

Processa Pharmaceuticals, Inc.

1,030,972 Shares of Common Stock
7,019,700 Pre-Funded Warrants to Purchase up to 7,019,700 Shares of Common Stock
8,050,672 Series A Warrants to Purchase up to 8,050,672 Shares of Common Stock
4,025,336 Series B Warrants to Purchase up to 4,025,336 Shares of Common Stock
19,095,708 Shares of Common Stock underlying the Pre-Funded Warrants, Series A Warrants and Series B Warrants

This is a reasonable best efforts public offering of 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 are also offering to each purchaser whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the investor 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, 7,019,700 pre-funded warrants (the “Pre-Funded Warrants”), in lieu of shares of common stock that would otherwise result in the purchaser’s beneficial ownership exceeding 4.99% of our outstanding common stock. Subject to limited exceptions, a holder of Pre-Funded Warrants will not have the right to exercise any portion of its Pre-Funded Warrants if the investor, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each Pre-Funded Warrant will be 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. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the pre-funded warrants.

Because the Common Warrants are being sold together in this offering with each share of common stock and, in the alternative, each Pre-Funded Warrant to purchase one share of common stock, the number of Common Warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and Pre-Funded Warrants sold. The shares of common stock or Pre-Funded Warrants, as applicable, and the accompanying Common Warrants, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance.

We are also registering shares of common stock that are issuable from time to time upon exercise of the Pre-Funded Warrants and Common Warrants.

We have engaged A.G.P./Alliance Global Partners (the “placement agent”), to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number or dollar amount of securities. We have agreed to pay to the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. Since we will deliver the securities to be issued in this offering upon our receipt of investor funds, there is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement as a condition of closing of this offering. Because there is no minimum offering amount required as a condition to closing this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue our business goals described in this prospectus. In addition, because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill all of our contemplated objectives due to a lack of interest in this offering. Further, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. See the section entitled “Risk Factors” for more information. We will bear all costs associated with the offering. See “Plan of Distribution” on page 37 of this prospectus for more information regarding these arrangements.

Our common stock is listed on The Nasdaq Capital Market under the symbol “PCSA.” The closing price of our common stock on January 24, 2025, as reported by The Nasdaq Capital Market, was \$0.68 per share. There is no established public trading market for the Pre-Funded Warrants or the Common Warrants, and we do not expect a market to develop. We do not intend to apply for listing of the Pre-Funded Warrants or the Common Warrants on any securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the Pre-Funded Warrants and the Common Warrants will be limited.

Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 9 of this prospectus before investing. You should also consider the risk factors described or referred to in any documents incorporated by reference in this prospectus, and in any applicable prospectus supplement, before investing in these securities.

We are a “smaller reporting company” as defined under federal securities law and we have elected to comply with certain reduced public company reporting requirements available to smaller reporting companies. See the section titled “Prospectus Summary — Implications of Being a Smaller Reporting Company.”

	Per share of Common Stock and accompanying Common Warrants	Per Pre-Funded Warrant and accompanying Common Warrants	Total
Public offering price	\$ 0.61500	\$ 0.61490	\$ 4,785,887
Insider offering price	\$ 0.79750	N/A	\$ 213,411
Placement agent fees ⁽¹⁾	\$ 0.03998 ⁽³⁾	\$ 0.03997	\$ 319,619
Proceeds to us, before expenses ⁽²⁾	\$ 0.57503 ⁽⁴⁾	\$ 0.57493	\$ 4,679,679

(1) We have agreed to pay the placement agent a cash fee equal to 6.5% of the gross proceeds raised in this offering (other than proceeds received from the Company’s current directors and officers and any issuer-directed investors, in which case the cash fee shall be 4.0% of the gross proceeds). We will also pay the placement agent a non-accountable expense allowance of up to \$20,000 and will reimburse the placement agent for its legal fees and expenses in an amount of up to \$75,000. For a description of compensation to be received by the placement agent, see “Plan of Distribution” for more information

(2) We estimate the total expenses in this offering payable by us, excluding the placement agent fees, will be approximately \$215,000. All costs associated with the registration will be borne by us.

(3) This amount relates to the 6.5% fee for non-insiders.

(4) This is based on the proceeds received from non-insiders.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Delivery of the securities is expected to be made on or about January 29, 2025.

Sole Placement Agent

A.G.P.

Prospectus dated January 27, 2025

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ABOUT THIS PROSPECTUS

You should rely only on the information we have provided or incorporated by reference into this prospectus, any applicable prospectus supplement and any related free writing prospectus. We incorporate by reference important information into this prospectus. You may obtain the information incorporated by reference without charge by following the instructions under “Where You Can Find More Information.” You should carefully read this prospectus as well as additional information described under “Incorporation of Certain Information By Reference,” before deciding to invest in our securities.

We have not, and the placement agent and its affiliates have not, authorized anyone to provide you with any information or to make any representation not contained or incorporated by reference in this prospectus or any related free writing prospectus. We do not, and the placement agent and its affiliates do not, take any responsibility for, and can provide no assurance as to the reliability of, any information that others may provide to you. This prospectus is not an offer to sell or an offer to buy securities in any jurisdiction where offers and sales are not permitted. The information in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or any sale of securities. You should also read and consider the information in the documents to which we have referred you under the caption “Where You Can Find More Information” in the prospectus.

To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference filed with the Securities and Exchange Commission (“SEC”) before the date of this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in a document incorporated by reference is inconsistent with a statement in another document incorporated by reference having a later date, the statement in the document having the late date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is incorporated by reference or filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

For investors outside the United States: neither we nor the placement agent have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States of America. Persons outside the U.S. who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus and any such free writing prospectus outside of the U.S.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management’s estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe that the information from these third-party publications, research, surveys and studies included in this prospectus is reliable. Management’s estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. These data involve a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause our future performance to differ materially from our assumptions and estimates.

This prospectus includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this prospectus are the property of their respective owners.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making an investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including the information set forth under the “Risk Factors” section of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of the risks involved in investing in our securities.

Overview

We are a clinical-stage biopharmaceutical company focused on utilizing our Regulatory Science Approach, which includes the principles associated with FDA’s Project Optimus Oncology initiative and the related FDA Draft Guidance, in the development of Next Generation Chemotherapy (“NGC”) oncology drug products. Our mission is to provide better treatment options than those that presently exist by extending a patient’s survival and/or improving a patient’s quality of life. This is achieved by improving upon FDA-approved, widely used oncology drugs or the cancer-killing metabolites of these drugs by altering how they are metabolized and/or distributed in the body, including how they are distributed to the actual cancer cells.

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 Guidance Documents. 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. Over the last 30 years, two of our founders, Dr. David Young and Dr. Sian Bigora, have expanded the original regulatory science concept by adding focused 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 identifies the scientific information that the FDA requires to determine whether 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 has taken steps to define some of the regulatory science required for the FDA approval of oncology products. Through the FDA’s Project Optimus Oncology Initiative and the related Draft Guidance on determining the “optimal” dosage regimen for an oncology drug, the FDA has chosen 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 in the past, 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 strategic prioritization is to advance our pipeline of NGC proprietary small molecule oncology drugs. The NGC products are new chemical entities that change the metabolism, distribution and/or elimination of already FDA-approved cancer drugs, or their active metabolites, while maintaining the drug’s proven mechanism of action in killing cancer cells. We believe our NGC treatments will provide improved safety-efficacy profiles when compared to their currently marketed counterparts – capecitabine, gemcitabine, and irinotecan.

Our Strategy

Our strategy is to develop our pipeline of NGC proprietary small molecule oncology drugs using our regulatory science approach to determine the optimal dosage regimen of our oncology drugs. 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 three new oncology drugs represent the next generation of chemotherapy with an improved safety profile, improved efficacy profile and/or 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.

Our pipeline of NGCs (i) already has data demonstrating the desired pharmacological activity in humans or appropriate animal models and is able to provide improved safety and/or efficacy by some modification in the formation and/or distribution of the active moieties associated with the drug and (ii) targets cancers for which a single positive pivotal trial demonstrating efficacy might provide enough evidence that the clinical benefits of the drug and its approval outweighs the risks associated with the drug.

Our Drug Pipeline



Our 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). The non-oncology drugs are not included in the pipeline chart above, as we are seeking partners to continue their clinical and commercial development. A summary of each drug is provided below.

Next Generation Chemotherapy

Historically, much of oncology drug development has searched for novel or different ways to treat cancer. Our approach is to take three current FDA-approved cancer drugs, e.g. capecitabine, gemcitabine and irinotecan, and modify and improve how the human body metabolizes and/or distributes these NGC treatments compared to their presently approved counterpart chemotherapy drugs while maintaining the cancer-killing mechanism of action; thus, our reason for calling our drugs Next Generation Chemotherapy treatments. Part of the development includes determining the optimal dosage regimen based on the dose-response relationship as described in the FDA’s Project Optimus Initiative and Draft Optimal Dosage Regimen Oncology Guidance. To date, we have data that we believe suggests our NGC treatments are likely to have much better safety-efficacy profiles than the current widely used marketed counterpart drugs, not only potentially making the development and approval process more efficient, but also clearly differentiating our NGC treatments from the existing treatment. We believe our NGC treatments have the potential to extend the survival and/or quality of life for more patients diagnosed with cancer while decreasing the number of patients who are required to dose-adjust or discontinue treatment because of side effects or lack of response.

Next Generation Chemotherapy Pipeline

- Next Generation Capecitabine (“NGC-Cap”) is a combination of PCS6422 and a lower dose of the FDA-approved cancer drug capecitabine. PCS6422 is an orally administered irreversible inhibitor of the enzyme dihydropyrimidine dehydrogenase (“DPD”). DPD metabolizes 5-Fluorouracil (“5-FU”), the major metabolite of capecitabine and widely used itself as an intravenous chemotherapeutic agent in many types of cancer, to multiple metabolites classified as catabolites. These catabolites do not have any cancer-killing properties but frequently cause dose-limiting side effects that may require dose adjustments or discontinuation of therapy.

Capecitabine, as presently prescribed and FDA-approved, forms the cancer drug 5-FU which is then further metabolized to anabolites (which kill both cancer cells and normal duplicating cells) and catabolites (which cause side effects and have no cancer killing properties). When capecitabine is given in combination with PCS6422 in 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 also greater than FDA-approved capecitabine based on the 5-FU systemic exposure per mg of capecitabine administered, the amount of capecitabine anabolites formed from 1 mg of capecitabine administered in NGC-Cap will, therefore, be much greater than formed from the administration of 1 mg of existing capecitabine.

The Phase 1B trial in patients with advanced refractory gastrointestinal tract tumors 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 order for NGC-Cap to provide a safer and more efficacious profile for cancer patients compared to existing chemotherapy, understanding how the different regimens of PCS6422 and capecitabine may affect the systemic and tumor exposure to the anabolites, as well as the systemic exposure to the catabolites, is required. This can be achieved by following the timeline of DPD irreversible inhibition and the formation of new DPD using the plasma concentrations of 5-FU and its catabolites.

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 chemotherapy 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 dose-limiting toxicities (“DLTs”). One of the early regimens in the Phase 1B trial did cause DLTs in two patients, one of whom died. No other DLTs were noted in the study. The Phase 1B trial has completed enrollment.

Although the primary objective of the NGC-Cap Phase 1B trial in patients with advanced, progressive cancer was to evaluate safety, the Phase 1B trial showed that treatment with NGC-Cap resulted in both a much greater efficacy response rate and a longer period of progression-free survival than what has been reported for capecitabine. In all evaluable progressive disease patients receiving PCS6422 and seven days of capecitabine, partial response and stable disease were observed in 66.7% (8 out of 12) of the evaluable patients, including two with partial response and six with stable disease. The length of progression-free survival was approximately five to 11 months across these patients. By comparison, in the capecitabine product label, 301 metastatic colorectal cancer patients treated with monotherapy capecitabine had an overall response rate of approximately 21% and the time to progression of approximately 4.5 months. In addition, even with up to 10x greater exposure to its 5-FU cancer treatment metabolite than capecitabine, only one patient on NGC-Cap had a mild case of hand-foot syndrome, meaning the hand-foot syndrome rate in our Phase 1B trial was 6% versus the expected ~50% based upon published data. Other side effects, even with 10x greater exposure, were similar or better than seen with capecitabine as approved by FDA.

Based on communications and meetings with the FDA, we submitted a new IND for the treatment of advanced and metastatic breast cancer and received IND clearance from the FDA on July 24, 2024. The Phase 2 trial has been initiated and will be a global multicenter, open-label, adaptive design 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. Our license agreement with Elion for NGC-Cap requires us to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that include dosing a first patient with a product in a Phase 2 or 3 clinical trial on or before October 6, 2024. On October 2, 2024, the first patient in our Phase 2 trial of NGC-Cap was dosed.

- 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 PCS3117 than gemcitabine. In addition, we believe those patients inherently resistant or who acquire resistance to gemcitabine are likely not to 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. The Phase 2A trial in patients with relapsed or refractory pancreatic cancer was completed by Ocuphire prior to us licensing NGC-Gem. We plan to meet with the FDA to discuss potential trial designs including implementation of the Project Optimus initiative as part of the design. Similar to NGC-Cap, we will need to obtain additional funding before we can begin any future trial for NGC-Gem.

Our license agreement with Ocuphire Pharma, Inc. (“Ocuphire”) for NGC-Gem requires us 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) dosing a patient in a clinical trial prior to June 16, 2024; and (ii) dosing a patient in a pivotal clinical trial or in a clinical trial for a second indication of the drug prior to June 16, 2026. We are currently in discussions with Ocuphire to extend these deadlines.

- NGC-Iri is an analog of SN38 (SN38 is the active metabolite of irinotecan) and should have an improved safety/efficacy profile in every type of cancer that irinotecan is presently used. The manufacturing process and sites for drug substance and drug product are presently being evaluated and IND-enabling toxicology studies will then be initiated. A preclinical study in mouse xenograft models showed that after PCS11T 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 defining the potential paths to approval, which include defining the targeted patient population and the type of cancer. In 2025, we plan to expand the preclinical analysis, including additional preclinical efficacy and toxicity studies; evaluate manufacturing options for PCS11T; and conduct chemistry, manufacturing and control (CMC) activities and pre-IND enabling studies.

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

In 2023, we completed our Phase 2A trial for PCS12852 in gastroparesis patients with positive results. Additionally, in February 2023, due primarily to the inability to identify and enroll patients in our rare disease Phase 2 trial for PCS499 in ulcerative Necrobiosis Lipoidica, we decided to cease further enrollment in the PCS499 trial and terminated the trial. We did not experience any safety concerns during the conduct of either the PCS12852 or PCS499 trial. We continue to evaluate options to monetize these non-core drug assets, which may include out-licensing or partnering these assets with one or more third parties. We are currently in discussions with Yuhan to amend our existing license agreement for PCS12852.

Going Concern

This offering is being made on a best-efforts basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering. We believe that the net proceeds from this offering, together with our cash on hand, will satisfy our capital needs into the third quarter of 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.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). We may take advantage of certain of the scaled disclosures available to smaller reporting companies such as including: (i) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act of 2002, as amended; (ii) scaled executive compensation disclosures; and (iii) the requirement to provide only two years of audited financial statements, instead of three years.

Corporate Information

We were incorporated under the laws of the state of Delaware on March 29, 2011. Our principal executive offices are located at 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076, and our telephone number is (443) 776-3133. Our website address is www.processpharmaceuticals.com. The information contained in, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

Additional Information

For additional information related to our business and operations, please refer to the reports incorporated herein by reference, including our Annual Report on Form 10-K for the year ended December 31, 2023 and our subsequently filed reports on Form 10-Q, as described in the section entitled “Incorporation of Certain Documents by Reference” in this prospectus.

THE OFFERING

Issuer	Processa Pharmaceuticals, Inc.
Shares of common stock being offered by us	1,030,972 shares of common stock 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
Pre-Funded Warrants offered by us	We are also offering to each purchaser whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the investor, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if the purchaser so chooses, 7,019,700 Pre-Funded Warrants, in lieu of shares of common stock that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% (or, at the election of the investor, 9.99%) of our outstanding common stock. Subject to limited exceptions, a holder of Pre-Funded Warrants will not have the right to exercise any portion of its Pre-Funded Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each Pre-Funded Warrant will be exercisable upon issuance for one share of our common stock and will expire when exercised in full. The purchase price of each Pre-Funded Warrant will equal the public offering price per share of common stock and accompanying Common Warrants less \$0.0001, and the exercise price of each Pre-Funded Warrant will be \$0.0001 per share. This offering also relates to the shares of common stock issuable upon exercise of any Pre-Funded Warrants sold in this offering. The exercise price and number of shares of common stock issuable upon exercise will be subject to certain further adjustments as described herein. See "Description of Securities" on page 29 of this prospectus.
Common Warrants offered by us	We are offering 8,050,672 Series A Warrants to purchase up to 8,050,672 shares of common stock and 4,025,336 Series B Warrants to purchase up to 4,025,336 shares of common Stock. 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 ("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. See "Description of Securities We Are Offering" for additional information.

Common Stock Outstanding prior to this Offering⁽¹⁾	3,706,316 shares
Common Stock to be Outstanding After this Offering⁽¹⁾	4,737,288 shares
Use of Proceeds	We estimate that the net proceeds of this offering, after deducting placement agent fees and estimated offering expenses, will be approximately \$4.5 million. We intend to use the net proceeds from the offering for continued research and development for NCG-Cap and general corporate purposes. See the section titled "Use of Proceeds" for more information.
Risk Factors	Investing in our securities involves a high degree of risk. For a discussion of factors to consider before deciding to invest in our securities, you should carefully review and consider the "Risk Factors" section of this prospectus, as well as the risk factors described or referred to in any documents incorporated by reference in this prospectus, and in any applicable prospectus supplement.
Market Symbol and trading	Our common stock is listed on The Nasdaq Capital Market under the symbol "PCSA." There is no established trading market for any of the warrants being issued and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Common Warrants or Pre-Funded Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Common Warrants and Pre-Funded Warrants will be limited.

(1) The number of shares of our common stock to be outstanding immediately after this offering as shown above is based on 3,706,316 shares of common stock outstanding as of January 24, 2025. The number of shares outstanding used throughout this prospectus, unless otherwise indicated, excludes as of January 24, 2025:

- 2,747 shares of our common stock issuable upon exercise of outstanding options, which have a weighted average exercise price of \$409.09 per share;
- 376,393 shares of common stock issuable for restricted stock units (RSUs) (of which 173,030 are vested) issuable upon meeting distribution restrictions;
- 1,775,784 shares of common stock issuable upon exercise of outstanding vested common warrants at a weighted-average exercise price of \$5.95 per share; and
- 355,415 shares of common stock reserved for issuance and available for future grant under our 2019 Omnibus Incentive Plan.

Unless otherwise indicated or the context requires otherwise, all information in this prospectus assumes no exercise of the Pre-Funded Warrants and Common Warrants offered hereby.

RISK FACTORS

An investment in our securities involves a high degree of risk. Before deciding whether to purchase our securities, including the shares of common stock offered by this prospectus, you should carefully consider the risks and uncertainties described under "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, any subsequent Quarterly Report on Form 10-Q and our other filings with the SEC, all of which are incorporated by reference herein. If any of these risks actually occur, our business, financial condition and results of operations could be materially and adversely affected and we may not be able to achieve our goals, the value of our securities could decline and you could lose some or all of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. If any of these risks occur, our business, results of operations or financial condition and prospects could be harmed. In that event, the market price of our common stock and the value of the warrants could decline, and you could lose all or part of your investment.

Risks Related to Our Financial Position and Need for 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 \$84.5 million as of September 30, 2024. At December 31, 2024, based on the information currently available to us, 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. We believe that the net proceeds from this offering, together with our cash on hand, will allow us to continue our Phase 2 trial of NGC-Cap and satisfy our capital needs into the third quarter of 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.

Following this offering, 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.

Following this offering, we will need to raise additional capital to fund our operations and continue to support our planned development of our next generation chemotherapy 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;

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- 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.

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 incurred recurring losses since inception and had an accumulated deficit of approximately \$84.5 million as of September 30, 2024. We expect continued operating losses and negative cash flow from operations for the foreseeable future. We have never generated revenue from operations, nor do we have any revenue under contract or any immediate sales prospects. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the United States or internationally. Even if we obtain regulatory approval for any drug candidates, development expenses will continue to increase. These conditions raise substantial doubt about our ability to continue as a going concern, meaning that we may be unable to continue operations for the foreseeable future or realize assets and discharge liabilities in the ordinary course of operations. If we are unable to obtain funding, we will be forced to delay, reduce or eliminate some or all of our research and development programs, or we may be unable to continue operations. Although we continue to pursue these plans, there can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

We will continue to expend substantial cash resources for the foreseeable future for the clinical development of our product candidates and development of any other indications and product candidates we may choose to pursue. These expenditures will include costs associated with manufacturing and clinical development, such as conducting clinical trials, manufacturing operations and product candidate supply. Because the conduct and results of any clinical trial are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development of our current and any future product candidates.

This offering is being made on a best efforts public basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering. We believe that the net proceeds from this offering, together with our cash on hand, will satisfy our capital needs into the third quarter of 2025 under our current business plan. Following this offering, we will need to raise additional capital to fund our operations and continue to support our planned development and commercialization activities.

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 22, 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.

Risks Related to This Offering and Ownership of Our Common Stock

Because management has broad discretion as to the use of the net proceeds from this offering, you may not agree with how we use them, and such proceeds may not be applied successfully.

Our management will have considerable discretion over the use of proceeds from this offering. We currently intend to use the net proceeds from this offering for continued research and development for NCG-Cap, and for working capital, capital expenditures, and general corporate purposes, including investing further in research and development efforts. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our securities, or that you otherwise do not agree with. You will be relying on the judgment of our management concerning these uses and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The failure of our management to apply these funds effectively could, among other things, result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our securities to decline.

Pending their use, we may invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

We may issue additional equity or convertible debt securities in the future, which may result in dilution to investors.

To the extent we need to raise additional capital in the future and we issue additional shares of common stock or securities exercisable, convertible or exchangeable for our common stock, our then existing stockholders may experience dilution and the new securities may have rights senior to those of our common stock offered in this offering.

There is no public market for the Pre-Funded Warrants or Common Warrants offered by us.

There is no established public trading market for the Pre-Funded Warrants or Common Warrants being offered in this offering, and we do not expect such a market to develop. In addition, we do not intend to apply to list the Pre-Funded Warrants or Common Warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Pre-Funded Warrants and Common Warrants will be limited.

Holders of Pre-Funded Warrants and Common warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Pre-Funded Warrants or Common Warrants and acquire our common stock.

Until holders of Pre-Funded Warrants or Common Warrants acquire shares of our common stock upon exercise of such warrants, holders of Pre-Funded Warrants and Common Warrants will have no rights with respect to the shares of our common stock underlying such Pre-Funded Warrants and Common Warrants. Upon exercise of the Pre-Funded Warrants and Common Warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The Common Warrants are speculative in nature.

The Common Warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Moreover, following this offering, the market value of the Common Warrants, if any, will be uncertain and there can be no assurance that the market value of the Common Warrants will equal or exceed their imputed offering price. The Common Warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of the Common Warrants, and consequently, the Common Warrants may expire valueless.

The Common Warrants being offered may not have value.

The Series A Warrants and the Series B warrants being offered by us in this offering 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, subject to certain adjustments, and expire on the five-year or eighteen-month anniversary, as applicable, from the date of stockholder approval, upon which date such Common Warrants will expire and have no further value. In the event that the market price of our common stock does not exceed the exercise price of the Common Warrants during the period when they are exercisable, the Common Warrants may not have any value.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including: (i) timely delivery of shares; (ii) agreement to not enter into variable rate financings for six months from closing, subject to certain exceptions; (iii) agreement to not enter into any equity sales for 60 days from closing; and (iv) indemnification for breach of contract.

This is a best efforts public offering, with no minimum amount of securities required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell a sufficient number of securities to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations in the short term and may need to raise additional funds, which may not be available or available on terms acceptable to us.

Because there is no minimum required for the offering to close, investors in this offering will not receive a refund in the event that we do not sell a sufficient number of securities to pursue the business goals outlined in this prospectus.

We have not specified a minimum offering amount nor have we will we establish an escrow account in connection with this offering. Because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Further, because there is no escrow account in operation and no minimum investment amount, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. Investor funds will not be returned under any circumstances whether during or after the offering.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock and warrants will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited research coverage by securities and industry analysts. If we fail to maintain adequate coverage by securities or industry analysts, the trading price for our stock would be negatively impacted. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Future sales of our common stock, warrants, or securities convertible into our common stock may depress our stock price.

The price of our common stock could decline as a result of sales of a large number of shares of our common stock or warrants or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

In addition, in the future, we may issue additional shares of common stock, warrants or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. We may also issue additional shares of common stock to satisfy the exercise of outstanding warrants. Any such issuances could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain any future earnings to finance the operation and expansion of our business. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

The sale of our common stock in this offering, including any shares issuable upon exercise of any Pre-Funded Warrants or Common Warrants, and any future sales of our common stock, or the perception that such sales could occur, may depress our stock price and our ability to raise funds in new stock offerings.

We may from time-to-time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such a discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. Sales of shares of our common stock in this offering, including any shares issuable upon exercise of any Pre-Funded Warrants or Common Warrants issued in this offering and in the public market following this offering, or the perception that such sales could occur, may lower the market price of our common stock and may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all.

Significant holders or beneficial holders of our common stock may not be permitted to exercise Pre-Funded Warrants that they hold.

A holder of a Pre-Funded Warrant will not be entitled to exercise any portion of any Pre-Funded Warrants which, upon giving effect to such exercise, would cause the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% (or, at the election of the purchaser, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise. Such percentage may be increased or decreased by written notice by the holder of the Pre-Funded Warrants to any other percentage not in excess of 9.99%. Such increase or decrease will not be effective until the sixty-first (61st) day after such

notice is delivered to us. As a result, you may not be able to exercise your Pre-Funded Warrants for shares of our common stock at a time when it would be financially beneficial for you to do so. In such circumstances, you could seek to sell your Pre-Funded Warrants to realize value, but you may be unable to do so in the absence of an established trading market for the Pre-Funded Warrants.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements. All statements other than statements of historical facts contained in this prospectus and the documents incorporated by reference herein are forward-looking statements, including statements regarding our future results of operations and financial position, business strategy, regulatory developments, research and development costs, the timing and likelihood of commercial success, the potential to develop future product candidates, plans and objectives of management for future operations, and future results of current and anticipated products. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. This prospectus and the documents incorporated by reference herein also contain estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus and the documents incorporated by reference herein are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions, which we discuss in greater detail in the documents incorporated by reference herein, including under the heading “Risk Factors” and elsewhere in this prospectus. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained in this prospectus or the documents incorporated by reference herein, whether as a result of any new information, future events, changed circumstances or otherwise. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$4.5 million, based on the combined purchase price per share of common stock and accompanying Common Warrants of \$0.615 for institutional investors and \$0.7975 for the Company’s Chief Executive Officer and certain board members and the sale of 1,030,972 shares of common stock, 7,019,000 Pre-Funded Warrants, 8,050,672 Series A Common Warrants, and 4,025,336 Series B Common Warrants in this offering after deducting the placement agent fees and estimated offering expenses payable by us. The amount excludes the proceeds, if any, from the exercise of Common Warrants in this offering. If all the Common Warrants sold in this offering were to be exercised in cash at an exercise price of \$0.65 per share, we would receive additional gross proceeds of approximately \$7.8 million. We cannot predict when or if these Common Warrants will be exercised. It is possible that these Common Warrants may expire and never be exercised.

We intend to use the net proceeds from the offering for continued research and development for NCG-Cap and general corporate purposes, including working capital, operating expenses and capital expenditures, and shall not use such proceeds: (i) for the satisfaction of any portion of the Company’s debt (other than payment of trade payables in the ordinary course of the Company’s business and prior practices or as disclosed in the Registration Statement), (ii) for the redemption of any common stock or common stock equivalents, (iii) for the settlement of any outstanding litigation, or (iv) in violation of FCPA or OFAC regulations.

We believe, based on our current operating plan, that our existing cash and cash equivalents together with the net proceeds from this offering and assuming no exercise of the Common Warrants, will be sufficient to fund our operations into the third quarter of 2025. However, the amounts and timing of our actual expenditures will depend on numerous factors, including the costs associated with our Phase 2 trial for NGC-Cap; any costs we incur related to NGC-Gem and NGC-Iri; for general and administrative costs to support operations; and other factors as described under “Risk Factors” in this prospectus and in the documents incorporated by reference herein. We therefore cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceed and it may be necessary to reallocate funds. Accordingly, our management will have flexibility in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

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If we have based our estimates on assumptions that are incorrect, or we increase our anticipated clinical trials, then we could use our available capital resources sooner than we currently expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our Board of Directors deems relevant, and subject to the restrictions contained in any future financing instruments.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2024 as follows:

- on an actual basis; and

- on an adjusted basis to give effect to the issuance by us of 1,030,972 shares of our common stock and 7,019,700 Pre-Funded Warrants in this offering at \$0.615 per share of common stock for institutional investors and \$0.7975 per share of common stock for the Company's Chief Executive Officer and certain board members, after deducting the placement agent fees and estimated offering expenses payable by us.

You should read this information in conjunction with our consolidated financial statements and notes thereto incorporated by reference into this prospectus.

	As of September 30, 2024	
	Actual	As adjusted
Cash and cash equivalents	\$ 2,891,464	\$ 7,356,799
Preferred stock, \$0.0001 par value: 1,000,000 shares authorized, no shares issued or outstanding	-	-
Common stock \$0.0001 par value: 100,000,000 shares authorized, 3,271,944 issued and 3,266,944 outstanding, actual; 11,322,616 shares issued and 11,317,616 outstanding, as adjusted ⁽¹⁾	327	1,132
Additional paid-in capital	88,510,949	92,975,479
Treasury stock at cost – 5,000 shares	(300,000)	(300,000)
Accumulated equity	(84,490,491)	(84,490,491)
Total stockholders' equity	3,720,785	8,186,120
Total capitalization	\$ 3,720,785	\$ 8,186,120

⁽¹⁾ The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on 3,266,944 shares of common stock outstanding as of September 30, 2024, and exclude:

- 2,747 shares of our common stock issuable upon exercise of outstanding options, which have a weighted average exercise price of \$409.09 per share;
- 384,799 shares of common stock issuable for restricted stock units (RSUs) (of which 144,450 are vested) issuable upon meeting distribution restrictions;
- 1,775,784 shares of common stock issuable upon exercise of outstanding vested common warrants at a weighted-average exercise price of \$5.95 per share;
- 353,641 shares of common stock reserved for issuance and available for future grant under our 2019 Omnibus Incentive Plan; and
- the exercise of the Pre-Funded Warrants and Common Warrants issued in this offering.

In addition, to the extent that any outstanding options, RSUs, or warrants described above are exercised, new options are issued, or we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

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⁾ Chief Executive Officer	2024	400,000 ⁽⁵⁾	100,000 ⁽⁴⁾	-	-	21,033	521,033
	2023	159,091	-	312,000	-	-	471,091
David Young President, Research and Development and former Chief Executive Officer	2024	290,940 ⁽⁶⁾	-	14,484	-	-	305,424
	2023	160,200	-	26,433	-	-	186,633
Sian Bigora Chief Development Officer	2024	290,940 ⁽⁷⁾	-	14,484	-	22,827	328,251
	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 Procesa 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.

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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.

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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

With the exception of an executive employment agreement with Mr. Ng and Mr. Skibsted, we do not currently have any executive employment agreements with any of our

named executive officers in connection with their employment. Mr. Ng's and Mr. Skibsted's executive employment agreements are summarized below.

George Ng Employment Agreement. On August 8, 2023, we entered into an 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) a bonus of \$50,000 upon the achievement of each of the following two milestones: (1) upon the closing stock price above \$1.00 per share for at least ten consecutive trading days on or before February 28, 2024, and (2) upon enrolling the first patient in a Processa-sponsored clinical study for a Next Generation Chemotherapy drug; (iii) pursuant to our 2019 Omnibus Incentive Plan, a grant of RSUs for 20,000 shares which shall vest over three years and a grant of RSUs for an additional 20,000 shares delivered in two tranches when certain milestones have been met; (iv) participation in equity-based long-term incentive compensation plans generally available to senior executive officers of the Company (beginning in 2025); and (v) 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 July 16, 2024, we entered into an 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) pursuant to our 2019 Omnibus Incentive Plan, a grant of RSUs for 14,000 shares which vest on July 16, 2025; RSUs for 7,000 shares which vest upon Processa 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 RSUs for 7,000 shares which vest upon a cumulative (one or multiple) financing of at least \$15 million that he leads and substantially participates in; (iv) participation in equity-based long-term incentive compensation plans generally available to senior executive officers of the Company (beginning in 2025); and (v) 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 35% of his base compensation.

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Potential Payments Upon Termination or Change in Control

Both Mr. Ng's and Mr. Skibsted's employment agreements provide that either party may terminate the agreement at-will, and regardless of the manner in which such executive's service terminates, he 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 of his 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 his 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.

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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:

Name	Grant Date	Stock Option Awards			Restricted Stock Units	
		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 Cash (\$)	Stock Awards (\$) ⁽¹⁾	Total (\$)
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:

Name	Grant Date	Stock Option Awards			Restricted Stock Units	
		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.

BENEFICIAL OWNERSHIP OF COMMON STOCK

The following table sets forth certain information with respect to the beneficial ownership of our common stock at January 24, 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 January 24, 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 3,706,316 shares of our common stock outstanding as of January 24, 2025. Shares of our common stock that a person has the right to acquire within 60 days of January 24, 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.

Name and address of beneficial owner ⁽¹⁾	Shares beneficially owned	
	Shares	Percent
Officers and Directors		
Sian Bigora ⁽²⁾	54,005	1.4%
Wendy Guy ⁽³⁾	42,972	1.2%
Patrick Lin ⁽⁴⁾	51,839	1.4%
George Ng ⁽⁵⁾	30,559	*
Russell Skibsted	-	*
David Young ⁽⁶⁾	164,280	4.4%
Khoso Baluch ⁽⁷⁾	6,467	*
James Neal ⁽⁸⁾	5,790	*
Geraldine Pannu ⁽⁹⁾	7,951	*
Justin Yorke ⁽¹⁰⁾	40,038	1.1%
Total for all Officers and Directors	403,901	10.5%

* 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 25,459 shares of common stock issuable within 60 days of January 24, 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 22,780 shares of common stock issuable within 60 days of January 24, 2025.

(4) Consists of (i) 29,059 shares of common stock held directly by Mr. Lin and (ii) restricted stock units representing 22,780 shares of common stock issuable within 60 days of January 24, 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 and (ii) restricted stock units representing 10,559 shares of common stock issuable within 60 days of January 24, 2025.

(6) Consists of (i) 80,905 shares of common stock held directly by Dr. Young; (ii) 18,851 shares held by family entities; (iii) 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 (iv) restricted stock units for 23,060 shares of our common stock issuable within 60 days of January 24, 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 January 24, 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 January 24, 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 January 24, 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) restricted stock units representing 5,069 shares of common stock issuable within 60 days of January 24, 2025; and (iii) the shares held by the Richland Fund, LLC which total 31,232 shares.

DESCRIPTION OF CAPITAL STOCK

The following description of the material terms of our capital stock and the provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to copies of the amended and restated certificate of incorporation and bylaws, which are filed with the SEC as exhibits to our registration statement of which this prospectus forms a part.

We have the authority to issue an aggregate of 100,000,000 shares of \$0.0001 par value common stock and 1,000,000 shares of \$0.0001 par value preferred stock. As of January 24, 2025, there were 3,706,316 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

Dividend Rights. Subject to the rights of holders of preferred stock of any series that may be issued and outstanding from time to time, holders of our common stock are entitled to receive such dividends and other distributions as may be declared by our Board of Directors from time to time.

Voting Rights. Each outstanding share of our common stock is entitled to one vote on all matters submitted to a vote of stockholders generally. In the event we issue one or more series of preferred or other securities in the future such preferred stock or other securities may be given rights to vote, either together with the common stock or as a separate class on one or more types of matters. The holders of our common stock do not have cumulative voting rights.

Liquidation Rights. In the event of any liquidation, dissolution or winding up of the Company, the holders of our common stock will be entitled, subject to any preferential or other rights of any then outstanding preferred stock, to receive all assets of the Company available for distribution to stockholders.

Preemptive Rights. As of the date hereof, the holders of our common stock have no preemptive rights in their capacities as such holders.

Board of Directors. Holders of common stock do not have cumulative voting rights with respect to the election of directors. At any meeting to elect directors by holders of our common stock, the presence, in person or by proxy, of the holders of a majority of the voting power of shares of our capital stock then outstanding will constitute a quorum for such election. Directors may be elected by a plurality of the votes of the shares present and entitled to vote on the election of directors, except for directors whom the holders of any then outstanding preferred stock have the right to elect, if any.

Preferred Stock

Our Board is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 1,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series. The rights of holders of our common stock may be subject to, and adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control and may adversely affect the voting and other rights of holders of our common stock.

Indemnification of Directors and Officers

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by the Delaware General Corporate Law (“DGCL”) as it may hereafter be amended, none of our directors will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director. Under the DGCL as it now reads, such limitation of liability is not permitted:

- for any breach of the director’s duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for payments of unlawful dividends or unlawful stock purchases or redemptions under Section 174 of the DGCL; or
- for any transaction from which the director derived an improper personal benefit.

These provisions will have no effect on the availability of equitable remedies such as an injunction or rescission based on a director’s breach of his or her duty of care.

Our amended and restated certificate of incorporation and our amended and restated bylaws include provisions that require us to indemnify and advance expenses, to the fullest extent allowable under the DGCL as it now exists or may hereafter be amended, to our directors or officers for actions taken as a director or officer of us, or for serving at our request as a director or officer at another corporation or enterprise, as the case may be.

Section 145 of the DGCL provides that a corporation may indemnify directors and officers, as well as other employees and individuals, against expenses, including attorneys’ fees, judgments, fines and amounts paid in settlement, that are incurred in connection with various actions, suits or proceedings, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, known as a derivative action, if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, if they had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification only extends to expenses, including attorneys’ fees, incurred in connection with the defense or settlement of such actions, and the statute requires court approval before there can be any indemnification if the person seeking indemnification has been found liable to the corporation. The statute provides that it is not exclusive of other indemnification that may be granted by a corporation’s bylaws, disinterested director vote, stockholder vote, agreement or otherwise.

Our amended and restated bylaws require us to indemnify any person who was or is a party or is threatened to be made a party to, or was otherwise involved in, a legal proceeding by reason of the fact that he or she is or was a director or officer of the Company or is or was serving at our request as a director or officer of another corporation or enterprise, as the case may be, to the fullest extent authorized by the DGCL as it now exists or may hereafter be amended, against all expense, liability and loss (including attorneys’ fees, judgments, fines, Employee Retirement Income Security Act excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such director or officer in connection with such service. The right to indemnification in our amended and restated bylaws includes the right to be paid by the Company the expenses incurred in defending any proceeding for which indemnification may be sought in advance of the final disposition of such proceeding, subject to certain limitations. We carry directors’ and officers’ insurance protecting us, any director, officer, employee or agent of ours or who was serving at the request of the Company as a director, officer, employee or agent of another corporation or enterprise, as the case may be, against any expense, liability or loss, whether or not we would have the power to indemnify the person under the DGCL.

The limitation of liability and indemnification and advancement provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of fiduciary duty. These provisions also may reduce the likelihood of derivative litigation against our directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, your investment in our common stock may be adversely affected to the extent we pay the costs of settlement and damage awards under these indemnification provisions.

Certain Anti-Takeover Effects

Provisions of Delaware Law. We are a Delaware corporation and Section 203 of the DGCL applies to us. It is an anti-takeover statute that is designed to protect stockholders against coercive, unfair or inadequate tender offers and other abusive tactics and to encourage any person contemplating a business combination with us to negotiate with our Board of Directors for the fair and equitable treatment of all stockholders.

Under Section 203 of the DGCL, a Delaware corporation is not permitted to engage in a “business combination” with an “interested stockholder” for a period of three years following the date that the stockholder became an interested stockholder. As defined for this purpose, the term “business combination” includes a merger, consolidation, asset sale or other transaction resulting in a financial benefit to the interested stockholder. The term “interested stockholder” is defined to mean a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation’s outstanding voting stock. This prohibition does not apply if:

- prior to the time that the stockholder became an interested stockholder, the Board of Directors of the corporation approved either the business combination or the transaction resulting in the stockholder becoming an interested stockholder;
- upon completion of the transaction resulting in the stockholder becoming an interested stockholder, the stockholder owns at least 85% of the outstanding voting stock of the corporation, excluding voting stock owned by directors who are also officers and by certain employee stock plans; or

- at or subsequent to the time that the stockholder became an interested stockholder, the business combination is approved by the Board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that the interested stockholder does not own.

A Delaware corporation may elect not to be governed by these restrictions. We have not opted out of Section 203.

Advance Notice Procedures. Our bylaws establish an advance notice procedure for stockholder nominations of persons for election to our Board of Directors and for any proposals to be presented by stockholders at an annual meeting. Stockholders at an annual meeting will only be able to consider nominations and other proposals specified in the notice of meeting or brought before the meeting by or at the direction of our Board of Directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our corporate secretary timely written notice, in proper form, of the stockholder's intention to nominate a person for election as a director or to bring a proposal for action at the meeting.

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Potential Effects of Authorized but Unissued Stock

Pursuant to our amended and restated certificate of incorporation, we have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our Board of Directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

Choice of Forum

Unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any stockholder to bring (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Company or the Company's stockholders, (iii) any action asserting a claim against the Company or any director or officer of the Company arising pursuant to, or a claim against the Company or any director or officer of the Company, with respect to the interpretation or application of any provision of the DGCL, our certificate of incorporation or bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine, except for, in each of the aforementioned actions, any claims to which the Court of Chancery of the State of Delaware determines it lacks jurisdiction. This provision will not apply to claims arising under the Exchange Act, or for any other federal securities laws which provide for exclusive federal jurisdiction. However, the exclusive forum provision provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Therefore, this provision could apply to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and that asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. There is uncertainty as to whether a court would enforce such an exclusive forum provision with respect to claims under the Securities Act.

We note that there is uncertainty as to whether a court would enforce the provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

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DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering (i) 1,030,972 shares of our common stock, (ii) 1,030,972 Series A Common Warrants, and (iii) 515,486 Series B Common Warrants at a combined offering price of \$0.615 for institutional investors and \$0.7975 for the Company's Chief Executive Officer and certain board members. We are also offering (i) 7,019,700 Pre-Funded Warrants, (ii) 7,019,700 Series A Common Warrants and (iii) 3,509,850 Series B Common Warrants at a combined offering price of \$0.6149 to those purchasers whose purchase of shares of our common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock following the consummation of this offering in lieu of the shares of common stocks that would result in such excess ownership. Each share of our common stock or Pre-Funded Warrant is being sold together with one Series A Warrant to purchase one share of common stock and one Series B Warrant to purchase 0.5 shares of common stock. The shares of our common stock and/or Pre-Funded Warrants and related Common Warrants will be issued separately. We are also registering the shares of our common stock issuable from time to time upon exercise of the Pre-Funded Warrants and Common Warrants offered hereby.

Common Stock

The material terms and provisions of our common stock are described under the caption "Description of Capital Stock" in this prospectus.

Common Warrants

The following summary of certain terms and provisions of the Common Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of Common Warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the forms of Common Warrants for a complete description of the terms and conditions of such warrant.

Duration and Exercise Price

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. The exercise price and number of shares of common stock issuable upon exercise of the warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Common Warrants will be issued separately from the common stock and Pre-Funded Warrants and may be transferred separately immediately thereafter. The Common Warrants will be issued in certificated form only.

We intend to promptly, and in no event later than ninety (90) days after the consummation of this offering, seek stockholder approval for the issuance of shares of our common stock issuable upon exercise of the Common Warrants but we cannot assure you that such stockholder approval will be obtained. We have agreed with the investors in this offering that, if we do not obtain stockholder approval for the issuance of the shares of our common stock upon exercise of the Common Warrants at the first stockholder meeting for such purpose after this offering, we will call a stockholder meeting every ninety (90) days thereafter until the earlier of the date we obtain such approval or the Common Warrants are no longer outstanding.

Exercisability

The Common Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of such holder's Common Warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Common Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Common Warrants.

Cashless Exercise

If, at the time a holder exercises its Common Warrants, a registration statement registering the issuance or resale of the shares of common stock underlying the Common Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Common Warrant.

Fundamental Transactions

In the event of a fundamental transaction, as described in the Common Warrants and generally including any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the voting power represented by our outstanding shares of capital stock, any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding shares of capital stock, any merger with or into another entity or a tender offer or exchange offer approved by more than 50% of the voting power represented by our outstanding shares of capital, then upon any subsequent exercise of a Common Warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the same consideration receivable as a result of such transaction by a holder of the number of shares of our common stock for which the Common Warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the Common Warrants have the right to require us or a successor entity to redeem the Common Warrants for cash in the amount of the Black-Scholes Value (as defined in each warrant) of the unexercised portion of the Common Warrants concurrently with or within days following the consummation of a fundamental transaction; subject to certain exceptions.

However, in the event of a fundamental transaction which is not in our control, including a fundamental transaction not approved by our Board of Directors, the holders of the Common Warrants will only be entitled to receive from us or our successor entity, as of the date of consummation of such fundamental transaction the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the Common Warrant that is being offered and paid to the holders of our common stock in connection with the fundamental transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of our common stock are given the choice to receive alternative forms of consideration in connection with the fundamental transaction, and in certain circumstances, upon a fundamental transaction with certain companies, the holder will receive warrants in the new entity.

Transferability

Subject to applicable laws, a Common Warrant may be transferred at the option of the holder upon surrender of the Common Warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Common Warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the next whole share or we will pay a cash adjustment in an amount equal to such fraction multiplied by the exercise price.

Trading Market

There is no established trading market for the Common Warrants, and we do not expect such a market to develop. We do not intend to apply to list the Common Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Common Warrants will be extremely limited.

Right as a Stockholder

Except as otherwise provided in the Common Warrants or by virtue of the holder's ownership of shares of our common stock, such holder of warrants does not have the rights or privileges of a holder of our common stock, including any voting rights, until such holder exercises such holder's Common Warrants. The Common Warrants will provide that the holders of the Common Warrants have the right to participate in distributions or dividends paid on our shares of common stock.

Waivers and Amendments

The Common Warrants may be modified or amended, or the provisions of such Common Warrants waived with our consent and the consent of the holders of at least a majority of the outstanding Common Warrants.

Pre-Funded Warrants

The following summary of certain terms and provisions of the Pre-Funded Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Pre-Funded Warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of the Pre-Funded Warrant for a complete description of the terms and conditions of the Pre-Funded Warrants.

Duration and Exercise Price

Each Pre-Funded Warrant offered hereby will have an initial exercise price per share of common stock equal to \$0.0001. The Pre-Funded Warrants will be immediately exercisable and will expire when exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of share dividends, share splits, reorganizations or similar events affecting our shares of common stock and the exercise price.

Exercisability

The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than 4.99% of the outstanding shares of common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding shares after exercising the holder's Pre-Funded Warrants up to 9.99% of the number of our shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. Purchasers of Pre-Funded Warrants in this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99% of our outstanding shares of common stock.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Pre-Funded Warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Pre-Funded Warrants. Rather, at the Company's election, the number of shares of common stock to be issued will be rounded up to the next whole share or the Company will pay a cash adjustment in an amount equal to such fraction multiplied by the exercise price.

Transferability

Subject to applicable laws, a Pre-Funded Warrant may be transferred at the option of the holder upon surrender of the Pre-Funded Warrants to us together with the appropriate instruments of transfer.

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Trading Market

There is no established trading market for the Pre-Funded Warrants, and we do not expect such a market to develop. We do not intend to apply to list the Pre-Funded Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Pre-Funded Warrants will be extremely limited.

Right as a Shareholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of shares of common stock, the holders of the Pre-Funded Warrants do not have the rights or privileges of holders of our shares of common stock, including any voting rights, until they exercise their Pre-Funded Warrants. The Pre-Funded Warrants will provide that the holders of the Pre-Funded Warrants have the right to participate in distributions or dividends paid on our shares of common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the voting power represented by our outstanding shares of capital stock, any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding shares of capital stock, any merger with or into another entity or a tender offer or exchange offer approved by more than 50% of the voting power represented by our outstanding shares of capital, then upon any subsequent exercise of a Pre-Funded Warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the Pre-Funded Warrant is exercisable immediately prior to such event.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following discussion describes certain material U.S. federal income tax consequences relating to the acquisition, ownership and disposition of our common stock, pre-funded warrants and common warrants by a U.S. Holder or Non-U.S. Holder (as each term is defined below). This discussion is based on the current provisions of the Internal Revenue Code of 1986, as amended (referred to as the "Code"), existing and proposed U.S. Treasury regulations promulgated thereunder, and administrative rulings and court decisions in effect as of the date hereof, all of which are subject to change at any time, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service, or IRS, with respect to the matters discussed below, and there can be no assurance the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, pre-funded warrants or common warrants, or that any such contrary position would not be sustained by a court.

We assume in this discussion that the shares of our common stock, pre-funded warrants and common warrants will be held as capital assets (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxes and does not address state or local taxes or U.S. federal gift and estate tax laws, or any non-U.S. tax consequences that may be relevant to holders in light of their particular circumstances. This discussion also does not address the special tax rules applicable to particular holders, such as:

- a bank, insurance company, or other financial institution;
- a tax-exempt entity, organization, or arrangement;
- a government or any agency, instrumentality, or controlled entity thereof;
- a real estate investment trust;
- an S corporation or other pass-through entity (or an investor in an S corporation or other pass-through entity);

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- a regulated investment company;
- a "controlled foreign corporation" or a "passive foreign investment company";
- a dealer or broker in stocks and securities, or currencies;
- a trader in securities that elects mark-to-market treatment or any other holder subject to mark-to-market treatment;
- a holder of our common stock, pre-funded warrants or common warrants that is liable for the alternative minimum tax;
- a holder of our common stock, pre-funded warrants or common warrants that received such security through the exercise of options, warrants, or similar derivative securities or otherwise as compensation;

- a holder of our common stock, pre-funded warrants that holds such security in a tax-deferred account (such as an individual retirement account or a plan qualifying under Section 401(k) of the Code);
- a holder of our common stock, pre-funded warrants or common warrants that has a functional currency other than the U.S. dollar;
- a holder of our common stock, pre-funded warrants or common warrants that holds such security as part of a hedge, straddle, constructive sale, conversion or other integrated transaction;
- a holder of our common stock, pre-funded warrants or common warrants required to accelerate the recognition of any item of gross income with respect to such security, as a result of such income being recognized on an applicable financial statement;
- a holder of our common stock, pre-funded warrants or common warrants that is a U.S. expatriate or former citizen or long-term resident of the United States;
- a holder of our common stock, pre-funded warrants or common warrants that does not hold such security as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes);
- a holder of our common stock, pre-funded warrants or common warrants whose security may constitute “qualified small business stock” under Section 1202 of the Code or “Section 1244 stock” for purposes of Section 1244 of the Code; or
- a holder of our common stock, pre-funded warrants or common warrants that acquired such security in a transaction subject to the gain rollover provisions of Section 1045 of the Code;

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities or of persons who hold our common stock, pre-funded warrants or common warrants through partnerships or other entities which are pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock, pre-funded warrants or common warrants should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock, pre-funded warrants or common warrants through a partnership or other pass-through entity, as applicable.

For the purposes of this discussion, a “U.S. Holder” means a beneficial owner of our common stock, pre-funded warrants or common warrants that is for U.S. federal income tax purposes (a) an individual citizen or resident of the United States, (b) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes), organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) has the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. A “Non-U.S. Holder” is, for U.S. federal income tax purposes, a beneficial owner of common stock, pre-funded warrants or common warrants (other than a partnership or other entity or arrangement classified as a partnership for U.S. federal income tax purposes) that is not a U.S. Holder.

The discussion of U.S. federal income tax considerations is for information purposes only and is not tax advice. Investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock, pre-funded warrants or common warrants.

Allocation of Purchase Price to Common Stock, Pre-Funded Warrants and Common Warrants

For U.S. federal income tax purposes, a holder’s acquisition of the common warrants and common stock or pre-funded warrants, as applicable, should be treated as the acquisition of an “investment unit” consisting of one share of common stock or one pre-funded warrant, as applicable, and a warrant to acquire one share of our common stock, subject to adjustment. The purchase price for each investment unit will be allocated between these two components in proportion to their relative fair market values at the time the unit is purchased by the holder. This allocation of the purchase price for each unit will establish the holder’s initial tax basis for U.S. federal income tax purposes in the common stock or pre-funded warrant, as applicable, and the common stock warrant included in each unit. We do not intend to advise holders of the common warrants and common stock or pre-funded warrants, as applicable, with respect to this determination, and holders are advised to consult their tax and financial advisors with respect to the relative fair market values of the common stock or pre-funded warrant, as applicable, and the common warrants for U.S. federal income tax purposes.

Tax Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, we believe a pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of common stock as described below. Accordingly, for U.S. federal income tax purposes, no gain or loss should be recognized upon the exercise of a pre-funded warrant, and upon exercise, the holding period of the share of common stock received should include the holding period of the pre-funded warrant. Similarly, the tax basis of a share of common stock received upon exercise of a pre-funded warrant should include the tax basis of the pre-funded warrant (discussed below) increased by the exercise price of \$0.0001. The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

Tax Considerations Applicable to U.S. Holders

Exercise and Expiration of the Pre-Funded Warrants and Common Warrants

In general, a U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a pre-funded warrant or common warrant (for the balance of this discussion a “warrant”), except to the extent such U.S. Holder receives a cash payment for a fractional share that would otherwise have been issuable upon exercise of the warrant, which will be treated as a sale subject to the rules described below under “U.S. Holders — Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants.” The U.S. Holder will take a tax basis in the shares acquired on the exercise of a warrant equal to the exercise price of the warrant, increased by the U.S. Holder’s adjusted tax basis in the warrant exercised. A U.S. holder’s holding period in the common stock received upon exercise of a pre-funded warrant generally should include such U.S. holder’s holding period in the pre-funded warrants exchanged therefor. The U.S. Holder’s holding period in the shares of our common stock acquired on exercise of the common warrant will begin on the date of exercise of the common warrant (or possibly, the day after), and will not include any period for which the U.S. Holder held the common warrant.

In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a warrant described in the preceding paragraph. Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance as to the tax treatment that would be adopted by the IRS or a court of law. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

The lapse or expiration of a warrant will be treated as if the U.S. Holder sold or exchanged the warrant and recognized a capital loss equal to the U.S. Holder’s tax basis in the warrant. The deductibility of capital losses is subject to limitations.

Certain Adjustments to and Distributions on the Pre-Funded Warrants and Common Warrants

The exercise terms of the warrants may be adjusted in certain circumstances. An adjustment to the number of shares of common stock that will be issued on the exercise of the warrants or an adjustment to the exercise price of the warrants may be treated as a constructive distribution to a U.S. Holder of the warrants even if such holder does not receive any cash or other property in connection with the adjustment. If the exercise price is adjusted in certain other circumstances (or in certain circumstances, there is a failure to make adjustments), such adjustments may also result in a constructive distribution to a U.S. Holder. U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to the warrants. Any constructive distribution will generally be taxed in the same manner as an actual distribution received by a U.S. Holder as discussed below under “Distributions.”

Distributions

We currently anticipate that we will retain all available funds and any future earnings for use in the operation of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. In the event that we do make distributions to a U.S. Holder, those distributions generally will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions to a U.S. Holder that are not derived from our current or accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, the U.S. Holder's adjusted tax basis in our common stock, pre-funded warrants or common warrants, as applicable, and to the extent in excess of such basis, will be treated as gain realized on the sale or exchange of our common stock, pre-funded warrants or common warrants, as applicable, as described below.

The U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the applicable common stock, pre-funded warrants or common warrants. Capital gain or loss will constitute long-term capital gain or loss if the U.S. Holder's holding period for the applicable common stock, pre-funded warrants or common warrants exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. Holders who recognize losses with respect to a disposition of our common stock, pre-funded warrants or common warrants should consult their own tax advisors regarding the tax treatment of such losses.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of securities. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our securities.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on our common stock, pre-funded warrants and common warrants and to the proceeds of a sale or other disposition of common stock, pre-funded warrants and common warrants by a U.S. Holder unless such U.S. Holder is an exempt recipient, such as a corporation. Backup withholding will apply to those payments if the U.S. Holder fails to provide the holder's taxpayer identification number, or certification of exempt status, or if the holder otherwise fails to comply with applicable requirements to establish an exemption. Backup withholding is not an additional tax. Rather, amounts withheld as backup withholding may be credited against a person's U.S. federal income tax liability, and a holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the IRS and furnishing any required information.

Tax Considerations Applicable to Non-U.S. Holders

Exercise and Expiration of Pre-Funded Warrants and Common Warrants

In general, a Non-U.S. Holder will not be subject to U.S. federal income tax on the exercise of the warrants into shares of common stock. As described under "U.S. Holders - Exercise and Expiration of the Pre-Funded Warrants and Common Warrants" the U.S. federal income tax treatment of a cashless exercise of warrants into our common stock is unclear. A Non-U.S. Holder should consult his, her, or its own tax advisor regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

The expiration of a warrant will be treated as if the Non-U.S. Holder sold or exchanged the warrant and recognized a capital loss equal to the Non-U.S. Holder's tax basis in the warrant. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a warrant against the Non-U.S. Holder's U.S. federal income tax liability unless the loss is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment or fixed base in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is an individual nonresident and present 183 days or more in the taxable year of disposition in the United States and certain other conditions are met.

Certain Adjustments to and Distributions on the Pre-Funded Warrants and Common Warrants

As described under "U.S. Holders - Certain Adjustments to and Distributions on the Pre-Funded Warrants and Common Warrants" an adjustment to the warrants could result in a constructive distribution to a Non-U.S. Holder, which would be treated as described under "Distributions" below, and the tax treatment of a distribution on a warrant is unclear. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the Non-U.S. Holder. Non-U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to or distributions on the warrants.

Distributions

We currently anticipate that we will retain all available funds and any future earnings for use in the operation of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. In the event that we do make distributions on our common stock or warrants to a Non-U.S. Holder, those distributions generally will be treated as dividends, as return of capital or as gain on the sale or exchange of common stock or warrants for U.S. federal income tax purposes as described in "U.S. Holders - Distributions."

Subject to the discussions below under the sections titled "Information Reporting and Backup Withholding" and "Foreign Accounts," any distribution (including constructive distributions) on our common stock or warrants that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with the holder's conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder's country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically and when otherwise required by law.

We generally are not required to withhold tax on dividends paid (or constructive dividends deemed paid) to a Non-U.S. Holder that are effectively connected with such holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us. In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

Distributions to a Non-U.S. Holder that are not derived from our current or accumulated earnings and profits generally will be treated as a return of capital that will be applied against and reduce (but not below zero) the Non-U.S. Holder's basis in its common stock or warrants, as applicable, and to the extent in excess of such basis, will be treated as gain from the sale or exchange of such common stock or warrants, as applicable, as described under "Disposition of Our Common Stock, Pre-Funded Warrants or

Common Warrants” below.

If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder’s behalf, the holder will be required to provide appropriate documentation to such agent. The holder’s agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries.

Disposition of Our Common Stock, Pre-Funded Warrants or Common Warrants

Subject to the discussions below under the sections titled “Information Reporting and Backup Withholding” and “Foreign Accounts,” a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock, pre-funded warrants or common warrants unless:

- the gain is effectively connected with the Non-U.S. Holder’s conduct of a trade or business in the United States (and, if required by an applicable income tax treaty between the United States and such Non-U.S. Holder’s country of residence, the gain is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the U.S.), in which case the Non-U.S. Holder will be taxed on a net income basis at the regular rates and in the manner applicable to U.S. persons, and if the Non-U.S. Holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the Non-U.S. Holder is a nonresident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the Non-U.S. Holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the Non-U.S. Holder, if any, provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns reporting those losses; or

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- we are, or have been, a “United States real property holding corporation,” or USRPHC, for U.S. federal income tax purposes during the five-year period preceding such disposition (or the Non-U.S. Holder’s holding period, if shorter). We do not believe that we are or have been a USRPHC and, even if we are or were a USRPHC, as long as our common stock is regularly traded on an established securities market, dispositions will not be subject to tax for a Non-U.S. Holder that has not held more than 5% of our common stock, actually or constructively, during the five-year period preceding such Non-U.S. Holder’s disposition (or the Non-U.S. Holder’s holding period, if shorter). Special rules may apply to the determination of the 5% threshold in the case of a holder of a pre-funded warrant.

See the sections titled “Information Reporting and Backup Withholding” and “Foreign Accounts” below for additional information regarding withholding rules that may apply to proceeds of a disposition of our common stock, pre-funded warrants or common warrants paid to foreign financial institutions or non-financial foreign entities.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions (including constructive distributions) on our common stock, pre-funded warrants or common warrants paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. Holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 24%. Generally, a Non-U.S. Holder will comply with such procedures if it provides a properly executed applicable IRS Form W-8 or by otherwise establishing an exemption. Dividends paid to Non-U.S. Holders subject to withholding of U.S. federal income tax, as described above under the heading “Distributions,” will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock, pre-funded warrants or common warrants by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the Non-U.S. Holder certifies its status as a Non-U.S. Holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. Holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder’s U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Foreign Accounts

Legislation commonly referred to as the “Foreign Account Tax Compliance Act,” or “FATCA,” generally imposes a 30% withholding tax on dividends on common stock, pre-funded warrants and common warrants if paid to a non-U.S. entity unless (i) if the non-U.S. entity is a “foreign financial institution,” the non-U.S. entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the non-U.S. entity is not a “foreign financial institution,” the non-U.S. entity identifies certain of its U.S. investors, if any, or (iii) the non-U.S. entity is otherwise exempt under FATCA.

Intergovernmental agreements between the United States and foreign countries with respect to FATCA may significantly modify the requirements described in this section for Non-U.S. Holders. Holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock, pre-funded warrants or common warrants.

The preceding discussion of material U.S. federal tax considerations is for information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, pre-funded warrants or common warrants, including the consequences of any proposed changes in applicable laws.

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PLAN OF DISTRIBUTION

We have engaged A.G.P./Alliance Global Partners (the “placement agent”), to act as our exclusive placement agent to solicit offers to purchase the shares of our common stock, pre-funded warrants and common warrants offered by this prospectus. The placement agent is not purchasing or selling any such securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of such securities, other than to use its “reasonable best efforts” to arrange for the sale of such securities by us. Therefore, we may not sell all of the securities being offered. The terms of this offering are subject to market conditions and negotiations between us, the placement agent and prospective investors. The placement agent will have no authority to bind us by virtue of the engagement letter. This is a best efforts public offering and there is no minimum

offering amount required as a condition to the closing of this offering. The placement agent may retain sub-agents and selected dealers in connection with this offering.

Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement, including but not limited to: (i) a covenant to not enter into variable rate financings for a period of six months following the closing of the offering, subject to exceptions; and (ii) a covenant to not enter into any equity financings for 60 days from closing of the offering, subject to certain exceptions.

The nature of the representations, warranties and covenants in the securities purchase agreements shall include, but are not limited to:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and
- covenants regarding matters such as registration of shares issued and issuable upon exercise of the common stock purchase warrants, no integration with other offerings, no shareholder rights plans, use of proceeds, indemnification of purchasers, reservation and listing of common stock, and no subsequent equity sales for 60 days, and no entry into or sales under a variable-rate-transaction for six months, subject to certain exceptions.

Delivery of the securities offered hereby is expected to occur on or about January 29, 2025, subject to satisfaction of certain customary closing conditions.

Fees and Expenses

The following table shows the per share price and total cash fees we will pay to the placement agent in connection with the sale of the securities pursuant to this prospectus.

	Per share of Common Stock and accompanying Common Warrants	Per Pre-Funded Warrant and accompanying Common Warrants	Total
Public offering price	\$ 0.61500	\$ 0.61490	\$ 4,785,887
Insider offering price	\$ 0.79750	N/A	\$ 213,411
Placement agent fees ⁽¹⁾	\$ 0.03998 ⁽³⁾	\$ 0.03997	\$ 319,619
Proceeds to us, before expenses ⁽²⁾	\$ 0.57503 ⁽⁴⁾	\$ 0.57493	\$ 4,679,679

(1) We have agreed to pay the placement agent a cash fee equal to 6.5% of the gross proceeds raised in this offering (other than proceeds received from the Company's current directors and officers and any issuer-directed investors, in which case the cash fee shall be 4.0% of the gross proceeds). We will also pay the placement agent a non-accountable expense allowance of up to \$20,000 and will reimburse the placement agent for its legal fees and expenses in an amount of up to \$75,000. For a description of compensation to be received by the placement agent, see "Plan of Distribution" for more information

(2) We estimate the total expenses in this offering payable by us, excluding the placement agent fees, will be approximately \$215,000. All costs associated with the registration will be borne by us.

(3) This amount relates to the 6.5% fee for non-insiders.

(4) This is based on the proceeds received from non-insiders.

We estimate the total expenses of this offering paid or payable by us, exclusive of the placement agent's cash fee and expenses payable by us, will be approximately \$215,000. After deducting the fees and expenses due to the placement agent and our estimated expenses in connection with this offering, we expect the net proceeds from this offering will be approximately \$4.5 million.

Lock-Up Agreements

Our officers and directors have agreed with the placement agent to be subject to a lock-up period of 90 days following the closing of this offering. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed to similar lock-up restrictions on the issuance and sale of our securities for 60 days following the closing of this offering, subject to certain exceptions. The placement agent may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

In addition, subject to certain exceptions, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our common stock or upon a specified or contingent event in the future, or enter into any agreement to issue securities at a future determined price for a period of six months following the closing date of this offering.

Tail

In the event that any investors that (i) were contacted by the placement agent or contacted by the placement agent and took a meeting with the Company during the term of the engagement agreement with the placement agent in accordance with the terms of the placement agency agreement and (ii) provide any capital to us in a public or private offering or other financing or capital-raising transaction of any kind (each, a "Tail Financing") at any time within the six (6)-month period following the expiration or termination of our engagement agreement with the placement agent, we shall pay the placement agent the cash and warrant compensation provided above on the gross proceeds raised in such Tail Financing from such investors.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including certain liabilities under the Securities Act, or to contribute to payments that the placement agent may be required to make in respect of those liabilities.

In addition, we will indemnify the purchasers of securities in this offering against liabilities arising out of or relating to (i) any breach of any of the representations, warranties, covenants or agreements made by us in the securities purchase agreement or related documents or (ii) any action instituted against a purchaser by a third party (other than a third party who is affiliated with such purchaser) with respect to the securities purchase agreement or related documents and the transactions contemplated thereby, subject to certain exceptions

Other Relationships

The placement agent and its affiliates have engaged, and may in the future engage, in investment banking transactions and other commercial dealings in the ordinary course of business with us or our affiliates. The placement agent has received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the placement agent and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The placement agent and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agent and the placement agent may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent and should not be relied upon by investors.

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Transfer Agent

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company, LLC (“Continental”). We will act as the registrar and transfer agent for the pre-funded warrants and Common Warrants.

Nasdaq listing

Our shares of common stock are listed on the NASDAQ Capital Market under the symbol “PCSA.”

LEGAL MATTERS

Certain legal matters relating to this offering and the validity of the securities offered by this prospectus will be passed upon for us by Foley & Lardner, LLP. Thompson Hine LLP is acting as counsel for the placement agent in connection with this offering.

EXPERTS

The consolidated financial statements as of and for the fiscal years ended December 31, 2023 and 2022, incorporated by reference into this prospectus from the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, have been so incorporated in reliance on the report of BD & Company, an independent registered public accounting firm, as stated in their report which is incorporated by reference herein, and has been so incorporated in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” information that we file with it into this prospectus, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the SEC will automatically update and supersede information contained in this prospectus.

We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act made after the date of the initial registration statement of which this prospectus forms a part and prior to effectiveness of the registration statement and subsequent to the date of this prospectus until the termination of the offering of the securities described in this prospectus (other than information in such filings that was “furnished,” under applicable SEC rules, rather than “filed”). We incorporate by reference the following documents or information that we have filed with the SEC:

- Our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2023, filed with the SEC on March 29, 2024;
- Our Quarterly Report on Form 10-Q for the quarters ended [March 31, 2024](#), [June 30, 2024](#) and [September 30, 2024](#), filed with the SEC on May 10, 2024, August 13, 2024 and October 30, 2024, respectively;
- Our Current Reports on Form 8-K, filed with the SEC on [January 8, 2024](#); [January 18, 2024](#); [January 25, 2024](#); [January 30, 2024](#) (excluding Item 7.01 and the exhibit related thereto); [February 6, 2024](#); [May 21, 2024](#); [July 2, 2024](#); [July 17, 2024](#); [July 30, 2024](#); [August 28, 2024](#); [October 2, 2024](#); and [November 6, 2024](#);
- Our Definitive Proxy Statement on [Schedule 14A](#), filed with the SEC on April 29, 2024; and
- The description of our common stock contained in our Registration Statement on [Form 8-A](#), filed on September 17, 2020 pursuant to Section 12(b) of the Exchange Act, which incorporates by reference the description of the shares of our common stock contained in the “Description of Securities.”

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to Wendy Guy, Chief Administrative Officer at Processa Pharmaceuticals, Inc. 7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076 or at (443) 776-3133.

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You also may access these filings on our website at www.processapharmaceuticals.com. We do not incorporate the information on our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You should rely only on the information contained in this prospectus or incorporated by reference into this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should assume that the information contained in this prospectus, or any document incorporated by reference in this prospectus, is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus or any sale of our securities.

We file annual, quarterly and current reports, proxy statements and other information with the SEC under the Exchange Act. Our SEC filings are available to the public from commercial document retrieval services and over the Internet at the SEC's website at <http://www.sec.gov>.

We maintain a website at www.processapharmaceuticals.com. You may access our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference into, and is not part of, this prospectus.

You may also request a copy of these filings, at no cost to you, by writing or telephoning us at the following address:

Processa Pharmaceuticals, Inc.
Attn: Corporate Secretary
7380 Coca Cola Drive, Suite 106
Hanover, Maryland 21076
Telephone (443) 776-3133

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Processa Pharmaceuticals, Inc.

1,030,972 Shares of Common Stock
7,019,700 Pre-Funded Warrants to Purchase up to 7,019,700 Shares of Common Stock
8,050,672 Series A Warrants to Purchase up to 8,050,672 Shares of Common Stock
4,025,336 Series B Warrants to Purchase up to 4,025,336 Shares of Common Stock
19,095,708 Shares of Common Stock underlying the Pre-Funded Warrants, Series A Warrants and Series B Warrants

PRELIMINARY PROSPECTUS

January 27, 2025

Sole Placement Agent

A.G.P.
