation, as the same may be amended or restated from time to time (the "***Certificate of Incorporation***") or these Bylaws, the presence, in person or by proxy, at a stockholders meeting of the holders of shares of outstanding capital stock of the Corporation representing one third (1/3) of the voting power of all outstanding shares of capital stock of the Corporation entitled to vote at such meeting shall constitute a quorum for the transaction of business at such meeting, except that when specified business is to be voted on by a class or series of stock voting as a class, the holders of shares representing one third (1/3) of the voting power of the outstanding shares of such class or series shall constitute a quorum of such class or series for the transaction of such business. If a quorum shall not be present or represented by proxy at any meeting of the stockholders of the Corporation, the chair of the meeting may adjourn the meeting from time to time in the manner provided in Section 2.6 until a quorum shall attend. The stockholders present at a duly convened meeting may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum.

Section 2.5. Voting of Shares.

(a) Voting Lists. The Secretary of the Corporation (the "***Secretary***") shall prepare, or shall cause the officer or agent who has charge of the stock ledger of the Corporation to prepare and make, at least 10 days before every meeting of stockholders, a complete list of the stockholders of record entitled to vote at such meeting; provided, however, that if the record date for determining the stockholders entitled to vote is less than 10 days before the meeting date, the list shall reflect the stockholders entitled to vote as of the 10th day before the meeting date, arranged in alphabetical order and showing the address and the number and class of shares registered in the name of each stockholder. Nothing contained in this Section 2.5(a) shall require the Corporation to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least 10 days prior to the meeting: (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the principal place of business of the Corporation. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. Except as provided by applicable law, the stock ledger shall be the only evidence as to who are the stockholders entitled to examine the list required by this Section 2.5(a) or to vote in person or by proxy at any meeting of stockholders.

(b) Manner of Voting. At any stockholders meeting, every stockholder entitled to vote may vote in person or by proxy. If authorized by the Board, the voting by stockholders or proxy holders at any meeting conducted by remote communication may be effected by a ballot submitted by electronic transmission (as defined in Section 9.3(c)), provided that any such electronic transmission must either set forth or be submitted with information from which the Corporation can determine that the electronic transmission was authorized by the stockholder or proxy holder. The Board, in its discretion, or the chair of the meeting of stockholders, in such person's discretion, may require that any votes cast at such meeting shall be cast by written ballot.

(c) Proxies. Each stockholder entitled to vote at a meeting of stockholders or to express consent or dissent to corporate action in writing without a meeting may authorize another person or persons to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. Proxies need not be filed with the Secretary until the meeting is called to order, but shall be filed with the Secretary before being voted or the delivery of a consent action in writing to the Corporation pursuant to Section 2.9. Without limiting the manner in which a stockholder may authorize another person or persons to act for such stockholder as proxy, either of the following shall constitute a valid means by which a stockholder may grant such authority. No stockholder shall have cumulative voting rights.

(i) A stockholder may execute a writing authorizing another person or persons to act for such stockholder as proxy. Execution may be accomplished by the stockholder or such stockholder's authorized officer, director, employee or agent signing such writing or causing such person's signature to be affixed to such writing by any reasonable means, including, but not limited to, by facsimile signature.

(ii) A stockholder may authorize another person or persons to act for such stockholder as proxy by transmitting or authorizing the transmission of an electronic transmission to the person who will be the holder of the proxy or to a proxy solicitation firm, proxy support service organization or like agent duly authorized by the person who will be the holder of the proxy to receive such transmission, provided that any such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the stockholder. Any copy, facsimile telecommunication or other reliable reproduction of the writing or transmission authorizing another person or persons to act as proxy for a stockholder may be substituted or used in lieu of the original writing or transmission for any and all purposes for which the original writing or transmission could be used; provided that such copy, facsimile telecommunication or other reproduction shall be a complete reproduction of the entire original writing or transmission.

(d) Required Vote. Subject to the rights of the holders of one or more series of Preferred Stock, voting separately by class or series, to elect directors pursuant to the terms of one or more series of Preferred Stock, at all meetings of stockholders at which a quorum is present, the election of directors shall be determined by a plurality of the votes cast by the stockholders present in person or represented by proxy at the meeting and entitled to vote thereon. All other matters presented to the stockholders at a meeting at which a quorum is present shall be determined by the vote of a majority of the votes cast by the stockholders present in person or represented by proxy at the meeting and entitled to vote thereon, unless the matter is one upon which, by applicable law, the Certificate of Incorporation, these Bylaws or applicable stock exchange rules, a different vote is required, in which case such provision shall govern and control the decision of such matter.

(e) Inspectors of Election. In advance of any meeting of the stockholders, the Board shall appoint one or more inspectors, who may be employees of the Corporation, to act at the meeting or any adjournment thereof and to make a written report thereof. The Board may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his or her ability. The inspector or inspectors may appoint or retain other persons or entities to assist the inspector or inspectors in the performance of their duties. In determining the validity and counting of proxies and ballots cast at any meeting of stockholders, the inspector or inspectors may consider such information as is permitted by applicable law. No person who is a candidate for office at an election may serve as an inspector at such election. When executing the duties of inspector, the inspector or inspectors shall: (i) ascertain the number of shares outstanding and the voting power of each; (ii) determine the shares represented at the meeting and the validity of proxies and ballots; (iii) count all votes and ballots; (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors; and (v) certify their determination of the number of shares represented at the meeting and their count of all votes and ballots.

Section 2.6. Adjournments. Any meeting of stockholders, annual or special, may be adjourned by the chair of the meeting, from time to time, whether or not there is a quorum, to reconvene at the same or some other place, if any. Notice need not be given of any such adjourned meeting if the date, time, and place, if any, thereof, and the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are (i) announced at the meeting at which the adjournment is taken, (ii) displayed, during the time scheduled for the meeting, on the same electronic network used to enable stockholders and proxy holders to participate in the meeting by means of remote communication, or (iii) set forth in the notice of meeting given in accordance with Section 2.3. At the adjourned meeting, the stockholders, or the holders of any class or series of stock entitled to vote separately as a class, as the case may be, may transact any business that might have been transacted at the original meeting. If the adjournment is for more than 30 days, notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board shall fix a new record date for notice of such adjourned meeting in accordance with Section 9.2, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

Section 2.7. Advance Notice of Stockholder Nominations and Proposals.

(a) Annual Meetings of Stockholders.

(i) At a meeting of the stockholders, only such nominations of persons for the election of directors and such other business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, nominations or such other business must be: (A) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board or any committee thereof; (B) otherwise properly brought before the meeting by or at the direction of the Board or any committee thereof; or (C) otherwise properly brought before an annual meeting by a stockholder who is a stockholder of record of the Corporation at the time such notice of meeting is delivered, who is entitled to vote at the meeting, and who complies with the notice procedures set forth in this Section 2.7.

(ii) In addition, any proposal of business (other than the nomination of persons for election to the Board) must be a proper matter for stockholder action. For business (including, but not limited to, director nominations) to be properly brought before an annual meeting by a stockholder pursuant to Section 2.7(a)(i)(D), the stockholder or stockholders of record intending to propose the business (the "***Proposing Stockholder***") must have given timely notice thereof pursuant to this Section 2.7(a), in writing to the Secretary even if such matter is already the subject of any notice to the stockholders or Public Disclosure from the Board. To be timely, a Proposing Stockholder's notice for an annual meeting must be delivered to the Secretary at the principal executive offices of the Corporation: (x) not later than the close of business on the 90th day, nor earlier than the close of business on the 120th day, in advance of the anniversary of the previous year's annual meeting if such meeting is to be held on a day which is not more than 30 days in advance of the anniversary of the previous year's annual meeting or not later than 60 days after the anniversary of the previous year's annual meeting; and (y) with respect to any other annual meeting of stockholders, including in the event that no annual meeting was held in the previous year, not earlier than the close of business on the 120th day prior to the annual meeting and not later than the close of business on the later of: (1) the 90th day prior to the annual meeting and (2) the close of business on the 10th day following the first date of Public Disclosure of the date of such meeting. In no event shall the Public Disclosure of an adjournment or postponement of an annual meeting commence a new notice time period (or extend any notice time period). For the purposes of this Section 2.7, "***Public Disclosure***" shall mean a disclosure made in a press release reported by the Dow Jones News Services, The Associated Press, or a comparable national news service or in a document filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14, or 15(d) of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***").

(b) Stockholder Nominations. For the nomination of any person or persons for election to the Board pursuant to Section 2.7(a)(i)(D) or Section 2.7(d), a Proposing Stockholder's notice to the Secretary shall set forth or include: (i) the name, age, business address, and residence address of each nominee proposed in such notice; (ii) the principal occupation or employment of each such nominee; (iii) the class and number of shares of capital stock of the Corporation which are owned of record and beneficially by each such nominee (if any); (iv) such other information concerning each such nominee as would be required to be disclosed in a proxy statement soliciting proxies for the election of such nominee as a director in an election contest (even if an election contest is not involved) or that is otherwise required to be disclosed, under Section 14(a) of the Exchange Act; (v) a written statement executed by each such nominee acknowledging that such person consents to being named in the Company's proxy statement as a nominee and to serving as a director if elected, and (vi) as to the Proposing Stockholder: (A) the name and address of the Proposing Stockholder as they appear on the Corporation's books and of the beneficial owner, if any, on whose behalf the nomination is being made, (B) the class and number of shares of the Corporation which are owned by the Proposing Stockholder (beneficially and of record) and owned by the beneficial owner, if any, on whose behalf the nomination is being made, as of the date of the Proposing Stockholder's notice, and a representation that the Proposing Stockholder will notify the Corporation in writing of the class and number of such shares owned of record and beneficially as of the record date for the meeting within five business days after the record date for such meeting, (C) a description of any agreement, arrangement, or understanding with respect to such nomination between or among the Proposing Stockholder or the beneficial owner, if any, on whose behalf the nomination is being made and any of their affiliates or associates, and any others (including their names) acting in concert with any of the foregoing, and a representation that the Proposing Stockholder will notify the Corporation in writing of any such agreement, arrangement, or understanding in effect as of the record date for the meeting within five business days after the record date for such meeting, (D) a description of any agreement, arrangement, or understanding (including any derivative or short positions, profit interests, options, hedging transactions, and borrowed or loaned shares) that has been entered into as of the date of the Proposing Stockholder's notice by, or on behalf of, the Proposing Stockholder or the beneficial owner, if any, on whose behalf the nomination is being made and any of their affiliates or associates, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of such person or any of their affiliates or associates with respect to shares of stock of the Corporation, and a representation that the Proposing Stockholder will notify the Corporation in writing of any such agreement, arrangement, or understanding in effect as of the record date for the meeting within five business days after the record date for such meeting, (E) a representation that the Proposing Stockholder is a holder of record of shares of the Corporation entitled to vote at the meeting and intends to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice, and (F) a representation whether the Proposing Stockholder intends to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to approve the nomination and/or otherwise to solicit proxies from stockholders in support of the nomination.

The Corporation may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as an independent director of the Corporation or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such nominee. Any such update or supplement shall be delivered to the Secretary at the Corporation's principal executive offices no later than five business days after the request by the Corporation for subsequent information has been delivered to the Proposing Stockholder.

(c) Other Stockholder Proposals. For all business other than director nominations, a Proposing Stockholder's notice to the Secretary shall set forth as to each matter the Proposing Stockholder proposes to bring before the annual meeting: (i) a brief description of the business desired to be brought before the annual meeting; (ii) the reasons for conducting such business at the annual meeting; (iii) the text of any proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend these Bylaws, the language of the proposed amendment); (iv) any substantial interest (within the meaning of Item 5 of Schedule 14A under the Exchange Act) in such business of such stockholder and the beneficial owner (within the meaning of Section 13(d) of the Exchange Act), if any, on whose behalf the business is being proposed; (v) any other information relating to such stockholder and beneficial owner, if any, on whose behalf the proposal is being made, required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for the proposal and pursuant to and in accordance with Section 14(a) of the Exchange Act and the rules and regulations promulgated thereunder; (vi) a description of all agreements, arrangements, or understandings between or among such stockholder, the beneficial owner, if any, on whose behalf the proposal is being made, any of their affiliates or associates, and any other person or persons (including their names) in connection with the proposal of such business and any material interest of such stockholder, beneficial owner, or any of their affiliates or associates, in such business, including any anticipated benefit therefrom to such stockholder, beneficial owner, or their affiliates or associates; and (vii) the information required by Section 2.7(b)(vi) above.

(d) Special Meetings of Stockholders.

(i) Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of meeting. Nominations of persons for election to the Board may be made at a special meeting of stockholders called by the Board at which directors are to be elected pursuant to the Corporation's notice of meeting: (i) by or at the direction of the Board or any committee thereof, or (ii) provided that the Board has determined that directors shall be elected at such meeting, by any stockholder of the Corporation who is a stockholder of record at the time the notice provided for in this Section 2.7(d) is delivered to the Secretary, who is entitled to vote at the meeting, and upon such election and who complies with the notice procedures set forth in this Section 2.7.

(ii) In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board, any such stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the Corporation's notice of meeting, if such stockholder delivers a stockholder's notice that complies with the requirements of Section 2.7(b) to the Secretary at the principal executive offices of the Corporation not earlier than the close of business on the 120th day prior to such special meeting and not later than the close of business on the later of: (x) the 90th day prior to such special meeting; or (y) the 10th day following the date of the first Public Disclosure of the date of the special meeting and of the nominees proposed by the Board to be elected at such meeting. In no event shall the Public Disclosure of an adjournment or postponement of a special meeting commence a new time period (or extend any notice time period).

(e) Effect of Noncompliance. Only such persons who are nominated in accordance with the procedures set forth in this Section 2.7 shall be eligible to be elected at any meeting of stockholders of the Corporation to serve as directors and only such other business shall be conducted at a meeting as shall be brought before the meeting in accordance with the procedures set forth in this Section 2.7. If any proposed nomination was not made or proposed in compliance with this Section 2.7, or other business was not made or proposed in compliance with this Section 2.7, then except as otherwise required by law, the chair of the meeting shall have the power and duty to declare that such nomination shall be disregarded or that such proposed other business shall not be transacted. Notwithstanding anything in these Bylaws to the contrary, unless otherwise required by law, if a Proposing Stockholder intending to propose business or make nominations at an annual meeting or propose a nomination at a special meeting pursuant to this Section 2.7 does not provide the information required under this Section 2.7 to the Corporation, including the updated information required by Section 2.7(b)(vi)(B), Section 2.7(b)(vi)(C), and Section 2.7(b)(vi)(D) within five business days after the record date for such meeting or the Proposing Stockholder (or a qualified representative of the Proposing Stockholder) does not appear at the meeting to present the proposed business or nominations, such business or nominations shall not be considered, notwithstanding that proxies in respect of such business or nominations may have been received by the Corporation.

(f) Rule 14a-8. This Section 2.7 shall not apply to a proposal proposed to be made by a stockholder if the stockholder has notified the Corporation of the stockholder's intention to present the proposal at an annual or special meeting only pursuant to and in compliance with Rule 14a-8 under the Exchange Act and such proposal has been included in a proxy statement that has been prepared by the Corporation to solicit proxies for such meeting.

(g) In addition to the provisions of this Section 2.7, a stockholder shall also comply with all of the applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth herein. Nothing in this Section 2.7 shall be deemed to affect any rights of the holders of Preferred Stock to elect directors pursuant to the Certificate of Incorporation.

(h) Notwithstanding anything in Section 2.7 to the contrary, in the event that the number of directors is increased and there is no Public Disclosure of the appointment of a director, or, if no appointment was made, of the vacancy, made by the Corporation at least 10 days before the last day a stockholder may deliver a notice of nomination in accordance with Section 2.7, a stockholder's notice required by this Section 2.7 and which complies with the requirements in Section 2.7(b), other than the timing requirements in Section 2.7(a), shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it is received by the Secretary at the principal executive offices of the Corporation not later than the close of business on the 10th day following the day on which such Public Disclosure is first made by the Corporation.

Section 2.8. Conduct of Meetings. The chair of each annual and special meeting of stockholders shall be the Chair of the Board or, in the absence (or inability or refusal to act) of the Chair of the Board, the Chief Executive Officer (if he or she shall be a director) or, in the absence (or inability or refusal to act of the Chief Executive Officer or if the Chief Executive Officer is not a director, the President (if he or she shall be a director) or, in the absence (or inability or refusal to act) of the President or if the President is not a director, such other person as shall be appointed by the Board. The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting by the chair of the meeting. The Board may adopt such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with these Bylaws or such rules and regulations as adopted by the Board, the chair of any meeting of stockholders shall have the right and authority to convene and to adjourn the meeting, to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chair, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the chair of the meeting, may include, without limitation, the following:

(a) the establishment of an agenda or order of business for the meeting;

(b) the determination of when the polls shall open and close for any given matter to be voted on at the meeting;

(c) rules and procedures for maintaining order at the meeting and the safety of those present;

(d) limitations on attendance at or participation in the meeting to stockholders of record of the Corporation, their duly authorized and constituted proxies or such other persons as the chair of the meeting shall determine;

(e) restrictions on entry to the meeting after the time fixed for the commencement thereof; and

(f) limitations on the time allotted to questions or comments by participants. Unless and to the extent determined by the Board or the chair of the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

The secretary of each annual and special meeting of stockholders shall be the Secretary or, in the absence (or inability or refusal to act) of the Secretary, an Assistant Secretary so appointed to act by the chair of the meeting. In the absence (or inability or refusal to act) of the Secretary and all Assistant Secretaries, the chair of the meeting may appoint any person to act as secretary of the meeting.

Section 2.9. Action by Stockholders Without a Meeting. Subject to the following paragraph, any action that is properly brought before the stockholders by or at the direction of the Board and that could be taken at an annual or special meeting of stockholders may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall (a) be signed by the holders of outstanding shares of capital stock entitled to be voted with respect to the subject matter thereof having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted (as determined in accordance with Section 9.4 hereof) and (b) be delivered to the Corporation by delivery to its registered office in the State of Delaware, its principal place of business, or an officer or agent of the Corporation having custody of the records of proceedings of meetings of stockholders. Delivery made to the Corporation's registered office shall be by hand or by certified mail or registered mail, return receipt requested. Every written consent shall bear the date of signature of each stockholder who signs the consent, and no written consent shall be effective to take the corporate action referred to therein unless written consents signed by the requisite number of stockholders entitled to vote with respect to the subject matter thereof are delivered to the Corporation, in the manner required by this Section 2.9, within 60 (or the maximum number permitted by applicable law) days of the earliest dated consent delivered to the corporation in the manner required by this Section 2.9. The validity of any consent executed by a proxy for a stockholder pursuant to an electronic transmission transmitted to such proxy holder by or upon the authorization of the stockholder shall be determined by or at the direction of the Secretary. A written record of the information upon which the person making such determination relied shall be made and kept in the records of the proceedings of the stockholders. Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing. Any such consent shall be inserted in the minute book as if it were the minutes of a meeting of the stockholders.

ARTICLE III
DIRECTORS

Section 3.1. Powers; Number. The business and affairs of the Corporation shall be managed by or under the direction of the Board, which may exercise all such powers of the Corporation and do all such lawful acts and things, including, without limitation, adopting rules and procedures as it may deem proper for the conduct of its meetings and the management of the Corporation, as are not by statute or by the Certificate of Incorporation or by these Bylaws required to be exercised or done by the stockholders. Directors need not be stockholders or residents of the State of Delaware. Subject to any limitations in the laws of the State of Delaware, the Certificate of Incorporation or these Bylaws, the number of directors may be changed from time to time by resolutions adopted by the Board of Directors and/or the stockholders. No reduction of the number of directors shall have the effect of removing any director prior to the expiration of his or her term of office.

Section 3.2. Vacancies. Unless otherwise provided in the Certificate of Incorporation, and subject to the rights of the holders of any series of Preferred Stock or as otherwise provided by applicable law, any vacancies on the Board resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board, or by a sole remaining director, and not by the stockholders, *provided, however*, that whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the Certificate of Incorporation, vacancies and newly created directorships of such class or classes or series shall be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified. A vacancy in the Board shall be deemed to exist under this Bylaw in the case of the death, removal or resignation of any director.

Section 3.3. Resignation. Any director may resign at any time by notice given in writing or by electronic transmission to the Corporation. Such resignation shall take effect at the date of receipt of such notice by the Corporation or at such later effective date or upon the happening of an event or events as is therein specified. A verbal resignation shall not be deemed effective until confirmed by the director in writing or by electronic transmission to the Corporation. When one or more directors shall resign from the Board, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office for the unexpired portion of the term of the director whose place shall be vacated and until his successor shall have been duly elected and qualified.

Section 3.4. Removal. Subject to any limitations imposed by applicable law, any individual director or directors may be removed with cause by the affirmative vote of the holders of at least 66 2/3% of the voting power of all then-outstanding shares of capital stock of the Corporation entitled to vote generally at an election of directors. Directors shall not be removed without cause pursuant to this Section 3.4.

Section 3.5. Compensation. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, the Board shall have the authority to fix the compensation of directors, including for service on a committee of the Board, and may be paid either a fixed sum for attendance at each meeting of the Board or other compensation as director. The directors may be reimbursed their expenses, if any, of attendance at each meeting of the Board. No such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor. Members of committees of the Board may be allowed like compensation and reimbursement of expenses for service on the committee.

ARTICLE IV
BOARD MEETINGS

Section 4.1. Regular Meetings. Regularly scheduled, periodic meetings of the Board may be held without notice at such times, dates and places, within or without the State of Delaware, as shall from time to time be determined by the Board.

Section 4.2. Special Meetings. Special meetings of the Board (a) may be called by the Chair of the Board or President and (b) shall be called by the Chair of the Board, President or Secretary on the written request of at least a majority of directors then in office, or the sole director, as the case may be, and shall be held at such time, date and place, within or without the State of Delaware, as may be determined by the person calling the meeting or, if called upon the request of directors or the sole director, as specified in such written request. Notice of each special meeting of the Board shall be given, as provided in Section 9.3, to each director (i) at least 24 hours before the meeting if such notice is oral notice given personally or by telephone or written notice given by hand delivery or by means of a form of electronic transmission and delivery; (ii) at least two days before the meeting if such notice is sent by a nationally recognized overnight delivery service; and (iii) at least three days before the meeting if such notice is sent through the United States mail. If the Secretary shall fail or refuse to give such notice, then the notice may be given by the officer who called the meeting or the directors who requested the meeting. Any and all business that may be transacted at a regular meeting of the Board may be transacted at a special meeting. Except as may be otherwise expressly provided by applicable law, the Certificate of Incorporation, or these Bylaws, neither the business to be transacted at, nor the purpose of, any special meeting need be specified in the notice or waiver of notice of such meeting. A special meeting may be held at any time without notice if all the directors are present or if those not present waive notice of the meeting in accordance with Section 9.4.

Section 4.3. Quorum; Required Vote. A majority of the Board shall constitute a quorum for the transaction of business at any meeting of the Board, and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board, except as may be otherwise specifically provided by applicable law, the Certificate of Incorporation or these Bylaws. If a quorum shall not be present at any meeting, a majority of the directors present may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

Section 4.4. Consent In Lieu of Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board or any committee thereof may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions (or paper reproductions thereof) are filed with the minutes of proceedings of the Board or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

Section 4.5. Organization. The chair of each meeting of the Board shall be the Chair of the Board or, in the absence (or inability or refusal to act) of the Chair of the Board, the Chief Executive Officer (if he or she shall be a director) or, in the absence (or inability or refusal to act) of the Chief Executive Officer or if the Chief Executive Officer is not a director, the President (if he or she shall be a director) or in the absence (or inability or refusal to act) of the President or if the President is not a director, a chair elected from the directors present. The Secretary shall act as secretary of all meetings of the Board. In the absence (or inability or refusal to act) of the Secretary, an Assistant Secretary shall perform the duties of the Secretary at such meeting. In the absence (or inability or refusal to act) of the Secretary and all Assistant Secretaries, the chair of the meeting may appoint any person to act as secretary of the meeting.

ARTICLE V
COMMITTEES OF DIRECTORS

Section 5.1. Establishment. The Board may designate one or more committees, each committee to consist of one or more of the directors of the Corporation. Each committee shall keep regular minutes of its meetings and report the same to the Board when required by the resolution designating such committee. The Board shall have the power at any time to fill vacancies in, to change the membership of, or to dissolve any such committee.

Section 5.2. Available Powers. Any committee established pursuant to Section 5.1 hereof, to the extent permitted by applicable law and by resolution of the Board, shall have and may exercise all of the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers that may require it.

Section 5.3. Alternate Members. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of such committee. In the absence or disqualification of a member of the committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he, she or they constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in place of any such absent or disqualified member.

Section 5.4. Procedures. Unless the Board otherwise provides, the time, date, place, if any, and notice of meetings of a committee shall be determined by such committee. At meetings of a committee, a majority of the number of members of the committee (but not including any alternate member, unless such alternate member has replaced any absent or disqualified member at the time of, or in connection with, such meeting) shall constitute a quorum for the transaction of business. The act of a majority of the members present at any meeting at which a quorum is present shall be the act of the committee, except as otherwise specifically provided by applicable law, the Certificate of Incorporation, these Bylaws or the Board. If a quorum is not present at a meeting of a committee, the members present may adjourn the meeting from time to time, without notice other than an announcement at the meeting, until a quorum is present. Unless the Board otherwise provides and except as provided in these Bylaws, each committee designated by the Board may make, alter, amend and repeal rules for the conduct of its business. In the absence of such rules each committee shall conduct its business in the same manner as the Board is authorized to conduct its business pursuant to Article III and Article IV of these Bylaws.

ARTICLE VI
OFFICERS

Section 6.1. Officers. The officers of the Corporation elected by the Board shall be a Chief Executive Officer, a Chief Financial Officer, a Secretary and such other officers (including without limitation, a Chair of the Board, Presidents, Vice Presidents, Assistant Secretaries and a Treasurer) as the Board from time to time may determine. Officers elected by the Board shall each have such powers and duties as generally pertain to their respective offices, subject to the specific provisions of this Article VI. Such officers shall also have such powers and duties as from time to time may be conferred by the Board. The Chief Executive Officer or President may also appoint such other officers (including without limitation one or more Vice Presidents and Controllers) as may be necessary or desirable for the conduct of the business of the Corporation. Such other officers shall have such powers and duties and shall hold their offices for such terms as may be provided in these Bylaws or as may be prescribed by the Board or, if such officer has been appointed by the Chief Executive Officer or President, as may be prescribed by the appointing officer.

(a) Chair of the Board. The Chair of the Board shall preside when present at all meetings of the stockholders and the Board. The Chair of the Board shall have general supervision and control of the acquisition activities of the Corporation subject to the ultimate authority of the Board, and shall be responsible for the execution of the policies of the Board with respect to such matters. In the absence (or inability or refusal to act) of the Chair of the Board, the Chief Executive Officer (if he or she shall be a director) shall preside when present at all meetings of the stockholders and the Board. The powers and duties of the Chair of the Board shall not include supervision or control of the preparation of the financial statements of the Corporation (other than through participation as a member of the Board). The position of Chair of the Board and Chief Executive Officer may be held by the same person.

(b) Chief Executive Officer. The Chief Executive Officer shall be the chief executive officer of the Corporation, shall have general supervision of the affairs of the Corporation and general control of all of its business subject to the ultimate authority of the Board, and shall be responsible for the execution of the policies of the Board with respect to such matters, except to the extent any such powers and duties have been prescribed to the Chair of the Board pursuant to Section 6.1(a) above. In the absence (or inability or refusal to act) of the Chair of the Board, the Chief Executive Officer (if he or she shall be a director) shall preside when present at all meetings of the stockholders and the Board. The position of Chief Executive Officer and President may be held by the same person.

(c) President. The President shall make recommendations to the Chief Executive Officer on all operational matters that would normally be reserved for the final executive responsibility of the Chief Executive Officer. In the absence (or inability or refusal to act) of the Chair of the Board and Chief Executive Officer, the President (if he or she shall be a director) shall preside when present at all meetings of the stockholders and the Board. The President shall also perform such duties and have such powers as shall be designated by the Board. The position of President and Chief Executive Officer may be held by the same person.

(d) Vice Presidents. In the absence (or inability or refusal to act) of the President, the Vice President (or in the event there be more than one Vice President, the Vice Presidents in the order designated by the Board) shall perform the duties and have the powers of the President. Each Vice President of the Corporation shall have such powers and perform such duties as may be assigned to him or her from time to time by the Board, the Chief Executive Officer or the President, or that are incident to the office of Vice President.

(e) Secretary.

(i) The Secretary shall attend all meetings of the stockholders, the Board and (as required) committees of the Board and shall record the proceedings of such meetings in books to be kept for that purpose. The Secretary shall give, or cause to be given, notice of all meetings of the stockholders and special meetings of the Board and shall perform such other duties as may be prescribed by the Board, the Chair of the Board, Chief Executive Officer or President. The Secretary shall have custody of the corporate seal of the Corporation and the Secretary, or any Assistant Secretary, shall have authority to affix the same to any instrument requiring it, and when so affixed, it may be attested by his or her signature or by the signature of such Assistant Secretary. The Board may give general authority to any other officer to affix the seal of the Corporation and to attest the affixing thereof by his or her signature.

(ii) The Secretary shall keep, or cause to be kept, at the principal executive office of the Corporation or at the office of the Corporation's transfer agent or registrar, if one has been appointed, a stock ledger, or duplicate stock ledger, showing the names of the stockholders and their addresses, the number and classes of shares held by each and, with respect to certificated shares, the number and date of certificates issued for the same and the number and date of certificates cancelled.

(f) Assistant Secretaries. The Assistant Secretary or, if there be more than one, the Assistant Secretaries in the order determined by the Board shall, in the absence (or inability or refusal to act) of the Secretary, perform the duties and have the powers of the Secretary.

(g) Chief Financial Officer. The Chief Financial Officer shall perform all duties commonly incident to that office (including, without limitation, the care and custody of the funds and securities of the Corporation, which from time to time may come into the Chief Financial Officer's hands and the deposit of the funds of the Corporation in such banks or trust companies as the Board, the Chief Executive Officer or the President may authorize).

(h) Treasurer. The Treasurer shall, in the absence (or inability or refusal to act) of the Chief Financial Officer, perform the duties and exercise the powers of the Chief Financial Officer. The Treasurer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board, the Chief Executive Officer, the President and the Chief Financial Officer (if not the Treasurer) shall designate from time to time.

Section 6.2. Resignations. Any officer may resign at any time by giving notice in writing or by electronic transmission to the Board or to the Chief Executive Officer, or if no Chief Executive Officer is then serving, the President or to the Secretary. Any such resignation shall be effective when received by the person or persons to whom such notice is given, unless a later time is specified therein, in which event the resignation shall become effective at such later time. Unless otherwise specified in such notice, the acceptance of any such resignation shall not be necessary to make it effective. Any resignation shall be without prejudice to the rights, if any, of the Corporation under any contract with the resigning officer.

Section 6.3. Term of Office; Removal; Vacancies. The elected officers of the Corporation shall be appointed by the Board and shall hold office until their successors are duly elected and qualified by the Board or until their earlier death, resignation, retirement, disqualification, or removal from office. Any officer may be removed, with or without cause, at any time by the majority vote of the members of the Board then in office. Any officer appointed by the Chief Executive Officer or President may also be removed, with or without cause, by the Chief Executive Officer or President, as the case may be, unless the Board otherwise provides. Any vacancy occurring in any elected office of the Corporation may be filled by the Board. Any vacancy occurring in any office appointed by the Chief Executive Officer or President may be filled by the Chief Executive Officer, or President, as the case may be, unless the Board then determines that such office shall thereupon be elected by the Board, in which case the Board shall elect such officer.

Section 6.4. Other Officers; Duties of Officers May Be Delegated. Such other officers as the Board may choose shall perform such duties and have such powers as from time to time may be assigned to them by the Board. The Board may delegate to any other officer of the Corporation the power to choose such other officers and to prescribe their respective duties and powers. In case any officer is absent, or for any other reason that the Board may deem sufficient, the Chief Executive Officer or the President or the Board may delegate for the time being the powers or duties of such officer to any other officer or to any director.

Section 6.5. Multiple Officeholders; Stockholder and Director Officers. Any number of offices may be held by the same person unless the Certificate of Incorporation or these Bylaws otherwise provide. Officers need not be stockholders or residents of the State of Delaware.

ARTICLE VII
SHARES

Section 7.1. Certificated and Uncertificated Shares. The shares of the Corporation may be certificated or uncertificated, subject to the sole discretion of the Board and the requirements of the DGCL.

Section 7.2. Multiple Classes of Stock. If the Corporation shall be authorized to issue more than one class of stock or more than one series of any class, the Corporation shall (a) cause the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights to be set forth in full or summarized on the face or back of any certificate that the Corporation issues to represent shares of such class or series of stock or (b) in the case of uncertificated shares, within a reasonable time after the issuance or transfer of such shares, send to the registered owner thereof a written notice containing the information required to be set forth on certificates as specified in clause (a) above; provided, however, that, except as otherwise provided by applicable law, in lieu of the foregoing requirements, there may be set forth on the face or back of such certificate or, in the case of uncertificated shares, on such written notice a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences or rights.

Section 7.3. Signatures. Each certificate representing capital stock of the Corporation shall be signed by or in the name of the Corporation by (a) the Chair of the Board, Chief Executive Officer, the President or a Vice President and (b) the Treasurer, an Assistant Treasurer, the Secretary or an Assistant Secretary of the Corporation. Any or all the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, such certificate may be issued by the Corporation with the same effect as if such person were such officer, transfer agent or registrar on the date of issue.

Section 7.4. Consideration and Payment for Shares.

(a) Subject to applicable law and the Certificate of Incorporation, shares of stock may be issued for such consideration, having in the case of shares with par value a value not less than the par value thereof, and to such persons, as determined from time to time by the Board. The consideration may consist of any tangible or intangible property or any benefit to the Corporation including cash, promissory notes, services performed, contracts for services to be performed or other securities, or any combination thereof.

(b) Subject to applicable law and the Certificate of Incorporation, shares may not be issued until the full amount of the consideration has been paid, unless upon the face or back of each certificate issued to represent any partly paid shares of capital stock or upon the books and records of the Corporation in the case of partly paid uncertificated shares, there shall have been set forth the total amount of the consideration to be paid therefor and the amount paid thereon up to and including the time said certificate representing certificated shares or said uncertificated shares are issued.

Section 7.5. Lost, Stolen or Destroyed Certificates. The Board or the Secretary may direct a new certificate or uncertificated shares to be issued in place of any certificate theretofore issued by the Corporation alleged to have been lost, stolen, or destroyed upon the making of an affidavit of that fact by the owner of the allegedly lost, stolen, or destroyed certificate. When authorizing such issue of a new certificate or uncertificated shares, the Board or the Secretary may, in its discretion and as a condition precedent to the issuance thereof, require the owner of the lost, stolen, or destroyed certificate, or the owner's legal representative to give the Corporation a bond sufficient to indemnify it against any claim that may be made against the Corporation with respect to the certificate alleged to have been lost, stolen, or destroyed or the issuance of such new certificate or uncertificated shares.

Section 7.6. Transfer of Stock.

(a) If a certificate representing shares of the Corporation is presented to the Corporation with an endorsement requesting the registration of transfer of such shares or an instruction is presented to the Corporation requesting the registration of transfer of uncertificated shares, the Corporation shall register the transfer as requested if:

(i) in the case of certificated shares, the certificate representing such shares has been surrendered;

(ii) (A) with respect to certificated shares, the endorsement is made by the person specified by the certificate as entitled to such shares; (B) with respect to uncertificated shares, an instruction is made by the registered owner of such uncertificated shares; or (C) with respect to certificated shares or uncertificated shares, the endorsement or instruction is made by any other appropriate person or by an agent who has actual authority to act on behalf of the appropriate person;

(iii) the Corporation has received a guarantee of signature of the person signing such endorsement or instruction or such other reasonable assurance that the endorsement or instruction is genuine and authorized as the Corporation may request;

(iv) the transfer does not violate any restriction on transfer imposed by the Corporation that is enforceable in accordance with Section 7.8(a); and

(v) such other conditions for such transfer as shall be provided for under applicable law have been satisfied.

(b) Whenever any transfer of shares shall be made for collateral security and not absolutely, the Corporation shall so record such fact in the entry of transfer if, when the certificate for such shares is presented to the Corporation for transfer or, if such shares are uncertificated, when the instruction for registration of transfer thereof is presented to the Corporation, both the transferor and transferee request the Corporation to do so.

Section 7.7. Registered Stockholders. Before due presentment for registration of transfer of a certificate representing shares of the Corporation or of an instruction requesting registration of transfer of uncertificated shares, the Corporation may treat the registered owner as the person exclusively entitled to inspect for any proper purpose the stock ledger and the other books and records of the Corporation, vote such shares, receive dividends or notifications with respect to such shares and otherwise exercise all the rights and powers of the owner of such shares, except that a person who is the beneficial owner of such shares (if held in a voting trust or by a nominee on behalf of such person) may, upon providing documentary evidence of beneficial ownership of such shares and satisfying such other conditions as are provided under applicable law, may also so inspect the books and records of the Corporation.

Section 7.8. Effect of the Corporation's Restriction on Transfer.

(a) A written restriction on the transfer or registration of transfer of shares of the Corporation or on the amount of shares of the Corporation that may be owned by any person or group of persons, if permitted by the DGCL and noted conspicuously on the certificate representing such shares or, in the case of uncertificated shares, contained in a notice, offering circular or prospectus sent by the Corporation to the registered owner of such shares within a reasonable time prior to or after the issuance or transfer of such shares, may be enforced against the holder of such shares or any successor or transferee of the holder including an executor, administrator, trustee, guardian or other fiduciary entrusted with like responsibility for the person or estate of the holder.

(b) A restriction imposed by the Corporation on the transfer or the registration of shares of the Corporation or on the amount of shares of the Corporation that may be owned by any person or group of persons, even if otherwise lawful, is ineffective against a person without actual knowledge of such restriction unless: (i) the shares are certificated and such restriction is noted conspicuously on the certificate; or (ii) the shares are uncertificated and such restriction was contained in a notice, offering circular or prospectus sent by the Corporation to the registered owner of such shares within a reasonable time prior to or after the issuance or transfer of such shares.

Section 7.9. Regulations. The Board shall have power and authority to make such additional rules and regulations, subject to any applicable requirement of law, as the Board may deem necessary and appropriate with respect to the issue, transfer or registration of transfer of shares of stock or certificates representing shares. The Board may appoint one or more transfer agents or registrars and may require for the validity thereof that certificates representing shares bear the signature of any transfer agent or registrar so appointed.

ARTICLE VIII
INDEMNIFICATION

Section 8.1. Right to Indemnification. To the fullest extent permitted by applicable law, as the same exists or may hereafter be amended, the Corporation shall indemnify and hold harmless each person who was or is made a party or is threatened to be made a party to or is otherwise involved in any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (hereinafter a "***proceeding***"), by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, other enterprise or nonprofit entity, including service with respect to an employee benefit plan (hereinafter an "***Indemnitee***"), whether the basis of such proceeding is alleged action in an official capacity as a director, officer, employee or agent, or in any other capacity while serving as a director, officer, employee or agent, against all liability and loss suffered and expenses (including, without limitation, attorneys' fees) actually and reasonably incurred by such Indemnitee in connection with such proceeding; provided, however, that, with respect to proceedings to enforce rights to indemnification, the Corporation shall indemnify an Indemnitee in connection with a proceeding (or part thereof) initiated by such Indemnitee only if such proceeding (or part thereof) was authorized by the Board.

Section 8.2. Right to Advancement of Expenses. In addition to the right to indemnification conferred in Section 8.1, an Indemnitee shall also have the right to be paid by the Corporation to the fullest extent not prohibited by applicable law the expenses (including, without limitation, attorneys' fees) actually and reasonably incurred in defending or otherwise participating in any such proceeding in advance of its final disposition (hereinafter an "***advancement of expenses***"); provided, however, that an advancement of expenses incurred by an Indemnitee in his or her capacity as a director or officer of the Corporation (and not in any other capacity in which service was or is rendered by such Indemnitee, including, without limitation, service to an employee benefit plan) shall be made only upon the Corporation's receipt of an undertaking (hereinafter an "***undertaking***"), by or on behalf of such Indemnitee, to repay all amounts so advanced if it shall ultimately be determined that such Indemnitee is not entitled to be indemnified under this Article VIII or otherwise. Payment of such expenses actually and reasonably incurred by such person, may be made by the Corporation, subject to such terms and conditions as the general counsel of the Corporation in his or her discretion deems appropriate.

Section 8.3. Non-Exclusivity of Rights. The rights provided to any Indemnitee pursuant to this Article VIII shall not be exclusive of any other right, which such Indemnitee may have or hereafter acquire under applicable law, the Certificate of Incorporation, these Bylaws, an agreement, a vote of stockholders or disinterested directors, or otherwise. The Corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advances, to the fullest extent not prohibited by the DGCL.

Section 8.4. Insurance. The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee, or agent of the Corporation, or is or was serving at the request of Corporation as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust, enterprise, or nonprofit entity against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify him or her against such liability under the provisions of the DGCL.

Section 8.5. Indemnification of Other Persons; Other Indemnification. This Article VIII shall not limit the right of the Corporation to the extent and in the manner authorized or permitted by law to indemnify and to advance expenses to persons other than Indemnitees. Without limiting the foregoing, the Corporation may, to the extent authorized from time to time by the Board, grant rights to indemnification and to the advancement of expenses to any employee or agent of the Corporation and to any other person who is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan, to the fullest extent of the provisions of this Article VIII with respect to the indemnification and advancement of expenses of Indemnitees under this Article VIII. The Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, enterprise or nonprofit entity shall be reduced by any amount such person may collect as indemnification from such other corporation, partnership, joint venture, trust, enterprise or nonprofit entity.

Section 8.6. Amendments. Any amendment, repeal, or modification of this Article VIII shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification.

Section 8.7. Certain Definitions. For purposes of this Article VIII, (a) references to "***other enterprise***" shall include any employee benefit plan; (b) references to "***fines***" shall include any excise taxes assessed on a person with respect to an employee benefit plan; (c) references to "***serving at the request of the Corporation***" shall include any service that imposes duties on, or involves services by, a person with respect to any employee benefit plan, its participants, or beneficiaries; and (d) a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "***not opposed to the best interest of the Corporation***" for purposes of Section 145 of the DGCL.

Section 8.8. Contract Rights. The rights provided to Indemnitees pursuant to this Article VIII shall be contract rights and such rights shall continue as to an Indemnitee who has ceased to be a director, officer, agent or employee and shall inure to the benefit of the Indemnitee's heirs, executors and administrators.

Section 8.9. Severability. If any provision or provisions of this Article VIII shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Article VIII shall not in any way be affected or impaired thereby; and (b) to the fullest extent possible, the provisions of this Article VIII (including, without limitation, each such portion of this Article VIII containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested by the provision held invalid, illegal or unenforceable.

ARTICLE IX
MISCELLANEOUS

Section 9.1. Place of Meetings. If the place of any meeting of stockholders, the Board or committee of the Board for which notice is required under these Bylaws is not designated in the notice of such meeting, such meeting shall be held at the principal business office of the Corporation; provided, however, if the Board has, in its sole discretion, determined that a meeting shall not be held at any place, but instead shall be held by means of remote communication pursuant to Section 9.5 hereof, then such meeting shall not be held at any place.

Section 9.2. Fixing Record Dates.

(a) In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the business day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the business day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the foregoing provisions of this Section 9.2(a) at the adjourned meeting.

(b) For the purpose of determining stockholders entitled to consent to corporate action in writing without a meeting, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which date shall not be more than 10 (or the maximum number permitted by applicable law) days after the date upon which the resolution fixing the record date is adopted by the Board. If no record date has been fixed by the Board, the record date for determining stockholders entitled to consent to corporate action in writing without a meeting, when no prior action by the Board is required by Chapter 1 of the DGCL, shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Corporation by delivery to its registered office in the State of Delaware, its principal place of business, or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to the Corporation's registered office shall be by hand or by certified or registered mail, return receipt requested. If no record date has been fixed by the Board and prior action by the Board is required by Chapter 1 of the DGCL, the record date for determining stockholders entitled to consent to corporate action in writing without a meeting shall be at the close of business on the day on which the Board adopts the resolution taking such prior action.

(c) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

Section 9.3. Means of Giving Notice.

(a) Notice to Directors. Whenever under applicable law, the Certificate of Incorporation or these Bylaws notice is required to be given to any director, such notice shall be given either (i) in writing and sent by mail, or by a nationally recognized delivery service, (ii) by means of facsimile telecommunication or other form of electronic transmission, or (iii) by oral notice given personally or by telephone. A notice to a director will be deemed given as follows: (i) if given by hand delivery, orally, or by telephone, when actually received by the director, (ii) if sent through the United States mail, when deposited in the United States mail, with postage and fees thereon prepaid, addressed to the director at the director's address appearing on the records of the Corporation, (iii) if sent for next day delivery by a nationally recognized overnight delivery service, when deposited with such service, with fees thereon prepaid, addressed to the director at the director's address appearing on the records of the Corporation, (iv) if sent by facsimile telecommunication, when sent to the facsimile transmission number for such director appearing on the records of the Corporation, (v) if sent by electronic mail, when sent to the electronic mail address for such director appearing on the records of the Corporation, or (vi) if sent by any other form of electronic transmission, when sent to the address, location or number (as applicable) for such director appearing on the records of the Corporation.

(b) Notice to Stockholders. Whenever under applicable law, the Certificate of Incorporation or these Bylaws notice is required to be given to any stockholder, such notice may be given (i) in writing and sent either by hand delivery, through the United States mail, or by a nationally recognized overnight delivery service for next day delivery, or (ii) by means of a form of electronic transmission consented to by the stockholder, to the extent permitted by, and subject to the conditions set forth in Section 232 of the DGCL. A notice to a stockholder shall be deemed given as follows: (i) if given by hand delivery, when actually received by the stockholder, (ii) if sent through the United States mail, when deposited in the United States mail, with postage and fees thereon prepaid, addressed to the stockholder at the stockholder's address appearing on the stock ledger of the Corporation, (iii) if sent for next day delivery by a nationally recognized overnight delivery service, when deposited with such service, with fees thereon prepaid, addressed to the stockholder at the stockholder's address appearing on the stock ledger of the Corporation, and (iv) if given by a form of electronic transmission consented to by the stockholder to whom the notice is given and otherwise meeting the requirements set forth above, (A) if by facsimile transmission, when directed to a number at which the stockholder has consented to receive notice, (B) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice, (C) if by a posting on an electronic network together with separate notice to the stockholder of such specified posting, upon the later of (1) such posting and (2) the giving of such separate notice, and (D) if by any other form of electronic transmission, when directed to the stockholder. A stockholder may revoke such stockholder's consent to receiving notice by means of electronic communication by giving written notice of such revocation to the Corporation. Any such consent shall be deemed revoked if (1) the Corporation is unable to deliver by electronic transmission two consecutive notices given by the Corporation in accordance with such consent and (2) such inability becomes known to the Secretary or an Assistant Secretary or to the Corporation's transfer agent, or other person responsible for the giving of notice; provided, however, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

(c) Electronic Transmission. "***Electronic transmission***" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process, including but not limited to transmission by telex, facsimile telecommunication, electronic mail, telegram and cablegram.

(d) Notice to Stockholders Sharing Same Address. Without limiting the manner by which notice otherwise may be given effectively by the Corporation to stockholders, any notice to stockholders given by the Corporation under any provision of the DGCL, the Certificate of Incorporation or these Bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. A stockholder may revoke such stockholder's consent by delivering written notice of such revocation to the Corporation. Any stockholder who fails to object in writing to the Corporation within 60 days of having been given written notice by the Corporation of its intention to send such a single written notice shall be deemed to have consented to receiving such single written notice.

(e) Exceptions to Notice Requirements. Whenever notice is required to be given, under the DGCL, the Certificate of Incorporation or these Bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting that shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the Corporation is such as to require the filing of a certificate with the Secretary of State of Delaware, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

Whenever notice is required to be given by the Corporation, under any provision of the DGCL, the Certificate of Incorporation or these Bylaws, to any stockholder to whom (1) notice of two consecutive annual meetings of stockholders and all notices of stockholder meetings or of the taking of action by written consent of stockholders without a meeting to such stockholder during the period between such two consecutive annual meetings, or (2) all, and at least two payments (if sent by first-class mail) of dividends or interest on securities during a 12-month period, have been mailed addressed to such stockholder at such stockholder's address as shown on the records of the Corporation and have been returned undeliverable, the giving of such notice to such stockholder shall not be required. Any action or meeting that shall be taken or held without notice to such stockholder shall have the same force and effect as if such notice had been duly given. If any such stockholder shall deliver to the Corporation a written notice setting forth such stockholder's then current address, the requirement that notice be given to such stockholder shall be reinstated. In the event that the action taken by the Corporation is such as to require the filing of a certificate with the Secretary of State of Delaware, the certificate need not state that notice was not given to persons to whom notice was not required to be given pursuant to Section 230(b) of the DGCL. The exception in subsection (1) of the first sentence of this paragraph to the requirement that notice be given shall not be applicable to any notice returned as undeliverable if the notice was given by electronic transmission.

Section 9.4. Waiver of Notice. Whenever any notice is required to be given under applicable law, the Certificate of Incorporation, or these Bylaws, a written waiver of such notice, signed by the person or persons entitled to said notice, or a waiver by electronic transmission by the person entitled to said notice, whether before or after the time stated therein, shall be deemed equivalent to such required notice. All such waivers shall be kept with the books of the Corporation. Attendance at a meeting shall constitute a waiver of notice of such meeting, except where a person attends for the express purpose of objecting to the transaction of any business on the ground that the meeting was not lawfully called or convened.

Section 9.5. Meeting Attendance via Remote Communication Equipment.

(a) Stockholder Meetings. If authorized by the Board in its sole discretion, and subject to such guidelines and procedures as the Board may adopt, stockholders entitled to vote at such meeting and proxy holders not physically present at a meeting of stockholders may, by means of remote communication:

(i) participate in a meeting of stockholders; and

(ii) be deemed present in person and vote at a meeting of stockholders, whether such meeting is to be held at a designated place or solely by means of remote communication, provided that (A) the Corporation shall implement reasonable measures to verify that each person deemed present and permitted to vote at the meeting by means of remote communication is a stockholder or proxy holder, (B) the Corporation shall implement reasonable measures to provide such stockholders and proxy holders a reasonable opportunity to participate in the meeting and, if entitled to vote, to vote on matters submitted to the applicable stockholders, including an opportunity to read or hear the proceedings of the meeting substantially concurrently with such proceedings, and (C) if any stockholder or proxy holder votes or takes other action at the meeting by means of remote communication, a record of such votes or other action shall be maintained by the Corporation.

(b) Board Meetings. Unless otherwise restricted by applicable law, the Certificate of Incorporation or these Bylaws, members of the Board or any committee thereof may participate in a meeting of the Board or any committee thereof by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other and be heard. Such participation in a meeting shall constitute presence in person at the meeting.

Section 9.6. Dividends. The Board may from time to time declare, and the Corporation may pay, dividends (payable in cash, property or shares of the Corporation's capital stock) on the Corporation's outstanding shares of capital stock, subject to applicable law and the Certificate of Incorporation.

Section 9.7. Reserves. Before payment of any dividend, there may be set aside out of any funds of the Corporation available for dividends such sum or sums as the Board from time to time, in their absolute discretion, think proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the Corporation, or for such other purpose as the Board shall think conducive to the interests of the Corporation, and the Board may modify or abolish any such reserve in the manner in which it was created.

Section 9.8. Contracts and Negotiable Instruments. Except as otherwise provided by applicable law, the Certificate of Incorporation or these Bylaws, any contract, bond, deed, lease, mortgage or other instrument may be executed and delivered in the name and on behalf of the Corporation by such officer or officers or other employee or employees of the Corporation as the Board may from time to time authorize. Such authority may be general or confined to specific instances as the Board may determine. The Chair of the Board, the Chief Executive Officer, the President, the Chief Financial Officer, the Treasurer or any Vice President may execute and deliver any contract, bond, deed, lease, mortgage or other instrument in the name and on behalf of the Corporation. Subject to any restrictions imposed by the Board, the Chair of the Board, the Chief Executive Officer, the President, the Chief Financial Officer, the Treasurer or any Vice President may delegate powers to execute and deliver any contract, bond, deed, lease, mortgage or other instrument in the name and on behalf of the Corporation to other officers or employees of the Corporation under such person's supervision and authority, it being understood, however, that any such delegation of power shall not relieve such officer of responsibility with respect to the exercise of such delegated power. All checks, notes, drafts, or other orders for the payment of money of the Corporation shall be signed, endorsed, or accepted in the name of the Corporation by such officer, officers, person, or persons as from time to time may be designated by the Board or by an officer or officers authorized by the Board to make such designation.

Section 9.9. Fiscal Year. The fiscal year of the Corporation shall be fixed by the Board.

Section 9.10. Seal. The Board may adopt a corporate seal, which shall be in such form as the Board determines. The seal may be used by causing it or a facsimile thereof to be impressed, affixed or otherwise reproduced, as may be prescribed by law or by the Board.

Section 9.11. Books and Records. The books and records of the Corporation may be kept within or outside the State of Delaware at such place or places as may from time to time be designated by the Board. Any records administered by or on behalf of the Corporation in the regular course of its business, including its stock ledger, books of account, and minute books, may be maintained on any information storage device, method, or one or more electronic networks or databases (including one or more distributed electronic networks or databases); provided that the records so kept can be converted into clearly legible paper form within a reasonable time, and, with respect to the stock ledger, the records so kept comply with Section 224 of the DGCL. The Corporation shall so convert any records so kept upon the request of any person entitled to inspect such records pursuant to applicable law.

Section 9.12. Surety Bonds. Such officers, employees and agents of the Corporation (if any) as the Chair of the Board, Chief Executive Officer, President or the Board may direct, from time to time, shall be bonded for the faithful performance of their duties and for the restoration to the Corporation, in case of their death, resignation, retirement, disqualification or removal from office, of all books, papers, vouchers, money and other property of whatever kind in their possession or under their control belonging to the Corporation, in such amounts and by such surety companies as the Chair of the Board, Chief Executive Officer, President or the Board may determine. The premiums on such bonds shall be paid by the Corporation and the bonds so furnished shall be in the custody of the Secretary.

Section 9.13. Securities of Other Corporations. Powers of attorney, proxies, waivers of notice of meeting, consents in writing and other instruments relating to securities owned by the Corporation may be executed in the name of and on behalf of the Corporation by the Chair of the Board, Chief Executive Officer, President, any Vice President or any officers authorized by the Board. Any such officer, may, in the name of and on behalf of the Corporation, take all such action as any such officer may deem advisable to vote in person or by proxy at any meeting of security holders of any corporation in which the Corporation may own securities, or to consent in writing, in the name of the Corporation as such holder, to any action by such corporation, and at any such meeting or with respect to any such consent shall possess and may exercise any and all rights and power incident to the ownership of such securities and which, as the owner thereof, the Corporation might have exercised and possessed. The Board may from time to time confer like powers upon any other person or persons.

Section 9.14. Amendments. The Board shall have the power to adopt, amend, alter or repeal the Bylaws. The affirmative vote of a majority of the Board shall be required to adopt, amend, alter or repeal the Bylaws. The Bylaws also may be adopted, amended, altered or repealed by the stockholders; provided, however, that in addition to any vote of the holders of any class or series of capital stock of the Corporation required by applicable law or the Certificate of Incorporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power (except as otherwise provided in Section 8.6) of all outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required for the stockholders to adopt, amend, alter or repeal the Bylaws.

Section 9.15. Exclusive Forum. Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery lacks jurisdiction, the federal district court for the District of Delaware unless said court lacks subject matter jurisdiction in which case the Superior Court of the State of Delaware) shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Corporation, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (c) any action asserting a claim arising under any provision of the DGCL, the Certificate of Incorporation or these Bylaws or (d) any action asserting a claim governed by the internal affairs doctrine, except for, as to each of (a) through (d) above, any claim (A) as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), (B) which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or (C) for which the Court of Chancery does not have subject matter jurisdiction. Notwithstanding any of the foregoing to the contrary, unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under federal securities laws, including the Securities Act of 1933, as amended. Notwithstanding any of the foregoing to the contrary, the provisions of this Section 9.15 will not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. If any action the subject matter of which is within the scope of the preceding sentence is filed in a court other than a court located within the State of Delaware (a "***Foreign Action***") in the name of any stockholder, then such stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the preceding sentence and (ii) having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

Adopted March 18, 2025

Exhibit 10.11

Processa Pharmaceuticals

EXECUTIVE EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made and entered into as of March 19, 2025 ("**Effective Date**"), by and between George Ng (the "**Executive**") and Processa Pharmaceuticals, Inc., a Delaware corporation (the "**Company**" or "**Processa**") (collectively referred to herein as the "Parties").

WHEREAS, the Company desires to employ the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to be employed by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

1. **Term**. This Agreement shall be effective for the term beginning on the Effective Date and continue until terminated or modified pursuant to Section 4 of this Agreement. The period during which the Executive is employed by the Company hereunder is hereinafter referred to as the "**Employment Term.**"

2. **Position and Duties**. During the Employment Term, the Executive shall serve as the Chief Financial Officer of the Company. In such position, the Executive shall have such duties, authority, and responsibilities as shall be mutually agreed upon by the Chief Executive Officer and the Executive, which duties, authority, and responsibilities are consistent with the Executive's position and prevailing industry standards. During the Employment Term, the Executive shall devote substantially all of the Executive's business time and attention to the performance of the Executive's duties hereunder and will not engage in any other business, profession, or occupation for compensation, which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the Company's Chief Executive Officer ("**CEO**"). Notwithstanding, the Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, investments and holdings, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, (iv) serve on the board of directors of for-profit organizations that do not directly compete with the Company, with the prior approval of the CEO and (iv) conduct business and other matters that were previously disclosed to the Company prior to the Employment Term, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder.

3. **Compensation and Benefits**.

3.1 Base Salary. The Company shall pay the Executive an annual base salary of $400,000, less all lawfully required deductions and withholdings ("**Base Salary**"), which will be paid in periodic installments in accordance with the Company's customary payroll practices and applicable wage payment laws, but no less frequently than monthly. The Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the CEO and Compensation Committee of the Company's Board. Executive's Base Salary may not be subject to reduction from the level set forth above, unless pursuant to a salary reduction program of general application to employment contract executives of the Company, provided that, unless agreed to in writing by Executive, the percentage reduction of Executive's Base Salary shall not be greater than the percentage reduction applied to any other employment contract executive of the Company.

3.2 Bonus. This is a non-qualified plan used by the Company to provide special compensation to key executives. The Company's contribution to an executive bonus plan is considered salary to the Executive and is therefore subject to taxation. The Executive is eligible to participate in the bonus pool with a target bonus equal to 50% of Executive's Base Salary, as then in effect (the "Target Bonus"), as may be awarded pursuant to any annual executive bonus plan and related corporate goals approved solely at the discretion of the Compensation Committee of the Board. Any such Annual Bonus shall contain such rights and features as are typically afforded to other contract executives of the Company.

3.3 Equity Compensation (RSUs, RSAs, Stock Options, Other). The Compensation Committee of the Board (the "**Compensation Committee**"), and pursuant to Processa's 2019 Omnibus Incentive Plan, or any such additional incentive plans that may be in place at such time, (the "**Plan**") has previously granted new hire RSUs to Employee. Any additional equity grants will be at the reasonable discretion of the Compensation Committee of the Board. The specifics of the grants will be described in the Award Agreement to be provided to the Executive. Notwithstanding the above and any other sections in this Agreement, all unvested equity granted herein, any additional unvested granted and any other unvested equity-linked securities that may be granted in the future shall immediately vest upon a Change in Control (as defined in Section 4.5).

3.4 Incentive and Deferred Compensation. Employee shall be eligible to participate in all incentive and deferred compensation programs available to other executives or officers of Processa, such participation to be in the same form, under the same terms, and to the same extent that such programs are made available to other such similarly situated executives or officers. Except as otherwise provided herein, nothing in this Agreement shall be deemed to require the payment of bonuses, awards, or incentive compensation to Employee if such payment would not otherwise be required under the terms of Processa's incentive compensation programs. The Company reserves the right to interpret, amend or terminate any incentive compensation program at any time in its sole discretion, subject to the terms of such incentive compensation program and applicable law.

3.5 Employee Benefits. During the Employment Term, the Executive shall be entitled to participate in all employee benefit plans, practices, and programs maintained by the Company, as in effect from time to time (collectively, "**Employee Benefit Plans**"), on a basis which is no less favorable than is provided to other similarly situated executives of the Company, to the extent consistent with applicable law and the terms of the applicable Employee Benefit Plans. The Company reserves the right to amend or terminate any Employee Benefit Plans at any time in its sole discretion, subject to the terms of such Employee Benefit Plan and applicable law.

3.6 Paid Time Off. During the Employment Term, the Executive will be entitled to earn and use paid time off ("**PTO**") in accordance with the terms of the Company's PTO policy.

3.7 Business Expenses. The Executive shall be entitled to reimbursement for all reasonable and necessary out-of-pocket business, entertainment, and travel expenses incurred by the Executive in connection with the performance of the Executive's duties hereunder in accordance with the Company's expense reimbursement policies and procedures.

3.8 Withholding. By signing this Agreement, the Executive hereby authorizes the Company to withhold from any amount payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

4. **Termination of Employment**. The Employment Term and the Executive's employment with the Company may be terminated upon the following conditions or events:

4.1 Death or Permanent Disability. The Executive employment under this Agreement and the Employment Term shall terminate immediately in the event of the death or Permanent Disability of Executive. "Permanent Disability" shall be defined as (1) Executive's inability to perform the essential functions of his position, with or without reasonable accommodation, for a period of six consecutive months or for an aggregate of six months in any twelve month period, as determined by a physician licensed to practice medicine and designated by Employer and acceptable to the Executive, having reviewed and considered information provided by the Executive's healthcare provider(s); (2) if the Executive is subject to a legal decree of incompetency; or (3) the Executive receives benefits pursuant to a long-term disability insurance plan, and the person or persons required to make disability determinations under the long-term disability plan determines that the Executive has a disability that, if Executive qualified for such disability benefits, would provide coverage for the longest period of time.. Any refusal by the Executive to submit to a medical examination for the purpose of determining a Permanent Disability shall be deemed to constitute conclusive evidence of the Executive's Permanent Disability.

4.2 Termination by Executive. The Executive may voluntarily terminate their employment with the Company by providing at least ninety (90) days written notice to the Company of such termination. Once such notice is given, the Company may elect to terminate the Executive prior to the conclusion of the ninety-day period. The Executive shall be paid their Base Salary through the end of the 90-day period. The Executive may also terminate their employment hereunder for "Good Reason." For the purpose of determining Executive's right to Severance Pay and other payments described in Section 5.2 and elsewhere in this Agreement, the Executive's resignation will be for "Good Reason" if the Executive resigns after any of the following events: (A) a decrease of more than 5% in Executive's Base Salary or annual target bonus opportunity other than a reduction in Executive's Base Salary or annual target bonus opportunity that is implemented in connection with a contemporaneous, temporary reduction in annual base salaries by the same percentage affecting other senior executives of the Company or (B) a material decrease in the Executive's authority or areas of responsibility as are commensurate with such Executive's title or position.

4.3 Termination by the Company Without Cause. The Company may terminate the Executive's employment hereunder for any reason other than Cause by delivering written notice of termination to the Executive at least ninety (90) days prior to the date of termination. The Company may elect to earlier terminate and pay Executive their regular Base Salary and benefits through the end of the 90-day period as an addition to severance pay in lieu of such notice.

4.4 Termination by the Company for Cause. Employer may terminate the Executive immediately for Cause. For purposes of this Agreement, "Cause" shall mean:

a) the Executive's refusal or inability to perform or observe any of the Executive's material duties, responsibilities or obligations set forth in this Agreement (other than any such refusal or inability resulting from Executive's Permanent Disability); provided, however, that Employer shall not be deemed to have Cause pursuant to this clause unless the Company gives the Executive written notice that the specified conduct has occurred and the Executive fails to cure the conduct within thirty (30) days after receipt of such notice;

b) any act of the Executive involving fraud, theft, misappropriation of funds, or embezzlement;

c) the Executive is convicted of any felony or misdemeanor involving dishonesty, violence or moral turpitude, or which in the reasonable judgment of the Company, reflects materially and adversely on the reputation of the Company;

d) the Executive's material failure to comply with any of the Company's policies, including but not limited to by engaging in the illegal use of controlled substances, the knowing abuse of prescribed medications, or the misuse of alcohol;

e) the Executive's material breach of fiduciary duty of care, loyalty, and good faith, ensuring diligent, company-focused actions and legal compliance.

4.5 Termination of Employment Involving a Change of Control. The Executive's employment with the Company may be terminated in the event that a Change in Control occurs, and the Executive's employment with the Company is terminated by the Company Without Cause or by the Executive for Good Reason at any time within the three (3) month period before the date of and in connection with such Change in Control or during the twelve (12) month period following the date of such Change in Control ("**Termination as a Result of a Change in Control**"). For purposes of this Section, "**Change in Control**" shall mean and include:

a) Acquisition by any "Person" or "Group" of securities entitled to vote generally in the election of directors ("voting securities") of the Company that represent 50% or more of the combined voting power of the Company's then outstanding voting securities;

b) A change in the composition of the Board occurring within a twelve (12) month period, as a result of which a majority of the incumbent directors are replaced by directors whose appointment or election is not endorsed by a majority of the incumbent directors before the date of the appointment or election;

c) Merger or consolidation in which the seller's shareholders no longer control the surviving entity;

d) Sale of substantially all assets to an unrelated entity.

4.6 Resignation of All Other Positions. On termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned from all positions that the Executive holds as an officer or member of the Board (or a committee thereof) of the Company or any of its affiliates (and shall confirm such resignation in writing upon the request of the Company).

4.7 Termination Date. The final date on which the Executive is actually employed by the Company pursuant to this Agreement shall be the "**Termination Date**."

5. **Compensation on Termination of Employment**.

5.1 Earned and Accrued Payments. In the event that the Executive's employment is terminated, the Executive shall be entitled to receive: (a) any accrued but unpaid Base Salary, which shall be paid on the pay date immediately following the Executive's Termination Date, unless earlier required by applicable law; (b) any accrued but unpaid target annual bonus or any other granted bonus where such bonus was determined prior to the Termination Date, which shall be paid on the otherwise applicable payment date; (c) reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and (d) such employee benefits (including equity compensation), if any, to which the Executive may be entitled under the Company's employee benefit plans as of the Termination Date; provided that, in no event shall the Executive be entitled to any payments in the nature of severance or termination payments except as specifically provided herein. The treatment of any outstanding equity awards shall be determined in accordance with the terms in this Agreement, of the Plan and the applicable award agreements. For clarification purposes, if the Termination Date occurs prior to the date of payment of the prior year bonus, the entire unpaid bonus from the prior year plus the pro-rata accrued but unpaid bonus from the year of the Termination date would be included in 5.1(b).

5.2 Severance Pay. In the event that the Executive's employment with the Company is terminated due to death or Permanent Disability, by the Company Without Cause, the Executive terminates employment with the Company for Good Reason, and/or there is a Termination as a Result of a Change in Control (each a "Separation Event"), the Executive shall be entitled to:

a. One year of Base Salary and Target Bonus ("**Severance Pay**"), paid out in accordance with the normal payroll practices of the Company following the Termination Date and paid out over the twelve (12) month period. Payment of any Severance Pay shall be conditioned upon the Executive executing and not revoking a separation agreement reasonably satisfactory to the Company (or its successor) and to the Executive, including a general release of all claims that is reasonably satisfactory with terms substantially similar to typical agreements to the Company (or its successor) and the Executive; and

b. For the twelve (12) month period following the Separation Event, (or, if earlier, the date on which the applicable continuation period under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") expires), and the Executive has elected COBRA coverage then the Company shall arrange to provide Executive and his eligible dependents who were covered under the Company's health insurance plans as of the date of the Separation Event with health (including medical and dental) insurance benefits substantially similar to those provided to such dependents immediately prior to the date of such Separation Event. The Executive will be responsible for any portion of the premium associated with such coverage that he was responsible for during employment. If the Company is not reasonably able to continue health insurance benefits coverage under the Company's insurance plans, the Company shall provide substantially equivalent coverage under other third-party insurance sources. If any of the Company's health benefits are self-funded as of the date of Separation Event, or if the Company cannot provide the foregoing benefits in a manner that exempt from Section 409A of the Code or that is otherwise compliant with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), instead of providing continued health insurance benefits as set forth above, the Company shall instead pay to the Executive an amount equal to twelve (12) multiplied by the monthly premium the Executive would be required to pay for continuation coverage pursuant to the COBRA for his/her eligible dependents who were covered under the Company's health plans as of the date of the Separation Event (calculated by reference to the premium as of the date of the Separation Event), which amount shall be paid on the Payment Date. Eligibility for this benefit is contingent upon the execution and nonrevocation of the separation agreement referenced above.

5.3 Section 280G. If the Executive becomes entitled to any amount in the nature of compensation payable by the Company that is contingent on a change in ownership, effective control, or substantial ownership of a substantial portion of the Company's assets within the meaning of Section 280G of the Internal Revenue Code ("Covered Payments") and constitute "Parachute Payments" within the meaning within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and that is subject to the excise tax imposed by Section 4999 of the Code ("Excise Tax"), a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the "Reduced Amount"). "Net Benefit" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes. In the event reduction is required, the Covered Payments shall be reduced by the Company in the following order: (i) cash severance payments hereunder to the extent not subject to Section 409A of the Code in the reverse order of payment; (ii) any other portion of the Covered Payments that are not subject to Section 409A of the Code in the reverse order of payment (other than any acceleration of vesting of equity awards); (iii) Covered Payments that are not subject to Section 409A of the Code that arise from the accelerated vesting of equity awards, and; (iv) Covered Payments that are subject to Section 409A of the Code in a manner consistent with Section 409A of the Code. All determinations pursuant to this Section 5.4 shall be made by tax accountants selected by the Company and reasonably acceptable to Executive (the "Accountants"), whose determinations shall be binding on the Company and the Executive absent manifest error. The Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order for the Accountants to make their determinations.

6. **Return of Property and Employee Non-Solicit**.

6.1 Return of Property. Upon termination of Executive's employment with the Company for any reason, upon request, Executive will use reasonable efforts to promptly deliver to the Company all equipment, correspondence, drawings, manuals, letters, notes, notebooks, reports, programs, plans, proposals, financial documents, or any other documents or property containing material information pertaining to the Company's customers, business plans, marketing strategies, products, property or processes..

6.2 Non-Solicitation of Employees Covenant. Executive acknowledges that the Company's employees and consultants are a valuable asset to the Company, especially because such employees have access to and knowledge of the Company's confidential information and trade secrets. As such, Executive agrees for a period of one-year from the Termination Date, with respect to any Company employee with whom Executive had material business contact during their employment with the Company, Executive will not (i) induce or attempt to induce such employee of the Company to leave employment or contracting with the Company; or (ii) directly solicit the services of or hire away such current employee of the Company.

6.3 Notification of Future Employers. Executive hereby agrees to notify any future employers or prospective employers of the foregoing obligations and authorizes the Company to provide a single notice of the terms in Section 6 to Executive's actual or future employers (or persons or entities that contract or seek to contract for Executive's services).

6.4 Remedies. In the event of a breach or threatened breach by either party, each party hereby consents and agrees that the non-breaching party may (as determined by a court of law or proper judicial authority) be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, and that money damages would not afford an adequate remedy, without the necessity of showing any actual damages. The aforementioned equitable relief may (as determined by a court of law or proper judicial authority) be in addition to, not in lieu of, legal remedies, monetary damages, or other available forms of relief.

7. **Assignment of Inventions and Rights**.

7.1 Work Product. The Executive acknowledges and agrees that all designs, devices, discoveries, processes, proprietary software, writings, inventions, improvements and documentation, and any other works of authorship (collectively, "**Work Product**"), and all related know-how, produced, made, conceived or authored by the Executive, solely or jointly with others, in the course of his employment with the Company together with any intellectual property rights concerning the Work Product produced, made, conceived or authored by the Executive, including any moral rights relating to any of the foregoing, are works made for hire and the property of the Company if such works (i) result or are derived from, at the time the Work Product is produced, made, conceived or reduced to practice, the actual business, research, or development of the Company; or (ii) are result from any work performed by the Executive for or on behalf of the Company; or (iii) are created or developed with the use of Proprietary Information or Company equipment, supplies, facilities, information, materials or other Company resources ("Company IP"). The Executive shall disclose in writing any such Company IP promptly to the Company and hereby irrevocably assign any and all rights in their entirety, throughout the world, in and to such works to the Company or its assignees.

7.2 To the extent that any such Company IP may not, by operation of law, be deemed works made for hire, this Agreement shall constitute an irrevocable assignment by the Executive to the Company of the ownership of, and all right, title, and interest in and to such items, including an irrevocable assignment of all moral rights relating thereto, and the Company shall have the right to obtain and hold in its own name, all intellectual property rights, including without limitation, patent, trade secret, copyright and similar protections which may be available in such Company IP throughout the world.

7.3 The Executive agrees that all work product made by them after the end of employment with the Company, whether created solely by the Executive or jointly with others, that is based on or contains Confidential Information of the Company, shall belong to the Company; and the Executive irrevocably assigns any and all rights in their entirety, throughout the world, in and to such future Work Product to the Company.

7.4 The Executive agrees to use reasonable efforts to assist the Company, or its designee or assignee, to secure and perfect the Company's (and/or such designee's) rights in such Work Product and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights relating thereto in any and all countries, including the written disclosure to the Company of all information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments which the Company shall deem necessary in order to apply for, obtain and protect such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title and interest in and to such Company IP, and any copyright, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights contained therein and/or relating thereto. The Executive further agrees that their obligation to execute or cause to be executed any such instrument or papers shall continue after employment with the Company ends. The Executive shall be entitled to reimbursement for reasonable expenses in providing such post-employment assistance.

7.5 In the event the Company is unable due to Executive's subsequent disability, incapacity or for any other reason whatsoever to secure his signature to any lawful and necessary document required to apply for, register or execute any patent, copyright or other applications with respect to any such Company IP, the Executive hereby irrevocably appoints the Company and its duly authorized officers and agents as its agents and attorneys-in-fact to execute and file any such application and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights or other rights thereon with the same legal force and effect as if executed by the Executive.

7.6 In the event Company should not desire to secure and perfect its rights to any Company IP, but should desire to keep the same secret, the Executive agrees that they will do everything reasonably in his power to assist Company in this and will not disclose any information relating to such Company IP except with the prior written consent of Company.

7.7 In order to permit the Company to claim rights to which it may be entitled, Executive agrees to disclose to the Company in writing and in confidence all inventions or Company IP that Executive makes or conceive of, either solely or jointly with others, during the term of his employment with the Company.

7.8 All Work Product that was made by the Executive before his employment with the Company (collectively referred to as "Prior Inventions") are excluded from Section 5 of this Agreement. The Executive agrees not to incorporate into a Company product, process or code, or other Company Work Product, a Prior Invention.

8. Acknowledgement. The Executive acknowledges and agrees that the services to be rendered by the Executive to the Company are of a special and unique character; that the Executive will obtain knowledge and skill relevant to the Company's industry, methods of doing business and marketing strategies by virtue of the Executive's employment; and that the restrictive covenants and other terms and conditions of this Agreement are reasonable and reasonably necessary to protect the legitimate business interest of the Company.

9. Governing Law: Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of Delaware without regard to conflicts of law principles. Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the State of Delaware. The parties hereby irrevocably submit to the exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

10. Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court and can be cited as evidence in legal proceedings alleging breach of the Agreement.

11. Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

12. Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement. The parties further agree that any such court is expressly authorized to modify any such unenforceable provision of this Agreement in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Agreement, or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties as embodied herein to the maximum extent permitted by law. The parties expressly agree that this Agreement as so modified by the court shall be binding upon and enforceable against each of them. In any event, should one or more of the provisions of this Agreement be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions hereof, and if such provision or provisions are not modified as provided above, this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had not been set forth herein.

13. Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

14. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

15. Section 409A.

15.1 General. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

15.2 Separation from Service. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is considered nonqualified deferred compensation under Section 409A and is designated under this Agreement as payable upon the Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4(b) shall not be paid until the fifty-fifth (55th) day following Executive's Separation from Service (the "First Payment Date").

15.3 Specified Employee. Notwithstanding anything in this Agreement to the contrary, if the Executive is deemed by the Company at the time of the Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of the Executive's benefits shall not be provided to the Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of the Executive's Separation from Service with the Company or (ii) the date of the Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to the Executive (or the Executive's estate or beneficiaries), and any remaining payments due to the Executive under this Agreement shall be paid as otherwise provided herein.

15.4 Expense Reimbursements. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to the Executive shall be paid to the Executive no later than December 31st of the calendar year following the calendar year in which the expense was incurred; provided, that the Executive submits the Executive's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one calendar year shall not affect the amount eligible for reimbursement in any subsequent calendar year, other than medical expenses referred to in Section 105(b) of the Code, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

15.5 Installments. The Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on the Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

16. Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

17. Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company: Chief Administrative Officer
Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076

If to the Executive: Mr. George Ng
6411 Lilac Mist Bend
San Diego, CA 92130

18. Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

19. Acknowledgement of Full Understanding. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS FULLY READ, UNDERSTANDS AND VOLUNTARILY ENTERS INTO THIS AGREEMENT. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS HAD AN OPPORTUNITY TO ASK QUESTIONS AND CONSULT WITH AN ATTORNEY OF THE EXECUTIVE'S CHOICE BEFORE SIGNING THIS AGREEMENT.

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SIGNATURES TO FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

PROCESSA PHARMACEUTICALS, INC.	**MR. GEORGE NG**
By: */s/ Justin Yorke* Justin Yorke, Chairman of the Board	*/s/ George Ng*

Exhibit 10.12

Processa Pharmaceuticals

EXECUTIVE EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made and entered into as of March 19, 2025 ("**Effective Date**"), by and between Russell Skibsted (the "**Executive**") and Processa Pharmaceuticals, Inc., a Delaware corporation (the "**Company**" or "**Processa**") (collectively referred to herein as the "Parties").

WHEREAS, the Company desires to employ the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to be employed by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

1. **Term**. This Agreement shall be effective for the term beginning on the Effective Date and continue until terminated or modified pursuant to Section 4 of this Agreement. The period during which the Executive is employed by the Company hereunder is hereinafter referred to as the "**Employment Term.**"

2. **Position and Duties**. During the Employment Term, the Executive shall serve as the Chief Financial Officer of the Company. In such position, the Executive shall have such duties, authority, and responsibilities as shall be mutually agreed upon by the Chief Executive Officer and the Executive, which duties, authority, and responsibilities are consistent with the Executive's position and prevailing industry standards. During the Employment Term, the Executive shall devote substantially all of the Executive's business time and attention to the performance of the Executive's duties hereunder and will not engage in any other business, profession, or occupation for compensation, which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the Company's Chief Executive Officer ("**CEO**"). Notwithstanding, the Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, investments and holdings, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, (iv) serve on the board of directors of for-profit organizations that do not directly compete with the Company, with the prior approval of the CEO and (iv) conduct business and other matters that were previously disclosed to the Company prior to the Employment Term, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder.

3. **Compensation and Benefits**.

3.1 Base Salary. The Company shall pay the Executive an annual base salary of $400,000, less all lawfully required deductions and withholdings ("**Base Salary**"), which will be paid in periodic installments in accordance with the Company's customary payroll practices and applicable wage payment laws, but no less frequently than monthly. The Executive will be eligible for a $50,000 base salary increase upon a cumulative (one or multiple) financing of at least $15 Million that he leads and substantially participates in. The Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the CEO and Compensation Committee of the Company's Board. Executive's Base Salary may not be subject to reduction from the level set forth above, unless pursuant to a salary reduction program of general application to employment contract executives of the Company, provided that, unless agreed to in writing by Executive, the percentage reduction of Executive's Base Salary shall not be greater than the percentage reduction applied to any other employment contract executive of the Company.

3.2 Bonus. This is a non-qualified plan used by the Company to provide special compensation to key executives. The Company's contribution to an executive bonus plan is considered salary to the Executive and is therefore subject to taxation. The Executive is eligible to participate in the bonus pool with a target bonus equal to 40% of Executive's Base Salary, as then in effect (the "Target Bonus"), as may be awarded pursuant to any annual executive bonus plan and related corporate goals approved solely at the discretion of the Compensation Committee of the Board. Any such Annual Bonus shall contain such rights and features as are typically afforded to other contract executives of the Company.

3.3 Equity Compensation (RSUs, RSAs, Stock Options, Other). The Compensation Committee of the Board (the "**Compensation Committee**"), and pursuant to Processa's 2019 Omnibus Incentive Plan, or any such additional incentive plans that may be in place at such time, (the "**Plan**") has previously granted new hire RSUs to Employee. Any additional equity grants will be at the reasonable discretion of the Compensation Committee of the Board. The specifics of the grants will be described in the Award Agreement to be provided to the Executive. Notwithstanding the above and any other sections in this Agreement, all unvested equity granted herein, any additional unvested granted and any other unvested equity-linked securities that may be granted in the future shall immediately vest upon a Change in Control (as defined in Section 4.5).

3.4 Incentive and Deferred Compensation. Employee shall be eligible to participate in all incentive and deferred compensation programs available to other executives or officers of Processa, such participation to be in the same form, under the same terms, and to the same extent that such programs are made available to other such similarly situated executives or officers. Except as otherwise provided herein, nothing in this Agreement shall be deemed to require the payment of bonuses, awards, or incentive compensation to Employee if such payment would not otherwise be required under the terms of Processa's incentive compensation programs. The Company reserves the right to interpret, amend or terminate any incentive compensation program at any time in its sole discretion, subject to the terms of such incentive compensation program and applicable law.

3.5 Employee Benefits. During the Employment Term, the Executive shall be entitled to participate in all employee benefit plans, practices, and programs maintained by the Company, as in effect from time to time (collectively, "**Employee Benefit Plans**"), on a basis which is no less favorable than is provided to other similarly situated executives of the Company, to the extent consistent with applicable law and the terms of the applicable Employee Benefit Plans. The Company reserves the right to amend or terminate any Employee Benefit Plans at any time in its sole discretion, subject to the terms of such Employee Benefit Plan and applicable law.

3.6 Paid Time Off. During the Employment Term, the Executive will be entitled to earn and use paid time off ("**PTO**") in accordance with the terms of the Company's PTO policy.

3.7 Business Expenses. The Executive shall be entitled to reimbursement for all reasonable and necessary out-of-pocket business, entertainment, and travel expenses incurred by the Executive in connection with the performance of the Executive's duties hereunder in accordance with the Company's expense reimbursement policies and procedures.

3.8 Withholding. By signing this Agreement, the Executive hereby authorizes the Company to withhold from any amount payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

4. **Termination of Employment**. The Employment Term and the Executive's employment with the Company may be terminated upon the following conditions or events:

4.1 Death or Permanent Disability. The Executive employment under this Agreement and the Employment Term shall terminate immediately in the event of the death or Permanent Disability of Executive. "Permanent Disability" shall be defined as (1) Executive's inability to perform the essential functions of his position, with or without reasonable accommodation, for a period of six consecutive months or for an aggregate of six months in any twelve month period, as determined by a physician licensed to practice medicine and designated by Employer and acceptable to the Executive, having reviewed and considered information provided by the Executive's healthcare provider(s); (2) if the Executive is subject to a legal decree of incompetency; or (3) the Executive receives benefits pursuant to a long-term disability insurance plan, and the person or persons required to make disability determinations under the long-term disability plan determines that the Executive has a disability that, if Executive qualified for such disability benefits, would provide coverage for the longest period of time.. Any refusal by the Executive to submit to a medical examination for the purpose of determining a Permanent Disability shall be deemed to constitute conclusive evidence of the Executive's Permanent Disability.

4.2 Termination by Executive. The Executive may voluntarily terminate their employment with the Company by providing at least ninety (90) days written notice to the Company of such termination. Once such notice is given, the Company may elect to terminate the Executive prior to the conclusion of the ninety-day period. The Executive shall be paid their Base Salary through the end of the 90-day period. The Executive may also terminate their employment hereunder for "Good Reason." For the purpose of determining Executive's right to Severance Pay and other payments described in Section 5.2 and elsewhere in this Agreement, the Executive's resignation will be for "Good Reason" if the Executive resigns after any of the following events: (A) a decrease of more than 5% in Executive's Base Salary or annual target bonus opportunity other than a reduction in Executive's Base Salary or annual target bonus opportunity that is implemented in connection with a contemporaneous, temporary reduction in annual base salaries by the same percentage affecting other senior executives of the Company or (B) a material decrease in the Executive's authority or areas of responsibility as are commensurate with such Executive's title or position.

4.3 Termination by the Company Without Cause. The Company may terminate the Executive's employment hereunder for any reason other than Cause by delivering written notice of termination to the Executive at least ninety (90) days prior to the date of termination. The Company may elect to earlier terminate and pay Executive their regular Base Salary and benefits through the end of the 90-day period as an addition to severance pay in lieu of such notice.

4.4 Termination by the Company for Cause. Employer may terminate the Executive immediately for Cause. For purposes of this Agreement, "Cause" shall mean:

a) the Executive's refusal or inability to perform or observe any of the Executive's material duties, responsibilities or obligations set forth in this Agreement (other than any such refusal or inability resulting from Executive's Permanent Disability); provided, however, that Employer shall not be deemed to have Cause pursuant to this clause unless the Company gives the Executive written notice that the specified conduct has occurred and the Executive fails to cure the conduct within thirty (30) days after receipt of such notice;

b) any act of the Executive involving fraud, theft, misappropriation of funds, or embezzlement;

c) the Executive is convicted of any felony or misdemeanor involving dishonesty, violence or moral turpitude, or which in the reasonable judgment of the Company, reflects materially and adversely on the reputation of the Company;

d) the Executive's material failure to comply with any of the Company's policies, including but not limited to by engaging in the illegal use of controlled substances, the knowing abuse of prescribed medications, or the misuse of alcohol;

e) the Executive's material breach of fiduciary duty of care, loyalty, and good faith, ensuring diligent, company-focused actions and legal compliance.

4.5 Termination of Employment Involving a Change of Control. The Executive's employment with the Company may be terminated in the event that a Change in Control occurs, and the Executive's employment with the Company is terminated by the Company Without Cause or by the Executive for Good Reason at any time within the three (3) month period before the date of and in connection with such Change in Control or during the twelve (12) month period following the date of such Change in Control ("**Termination as a Result of a Change in Control**"). For purposes of this Section, "**Change in Control**" shall mean and include:

a) Acquisition by any "Person" or "Group" of securities entitled to vote generally in the election of directors ("voting securities") of the Company that represent 50% or more of the combined voting power of the Company's then outstanding voting securities;

b) A change in the composition of the Board occurring within a twelve (12) month period, as a result of which a majority of the incumbent directors are replaced by directors whose appointment or election is not endorsed by a majority of the incumbent directors before the date of the appointment or election;

c) Merger or consolidation in which the seller's shareholders no longer control the surviving entity;

d) Sale of substantially all assets to an unrelated entity.

4.6 Resignation of All Other Positions. On termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned from all positions that the Executive holds as an officer or member of the Board (or a committee thereof) of the Company or any of its affiliates (and shall confirm such resignation in writing upon the request of the Company).

4.7 Termination Date. The final date on which the Executive is actually employed by the Company pursuant to this Agreement shall be the "**Termination Date**."

5. **Compensation on Termination of Employment**.

5.1 Earned and Accrued Payments. In the event that the Executive's employment is terminated, the Executive shall be entitled to receive: (a) any accrued but unpaid Base Salary, which shall be paid on the pay date immediately following the Executive's Termination Date, unless earlier required by applicable law; (b) any accrued but unpaid target annual bonus or any other granted bonus where such bonus was determined prior to the Termination Date, which shall be paid on the otherwise applicable payment date; (c) reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and (d) such employee benefits (including equity compensation), if any, to which the Executive may be entitled under the Company's employee benefit plans as of the Termination Date; provided that, in no event shall the Executive be entitled to any payments in the nature of severance or termination payments except as specifically provided herein. The treatment of any outstanding equity awards shall be determined in accordance with the terms in this Agreement, of the Plan and the applicable award agreements. For clarification purposes, if the Termination Date occurs prior to the date of payment of the prior year bonus, the entire unpaid bonus from the prior year plus the pro-rata accrued but unpaid bonus from the year of the Termination date would be included in 5.1(b).

5.2 Severance Pay. In the event that the Executive's employment with the Company is terminated due to death or Permanent Disability, by the Company Without Cause, the Executive terminates employment with the Company for Good Reason, and/or there is a Termination as a Result of a Change in Control (each a "Separation Event"), the Executive shall be entitled to:

a. One year of Base Salary and Target Bonus ("**Severance Pay**"), paid out in accordance with the normal payroll practices of the Company following the Termination Date and paid out over the twelve (12) month period. Payment of any Severance Pay shall be conditioned upon the Executive executing and not revoking a separation agreement reasonably satisfactory to the Company (or its successor) and to the Executive, including a general release of all claims that is reasonably satisfactory with terms substantially similar to typical agreements to the Company (or its successor) and the Executive; and

b. For the twelve (12) month period following the Separation Event, (or, if earlier, the date on which the applicable continuation period under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") expires), and the Executive has elected COBRA coverage then the Company shall arrange to provide Executive and his eligible dependents who were covered under the Company's health insurance plans as of the date of the Separation Event with health (including medical and dental) insurance benefits substantially similar to those provided to such dependents immediately prior to the date of such Separation Event. The Executive will be responsible for any portion of the premium associated with such coverage that he was responsible for during employment. If the Company is not reasonably able to continue health insurance benefits coverage under the Company's insurance plans, the Company shall provide substantially equivalent coverage under other third-party insurance sources. If any of the Company's health benefits are self-funded as of the date of Separation Event, or if the Company cannot provide the foregoing benefits in a manner that exempt from Section 409A of the Code or that is otherwise compliant with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), instead of providing continued health insurance benefits as set forth above, the Company shall instead pay to the Executive an amount equal to twelve (12) multiplied by the monthly premium the Executive would be required to pay for continuation coverage pursuant to the COBRA for his/her eligible dependents who were covered under the Company's health plans as of the date of the Separation Event (calculated by reference to the premium as of the date of the Separation Event), which amount shall be paid on the Payment Date. Eligibility for this benefit is contingent upon the execution and nonrevocation of the separation agreement referenced above.

5.3 Section 280G. If the Executive becomes entitled to any amount in the nature of compensation payable by the Company that is contingent on a change in ownership, effective control, or substantial ownership of a substantial portion of the Company's assets within the meaning of Section 280G of the Internal Revenue Code ("Covered Payments") and constitute "Parachute Payments" within the meaning within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and that is subject to the excise tax imposed by Section 4999 of the Code ("Excise Tax"), a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the "Reduced Amount"). "Net Benefit" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes. In the event reduction is required, the Covered Payments shall be reduced by the Company in the following order: (i) cash severance payments hereunder to the extent not subject to Section 409A of the Code in the reverse order of payment; (ii) any other portion of the Covered Payments that are not subject to Section 409A of the Code in the reverse order of payment (other than any acceleration of vesting of equity awards); (iii) Covered Payments that are not subject to Section 409A of the Code that arise from the accelerated vesting of equity awards, and; (iv) Covered Payments that are subject to Section 409A of the Code in a manner consistent with Section 409A of the Code. All determinations pursuant to this Section 5.4 shall be made by tax accountants selected by the Company and reasonably acceptable to Executive (the "Accountants"), whose determinations shall be binding on the Company and the Executive absent manifest error. The Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order for the Accountants to make their determinations.

6. **Return of Property and Employee Non-Solicit**.

6.1 Return of Property. Upon termination of Executive's employment with the Company for any reason, upon request, Executive will use reasonable efforts to promptly deliver to the Company all equipment, correspondence, drawings, manuals, letters, notes, notebooks, reports, programs, plans, proposals, financial documents, or any other documents or property containing material information pertaining to the Company's customers, business plans, marketing strategies, products, property or processes..

6.2 Non-Solicitation of Employees Covenant. Executive acknowledges that the Company's employees and consultants are a valuable asset to the Company, especially because such employees have access to and knowledge of the Company's confidential information and trade secrets. As such, Executive agrees for a period of one-year from the Termination Date, with respect to any Company employee with whom Executive had material business contact during their employment with the Company, Executive will not (i) induce or attempt to induce such employee of the Company to leave employment or contracting with the Company; or (ii) directly solicit the services of or hire away such current employee of the Company.

6.3 Notification of Future Employers. Executive hereby agrees to notify any future employers or prospective employers of the foregoing obligations and authorizes the Company to provide a single notice of the terms in Section 6 to Executive's actual or future employers (or persons or entities that contract or seek to contract for Executive's services).

6.4 Remedies. In the event of a breach or threatened breach by either party, each party hereby consents and agrees that the non-breaching party may (as determined by a court of law or proper judicial authority) be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, and that money damages would not afford an adequate remedy, without the necessity of showing any actual damages. The aforementioned equitable relief may (as determined by a court of law or proper judicial authority) be in addition to, not in lieu of, legal remedies, monetary damages, or other available forms of relief.

7. **Assignment of Inventions and Rights**.

7.1 Work Product. The Executive acknowledges and agrees that all designs, devices, discoveries, processes, proprietary software, writings, inventions, improvements and documentation, and any other works of authorship (collectively, "**Work Product**"), and all related know-how, produced, made, conceived or authored by the Executive, solely or jointly with others, in the course of his employment with the Company together with any intellectual property rights concerning the Work Product produced, made, conceived or authored by the Executive, including any moral rights relating to any of the foregoing, are works made for hire and the property of the Company if such works (i) result or are derived from, at the time the Work Product is produced, made, conceived or reduced to practice, the actual business, research, or development of the Company; or (ii) are result from any work performed by the Executive for or on behalf of the Company; or (iii) are created or developed with the use of Proprietary Information or Company equipment, supplies, facilities, information, materials or other Company resources ("Company IP"). The Executive shall disclose in writing any such Company IP promptly to the Company and hereby irrevocably assign any and all rights in their entirety, throughout the world, in and to such works to the Company or its assignees.

7.2 To the extent that any such Company IP may not, by operation of law, be deemed works made for hire, this Agreement shall constitute an irrevocable assignment by the Executive to the Company of the ownership of, and all right, title, and interest in and to such items, including an irrevocable assignment of all moral rights relating thereto, and the Company shall have the right to obtain and hold in its own name, all intellectual property rights, including without limitation, patent, trade secret, copyright and similar protections which may be available in such Company IP throughout the world.

7.3 The Executive agrees that all work product made by them after the end of employment with the Company, whether created solely by the Executive or jointly with others, that is based on or contains Confidential Information of the Company, shall belong to the Company; and the Executive irrevocably assigns any and all rights in their entirety, throughout the world, in and to such future Work Product to the Company.

7.4 The Executive agrees to use reasonable efforts to assist the Company, or its designee or assignee, to secure and perfect the Company's (and/or such designee's) rights in such Work Product and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights relating thereto in any and all countries, including the written disclosure to the Company of all information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments which the Company shall deem necessary in order to apply for, obtain and protect such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title and interest in and to such Company IP, and any copyright, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights contained therein and/or relating thereto. The Executive further agrees that their obligation to execute or cause to be executed any such instrument or papers shall continue after employment with the Company ends. The Executive shall be entitled to reimbursement for reasonable expenses in providing such post-employment assistance.

7.5 In the event the Company is unable due to Executive's subsequent disability, incapacity or for any other reason whatsoever to secure his signature to any lawful and necessary document required to apply for, register or execute any patent, copyright or other applications with respect to any such Company IP, the Executive hereby irrevocably appoints the Company and its duly authorized officers and agents as its agents and attorneys-in-fact to execute and file any such application and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights or other rights thereon with the same legal force and effect as if executed by the Executive.

7.6 In the event Company should not desire to secure and perfect its rights to any Company IP, but should desire to keep the same secret, the Executive agrees that they will do everything reasonably in his power to assist Company in this and will not disclose any information relating to such Company IP except with the prior written consent of Company.

7.7 In order to permit the Company to claim rights to which it may be entitled, Executive agrees to disclose to the Company in writing and in confidence all inventions or Company IP that Executive makes or conceive of, either solely or jointly with others, during the term of his employment with the Company.

7.8 All Work Product that was made by the Executive before his employment with the Company (collectively referred to as "Prior Inventions") are excluded from Section 5 of this Agreement. The Executive agrees not to incorporate into a Company product, process or code, or other Company Work Product, a Prior Invention.

8. Acknowledgement. The Executive acknowledges and agrees that the services to be rendered by the Executive to the Company are of a special and unique character; that the Executive will obtain knowledge and skill relevant to the Company's industry, methods of doing business and marketing strategies by virtue of the Executive's employment; and that the restrictive covenants and other terms and conditions of this Agreement are reasonable and reasonably necessary to protect the legitimate business interest of the Company.

9. Governing Law: Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of Delaware without regard to conflicts of law principles. Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the State of Delaware. The parties hereby irrevocably submit to the exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

10. Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court and can be cited as evidence in legal proceedings alleging breach of the Agreement.

11. Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

12. Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement. The parties further agree that any such court is expressly authorized to modify any such unenforceable provision of this Agreement in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Agreement, or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties as embodied herein to the maximum extent permitted by law. The parties expressly agree that this Agreement as so modified by the court shall be binding upon and enforceable against each of them. In any event, should one or more of the provisions of this Agreement be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions hereof, and if such provision or provisions are not modified as provided above, this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had not been set forth herein.

13. Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

14. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

15. Section 409A.

15.1 General. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

15.2 Separation from Service. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is considered nonqualified deferred compensation under Section 409A and is designated under this Agreement as payable upon the Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4(b) shall not be paid until the fifty-fifth (55th) day following Executive's Separation from Service (the "First Payment Date").

15.3 Specified Employee. Notwithstanding anything in this Agreement to the contrary, if the Executive is deemed by the Company at the time of the Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of the Executive's benefits shall not be provided to the Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of the Executive's Separation from Service with the Company or (ii) the date of the Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to the Executive (or the Executive's estate or beneficiaries), and any remaining payments due to the Executive under this Agreement shall be paid as otherwise provided herein.

15.4 Expense Reimbursements. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to the Executive shall be paid to the Executive no later than December 31st of the calendar year following the calendar year in which the expense was incurred; provided, that the Executive submits the Executive's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one calendar year shall not affect the amount eligible for reimbursement in any subsequent calendar year, other than medical expenses referred to in Section 105(b) of the Code, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

15.5 Installments. The Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on the Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

16. Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

17. Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company: Chief Executive Officer
Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076

If to the Executive: Mr. Russell Skibsted
306 Trinity Overlook
Canton, GA 30115-7579

18. Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

19. Acknowledgement of Full Understanding. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS FULLY READ, UNDERSTANDS AND VOLUNTARILY ENTERS INTO THIS AGREEMENT. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS HAD AN OPPORTUNITY TO ASK QUESTIONS AND CONSULT WITH AN ATTORNEY OF THE EXECUTIVE'S CHOICE BEFORE SIGNING THIS AGREEMENT.

[REST OF PAGE INTENTIONALLY BLANK
SIGNATURES TO FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

PROCESSA PHARMACEUTICALS, INC.	**MR. RUSSELL SKIBSTED**
By: */s/ George Ng* George Ng, Chief Executive Officer	*/s/ Russell Skibsted*

Exhibit 10.13

EXECUTIVE EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made and entered into as of March 19, 2025 ("**Effective Date**"), by and between Dr. Sian Bigora (the "**Executive**") and Processa Pharmaceuticals, Inc., a Delaware corporation (the "**Company**" or "**Processa**") (collectively referred to herein as the "Parties").

WHEREAS, the Company desires to employ the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to be employed by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

1. **Term**. This Agreement shall be effective for the term beginning on the Effective Date and continue until terminated or modified pursuant to Section 4 of this Agreement. The period during which the Executive is employed by the Company hereunder is hereinafter referred to as the "**Employment Term.**"

2. **Position and Duties**. During the Employment Term, the Executive shall serve as the Chief Development and Regulatory Officer of the Company. In such position, the Executive shall have such duties, authority, and responsibilities as shall be mutually agreed upon by the Chief Executive Officer and the Executive, which duties, authority, and responsibilities are consistent with the Executive's position and prevailing industry standards. During the Employment Term, the Executive shall devote substantially all of the Executive's business time and attention to the performance of the Executive's duties hereunder and will not engage in any other business, profession, or occupation for compensation, which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the Company's Chief Executive Officer ("**CEO**"). Notwithstanding, the Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, investments and holdings, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, (iv) serve on the board of directors of for-profit organizations that do not directly compete with the Company, with the prior approval of the CEO and (iv) conduct business and other matters that were previously disclosed to the Company prior to the Employment Term, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder.

3. **Compensation and Benefits**.

3.1 Base Salary. The Company shall pay the Executive an annual base salary of $387,920, less all lawfully required deductions and withholdings ("**Base Salary**"), which will be paid in periodic installments in accordance with the Company's customary payroll practices and applicable wage payment laws, but no less frequently than monthly. The Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the CEO and Compensation Committee of the Company's Board. Executive's Base Salary may not be subject to reduction from the level set forth above, unless pursuant to a salary reduction program of general application to employment contract executives of the Company, provided that, unless agreed to in writing by Executive, the percentage reduction of Executive's Base Salary shall not be greater than the percentage reduction applied to any other employment contract executive of the Company.

3.2 Bonus. This is a non-qualified plan used by the Company to provide special compensation to key executives. The Company's contribution to an executive bonus plan is considered salary to the Executive and is therefore subject to taxation. The Executive is eligible to participate in the bonus pool with a target bonus equal to 40% of Executive's Base Salary, as then in effect (the "Target Bonus"), as may be awarded pursuant to any annual executive bonus plan and related corporate goals approved solely at the discretion of the Compensation Committee of the Board. Any such Annual Bonus shall contain such rights and features as are typically afforded to other contract executives of the Company.

3.3 Equity Compensation (RSUs, RSAs, Stock Options, Other). The Compensation Committee of the Board (the "**Compensation Committee**"), and pursuant to Processa's 2019 Omnibus Incentive Plan, or any such additional incentive plans that may be in place at such time, (the "**Plan**") has previously granted new hire RSUs to Employee. Any additional equity grants will be at the reasonable discretion of the Compensation Committee of the Board. The specifics of the grants will be described in the Award Agreement to be provided to the Executive. Notwithstanding the above and any other sections in this Agreement, all unvested equity granted herein, any additional unvested granted and any other unvested equity-linked securities that may be granted in the future shall immediately vest upon a Change in Control (as defined in Section 4.5).

3.4 Incentive and Deferred Compensation. Employee shall be eligible to participate in all incentive and deferred compensation programs available to other executives or officers of Processa, such participation to be in the same form, under the same terms, and to the same extent that such programs are made available to other such similarly situated executives or officers. Except as otherwise provided herein, nothing in this Agreement shall be deemed to require the payment of bonuses, awards, or incentive compensation to Employee if such payment would not otherwise be required under the terms of Processa's incentive compensation programs. The Company reserves the right to interpret, amend or terminate any incentive compensation program at any time in its sole discretion, subject to the terms of such incentive compensation program and applicable law.

3.5 Employee Benefits. During the Employment Term, the Executive shall be entitled to participate in all employee benefit plans, practices, and programs maintained by the Company, as in effect from time to time (collectively, "**Employee Benefit Plans**"), on a basis which is no less favorable than is provided to other similarly situated executives of the Company, to the extent consistent with applicable law and the terms of the applicable Employee Benefit Plans. The Company reserves the right to amend or terminate any Employee Benefit Plans at any time in its sole discretion, subject to the terms of such Employee Benefit Plan and applicable law.

3.6 Paid Time Off. During the Employment Term, the Executive will be entitled to earn and use paid time off ("**PTO**") in accordance with the terms of the Company's PTO policy.

3.7 Business Expenses. The Executive shall be entitled to reimbursement for all reasonable and necessary out-of-pocket business, entertainment, and travel expenses incurred by the Executive in connection with the performance of the Executive's duties hereunder in accordance with the Company's expense reimbursement policies and procedures.

3.8 Withholding. By signing this Agreement, the Executive hereby authorizes the Company to withhold from any amount payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

4. **Termination of Employment**. The Employment Term and the Executive's employment with the Company may be terminated upon the following conditions or events:

4.1 Death or Permanent Disability. The Executive employment under this Agreement and the Employment Term shall terminate immediately in the event of the death or Permanent Disability of Executive. "Permanent Disability" shall be defined as (1) Executive's inability to perform the essential functions of his position, with or without reasonable accommodation, for a period of six consecutive months or for an aggregate of six months in any twelve month period, as determined by a physician licensed to practice medicine and designated by Employer and acceptable to the Executive, having reviewed and considered information provided by the Executive's healthcare provider(s); (2) if the Executive is subject to a legal decree of incompetency; or (3) the Executive receives benefits pursuant to a long-term disability insurance plan, and the person or persons required to make disability determinations under the long-term disability plan determines that the Executive has a disability that, if Executive qualified for such disability benefits, would provide coverage for the longest period of time.. Any refusal by the Executive to submit to a medical examination for the purpose of determining a Permanent Disability shall be deemed to constitute conclusive evidence of the Executive's Permanent Disability.

4.2 Termination by Executive. The Executive may voluntarily terminate their employment with the Company by providing at least ninety (90) days written notice to the Company of such termination. Once such notice is given, the Company may elect to terminate the Executive prior to the conclusion of the ninety-day period. The Executive shall be paid their Base Salary through the end of the 90-day period. The Executive may also terminate their employment hereunder for "Good Reason." For the purpose of determining Executive's right to Severance Pay and other payments described in Section 5.2 and elsewhere in this Agreement, the Executive's resignation will be for "Good Reason" if the Executive resigns after any of the following events: (A) a decrease of more than 5% in Executive's Base Salary or annual target bonus opportunity other than a reduction in Executive's Base Salary or annual target bonus opportunity that is implemented in connection with a contemporaneous, temporary reduction in annual base salaries by the same percentage affecting other senior executives of the Company or (B) a material decrease in the Executive's authority or areas of responsibility as are commensurate with such Executive's title or position.

4.3 Termination by the Company Without Cause. The Company may terminate the Executive's employment hereunder for any reason other than Cause by delivering written notice of termination to the Executive at least ninety (90) days prior to the date of termination. The Company may elect to earlier terminate and pay Executive their regular Base Salary and benefits through the end of the 90-day period as an addition to severance pay in lieu of such notice.

4.4 Termination by the Company for Cause. Employer may terminate the Executive immediately for Cause. For purposes of this Agreement, "Cause" shall mean:

a) the Executive's refusal or inability to perform or observe any of the Executive's material duties, responsibilities or obligations set forth in this Agreement (other than any such refusal or inability resulting from Executive's Permanent Disability); provided, however, that Employer shall not be deemed to have Cause pursuant to this clause unless the Company gives the Executive written notice that the specified conduct has occurred and the Executive fails to cure the conduct within thirty (30) days after receipt of such notice;

b) any act of the Executive involving fraud, theft, misappropriation of funds, or embezzlement;

c) the Executive is convicted of any felony or misdemeanor involving dishonesty, violence or moral turpitude, or which in the reasonable judgment of the Company, reflects materially and adversely on the reputation of the Company;

d) the Executive's material failure to comply with any of the Company's policies, including but not limited to by engaging in the illegal use of controlled substances, the knowing abuse of prescribed medications, or the misuse of alcohol;

e) the Executive's material breach of fiduciary duty of care, loyalty, and good faith, ensuring diligent, company-focused actions and legal compliance.

4.5 Termination of Employment Involving a Change of Control. The Executive's employment with the Company may be terminated in the event that a Change in Control occurs, and the Executive's employment with the Company is terminated by the Company Without Cause or by the Executive for Good Reason at any time within the three (3) month period before the date of and in connection with such Change in Control or during the twelve (12) month period following the date of such Change in Control ("**Termination as a Result of a Change in Control**"). For purposes of this Section, "**Change in Control**" shall mean and include:

a) Acquisition by any "Person" or "Group" of securities entitled to vote generally in the election of directors ("voting securities") of the Company that represent 50% or more of the combined voting power of the Company's then outstanding voting securities;

b) A change in the composition of the Board occurring within a twelve (12) month period, as a result of which a majority of the incumbent directors are replaced by directors whose appointment or election is not endorsed by a majority of the incumbent directors before the date of the appointment or election;

c) Merger or consolidation in which the seller's shareholders no longer control the surviving entity;

d) Sale of substantially all assets to an unrelated entity.

4.6 Resignation of All Other Positions. On termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned from all positions that the Executive holds as an officer or member of the Board (or a committee thereof) of the Company or any of its affiliates (and shall confirm such resignation in writing upon the request of the Company).

4.7 Termination Date. The final date on which the Executive is actually employed by the Company pursuant to this Agreement shall be the "**Termination Date**."

5. **Compensation on Termination of Employment**.

5.1 Earned and Accrued Payments. In the event that the Executive's employment is terminated, the Executive shall be entitled to receive: (a) any accrued but unpaid Base Salary, which shall be paid on the pay date immediately following the Executive's Termination Date, unless earlier required by applicable law; (b) any accrued but unpaid target annual bonus or any other granted bonus where such bonus was determined prior to the Termination Date, which shall be paid on the otherwise applicable payment date; (c) reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and (d) such employee benefits (including equity compensation), if any, to which the Executive may be entitled under the Company's employee benefit plans as of the Termination Date; provided that, in no event shall the Executive be entitled to any payments in the nature of severance or termination payments except as specifically provided herein. The treatment of any outstanding equity awards shall be determined in accordance with the terms in this Agreement, of the Plan and the applicable award agreements. For clarification purposes, if the Termination Date occurs prior to the date of payment of the prior year bonus, the entire unpaid bonus from the prior year plus the pro-rata accrued but unpaid bonus from the year of the Termination date would be included in 5.1(b).

5.2 Severance Pay. In the event that the Executive's employment with the Company is terminated due to death or Permanent Disability, by the Company Without Cause, the Executive terminates employment with the Company for Good Reason, and/or there is a Termination as a Result of a Change in Control (each a "Separation Event"), the Executive shall be entitled to:

a. One year of Base Salary and Target Bonus ("**Severance Pay**"), paid out in accordance with the normal payroll practices of the Company following the Termination Date and paid out over the twelve (12) month period. Payment of any Severance Pay shall be conditioned upon the Executive executing and not revoking a separation agreement reasonably satisfactory to the Company (or its successor) and to the Executive, including a general release of all claims that is reasonably satisfactory with terms substantially similar to typical agreements to the Company (or its successor) and the Executive; and

b. For the twelve (12) month period following the Separation Event, (or, if earlier, the date on which the applicable continuation period under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") expires), and the Executive has elected COBRA coverage then the Company shall arrange to provide Executive and his eligible dependents who were covered under the Company's health insurance plans as of the date of the Separation Event with health (including medical and dental) insurance benefits substantially similar to those provided to such dependents immediately prior to the date of such Separation Event. The Executive will be responsible for any portion of the premium associated with such coverage that he was responsible for during employment. If the Company is not reasonably able to continue health insurance benefits coverage under the Company's insurance plans, the Company shall provide substantially equivalent coverage under other third-party insurance sources. If any of the Company's health benefits are self-funded as of the date of Separation Event, or if the Company cannot provide the foregoing benefits in a manner that exempt from Section 409A of the Code or that is otherwise compliant with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), instead of providing continued health insurance benefits as set forth above, the Company shall instead pay to the Executive an amount equal to twelve (12) multiplied by the monthly premium the Executive would be required to pay for continuation coverage pursuant to the COBRA for his/her eligible dependents who were covered under the Company's health plans as of the date of the Separation Event (calculated by reference to the premium as of the date of the Separation Event), which amount shall be paid on the Payment Date. Eligibility for this benefit is contingent upon the execution and nonrevocation of the separation agreement referenced above.

5.3 Section 280G. If the Executive becomes entitled to any amount in the nature of compensation payable by the Company that is contingent on a change in ownership, effective control, or substantial ownership of a substantial portion of the Company's assets within the meaning of Section 280G of the Internal Revenue Code ("Covered Payments") and constitute "Parachute Payments" within the meaning within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and that is subject to the excise tax imposed by Section 4999 of the Code ("Excise Tax"), a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the "Reduced Amount"). "Net Benefit" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes. In the event reduction is required, the Covered Payments shall be reduced by the Company in the following order: (i) cash severance payments hereunder to the extent not subject to Section 409A of the Code in the reverse order of payment; (ii) any other portion of the Covered Payments that are not subject to Section 409A of the Code in the reverse order of payment (other than any acceleration of vesting of equity awards); (iii) Covered Payments that are not subject to Section 409A of the Code that arise from the accelerated vesting of equity awards, and; (iv) Covered Payments that are subject to Section 409A of the Code in a manner consistent with Section 409A of the Code. All determinations pursuant to this Section 5.4 shall be made by tax accountants selected by the Company and reasonably acceptable to Executive (the "Accountants"), whose determinations shall be binding on the Company and the Executive absent manifest error. The Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order for the Accountants to make their determinations.

6. **Return of Property and Employee Non-Solicit**.

6.1 Return of Property. Upon termination of Executive's employment with the Company for any reason, upon request, Executive will use reasonable efforts to promptly deliver to the Company all equipment, correspondence, drawings, manuals, letters, notes, notebooks, reports, programs, plans, proposals, financial documents, or any other documents or property containing material information pertaining to the Company's customers, business plans, marketing strategies, products, property or processes..

6.2 Non-Solicitation of Employees Covenant. Executive acknowledges that the Company's employees and consultants are a valuable asset to the Company, especially because such employees have access to and knowledge of the Company's confidential information and trade secrets. As such, Executive agrees for a period of one-year from the Termination Date, with respect to any Company employee with whom Executive had material business contact during their employment with the Company, Executive will not (i) induce or attempt to induce such employee of the Company to leave employment or contracting with the Company; or (ii) directly solicit the services of or hire away such current employee of the Company.

6.3 Notification of Future Employers. Executive hereby agrees to notify any future employers or prospective employers of the foregoing obligations and authorizes the Company to provide a single notice of the terms in Section 6 to Executive's actual or future employers (or persons or entities that contract or seek to contract for Executive's services).

6.4 Remedies. In the event of a breach or threatened breach by either party, each party hereby consents and agrees that the non-breaching party may (as determined by a court of law or proper judicial authority) be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, and that money damages would not afford an adequate remedy, without the necessity of showing any actual damages. The aforementioned equitable relief may (as determined by a court of law or proper judicial authority) be in addition to, not in lieu of, legal remedies, monetary damages, or other available forms of relief.

7. **Assignment of Inventions and Rights**.

7.1 Work Product. The Executive acknowledges and agrees that all designs, devices, discoveries, processes, proprietary software, writings, inventions, improvements and documentation, and any other works of authorship (collectively, "**Work Product**"), and all related know-how, produced, made, conceived or authored by the Executive, solely or jointly with others, in the course of his employment with the Company together with any intellectual property rights concerning the Work Product produced, made, conceived or authored by the Executive, including any moral rights relating to any of the foregoing, are works made for hire and the property of the Company if such works (i) result or are derived from, at the time the Work Product is produced, made, conceived or reduced to practice, the actual business, research, or development of the Company; or (ii) are result from any work performed by the Executive for or on behalf of the Company; or (iii) are created or developed with the use of Proprietary Information or Company equipment, supplies, facilities, information, materials or other Company resources ("Company IP"). The Executive shall disclose in writing any such Company IP promptly to the Company and hereby irrevocably assign any and all rights in their entirety, throughout the world, in and to such works to the Company or its assignees.

7.2 To the extent that any such Company IP may not, by operation of law, be deemed works made for hire, this Agreement shall constitute an irrevocable assignment by the Executive to the Company of the ownership of, and all right, title, and interest in and to such items, including an irrevocable assignment of all moral rights relating thereto, and the Company shall have the right to obtain and hold in its own name, all intellectual property rights, including without limitation, patent, trade secret, copyright and similar protections which may be available in such Company IP throughout the world.

7.3 The Executive agrees that all work product made by them after the end of employment with the Company, whether created solely by the Executive or jointly with others, that is based on or contains Confidential Information of the Company, shall belong to the Company; and the Executive irrevocably assigns any and all rights in their entirety, throughout the world, in and to such future Work Product to the Company.

7.4 The Executive agrees to use reasonable efforts to assist the Company, or its designee or assignee, to secure and perfect the Company's (and/or such designee's) rights in such Work Product and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights relating thereto in any and all countries, including the written disclosure to the Company of all information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments which the Company shall deem necessary in order to apply for, obtain and protect such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title and interest in and to such Company IP, and any copyright, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights contained therein and/or relating thereto. The Executive further agrees that their obligation to execute or cause to be executed any such instrument or papers shall continue after employment with the Company ends. The Executive shall be entitled to reimbursement for reasonable expenses in providing such post-employment assistance.

7.5 In the event the Company is unable due to Executive's subsequent disability, incapacity or for any other reason whatsoever to secure his signature to any lawful and necessary document required to apply for, register or execute any patent, copyright or other applications with respect to any such Company IP, the Executive hereby irrevocably appoints the Company and its duly authorized officers and agents as its agents and attorneys-in-fact to execute and file any such application and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights or other rights thereon with the same legal force and effect as if executed by the Executive.

7.6 In the event Company should not desire to secure and perfect its rights to any Company IP, but should desire to keep the same secret, the Executive agrees that they will do everything reasonably in his power to assist Company in this and will not disclose any information relating to such Company IP except with the prior written consent of Company.

7.7 In order to permit the Company to claim rights to which it may be entitled, Executive agrees to disclose to the Company in writing and in confidence all inventions or Company IP that Executive makes or conceive of, either solely or jointly with others, during the term of his employment with the Company.

7.8 All Work Product that was made by the Executive before his employment with the Company (collectively referred to as "Prior Inventions") are excluded from Section 5 of this Agreement. The Executive agrees not to incorporate into a Company product, process or code, or other Company Work Product, a Prior Invention.

8. Acknowledgement. The Executive acknowledges and agrees that the services to be rendered by the Executive to the Company are of a special and unique character; that the Executive will obtain knowledge and skill relevant to the Company's industry, methods of doing business and marketing strategies by virtue of the Executive's employment; and that the restrictive covenants and other terms and conditions of this Agreement are reasonable and reasonably necessary to protect the legitimate business interest of the Company.

9. Governing Law: Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of Delaware without regard to conflicts of law principles. Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the State of Delaware. The parties hereby irrevocably submit to the exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

10. Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court and can be cited as evidence in legal proceedings alleging breach of the Agreement.

11. Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

12. Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement. The parties further agree that any such court is expressly authorized to modify any such unenforceable provision of this Agreement in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Agreement, or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties as embodied herein to the maximum extent permitted by law. The parties expressly agree that this Agreement as so modified by the court shall be binding upon and enforceable against each of them. In any event, should one or more of the provisions of this Agreement be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions hereof, and if such provision or provisions are not modified as provided above, this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had not been set forth herein.

13. Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

14. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

15. Section 409A.

15.1 General. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

15.2 Separation from Service. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is considered nonqualified deferred compensation under Section 409A and is designated under this Agreement as payable upon the Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4(b) shall not be paid until the fifty-fifth (55th) day following Executive's Separation from Service (the "First Payment Date").

15.3 Specified Employee. Notwithstanding anything in this Agreement to the contrary, if the Executive is deemed by the Company at the time of the Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of the Executive's benefits shall not be provided to the Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of the Executive's Separation from Service with the Company or (ii) the date of the Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to the Executive (or the Executive's estate or beneficiaries), and any remaining payments due to the Executive under this Agreement shall be paid as otherwise provided herein.

15.4 Expense Reimbursements. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to the Executive shall be paid to the Executive no later than December 31st of the calendar year following the calendar year in which the expense was incurred; provided, that the Executive submits the Executive's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one calendar year shall not affect the amount eligible for reimbursement in any subsequent calendar year, other than medical expenses referred to in Section 105(b) of the Code, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

15.5 Installments. The Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on the Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

16. Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

17. Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company: **Chief Executive Officer**
Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076

If to the Executive: **Dr. Sian Bigora**
11608 Periwinkle Drive
Naples, FL 34120

18. Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

19. Acknowledgement of Full Understanding. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS FULLY READ, UNDERSTANDS AND VOLUNTARILY ENTERS INTO THIS AGREEMENT. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS HAD AN OPPORTUNITY TO ASK QUESTIONS AND CONSULT WITH AN ATTORNEY OF THE EXECUTIVE'S CHOICE BEFORE SIGNING THIS AGREEMENT.

[REST OF PAGE INTENTIONALLY BLANK
SIGNATURES TO FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

PROCESSA PHARMACEUTICALS, INC.	**DR. SIAN BIGORA**
By: */s/ George Ng* George Ng, Chief Executive Officer	*/s/ Sian Bigora*

Exhibit 10.14

EXECUTIVE EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made and entered into as of March 19, 2025 ("**Effective Date**"), by and between Wendy Guy (the "**Executive**") and Processa Pharmaceuticals, Inc., a Delaware corporation (the "**Company**" or "**Processa**") (collectively referred to herein as the "Parties").

WHEREAS, the Company desires to employ the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to be employed by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

1. **Term**. This Agreement shall be effective for the term beginning on the Effective Date and continue until terminated or modified pursuant to Section 4 of this Agreement. The period during which the Executive is employed by the Company hereunder is hereinafter referred to as the "**Employment Term.**"

2. **Position and Duties**. During the Employment Term, the Executive shall serve as the Chief Administrative Officer of the Company. In such position, the Executive shall have such duties, authority, and responsibilities as shall be mutually agreed upon by the Chief Executive Officer and the Executive, which duties, authority, and responsibilities are consistent with the Executive's position and prevailing industry standards. During the Employment Term, the Executive shall devote substantially all of the Executive's business time and attention to the performance of the Executive's duties hereunder and will not engage in any other business, profession, or occupation for compensation, which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the Company's Chief Executive Officer ("**CEO**"). Notwithstanding, the Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, investments and holdings, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, (iv) serve on the board of directors of for-profit organizations that do not directly compete with the Company, with the prior approval of the CEO and (iv) conduct business and other matters that were previously disclosed to the Company prior to the Employment Term, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder.

3. **Compensation and Benefits**.

3.1 Base Salary. The Company shall pay the Executive an annual base salary of $325,520, less all lawfully required deductions and withholdings ("**Base Salary**"), which will be paid in periodic installments in accordance with the Company's customary payroll practices and applicable wage payment laws, but no less frequently than monthly. The Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the CEO and Compensation Committee of the Company's Board. Executive's Base Salary may not be subject to reduction from the level set forth above, unless pursuant to a salary reduction program of general application to employment contract executives of the Company, provided that, unless agreed to in writing by Executive, the percentage reduction of Executive's Base Salary shall not be greater than the percentage reduction applied to any other employment contract executive of the Company.

3.2 Bonus. This is a non-qualified plan used by the Company to provide special compensation to key executives. The Company's contribution to an executive bonus plan is considered salary to the Executive and is therefore subject to taxation. The Executive is eligible to participate in the bonus pool with a target bonus equal to 30% of Executive's Base Salary, as then in effect (the "Target Bonus"), as may be awarded pursuant to any annual executive bonus plan and related corporate goals approved solely at the discretion of the Compensation Committee of the Board. Any such Annual Bonus shall contain such rights and features as are typically afforded to other contract executives of the Company.

3.3 Equity Compensation (RSUs, RSAs, Stock Options, Other). The Compensation Committee of the Board (the "**Compensation Committee**"), and pursuant to Processa's 2019 Omnibus Incentive Plan, or any such additional incentive plans that may be in place at such time, (the "**Plan**") has previously granted new hire RSUs to Employee. Any additional equity grants will be at the reasonable discretion of the Compensation Committee of the Board. The specifics of the grants will be described in the Award Agreement to be provided to the Executive. Notwithstanding the above and any other sections in this Agreement, all unvested equity granted herein, any additional unvested granted and any other unvested equity-linked securities that may be granted in the future shall immediately vest upon a Change in Control (as defined in Section 4.5).

3.4 Incentive and Deferred Compensation. Employee shall be eligible to participate in all incentive and deferred compensation programs available to other executives or officers of Processa, such participation to be in the same form, under the same terms, and to the same extent that such programs are made available to other such similarly situated executives or officers. Except as otherwise provided herein, nothing in this Agreement shall be deemed to require the payment of bonuses, awards, or incentive compensation to Employee if such payment would not otherwise be required under the terms of Processa's incentive compensation programs. The Company reserves the right to interpret, amend or terminate any incentive compensation program at any time in its sole discretion, subject to the terms of such incentive compensation program and applicable law.

3.5 Employee Benefits. During the Employment Term, the Executive shall be entitled to participate in all employee benefit plans, practices, and programs maintained by the Company, as in effect from time to time (collectively, "**Employee Benefit Plans**"), on a basis which is no less favorable than is provided to other similarly situated executives of the Company, to the extent consistent with applicable law and the terms of the applicable Employee Benefit Plans. The Company reserves the right to amend or terminate any Employee Benefit Plans at any time in its sole discretion, subject to the terms of such Employee Benefit Plan and applicable law.

3.6 Paid Time Off. During the Employment Term, the Executive will be entitled to earn and use paid time off ("**PTO**") in accordance with the terms of the Company's PTO policy.

3.7 Business Expenses. The Executive shall be entitled to reimbursement for all reasonable and necessary out-of-pocket business, entertainment, and travel expenses incurred by the Executive in connection with the performance of the Executive's duties hereunder in accordance with the Company's expense reimbursement policies and procedures.

3.8 Withholding. By signing this Agreement, the Executive hereby authorizes the Company to withhold from any amount payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

4. **Termination of Employment**. The Employment Term and the Executive's employment with the Company may be terminated upon the following conditions or events:

4.1 Death or Permanent Disability. The Executive employment under this Agreement and the Employment Term shall terminate immediately in the event of the death or Permanent Disability of Executive. "Permanent Disability" shall be defined as (1) Executive's inability to perform the essential functions of his position, with or without reasonable accommodation, for a period of six consecutive months or for an aggregate of six months in any twelve month period, as determined by a physician licensed to practice medicine and designated by Employer and acceptable to the Executive, having reviewed and considered information provided by the Executive's healthcare provider(s); (2) if the Executive is subject to a legal decree of incompetency; or (3) the Executive receives benefits pursuant to a long-term disability insurance plan, and the person or persons required to make disability determinations under the long-term disability plan determines that the Executive has a disability that, if Executive qualified for such disability benefits, would provide coverage for the longest period of time.. Any refusal by the Executive to submit to a medical examination for the purpose of determining a Permanent Disability shall be deemed to constitute conclusive evidence of the Executive's Permanent Disability.

4.2 Termination by Executive. The Executive may voluntarily terminate their employment with the Company by providing at least ninety (90) days written notice to the Company of such termination. Once such notice is given, the Company may elect to terminate the Executive prior to the conclusion of the ninety-day period. The Executive shall be paid their Base Salary through the end of the 90-day period. The Executive may also terminate their employment hereunder for "Good Reason." For the purpose of determining Executive's right to Severance Pay and other payments described in Section 5.2 and elsewhere in this Agreement, the Executive's resignation will be for "Good Reason" if the Executive resigns after any of the following events: (A) a decrease of more than 5% in Executive's Base Salary or annual target bonus opportunity other than a reduction in Executive's Base Salary or annual target bonus opportunity that is implemented in connection with a contemporaneous, temporary reduction in annual base salaries by the same percentage affecting other senior executives of the Company or (B) a material decrease in the Executive's authority or areas of responsibility as are commensurate with such Executive's title or position.

4.3 Termination by the Company Without Cause. The Company may terminate the Executive's employment hereunder for any reason other than Cause by delivering written notice of termination to the Executive at least ninety (90) days prior to the date of termination. The Company may elect to earlier terminate and pay Executive their regular Base Salary and benefits through the end of the 90-day period as an addition to severance pay in lieu of such notice.

4.4 Termination by the Company for Cause. Employer may terminate the Executive immediately for Cause. For purposes of this Agreement, "Cause" shall mean:

a) the Executive's refusal or inability to perform or observe any of the Executive's material duties, responsibilities or obligations set forth in this Agreement (other than any such refusal or inability resulting from Executive's Permanent Disability); provided, however, that Employer shall not be deemed to have Cause pursuant to this clause unless the Company gives the Executive written notice that the specified conduct has occurred and the Executive fails to cure the conduct within thirty (30) days after receipt of such notice;

b) any act of the Executive involving fraud, theft, misappropriation of funds, or embezzlement;

c) the Executive is convicted of any felony or misdemeanor involving dishonesty, violence or moral turpitude, or which in the reasonable judgment of the Company, reflects materially and adversely on the reputation of the Company;

d) the Executive's material failure to comply with any of the Company's policies, including but not limited to by engaging in the illegal use of controlled substances, the knowing abuse of prescribed medications, or the misuse of alcohol;

e) the Executive's material breach of fiduciary duty of care, loyalty, and good faith, ensuring diligent, company-focused actions and legal compliance.

4.5 Termination of Employment Involving a Change of Control. The Executive's employment with the Company may be terminated in the event that a Change in Control occurs, and the Executive's employment with the Company is terminated by the Company Without Cause or by the Executive for Good Reason at any time within the three (3) month period before the date of and in connection with such Change in Control or during the twelve (12) month period following the date of such Change in Control ("**Termination as a Result of a Change in Control**"). For purposes of this Section, "**Change in Control**" shall mean and include:

a) Acquisition by any "Person" or "Group" of securities entitled to vote generally in the election of directors ("voting securities") of the Company that represent 50% or more of the combined voting power of the Company's then outstanding voting securities;

b) A change in the composition of the Board occurring within a twelve (12) month period, as a result of which a majority of the incumbent directors are replaced by directors whose appointment or election is not endorsed by a majority of the incumbent directors before the date of the appointment or election;

c) Merger or consolidation in which the seller's shareholders no longer control the surviving entity;

d) Sale of substantially all assets to an unrelated entity.

4.6 Resignation of All Other Positions. On termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned from all positions that the Executive holds as an officer or member of the Board (or a committee thereof) of the Company or any of its affiliates (and shall confirm such resignation in writing upon the request of the Company).

4.7 Termination Date. The final date on which the Executive is actually employed by the Company pursuant to this Agreement shall be the "**Termination Date**."

5. **Compensation on Termination of Employment**.

5.1 Earned and Accrued Payments. In the event that the Executive's employment is terminated, the Executive shall be entitled to receive: (a) any accrued but unpaid Base Salary, which shall be paid on the pay date immediately following the Executive's Termination Date, unless earlier required by applicable law; (b) any accrued but unpaid target annual bonus or any other granted bonus where such bonus was determined prior to the Termination Date, which shall be paid on the otherwise applicable payment date; (c) reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and (d) such employee benefits (including equity compensation), if any, to which the Executive may be entitled under the Company's employee benefit plans as of the Termination Date; provided that, in no event shall the Executive be entitled to any payments in the nature of severance or termination payments except as specifically provided herein. The treatment of any outstanding equity awards shall be determined in accordance with the terms in this Agreement, of the Plan and the applicable award agreements. For clarification purposes, if the Termination Date occurs prior to the date of payment of the prior year bonus, the entire unpaid bonus from the prior year plus the pro-rata accrued but unpaid bonus from the year of the Termination date would be included in 5.1(b).

5.2 Severance Pay. In the event that the Executive's employment with the Company is terminated due to death or Permanent Disability, by the Company Without Cause, the Executive terminates employment with the Company for Good Reason, and/or there is a Termination as a Result of a Change in Control (each a "Separation Event"), the Executive shall be entitled to:

a. One year of Base Salary and Target Bonus ("**Severance Pay**"), paid out in accordance with the normal payroll practices of the Company following the Termination Date and paid out over the twelve (12) month period. Payment of any Severance Pay shall be conditioned upon the Executive executing and not revoking a separation agreement reasonably satisfactory to the Company (or its successor) and to the Executive, including a general release of all claims that is reasonably satisfactory with terms substantially similar to typical agreements to the Company (or its successor) and the Executive; and

b. For the twelve (12) month period following the Separation Event, (or, if earlier, the date on which the applicable continuation period under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") expires), and the Executive has elected COBRA coverage then the Company shall arrange to provide Executive and his eligible dependents who were covered under the Company's health insurance plans as of the date of the Separation Event with health (including medical and dental) insurance benefits substantially similar to those provided to such dependents immediately prior to the date of such Separation Event. The Executive will be responsible for any portion of the premium associated with such coverage that he was responsible for during employment. If the Company is not reasonably able to continue health insurance benefits coverage under the Company's insurance plans, the Company shall provide substantially equivalent coverage under other third-party insurance sources. If any of the Company's health benefits are self-funded as of the date of Separation Event, or if the Company cannot provide the foregoing benefits in a manner that exempt from Section 409A of the Code or that is otherwise compliant with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), instead of providing continued health insurance benefits as set forth above, the Company shall instead pay to the Executive an amount equal to twelve (12) multiplied by the monthly premium the Executive would be required to pay for continuation coverage pursuant to the COBRA for his/her eligible dependents who were covered under the Company's health plans as of the date of the Separation Event (calculated by reference to the premium as of the date of the Separation Event), which amount shall be paid on the Payment Date. Eligibility for this benefit is contingent upon the execution and nonrevocation of the separation agreement referenced above.

5.3 Section 280G. If the Executive becomes entitled to any amount in the nature of compensation payable by the Company that is contingent on a change in ownership, effective control, or substantial ownership of a substantial portion of the Company's assets within the meaning of Section 280G of the Internal Revenue Code ("Covered Payments") and constitute "Parachute Payments" within the meaning within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and that is subject to the excise tax imposed by Section 4999 of the Code ("Excise Tax"), a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the "Reduced Amount"). "Net Benefit" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes. In the event reduction is required, the Covered Payments shall be reduced by the Company in the following order: (i) cash severance payments hereunder to the extent not subject to Section 409A of the Code in the reverse order of payment; (ii) any other portion of the Covered Payments that are not subject to Section 409A of the Code in the reverse order of payment (other than any acceleration of vesting of equity awards); (iii) Covered Payments that are not subject to Section 409A of the Code that arise from the accelerated vesting of equity awards, and; (iv) Covered Payments that are subject to Section 409A of the Code in a manner consistent with Section 409A of the Code. All determinations pursuant to this Section 5.4 shall be made by tax accountants selected by the Company and reasonably acceptable to Executive (the "Accountants"), whose determinations shall be binding on the Company and the Executive absent manifest error. The Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order for the Accountants to make their determinations.

6. **Return of Property and Employee Non-Solicit**.

6.1 Return of Property. Upon termination of Executive's employment with the Company for any reason, upon request, Executive will use reasonable efforts to promptly deliver to the Company all equipment, correspondence, drawings, manuals, letters, notes, notebooks, reports, programs, plans, proposals, financial documents, or any other documents or property containing material information pertaining to the Company's customers, business plans, marketing strategies, products, property or processes..

6.2 Non-Solicitation of Employees Covenant. Executive acknowledges that the Company's employees and consultants are a valuable asset to the Company, especially because such employees have access to and knowledge of the Company's confidential information and trade secrets. As such, Executive agrees for a period of one-year from the Termination Date, with respect to any Company employee with whom Executive had material business contact during their employment with the Company, Executive will not (i) induce or attempt to induce such employee of the Company to leave employment or contracting with the Company; or (ii) directly solicit the services of or hire away such current employee of the Company.

6.3 Notification of Future Employers. Executive hereby agrees to notify any future employers or prospective employers of the foregoing obligations and authorizes the Company to provide a single notice of the terms in Section 6 to Executive's actual or future employers (or persons or entities that contract or seek to contract for Executive's services).

6.4 Remedies. In the event of a breach or threatened breach by either party, each party hereby consents and agrees that the non-breaching party may (as determined by a court of law or proper judicial authority) be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, and that money damages would not afford an adequate remedy, without the necessity of showing any actual damages. The aforementioned equitable relief may (as determined by a court of law or proper judicial authority) be in addition to, not in lieu of, legal remedies, monetary damages, or other available forms of relief.

7. **Assignment of Inventions and Rights**.

7.1 Work Product. The Executive acknowledges and agrees that all designs, devices, discoveries, processes, proprietary software, writings, inventions, improvements and documentation, and any other works of authorship (collectively, "**Work Product**"), and all related know-how, produced, made, conceived or authored by the Executive, solely or jointly with others, in the course of his employment with the Company together with any intellectual property rights concerning the Work Product produced, made, conceived or authored by the Executive, including any moral rights relating to any of the foregoing, are works made for hire and the property of the Company if such works (i) result or are derived from, at the time the Work Product is produced, made, conceived or reduced to practice, the actual business, research, or development of the Company; or (ii) are result from any work performed by the Executive for or on behalf of the Company; or (iii) are created or developed with the use of Proprietary Information or Company equipment, supplies, facilities, information, materials or other Company resources ("Company IP"). The Executive shall disclose in writing any such Company IP promptly to the Company and hereby irrevocably assign any and all rights in their entirety, throughout the world, in and to such works to the Company or its assignees.

7.2 To the extent that any such Company IP may not, by operation of law, be deemed works made for hire, this Agreement shall constitute an irrevocable assignment by the Executive to the Company of the ownership of, and all right, title, and interest in and to such items, including an irrevocable assignment of all moral rights relating thereto, and the Company shall have the right to obtain and hold in its own name, all intellectual property rights, including without limitation, patent, trade secret, copyright and similar protections which may be available in such Company IP throughout the world.

7.3 The Executive agrees that all work product made by them after the end of employment with the Company, whether created solely by the Executive or jointly with others, that is based on or contains Confidential Information of the Company, shall belong to the Company; and the Executive irrevocably assigns any and all rights in their entirety, throughout the world, in and to such future Work Product to the Company.

7.4 The Executive agrees to use reasonable efforts to assist the Company, or its designee or assignee, to secure and perfect the Company's (and/or such designee's) rights in such Work Product and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights relating thereto in any and all countries, including the written disclosure to the Company of all information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments which the Company shall deem necessary in order to apply for, obtain and protect such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title and interest in and to such Company IP, and any copyright, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights contained therein and/or relating thereto. The Executive further agrees that their obligation to execute or cause to be executed any such instrument or papers shall continue after employment with the Company ends. The Executive shall be entitled to reimbursement for reasonable expenses in providing such post-employment assistance.

7.5 In the event the Company is unable due to Executive's subsequent disability, incapacity or for any other reason whatsoever to secure his signature to any lawful and necessary document required to apply for, register or execute any patent, copyright or other applications with respect to any such Company IP, the Executive hereby irrevocably appoints the Company and its duly authorized officers and agents as its agents and attorneys-in-fact to execute and file any such application and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights or other rights thereon with the same legal force and effect as if executed by the Executive.

7.6 In the event Company should not desire to secure and perfect its rights to any Company IP, but should desire to keep the same secret, the Executive agrees that they will do everything reasonably in his power to assist Company in this and will not disclose any information relating to such Company IP except with the prior written consent of Company.

7.7 In order to permit the Company to claim rights to which it may be entitled, Executive agrees to disclose to the Company in writing and in confidence all inventions or Company IP that Executive makes or conceive of, either solely or jointly with others, during the term of his employment with the Company.

7.8 All Work Product that was made by the Executive before his employment with the Company (collectively referred to as "Prior Inventions") are excluded from Section 5 of this Agreement. The Executive agrees not to incorporate into a Company product, process or code, or other Company Work Product, a Prior Invention.

8. Acknowledgement. The Executive acknowledges and agrees that the services to be rendered by the Executive to the Company are of a special and unique character; that the Executive will obtain knowledge and skill relevant to the Company's industry, methods of doing business and marketing strategies by virtue of the Executive's employment; and that the restrictive covenants and other terms and conditions of this Agreement are reasonable and reasonably necessary to protect the legitimate business interest of the Company.

9. Governing Law: Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of Delaware without regard to conflicts of law principles. Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the State of Delaware. The parties hereby irrevocably submit to the exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

10. Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court and can be cited as evidence in legal proceedings alleging breach of the Agreement.

11. Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

12. Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement. The parties further agree that any such court is expressly authorized to modify any such unenforceable provision of this Agreement in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Agreement, or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties as embodied herein to the maximum extent permitted by law. The parties expressly agree that this Agreement as so modified by the court shall be binding upon and enforceable against each of them. In any event, should one or more of the provisions of this Agreement be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions hereof, and if such provision or provisions are not modified as provided above, this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had not been set forth herein.

13. Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

14. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

15. Section 409A.

15.1 General. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

15.2 Separation from Service. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is considered nonqualified deferred compensation under Section 409A and is designated under this Agreement as payable upon the Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4(b) shall not be paid until the fifty-fifth (55th) day following Executive's Separation from Service (the "First Payment Date").

15.3 Specified Employee. Notwithstanding anything in this Agreement to the contrary, if the Executive is deemed by the Company at the time of the Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of the Executive's benefits shall not be provided to the Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of the Executive's Separation from Service with the Company or (ii) the date of the Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to the Executive (or the Executive's estate or beneficiaries), and any remaining payments due to the Executive under this Agreement shall be paid as otherwise provided herein.

15.4 Expense Reimbursements. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to the Executive shall be paid to the Executive no later than December 31st of the calendar year following the calendar year in which the expense was incurred; provided, that the Executive submits the Executive's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one calendar year shall not affect the amount eligible for reimbursement in any subsequent calendar year, other than medical expenses referred to in Section 105(b) of the Code, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

15.5 Installments. The Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on the Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

16. Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

17. Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company: **Chief Executive Officer**
Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076

If to the Executive: **Ms. Wendy Guy**
4245 Amelia Plantation Court
Vero Beach, FL 32967

18. Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

19. Acknowledgement of Full Understanding. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS FULLY READ, UNDERSTANDS AND VOLUNTARILY ENTERS INTO THIS AGREEMENT. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS HAD AN OPPORTUNITY TO ASK QUESTIONS AND CONSULT WITH AN ATTORNEY OF THE EXECUTIVE'S CHOICE BEFORE SIGNING THIS AGREEMENT.

[REST OF PAGE INTENTIONALLY BLANK
SIGNATURES TO FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

PROCESSA PHARMACEUTICALS, INC.

By: */s/ George Ng*
George Ng, Chief Executive Officer

MS. WENDY GUY

/s/ Wendy Guy

Exhibit 10.15

EXECUTIVE EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made and entered into as of March 19, 2025 ("**Effective Date**"), by and between Patrick Lin (the "**Executive**") and Processa Pharmaceuticals, Inc., a Delaware corporation (the "**Company**" or "**Processa**") (collectively referred to herein as the "Parties").

WHEREAS, the Company desires to employ the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to be employed by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

1. **Term**. This Agreement shall be effective for the term beginning on the Effective Date and continue until terminated or modified pursuant to Section 4 of this Agreement. The period during which the Executive is employed by the Company hereunder is hereinafter referred to as the "**Employment Term.**"

2. **Position and Duties**. During the Employment Term, the Executive shall serve as the Chief Business and Strategy Officer of the Company. In such position, the Executive shall have such duties, authority, and responsibilities as shall be mutually agreed upon by the Chief Executive Officer and the Executive, which duties, authority, and responsibilities are consistent with the Executive's position and prevailing industry standards. During the Employment Term, the Executive shall devote substantially all of the Executive's business time and attention to the performance of the Executive's duties hereunder and will not engage in any other business, profession, or occupation for compensation, which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the Company's Chief Executive Officer ("**CEO**"). Notwithstanding, the Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, investments and holdings, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, (iv) serve on the board of directors of for-profit organizations that do not directly compete with the Company, with the prior approval of the CEO and (iv) conduct business and other matters that were previously disclosed to the Company prior to the Employment Term, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder.

3. **Compensation and Benefits**.

3.1 Base Salary. The Company shall pay the Executive an annual base salary of $325,520, less all lawfully required deductions and withholdings ("**Base Salary**"), which will be paid in periodic installments in accordance with the Company's customary payroll practices and applicable wage payment laws, but no less frequently than monthly. The Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the CEO and Compensation Committee of the Company's Board. Executive's Base Salary may not be subject to reduction from the level set forth above, unless pursuant to a salary reduction program of general application to employment contract executives of the Company, provided that, unless agreed to in writing by Executive, the percentage reduction of Executive's Base Salary shall not be greater than the percentage reduction applied to any other employment contract executive of the Company.

3.2 Bonus. This is a non-qualified plan used by the Company to provide special compensation to key executives. The Company's contribution to an executive bonus plan is considered salary to the Executive and is therefore subject to taxation. The Executive is eligible to participate in the bonus pool with a target bonus equal to 30% of Executive's Base Salary, as then in effect (the "Target Bonus"), as may be awarded pursuant to any annual executive bonus plan and related corporate goals approved solely at the discretion of the Compensation Committee of the Board. Any such Annual Bonus shall contain such rights and features as are typically afforded to other contract executives of the Company.

3.3 Equity Compensation (RSUs, RSAs, Stock Options, Other). The Compensation Committee of the Board (the "**Compensation Committee**"), and pursuant to Processa's 2019 Omnibus Incentive Plan, or any such additional incentive plans that may be in place at such time, (the "**Plan**") has previously granted new hire RSUs to Employee. Any additional equity grants will be at the reasonable discretion of the Compensation Committee of the Board. The specifics of the grants will be described in the Award Agreement to be provided to the Executive. Notwithstanding the above and any other sections in this Agreement, all unvested equity granted herein, any additional unvested granted and any other unvested equity-linked securities that may be granted in the future shall immediately vest upon a Change in Control (as defined in Section 4.5).

3.4 Incentive and Deferred Compensation. Employee shall be eligible to participate in all incentive and deferred compensation programs available to other executives or officers of Processa, such participation to be in the same form, under the same terms, and to the same extent that such programs are made available to other such similarly situated executives or officers. Except as otherwise provided herein, nothing in this Agreement shall be deemed to require the payment of bonuses, awards, or incentive compensation to Employee if such payment would not otherwise be required under the terms of Processa's incentive compensation programs. The Company reserves the right to interpret, amend or terminate any incentive compensation program at any time in its sole discretion, subject to the terms of such incentive compensation program and applicable law.

3.5 Employee Benefits. During the Employment Term, the Executive shall be entitled to participate in all employee benefit plans, practices, and programs maintained by the Company, as in effect from time to time (collectively, "**Employee Benefit Plans**"), on a basis which is no less favorable than is provided to other similarly situated executives of the Company, to the extent consistent with applicable law and the terms of the applicable Employee Benefit Plans. The Company reserves the right to amend or terminate any Employee Benefit Plans at any time in its sole discretion, subject to the terms of such Employee Benefit Plan and applicable law.

3.6 Paid Time Off. During the Employment Term, the Executive will be entitled to earn and use paid time off ("**PTO**") in accordance with the terms of the Company's PTO policy.

3.7 Business Expenses. The Executive shall be entitled to reimbursement for all reasonable and necessary out-of-pocket business, entertainment, and travel expenses incurred by the Executive in connection with the performance of the Executive's duties hereunder in accordance with the Company's expense reimbursement policies and procedures.

3.8 Withholding. By signing this Agreement, the Executive hereby authorizes the Company to withhold from any amount payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

4. **Termination of Employment**. The Employment Term and the Executive's employment with the Company may be terminated upon the following conditions or events:

4.1 Death or Permanent Disability. The Executive employment under this Agreement and the Employment Term shall terminate immediately in the event of the death or Permanent Disability of Executive. "Permanent Disability" shall be defined as (1) Executive's inability to perform the essential functions of his position, with or without reasonable accommodation, for a period of six consecutive months or for an aggregate of six months in any twelve month period, as determined by a physician licensed to practice medicine and designated by Employer and acceptable to the Executive, having reviewed and considered information provided by the Executive's healthcare provider(s); (2) if the Executive is subject to a legal decree of incompetency; or (3) the Executive receives benefits pursuant to a long-term disability insurance plan, and the person or persons required to make disability determinations under the long-term disability plan determines that the Executive has a disability that, if Executive qualified for such disability benefits, would provide coverage for the longest period of time.. Any refusal by the Executive to submit to a medical examination for the purpose of determining a Permanent Disability shall be deemed to constitute conclusive evidence of the Executive's Permanent Disability.

4.2 Termination by Executive. The Executive may voluntarily terminate their employment with the Company by providing at least ninety (90) days written notice to the Company of such termination. Once such notice is given, the Company may elect to terminate the Executive prior to the conclusion of the ninety-day period. The Executive shall be paid their Base Salary through the end of the 90-day period. The Executive may also terminate their employment hereunder for "Good Reason." For the purpose of determining Executive's right to Severance Pay and other payments described in Section 5.2 and elsewhere in this Agreement, the Executive's resignation will be for "Good Reason" if the Executive resigns after any of the following events: (A) a decrease of more than 5% in Executive's Base Salary or annual target bonus opportunity other than a reduction in Executive's Base Salary or annual target bonus opportunity that is implemented in connection with a contemporaneous, temporary reduction in annual base salaries by the same percentage affecting other senior executives of the Company or (B) a material decrease in the Executive's authority or areas of responsibility as are commensurate with such Executive's title or position.

4.3 Termination by the Company Without Cause. The Company may terminate the Executive's employment hereunder for any reason other than Cause by delivering written notice of termination to the Executive at least ninety (90) days prior to the date of termination. The Company may elect to earlier terminate and pay Executive their regular Base Salary and benefits through the end of the 90-day period as an addition to severance pay in lieu of such notice.

4.4 Termination by the Company for Cause. Employer may terminate the Executive immediately for Cause. For purposes of this Agreement, "Cause" shall mean:

a) the Executive's refusal or inability to perform or observe any of the Executive's material duties, responsibilities or obligations set forth in this Agreement (other than any such refusal or inability resulting from Executive's Permanent Disability); provided, however, that Employer shall not be deemed to have Cause pursuant to this clause unless the Company gives the Executive written notice that the specified conduct has occurred and the Executive fails to cure the conduct within thirty (30) days after receipt of such notice;

b) any act of the Executive involving fraud, theft, misappropriation of funds, or embezzlement;

c) the Executive is convicted of any felony or misdemeanor involving dishonesty, violence or moral turpitude, or which in the reasonable judgment of the Company, reflects materially and adversely on the reputation of the Company;

d) the Executive's material failure to comply with any of the Company's policies, including but not limited to by engaging in the illegal use of controlled substances, the knowing abuse of prescribed medications, or the misuse of alcohol;

e) the Executive's material breach of fiduciary duty of care, loyalty, and good faith, ensuring diligent, company-focused actions and legal compliance.

4.5 Termination of Employment Involving a Change of Control. The Executive's employment with the Company may be terminated in the event that a Change in Control occurs, and the Executive's employment with the Company is terminated by the Company Without Cause or by the Executive for Good Reason at any time within the three (3) month period before the date of and in connection with such Change in Control or during the twelve (12) month period following the date of such Change in Control ("**Termination as a Result of a Change in Control**"). For purposes of this Section, "**Change in Control**" shall mean and include:

a) Acquisition by any "Person" or "Group" of securities entitled to vote generally in the election of directors ("voting securities") of the Company that represent 50% or more of the combined voting power of the Company's then outstanding voting securities;

b) A change in the composition of the Board occurring within a twelve (12) month period, as a result of which a majority of the incumbent directors are replaced by directors whose appointment or election is not endorsed by a majority of the incumbent directors before the date of the appointment or election;

c) Merger or consolidation in which the seller's shareholders no longer control the surviving entity;

d) Sale of substantially all assets to an unrelated entity.

4.6 Resignation of All Other Positions. On termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned from all positions that the Executive holds as an officer or member of the Board (or a committee thereof) of the Company or any of its affiliates (and shall confirm such resignation in writing upon the request of the Company).

4.7 Termination Date. The final date on which the Executive is actually employed by the Company pursuant to this Agreement shall be the "**Termination Date**."

5. **Compensation on Termination of Employment**.

5.1 Earned and Accrued Payments. In the event that the Executive's employment is terminated, the Executive shall be entitled to receive: (a) any accrued but unpaid Base Salary, which shall be paid on the pay date immediately following the Executive's Termination Date, unless earlier required by applicable law; (b) any accrued but unpaid target annual bonus or any other granted bonus where such bonus was determined prior to the Termination Date, which shall be paid on the otherwise applicable payment date; (c) reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and (d) such employee benefits (including equity compensation), if any, to which the Executive may be entitled under the Company's employee benefit plans as of the Termination Date; provided that, in no event shall the Executive be entitled to any payments in the nature of severance or termination payments except as specifically provided herein. The treatment of any outstanding equity awards shall be determined in accordance with the terms in this Agreement, of the Plan and the applicable award agreements. For clarification purposes, if the Termination Date occurs prior to the date of payment of the prior year bonus, the entire unpaid bonus from the prior year plus the pro-rata accrued but unpaid bonus from the year of the Termination date would be included in 5.1(b).

5.2 Severance Pay. In the event that the Executive's employment with the Company is terminated due to death or Permanent Disability, by the Company Without Cause, the Executive terminates employment with the Company for Good Reason, and/or there is a Termination as a Result of a Change in Control (each a "Separation Event"), the Executive shall be entitled to:

a. One year of Base Salary and Target Bonus ("**Severance Pay**"), paid out in accordance with the normal payroll practices of the Company following the Termination Date and paid out over the twelve (12) month period. Payment of any Severance Pay shall be conditioned upon the Executive executing and not revoking a separation agreement reasonably satisfactory to the Company (or its successor) and to the Executive, including a general release of all claims that is reasonably satisfactory with terms substantially similar to typical agreements to the Company (or its successor) and the Executive; and

b. For the twelve (12) month period following the Separation Event, (or, if earlier, the date on which the applicable continuation period under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") expires), and the Executive has elected COBRA coverage then the Company shall arrange to provide Executive and his eligible dependents who were covered under the Company's health insurance plans as of the date of the Separation Event with health (including medical and dental) insurance benefits substantially similar to those provided to such dependents immediately prior to the date of such Separation Event. The Executive will be responsible for any portion of the premium associated with such coverage that he was responsible for during employment. If the Company is not reasonably able to continue health insurance benefits coverage under the Company's insurance plans, the Company shall provide substantially equivalent coverage under other third-party insurance sources. If any of the Company's health benefits are self-funded as of the date of Separation Event, or if the Company cannot provide the foregoing benefits in a manner that exempt from Section 409A of the Code or that is otherwise compliant with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), instead of providing continued health insurance benefits as set forth above, the Company shall instead pay to the Executive an amount equal to twelve (12) multiplied by the monthly premium the Executive would be required to pay for continuation coverage pursuant to the COBRA for his/her eligible dependents who were covered under the Company's health plans as of the date of the Separation Event (calculated by reference to the premium as of the date of the Separation Event), which amount shall be paid on the Payment Date. Eligibility for this benefit is contingent upon the execution and nonrevocation of the separation agreement referenced above.

5.3 Section 280G. If the Executive becomes entitled to any amount in the nature of compensation payable by the Company that is contingent on a change in ownership, effective control, or substantial ownership of a substantial portion of the Company's assets within the meaning of Section 280G of the Internal Revenue Code ("Covered Payments") and constitute "Parachute Payments" within the meaning within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and that is subject to the excise tax imposed by Section 4999 of the Code ("Excise Tax"), a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the "Reduced Amount"). "Net Benefit" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes. In the event reduction is required, the Covered Payments shall be reduced by the Company in the following order: (i) cash severance payments hereunder to the extent not subject to Section 409A of the Code in the reverse order of payment; (ii) any other portion of the Covered Payments that are not subject to Section 409A of the Code in the reverse order of payment (other than any acceleration of vesting of equity awards); (iii) Covered Payments that are not subject to Section 409A of the Code that arise from the accelerated vesting of equity awards, and; (iv) Covered Payments that are subject to Section 409A of the Code in a manner consistent with Section 409A of the Code. All determinations pursuant to this Section 5.4 shall be made by tax accountants selected by the Company and reasonably acceptable to Executive (the "Accountants"), whose determinations shall be binding on the Company and the Executive absent manifest error. The Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order for the Accountants to make their determinations.

6. **Return of Property and Employee Non-Solicit**.

6.1 Return of Property. Upon termination of Executive's employment with the Company for any reason, upon request, Executive will use reasonable efforts to promptly deliver to the Company all equipment, correspondence, drawings, manuals, letters, notes, notebooks, reports, programs, plans, proposals, financial documents, or any other documents or property containing material information pertaining to the Company's customers, business plans, marketing strategies, products, property or processes..

6.2 Non-Solicitation of Employees Covenant. Executive acknowledges that the Company's employees and consultants are a valuable asset to the Company, especially because such employees have access to and knowledge of the Company's confidential information and trade secrets. As such, Executive agrees for a period of one-year from the Termination Date, with respect to any Company employee with whom Executive had material business contact during their employment with the Company, Executive will not (i) induce or attempt to induce such employee of the Company to leave employment or contracting with the Company; or (ii) directly solicit the services of or hire away such current employee of the Company.

6.3 Notification of Future Employers. Executive hereby agrees to notify any future employers or prospective employers of the foregoing obligations and authorizes the Company to provide a single notice of the terms in Section 6 to Executive's actual or future employers (or persons or entities that contract or seek to contract for Executive's services).

6.4 Remedies. In the event of a breach or threatened breach by either party, each party hereby consents and agrees that the non-breaching party may (as determined by a court of law or proper judicial authority) be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, and that money damages would not afford an adequate remedy, without the necessity of showing any actual damages. The aforementioned equitable relief may (as determined by a court of law or proper judicial authority) be in addition to, not in lieu of, legal remedies, monetary damages, or other available forms of relief.

7. **Assignment of Inventions and Rights**.

7.1 Work Product. The Executive acknowledges and agrees that all designs, devices, discoveries, processes, proprietary software, writings, inventions, improvements and documentation, and any other works of authorship (collectively, "**Work Product**"), and all related know-how, produced, made, conceived or authored by the Executive, solely or jointly with others, in the course of his employment with the Company together with any intellectual property rights concerning the Work Product produced, made, conceived or authored by the Executive, including any moral rights relating to any of the foregoing, are works made for hire and the property of the Company if such works (i) result or are derived from, at the time the Work Product is produced, made, conceived or reduced to practice, the actual business, research, or development of the Company; or (ii) are result from any work performed by the Executive for or on behalf of the Company; or (iii) are created or developed with the use of Proprietary Information or Company equipment, supplies, facilities, information, materials or other Company resources ("Company IP"). The Executive shall disclose in writing any such Company IP promptly to the Company and hereby irrevocably assign any and all rights in their entirety, throughout the world, in and to such works to the Company or its assignees.

7.2 To the extent that any such Company IP may not, by operation of law, be deemed works made for hire, this Agreement shall constitute an irrevocable assignment by the Executive to the Company of the ownership of, and all right, title, and interest in and to such items, including an irrevocable assignment of all moral rights relating thereto, and the Company shall have the right to obtain and hold in its own name, all intellectual property rights, including without limitation, patent, trade secret, copyright and similar protections which may be available in such Company IP throughout the world.

7.3 The Executive agrees that all work product made by them after the end of employment with the Company, whether created solely by the Executive or jointly with others, that is based on or contains Confidential Information of the Company, shall belong to the Company; and the Executive irrevocably assigns any and all rights in their entirety, throughout the world, in and to such future Work Product to the Company.

7.4 The Executive agrees to use reasonable efforts to assist the Company, or its designee or assignee, to secure and perfect the Company's (and/or such designee's) rights in such Work Product and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights relating thereto in any and all countries, including the written disclosure to the Company of all information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments which the Company shall deem necessary in order to apply for, obtain and protect such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title and interest in and to such Company IP, and any copyright, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights contained therein and/or relating thereto. The Executive further agrees that their obligation to execute or cause to be executed any such instrument or papers shall continue after employment with the Company ends. The Executive shall be entitled to reimbursement for reasonable expenses in providing such post-employment assistance.

7.5 In the event the Company is unable due to Executive's subsequent disability, incapacity or for any other reason whatsoever to secure his signature to any lawful and necessary document required to apply for, register or execute any patent, copyright or other applications with respect to any such Company IP, the Executive hereby irrevocably appoints the Company and its duly authorized officers and agents as its agents and attorneys-in-fact to execute and file any such application and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights or other rights thereon with the same legal force and effect as if executed by the Executive.

7.6 In the event Company should not desire to secure and perfect its rights to any Company IP, but should desire to keep the same secret, the Executive agrees that they will do everything reasonably in his power to assist Company in this and will not disclose any information relating to such Company IP except with the prior written consent of Company.

7.7 In order to permit the Company to claim rights to which it may be entitled, Executive agrees to disclose to the Company in writing and in confidence all inventions or Company IP that Executive makes or conceive of, either solely or jointly with others, during the term of his employment with the Company.

7.8 All Work Product that was made by the Executive before his employment with the Company (collectively referred to as "Prior Inventions") are excluded from Section 5 of this Agreement. The Executive agrees not to incorporate into a Company product, process or code, or other Company Work Product, a Prior Invention.

8. Acknowledgement. The Executive acknowledges and agrees that the services to be rendered by the Executive to the Company are of a special and unique character; that the Executive will obtain knowledge and skill relevant to the Company's industry, methods of doing business and marketing strategies by virtue of the Executive's employment; and that the restrictive covenants and other terms and conditions of this Agreement are reasonable and reasonably necessary to protect the legitimate business interest of the Company.

9. Governing Law: Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of Delaware without regard to conflicts of law principles. Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the State of Delaware. The parties hereby irrevocably submit to the exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

10. Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court and can be cited as evidence in legal proceedings alleging breach of the Agreement.

11. Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

12. Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement. The parties further agree that any such court is expressly authorized to modify any such unenforceable provision of this Agreement in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Agreement, or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties as embodied herein to the maximum extent permitted by law. The parties expressly agree that this Agreement as so modified by the court shall be binding upon and enforceable against each of them. In any event, should one or more of the provisions of this Agreement be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions hereof, and if such provision or provisions are not modified as provided above, this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had not been set forth herein.

13. Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

14. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

15. Section 409A.

15.1 General. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

15.2 Separation from Service. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is considered nonqualified deferred compensation under Section 409A and is designated under this Agreement as payable upon the Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4(b) shall not be paid until the fifty-fifth (55th) day following Executive's Separation from Service (the "First Payment Date").

15.3 Specified Employee. Notwithstanding anything in this Agreement to the contrary, if the Executive is deemed by the Company at the time of the Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of the Executive's benefits shall not be provided to the Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of the Executive's Separation from Service with the Company or (ii) the date of the Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to the Executive (or the Executive's estate or beneficiaries), and any remaining payments due to the Executive under this Agreement shall be paid as otherwise provided herein.

15.4 Expense Reimbursements. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to the Executive shall be paid to the Executive no later than December 31st of the calendar year following the calendar year in which the expense was incurred; provided, that the Executive submits the Executive's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one calendar year shall not affect the amount eligible for reimbursement in any subsequent calendar year, other than medical expenses referred to in Section 105(b) of the Code, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

15.5 Installments. The Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on the Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

16. Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

17. Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company: Chief Executive Officer
Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076

If to the Executive: Mr. Patrick Lin
45 Coachwood Terrace
Orinda, CA 94563

18. Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

19. Acknowledgement of Full Understanding. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS FULLY READ, UNDERSTANDS AND VOLUNTARILY ENTERS INTO THIS AGREEMENT. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS HAD AN OPPORTUNITY TO ASK QUESTIONS AND CONSULT WITH AN ATTORNEY OF THE EXECUTIVE'S CHOICE BEFORE SIGNING THIS AGREEMENT.

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SIGNATURES TO FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

PROCESSA PHARMACEUTICALS, INC.	**MR. PATRICK LIN**
By: */s/ George Ng* George Ng, Chief Executive Officer	*/s/ Patrick Lin*

Exhibit 10.16

EXECUTIVE EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made and entered into as of March 19, 2025 ("**Effective Date**"), by and between Dr. David Young (the "**Executive**") and Processa Pharmaceuticals, Inc., a Delaware corporation (the "**Company**" or "**Processa**") (collectively referred to herein as the "Parties").

WHEREAS, the Company desires to employ the Executive on the terms and conditions set forth herein; and

WHEREAS, the Executive desires to be employed by the Company on such terms and conditions.

NOW, THEREFORE, in consideration of the mutual covenants, promises, and obligations set forth herein, the parties agree as follows:

1. **Term**. This Agreement shall be effective for the term beginning on the Effective Date and continue until terminated or modified pursuant to Section 4 of this Agreement. The period during which the Executive is employed by the Company hereunder is hereinafter referred to as the "**Employment Term.**"

2. **Position and Duties**. During the Employment Term, the Executive shall serve as the President, Research & Development of the Company. In such position, the Executive shall have such duties, authority, and responsibilities as shall be mutually agreed upon by the Chief Executive Officer and the Executive, which duties, authority, and responsibilities are consistent with the Executive's position and prevailing industry standards. During the Employment Term, the Executive shall devote substantially all of the Executive's business time and attention to the performance of the Executive's duties hereunder and will not engage in any other business, profession, or occupation for compensation, which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the Company's Chief Executive Officer ("**CEO**"). Notwithstanding, the Executive shall be permitted to (i) manage Executive's personal, financial and legal affairs, investments and holdings, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, (iv) serve on the board of directors of for-profit organizations that do not directly compete with the Company, with the prior approval of the CEO and (iv) conduct business and other matters that were previously disclosed to the Company prior to the Employment Term, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder.

3. **Compensation and Benefits**.

3.1 Base Salary. The Company shall pay the Executive an annual base salary of $387,920, less all lawfully required deductions and withholdings ("**Base Salary**"), which will be paid in periodic installments in accordance with the Company's customary payroll practices and applicable wage payment laws, but no less frequently than monthly. The Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the CEO and Compensation Committee of the Company's Board. Executive's Base Salary may not be subject to reduction from the level set forth above, unless pursuant to a salary reduction program of general application to employment contract executives of the Company, provided that, unless agreed to in writing by Executive, the percentage reduction of Executive's Base Salary shall not be greater than the percentage reduction applied to any other employment contract executive of the Company.

3.2 Bonus. This is a non-qualified plan used by the Company to provide special compensation to key executives. The Company's contribution to an executive bonus plan is considered salary to the Executive and is therefore subject to taxation. The Executive is eligible to participate in the bonus pool with a target bonus equal to 40% of Executive's Base Salary, as then in effect (the "Target Bonus"), as may be awarded pursuant to any annual executive bonus plan and related corporate goals approved solely at the discretion of the Compensation Committee of the Board. Any such Annual Bonus shall contain such rights and features as are typically afforded to other contract executives of the Company.

3.3 Equity Compensation (RSUs, RSAs, Stock Options, Other). The Compensation Committee of the Board (the "**Compensation Committee**"), and pursuant to Processa's 2019 Omnibus Incentive Plan, or any such additional incentive plans that may be in place at such time, (the "**Plan**") has previously granted new hire RSUs to Employee. Any additional equity grants will be at the reasonable discretion of the Compensation Committee of the Board. The specifics of the grants will be described in the Award Agreement to be provided to the Executive. Notwithstanding the above and any other sections in this Agreement, all unvested equity granted herein, any additional unvested granted and any other unvested equity-linked securities that may be granted in the future shall immediately vest upon a Change in Control (as defined in Section 4.5).

3.4 Incentive and Deferred Compensation. Employee shall be eligible to participate in all incentive and deferred compensation programs available to other executives or officers of Processa, such participation to be in the same form, under the same terms, and to the same extent that such programs are made available to other such similarly situated executives or officers. Except as otherwise provided herein, nothing in this Agreement shall be deemed to require the payment of bonuses, awards, or incentive compensation to Employee if such payment would not otherwise be required under the terms of Processa's incentive compensation programs. The Company reserves the right to interpret, amend or terminate any incentive compensation program at any time in its sole discretion, subject to the terms of such incentive compensation program and applicable law.

3.5 Employee Benefits. During the Employment Term, the Executive shall be entitled to participate in all employee benefit plans, practices, and programs maintained by the Company, as in effect from time to time (collectively, "**Employee Benefit Plans**"), on a basis which is no less favorable than is provided to other similarly situated executives of the Company, to the extent consistent with applicable law and the terms of the applicable Employee Benefit Plans. The Company reserves the right to amend or terminate any Employee Benefit Plans at any time in its sole discretion, subject to the terms of such Employee Benefit Plan and applicable law.

3.6 Paid Time Off. During the Employment Term, the Executive will be entitled to earn and use paid time off ("**PTO**") in accordance with the terms of the Company's PTO policy.

3.7 Business Expenses. The Executive shall be entitled to reimbursement for all reasonable and necessary out-of-pocket business, entertainment, and travel expenses incurred by the Executive in connection with the performance of the Executive's duties hereunder in accordance with the Company's expense reimbursement policies and procedures.

3.8 Withholding. By signing this Agreement, the Executive hereby authorizes the Company to withhold from any amount payable hereunder any Federal, state, and local taxes in order for the Company to satisfy any withholding tax obligation it may have under any applicable law or regulation.

4. **Termination of Employment**. The Employment Term and the Executive's employment with the Company may be terminated upon the following conditions or events:

4.1 Death or Permanent Disability. The Executive employment under this Agreement and the Employment Term shall terminate immediately in the event of the death or Permanent Disability of Executive. "Permanent Disability" shall be defined as (1) Executive's inability to perform the essential functions of his position, with or without reasonable accommodation, for a period of six consecutive months or for an aggregate of six months in any twelve month period, as determined by a physician licensed to practice medicine and designated by Employer and acceptable to the Executive, having reviewed and considered information provided by the Executive's healthcare provider(s); (2) if the Executive is subject to a legal decree of incompetency; or (3) the Executive receives benefits pursuant to a long-term disability insurance plan, and the person or persons required to make disability determinations under the long-term disability plan determines that the Executive has a disability that, if Executive qualified for such disability benefits, would provide coverage for the longest period of time.. Any refusal by the Executive to submit to a medical examination for the purpose of determining a Permanent Disability shall be deemed to constitute conclusive evidence of the Executive's Permanent Disability.

4.2 Termination by Executive. The Executive may voluntarily terminate their employment with the Company by providing at least ninety (90) days written notice to the Company of such termination. Once such notice is given, the Company may elect to terminate the Executive prior to the conclusion of the ninety-day period. The Executive shall be paid their Base Salary through the end of the 90-day period. The Executive may also terminate their employment hereunder for "Good Reason." For the purpose of determining Executive's right to Severance Pay and other payments described in Section 5.2 and elsewhere in this Agreement, the Executive's resignation will be for "Good Reason" if the Executive resigns after any of the following events: (A) a decrease of more than 5% in Executive's Base Salary or annual target bonus opportunity other than a reduction in Executive's Base Salary or annual target bonus opportunity that is implemented in connection with a contemporaneous, temporary reduction in annual base salaries by the same percentage affecting other senior executives of the Company or (B) a material decrease in the Executive's authority or areas of responsibility as are commensurate with such Executive's title or position.

4.3 Termination by the Company Without Cause. The Company may terminate the Executive's employment hereunder for any reason other than Cause by delivering written notice of termination to the Executive at least ninety (90) days prior to the date of termination. The Company may elect to earlier terminate and pay Executive their regular Base Salary and benefits through the end of the 90-day period as an addition to severance pay in lieu of such notice.

4.4 Termination by the Company for Cause. Employer may terminate the Executive immediately for Cause. For purposes of this Agreement, "Cause" shall mean:

a) the Executive's refusal or inability to perform or observe any of the Executive's material duties, responsibilities or obligations set forth in this Agreement (other than any such refusal or inability resulting from Executive's Permanent Disability); provided, however, that Employer shall not be deemed to have Cause pursuant to this clause unless the Company gives the Executive written notice that the specified conduct has occurred and the Executive fails to cure the conduct within thirty (30) days after receipt of such notice;

b) any act of the Executive involving fraud, theft, misappropriation of funds, or embezzlement;

c) the Executive is convicted of any felony or misdemeanor involving dishonesty, violence or moral turpitude, or which in the reasonable judgment of the Company, reflects materially and adversely on the reputation of the Company;

d) the Executive's material failure to comply with any of the Company's policies, including but not limited to by engaging in the illegal use of controlled substances, the knowing abuse of prescribed medications, or the misuse of alcohol;

e) the Executive's material breach of fiduciary duty of care, loyalty, and good faith, ensuring diligent, company-focused actions and legal compliance.

4.5 Termination of Employment Involving a Change of Control. The Executive's employment with the Company may be terminated in the event that a Change in Control occurs, and the Executive's employment with the Company is terminated by the Company Without Cause or by the Executive for Good Reason at any time within the three (3) month period before the date of and in connection with such Change in Control or during the twelve (12) month period following the date of such Change in Control ("**Termination as a Result of a Change in Control**"). For purposes of this Section, "**Change in Control**" shall mean and include:

a) Acquisition by any "Person" or "Group" of securities entitled to vote generally in the election of directors ("voting securities") of the Company that represent 50% or more of the combined voting power of the Company's then outstanding voting securities;

b) A change in the composition of the Board occurring within a twelve (12) month period, as a result of which a majority of the incumbent directors are replaced by directors whose appointment or election is not endorsed by a majority of the incumbent directors before the date of the appointment or election;

c) Merger or consolidation in which the seller's shareholders no longer control the surviving entity;

d) Sale of substantially all assets to an unrelated entity.

4.6 Resignation of All Other Positions. On termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned from all positions that the Executive holds as an officer or member of the Board (or a committee thereof) of the Company or any of its affiliates (and shall confirm such resignation in writing upon the request of the Company).

4.7 Termination Date. The final date on which the Executive is actually employed by the Company pursuant to this Agreement shall be the "**Termination Date**."

5. **Compensation on Termination of Employment**.

5.1 Earned and Accrued Payments. In the event that the Executive's employment is terminated, the Executive shall be entitled to receive: (a) any accrued but unpaid Base Salary, which shall be paid on the pay date immediately following the Executive's Termination Date, unless earlier required by applicable law; (b) any accrued but unpaid target annual bonus or any other granted bonus where such bonus was determined prior to the Termination Date, which shall be paid on the otherwise applicable payment date; (c) reimbursement for unreimbursed business expenses properly incurred by the Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy; and (d) such employee benefits (including equity compensation), if any, to which the Executive may be entitled under the Company's employee benefit plans as of the Termination Date; provided that, in no event shall the Executive be entitled to any payments in the nature of severance or termination payments except as specifically provided herein. The treatment of any outstanding equity awards shall be determined in accordance with the terms in this Agreement, of the Plan and the applicable award agreements. For clarification purposes, if the Termination Date occurs prior to the date of payment of the prior year bonus, the entire unpaid bonus from the prior year plus the pro-rata accrued but unpaid bonus from the year of the Termination date would be included in 5.1(b).

5.2 Severance Pay. In the event that the Executive's employment with the Company is terminated due to death or Permanent Disability, by the Company Without Cause, the Executive terminates employment with the Company for Good Reason, and/or there is a Termination as a Result of a Change in Control (each a "Separation Event"), the Executive shall be entitled to:

a. One year of Base Salary and Target Bonus ("**Severance Pay**"), paid out in accordance with the normal payroll practices of the Company following the Termination Date and paid out over the twelve (12) month period. Payment of any Severance Pay shall be conditioned upon the Executive executing and not revoking a separation agreement reasonably satisfactory to the Company (or its successor) and to the Executive, including a general release of all claims that is reasonably satisfactory with terms substantially similar to typical agreements to the Company (or its successor) and the Executive; and

b. For the twelve (12) month period following the Separation Event, (or, if earlier, the date on which the applicable continuation period under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") expires), and the Executive has elected COBRA coverage then the Company shall arrange to provide Executive and his eligible dependents who were covered under the Company's health insurance plans as of the date of the Separation Event with health (including medical and dental) insurance benefits substantially similar to those provided to such dependents immediately prior to the date of such Separation Event. The Executive will be responsible for any portion of the premium associated with such coverage that he was responsible for during employment. If the Company is not reasonably able to continue health insurance benefits coverage under the Company's insurance plans, the Company shall provide substantially equivalent coverage under other third-party insurance sources. If any of the Company's health benefits are self-funded as of the date of Separation Event, or if the Company cannot provide the foregoing benefits in a manner that exempt from Section 409A of the Code or that is otherwise compliant with applicable law (including, without limitation, Section 2716 of the Public Health Service Act), instead of providing continued health insurance benefits as set forth above, the Company shall instead pay to the Executive an amount equal to twelve (12) multiplied by the monthly premium the Executive would be required to pay for continuation coverage pursuant to the COBRA for his/her eligible dependents who were covered under the Company's health plans as of the date of the Separation Event (calculated by reference to the premium as of the date of the Separation Event), which amount shall be paid on the Payment Date. Eligibility for this benefit is contingent upon the execution and nonrevocation of the separation agreement referenced above.

5.3 Section 280G. If the Executive becomes entitled to any amount in the nature of compensation payable by the Company that is contingent on a change in ownership, effective control, or substantial ownership of a substantial portion of the Company's assets within the meaning of Section 280G of the Internal Revenue Code ("Covered Payments") and constitute "Parachute Payments" within the meaning within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and that is subject to the excise tax imposed by Section 4999 of the Code ("Excise Tax"), a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the "Reduced Amount"). "Net Benefit" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes. In the event reduction is required, the Covered Payments shall be reduced by the Company in the following order: (i) cash severance payments hereunder to the extent not subject to Section 409A of the Code in the reverse order of payment; (ii) any other portion of the Covered Payments that are not subject to Section 409A of the Code in the reverse order of payment (other than any acceleration of vesting of equity awards); (iii) Covered Payments that are not subject to Section 409A of the Code that arise from the accelerated vesting of equity awards, and; (iv) Covered Payments that are subject to Section 409A of the Code in a manner consistent with Section 409A of the Code. All determinations pursuant to this Section 5.4 shall be made by tax accountants selected by the Company and reasonably acceptable to Executive (the "Accountants"), whose determinations shall be binding on the Company and the Executive absent manifest error. The Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order for the Accountants to make their determinations.

6. **Return of Property and Employee Non-Solicit**.

6.1 Return of Property. Upon termination of Executive's employment with the Company for any reason, upon request, Executive will use reasonable efforts to promptly deliver to the Company all equipment, correspondence, drawings, manuals, letters, notes, notebooks, reports, programs, plans, proposals, financial documents, or any other documents or property containing material information pertaining to the Company's customers, business plans, marketing strategies, products, property or processes..

6.2 Non-Solicitation of Employees Covenant. Executive acknowledges that the Company's employees and consultants are a valuable asset to the Company, especially because such employees have access to and knowledge of the Company's confidential information and trade secrets. As such, Executive agrees for a period of one-year from the Termination Date, with respect to any Company employee with whom Executive had material business contact during their employment with the Company, Executive will not (i) induce or attempt to induce such employee of the Company to leave employment or contracting with the Company; or (ii) directly solicit the services of or hire away such current employee of the Company.

6.3 Notification of Future Employers. Executive hereby agrees to notify any future employers or prospective employers of the foregoing obligations and authorizes the Company to provide a single notice of the terms in Section 6 to Executive's actual or future employers (or persons or entities that contract or seek to contract for Executive's services).

6.4 Remedies. In the event of a breach or threatened breach by either party, each party hereby consents and agrees that the non-breaching party may (as determined by a court of law or proper judicial authority) be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, and that money damages would not afford an adequate remedy, without the necessity of showing any actual damages. The aforementioned equitable relief may (as determined by a court of law or proper judicial authority) be in addition to, not in lieu of, legal remedies, monetary damages, or other available forms of relief.

7. **Assignment of Inventions and Rights**.

7.1 Work Product. The Executive acknowledges and agrees that all designs, devices, discoveries, processes, proprietary software, writings, inventions, improvements and documentation, and any other works of authorship (collectively, "**Work Product**"), and all related know-how, produced, made, conceived or authored by the Executive, solely or jointly with others, in the course of his employment with the Company together with any intellectual property rights concerning the Work Product produced, made, conceived or authored by the Executive, including any moral rights relating to any of the foregoing, are works made for hire and the property of the Company if such works (i) result or are derived from, at the time the Work Product is produced, made, conceived or reduced to practice, the actual business, research, or development of the Company; or (ii) are result from any work performed by the Executive for or on behalf of the Company; or (iii) are created or developed with the use of Proprietary Information or Company equipment, supplies, facilities, information, materials or other Company resources ("Company IP"). The Executive shall disclose in writing any such Company IP promptly to the Company and hereby irrevocably assign any and all rights in their entirety, throughout the world, in and to such works to the Company or its assignees.

7.2 To the extent that any such Company IP may not, by operation of law, be deemed works made for hire, this Agreement shall constitute an irrevocable assignment by the Executive to the Company of the ownership of, and all right, title, and interest in and to such items, including an irrevocable assignment of all moral rights relating thereto, and the Company shall have the right to obtain and hold in its own name, all intellectual property rights, including without limitation, patent, trade secret, copyright and similar protections which may be available in such Company IP throughout the world.

7.3 The Executive agrees that all work product made by them after the end of employment with the Company, whether created solely by the Executive or jointly with others, that is based on or contains Confidential Information of the Company, shall belong to the Company; and the Executive irrevocably assigns any and all rights in their entirety, throughout the world, in and to such future Work Product to the Company.

7.4 The Executive agrees to use reasonable efforts to assist the Company, or its designee or assignee, to secure and perfect the Company's (and/or such designee's) rights in such Work Product and any copyrights, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights relating thereto in any and all countries, including the written disclosure to the Company of all information and data with respect thereto, the execution of all applications, specifications, oaths, assignments and all other instruments which the Company shall deem necessary in order to apply for, obtain and protect such rights and in order to assign and convey to the Company, its successors, assigns, and nominees the sole and exclusive rights, title and interest in and to such Company IP, and any copyright, patents, trade secrets, mask work rights or other intellectual property rights and/or moral rights contained therein and/or relating thereto. The Executive further agrees that their obligation to execute or cause to be executed any such instrument or papers shall continue after employment with the Company ends. The Executive shall be entitled to reimbursement for reasonable expenses in providing such post-employment assistance.

7.5 In the event the Company is unable due to Executive's subsequent disability, incapacity or for any other reason whatsoever to secure his signature to any lawful and necessary document required to apply for, register or execute any patent, copyright or other applications with respect to any such Company IP, the Executive hereby irrevocably appoints the Company and its duly authorized officers and agents as its agents and attorneys-in-fact to execute and file any such application and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights or other rights thereon with the same legal force and effect as if executed by the Executive.

7.6 In the event Company should not desire to secure and perfect its rights to any Company IP, but should desire to keep the same secret, the Executive agrees that they will do everything reasonably in his power to assist Company in this and will not disclose any information relating to such Company IP except with the prior written consent of Company.

7.7 In order to permit the Company to claim rights to which it may be entitled, Executive agrees to disclose to the Company in writing and in confidence all inventions or Company IP that Executive makes or conceive of, either solely or jointly with others, during the term of his employment with the Company.

7.8 All Work Product that was made by the Executive before his employment with the Company (collectively referred to as "Prior Inventions") are excluded from Section 5 of this Agreement. The Executive agrees not to incorporate into a Company product, process or code, or other Company Work Product, a Prior Invention.

8. Acknowledgement. The Executive acknowledges and agrees that the services to be rendered by the Executive to the Company are of a special and unique character; that the Executive will obtain knowledge and skill relevant to the Company's industry, methods of doing business and marketing strategies by virtue of the Executive's employment; and that the restrictive covenants and other terms and conditions of this Agreement are reasonable and reasonably necessary to protect the legitimate business interest of the Company.

9. Governing Law: Jurisdiction and Venue. This Agreement, for all purposes, shall be construed in accordance with the laws of Delaware without regard to conflicts of law principles. Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in a state or federal court located in the State of Delaware. The parties hereby irrevocably submit to the exclusive jurisdiction of such courts and waive the defense of inconvenient forum to the maintenance of any such action or proceeding in such venue.

10. Entire Agreement. Unless specifically provided herein, this Agreement contains all of the understandings and representations between the Executive and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. The parties mutually agree that the Agreement can be specifically enforced in court and can be cited as evidence in legal proceedings alleging breach of the Agreement.

11. Modification and Waiver. No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in writing and signed by the Executive and by the Company. No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

12. Severability. Should any provision of this Agreement be held by a court of competent jurisdiction to be enforceable only if modified, or if any portion of this Agreement shall be held as unenforceable and thus stricken, such holding shall not affect the validity of the remainder of this Agreement, the balance of which shall continue to be binding upon the parties with any such modification to become a part hereof and treated as though originally set forth in this Agreement. The parties further agree that any such court is expressly authorized to modify any such unenforceable provision of this Agreement in lieu of severing such unenforceable provision from this Agreement in its entirety, whether by rewriting the offending provision, deleting any or all of the offending provision, adding additional language to this Agreement, or by making such other modifications as it deems warranted to carry out the intent and agreement of the parties as embodied herein to the maximum extent permitted by law. The parties expressly agree that this Agreement as so modified by the court shall be binding upon and enforceable against each of them. In any event, should one or more of the provisions of this Agreement be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions hereof, and if such provision or provisions are not modified as provided above, this Agreement shall be construed as if such invalid, illegal, or unenforceable provisions had not been set forth herein.

13. Captions. Captions and headings of the sections and paragraphs of this Agreement are intended solely for convenience and no provision of this Agreement is to be construed by reference to the caption or heading of any section or paragraph.

14. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

15. Section 409A.

15.1 General. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively, "Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

15.2 Separation from Service. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is considered nonqualified deferred compensation under Section 409A and is designated under this Agreement as payable upon the Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4(b) shall not be paid until the fifty-fifth (55th) day following Executive's Separation from Service (the "First Payment Date").

15.3 Specified Employee. Notwithstanding anything in this Agreement to the contrary, if the Executive is deemed by the Company at the time of the Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of the Executive's benefits shall not be provided to the Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of the Executive's Separation from Service with the Company or (ii) the date of the Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to the Executive (or the Executive's estate or beneficiaries), and any remaining payments due to the Executive under this Agreement shall be paid as otherwise provided herein.

15.4 Expense Reimbursements. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to the Executive shall be paid to the Executive no later than December 31st of the calendar year following the calendar year in which the expense was incurred; provided, that the Executive submits the Executive's reimbursement request promptly following the date the expense is incurred, the amount of expenses reimbursed in one calendar year shall not affect the amount eligible for reimbursement in any subsequent calendar year, other than medical expenses referred to in Section 105(b) of the Code, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

15.5 Installments. The Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on the Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

16. Successors and Assigns. This Agreement is personal to the Executive and shall not be assigned by the Executive. Any purported assignment by the Executive shall be null and void from the initial date of the purported assignment. The Company may assign this Agreement to any successor or assign (whether direct or indirect, by purchase, merger, consolidation, or otherwise) to all or substantially all of the business or assets of the Company. This Agreement shall inure to the benefit of the Company and permitted successors and assigns.

17. Notice. Notices and all other communications provided for in this Agreement shall be in writing and shall be delivered personally or sent by registered or certified mail, return receipt requested, or by overnight carrier to the parties at the addresses set forth below (or such other addresses as specified by the parties by like notice):

If to the Company: **Chief Executive Officer**
Processa Pharmaceuticals, Inc.
7380 Coca Cola Drive, Suite 106
Hanover, MD 21076

If to the Executive: **Dr. David Young**
2716 Vardon Lane
Ellicott City, MD 21042

18. Survival. Upon the expiration or other termination of this Agreement, the respective rights and obligations of the parties hereto shall survive such expiration or other termination to the extent necessary to carry out the intentions of the parties under this Agreement.

19. Acknowledgement of Full Understanding. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS FULLY READ, UNDERSTANDS AND VOLUNTARILY ENTERS INTO THIS AGREEMENT. THE EXECUTIVE ACKNOWLEDGES AND AGREES THAT THE EXECUTIVE HAS HAD AN OPPORTUNITY TO ASK QUESTIONS AND CONSULT WITH AN ATTORNEY OF THE EXECUTIVE'S CHOICE BEFORE SIGNING THIS AGREEMENT.

[REST OF PAGE INTENTIONALLY BLANK
SIGNATURES TO FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

PROCESSA PHARMACEUTICALS, INC.

By: */s/ George Ng*
George Ng, Chief Executive Officer

DR. DAVID YOUNG

/s/ David Young

Insider Trading Policy

Introduction

The Board of Directors of Processa Pharmaceuticals, Inc. ("Processa") has adopted this policy to provide guidelines to all directors, officers, employees, and consultants of Processa with respect to trading in Processa securities, as well as the securities of publicly traded companies with whom Processa has a business relationship.

This policy has been designed to prevent insider trading or even allegations of insider trading. Your strict adherence to this policy will help safeguard Processa's reputation and will further ensure that Processa conducts its business with the highest level of integrity and in accordance with the highest ethical standards. Each Processa employee is responsible for the consequences of his or her actions. You are responsible for understanding and complying with this policy.

Federal and state securities laws prohibit the purchase or sale of a company's securities by anyone who is aware of material information about that company that is not generally known or available to the public. These laws also prohibit anyone who is aware of material nonpublic information from disclosing this information to others who may trade. Companies and their controlling persons may also be subject to liability if they fail to take reasonable steps to prevent insider trading by company personnel.

It is important that you understand the breadth of activities that constitute illegal insider trading and the consequences, which can be severe. Both the U.S. Securities and Exchange Commission (the "SEC") and the Financial Industry Regulatory Authority ("FINRA") investigate and are very effective at detecting insider trading. Both the SEC and the U.S. Department of Justice pursue insider trading violations vigorously.

Sanctions and Penalties

Violations of the insider trading laws can result in severe civil and criminal sanctions. For example, under U.S. securities laws, individuals may be subject to imprisonment for up to 20 years, criminal fines of up to $5 million and civil fines of up to three times the profit gained or loss avoided. Failure to comply with this policy may also subject you to sanctions imposed by Processa, up to and including immediate dismissal for cause, whether or not your failure to comply with this policy results in a violation of law.

Persons Covered

As a director, officer, employee or consultant of Processa this policy applies to you. The same restrictions that apply to you apply to your family members who reside with you, anyone else who lives in your household, and any family members who do not live in your household but whose transactions in Processa securities are directed by you or are subject to your influence or control (such as parents or children who consult with you before they trade in Processa securities). You are responsible for making sure that any transaction in securities covered by this policy by any of these people complies with this policy.

Definition of Material Non-Public Information

"Material non-public information" is any material information about Processa that has not yet become publicly available.

Information is "material" if a reasonable investor would likely consider it important in deciding to buy, hold or sell securities. Any information that could reasonably be expected to affect the price of the security is material. The information may be positive or negative. Financial information is frequently material, even if it covers only part of a fiscal period or less than all Processa's operations, since either of these might convey enough information about Processa's results to be considered material information. Other common examples of information that may be material include:

- information regarding sales, revenues or earnings (including projections);
- financial forecasts of any kind, including earnings estimates or changes in previously announced earnings estimates;
- significant business trends and metrics;
- significant proposed mergers, acquisitions, investments or divestitures;
- significant developments in products or services;
- gain or loss of substantial customers;
- execution or termination of significant contracts;
- financings or restructurings;
- significant unusual gains or losses;
- changes in business strategies;
- developments in significant litigation or government investigations;
- public or private debt or equity offerings;
- significant changes in senior management;
- Processa share repurchases; or
- stock splits or dividend information.

It is not possible to define all categories of material information, and you should recognize that the public, the media, and the courts may use hindsight in judging what is material. Therefore, it is important to err on the safe side and assume information is material if there is any doubt.

Information is "non-public" if it is not generally known or available to the public. Information may still be non-public even though it is widely known within Processa.

Release of information to the media does not immediately mean the information has become publicly available. Information is considered to be available to the public only when it has been released broadly to the marketplace (such as by a press release or an SEC filing) and the investing public has had time to absorb and evaluate it.

Ordinarily, information about Processa should not be considered public until at least two full trading days have passed following its formal release to the market. For example, if Processa announces earnings before trading begins on a Tuesday, the first time you can buy or sell Processa securities is the opening of the market on Thursday (assuming you are not aware of other material non-public information at that time). If, however, Processa announces earnings after trading begins that Tuesday, the first time you can buy or sell Processa securities is the opening of the market on the Friday.

Requirements Applicable to Everyone

No trading in Processa securities while aware of material non-public information

You are prohibited from engaging in any transaction in Processa securities while aware of material non-public information about Processa. It makes no difference whether or not you relied upon or used material non-public information in deciding to trade – if you are aware of material non-public information about Processa, the prohibition applies. You should avoid even the appearance of an improper transaction to preserve Processa's reputation for adhering to the highest ethical standards of conduct.

This prohibition covers virtually all transactions in Processa securities. "Securities" includes common stock, options to purchase common stock, debt securities, preferred stock and derivative securities such as put and call options, warrants, swaps, caps and collars. Transactions in Processa securities include purchases, sales, pledges, hedges, loans and gifts of Processa securities, as well as other direct or indirect transfers of Processa securities. Certain of these transactions are addressed in more detail below and may not be permitted under this policy. This prohibition extends to trades of Processa securities in which you have any "beneficial" or other interest, or over which you exercise investment control, including:

- transactions in Processa securities held in joint accounts or accounts of persons or entities controlled directly or indirectly by you;
- transactions in Processa securities for which you act as trustee, executor, or custodian; and
- transactions in any other account or investment involving in any way any Processa securities over which you exercise any direct or indirect control.

Stock Option Exercises. This prohibition does not apply to the exercise of stock options issued under Processa plans if the exercise price is paid in cash or through Processa withholding a portion of the shares underlying the options. Similarly, Processa may withhold underlying shares to satisfy tax withholding requirements. This prohibition does apply, however, to sales of the underlying stock and broker-assisted cashless exercises of options, as well as to any other market sales for the purpose of generating the cash needed to cover the costs of exercise.

Vesting of Restricted Stock or Settlement of Performance Stock Units. This prohibition does not apply to the automatic deduction of shares by Processa from your restricted stock or performance stock unit account to satisfy the minimum statutory tax withholding liability upon the vesting of restricted stock or settlement of performance stock units. The prohibition does apply, however, to any open market sale of vested shares, including to satisfy tax liabilities.

10b5-1 Plans. This prohibition does not apply to trades made pursuant to a valid "10b5-1 plan" approved by Processa as described below.

Gifts. Gifts are often allowed during a blackout with the requirement that the donee will not trade until the blackout is lifted.

Event-specific blackout periods may apply

Although you are always responsible for monitoring for yourself whether you possess material non-public information, from time-to-time Processa may decide to impose a special trading blackout on

those who are aware of information that Processa determines may be considered material non-public information. This kind of trading blackout may be imposed in connection with a potential acquisition, a financial analyst conference, an anticipated positive or negative earnings surprise or other material development. If you are subject to the blackout, you may not trade in any Processa securities, except pursuant to a 10b5-1 plan previously approved by Processa, until notified that the blackout has ended.

The Chief Executive Officer and the Chief Financial Officer will determine whether an event-specific blackout should be imposed. The existence of an event-specific blackout will not be generally announced. If you are covered by the event-specific blackout, you will be notified by the Chief Financial Officer. Any person made aware of an event-specific blackout should not disclose the existence of the blackout to anyone else.

No trading in securities of other companies while aware of material non-public information

Processa may engage in business transactions with companies whose securities are publicly traded. These transactions may include, among other things, mergers, acquisitions, divestitures or renewal or termination of significant contracts or other arrangements. Information learned in connection with these transactions or relationships may constitute material non-public information about the other company. You are prohibited from trading in the securities of these companies while aware of material non-public information about the companies and from communicating that information to any other person for such use.

No "tipping" of material non-public information

You may not pass material non-public information about Processa or any other company on to others or otherwise make unauthorized disclosure or use of this information, regardless of whether you profit or intend to profit by the tipping, disclosure, or use. This practice, known as "tipping," also violates the securities laws and can result in the same civil and criminal penalties that apply to insider trading, even though you did not trade and did not gain any benefit from another's trading.

Frequent trading of Processa securities is strongly discouraged

Frequent trading of Processa securities can create an appearance of wrongdoing even if the decision to trade was based solely on public information such as stock price ranges and other market events. You are strongly discouraged from trading in Processa securities for short-term trading profits. Daily or frequent trading, which can be time-consuming and distracting, is strongly discouraged. Processa reserves the right to request brokerage account statements to assure compliance with this and other provisions of the policy.

If a Section 16 reporting person buys and sells (or sells and buys) Processa securities within a six-month time frame without an exemption under SEC rules, the two transactions may be "matched" for purposes of Section 16. The person may be sued and held strictly liable for any profits made, regardless of whether the person was in possession of material nonpublic information.

No short sales of Processa securities

You may not engage in short sales of Processa securities (sales of securities that are not then owned), including "sales against the box" (short sales not exceeding the number of shares already owned). Generally, short sales are transactions whereby a person will benefit from a decline in the price of the securities, and Processa believes it is inappropriate for associates to engage in these transactions with

respect to Processa securities. Directors and executive officers are also prohibited by Section 16(c) from selling short.

No trading in derivatives of Processa

You may not trade in derivatives of a Processa security, such as exchange-traded put or call options and forward transactions.

No hedging transactions

Certain forms of hedging or monetization transactions may offset a decrease, or limit your ability to profit from an increase, in the value of Processa securities you hold, enabling you to continue to own Processa securities without the full risks and rewards of ownership. Processa believes that such transactions separate the holder's interests from those of other stockholders. Therefore, you and any person acting on your behalf are prohibited from purchasing any financial instruments (such as prepaid variable forward contracts, equity swaps, collars or exchange funds) or otherwise engaging in any transactions that hedge or offset any decrease in the market value of Processa securities or limit your ability to profit from an increase in the market value of Processa securities.

No margin accounts or pledges

Securities held in a margin account or pledged as collateral for a loan may be sold without your consent by the broker if you fail to meet a margin call or by the lender in foreclosure if you default on the loan. Because a margin or foreclosure sale may occur at a time when you are aware of material nonpublic information or otherwise are not permitted to trade in Processa securities, you are prohibited from holding Processa securities in a margin account or pledging Processa securities as collateral for a loan.

Limited use of standing orders

Standing orders should be used only for three business days. A standing order placed with a broker to sell or purchase stock at a specified price leaves you with no control over the timing of the transaction. A standing order transaction executed by the broker when you are aware of material nonpublic information may result in unlawful insider trading. A standing order incorporated into a 10b5-1 plan approved by Processa is permitted.

No trading on rumors

Rumors within Processa concerning matters which, if true, would be material non-public information are deemed to constitute material non-public information for purposes of this policy. Accordingly, you should not trade based on these rumors.

Material non-public information must be kept confidential

Material non-public information about Processa or its business partners is the property of Processa, and unauthorized disclosure or use of that information is prohibited. That information should be maintained in strict confidence and should be discussed, even within Processa, only with persons who have a "need to know." You should exercise the utmost care and circumspection in dealing with information that may be material non-public information. Conversations in public places, such as hallways, elevators, restaurants, and airplanes, involving information of a sensitive or confidential nature should be avoided. Written information should be appropriately safeguarded and should not be

left where it may be seen by persons not entitled to the information. The unauthorized disclosure of information could result in serious consequences to Processa, whether the disclosure is made for the purpose of facilitating improper trading in securities.

Participation in electronic bulletin boards, chat rooms, blogs or websites must be consistent with this Policy

Any written or verbal statement that would be prohibited under the law or under this policy is equally prohibited if made on electronic bulletin boards, chat rooms, blogs, websites, or any other form of social media, including the disclosure of material non-public information about Processa or material non-public information with respect to other companies that you come into possession of as an associate of Processa.

Public disclosures should be made only by designated persons

No individuals other than specifically authorized personnel should release material information to the public or respond to inquiries from the media, analysts, investors or others outside of Processa. You should not respond to these inquiries unless expressly authorized to do so and should refer any inquiries to the Chief Administrative Officer.

Post-employment transactions may be prohibited

The portions of this policy relating to trading while in possession of material non-public information and the use or disclosure of that information continue to apply to transactions in Processa securities even after termination of employment or association with Processa. If you are aware of material non-public information about Processa when your employment or other business relationship with Processa ends, you may not trade in Processa securities or disclose the material non-public information to anyone else until that information is made public or becomes no longer material.

Exceptions

In certain limited circumstances, a transaction otherwise prohibited by this policy may be permitted if, prior to the transaction, the Chief Administrative Officer or Chief Financial Officer determines that the transaction is not inconsistent with the purposes of this policy. The existence of a personal financial emergency does not excuse you from compliance with this policy and will not be the basis for an exception to the policy for a transaction that is inconsistent with the purposes of the policy.

Additional Requirements Applicable to Restricted Persons

"Restricted Persons" are those who are at an enhanced risk of possessing inside information and who therefore must exercise greater diligence to comply with insider trading prohibitions. Due to the limited number of employees and the robustness of collaborations and communications within Processa, we consider members of the Board of Directors and all our employees, as well as any other individual in a role that makes it likely they will are involved with material non-public information, to be Restricted Persons.

If you are a Restricted Person that is not a director or executive officer, the procedures set forth in this section of the policy will cease to apply to your transactions in Processa securities upon the expiration of any blackout period that is applicable to your transactions at the time your employment or other relationship with Processa ends. Directors will remain Restricted Persons for a period of six months

following the last day of service as a director of Processa, and executive officers will remain Restricted Persons for a period of six months following the last day of employment with Processa.

Quarterly blackout periods

No Restricted Person may trade in Processa securities during a quarterly blackout period, regardless of whether they are then actually aware of material non-public information.

A quarterly blackout period is in effect with respect to each quarterly earnings announcement, starting on the last day of the third month of the applicable Processa fiscal quarter and ending when two full trading days have passed following the public announcement of Processa's quarterly financial results. Processa has selected this period because it is the time when there is likely to be material non-public information about Processa that may be available to Restricted Persons.

A quarterly blackout period does not prohibit trading in Processa securities pursuant to a valid pre-existing 10b5-1 plan approved by Processa as described below.

Trading pre-clearance requirement

Restricted Persons must obtain pre-clearance by Processa's Chief Financial Officer or, in his absence, Processa's Chief Administrative Officer (each an "Approving Person") before engaging in any transaction involving Processa securities, including, but not limited to, purchases, sales, and gifts. Each Approving Person should consult with the other Approving Person, or his or her designee, prior to granting pre-clearance for trades. Neither Approving Person may engage in a transaction in Processa securities unless the other Approving Person has pre-cleared the transaction.

The Approving Persons are under no obligation to approve a transaction submitted for pre-clearance and may determine not to permit a transaction, even if it would not violate the federal securities laws or a specific provision of this policy. In certain circumstances, other individuals may be asked to clear with an Approving Person all proposed transactions before initiating them. The fact that a particular intended trade has been denied pre-clearance should be treated as confidential information and should not be disclosed to any person unless authorized by the Approving Person.

If a request for pre-clearance is approved, you have three business days to effect the transaction (or, if sooner, before commencement of a quarterly or event-specific blackout period). Under no circumstance may a person trade while aware of material non-public information about Processa, even if pre-cleared. Thus, if you become aware of material non-public information after receiving pre-clearance, but before the trade has been executed, you must not effect the pre-cleared transaction.

Processa's approval of any particular transaction under this pre-clearance procedure does not insulate any Restricted Person from liability under the securities laws. Under the law, the ultimate responsibility for determining whether an individual is aware of material non-public information about Processa rests with that individual in all cases.

10b5-1 Plans

SEC Rule 10b5-1(c) of the Securities Exchange Act of 1934 permits corporate insiders to establish written trading plans (commonly referred to as "10b5-1 plans") that can be useful in enabling insiders to plan without fear that they might become exposed to material non-public information that will prevent them from trading. Where a valid 10b5-1 plan has been established at a time when the insider was not in possession of material non-public information, trades executed as specified by the plan do

not violate the securities laws or this policy even if the insider is in possession of material non-public information at the time the trade is executed. Trades executed as specified by the plan are not subject to the pre-clearance requirement.

To qualify as a 10b5-1 plan for purposes of this policy, the plan must be approved in advance (currently trading under a 10b5-1 plan cannot commence for 30 days following its creation) by an Approving Person, and you should allow at least five business days for that approval. For more information about how to establish a 10b5-1 plan, please contact one of the Approving Persons. Processa reserves the right to disapprove any submitted plan, and to suspend or instruct you to terminate any plan that it has previously approved.

Inquiries

Any questions about this policy, its application to a proposed transaction, or the requirements of applicable laws should be directed to the Chief Administrative Officer or the Chief Financial Officer.

Effective: May 31, 2021

REQUEST FOR PRE-CLEARANCE

For use by individual seeking pre-clearance to transact in Processa Pharmaceuticals, Inc. securities.

Processa Pharmaceuticals, Inc. has established an Insider Trading Policy to provide assistance in preventing inadvertent violations and avoiding even the appearance of an improper transaction by members of the Board of Directors, officers, and employees of Processa Pharmaceuticals, Inc. ("Processa") and certain others. These individuals must obtain pre-clearance in writing from the Chief Financial Officer or, in his absence, the Chief Administrative Officer for all transactions in Processa securities. The written request for pre-clearance of a transaction must be submitted no later than three (3) business days before the proposed date of execution of the transaction.

- All personnel subject to the Processa Insider Trading Policy must obtain pre-clearance to transact in Processa securities.
- Prior to requesting pre-clearance, the person must not be in possession of Material Non-Public Information.
- If not in possession of Material Non-Public information, the person may transact only when no Black-Out Period is in effect.
- Upon executing a transaction, Section 16 Individuals must immediately notify the Chief Financial Officer in order to allow timely filing of Form 4 with the Securities and Exchange Commission.

Type of Transaction (check one)

☐ Purchase or acquire common stock

☐ Sell or dispose of common stock

☐ Move Company securities from one account to another (*e.g.*, in or out of a trust)

☐ Cashless exercise of stock option (involving sale of shares to fund exercise)

☐ Other (describe): _____

Transaction Initiated By (check one)

☐ Company employee or immediate family member directly

☐ Broker *(provide firm, name, telephone, and email)*:

Firm name: _____

Broker name: _____

Telephone: _____

Email: _____

☐ Court or government decree (e.g., divorce decree)

Transaction Detail (complete each blank)

Number of Securities: _____

Estimated Share Price: _____

Contemplated Execution Date _____

Date of your last "opposite-way" transaction** (if any) _____

Certification

I certify that I have fully disclosed the information requested in this form, and that I have read and understand my obligations as described in the Processa Pharmaceuticals, Inc. Insider Trading Policy. As defined, I am not in possession of Material Non-Public Information, and to the best of my knowledge and belief the proposed transaction will not violate the Processa Pharmaceuticals, Inc. Insider Trading Policy.

Signature:	_____	Approval Signature:	_____
Print Name	_____	Print Name	_____
Date:	_____	Date:	_____

* If a Section 16 reporting person buys and sells (or sells and buys) Processa securities within a six-month time frame without an exemption under SEC rules, the two transactions may be "matched" for purposes of Section 16. The person may be sued and held strictly liable for any profits made, regardless of whether the person was in possession of material nonpublic information.

Processa Pharmaceuticals

To: Wendy Guy
Cc: James Stanker

I have been informed about the Processa Pharmaceuticals, Inc. Insider Trading Policy. I have received a copy of the Policy and agree to abide by the policy guidelines as a condition of my employment and my continuing employment at Processa Pharmaceuticals, Inc.

I understand that if I have questions, at any time, regarding the Insider Trading Policy, I can consult with the Chief Administrative Officer or the Chief Financial Officer.

I acknowledge that I have read the attached Insider Trading Policy carefully to ensure that I understand the policy before signing this document.

Employee Signature: _____

Printed Name _____

Date: _____

Exhibit 21.1

Subsidiaries of Processa Pharmaceuticals, Inc.

Subsidiary	State of Incorporation	Percent Ownership
Processa Therapeutics LLC	Delaware	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-279588 and No. 333-254983) and Form S-1 (No. 333-283986) of Processa Pharmaceuticals, Inc., and Registration Statement Form S-8 (No. 333-280952) pertaining to the Amended and Restated Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan of our report dated March 29, 2024, relating to the consolidated financial statements, which appear in this Form 10-K.

/s/ BD & Company, Inc.
Owings Mills, MD
March 20, 2025

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion or incorporation by reference of our report, dated March 20, 2025, with respect to the consolidated balance sheet of Processa Pharmaceutical, Inc. (the "Company") as of December 31, 2024 and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, in (i) the Company's Registration Statement on Form S-1 (No. 333-283986), (ii) the Company's Registration Statements on Form S-3 (No. 333-279588 and No. 333-254983), and (iii) the Company's Registration Statement on Form S-8 (No. 333-280952).

/s/ Cherry Bekaert LLP
Tampa, Florida
March 20, 2025

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
of the Securities Exchange Act of 1934, as Amended

I, George Ng, certify that:

1. I have reviewed this Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company");

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 Registrants other certifying officers 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 the material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly through 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 evaluations, 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 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 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 registrant's board of directors (or persons performing the equivalent function):

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 20, 2025

/s/ George Ng
George Ng
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
of the Securities Exchange Act of 1934, as Amended

I, Russell Skibsted, certify that:

1. I have reviewed this Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company");

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 Registrants other certifying officers 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 the material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly through 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 evaluations, 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 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 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 registrant's board of directors (or persons performing the equivalent function):

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 20, 2025

/s/ Russell Skibsted
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2024 (the "Report"), George Ng, as Chief Executive Officer of the Company, and Russell Skibsted, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ George Ng
George Ng
Chief Executive Officer
(Principal Executive Officer)
March 20, 2025

/s/ Russell Skibsted
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
March 20, 2025

This certification accompanies each Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of § 18 of the Securities Exchange Act of 1934, as amended.