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

FORM 10-K

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

For the fiscal year ended December 31, 2022

or

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

Commission File Number 001-39531

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2022, the last business day of the most recently completed second quarter, based upon the closing price of Common Stock on such date as reported on Nasdaq Capital Market, was approximately $33.8 million.

The number of outstanding shares of the registrant's common stock as of March 27, 2023 was 24,557,592.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2023 Annual Meeting of Stockholders (the "Proxy Statement") to be filed within 120 days of the end of the fiscal year ended December 31, 2022 are incorporated by reference into Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as a part hereof.

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GLOSSARY OF CERTAIN SCIENTIFIC TERMS

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

"Active metabolite" means a drug that is processed by the body into an altered form which effects the body.

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

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

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

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

"CMO" means Contract Manufacturing Organization.

"CRO" means Contract Research Organization.

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

"EMA" means the European Medicines Agency.

"FDA" means the Food and Drug Administration.

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

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

"Moiety" means an active or functional part of a molecule.

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

"NGC" means Next Generation Chemotherapy, referring to the drugs in our pipeline that have active cancer killing metabolites that are the same or have very similar chemical structure to existing FDA-approved chemotherapy treatments, resulting in our NGCs killing cancer cells following the same mechanism as the FDA-approved treatments.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTOR SUMMARY

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

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

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

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

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

Part I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on utilizing the Processa Regulatory Science Approach, including 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 taking FDA-approved, widely used oncology drugs or the cancer killing metabolites of these drugs and altering how they are metabolized and/or distributed in the body, including how they are distributed to the actual cancer cells.

Regulatory science was conceived in the early 1990s when the founders of Processa and other faculty at the University of Maryland worked with the FDA to develop multiple FDA Guidances. Over the last 30 years, two of our founders, Dr. David Young and Dr. Sian Bigora, have expanded the original regulatory science concept to include other factors, such as the principles of Project Optimus, that can affect the risk-benefit analyses that FDA conducts for every FDA drug approval. In fact, the principles of FDA's Project Optimus have been used by Drs. Young and Bigora to identify and justify an "optimal" dosage regimen for a number of non-oncology FDA-approved drugs. The Processa Regulatory Science Approach and our past 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 the Processa Regulatory Science Approach provides us with three distinct advantages:

- greater efficiencies (e.g., the right study design and study readouts);
- greater possibility of drug approval by the FDA or other regulatory authorities; and
- improvement over existing therapy and greater acceptance by patients/doctors.

In January 2023, we announced our strategic prioritization to advance our pipeline of Next Generation Chemotherapy proprietary small molecule oncology drugs. By changing either the metabolism, distribution and/or elimination of already FDA-approved cancer drugs while maintaining the mechanism of how the drug kills cancer cells, we believe our three Next Generation Chemotherapy (NGC) treatments will provide improved safety-efficacy profiles when compared to their currently marketed counterparts - capecitabine, gemcitabine, and irinotecan. All future studies of these drugs are subject to availability of capital to conduct the trials.

The three NGC treatments in our pipeline are as follows:

- NGC-Capecitabine is a combination of PCS6422 and capecitabine. NGC-Capecitabine alters the metabolism of capecitabine without having any clinically meaningful biological effect itself. In clinical trials, NGC-Capecitabine has a safety profile different than capecitabine when administered by itself. Side effects, such as Hand-Foot Syndrome (HFS) and cardiotoxicity that typically occur in 50-70% of patients treated with capecitabine and caused by specific capecitabine metabolites that are not formed to any extent with NGC-Capecitabine, do not appear to be side effects associated with NGC-Capecitabine. These types of toxicities can result in decreased doses, interrupted doses or discontinuation of treatment with capecitabine. In addition, NGC-Capecitabine has been found to be greater than 50 times more potent than capecitabine based on the systemic exposure of the capecitabine metabolite 5-FU, which is metabolized to the cancer-killing metabolites. Like capecitabine, NGC-Capecitabine could be used to treat patients with various cancers, such as metastatic colorectal, gastrointestinal, breast, and pancreatic. We estimate at least 200,000 patients in the United States were diagnosed in 2022 with metastatic colorectal, gastrointestinal, breast, and pancreatic cancers. In mid-April of 2023, we are scheduled to begin discussions with the FDA regarding the design of our Phase 2B trial and Project Optimus in order to initiate the Phase 2B trial in the second half of 2023.

- NGC-Gemcitabine (also identified as PCS3117) is an oral analog of gemcitabine that is converted to its active metabolite by a different enzyme system than gemcitabine resulting in a positive response in gemcitabine patients as well as some gemcitabine treatment-resistant patients. Like gemcitabine, NGC-Gemcitabine could be used to treat patients with various cancers such as pancreatic, lung, ovarian, and breast. We estimate at least 275,000 patients in the United States were diagnosed in 2022 with pancreatic, lung, ovarian, and breast cancer. We plan to meet with the FDA in 2023 to discuss potential study designs including implementation of Project Optimus as part of the design, and then submit the Phase 2B protocol to the Investigational New Drug (IND Application) in the second half of 2023.

- NGC-Irinotecan (also identified as PCS11T) is a prodrug of the active metabolite of irinotecan (SN-38). The chemical structure of NGC-Irinotecan influences the uptake of the drug into cancer cells, resulting in more NGC-Irinotecan entering cancer cells than normal cells in mice. These levels were significantly greater than those seen with irinotecan, resulting in lower doses of NGC-Irinotecan having greater efficacy than irinotecan and improved safety in animal models. Like irinotecan, NGC-Irinotecan could be used to treat patients with various cancers such as lung, colorectal, gastrointestinal, and pancreatic cancer. We estimate at least 200,000 patients in the United States were diagnosed in 2022 with lung, colorectal, gastrointestinal, and pancreatic cancer. We plan to conduct IND-enabling and toxicology studies in 2023 and 2024.

Due to enrollment difficulties that we have experienced since the beginning of our rare disease trial for PCS499 in ulcerative Necrobiosis Lipoidica (uNL), we decided to suspend further enrollment in the PCS499 trial in February 2023. In addition, the clinical findings for PCS12852 were positive in gastroparesis patients and there were no safety concerns during the conduct of either the PCS12842 or PCS499 trials. With our focus on the NGCs in our pipeline, we are evaluating options to monetize PCS12852 and PCS499.

Our shift in prioritization of the products does not change our mission. We continue to be 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 path to FDA approval, increasing the probability of FDA approval, and differentiating our drugs from those on the market or are currently being developed.

Historically, much of oncology drug development has searched for a new or different way to treat cancer. Our approach is to modify and improve three different, currently approved, and widely used chemotherapy treatments so that the human body handles these NGC treatments differently than their presently approved counterpart drugs while the cancer killing mechanism of action remains the same. FDA's Project Optimus Oncology initiative and Oncology Guidance recommends that the dose-response (both safety and efficacy) relationships be evaluated for all oncology drugs. We have begun this process for our NGC treatments. To date, we have found that our NGC treatments are likely to have a better safety-efficacy profile than the current widely used marketed counterpart drugs, not only potentially making the development and approval process more efficient, but also differentiating our NGC treatments from the existing treatment. 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.

Our Strategy

With the Processa Regulatory Science Approach, our strategy is to obtain and develop drugs that will not only treat patients with unmet medical need conditions, but also have the potential to be more efficiently developed with a greater probability of development success than what typically occurs in the biotech-pharma industry, as well as a better return on investment given more efficient development and high commercial value. We applied rigorous standards to identify drugs for our portfolio, the three most important being:

- The drug must represent a treatment option to patients with a high unmet medical need condition by improving survival and/or quality of life for these patients,

- The drug or its metabolite or a drug with similar pharmacological properties must have demonstrated some clinical evidence of efficacy in the target population, and

- The probability of approval and the efficiency of development for the drug will be improved using the Processa Regulatory Science Approach.

Our rigorous requirement resulted in the in-licensing of five drugs: three NGC drugs and two non-oncology drugs. These clinical candidates had significant pre-clinical and clinical data that de-risked the programs.

In January 2023, we announced our plan to prioritize our team's time and our capital resources on the continued development of our NGC drugs while exploring opportunities, including non-dilutive licensing, collaborations, and other strategic transactions, for our non-oncology drugs. By changing either the metabolism, distribution and/or elimination of FDA-approved drugs while still maintaining the mechanism of killing cancer cells, we believe that our three NGC treatments provide improved safety-efficacy profiles when compared to their currently marketed counterparts of capecitabine, gemcitabine and irinotecan. These modifications differentiate our NGC treatments from the existing therapies while being potential life-changing treatments for patients.

Our pipeline of NGCs (i) already have 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) target cancers for which a single positive pivotal study demonstrating efficacy might provide enough evidence that the clinical benefits of the drug and its approval outweighs the risks associated with the drug.

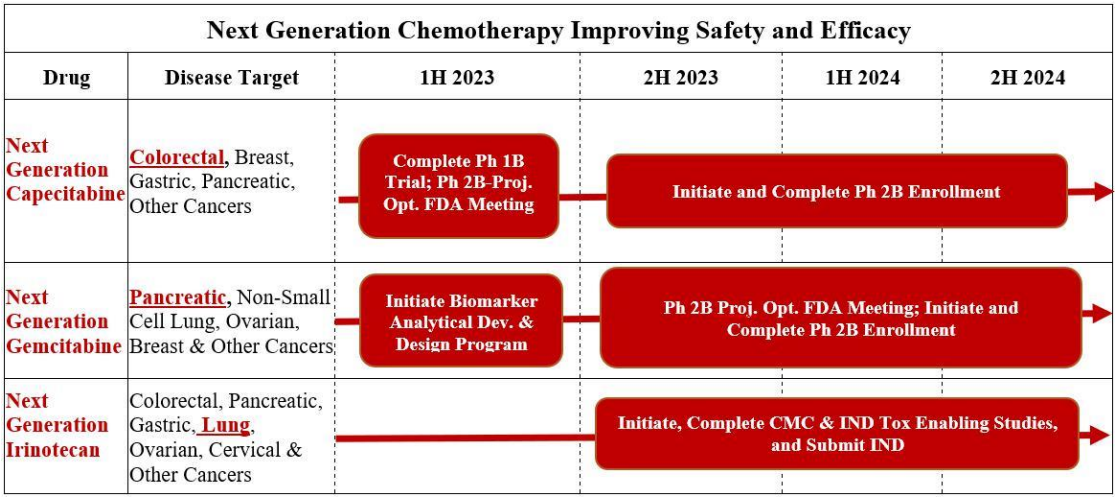
Our Team

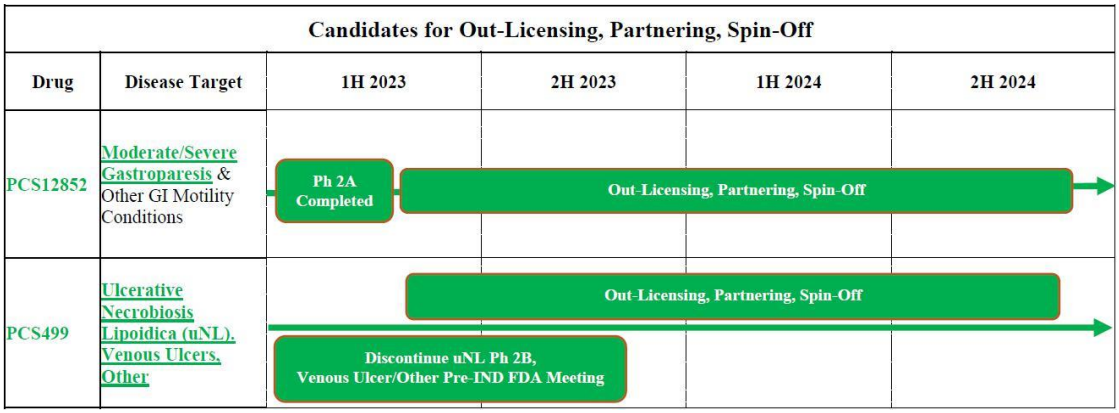
Our drug development efforts are guided by our knowledge and experience in applying the Processa Regulatory Science Approach to decrease manageable risks, costs, and time toward achieving marketing authorization from regulatory authorities including the FDA. We have assembled a seasoned management team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

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

Our Drug Pipeline

Our pipeline currently consists of three oncology drugs (NGC-Capecitabine, NGC-Gemcitabine and NGC-Irinotecan previously identified as PCS6422, PCS3117 and PCS11T, respectively) and two non-oncology drugs (PCS12852 and PCS499). A timeline and summary of each drug is provided below.





Next Generation Chemotherapy Pipeline

- Next Generation Capecitabine (NGC-Capecitabine), also identified as PCS6422, is a combination of PCS6422 and the FDA-approved cancer drug capecitabine. NGC-Capecitabine 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.

  When combining capecitabine with PCS6422 in NGC-Capecitabine, PCS6422 significantly changes the metabolism and distribution of 5-FU. After formation from capecitabine, 5-FU is metabolized to anabolites (which kill both cancer cells and normal duplicating cells) and catabolites (which cause side effects and have no cancer killing properties). Due to this change in metabolism of capecitabine and the change in the overall metabolite profile of anabolites and catabolites, the side effect and efficacy profile of NGC-Capecitabine has been found to be different than the existing FDA-approved capecitabine. Since the potency of NGC-Capecitabine is also more potent 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-Capecitabine will, therefore, be much greater than formed from the administration of 1 mg of existing capecitabine.

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

  In order for NGC-Capecitabine 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 DLTs. One of the regimens in the Phase 1B trial did cause DLTs in two patients, one of whom died. The Phase 1B study is continuing to enroll patients and is expected to complete enrollment in 2023. The next study will be a Phase 2B trial to determine which regimens provide an improved efficacy-safety profile over present therapy using the principles of the FDA's Project Optimus initiative to help guide the design of the trial. This FDA initiative requires us to consider NGC regimens that are not at the maximum tolerated dose or exposure level. In mid-April of 2023, we are scheduled to begin discussions with FDA regarding the design of our Phase 2B trial and Project Optimus in order to initiate the Phase 2B trial in the second half of 2023. We will need to obtain additional funding before we can conduct this trial.

- NGC-Gemcitabine, also identified as PCS3117, 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. The difference in response occurs because NGC-Gemcitabine is metabolized to its active metabolite through a different enzyme system than gemcitabine. We continue to evaluate the potential use of NGC-Gemcitabine in patients with pancreatic cancer and to evaluate ways to identify patients who are more likely to respond to NGC-Gemcitabine than gemcitabine. We plan to meet with the FDA in 2023 to discuss potential study designs including implementation of the FDA's Project Optimus initiative as part of the design and then submit the Phase 2B protocol to the IND.

- NGC-Irinotecan, also identified as PCS11T, 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. In addition, we are defining the potential paths to approval, which include defining the targeted patient population and the type of cancer. We plan to conduct IND enabling and toxicology studies in 2023 and 2024, subject to available funding.

Non-Oncology Pipeline for Out-licensing or Partnership

- PCS12852 is a highly specific and potent 5HT4 agonist that has already been evaluated in clinical studies in South Korea for gastric emptying and gastrointestinal motility in healthy volunteers and volunteers with a history of constipation. In October 2021, the FDA cleared our IND application to proceed with a Phase 2A trial for the treatment of gastroparesis. We enrolled our first patient on April 5, 2022 and completed enrollment of the trial on September 2, 2022. Results from this Phase 2A study which included 25 patients with moderate to severe gastroparesis, demonstrated improvements in gastric emptying in patients receiving 0.5 mg of PCS12852 as compared to placebo. The results indicated that for the patients in the PCS12852 group, the mean time for 50% of the gastric contents to empty (t50) compared to their baseline value (±SD) decreased by -31.90 min (±50.53) (compared to the change seen in the placebo group of only -9.36 min (±42.43). Significant gastric emptying differences were not observed between the placebo and the 0.1 mg dose. Adverse events associated with the administration of PCS12852 were generally mild to moderate as expected, limited in duration, and quickly resolved without any sequelae. There were no clinically significant cardiovascular safety events or serious adverse events (SAEs) reported during the study. Additionally, the 0.5 mg of PCS12852 showed a greater improvement than placebo in the gastroparesis symptomology scales (including both total scores in the scales, as well as sub-scores such as nausea, vomiting and abdominal pain) used in the study. With the study now complete, we have the data necessary to finalize the development plan for the treatment of diabetic gastroparesis patients. We plan to monetize PCS12852 by looking for licensing and/or partnering opportunities.

- PCS499 is an oral tablet of the deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). PCS499 is a drug that can be used to treat unmet medical need conditions caused by multiple pathophysiological changes. We completed a Phase 2A trial for PCS499 in patients with ulcerative and non-ulcerative necrobiosis lipoidica (uNL and NL, respectively) in late 2020, and in May 2021, we enrolled the first patient in our Phase 2B trial for the treatment of uNL. Although we initiated several recruitment programs to increase the enrollment of patients in this study, we were only able to recruit four patients. We will complete the study for those currently enrolled, but will halt further efforts to enroll new patients for our PCS499 Phase 2B uNL trial. We have experienced extremely slow enrollment in the trial given the extreme rarity of the condition (rarer than reported in the literature), the impact of COVID-19, and the reluctance of patients to be in a clinical trial. There have been no safety concerns during the conduct of the trial. Although we believe that PCS499 can be effective in treating uNL, in late February 2023, we received preliminary data that indicated that the placebo response is likely much greater than the literature and clinical experts believe; thus, a much larger sample size would be required in a pivotal trial for an indication where it was extremely difficult to enroll even 10 patients. We are also evaluating other, less rare indications for PCS499. As with PCS12852, we plan to monetize PCS499 by looking for licensing and/or partnership opportunities.

Manufacturing and Clinical Supplies

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

We anticipate that these CMOs will have the capacity to support both clinical supply and commercial-scale production, but we do not have any formal agreements at this time with any of these CMOs to cover commercial production.

We also may elect to pursue additional CMOs for manufacturing supplies of drug substance and finished drug product in the future. We believe that our standardized manufacturing process can be transferred to a number of other CMOs for the production of clinical and commercial supplies of our product candidates in the ordinary course of business.

Competition

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

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

For NGC-Capecitabine, the competitive factors will be related to the efficacy and safety of the product when used in combination with existing cytotoxic drugs such as capecitabine and fluoropyrimidines compared to the efficacy and safety when these cytotoxic agents are administered without PCS6422 or with reversible enzyme inhibitors. The market penetration will depend on how much improvement will occur in the efficacy and/or safety profiles when administered in combination with PCS6422. Currently, there are no other reversible or irreversible enzyme inhibitor products approved in the US and no irreversible enzyme inhibitors approved ex-US, which may make PCS6422 the first DPD irreversible inhibitor available.

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

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

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

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

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

Intellectual Property

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

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

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

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

	CoNCERT	Yuhan	Aposense	Elion	Ocuphire	Total
U.S. patents	9	5	3	2	6	25

A provisional patent for NGC-Capecitabine has been filed.

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

License Agreements

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

License Agreement with Elion Oncology, Inc.

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

On October 6, 2020, all conditions were satisfied, resulting in the addition of PCS6422 to our portfolio, and we paid $100,000 cash and issued 825,000 shares of our common stock to Elion. Such shares were subject to a lock-up, with 50% of such shares released from such lock-up after six months and the remaining 25% tranches were released following 9 months and 12 months, respectively.

As part of the Elion License Agreement, we agreed to issue to Elion 100,000 shares of our common stock on each of the first and second anniversary dates of the Elion License Agreement, which we fulfilled on October 5, 2021 and 2022, respectively.

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

On May 17, 2022, we amended the third Milestone Event of Section 6.4 of our License Agreement with Elion Oncology, Inc. changing the third Milestone Event from "1st Patient in Dose Confirmation Study" to (a) determination of the maximum tolerated dose (MTD) or (b) determination of the recommended Phase 2 Dose. Prior to this amendment, the third milestone was not considered probable since it was unknown when, or if a dose confirmation study was going to be conducted. As a result of the modification, we consider it probable that the recommended Phase 2 dosage regimen could be determined in connection with our current Phase 1B trial for PCS6422. We recorded an expense and related liability of $189,000 representing the value of the shares we anticipate issuing to Elion at the fair value on the date of modification. No other terms or conditions of the License Agreement were modified.

We are required to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) dosing a first patient in a Phase 1B clinical trial with a product within 12 months; and (ii) dosing a first patient with a product in a Phase 2 or 3 clinical trial within 48 months. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 90-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

License Agreement with Ocuphire Pharma, Inc.

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

As consideration for the Ocuphire Agreement, we issued 44,689 shares of our common stock to Ocuphire, a cash payment of $200,000 and assumed certain liabilities. Additional consideration includes future development and regulatory milestones payments to Ocuphire upon our achievement of certain defined clinical milestones, such as dosing a patient in pivotal trials and receiving marketing authorization by a regulatory authority in the United States or another country. In addition, we are required to pay Ocuphire one-time sales milestone payments based on the achievement during a calendar year of the highest annual Net Sales for products made and pay royalties based on annual Net Sales, as defined in the Ocuphire Agreement.

We are required to use commercially reasonable efforts, at our sole cost and expense to oversee such commercialization efforts, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) first patient administered drug in a Clinical Trial of a Product prior to June 16, 2024; and (ii) first patient administered drug in a Pivotal Clinical Trial of a Product or first patient administered drug in a Clinical Trial for a Second Indication of a Product prior to June 16, 2026. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 120-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

License Agreement with Aposense, Ltd.

On May 24, 2020, we entered into a condition precedent License Agreement with Aposense, Ltd. ("Aposense License Agreement"), pursuant to which we were granted Aposense's patent rights and Know-How to develop and commercialize their next generation irinotecan cancer drug, PCS11T (formerly known as ATT-11T). The Aposense License Agreement provides us with an exclusive worldwide license (excluding China) to research, develop and commercialize products comprising or containing PCS11T. The grant of license was conditioned on the following being satisfied within nine months of May 24, 2020: (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the Aposense License Agreement.

On October 6, 2020, all conditions were satisfied, resulting in the addition of PCS11T to our portfolio, and we issued 625,000 shares of our common stock to Aposense. Such shares were subject to a lock-up, with 40% of such shares released from such lock-up after six months and the remaining two 30% tranches were released upon completion of the next two subsequent quarters. As additional consideration, we will pay Aposense development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we will pay Aposense one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any sales milestone payments or royalties we receive with Aposense based on any sub-license agreement we may enter into.

License Agreement with Yuhan Corporation

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

As consideration for the Yuhan License Agreement and related Share Issuance Agreement, we issued to Yuhan 500,000 shares of common stock. As additional consideration, we will pay Yuhan development and regulatory milestone payments (a portion of which are payable in shares of our common stock based on the volume weighted average trading price during the period prior to such achievement and a portion of which are payable in cash) upon the achievement of certain milestones, based on a Yuhan affiliate purchasing 750,000 shares of common stock for $3,000,000 in our October 2020 underwritten public offering. The milestones primarily consist of dosing a patient in pivotal trials or having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Yuhan one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments received with Yuhan based on any sub-license agreement we may enter into.

In conjunction with a joint Processa-Yuhan Board to oversee such commercialization efforts, we are required to use commercially reasonable efforts, at our sole cost and expense, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) preparing a first draft of the product development plan within 90 days; (ii) requesting an FDA pre-IND meeting for a product within 6 months; (iii) dosing a first patient in a Phase 2A clinical trial with a product within 24 months; and (iv) dosing a first patient with a product in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial with a product within 48 months. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 60-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

License Agreement with CoNCERT Pharmaceuticals, Inc.

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

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

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

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

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

Government Regulation

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

U.S. Government Regulation

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

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

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

Pre-clinical studies

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

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

Clinical trials

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

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

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

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

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

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

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

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

Marketing Approval

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

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

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

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

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

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

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

Orphan drug designation

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

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

Expedited review and approval

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

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

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

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

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

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

Post-approval requirements

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

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

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

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

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

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

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

Other Regulatory Matters

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

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

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

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

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

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

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

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

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

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

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

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

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

U.S. Patent-Term Restoration and Marketing Exclusivity

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

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

European Union Drug Development

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

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

European Union Drug Review and Approval

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

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

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

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

Coverage and Reimbursement

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

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

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

Healthcare Reform

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

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price (AMP), to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Effective April 1, 2020, Medicaid rebate liability will be expanded to include the territories of the United States as well. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

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

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

Human Capital

As of March 27, 2023, we had 15 full and part time employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union and we believe our relationships with our employees are good.

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

Corporate Information

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

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

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

Item 1A. Risk Factors

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

Risks Related to Our Financial Position

We have a history of losses and we may never become profitable.

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

At December 31, 2022, the accumulated deficit was approximately $64.2 million. We will incur additional losses as we continue our research and development activities, seek regulatory approvals for our product candidates and engage in clinical trials. These losses will cause, among other things, our stockholders' equity and working capital to decrease. Any future earnings and cash flow from the operations of our business are dependent on our ability to further develop our products and on revenues and profitability from sales of products or successful joint venture relationships.

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

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

We have limited cash resources and will require additional financing.

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

We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations, including sales of our common stock under our agreement with Lincoln Park, LLC or through a future at-the-market offering. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

The ongoing COVID-19 pandemic or another pandemic may disrupt our operations and affect our ability to successfully conduct clinical studies and raise capital.

The COVID-19 pandemic continues to have a negative impact on the global economy, disrupted global supply chains, and created volatility and disruption in the financial and capital markets. We are unable to accurately predict the full impact the COVID-19 will have on our future results from operations, financial condition, and scientific and clinical activities due to numerous factors that are not within our control, including the duration and severity of the outbreak, stay-at-home orders, business closures, travel restrictions, supply chain disruptions and employee illness or quarantines, which could result in disruptions to our operations and adversely impact our results from operations and financial condition. In addition, the COVID-19 pandemic has resulted in ongoing volatility in the financial and capital markets. If our access to capital is restricted or associated borrowing costs increase as a result of developments in financial markets relating to the COVID-19 pandemic, our operations and financial condition could be adversely impacted.

Along with uNL being a rare disease, COVID-19 had a negative impact on the enrollment of patients in our PCS499 Phase 2B trial. In February 2023, after having experienced a significantly slower than expected enrollment rate with no signs of improvement, we decided to stop enrollment of new patients into the trial, effectively terminating it. Potential patients had died from COVID-19 complications prior to screening, and we had patients who were reluctant to travel to our testing sites for fear of contracting COVID-19. While we are hopeful the infection rate of COVID-19 will continue to decline, we cannot predict the future impact COVID-19 or future pandemics from other viruses will have on our current and future clinical trials.

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

As of December 31, 2022, we had net operating loss (NOL) carryforwards of approximately $24.0 million for federal and state income tax available to offset future taxable income, and federal and state research and development tax credits of approximately $1.0 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended (Section 382). NOL carryforwards prior to 2018 will expire in 2037 if not utilized.

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

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

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

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

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

Our licenses are subject to termination by the licensor in certain circumstances.

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

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

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

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

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

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

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

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

Our operations to date have been limited to financing and staffing, conducting research and developing our core technologies, identifying and optimizing our lead product clinical candidates, performing due diligence on other potential drug in-licensing opportunities and further moving the clinical product candidates through the development programs identified. Some of the activities in the development programs include receiving FDA IND clearance on one indication for two product candidates, completing a Phase 2A trial for PCS12852 in gastroparesis patients, conducting a Phase 1B trial for PCS6422 in patients with advanced gastrointestinal tumors, completing a Phase 1 healthy human volunteer trial, completing a Phase 2A clinical trial and conducting a Phase 2 clinical trial in patients with NL and receiving FDA orphan designation on PCS499 in NL. Other activities include improving the manufacturing of PCS499, PCS6422 and PCS11T final products and developing regulatory strategy plans for each of the products including expedited review plans, as applicable. Although we have recruited a team that has experience with clinical trials in the United States and outside the United States, as a company, we have only conducted four clinical trials in any jurisdiction and have not had previous experience commercializing product candidates through the FDA or similar submissions to initiate clinical trials or obtain marketing authorization to foreign regulatory authorities. We cannot be certain that other planned clinical trials will begin or be completed on time, if at all; that our development program and studies would be acceptable to the FDA or other regulatory authorities; or that, if regulatory approval is obtained, our product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third-party clinical investigators, CROs, consultants and collaborators. Relying on third-party clinical investigators, CROs or collaborators may result in delays that are outside of our control.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. While the FDA granted orphan-drug designation to PCS499 for the treatment of NL and to PCS3117 for the treatment of pancreatic cancer, there can be no assurance that we will receive orphan drug designation for any additional product candidates in the indications for which we think they might qualify, if we elect to seek such applications.

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

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

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

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

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

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

Federal and state governments may adopt policies affecting drug pricing and contracting practices outside of the context of federal programs such as Medicare and Medicaid, which may adversely affect our business. For example, several states have adopted laws that require drug manufacturers to provide advance notice of certain price increases and to report information relating to those price increases. On May 11, 2018, the Department of Health and Human Services requested comments on a "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," which outlines a wide range of proposals and policy considerations intended to improve competition; lower patient out-of-pocket costs; enhance negotiation; and provide incentives for lower manufacturer list prices. Some of the proposals would require Congressional approval, while others could be adopted administratively. There can be no assurances that future changes to Medicare and/or Medicaid prescription drug reimbursement policies, drug pricing and contracting practices, or government drug price regulation programs such as the Medicaid Drug Rebate Program or 340B Drug Pricing Program will not have an adverse impact on our business and future prospects.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to Our Intellectual Property Rights

We depend on rights to certain pharmaceutical compounds that are or will be licensed to us. We do not own the intellectual property rights to these pharmaceutical compounds and any loss of our rights to them could prevent us from selling our products.

Within our present pipeline and potentially future pipeline of drugs, our drugs are in-licensed from other biotech or pharmaceutical companies. We do not currently own any intellectual property rights, including the patents that underlie these licenses. Our rights to use the pharmaceutical compounds we license are subject to the negotiation of, continuation of and compliance with the terms of those licenses. Thus, these patents and patent applications are not written by us or our attorneys, and we did not have control over the drafting and prosecution. The former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting. Moreover, under certain of our licenses, patent prosecution activities remain under the control of the licensor. We cannot be certain that drafting of the licensed patents and patent applications, or patent prosecution, by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Significant additional research and development activity, pre-clinical testing, and/or clinical testing of our drug product candidates are required before we will have a chance to achieve a viable product for licensing or commercialization. Our business currently depends entirely on the successful development, regulatory approval, and licensing or commercialization of our product candidates, which may never occur.

Enforcement of our licensed patents or defense of any claims asserting invalidity of these patents is often subject to the control or cooperation of our licensors. Legal action could be initiated against the owners of the intellectual property that we license and an adverse outcome in such legal action could harm our business because it might prevent such companies or institutions from continuing to license intellectual property that we may need to operate our business. In addition, such licensors may resolve such litigation in a way that benefits them but adversely affects our ability to have freedom to operate to develop and commercialize our product candidates.

We cannot ensure protection of our licensed intellectual property rights.

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

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

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

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

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

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

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

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

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

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

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

General Company-Related Risks

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development and commercialization plans and strategies develop, we may need to expand the size of our employee and consultant/contractor base. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage all our development efforts effectively, especially our clinical trials;
- integrate additional management, administrative, scientific, operation and regulatory personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

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

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

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

Our common stock is currently listed for trading on The Nasdaq Capital Market. We must satisfy The Nasdaq Capital Market's continued listing requirements, including, among other things, a minimum bid price requirement of $1.00 per share or risk delisting, which would have a material adverse effect on our business. A delisting of our common stock from The Nasdaq Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

On March 22, 2023, we received notice from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq as set forth in Nasdaq Listing Rule 5550(a)(2). We will have 180 days from March 22, 2023, or through September 18, 2023, to regain compliance. If we do not regain compliance during the compliance period ending September 18, 2023, then Nasdaq may grant us a second 180 calendar day period to regain compliance, provided we meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for The Nasdaq Capital Market, other than the minimum closing bid price requirement, and notify Nasdaq of our intent to cure the deficiency. If we do not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, we may be subject to delisting. If Nasdaq determines to delist our common stock, we will have the right to appeal to the Nasdaq Hearings Panel.

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

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

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

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

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

Our common stock price is expected to be volatile.

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

- relatively low trading volume, which can result in significant volatility in the market price of our common stock based on a relatively smaller number of trades and dollar amount of transactions;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- the timing and results of our current and any future preclinical or clinical trials of our product candidates;
- the entry into or termination of key agreements, including, among others, key collaboration and license agreements;
- the results and timing of regulatory reviews relating to the approval of our product candidates;
- the initiation of, material developments in, or conclusion of, litigation to enforce or defend any of our intellectual property rights;
- failure of any of our product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the results of clinical trials conducted by others on products that would compete with our product candidates;
- issues in manufacturing our product candidates or any approved products;
- the introduction of technological innovations or new commercial products by our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- future sales of our common stock by us, our insiders or our other stockholders;
- a negative outcome in any litigation or potential legal proceeding;
- additions and departures of key personnel;
- negative publicity or announcements regarding regulatory developments relating to our products;
- actual or anticipated fluctuations in our financial condition and operating results, including our cash and cash equivalents balance, operating expenses, cash burn rate or revenue levels;
- our filing for protection under federal bankruptcy laws; or
- the other factors described in this “Risk Factors” section.

The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock, especially in light of the COVID-19 pandemic. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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

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

Our executive officers, directors and principal stockholders and their affiliates, if they choose to act together, have the ability to exercise significant influence over all matters submitted to stockholders for approval, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

Our executive officers and directors, combined with our stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, beneficially own shares representing approximately 23.1% of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and potentially control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power may adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change in control;
- entrenching our management and the Board of Directors;
- impeding a merger, consolidation, takeover or other business combination involving us that other stockholders may desire; and/or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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

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

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties.

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

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

None.

Part II

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

Our common stock commenced trading on the Nasdaq Capital Market on October 2, 2020 under the symbol "PCSA." Prior to October 2, 2020, we traded on the OTCQB.

On January 1, 2022, we amended our Certificate of Incorporation to increase the number of authorized shares of our common stock from 30,000,000 to 50,000,000. The number of authorized shares of preferred stock remains unchanged at 1,000,000 shares.

Holders

As of March 27, 2023, there were 24,557,592 shares of common stock outstanding and 199 shareholders of record.

Transfer Agent and Registrar

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

Dividend Policy

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

Securities Authorized for Issuance under Equity Compensation Plans

The table below provides information as to our 2019 Omnibus Incentive Plan as of December 31, 2022.

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,764,658[(1)]	$ 11.45	2,387,622
Equity compensation plans not approved by security holders	47,772	19.88	-
Total	3,812,430		2,387,622[(2)]

(1) Includes stock options to purchase 7,143 shares of our common stock issued under the prior equity compensation plan.
(2) Consists of shares available for issuance under the 2019 Omnibus Incentive Plan.

On January 1, 2023, we awarded restricted stock awards and units for 1,056,503 shares of our common stock to our employees and directors, which is not included in the table above.

Recent Sales of Unregistered Securities

During the fourth quarter of 2022, we did not issue any securities that were not registered under the Securities Act.

Repurchases of Equity Securities

On March 29, 2022, we purchased 100,000 shares of our common stock from Aposense Ltd. for $300,000 in a private transaction and are holding these shares as treasury stock until they are reissued or retired at the discretion of our Board of Directors.

Item 6. [Reserved]

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

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

Overview

We are a clinical-stage biopharmaceutical company focused on utilizing the Processa Regulatory Science Approach including 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 taking FDA-approved, widely used oncology drugs or the cancer killing metabolites of these drugs and altering how they are metabolized and/or distributed in the body, including how they are distributed to the actual cancer cells.

Regulatory science was conceived in the early 1990s when the founders of Processa worked with the FDA to develop multiple FDA Guidances supported by the regulatory science studies designed and conducted by the Processa founders and other faculty at the University of Maryland. Over the last 30 years, two of our founders, Dr. David Young and Dr. Sian Bigora, have expanded the original regulatory science concept to include other factors, such as the principles of Project Optimus, that can affect the risk-benefit analyses that FDA conducts for every FDA drug approval. In fact, the principles of FDA's Project Optimus have been used by Drs. Young and Bigora to identify and justify an "optimal" dosage regimen for a number of non-oncology FDA-approved drugs. The Processa Regulatory Science Approach and our past 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 associated with oncology drugs. We believe utilizing the Processa Regulatory Science Approach provides us with three distinct advantages:

- greater efficiencies (e.g., the right study design and study readouts);
- greater possibility of drug approval by the FDA or other regulatory authorities; and
- improvement over existing therapy and greater acceptance by patients/doctors.

In January 2023, we announced our strategic prioritization to advance our pipeline of Next Generation Chemotherapy proprietary small molecule oncology drugs. By changing either the metabolism, distribution and/or elimination of already FDA-approved cancer drugs while maintaining the mechanism of how the drug kills cancer cells, we believe our three Next Generation Chemotherapy (NGC) treatments will provide improved safety-efficacy profiles when compared to their currently marketed counterparts - capecitabine, gemcitabine, and irinotecan.

Historically, much of oncology drug development has searched for a new or different way to treat cancer. Our approach is to modify and improve three different, currently approved, and widely used chemotherapy treatments so that the human body handles these NGC treatments differently than their presently approved counterpart drugs while the cancer killing mechanism of action remains the same. FDA's Project Optimus Oncology initiative and Oncology Guidance recommends that the dose-response (both safety and efficacy) relationships be evaluated for all oncology drugs. We have begun this process for our NGC treatments. To date, we have found that our NGC treatments are likely to have a better safety-efficacy profile than the current widely used marketed counterpart drugs, not only potentially making the development and approval process more efficient, but also differentiating our NGC treatments from the existing treatment. 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.

To advance our mission, we have assembled an experienced and successful development team with a track record of drug approvals and successful exits. Our team is experienced in developing drug products through all principal regulatory tiers from IND enabling studies to NDA submission. The combined scientific, development and regulatory experience of our team members has resulted in more than 30 drug approvals by the FDA, over 100 meetings with the FDA and involvement with more than 50 drug development programs, including drug products targeted to patients who have an unmet medical need. Although we believe that the skills and experience of our team members in drug development and commercialization is an important indicator of our future success, the past successes of our team members in developing and commercializing pharmaceutical products does not guarantee that they will successfully develop and commercialize drugs in our current pipeline. In addition, the growth in revenues of companies at which our executive officers and directors served in was due to many factors and does not guarantee that they will successfully operate or manage us or that we will experience similar growth in revenues, even if they continue to serve as executive officers and/or directors.

Our ability to generate meaningful revenue from any products depends on our ability to out-license the drugs before or after we obtain FDA NDA approval. Even if our products are authorized and approved by the FDA, it should be noted that the products must still meet the challenges of successful marketing, distribution and consumer acceptance.

Our Strategy

Our strategy is to obtain and develop drugs that will not only treat patients with unmet medical need conditions, but also have the potential to be more efficiently developed with a greater probability of development success than what typically occurs in the biotech-pharma industry, as well as a better return on investment given more efficient development and high commercial value. By changing either the metabolism, distribution and/or elimination of FDA-approved drugs while still maintaining the mechanism of killing cancer cells, we believe that our three NGC treatments provide improved safety-efficacy profiles when compared to their currently marketed counterparts of capecitabine, gemcitabine and irinotecan. These modifications differentiate our NGC treatments from the existing therapies while being potential life-changing treatments for patients.

Our pipeline of NGCs (i) already have 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) target cancers for which a single positive pivotal study demonstrating efficacy might provide enough evidence that the clinical benefits of the drug and its approval outweighs the risks associated with the drug. We expect to move each NGC to the next Phase of development while continually evaluating opportunities to further advance each drug to approval by ourselves or with a larger partner.

Recent Developments

Financing Transactions

Subsequent to December 31, 2022, we raised gross proceeds of $7.0 million from the sale of 8,432,192 shares of our common stock through the Purchase Agreement with Lincoln Park Capital, the Sales Agreement with Oppenheimer, and a registered direct offering, as follows:

- In January 2023, we sold 50,000 shares at an average price of $1.08 per share for an aggregate gross proceedings of $54,000 through the Purchase Agreement we entered into with Lincoln Park Capital in March 2022, under which we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million of our shares of common stock, subject to the terms and conditions in the Purchase Agreement. We did not sell any shares to Lincoln Park under the Purchase Agreement during the year ended December 31, 2022.

- On February 3, 2023, we sold 569,648 shares at an average price of approximately $1.22 per share for an aggregate gross proceeds of approximately $693,000 (net proceeds of approximately $672,000) prior to deducting sales commissions, pursuant to our Sales Agreement with Oppenheimer & Co. Inc. under which we may issue and sell in a registered "at-the-market" offering shares of our common stock having an aggregate offering price of up to $30.0 million from time to time. On February 5, 2023, in connection with our Registered Direct Offering, we suspended the Sales Agreement with Oppenheimer & Co. Inc., but we expect to reinstate it during 2023.

- On February 14, 2023, we closed on a registered direct offering for the sale of 7,812,544 shares of our common stock at a purchase price of $0.80 per share to accredited investors for gross proceeds of $6.3 million. Net proceeds from the offering were $5.7 million.

We plan to use the net proceeds for these financings to prepare for future clinical trials, research and development expenses, working capital and other general corporate purposes.

Suspension of Further Enrollment in PCS499 Trials

Due to enrollment difficulties that we have experienced since the beginning of our rare disease trial for PCS499 in uNL, we decided to suspend further enrollment in the PCS499 trial in February 2023. There were no safety concerns noted during the trial.

Impact of COVID-19

The COVID-19 pandemic continues to create uncertainties in the expected timelines for clinical stage biopharmaceutical companies such as ours, including causing delays in clinical trials and disruptions in the supply chain for raw materials used in clinical trial work. Delays in enrollment lengthen the time of studies and increase their costs. While we are hopeful the infection rate of COVID-19 will continue to decline, we cannot predict the future impact COVID-19 will have on our current and future clinical trials. Continued delays could materially impact our business in future periods and further extend our timelines.

For more information on the risks associated with COVID-19, refer to Part I, Item 1A, "Risk Factors" herein.

Results of Operations

Comparison of the year ended December 31, 2022 and 2021

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

	Year Ended December 31,		
	2022	2021	Change
Operating Expenses			
Research and development costs	$ 11,494,230	$ 6,878,021	$ 4,616,209
Acquisition of in-process research and development	-	566,583	(566,583)
General and administrative expenses	8,763,058	4,688,939	4,074,119
Impairment of intangible asset	7,268,143	-	7,268,143
Operating Loss	(27,525,431)	(12,133,543)	
Other Income (Expense)			
Forgiveness of Payroll Protection Program loan and related accrued interest	-	163,771	(163,771)
Interest income, net	101,202	11,627	89,575
Total other income (expense)	101,202	175,398	
Net Operating Loss Before Income Tax Benefit	(27,424,229)	(11,958,145)	(15,466,084)
Income Tax Benefit	-	530,611	(530,611)
Net Loss	$ (27,424,229)	$ (11,427,534)	

Revenues.

We had no revenue during the years ended December 31, 2022 and 2021. We do not currently have any revenue under contract or any immediate sales prospects.

Research and Development Expenses.

Our research and development costs are expensed as incurred. Research and development expenses include (i) program and testing related expenses including external consulting and professional fees related to the product testing and our development activities, (ii) internal research and development staff related salaries and other payroll costs including stock-based compensation, payroll taxes and employee benefits, and (iii) amortization of the exclusive PCS499 license intangible asset used in research and development activities up to its impairment at December 31, 2022,. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as prepaid expenses and expensed when the research and development activities are performed.

Research and development costs for the years ended December 31, 2022 and 2021 were as follows:

	Year ended December 31,	
	2022	2021
Preclinical, clinical trial and other costs	$ 6,269,006	$ 4,171,836
Research and development salaries and benefits	4,436,729	1,915,697
Amortization of intangible assets	788,495	790,488
Total	$ 11,494,230	$ 6,878,021

During the year ended December 31, 2022, our research and development expenses increased by $4,616,209 to $11,479,331 when compared to $6,878,021 for the year ended December 31, 2021. We experienced increases in payroll and related costs of approximately $433,000 and increases in stock-based compensation of approximately $2.1 million, as a result of expanding our development team, and increasing salary rates and stock-based compensation.

We also experienced increases in preclinical, clinical trial and other costs from activities in our clinical trials. Expenses include costs we paid contract research organizations, regulatory filing and maintenance fees, drug product testing and stability, consulting, and other clinical fees. Additionally, on May 17, 2022, we amended the third Milestone Event of our License Agreement with Elion changing the third Milestone Event as described in Note 9 to our consolidated financial statements. As a result, we recorded research and development expense and a related liability of $189,000, which represents the value of the shares we anticipate issuing to Elion upon satisfaction of the third Milestone Event (as modified) at the fair value on the date of modification. We experienced a very different level of clinical activity in 2021 compared to 2022. In May 2021, we enrolled our first patient in our Phase 2B clinical trial for PCS499 and in August 2021, we enrolled our first patient in our Phase 1B clinical trial for PCS6422. We were also conducting pre-IND tasks for PCS12852 in 2021.

Unless we obtain additional funding, we anticipate our research and development costs will decrease in 2023 as we complete our trials and begin to fund development activities for the other drugs in our pipeline. Depending on our funding, we plan to (i) complete our current clinical trials; (ii) begin a Phase 2B trial for NGC-Capecitabine; (iii) obtain IND enabling data for NGC-Irinotecan; (iv) initiate a Phase 2 trial for NGC-Gemcitabine; and (v) manufacture drug product necessary to conduct future clinical trials.

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

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

In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related series are recorded as prepaid expenses until the services are rendered. At December 31, 2022, we recorded $1.1 million in prepaid expenses for advanced payments made to our CROs related to our clinical trials.

Acquisition of In-Process Research and Development.

In 2021, we recorded $566,583 of acquired in-process research and development expense in connection with the Ocuphire Agreement. The total acquisition cost includes the issuance of 44,689 shares (with a fair value of $300,000) of our common stock we issued to Ocuphire, a cash payment of $200,000 and $66,583 in expenses we agreed to pay on behalf of Ocuphire. We did not have a similar expense in 2022. We believe the in-process research and development asset acquired have no alternative future use.

General and Administrative Expenses.

Our general and administrative expenses for the year ended December 31, 2022 increased by $4,074,119 to $8,763,058 when compared to $4,688,939 for the same period in 2021. The majority of the increase was due to employee stock-based compensation of approximately $3.5 million. We share office space with CorLyst, a related party, and during the years ended December 31, 2022 and 2021, they reimbursed us $124,497 and $126,324, respectively, for rent and other costs we incurred on their behalf.

We expect the general and administrative expenses to continue to increase as we add staff to support our growing research and development activities and the administration required to operate as a public company.

Impairment of Intangible Asset.

Our gross intangible assets consisted primarily of costs we capitalized related to the acquisition of license rights to PCS499 from CoNCERT Pharmaceuticals. Inc. ("CoNCERT") for shares of our common stock. We capitalized $8.0 million, which was the fair value of the 298,615 shares of our common stock we issued to CoNCERT when we acquired the license rights to PCS499 on March 19, 2018.

We review amounts previously capitalized for impairment whenever events or changes in circumstances indicate to us that the carrying value of the assets might not be recoverable. In May 2021, we enrolled our first patient in our Phase 2B trial for the treatment of ulcerative NL with PCS499. Although we initiated a number of recruitment programs to increase the enrollment of patients in this study, we were only able to recruit four patients by December 31, 2022. We experienced extremely slow enrollment in the study given the extreme rarity of the condition (rarer than reported in the literature), the impact of COVID-19, and the reluctance of patients to be in a clinical study. We will complete the study for those currently enrolled, but have halted further efforts to enroll new patients. At December 31, 2022, as a result of our decision to halt future enrollment and terminate our PCS499 clinical trial for ulcerative necrobiosis lipoidica, we recognized an impairment of the remaining book value of the intangible asset of $7.3 million, thereby reducing the value of our intangible asset to zero. Our assessment was based on the uncertainty of determining whether we will be able to out-license PCS499 or enter into a partnering/collaborating arrangement for its future development.

Other Income and (Expense)

Net other income and (expense) was $101,202 and $175,398 for the years ended December 31, 2022 and 2021, respectively. During 2021, we recognized $163,771 as other income for the principal amount and related accrued interest related to the forgiveness of our Paycheck Protection Program loan. Interest income represents interest earned on money market funds. Interest expense in 2021 was related to our Paycheck Protection Program loan.

Income Tax Benefit.

We did not recognize any income tax benefit for the year ended December 31, 2022. An income tax benefit of $530,611 was recognized for the year ended December 31, 2021. A deferred tax liability was created as a result of our acquisition of CoNCERT's license and "Know-How" in exchange for our common stock that had been issued in the Internal Revenue Code Section 351 transaction on March 19, 2018. The Section 351 transaction treated the acquisition of the Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, we recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between the financial reporting basis of $11,038,929 and the tax basis of $1,782. The deferred tax liability has been reduced for the effect of the non-deductibility of the amortization of the intangible asset and has been offset by the deferred tax assets resulting from net operating tax losses and was fully offset at December 31, 2021. This offset resulted in the recognition of a deferred tax benefit shown in the consolidated statements of operations in 2021 and prior periods. At December 31, 2022, the remaining deferred tax liability was eliminated as a result of the impairment of the intangible asset.

At December 31, 2022, we have recorded deferred tax assets totaling $14,542,710, including $6,480,014 of net operating losses that are fully offset by a valuation allowance.

Liquidity

Sources of Liquidity

At December 31, 2022 we had $6.5 million in cash and cash equivalents. On a proforma basis, taking into consideration the following funding we closed subsequent to year end, our cash and cash equivalents would have been $12.9 million at December 31, 2022.

- In January 2023, we sold 50,000 shares at an average price of $1.08 per share for an aggregate gross proceedings of $54,000 through the Purchase Agreement we entered into with Lincoln Park Capital in March 2022, under which we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million of our shares of common stock, subject to the terms and conditions in the Purchase Agreement. We did not sell any shares to Lincoln Park under the Purchase Agreement during the year ended December 31, 2022.

- On February 3, 2023, we sold 569,648 shares at an average price of approximately $1.22 per share for an aggregate gross proceeds of approximately $693,000 (net proceeds of approximately $672,000) prior to deducting sales commissions, pursuant to our Sales Agreement with Oppenheimer & Co. Inc. under which we may issue and sell in a registered "at-the-market" offering shares of our common stock having an aggregate offering price of up to $30.0 million from time to time. On February 5, 2023, in connection with our Registered Direct Offering, we suspended the Sales Agreement with Oppenheimer & Co. Inc., but we expect to reinstate it during 2023.

- On February 14, 2023, we closed on a registered direct offering for the sale of 7,812,544 shares of our common stock at a purchase price of $0.80 per share to accredited investors for gross proceeds of $6.3 million. Net proceeds from the offering were $5.7 million.

We have incurred losses and net cash used in our operating activities during the year ended December 31, 2022, which we expect to continue for the foreseeable future. We have incurred losses since our inception, devoting substantially all of our efforts toward research and development, and have an accumulated deficit of approximately $64.2 million at December 31, 2022. During the year ended December 31, 2022, we generated a net loss of approximately $27.4 million, of which $17.4 million were non-cash expenses. Based on our current plans, we believe our current cash balance along with amounts we raised subsequent to year end will be adequate for at least the next twelve months. Our ability to execute our longer-term operating plans, including unplanned future clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions. We plan to continue to actively pursue financing alternatives, but there can be no assurance that we will obtain the necessary funding in the future when needed.

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

Our future capital requirements will depend on many factors, including:

- the cost of our current clinical trials and the cost of third-party manufacturing;
- the initiation, progress, timing, costs and results of drug manufacturing, pre-clinical studies, and clinical trials of PCS3117 and PCS11T, as well as any other future product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing, and costs of seeking regulatory approvals;
- the costs associated with hiring additional personnel and consultants for our pre-clinical and clinical activities;
- the emergence of competing therapies and other adverse market developments;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending, and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

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

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the years ended December 31, 2022 and 2021:

	For the Year Ended December 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (9,605,143)	$ (8,717,291)
Financing activities	(388,843)	9,798,648
Net (decrease) increase in cash and cash equivalents	$ (9,993,986)	$ 1,081,357

Net cash used in operating activities

We used net cash in our operating activities of $9,605,143 and $8,717,291 during the years ended December 31, 2022 and 2021, respectively. The increase in cash used in operating activities during the year ended December 31, 2022 compared to the same period in 2021 was primarily related to cash payments made to conduct our clinical trials and increased salaries to our employees.

At December 31, 2022, our prepaid expense and other balance consisted primarily of $1.1 million for advanced payments we made to our CROs that have not yet been applied to our clinical trials, representing a $100,000 reduction from the prepaid amount recorded at December 31, 2021 of $1.2 million. Our prepaid expense and other at December 31, 2022 also included the unamortized non-cash commitment fee we paid to Lincoln Park of approximately $334,000 and the unamortized ATM offering related costs of $186,000. The majority of the remaining change in prepaid expenses and other was the result of various insurance policies we hold, such as directors' and officers' insurance and product liability insurance for conducting our clinical trials.

As we complete our clinical trials and evaluate the other drugs in our portfolio, we anticipate our research and development efforts and ongoing general and administrative costs will continue to generate negative cash flows from operating activities for the foreseeable future. We expect these amounts to increase in the future as the drugs in our pipeline continue to advance and if new or additional clinical trials begin.

Net cash (used in) provided by financing activities

During the year ended December 31, 2022, we used net cash in financing activities of $300,000 to purchase 100,000 shares of our common stock from a licensee in early 2022 and $88,843 to pay income taxes owed on vested stock-based compensation. During the same period in 2021, we closed a private offering, raising net proceeds of $9.9 million, paid approximately $64,000 for income taxes owed on vested stock-based compensation and received $173,987 in net proceeds from the sale of 21,597 shares of our common stock under our ATM Offering. We capitalized $186,493 in expenses related to our ATM Offering, which we will amortize as we sell additional shares once we reinstate our ATM Offering.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2022:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	$ 256,241	$ 93,845	$ 162,396	$ -	$ -
Total	$ 256,241	$ 93,845	$ 162,396	$ -	$ -

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

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

Off Balance Sheet Arrangements

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

Critical Accounting Policies and Use of Estimates

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

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

Valuation of Intangible Assets

Our intangible assets consisted primarily of the costs we incurred when we acquired the exclusive license from CoNCERT related to patent rights and Know-How to develop and commercialize compounds and products for PCS499 and each metabolite thereof and the related income tax effects. In accordance with ASC Topic 730, *Research and Development*, we capitalized the costs of acquiring the exclusive license rights to PCS499 as the exclusive license rights represent intangible assets to be used in research and development activities that have future alternative uses, measured initially at the asset's acquisition date fair value.

We used a market approach to estimate the fair value of the common stock issued to CoNCERT in this transaction. Our estimate was based on the final negotiated number of shares of stock issued and the volume weighted average market price over a 45-day period preceding the mid-February 2018 finalized negotiation of the modification to the option and license agreement with CoNCERT. We believe the fair values used to record intangible assets acquired in this transaction are based upon reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Potential triggering events that could indicate whether an impairment of our intangible assets may have occurred include: clinical trial results where the drug did not meet pre-established criteria or clinical endpoints, failure to obtain regulatory approval, the inability to fund future clinical trials, inability to enroll the trial, adverse changes in the regulatory environment, the approval of competing therapies or compounds, and adverse changes in applicable laws or regulations. The impairment of our intangible assets could have a material adverse impact on our financial condition. In order to determine whether an impairment has occurred, we evaluate the events and incorporate multiple assumptions, including costs associated with continuing the development program, competing therapies or compounds, potential market size, and estimated future cash flows. When testing for impairment, we may assess qualitative factors for our indefinite-lived intangibles to determine whether it is more likely than not (that is, a likelihood of more than 50 percent) that the asset is impaired. Alternatively, we may bypass this qualitative assessment for some or all of our indefinite-lived intangibles and perform the quantitative impairment test that compares the fair value of the indefinite-lived intangible asset with the asset's carrying amount. We test our intangible assets for impairment as of December 31 of the presented years.

Impairment of PCS499 In-process Research and Development Asset

In February 2023, we suspended further enrollment in our PCS499 trial for uNL due to difficulties we encountered in enrolling the trial, along with our limited resources. In May 2021, we enrolled our first patient in our Phase 2B trial for the treatment of ulcerative NL with PCS499. Although we initiated a number of recruitment programs to increase the enrollment of patients in this study, we were only able to recruit four patients by December 31, 2022. We have experienced extremely slow enrollment in the study given the extreme rarity of the condition (rarer than reported in the literature), the impact of COVID-19, and the reluctance of patients to be in a clinical study. We will complete the study for those currently enrolled but have halted further efforts to enroll new patients. As a result, we recognized a non-cash expense of $7.3 million as of December 31, 2022 related to the impairment of the intangible asset for PCS499. We originally recognized this intangible asset in conjunction with its acquisition from CoNCERT Pharmaceuticals, Inc. in 2018.

Clinical Trial Accruals / Research and Development

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

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

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

Stock-Based Compensation

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

See Note 5 – Stock-Based Compensation for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options and warrants granted during the years ended December 31, 2022 and 2021.

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

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. As of December 31, 2022 and 2021, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets since it is more-likely-than-not that benefits from our deferred tax assets will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal. As part of an evaluation of our tax attributes in 2022, we recharacterized approximately $7.4 million of startup costs previously capitalized as an IRC Section 195 asset as net operating losses. The recharacterization has no impact on total deferred tax assets since we had previously and will continue to provide a full valuation allowance on our unutilized net deferred tax assets. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect of changes in tax rates on deferred tax assets and liabilities is recognized in income in the period such changes are enacted. No current income tax benefit or expense was recorded for 2022 or is expected in the foreseeable future since the deferred tax liability was offset completely as of December 31, 2021 and we expect to generate future taxable net operating losses.

We recognize the impact of an uncertain tax position if the position will more likely than not be sustained upon examination by a taxing authority, based on the technical merits of the position. Our policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2022, we had no unrecognized tax benefits and as such, no liability, interest or penalties were required to be recorded. We do not expect this to change significantly in the next twelve months.

Recently Issued Accounting Pronouncements

See Note 2 of our consolidated financial statements for new accounting pronouncements or changes to the recent accounting pronouncements during the year ended December 31, 2022.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

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

Item 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Processa Pharmaceuticals, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosures to which they relate.

Intangible Asset

As discussed in Notes 3 and 9 to the consolidated financial statements, the Company previously capitalized costs related to the acquisition of the exclusive license rights to PCS499. As of December 31, 2022, this intangible was deemed impaired and the Company recognized approximately $7.3 million in expense reducing the asset to zero.

We identified the impairment of this intangible asset as a critical audit matter due to the materiality of the asset. To test the impairment of the asset, we reviewed management's analysis and tested the significant assumptions used by management.

/s/ BD & Company, Inc.
Owings Mills, MD
March 30, 2023

We have served as the Company's auditor since 2017.

Processa Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash and cash equivalents	$ 6,503,595	$ 16,497,581
Due from tax agencies	-	70,274
Prepaid expenses and other	1,883,134	1,759,296
Total Current Assets	8,386,729	18,327,151
Other Assets		
Operating lease right-of-use assets, net	227,587	74,181
Intangible assets, net	-	8,056,638
Other	5,535	5,535
Total Other Assets	233,122	8,136,354
Total Assets	$ 8,619,851	$ 26,463,505
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of operating lease liability	$ 78,896	$ 71,078
Accounts payable	327,548	218,905
Due to licensor	189,000	400,000
Due to related parties	51	1,772
Accrued expenses	403,061	279,265
Total Current Liabilities	998,556	971,020
Non-current Liabilities		
Non-current operating lease liability	150,554	7,385
Total Liabilities	1,149,110	978,405
Commitments and Contingencies	-	-
Stockholders' Equity		
Common stock, par value $0.0001, 50,000,000 shares authorized; 16,135,400 issued and 16,035,400 outstanding at December 31, 2022 and 15,710,246 issued and outstanding at December 31, 2021	1,614	1,571
Additional paid-in capital	72,016,688	62,306,861
Treasury stock	(300,000)	-
Accumulated deficit	(64,247,561)	(36,823,332)
Total Stockholders' Equity	7,470,741	25,485,100
Total Liabilities and Stockholders' Equity	$ 8,619,851	$ 26,463,505

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2022	2021
Operating Expenses		
Research and development expenses	$ 11,494,230	$ 6,878,021
Acquisition of in-process research and development	-	566,583
General and administrative expenses	8,763,058	4,688,939
Impairment of intangible asset	7,268,143	-
Operating Loss	(27,525,431)	(12,133,543)
Other Income (Expense)		
Forgiveness of Payroll Protection Program loan and related accrued interest	-	163,771
Interest income, net	101,202	11,627
Net Operating Loss Before Income Tax Benefit	(27,424,229)	(11,958,145)
Income Tax Benefit	-	530,611
Net Loss	$ (27,424,229)	$ (11,427,534)
Net Loss Per Common Share - Basic and Diluted	$ (1.70)	$ (0.75)
Weighted Average Common Shares Used to Compute Net Loss Per Common Shares - Basic and Diluted	16,109,291	15,319,463

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

Processa Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
Years Ended December 31, 2022 and 2021

	Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance at January 1, 2021	14,181,734	$ 1,419	$48,333,857	$ -	$ -	$(25,395,798)	$ 22,939,478
Stock-based compensation	50,270	5	3,288,010	-	-	-	3,288,015
Shares issued in private placement, net of transaction costs	1,321,132	132	9,875,418	-	-	-	9,875,550
Shares issued in connection with license agreement	144,689	14	699,986	-	-	-	700,000
Shares withheld to pay income taxes on stock-based compensation	(9,176)	(1)	(64,395)	-	-	-	(64,396)
Shares issued in ATM purchase, net of transaction costs	21,597	2	173,985	-	-	-	173,987
Net loss	-	-	-	-	-	(11,427,534)	(11,427,534)
Balance, January 1, 2022	15,710,246	1,571	62,306,861	-	-	(36,823,332)	25,485,100
Acquisition of treasury stock	-	-	-	(100,000)	(300,000)	-	(300,000)
Stock-based compensation	237,690	24	8,948,689	-	-	-	8,948,713
Shares issued in connection with the Purchase Agreement with Lincoln Park	123,609	12	449,988	-	-	-	450,000
Shares issued in connection with license agreement	100,000	10	399,990	-	-	-	400,000
Shares withheld to pay income taxes on stock-based compensation	(36,145)	(3)	(88,840)	-	-	-	(88,843)
Net loss	-	-	-	-	-	(27,424,229)	(27,424,229)
Balance, December 31, 2022	16,135,400	$ 1,614	$72,016,688	(100,000)	$(300,000)	$(64,247,561)	$ 7,470,741

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2022	2021
Cash Flows From Operating Activities		
Net Loss	$ (27,424,229)	$ (11,427,534)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	-	484
Non-cash lease expense for right-of-use assets	85,518	84,377
Non-cash milestone expense in connection with license agreement	189,000	-
Non-cash acquisition of in-process research and development	-	300,000
Amortization of debt issuance costs	115,613	-
Amortization of intangible asset	788,495	790,488
Impairment of intangible asset	7,268,143	-
Deferred income tax (benefit) expense	-	(530,611)
Stock-based compensation	8,828,713	3,408,015
Forgiveness of Payroll Protection Program loan and related accrued interest	-	(163,771)
Net changes in operating assets and liabilities:		
Prepaid expenses and other	210,549	(1,018,095)
Operating lease liability	(87,937)	(87,200)
Accounts payable	108,643	(101,789)
Due (from) to related parties	(1,721)	86,644
Other receivables	70,274	6,750
Accrued expenses	243,796	(65,049)
Net cash (used in) operating activities	(9,605,143)	(8,717,291)
Cash Flows From Financing Activities		
Net proceeds from common stock sold	-	10,049,537
Shares withheld to pay taxes on stock-based compensation	(88,843)	(64,396)
Acquisition of treasury stock	(300,000)	-
Other	-	(186,493)
Net cash (used in) provided by financing activities	(388,843)	9,798,648
Net (Decrease) Increase in Cash and Cash Equivalents	(9,993,986)	1,081,357
Cash and Cash Equivalents - Beginning of Year	16,497,581	15,416,224
Cash and Cash Equivalents - End of Year	$ 6,503,595	$ 16,497,581

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

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

	Years Ended December 31,	
	2022	2021
Supplemental Cash Flow Information:		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	-	-
Non-Cash Financing Activities		
Issuance of 17,572 shares of common stock in satisfaction of accrued director fees	$ 120,000	-
Issuance of 123,609 shares of common stock in connection with the Purchase Agreement with Lincoln Park	$ 450,000	$ -
Issuance of 100,000 shares of common stock in connection with a licensing agreement which had previously been recorded as a due to licensor	$ 400,000	$ 400,000
		-
Right-of-use asset obtained in exchange for operating lease liability	$ (238,924)	$ -
Operating lease liability	238,924	
Net	$ -	$ -

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

Note 1 – Organization and Description of the Business

Business Activities and Organization

We are a clinical-stage biopharmaceutical company focused on utilizing the Processa Regulatory Science Approach including the principles associated with FDA's Project Optimus Oncology initiative and the related FDA Draft Guidance, in the development of 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 taking FDA-approved, widely used oncology drugs or the cancer killing metabolites of these drugs and altering how they are metabolized and/or distributed in the body, including how they are distributed to the actual cancer cells. By changing either the metabolism, distribution and/or elimination of already FDA-approved cancer drugs while maintaining the mechanism of how the drug kills cancer cells, we believe our three Next Generation Chemotherapy (NGC) treatments will provide improved safety-efficacy profiles when compared to their currently marketed counterparts - capecitabine, gemcitabine, and irinotecan. All future studies of these drugs are subject to availability of capital to conduct the trials.

The three NGC treatments in our pipeline are as follows:

- NGC-Capecitabine is a combination of PCS6422 and capecitabine. NGC-Capecitabine alters the metabolism of capecitabine without having any clinically meaningful biological effect itself. In clinical trials, NGC-Capecitabine has a safety profile different than capecitabine when administered by itself. Side effects, such as Hand-Foot Syndrome (HFS) and cardiotoxicity that typically occur in 50-70% of patients treated with capecitabine and caused by specific capecitabine metabolites that are not formed to any extent with NGC-Capecitabine, do not appear to be side effects associated with NGC-Capecitabine. These types of toxicities can result in decreased doses, interrupted doses, or discontinuation of treatment with capecitabine. In addition, NGC-Capecitabine has been found to be greater than 50 times more potent than capecitabine based on the systemic exposure of the capecitabine metabolite 5-FU, which is metabolized to the cancer-killing metabolites. Like capecitabine, NGC-Capecitabine could be used to treat patients with various cancers, such as metastatic colorectal, gastrointestinal, breast and pancreatic. We estimate at least 200,000 patients in the United States were diagnosed in 2022 with metastatic colorectal, gastrointestinal, breast, and pancreatic cancers. In mid-April of 2023, we are scheduled to begin discussions with the FDA regarding the design of our Phase 2B trial and Project Optimus in order to initiate the Phase 2B trial in the second half of 2023.

- NGC-Gemcitabine (also identified as PCS3117) is an oral analog of gemcitabine that is converted to its active metabolite by a different enzyme system than gemcitabine resulting in a positive response in gemcitabine patients as well as some gemcitabine treatment-resistant patients. Like gemcitabine, NGC-Gemcitabine could be used to treat patients with various cancers such as pancreatic, lung, ovarian, and breast. We estimate at least 275,000 patients in the United States were diagnosed in 2022 with pancreatic, lung, ovarian, and breast cancer. We plan to meet with the FDA in 2023 to discuss potential study designs including implementation of Project Optimus initiative as part of the design, and then submit the Phase 2B protocol to the Investigational New Drug (IND Application) in the second half of 2023.

- NGC-Irinotecan (also identified as PCS11T) is a prodrug of the active metabolite of irinotecan (SN-38). The chemical structure of NGC-Irinotecan influences the uptake of the drug into cancer cells, resulting in more NGC-Irinotecan entering cancer cells than normal cells in mice. These levels were significantly greater than those seen with irinotecan, resulting in lower doses of NGC-Irinotecan having greater efficacy than irinotecan and improved safety in animal models. Like irinotecan, NGC-Irinotecan could be used to treat patients with various cancers such as lung, colorectal, gastrointestinal, and pancreatic cancer. We estimate at least 200,000 patients in the United States were diagnosed in 2022 with lung, colorectal, gastrointestinal, and pancreatic cancer. We plan to conduct IND-enabling and toxicology studies in 2023 and 2024.

Historically, much of oncology drug development has searched for a new or different way to treat cancer. Our approach is to modify and improve three different, currently approved, and widely used chemotherapy treatments so that the human body handles these NGC treatments differently than their presently approved counterpart drugs while the cancer killing mechanism of action remains the same. FDA's Project Optimus Oncology initiative and Oncology Guidance recommends that the dose-response (both safety and efficacy) relationships be evaluated for all oncology drugs. We have begun this process for our NGC treatments. To date, we have found that our NGC treatments are likely to have a better safety-efficacy profile than the current widely used marketed counterpart drugs, not only potentially making the development and approval process more efficient, but also differentiating our NGC treatments from the existing treatment. 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.

As part of our shift in priority, including the allocation of resources to NGC drugs, we suspended further enrollment in the PCS499 trial for uNL. We are evaluating options to monetize both PCS12852 and PCS499. The clinical study findings for PCS12852 were positive in gastroparesis patients and there were no safety concerns noted during the conduct of either study.

Recent Financings

Registered Direct Offering

On February 9, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") relating to the issuance and sale of shares of common stock pursuant to a registered direct offering (the "Offering") with certain accredited investors (the "Investors"). The Investors purchased approximately $6.3 million of shares, consisting of an aggregate of 7,812,544 shares of common stock at a purchase price of $0.80 per share. The Purchase Agreement provides that, subject to certain exceptions, until the earlier of (i) 90 days after the closing of the Offering or (ii) the trading day following the date that our common stock's closing price exceeds $2.00 for a period of 10 consecutive trading days neither we nor our subsidiary will issue or enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or common stock equivalents.

The net proceeds from the Offering, after deducting the fees of the Placement Agent, Spartan Capital Securities, LLC ("Spartan"), and the estimated offering expenses, were approximately $5.7 million. The Offering closed on February 14, 2023.

The common stock was offered and sold pursuant to our Registration Statement on Form S-3 (Registration No. 333-257558) previously filed with the Securities and Exchange Commission and declared effective on July 9, 2021, the base prospectus included therein and the related prospectus supplement dated February 9, 2023.

We paid the Placement Agent a cash fee of 8.0% of the gross proceeds from the Offering, excluding proceeds received from our insiders, and reimbursed the Placement Agent for legal fees of $60,000. The engagement agreement with the Placement Agent requires us to indemnify the Placement Agent and certain of its affiliates against certain customary liabilities. We also amended our consulting agreement with Spartan, entered into on August 24, 2022, extending the term of the consulting agreement until February 10, 2024. We will compensate Spartan for financial consulting services provided under the amendment by granting Spartan warrants to purchase 3,160,130 shares of our common stock on April 17, 2023 with an exercise price of $1.02. The warrants will expire three years from the date of issuance and contain both call and cashless exercise provisions.

At-the-Market Transactions

On August 20, 2021, we entered into an equity distribution agreement (the "Sales Agreement") with Oppenheimer & Co. Inc. (the "Sales Agent") under which we may issue and sell in a registered "at-the-market" offering shares of our common stock having an aggregate offering price of up to $30.0 million from time to time through or to our Sales Agent (the "ATM Offering"). We expect to use net proceeds from the ATM Offering over time as a source for working capital and general corporate purposes. We are not obligated to make any sales of our common stock under the Sales Agreement and no assurance can be given that we will sell any shares under the Sales Agreement, or, if we do, as to the price or amount of shares that we will sell, or the dates on which any such sales will take place. We will pay the Sales Agent an aggregate of up to 3.0% of the gross proceeds of the sales price per share of common stock sold through the Sales Agent under the Sales Agreement. The shares under the ATM Offering will be sold and issued pursuant to our S-3 shelf registration statement (Registration No. 333-257588), declared effective on July 9, 2021.

On February 3, 2023, we sold 569,648 shares of our common stock under the ATM Offering resulting in net proceeds of $672,393. We did not sell any shares under our ATM Offering during the year ended December 31, 2022 and sold 21,597 shares of our common stock during the year ended December 31, 2021 for aggregate net proceeds of approximately $174,000. On February 5, 2023, we suspended the Sales Agreement and terminated the prospectus supplement.

Equity Line of Credit Transactions

On March 23, 2022, we entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $15.0 million of shares (the "Purchase Shares") of our common stock, subject to the terms and conditions in the Purchase Agreement. We issued 123,609 shares of common stock (valued at $450,000) to Lincoln Park as a commitment fee in connection with entering into the Purchase Agreement and reimbursed Lincoln Park $25,000 for fees incurred in connection with the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park (the "Registration Rights Agreement"), pursuant to which we agreed to take certain actions relating to the registration under the Securities Act of 1933, as amended, of the offer and sale of the shares of common stock available for issuance under the Purchase Agreement.

We did not draw on our Equity Line of Credit with Lincoln Park in 2022. In January 2023, we sold Lincoln Park 50,000 shares of our common stock for proceeds of $54,000.

Impairment of PCS499 In-process Research and Development Asset

In February 2023, we suspended further enrollment in our PCS499 trial for uNL due to difficulties we encountered in enrolling our PCS499 trial for uNL. As a result, we recognized a non-cash expense of $7.3 million at December 31, 2022 related to the impairment of the intangible asset for PCS499 (see Note 3). We originally recognized this intangible asset in conjunction with its acquisition from CoNCERT Pharmaceuticals, Inc. in 2018.

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

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission (the "SEC"), and reflect all of our activities, including those of our wholly-owned subsidiary. All material intercompany accounts and transactions have been eliminated in consolidation.

Liquidity

We have incurred losses since inception, devoting substantially all of our efforts toward moving the drugs in our pipeline through the regulatory process and other research and development activities, and have an accumulated deficit of approximately $64.2 million as of December 31, 2022. During the year ended December 31, 2022, we generated a net loss of approximately $27.4 million, of which $17.4 million represented non-cash expenses. Net cash used in our operating activities during the year ended December 31, 2022 was approximately $9.6 million. We expect to continue to generate operating losses and negative cash flow from operations for the foreseeable future. Based on our current plans, we believe our current cash balances along with net proceeds of $6.4 million recently raised (described above) are adequate for at least the next twelve months. Our ability to execute our longer-term operating plans, including planned future clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions. We plan to continue to actively pursue financing alternatives, but there can be no assurance that we will obtain the necessary funding in the future when needed.

We had no revenue during the year ended December 31, 2022 and do not have any revenue under contract or any immediate sales prospects. Our primary uses of cash are to fund our active clinical trials, research and development expenditures and operating expenses. Cash used to fund operating expenses is impacted by the timing of when we incur and pay these expenses.

Use of Estimates

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

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and money market funds. We consider all highly liquid investments with a maturity at the date of purchase of three months or less to be cash equivalents.

Property and Equipment

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

Intangible Assets

Intangible assets acquired individually or with a group of other assets from others (other than in a business combination) are recognized at cost, including transaction costs, and allocated to the individual assets acquired based on relative fair values and no goodwill is recognized. Cost is measured based on cash consideration paid. If consideration given is in the form of non-cash assets, liabilities incurred, or equity interests issued, measurement of cost is based on either the fair value of the consideration given or the fair value of the assets (or net assets) acquired, whichever is more clearly evident and more reliably measurable. Costs of internally developing, maintaining or restoring intangible assets that are not specifically identifiable, have indeterminate lives or are inherent in a continuing business are expensed as incurred.

Intangible assets purchased from others for use in research and development activities and that have alternative future uses (in research and development projects or otherwise) are capitalized in accordance with ASC Topic 350, *Intangibles – Goodwill and Other.* Those that have no alternative future uses (in research and development projects or otherwise), and therefore no separate economic value, are considered research and development costs and are expensed as incurred. Amortization of intangibles used in research and development activities is a research and development cost.

Intangibles with a finite useful life are amortized using the straight-line method unless the pattern in which the economic benefits of the intangible assets are consumed or used up are reliably determinable. The useful life is the best estimate of the period over which the asset is expected to contribute directly or indirectly to our future cash flows. The useful life is based on the duration of the expected use of the asset by us and the legal, regulatory or contractual provisions that constrain the useful life and future cash flows of the asset, including regulatory acceptance and approval, obsolescence, demand, competition and other economic factors. We evaluate the remaining useful life of intangible assets each reporting period to determine whether any revision to the remaining useful life is required. If the remaining useful life is changed, the remaining carrying amount of the intangible asset will be amortized prospectively over the revised remaining useful life. If an income approach is used to measure the fair value of an intangible asset, we consider the period of expected cash flows used to measure the fair value of the intangible asset, adjusted as appropriate for company-specific factors discussed above, to determine the useful life for amortization purposes.

If no regulatory, contractual, competitive, economic or other factors limit the useful life of the intangible to us, the useful life is considered indefinite. Intangibles with an indefinite useful life are not amortized until its useful life is determined to be no longer indefinite. If the useful life is determined to be finite, the intangible is tested for impairment and the carrying amount is amortized over the remaining useful life in accordance with intangibles subject to amortization. Indefinite-lived intangibles are tested for impairment annually and more frequently if events or circumstances indicate that it is more-likely-than-not that the asset is impaired.

Impairment of Long-Lived Assets and Intangibles Other Than Goodwill

We account for the impairment of long-lived assets in accordance with ASC 360, *Property, Plant and Equipment* and ASC 350, *Intangibles – Goodwill and Other,* which require that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to its expected future undiscounted net cash flows generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amounts of the assets exceed the fair value of the assets based on the present value of the expected future cash flows associated with the use of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. Based on management's evaluation, we recorded an impairment loss of $7.3 million during the year ended December 31, 2022. No impairment loss was recorded during the year ended December 31, 2021 (see Note 3).

Fair Value Measurements and Disclosure

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

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

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

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

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

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

Stock-based Compensation

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

When evaluating the assumptions required for the Black-Scholes model, we recognized that our previous volatility computation was based on a basket of peer companies, which was no longer representative of the actual measure of the distribution of returns of our common stock and began using our Company's historical closing stock prices for awards granted after September 1, 2021.

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

Net Loss Per Share

Basic loss per share is computed by dividing our net loss available to common shareholders by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock outstanding during the period. Since we experienced a net loss for all periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the years ended December 31, 2022 and 2021 excludes the impact of potentially dilutive common shares related to outstanding stock options, unvested restricted stock awards (RSAs), unvested restricted stock units (RSUs) and purchase warrants.

Our diluted net loss per share for the years ended December 31, 2022 and 2021 excluded 2,577,910 and 822,430 of potentially dilutive common shares, respectively, related to outstanding stock options, unvested RSAs, unvested RSUs and warrants since those shares would have had an anti-dilutive effect on loss per share during the years then ended.

As noted above, we amended our consulting agreement with Spartan, extending the term of the consulting agreement until February 10, 2024. We will compensate Spartan for financial consulting services provided under the amendment by granting Spartan warrants to purchase 3,160,130 shares of our common stock on April 17, 2023 with an exercise price of $1.02. The warrants have been excluded from the 2.6 million potentially dilutive common shares described above since they have not been issued yet. They will expire three years from the date of issuance and contain both call and cashless exercise provisions.

Segments

We operate in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. All our assets are located within the United States.

Fair Value of Financial Instruments

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

Research and development

Research and development costs are expensed as incurred and consisted of direct and overhead-related expenses related primarily to clinical trials, development personnel salaries and related costs. Research and development costs totaled $11,494,230 and $6,878,021 for the years ended December 31, 2022 and 2021, respectively. Expenditures to acquire technologies, including licenses, which are utilized in research and development and that have no alternative future use are expensed as the acquisition of in-process research and development when incurred. Technology we develop for use in our products is expensed as incurred until technological feasibility has been established after which it is capitalized and depreciated. No research and development costs were capitalized during the years ended December 31, 2022 and 2021.

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. As of December 31, 2022 and 2021, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets since it is more-likely-than-not that benefits from our deferred tax assets will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal. As part of an evaluation of our tax attributes in 2022, we recharacterized approximately $7.4 million of startup costs previously capitalized as an IRC Section 195 asset as net operating losses. The recharacterization has no impact on total deferred tax assets since we had previously and will continue to provide a full valuation allowance on our unutilized net deferred tax assets.

We recognize the impact of an uncertain tax position if the position will more likely than not be sustained upon examination by a taxing authority, based on the technical merits of the position. Our policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2022, we had no unrecognized tax benefits and as such, no liability, interest or penalties were required to be recorded. We do not expect this to change significantly in the next twelve months.

Recent Accounting Pronouncements

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

Note 3 - Intangible Assets

Our gross intangible assets consisted primarily of costs we capitalized related to the acquisition of license rights to PCS499 from CoNCERT Pharmaceuticals. Inc. ("CoNCERT") for shares of our common stock that had an issue date fair value of $8.0 million, $1,782 in transaction costs and $3,037,147 associated with the initial recognition of an offsetting deferred tax liability related to the acquired temporary difference for an asset purchased that is not a business combination and has a tax basis of $1,782 in accordance with ASC 740-10-25-51 *Income Taxes*. In accordance with ASC Topic 730, *Research and Development,* we capitalized the costs of acquiring the exclusive license rights to PCS499 from CoNCERT, as the exclusive license rights represented intangible assets to be used in research and development activities that management believed had future alternative uses.

Intangible assets at December 31, 2022 and 2021 consisted of the following:

	2022	2021
Gross intangible assets	$ 11,059,429	$ 11,059,429
Less: accumulated amortization	(3,791,286)	(3,002,791)
Less: impairment of intangible asset	(7,268,143)	-
Total intangible assets, net	$ -	$ 8,056,638

Amortization expense was $788,495 and $790,488 for the years ended December 31, 2022 and 2021, respectively and is included within research and development expense in the accompanying consolidated statements of operations.

We review amounts previously capitalized for impairment whenever events or changes in circumstances indicate to us that the carrying value of the assets might not be recoverable. In May 2021, we enrolled our first patient in our Phase 2B trial for the treatment of ulcerative NL with PCS499. Although we initiated a number of recruitment programs to increase the enrollment of patients in this study, we were only able to recruit four patients by December 31, 2022. We have experienced extremely slow enrollment in the study given the extreme rarity of the condition (rarer than reported in the literature), the impact of COVID-19, and the reluctance of patients to be in a clinical study. We will complete the study for those currently enrolled, but in February 2023, we suspended further enrollment in the PCS499 trial for uNL, effectively terminating the trial. At December 31, 2022, as a result of our decision to halt future enrollment and terminate our PCS499 clinical trial for uNL, we recognized an impairment for remaining book value of the intangible asset of $7.3 million, thereby reducing the value of our intangible asset to zero. Our assessment was based on the uncertainty of determining whether we will be able to out-license PCS499 or enter into a partnering/collaborating arrangement for its future development. We believe the rarity of the disease, along with other factors, makes enrollment not feasible for us due to time and cost constraints. We are evaluating our options to monetize this asset.

Note 4 - Income Taxes

We have incurred net operating losses since inception. At December 31, 2022 and 2021, we had available federal and state net operating loss carryforwards of $24.0 million and $12.5 million, respectively. The federal net operating losses generated in 2018 and later of $23.7 million will carry forward indefinitely. Net operating losses generated prior to 2018 will expire 2037. We have not recognized any deferred tax assets related to the federal orphan drug or other research and development tax credits as of December 31, 2022 or 2021. The federal research and development tax credits have a 20-year carryforward period.

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

Our provision (benefit) for income taxes for the years ended December 31, 2022 and 2021 was as follows:

	Year Ended December 31,	
	2022	2021
Current:		
Federal	$ -	$ -
State	-	-
Total deferred tax benefit	-	-
Deferred:		
Federal	(5,887,151)	(2,853,937)
State	(1,567,560)	(624,844)
Total deferred tax benefit	(7,454,711)	(3,478,781)
Valuation allowance	7,454,711	2,948,170
Net deferred tax benefit	-	(530,611)
Total tax provision (benefit)	$ -	$ (530,611)

A deferred tax liability was recorded on March 19, 2018 when we received CoNCERT's license and Know-How in exchange for our common stock that had been issued in an Internal Revenue Code Section 351 Transaction. The Section 351 Transaction treats the acquisition of the license and Know-How for stock as a tax-free exchange. As a result, under ASC 740-10-25-51 *Income Taxes*, we recorded a deferred tax liability of $3,037,147 for the acquired temporary difference between intangible assets for the financial reporting basis of $11,038,929 and the tax basis of $1,782.

We recorded the benefit of net operating losses in our consolidated financial statements to the extent possible as a reduction in the deferred tax liability created by the future financial statement amortization of the intangible asset from the acquired CoNCERT license and Know-How prior to its full impairment at December 31, 2022. For the year ended December 31, 2021, we recorded a federal income tax benefit of $530,611 as a result of offsetting our deferred tax liability (related to the CoNCERT asset) by the deferred tax assets resulting from our net operating loss and the amortization of the intangible asset related to CoNCERT. No current income tax benefit or expense was recorded for 2022 since the deferred tax liability was offset completely as of December 31, 2021 and we expect to generate future taxable net operating losses. At December 31, 2022, the remaining deferred tax liability was eliminated as a result of the impairment of the intangible.

A reconciliation of our effective income tax rate and statutory income tax rate for the years ended December 31, 2022 and 2021 is as follows:

	Year Ended December 31,	
	2022	2021
Federal statutory income tax rate	21.00%	21.00%
State tax rate, net	5.72%	5.23%
Permanent differences	(0.55)%	(0.18)%
Federal orphan drug tax credit	0.93%	3.04%
Deferred tax asset valuation allowance	(27.10)%	(24.65)%
Effective income tax rate	0.00%	4.44%

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

	December 31,	
	2022	2021
Deferred tax assets:		
Non-current:		
Net operating loss carry forward – Federal	$ 5,048,175	$ 2,615,518
Net operating loss carry forward – State	1,431,839	760,897
Stock compensation expense	2,590,890	593,365
Depreciation and other	976	13,200
Purchased in-process R&D	2,494,829	2,481,070
Federal orphan drug credits	1,046,539	791,151
Capitalized research and development costs	1,929,462	-
Start-up expenditures and amortization	-	1,978,418
Total non-current deferred tax assets	14,542,710	9,233,619
Valuation allowance for deferred tax assets	(14,542,710)	(7,087,999)
Total deferred tax assets	-	2,145,620
Deferred Tax Liabilities:		
Non-current:		
Intangible asset	-	(2,145,620)
Total non-current deferred tax liabilities	-	(2,145,620)
Total deferred tax asset (liability)	$ -	$ -

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 (TCJA) eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to amortize them over five or fifteen years pursuant to IRC Section 174. During 2022, for income tax purposes, we capitalized approximately $7.2 million of research and development expenditures.

In 2022, as part of an evaluation of our tax attributes, we recharacterized approximately $7.4 million of startup costs previously capitalized as an IRC Section 195 asset as net operating losses. The recharacterization has no impact on total deferred tax assets since we had previously and will continue to provide a full valuation allowance on our unutilized net deferred tax assets.

The valuation allowance generally reflects limitations on our ability to use the tax attributes and reduces the value of such attributes to the more-likely-than-not realizable amount. We assessed the available positive and negative evidence to estimate if sufficient taxable income will be generated to use the existing net deferred tax assets. Based on a weighting of the objectively verifiable negative evidence primarily in the form of cumulative operating losses, we believe that it is not more likely than not that the deferred tax assets will be realized and, accordingly, a full valuation allowance has been established. The valuation allowance increased by $7.4 million and $2.9 million for the years ended December 31, 2022 and 2021, respectively.

We recognize potential liabilities for uncertain tax positions using a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. We have not recorded any uncertain tax positions. As of December 31, 2022 and 2021, we had no accrued penalties or interest related to uncertain tax positions.

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

Note 5 - Stock-based Compensation

The Processa Pharmaceuticals Inc. 2019 Omnibus Equity Incentive Plan (the "2019 Plan") allows us to make grants of stock options, restricted and unrestricted stock and other stock-based awards to employees, including our executive officers, consultants and directors. The 2019 Plan originally provided for the aggregate issuance of 3,000,000 shares of our common stock. On July 11, 2022, our shareholders approved an increase in the aggregate number of shares of our common stock available for issuance under our 2019 plan by 3,000,000 shares to 6,000,000 shares in total. As of December 31, 2022, 2,387,622 shares were available for future grants.

Stock Compensation Expense

We recorded stock-based compensation expense for the years ended December 31, 2022 and 2021 as follows:

	Year Ended December 31,	
	2022	2021
Research and development	$2,895,653	$ 809,839
General and administrative	5,933,060	2,598,176
Total	$8,828,713	$3,408,015

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

Stock Options

We did not grant any stock options during 2022 and made one grant in 2021 to a consultant for the purchase of 30,000 shares.

The fair value of the stock option grant was estimated using the Black-Scholes option-pricing model at the date of grant. The expected volatility of stock options granted on or after September 1, 2021 will be calculated using the Company's historical closing stock prices. The expected term of our stock options was determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

The fair value of the option award granted during the year ended December 31, 2021 was estimated using the following assumptions:

Average risk-free rate of interest	1.85%
Expected term (years)	2
Expected stock price volatility	81.77%
Dividend yield	0%

The following table summarizes our stock option activity during the years ended December 31, 2022 and 2021:

	Total options Outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2021	152,806	$ 18.11	
Options granted	30,000	11.70	1.2
Forfeited	(4,310)	16.80	
Outstanding as of December 31, 2021	178,496	17.07	3.6
Options granted	-		
Forfeited	-		
Outstanding and exercisable as of December 31, 2022	178,496	$ 17.07	2.6

The weighted average grant-date fair value per share of options granted during the year ended December 31, 2021 was $5.23. No forfeiture rate was applied to these stock options. The aggregate fair value of stock options vested at December 31, 2022 and 2021 was $1,910,240 and $1,659,909, respectively. No stock options were exercised during the years ended December 31, 2021 or 2022.

Restricted Stock Awards

Activity in our Restricted Stock Awards ("RSAs") during the years ended December 31, 2022 and 2021 was as follows:

	Number of shares	Weighted-average grant-date fair value per share
Unvested as of January 1, 2021	122,782	$ 8.04
Granted	37,500	6.65
Vested and issued	(58,467)	7.90
Forfeited	(10,706)	6.54
Unvested as of December 31, 2021	91,109	7.74
Granted	187,058	3.71
Vested and Issued	(182,790)	5.04
Forfeited	(33,489)	5.53
Unvested as of December 31, 2022	61,888	$ 4.72

As of December 31, 2022, unrecognized stock-based compensation expense of approximately $199,000 for RSAs is expected to be fully recognized in 2023 and 2024.

During the year ended December 31, 2022, we granted RSAs related to the future issuance of 187,058 shares of our common stock as follows:

- RSAs for 59,766 shares of our common stock to consultants for services to be provided in 2022. These RSAs had a cumulative fair market value of $196,500 on the dates of grant and were expensed as stock-based compensation.
- RSAs for 109,720 shares of our common stock to our directors for their 2022-2023 service which had a fair market value of $378,000 on the date of grant. During the year ended December 31, 2022, 54,624 of these RSAs vested and were issued.
- 17,572 shares of our common stock to our directors in satisfaction of the $120,000 of directors' fees we had accrued at December 31, 2021.

On May 31, 2022, one of our directors did not seek reelection and forfeited RSAs for 18,208 shares of our common stock related to their 2022 service. On January 1, 2023, we awarded RSAs for 90,000 shares to three directors, which vest on the earlier of July 1, 2023 or our 2023 Annual Meeting of Stockholders.

Restricted Stock Units

Activity in our Restricted Stock Units ("RSUs") during the years ended December 31, 2022 and 2021 was as follows:

	Number of shares	Weighted-average grant-date fair value per share
Outstanding at January 1, 2021	-	
Granted	457,593	$ 7.75
Forfeited	(4,000)	8.61
Issued	(14,000)	7.12
Outstanding at December 31, 2021	439,593	7.76
Granted	2,428,285	3.08
Forfeited	(68,539)	5.09
Issued	(47,976)	3.95
Cancelled	(37,386)	8.61
Outstanding at December 31, 2022	2,713,977	3.69
Vested and unissued	(662,069)	4.54
Unvested at December 31, 2022	2,051,908	$ 3.42

As of December 31, 2022, unrecognized stock-based compensation expense of approximately $472,000 for RSUs is expected to be fully recognized over a weighted average period of 1.7 years. The unrecognized expense excludes approximately $320,000 of expense related to certain RSUs with a performance milestone that is not currently probable of occurring.

During the year ended December 31, 2022, we granted RSUs related to the future issuance of 417,073 shares of our common stock pursuant to agreements with our Executive team and certain other employees where a portion of their base compensation was paid in RSUs. The value of an RSU award was based on the average share price of the month services were provided. These RSUs vest quarterly, but must meet distribution requirements before any shares of common stock are issued. Effective July 1, 2022, we established a $5.00 per share floor for the computation of the number of shares our Executive team members could earn under this program. This program ended for all participants by December 31, 2022.

On April 1, 2022, we also granted RSUs for 1,979,818 shares of our common stock which vest on January 1, 2023 and are subject to distribution requirements before any shares of common stock are issued. The RSUs had a fair value of $6.2 million, which was fully recognized in stock-based compensation expense during the year ended December 31, 2022.

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

On June 1, 2022, in connection with the termination of a long-term employee, we accelerated the vesting of 62,940 restricted stock units. The incremental compensation costs recognized related to the acceleration of vesting of these awards totaled $90,228.

On January 1, 2023, we awarded RSUs for 966,503 shares to employees, of which 310,895 vest over one year and the remainder vest over three years.

Warrants

No stock purchase warrants were granted and 18,107 expired during the year ended December 31, 2022. As shown in the table below at December 31, 2022, we had outstanding and vested stock purchase warrants for the purchase of 285,618 shares with a weighted average exercise price of $10.25 and a weighted average remaining contractual life of 0.9 years.

The following table summarizes our warrant activity during the years ended December 31, 2022 and 2021.

	Total warrants outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2021	534,674	$ 18.34	
Warrants granted	229,268	8.09	
Forfeited	(460,217)	18.31	
Outstanding as of December 31, 2021	303,725	18.34	1.5
Warrants granted	-		
Forfeited	(18,107)	17.16	
Outstanding and exercisable as of December 31, 2022	285,618	$ 10.25	0.9

Our outstanding warrants expire at various dates through September 1, 2024.

In January 2021, we issued a warrant for the purchase of 100,000 shares of our common stock, with a fair value of $321,158, to a consultant in exchange for service to be provided in 2021. There were no vesting conditions associated with this warrant. In May 2022, we extended the expiration date of this warrant by one year to January 11, 2024 and recognized approximately $33,000 of incremental expense related to the warrant modification during the year ended December 31, 2022, based on an expected volatility of 84.39%. No other terms of the warrant, including the exercise price of $7.18, were changed.

In September 2021, we also issued a warrant for the purchase of 50,000 shares of our common stock, with a fair value of $139,900, to another consultant in exchange for service to be provided in 2021 and 2022. The warrant expires on September 1, 2024 and has an exercise price of $8.00 per share. The warrants were fully vested by June 30, 2022.

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

Average risk-free rate of interest	0.42 –1.85%
Expected term (years)	2.00–3.00
Expected stock price volatility	74.48–81.77%
Dividend yield	0%

We recognize expense based on the fair value of the warrants over their service or vesting periods and recorded $103,374 and $391,108 related to these warrants during the years ended December 31, 2022 and 2021, respectively.

In February 2021, we also issued warrants for the purchase of 79,268 shares of our common stock to our placement agent in connection with a private placement of 1,321,132 shares of our common stock as described in Note 6. These warrants are exercisable for cash at $9.30 per share and expire on February 16, 2023.

In February 2023, we amended our financial consulting agreement with Spartan by extending the term until February 10, 2024. We will compensate Spartan for financial consulting services provided under the amendment by granting warrants to purchase 3,160,130 shares of our common stock on April 17, 2023 with an exercise price of $1.02. The warrants will expire three years from the date of issuance and contain both call and cashless exercise provisions (see Note 1).

Note 6 – Stockholders' Equity

On January 1, 2022, we amended our Certificate of Incorporation to increase the number of authorized shares of our common stock from 30,000,000 to 50,000,000. We believe 50,000,000 authorized shares of common stock better aligns our capital structure with our future needs.

Preferred Stock

There were no issued or outstanding shares of preferred stock at either December 31, 2022 or 2021.

Common Stock

Subsequent to December 31, 2022, we raised gross proceeds of $7.0 million from the sale of 8,432,192 shares of our common stock through the Purchase Agreement with Lincoln Park, the Sales Agreement with Oppenheimer, and a registered direct offering, as follows:

- In January 2023, we sold 50,000 shares at an average price of $1.08 per share for an aggregate gross proceedings of $54,000 through the Purchase Agreement we entered into with Lincoln Park Capital in March 2022. We did not sell any shares to Lincoln Park under the Purchase Agreement during the year ended December 31, 2022.

- On February 3, 2023, we sold 569,648 shares at an average price of approximately $1.22 per share for an aggregate gross proceeds of approximately $693,000 (net proceeds of approximately $672,000) prior to deducting sales commissions, pursuant to our Sales Agreement with Oppenheimer & Co. Inc. under which we may issue and sell in a registered "at-the-market" offering shares of our common stock having an aggregate offering price of up to $30.0 million from time to time. On February 5, 2023, in connection with our Registered Direct Offering, we suspended the Sales Agreement with Oppenheimer & Co. Inc., but we expect to reinstate it during 2023.

- On February 14, 2023, we closed on a registered direct offering for the sale of 7,812,544 shares of our common stock at a purchase price of $0.80 per share to accredited investors for gross proceeds of $6.3 million. Net proceeds from the offering were $5.7 million.

During the year ended December 31, 2022, we had the following activity:

- On March 23, 2022, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $15.0 million of shares (the "Purchase Shares") of our common stock, subject to the terms and conditions in the Purchase Agreement. We issued 123,609 shares of common stock (valued at $450,000) to Lincoln Park as a commitment fee in connection with entering into the Purchase Agreement and agreed to reimburse Lincoln Park $25,000 for fees incurred in connection with the Purchase Agreement. Concurrent with entering into the Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park (the "Registration Rights Agreement"), pursuant to which we agreed to take certain actions relating to the registration under the Securities Act of 1933, as amended, of the offer and sale of the shares of common stock available for issuance under the Purchase Agreement.

  We have the right to present Lincoln Park with a purchase notice (a "Regular Purchase Notice"), directing Lincoln Park to purchase up to 25,000 Purchase Shares (the "Regular Purchase Amount") provided that the closing sale price of the common stock on the purchase date is not below a threshold price of $1.00, set forth in the Purchase Agreement (a "Regular Purchase"). The Regular Purchase Amount may be increased to up to 75,000 shares if the closing sale price of our common stock on the applicable purchase date equals or exceeds certain higher threshold prices set forth in the Purchase Agreement. We and Lincoln Park may mutually agree to increase the Regular Purchase Amount with respect to any Regular Purchase under the Purchase Agreement, provided that Lincoln Park's maximum committed purchase obligation under any single Regular Purchase shall not exceed $1,250,000. The above-referenced share amount limitations and closing sale price thresholds are subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement. The purchase price per share for each Regular Purchase will be based on prevailing market prices of the common stock immediately preceding the time of sale as computed in accordance with the terms set forth in the Purchase Agreement. There are no upper limits on the price per share that Lincoln Park must pay for shares of common stock under the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

  The aggregate number of shares that we can issue to Lincoln Park under the Purchase Agreement may not exceed 3,142,430 shares (subject to proportional adjustments for stock splits, reverse stock splits and similar events as described above), which is equal to 19.99% of the outstanding shares of common stock immediately prior to the execution of the Purchase Agreement (the "Exchange Cap"), unless (i) stockholder approval is obtained to issue shares of common stock in excess of the Exchange Cap, in which case the Exchange Cap will no longer apply, or (ii) the average price of all sales of Purchase Shares to Lincoln Park under the Purchase Agreement equals or exceeds the lower of (i) the Nasdaq official closing price immediately preceding the execution of the Purchase Agreement or (ii) the arithmetic average of the five Nasdaq official closing prices for the common stock immediately preceding the execution of the Purchase Agreement, plus an incremental amount to take into account the issuance of the commitment shares to Lincoln Park under the Purchase Agreement, such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules. In all instances, we may not sell shares of our common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of common stock.

We may terminate the Purchase Agreement at any time, at our sole discretion, without any cost or penalty, by giving one business day notice to Lincoln Park to terminate the Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the common stock.

There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings (other than restrictions on our ability to enter into variable rate transactions described in the Purchase Agreement), rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. We may deliver Purchase Notices under the Purchase Agreement, subject to market conditions, and in light of our capital needs from time to time and under the limitations contained in the Purchase Agreement. Any proceeds that we receive under the Purchase Agreement are expected to be used for working capital and general corporate purposes.

- We issued 100,000 shares to Elion for the second milestone payment.

- Also, during the year ended December 31, 2022, 36,145 vested RSAs and RSUs were forfeited to pay for federal, state and local income taxes and an additional 18,208 unvested RSAs were forfeited when one of our directors did not seek reelection.

During the year ended December 31, 2021, we had the following activity:

- On February 24, 2021, we sold in a private placement 1,321,132 shares of our common stock to accredited and institutional investors for gross proceeds of $10.2 million. Net proceeds from the offering were $9.9 million. In connection with the placement, we issued warrants for the purchase of 79,268 shares of our common stock to our placement agent. These warrants are exercisable for cash at $9.30 per share and expire on February 16, 2023.

- On June 8, 2021, we granted 37,500 RSAs to an employee in accordance with their employment agreement.

- On June 16, 2021, we issued 44,689 shares of our common stock to Ocuphire Pharma, Inc. pursuant to the Ocuphire Agreement (see Note 9).

- On August 20, 2021, we entered into an equity distribution agreement (the "Sales Agreement") with Oppenheimer & Co. Inc. (the "Sales Agent") under which we may issue and sell in a registered "at-the-market" offering shares of our common stock having an aggregate offering price of up to $30.0 million from time to time through or to our Sales Agent (the "ATM Offering"). During year ended December 31, 2021, we sold 21,597 shares of our common stock under the "at-the-market" offering sales agreement at an average price of approximately $8.33 per share.

- On October 6, 2021, we also issued 100,000 shares of our common stock to Elion Oncology pursuant to the Elion License Agreement.

- We granted 17,800 shares of common stock, along with a combination of warrants and stock options for the purchase of 180,000 shares of common stock, to consultants in accordance with consulting agreements for services that will be provided in 2021 and 2022. Of the 17,800 shares granted, 14,300 were issued and outstanding at December 31, 2021.

- During the year ended December 31, 2021, 9,176 vested RSAs were forfeited to pay for federal, state and local income taxes and an additional 1,530 unvested RSAs were forfeited upon employment termination.

Treasury Stock - Repurchase of Shares from Aposense, Ltd.

On March 29, 2022, we purchased 100,000 shares of our common stock from Aposense Ltd. for $300,000 in a private transaction and are holding these shares as treasury stock until they are reissued or retired at the discretion of our Board of Directors.

Note 7 – Net Loss per Share of Common Stock

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

The computation of net loss per share for the year ended December 31, 2022 and 2021 was as follows:

	2022	2021
Basic and diluted net loss per share:		
Net loss available to common shareholders	$ (27,424,229)	$ (11,427,534)
Weighted-average number of common shares-basic and diluted	16,109,291	15,319,463
Basic and diluted net loss per share	$ (1.70)	$ (0.75)

As described in Note 5, we issued various equity instruments during the years ended December 31, 2022 and 2021 which impact our EPS calculation. All granted RSAs are considered issued and outstanding for purposes of our financial statements. Unvested RSAs are included as dilutive securities, but are excluded from our denominator of basic EPS. At December 31, 2022 and 2021, 61,888 and 91,109 RSAs, respectively, were not vested and were excluded from the EPS calculation. Vested RSUs are include in our computation of the weighted average shares for basic EPS and unvested RSUs are included as dilutive securities. At December 31, 2022 and 2021, 2,051,908 and 249,100 unvested RSUs were excluded from the EPS calculation.

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

	2022	2021
Stock options, unvested RSAs, unvested RSUs and purchase warrants	2,577,910	822,430

The calculation of potentially dilutive securities at December 31, 2022 excludes the 1,056,503 RSAs and RSUs granted to employees and directors on January 1, 2023 and the warrants for 3,160,130 shares of our common stock, which will be issued to Spartan in April 2023 in connection with our extended consulting agreement. Basic net loss per share is computed by dividing net loss by the weighted average common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted average common shares outstanding without the impact of potential dilutive common shares outstanding because they would have an anti-dilutive impact on diluted net loss per share. The treasury-stock method is used to determine the dilutive effect of our stock options and warrants grants.

Note 8 – Leases

We lease our office space under an operating lease agreement, which was renewed on October 3, 2022 and its effects were recorded as of September 30, 2022. This lease does not have significant rent escalation, concessions, leasehold improvement incentives, or other build-out clauses. Further, the lease does not contain contingent rent provisions. Our office space lease includes both lease (e.g., fixed payments including rent, taxes, and insurance costs) and non-lease components (e.g., common-area or other maintenance costs), which are accounted for as a single lease component as we have elected the practical expedient to group lease and non-lease components for all leases. We also lease office equipment under an operating lease. Our leases do not provide an implicit rate and, as such, we have used our incremental borrowing rate of 8% to determine the present value of the lease payments based on the information available at the lease commencement date.

Lease costs included in our consolidated statements of operations totaled $96,785 and $94,263 for the years ended December 31, 2022 and 2021, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at December 31, 2022:

Remaining lease term (years) for our office lease	2.8
Remaining lease term (years) for our equipment lease	1.3
Weighted average remaining lease term (years) for our facility and equipment leases	2.7
Weighted average discount rate for our facility and equipment leases	8.0%

Annual lease liabilities for all operating leases were as follows as of December 31, 2022:

2023	$ 93,845
2024	92,356
2025	70,040
Total lease payments	256,241
Less: Interest	(26,791)
Present value of lease liabilities	229,450
Less: current maturities	(78,896)
Non-current lease liability	$ 150,554

Note 9 – License Agreements

Elion Oncology, Inc.

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

On October 6, 2020, all conditions were satisfied, resulting in the addition of PCS6422 to our portfolio, and we paid $100,000 cash and issued 825,000 shares of our common stock to Elion. Such shares were subject to a lock-up, with 50% of such shares released from such lock-up after six months and the remaining 25% tranches were released following 9 months and 12 months, respectively.

As part of the Elion License Agreement, we agreed to issue to Elion 100,000 shares of our common stock on each of the first and second anniversary dates of the Elion License Agreement, which we fulfilled on October 5, 2021 and 2022, respectively.

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

On May 17, 2022, we amended the third Milestone Event of Section 6.4 of our License Agreement with Elion Oncology, Inc. changing the third Milestone Event from "1st Patient in Dose Confirmation Study" to (a) determination of the maximum tolerated dose (MTD) or (b) determination of the recommended Phase 2 Dose. Prior to this amendment, the third milestone was not considered probable since it was unknown when, or if a dose confirmation study was going to be conducted. As a result of the modification, we consider it probable that the recommended Phase 2 dosage regimen could be determined in connection with our current Phase 1B trial for PCS6422. We recorded an expense and related liability of $189,000 representing the value of the shares we anticipate issuing to Elion at the fair value on the date of modification. No other terms or conditions of the License Agreement were modified.

We are required to use commercially reasonable efforts, at our sole cost and expense to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) dosing a first patient in a Phase 1B clinical trial with a product within 12 months; and (ii) dosing a first patient with a product in a Phase 2 or 3 clinical trial within 48 months. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 90-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

Ocuphire Pharma, Inc.

On June 16, 2021, we executed a License Agreement with Ocuphire Pharma, Inc. ("Ocuphire Agreement") under which we received a license to research, develop and commercialize PCS3117 (formerly RX-3117) globally, excluding the Republic of Singapore, China, Hong Kong, Macau and Taiwan.

As consideration for the Ocuphire Agreement, we issued 44,689 shares of our common stock to Ocuphire, a cash payment of $200,000 and assumed $66,583 in certain liabilities. Additional consideration includes future development and regulatory milestones payments to Ocuphire upon our achievement of certain defined clinical milestones, such as dosing a patient in pivotal trials and receiving marketing authorization by a regulatory authority in the United States or another country. In addition, we are required to pay Ocuphire one-time sales milestone payments based on the achievement during a calendar year of the highest annual Net Sales for products made and pay royalties based on annual Net Sales, as defined in the Ocuphire Agreement.

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

Aposense, Ltd.

On May 24, 2020, we entered into a condition precedent License Agreement with Aposense, Ltd. ("Aposense License Agreement"), pursuant to which we were granted Aposense's patent rights and Know-How to develop and commercialize their next generation irinotecan cancer drug, PCS11T (formerly known as ATT-11T). The Aposense License Agreement provides us with an exclusive worldwide license (excluding China), to research, develop and commercialize products comprising or containing PCS11T. The grant of license was conditioned on the following being satisfied within nine months of May 24, 2020 (or the Aposense License Agreement shall terminate): (i) our closing of an equity financing and successful up-listing to Nasdaq and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions contemplated by the Aposense License Agreement.

On October 6, 2020, all conditions were satisfied, resulting in the addition of PCS11T to our portfolio, and we issued 625,000 shares of our common stock to Aposense. Such shares were subject to a lock-up, with 40% of such shares released from such lock-up after six months and the remaining two 30% tranches were released upon completion of the next two subsequent quarters. As additional consideration, we will pay Aposense development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we will pay Aposense one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any sales milestone payments or royalties we receive with Aposense based on any sub-license agreement we may enter into.

Yuhan Corporation

On August 19, 2020, we entered into a License Agreement with Yuhan Corporation ("Yuhan License Agreement"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 (formerly known as YH12852) globally, excluding South Korea.

As consideration for the Yuhan License Agreement and related Share Issuance Agreement, we issued to Yuhan 500,000 shares of common stock. As additional consideration, we will pay Yuhan development and regulatory milestone payments (a portion of which are payable in shares of our common stock based on the volume weighted average trading price during the period prior to such achievement and a portion of which are payable in cash) upon the achievement of certain milestones, based on a Yuhan affiliate purchasing 750,000 shares of common stock for $3,000,000 in our October 2020 underwritten public offering. The milestones primarily consist of dosing a patient in pivotal trials or having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Yuhan one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments received with Yuhan based on any sub-license agreement we may enter into.

We are required to use commercially reasonable efforts, at our sole cost and expense, in conjunction with a joint Processa-Yuhan Board to oversee such commercialization efforts, to research, develop and commercialize products in one or more countries, including meeting specific diligence milestones that consist of: (i) preparing a first draft of the product development plan within 90 days; (ii) requesting an FDA pre-IND meeting for a product within 6 months; (iii) dosing a first patient in a Phase 2A clinical trial with a product within 24 months; and (iv) dosing a first patient with a product in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial with a product within 48 months. Either party may terminate the agreement in the event of a material breach of the agreement that has not been cured following written notice and a 60-day opportunity to cure such breach (which is shortened to 15 days for a payment breach).

CoNCERT Pharmaceuticals, Inc.

On March 19, 2018, Promet, Processa and CoNCERT amended the CoNCERT Agreement executed in October 2017. The Amendment assigned the CONCERT Agreement to us and we exercised the exclusive option for the PCS499 compound in exchange for CoNCERT receiving, in part, $8.0 million of our common stock that was held by Promet (298,615 shares at $26.79 per share), for the benefit of Processa in satisfaction of the obligation due for the exclusive license for PCS499 acquired by us. Promet contributed the payment of the obligation due for the exclusive license to us without consideration paid to them. As a result of the transaction, we recognized an exclusive license intangible asset with a fair value of $8.0 million and an offsetting increase in additional paid-in capital resulting from the exchange.

We estimated the fair value of the common stock issued based on the market approach and CoNCERT's requirement to receive shares valued at $8.0 million. The market approach was based on the final negotiated number of shares of stock determined on a volume weighted average price of our common stock over a 45-day period preceding the mid-February 2018 finalized negotiation of the modification to the option and license agreement with CoNCERT, an unrelated third party, for the exclusive license rights to PCS499. The total cost recognized for the exclusive license acquired represents the allocated fair value related to the stock transferred to CoNCERT plus the recognition of the deferred tax liability related to the acquired temporary difference and the transaction costs incurred to complete the transaction as discussed above.

We are required to pay CoNCERT royalties, on a product–by-product basis, on future worldwide net sales, or pay a percentage of any sublicense revenue, as described in the License Agreement with CoNCERT.

Note 10 – Related Party Transactions

CorLyst, LLC ("CorLyst") reimburses us for shared costs related to payroll, health insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses in our consolidated statement of operations. We recorded $124,497 and $126,324 of reimbursements during the years ended December 31, 2022 and 2021, respectively. No amounts were due from CorLyst at December 31, 2022 or 2021. At December 31, 2021, we recognized $1,772 in prepaid reimbursements as due to related parties in the accompanying consolidated balance sheet. Our CEO is also the CEO of CorLyst, and CorLyst is a shareholder.

Note 11 – Commitments and Contingencies

Purchase Obligations

We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If we terminated a cancellable contract with a specific vendor, we would only be obligated for products or services that we received as of the effective date of the termination and any applicable cancellation fees. As of December 31, 2022, we are contractually obligated to pay up to approximately $3.6 million of future services under the agreements with the CROs, of which approximately $1.1 million relates to our recently-closed clinical trial for PCS499. Our actual contractual obligations will also vary depending on the progress and results of the remaining clinical trials.

Note 12 – Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of our cash and cash equivalents. We utilize only well-established banks and financial institutions with high credit ratings. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by our banks at December 31, 2022, exceeded FDIC limits.

Item 9. Changes in and Disagreements with Accountants

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

In connection with the preparation of this Annual Report on Form 10-K, as of December 31, 2022, an evaluation was performed by management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022 to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Inherent Limitations on Effectiveness of Controls

Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles ("GAAP"). Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

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

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP.

Management assessed our internal control over financial reporting as of December 31, 2022. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment, management has concluded that, as of December 31, 2022, our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with GAAP.

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

Changes in Internal Control Over Financial Reporting

There were no changes to our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors and Executive Officers of the Registrant

The information required by this Item 10 of Form 10-K will be in our 2023 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for the Company's 2023 Annual Meeting of Stockholders ("2023 Proxy Statement") is incorporated herein by reference to our 2023 Proxy Statement. The 2023 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates. For information with respect to our executive officers, see "Executive Officers" at the end of Part I, Item 1 of this report.

Item 11. Executive Compensation

The information required by this Item 11 of Form 10-K is incorporated herein by reference to our 2023 Proxy Statement.

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

The information required by this Item 12 of Form 10-K is incorporated herein by reference to our 2023 Proxy Statement.

Item 13. Certain Relationships and Related Transactions

The information required by this Item 13 of Form 10-K is incorporated herein by reference to our 2023 Proxy Statement.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 of Form 10-K is incorporated herein by reference to our 2023 Proxy Statement.

Part IV

Item 15. Exhibits, Financial Statement Schedules

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

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

(3) Exhibits

Exhibit Number	Description of the Exhibit
1.1	Equity Distribution Agreement, dated August 20, 2021, by and among Processa Pharmaceuticals, Inc. and Oppenheimer & Co. Inc (incorporated by reference to Form 8-K filed on August 20, 2021)
3.1	Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1 to Form S-1 filed on September 17, 2020)
3.1.1	Amendment to Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1.1 to Form S-1 filed on September 17, 2020)
3.1.2	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation dated August 8, 2019 (incorporated by reference to Exhibit 3 to Form 10-Q filed on August 14, 2019)
3.1.3	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. dated June 25, 2020 (incorporated by reference to Exhibit 3.1.4 to Form S-1 filed on September 17, 2020)
3.1.4	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation dated January 1, 2022 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 6, 2022)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Form S-1 filed on September 17, 2020)
4.1	Specimen of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form S-1 filed on September 17, 2020)
4.2	Form of Warrant issued to Tribal Capital Markets LLC, dated February 16, 2021 (incorporated by reference to Exhibit 10.3 to Form 8-K, filed February 18, 2021)
4.3	Form of Warrant for the 8% Senior Convertible Notes (incorporated by reference to Exhibit 4.6 to Form S-1 filed on September 17, 2020)
4.4	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.4 to Form 10-K filed on March 30, 2022)
10.1+	Amended and Restated 2011 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Form S-1 filed on September 17, 2020)
10.2	License Option Agreement with CoNCERT (incorporated by reference to Exhibit 10.2 to Form S-1 filed on September 17, 2020)
10.3	Amendment to License Agreement and Securities Purchase Agreement with CoNCERT Pharmaceuticals (incorporated by reference to Exhibit 10.3 to Form S-1 filed on September 17, 2020)
10.4+	Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.5 to Form S-1 filed on September 17, 2020)
10.5	Employment Agreement dated October 1, 2020, between Processa and R. Michael Floyd (incorporated by reference to Form 8-K, filed October 13, 2020)
10.6	License Agreement with Aposense, Ltd. dated May 24, 2020 (incorporated by reference to Exhibit 10.9 to Form S-1 filed on September 17, 2020)
10.7	License Agreement with Yuhan Corporation (incorporated by reference to Exhibit 10.11 to Form S-1 filed on September 17, 2020)
10.8	License Agreement with Elion Oncology, Inc. (incorporated by reference to Exhibit 10.13 to Form S-1 filed on September 17, 2020)
10.9	Addendum No. 1 to the Aposense Ltd. License Agreement (incorporated by reference to Exhibit 10.15 to Form 10-K filed on March 25, 2021)
10.10	License Agreement with Ocuphire Pharma, Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed June 17, 2021)
10.11	Purchase Agreement, dated March 23, 2022, between Processa Pharmaceuticals, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to Form 8-K filed March 24, 2022)
10.12	Registration Rights Agreement, dated March 23, 2022, by and between Processa Pharmaceuticals, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to Form 8-K filed March 24, 2022)
10.13	First Amendment to Consulting Agreement with Spartan Capital Securities, LLC (filed herewith)
21.1	List of Subsidiaries (filed herewith)

23.1	Consent of Independent Registered Public Accounting Firm, BD & Co. Inc. (filed herewith)
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith)
99.1**	XBRL Files

+ Indicates a management contract or compensatory plan or arrangement.

** Furnished herewith. XBRL (eXtensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act is deemed not filed for purposes of Section 18 of the Exchange Act and otherwise is not subject to liability under these sections.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

PROCESSA PHARMACEUTICALS, INC.

By: */s/ David Young*
David Young
Chief Executive Officer
(Principal Executive Officer)
Dated: March 30, 2023

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: March 30, 2023

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

Name	Capacity	Date
/s/ David Young David Young	President and Chief Executive Officer	March 30, 2023
/s/ James Stanker James Stanker	Chief Financial Officer	March 30, 2023
/s/ Khoso Baluch Khoso Baluch	Director	March 30, 2023
/s/ James Neal James Neal	Director	March 30, 2023
/s/ Geraldine Pannu Geraldine Pannu	Director	March 30, 2023
/s/ Virgil Thompson Virgil Thompson	Director	March 30, 2023
/s/ Justin Yorke Justin Yorke	Director	March 30, 2023

Exhibit 10.13

FIRST AMENDMENT TO CONSULTING AGREEMENT

The consulting agreement (the "**Agreement**") entered into on August 24, 2022, by and between Spartan Capital Securities, LLC and Processa Pharmaceuticals, Inc. (collectively, the "Parties") is hereby amended (this "**Amendment**") effective as of February 14, 2023. The Parties further agree that all terms not defined in the Amendment shall have the meanings assigned to them in the Agreement,

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the Parties agree that the Agreement shall be amended as follows:

AMENDMENT

Section 1 of the Agreement is hereby amended and replaced in its entirety to read:

1. Term. This Agreement shall be effective as of the Effective Date and shall continue in effect until February 14, 2024. The Company may terminate this Agreement by providing written notice to the Consultant at any time after April 17, 2023.

Section 3.1 of the Agreement is hereby amended and replaced in its entirety to read:

3.1 Stock and Warrant Compensation.

(a) The Company issued Fifty Thousand (50,000) shares of the Company's common stock (the "**Shares**") on August 24, 2022 to Consultant. The Shares were non-refundable and earned upon the execution and delivery of this Agreement by each of the Company and the Consultant. Except as provided by the terms of the Warrants described below, no other shares of the Company's common stock will be issued to Consultant.

(b) Subject to the terms herein, the Company shall issue warrants to purchase 3,160,130 shares of the Company's common stock (the "**Warrants**") on April 17, 2023 (the "**Warrant Date**") to Consultant (or the Company's designee, subject to such designee making the representations and agreeing to the other terms of this Section 3.3 applicable to the Consultant). The Warrants shall be in the form attached hereto as Exhibit A. The Warrants shall be deemed earned on the Warrant Date by each of the Company and the Consultant.

(c) The Shares, Warrants and shares of common stock issuable upon exercise of the Warrants (together, the "**Securities**") will be "restricted securities" as that term is defined in the Securities Act of 1933, as amended (the "**Securities Act**"). The Securities are being acquired by the Consultant solely for its account for investment and not with a view to, or for resale in connection with, any distribution. The Consultant is an "accredited investor" as such term is defined in Rule 501(a) of Regulation D promulgated under the Securities Act. The Consultant does not intend to dispose of all or any part of the Securities except in compliance with the provisions of the Securities Act and applicable state securities laws and understands that the Securities are being issued pursuant to a specific exemption under the provisions of the Securities Act, which exemption depends, among other things, upon the compliance with the provisions of the Securities Act. Consultant consents to the placement of a legend on any certificate or other document evidencing the Securities that such

Securities have not been registered under the Securities Act or any state securities or "blue sky" laws. The Parties agree that the holding period of the Warrant and Warrant Shares for resales pursuant to Rule 144 under the Securities Acts shall commence on the Warrant Date.

Section 4 of the Agreement is hereby amended and replaced in its entirety to read:

4. Term and Termination. This Agreement will not be automatically renewed or extended for any successive term unless by written mutual agreement on mutually agreeable terms.

***

All other terms and conditions shall remain unchanged.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties have executed this Amendment to the Agreement on the date first set forth above.

PROCESSA PHARMACEUTICALS, INC.	SPARTAN CAPITAL SECURITIES, LLC
By: DocuSigned by: Wendy Guy 3E96D4CBD512AF	By: DocuSigned by: 29F9B16256474BD
Name: Wendy Guy	Name: KIM MONCHIK
Title: Chief Administrative Officer	Title: Chief Administrative Officer

Exhibit A

Form of Warrant

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

COMMON STOCK PURCHASE WARRANT

PROCESSA PHARMACEUTICALS, INC.

Warrant Shares: 3,160,130

Issue Date: April 17, 2023
Initial Exercise Date: April 17, 2023

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, Spartan Capital Securities LLC or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date set forth above (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on April 17, 2026 (the "Termination Date") but not thereafter, to subscribe for and purchase from PROCESSA PHARMACEUTICALS, Inc., a Delaware corporation (the "Company"), up to 3,160,130 shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant is being issued pursuant to that certain Consulting Agreement between the Company and Spartan Capital Securities, LLC, dated as of February 14, 2023.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. ("Bloomberg") (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market,

the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Subsidiary" means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the Common Stock is traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

"Transfer Agent" means Continental Stock Transfer and Trust Company, the current transfer agent of the Company, and any successor transfer agent of the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Warrants" means this Warrant.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The

Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be $1.02, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder or the resale of the Warrant Shares by the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B)*(X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised, and the holding period of the Warrant Shares being issued may be tacked on to the holding period of this Warrant. Without limiting any other provision in the Warrant, assuming (i) the

Holder is not an Affiliate of the Company, and (ii) all of the applicable conditions of Rule 144 promulgated under the Securities Act with respect to Holder and the Warrant Shares are met in the case of such a cashless exercise, the Company agrees that the Company will cause the removal of the legend from such Warrant Shares in connection with a sale of the Warrant Shares (including by delivering an opinion of the Company's counsel to the Company's transfer agent at its own expense to ensure the foregoing). The Company agrees not to take any position contrary to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company's transfer agent is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) the Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 (assuming cashless exercise of the Warrants), and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the third Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein,

"Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Reserved.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any incidental expense in respect of the issuance of such Warrant Shares.The Holder shall be responsible for any issuance or transfer tax. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the

foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company.

The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company or any Subsidiary, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock or 50% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires 50% or more of the outstanding shares of Common Stock or 50% or more of the voting power of the common equity of the Company (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder

shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant) the same consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term "Company" under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant referring to the "Company" shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company, may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(d) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

c) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

d) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email address as it shall appear upon the Warrant Register of the Company, at least 10 calendar days prior to the applicable record or effective date hereinafter specified, a notice (unless the information that would be set forth in the notice is filed with the Commission, in which instance no additional notice need be provided) stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains,

material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. This Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

d) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 5. Reserved.

Section 6. Call Provision. Subject to the provisions of this Section 6, if, after such date as the Warrant Shares are eligible for resale under Rule 144 (the "Eligibility Date"), (i) the Nasdaq Official Closing Price (https://www.nasdaq.com/market-activity/quotes/historical-nocp) for each of five (5) consecutive Trading Days (the "Measurement Period," which five (5) consecutive Trading Day period shall not have commenced until after the Eligibility Date) exceeds $3.00 (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and the like after the Initial Exercise Date) and (ii) the Holder is not in possession of any information that constitutes material non-public information which was provided by the Company, any of its Subsidiaries, or any of their officers, directors, employees, agents or Affiliates, then the Company may, within one (1) Trading Day of the end of such Measurement Period, call for cancellation of all or any portion of this Warrant for which a Notice of Exercise has not yet been delivered (such right, a "Call") for consideration equal to $0.001 per Warrant Share. To exercise this right, the Company must deliver to the Holder an irrevocable written notice (a "Call Notice"), indicating therein the portion of unexercised portion of this Warrant to which such notice applies. If the conditions set forth below for such Call are satisfied from the period from the date of the Call Notice through and including the Call Date (as defined below), then any portion of this Warrant subject to such Call Notice for which a Notice of Exercise shall not have been received by the Call Date will be cancelled at 6:30 p.m. (New York City time) on the fifth (5th) Trading Day after the date the Call Notice is received by the Holder (such date and time, the "Call Date"). Any unexercised portion of this Warrant to which the Call Notice does not pertain will be unaffected by such Call Notice. In furtherance thereof, the Company covenants and agrees that it will honor all Notices of Exercise with respect to Warrant Shares subject to a Call Notice that are tendered through 6:30 p.m. (New York City time) on the Call Date. The parties agree that any Notice of Exercise delivered following a Call Notice which calls less than all of the Warrants shall first reduce to zero the number of Warrant Shares subject to such Call Notice prior to reducing the remaining Warrant Shares available for purchase under this Warrant. For example, if (A) this Warrant then permits the Holder to acquire 100 Warrant Shares, (B) a Call Notice pertains to 75 Warrant Shares, and (C) prior to 6:30 p.m. (New York City time) on the Call Date the Holder tenders a Notice of Exercise in respect of 50 Warrant Shares, then (x) on the Call Date the right under this Warrant to acquire 25 Warrant Shares will be automatically cancelled, (y) the Company, in the time and manner required under this Warrant, will have issued and delivered to the Holder 50 Warrant Shares in respect of the exercises following receipt of the Call Notice, and (z) the Holder may, until the Termination Date, exercise this Warrant for 25 Warrant Shares (subject to adjustment as herein provided and subject to subsequent Call Notices). Subject again to the provisions of this Section 6, the Company may deliver subsequent Call Notices for any portion of this Warrant for which the Holder shall not have delivered a Notice of Exercise. Notwithstanding anything to the contrary set forth in this Warrant, the Company may not deliver a Call Notice or require the cancellation of this Warrant (and any such Call Notice shall be void), unless, from the beginning of the Measurement Period through the Call Date, (1) the Company shall have honored in accordance with the terms of this Warrant all Notices of Exercise delivered by 6:30 p.m. (New York City time) on the Call Date, and (2) the Common Stock shall be listed or quoted for trading on the Trading Market, and (3) there is a sufficient number of authorized shares of Common Stock for issuance of all Warrant Shares, and (4) the issuance of all Warrant Shares subject to a Call Notice shall not cause a breach of any provision of Section 2(e) herein. Notwithstanding the foregoing, in the event all of the

conditions above are satisfied other than subsection four (4) above, the Company may request that the Holder increase its Beneficial Ownership Limitation to 9.99% and the Holder shall promptly and irrevocably deliver such notice to the Company required in order to increase such percentage in accordance with the provisions of Section 2(e), excluding the 61 day effective day set forth in Section 2(e), and the Company may thereafter deliver a Call Notice on the date of such request.

Section 7. Miscellaneous.No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

Section 8. Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

Section 9. Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

Section 10. Authorized Shares. The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

Section 11. Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

Section 12. Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

Section 13. Non-waiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

Section 14. Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at 7380 Coca Cola Drive, Suite 106, Hanover MD 21076, Attention: Wendy Guy, email address: wguy@processapharmaceuticals.com or such other email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

Section 15. Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

Section 16. Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific

performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

Section 17. Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

Section 18. Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder, on the other hand.

Section 19. Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

Section 20. Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

PROCESSA PHARMACEUTICALS, INC.

By:_____
Name:
Title:

NOTICE OF EXERCISE

TO: PROCESSA PHARMACEUTICALS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity:

_____

Signature of Authorized Signatory of Investing Entity:

_____

Name of Authorized Signatory:

_____

Title of Authorized Signatory:

_____

Date:

_____

____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to exercise the Warrant to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____

Holder's Signature: _____

Holder's Address: _____

Exhibit 21.1

Subsidiaries of Processa Pharmaceuticals, Inc.

Subsidiary	State of Incorporation	Percent Ownership
Processa Therapeutics LLC	Delaware	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-257558 and No. 333-254983) of Processa Pharmaceuticals, Inc. and Registration Statements on Form S-8 (No. 333-257557 and No. 333-233264) pertaining to the Processa Pharmaceuticals, Inc. 2019 Omnibus Equity Plan and (No. 333-190697) pertaining to the Heatwurx, Inc. 2011 Equity Incentive Plan of our report dated March 30, 2023, relating to the consolidated financial statements of Processa Pharmaceuticals, Inc. for the years ended December 31, 2022 and 2021 included in the Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. for the year ended December 31, 2022.

/s/ BD & Company, Inc.

Owings Mills, MD
March 30, 2023

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
of the Securities Exchange Act of 1934, as Amended

I, David Young, certify that:

1. I have reviewed this Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company");

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

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

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

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

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

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

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

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

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

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

Date: March 30, 2023

/s/ David Young
David Young
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
of the Securities Exchange Act of 1934, as Amended

I, James Stanker, certify that:

1. I have reviewed this Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company");

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

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

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

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

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

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

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

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

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

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

Date: March 30, 2023

/s/ James Stanker
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2022 (the "Report"), David Young, as Chief Executive Officer of the Company, and James Stanker, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ David Young
David Young
Chief Executive Officer
(Principal Executive Officer)
March 30, 2023

/s/ James Stanker
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
March 30, 2023

This certification accompanies each Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of § 18 of the Securities Exchange Act of 1934, as amended.

Corporate Information

EXECUTIVE MANAGEMENT

David Young, Pharm.D., Ph.D.
President and CEO

Sian Bigora, Pharm.D.
Chief Development Officer

Michael Floyd
Chief Operating Officer

Wendy Guy
Chief Administrative Officer

Patrick Lin
Chief Business and Strategy Officer

James Stanker
Chief Financial Officer

BOARD OF DIRECTORS

Justin Yorke
Chairman

David Young
President and CEO

Khoso Baluch
Director

James Neal
Director

Geraldine Pannu
Director

Virgil Thompson
Director

CORPORATE HEADQUARTERS

7380 Coca Cola Dr. Suite 106
Hanover, MD 21076

INVESTOR RELATIONS CONTACTS

Michael Floyd
mfloyd@processapharma.com

Patrick Lin
plin@processapharma.com

CORPORATE COUNSEL

Foley and Lardner LLP
Jacksonville, Florida

TRANSFER AGENT

Continental Stock Transfer and Trust Company
New York, New York
800-509-5586
cstmail@continentalstock.com

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

BD & Company, Inc.
Owings Mills, Maryland