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, 2021

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 □

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, 2021, 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 $95.4 million.

The number of outstanding shares of the registrant's common stock as of March 24, 2022 was 15,843,621.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2022 Annual Meeting of Stockholders (the "Proxy Statement") to be filed within 120 days of the end of the fiscal year ended December 31, 2021 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.

Table of Contents

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.

"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.

"FPI" means First Patient In (enrolled into the clinical trial).

"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.

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

"Osteonecrosis" means the death of bone cells due to decreased blood flow. It can lead to pain and collapse of areas of bone.

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;
- the impact of the COVID-19 pandemic on our business, operations or ability to obtain funding;
- 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;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- 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 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

Our mission is to develop drug products that improve the survival and/or quality of life for patients with high unmet medical need conditions for which few or no treatment options currently exist. We are a clinical-stage development company, not a discovery company, that seeks to identify and develop drugs for patients who need better treatment options. In order to increase the probability of development success, our pipeline only includes drugs which have previously demonstrated some efficacy in the targeted population or a drug with very similar pharmacological properties that has been shown to be effective in the population.

Our screening criteria for identifying and selecting new candidates include:

- addressing an unmet or underserved clinical need,
- having demonstrated evidence of efficacy in humans, and
- leveraging our regulatory science approach to improve the probability for approval.

In many instances, these clinical candidates have significant pre-clinical and clinical data that we may leverage to high value inflection points while de-risking the programs and adding in optionality to potential future indications. Our regulatory science approach developed by our team over decades of work with regulatory authorities attempts to balance the "benefit/risk" equation to identify a regulatory path with higher clinical benefit and/or lower clinical risk with shorter timelines to deliver better treatment options to patients, physicians and caregivers.

Our pipeline includes drugs that (i) already have clinical proof-of-concept data demonstrating the desired pharmacological activity in humans or, minimally, clinical evidence in the form of case studies or clinical experience demonstrating the drug or a similar drug pharmacologically can successfully treat patients with the targeted indication; (ii) target indications 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 or the present standard of care (e.g., some orphan indications, many serious life-threatening conditions, some serious quality of life conditions); and/or (iii) target indications where the prevalence of the condition and the likelihood of patients enrolling in a study meet the desired timeframe to demonstrate that the drug can, at some level, treat or potentially treat patients with the condition.

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, with our regulatory science approach, 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 and a better return on investment given lower development costs, more efficient development and high commercial value. Given the prior successes of our regulatory science approach, we have selected drugs for our portfolio which may have greater chance for approval in a population of patients who desperately need better treatment options. We have applied rigorous standards to identify drugs for our portfolio, namely:

- 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 evidence of efficacy in the target population, and;
- The drug presents opportunities to be developed such that within 2-4 years, critical value-added clinical milestones can be achieved while advancing the drug closer to commercialization and adding to the potential for a high return on investment.

Our Team

Our drug development efforts are guided by our knowledge and experience in applying rigorous regulatory science 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 Chairman and CEO David Young, Pharm.D., Ph.D. who has extensive experience in research, regulatory approval and business development and who served at Questcor for eight years, initially as an independent director and subsequently as its Chief Scientific Officer. Dr. Young's guidance led to the approval of Acthar in Infantile Spasms and the ultimate sale of Questcor in 2014.

Our Drug Pipeline

We currently have five drugs: four in various stages of clinical development (PCS499, PCS12852, PCS3117 and PCS6422) and one in nonclinical development (PCS11T). We group our drugs into non-oncology (PCS499 and PCS12852) and oncology (PCS3117, PCS6422 and PCS11T). A summary of each drug is provided below:

Drug	Disease Target	Nonclin	Phase 1	Phase 2	Phase 3	2022 Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica			*		Interim Analysis and Complete Trial Enrollment by the end of 2022
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders			*		FPI Phase 2A 1st half of 2022 (1H'22); Complete Enrollment by the end of 2022
PCS3117 Phase 2B	Pancreatic and Other Cancers			*		Develop Biomarker Assays 1H'22
PCS6422 (Next Generation Capecitabine) Phase 1B	Metastatic Colorectal, Breast Cancer		*			Restart Phase 1B 2nd quarter of 2022; Complete Enrollment 2nd half of 2022
PCS11T Pre-IND	Small Cell Lung, Colorectal Cancer					Initiate IND Enabling Studies

*** Cleared by FDA for Clinical Trial**

PCS499

PCS499, an oral tablet of a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®), is classified by FDA as a new molecular entity. PCS499 and its metabolites act on multiple pharmacological targets that are important in a variety of conditions. We have targeted ulcerative Necrobiosis Lipoidica (uNL) as our lead indication for PCS499. NL is a chronic, disfiguring condition affecting the skin and tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and occurs more often in people with diabetes. Ulceration has been reported to occur in up to 30% of NL patients, which can lead to more severe complications, such as deep tissue infections and osteonecrosis threatening the life of the limb. Approximately 65,000 people in the United States and more than 120,000 people outside the United States are affected with uNL.

The degeneration of tissue occurring at the NL lesion site may be caused by a number of pathophysiological changes, which make it extremely difficult to develop effective treatments for this condition. Because PCS499 and its metabolites appear to affect most of the biological pathways that contribute to the pathophysiology associated with NL, PCS499 may provide a novel treatment solution for NL.

On June 18, 2018, the FDA granted orphan-drug designation for PCS499 for the treatment of NL. On September 28, 2018, the IND for PCS499 in NL became effective, such that we initiated and completed a Phase 2A multicenter, open-label prospective trial designed to determine the safety and tolerability of PCS499 in patients with NL. The study initially had a six-month treatment phase and a six-month optional extension phase. In December 2019, we informed patients and sites that the study would conclude after the treatment phase and there would no longer be an extension phase. The first enrolled NL patient in this Phase 2A clinical trial was dosed on January 29, 2019 and the study completed enrollment on August 23, 2019. The last patient visit took place in February 2020.

The primary objective of the Phase 2A trial was to evaluate the safety and tolerability of PCS499 in patients with NL (ulcerated and non-ulcerated patients) and to use the safety and efficacy data to design future clinical trials. Based on toxicology studies and healthy human volunteer studies, we and the FDA agreed that a PCS499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2A trial. As anticipated, the PCS499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of PTX, appeared to be well tolerated with no serious adverse events (SAEs) reported. All adverse events (AEs) reported in the study were mild in severity. As expected, gastrointestinal symptoms were the most frequent AEs and reported in four patients, all of which resolved within 1-2 weeks of starting dosing.

Two of the twelve patients in the study presented with uNL and had ulcers for more than two months prior to dosing. At baseline, the reference ulcer in one of the two patients measured 3.5 cm^2 and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 cm^2 which completely closed by Month 9 during the patient's treatment extension period. In addition, while in the trial, both patients also developed small ulcers at other sites, possibly related to contact trauma, and these ulcers resolved within one month. The other ten patients, presenting with mild to moderate NL and did not have ulceration, had more limited improvement of the NL lesions during treatment. Historically, 13 - 20% of all the patients with NL naturally progress to complete healing over many years after presenting with NL. Although the natural healing of the uNL patients has not been evaluated independently, medical experts who treat NL patients suggest that the natural progression of an open ulcerated wound to complete closure may be significantly less than 13% over 1-2 years and probably close to 0% in patients with the larger ulcers.

On March 25, 2020, we met with the FDA and discussed the clinical program, as well as the nonclinical and clinical pharmacology plans to ultimately support the submission of the PCS499 New Drug Application (NDA) in the U.S. for the treatment of ulcers in NL patients. With input from the FDA, we designed the next trial as a randomized, placebo-controlled Phase 2B study to evaluate the ability of PCS499 to completely close ulcers in patients with NL and better understand the potential response of NL patients on drug and on placebo. We currently have selected six clinical trial sites in the United States and are evaluating additional sites to add to our study. We had four sites in Europe, but these sites were unable to recruit patients timely, largely due to COVID-19, so we decided to close them and concentrate our efforts on recruiting patients within the United States.

We began recruiting for the clinical trial in the first half of 2021. On May 19, 2021, we dosed our first patient in the randomized, placebo-controlled trial and are planning to complete an interim analysis of the data from this trial by the end of 2022. After obtaining the results from this Phase 2B study, we expect to have an end of Phase 2 meeting with the FDA to agree on the design of the Phase 3 study, with the intent to define a Special Protocol Assessment for the Phase 3 study and to agree on the next steps to obtain approval.

PCS12852

On August 19, 2020, we in-licensed PCS12852 (formerly known as YH12852) from Yuhan Corporation ("Yuhan"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 globally, excluding South Korea.

PCS12852 is a novel, potent and highly selective 5-hydroxytryptamine 4 (5-HT4) receptor agonist. Other 5-HT receptor agonists with less 5-HT4 selectivity have been shown to successfully treat gastrointestinal (GI) motility disorders such as gastroparesis, chronic constipation, constipation-predominant irritable bowel syndrome and functional dyspepsia. Less selective 5-HT4 agonists, such as cisapride, have been either removed from the market or not approved because of the cardiovascular side effects associated with the drugs binding to other receptors, especially receptors other than 5-HT4.

Two clinical studies, both which have demonstrated the effectiveness of PCS12852 on GI motility, have been previously conducted by Yuhan with PCS12852. In a Phase 1 trial (Protocol YH12852-101), the initial safety and tolerability of PCS12852 were evaluated after single and multiple oral doses in healthy subjects. PCS12852 was shown to increase GI motility in this study, increasing stool frequency with faster onset when compared to prucalopride, a less specific 5-HT4 agonist FDA-approved drug for the treatment of chronic idiopathic constipation. Based on an increase of ≥1 spontaneous bowel movement (SBM)/week from baseline during 7-day multiple dosing, the PCS12852 dose group had a higher percent of patients with an increase than the prucalopride group. All doses of PCS12852 were safe and well tolerated and no SAEs occurred during the study. The most frequently reported AEs were headache, nausea and diarrhea which were temporal, manageable and reversible within 24 hours. There were no clinically significant changes in platelet aggregation and ECG parameters including a change in QTc prolongation in the study. In a Phase 1/2A clinical trial (Protocol YH12852-102), the safety, tolerability, gastric emptying rate and pharmacokinetics of multiple doses of a PCS12852 immediate release (IR) formulation and a delayed release (DR) formulation were evaluated. PCS12852 was safe and well tolerated after single and multiple administrations. The most frequent AEs for both the IR and DR formulations of PCS12852 were headache, nausea and diarrhea, but the incidences of these AEs were comparable with those of the 2mg prucalopride group. These AEs, which were transient and mostly mild in severity, are also commonly observed with other 5-HT4 agonists. Both formulations of PCS12852 also increased the gastric emptying rate and increased GI motility.

Yuhan had also conducted extensive toxicological studies for the product that demonstrated that the product is safe for use and can be moved into Phase 2 studies.

We received guidance from the FDA in the first half of 2021 and in October 2021 we received notice of safe to proceed for PCS12852 evaluation in a Phase 2A randomized, placebo-controlled study in patients with gastroparesis. We anticipate beginning to enroll patients in the first half of 2022, with expected completion in the first half of 2023. The purpose of the Phase 2A trial is to evaluate the safety, efficacy and pharmacokinetics of two different dosing regimens for PCS12852. Data obtained from this study will be used to better design a future Phase 2/3 efficacy study. Since patients with gastroparesis have an abnormal pattern of upper GI motility in the absence of mechanical obstruction, the Phase 2A study was designed to evaluate the change in gastric emptying in patients with gastroparesis from two different dosing regimens of PCS12852 compared to placebo. The only FDA-approved drug to treat gastroparesis is metoclopramide, a dopamine D2 receptor antagonist that has documented serious side effects which limit dosing to no more than 12 weeks. Other 5-HT4 drugs have been used clinically but the side effects, caused mainly by binding to other receptors, has resulted in these drugs not being a viable option to treat patients with gastroparesis. It should be noted that PCS12852 is a highly specific 5-HT4 agonist that has been shown in nonclinical studies to have a cardiovascular side effect only at concentrations greater than 1,000 times the maximum concentration seen in humans.

PCS3117

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 Republic of Singapore, China, Hong Kong, Macau and Taiwan.

PCS3117 is a novel, investigational, oral small molecule nucleoside compound. PCS3117 is an analog of the endogenous nucleoside, cytidine, and an analog of the cancer drug gemcitabine. Once intracellularly activated (phosphorylated) by the enzyme UCK2, it is incorporated into the DNA or RNA of cells and inhibits both DNA and RNA synthesis, which induces apoptotic cell death of tumor cells. PCS3117 has received orphan drug designation from the FDA and the European Commission for the treatment of patients with pancreatic cancer.

Gemcitabine is usually used as second line therapy for metastatic pancreatic cancer and non-small cell lung cancer, as well as used as second line therapy for other types of cancer. The difference between PCS3117 and gemcitabine is how they are activated to cancer killing nucleotides. PCS3117 also has additional pharmacological pathways which will result in cancer cell apoptosis. Since 45% - 85% of pancreatic cancer and non-small cell lung cancer patients are inherently resistant or acquire resistance to gemcitabine, the differences between PCS3117 and gemcitabine could potentially provide a therapeutic alternative to patients who do not or will not respond to gemcitabine.

Resistance to gemcitabine or PCS3117 is likely caused by:

- an increase in the cytidine deaminase (CDA) enzyme which breaks down gemcitabine and PCS3117,
- a deficiency in transportation of gemcitabine or PCS3117 across the cell membrane,
- down regulation of the activation enzyme (dCK for gemcitabine, UCK2 for PCS3117),
- a change in ribonucleotide reductase activity, and
- non-genetic influences that alter gene expression.

PCS3117 has shown broad spectrum anti-tumor activity against over 100 different human cancer cell lines and efficacy in 17 different mouse xenograft models. In preclinical trials, PCS3117 retained its anti-tumor activity in human cancer cell lines made resistant to the anti-tumor effects of gemcitabine. In August 2012, the completion of an exploratory Phase 1 clinical trial of PCS3117 in cancer patients to investigate the oral bioavailability, safety and tolerability of the compound was reported. In that study, oral administration of a 50 mg dose of PCS3117 indicated an oral bioavailability of 56% and a plasma half-life ($T_{1/2}$) of 14 hours. In addition, PCS3117 appeared to be well tolerated in all subjects throughout the dose range tested.

Final results from a Phase 1B clinical trial of PCS3117 were presented in June 2016 showing evidence of single agent activity. Patients in the study had generally received four or more cancer therapies prior to enrollment. In this study, 12 patients experienced stable disease persisting for up to 276 days and three patients showed evidence of tumor burden reduction. A maximum tolerated dose of 700 mg was identified in the study. At the doses tested, PCS3117 appeared to be well tolerated with a predictable pharmacokinetic profile following oral administration.

In March 2016, a multi-center Phase 2A clinical trial of PCS3117 in patients with relapsed or refractory pancreatic cancer was initiated to further evaluate safety and efficacy. The study was designed as a two-stage study with 10 patients in stage 1 and an additional 40 patients in stage 2. According to pre-set criteria, if greater than 20% of the patients had an increase in progression free survival of more than four months, or an objective clinical response rate and reduction in tumor size, additional pancreatic cancer patients would be enrolled into stage 2. Secondary endpoints included time to disease progression, overall response rate and duration of response, as well as pharmacokinetic assessments and safety parameters. In January 2018, the final data from this trial showed evidence of tumor shrinkage in some patients with metastatic pancreatic cancer that was resistant to gemcitabine and who had failed on multiple prior treatments was presented. In this study, 31% of patients experienced progression free survival for two months or more and five patients, or 12%, had disease stabilization for greater than four months. Although the pre-set criteria of 20% of the patients having an increase in progression free survival for four months was not met, some of the gemcitabine refractory patients did respond to PCS3117. However, an evaluation of why patients were resistant to PCS3117 was not undertaken within the study.

In November 2017, a Phase 2A trial of PCS3117 in combination with ABRAXANE in patients newly diagnosed with metastatic pancreatic cancer was initiated. The multicenter, single-arm, open-label study was designed to evaluate PCS3117 in combination with ABRAXANE in first line metastatic pancreatic cancer patients. In February 2019, the target enrollment of 40 evaluable patients in this trial was reached. An overall response rate of 23% had been observed in 40 patients that had at least one scan on treatment. Preliminary and unaudited data indicated that the median progression free survival for patients in the study was approximately 5.6 months. The most commonly reported related adverse events were nausea, diarrhea, fatigue, alopecia, decreased appetite, rash, vomiting and anemia. Again, evaluation of the cause of treatment resistance to PCS3117 was not undertaken.

In order to identify patients who would more likely respond to PCS3117 than gemcitabine, we will be refining existing assays and developing new assays of biological molecules (i.e., biomarkers) over the next 6-12 months that could help to identify which patients are more likely to respond to or activate PCS3117 over gemcitabine.

PCS6422

On August 23, 2020, we in-licensed PCS6422 from Elion Oncology, Inc. ("Elion"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS6422 globally.

PCS6422 is an oral, potent, selective and irreversible inhibitor of dihydropyrimidine dehydrogenase (DPD), the enzyme that rapidly metabolizes a common chemotherapy drug known as 5-FU, into inactive metabolites, such as α-fluoro-β-alanine (F-Bal). F-Bal is a metabolite that has no anti-cancer activity but causes unwanted side effects, which notably leads to dose interruptions and significantly affect a patient's quality of life. F-Bal is thought to cause the neurotoxicity and Hand–Foot Syndrome (HFS) associated with 5-FU, and greater formation of F-Bal appears to be associated with a decrease in the antitumor activity of 5-FU. HFS can affect activities of daily living, quality of life, and requires dose interruptions/adjustments and even therapy discontinuation resulting in suboptimal tumor effects. We believe that the inhibition of DPD by PCS6422 will significantly reduce 5-FU side effects related to a decrease in F-Bal, although the timeframe and magnitude for DPD inhibition has been shown to vary, ranging from 2-14 days depending on the de novo formation of DPD within a patient and the dosage regimen of PCS6422. With the inhibition of DPD, the level of the 5-FU anti-cancer metabolites could also be potentially higher within cancer and normal cells leading to an improved efficacy profile and/or increased side effects associated with these antimetabolites such as neutropenia. By combining capecitabine (oral pro-drug form of 5-FU) with PCS6422, the change in 5-FU metabolism should result in an increase in the systemic exposure of 5-FU based on the 5-FU Area Under the Plasma Concentration Curve (AUC) per mg of capecitabine dosed. This results in needing less capecitabine to kill cancer cells and treat each patient, making the combination of PCS6422 and capecitabine (the "Next Generation Capecitabine") more potent than current FDA approved capecitabine.

Fluoropyrimidines (e.g., 5-FU, capecitabine) remain the cornerstone of treatment for many different types of cancers, either as monotherapy or in combination with other chemotherapy agents by an estimated two million patients annually. Xeloda®, the brand name of capecitabine, is an oral pro-drug of 5-FU and approved as first-line therapy for metastatic colorectal and breast cancer. However, its use is limited by adverse effects such as the development of HFS in up to 60% of patients.

Elion evaluated the potential for the combination of PCS6422 with capecitabine as a treatment of advanced gastrointestinal (GI) tumors. Nonclinical efficacy data indicated that in colorectal cancer models, pretreatment with PCS6422 enhanced the antitumor activity of capecitabine. PCS6422 dramatically increased the antitumor potency of capecitabine without increasing the toxicity. The antitumor efficacy of the combination of PCS6422 and capecitabine was tested in several xenograft animal models with human breast, pancreatic and colorectal cancer cells. These preclinical xenograft models demonstrate that PCS6422 potentiates the antitumor activity of capecitabine and significantly reduces the dose of capecitabine required to be efficacious.

Other DPD enzyme inhibitors (e.g. Gimeracil used in Teysuno® approved only outside the US) act as competitive reversible inhibitors. These agents must be present when 5-FU or capecitabine are administered to inhibit 5-FU breakdown by DPD in order to improve the efficacy and safety profiles of 5-FU. Given the reversible nature of their effect on DPD, over time 5-FU metabolism to F-Bal will return if the reversible inhibitor is not present, decreasing the amount of 5-FU in the cancer cells and decreasing the potential cytotoxicity on the cancer cells. There is also evidence that administering large amounts of DPD inhibitors directly with 5-FU may also decrease the antitumor effect of the 5-FU. Because PCS6422 is an irreversible inactivator of DPD, it is dosed the day before capecitabine administration and its effect on DPD can last longer than the reversible DPD inhibitors and beyond the time 5-FU exists in the cancer cell, even after PCS6422 has been completely eliminated out of the body. We believe this can optimize the potential cytotoxic effect of the 5-FU nucleotide metabolites and minimize the catabolism of 5-FU to F-Bal.

Prior to Elion's involvement, two multicenter Phase 3 studies were conducted in patients with colorectal cancer with PCS6422 administered in 10-fold excess to 5-FU and administered with the 5-FU. Unfortunately, we believe the dose of PCS6422 during these trials was not optimal and that PCS6422 was not administered early enough to irreversibly affect the DPD enzyme, thus the regimen tended to produce less antitumor benefit than the control arm with the standard regimen of 5-FU/leucovorin (LV) without PCS6422. Later preclinical work suggested that when PCS6422 was present at the same time as and in excess to 5-FU, it diminished the antitumor activity of 5-FU, which we believe supports the proposed dosing PCS6422 several hours before 5-FU to allow PCS6422 to be cleared before the administration of 5-FU.

Elion met with the FDA in 2019 and agreed upon the clinical development program required for the combination of PCS6422 and capecitabine as first-line therapy for metastatic colorectal cancer when treatment with fluoropyrimidine therapy alone is preferred. On May 17, 2020, an IND for the Phase 1B study was granted safe to proceed by the FDA. This Phase 1B study was designed to evaluate: i) the safety and tolerability of PCS6422 and several doses of capecitabine in advanced GI tumor patients; ii) the pharmacokinetics of PCS6422, capecitabine, 5-FU and selected metabolites; iii) the activity of DPD over time after PCS6422 administration; and iv) the maximum tolerated dose in up to 30 patients over multiple cycles. The study began patient recruitment in the second half of 2021. On August 2, 2021, we enrolled the first patient in the study.

The interim analysis of Cohorts 1 and 2 was recently conducted. DLTs, drug related adverse events of greater than 1 and hand-foot syndrome were not observed in these patients. Also, this Next Generation Capecitabine effectively inhibited DPD enzyme activity 24-48 hours after PCS6422 administration with <10% of 5-FU metabolized to F-Bal as compared to ~80% with the FDA approved capecitabine. Additionally, 5-FU potency based on the 5-FU AUC systemic exposure per mg of capecitabine dosed was 50 times greater with Next Generation Capecitabine. The interim analysis showed, however, that the improved metabolic profile and increased potency was not sustained at Day 7 after PCS6422 single dose administration. In February 2022, we submitted a modified Phase 1B trial protocol to the FDA to not only determine the MTD of capecitabine but also to further evaluate the timeline of DPD inhibition and de novo formation as a function of PCS6422 dosing.

We anticipate that this additional data will allow us to select PCS6422 dosage regimens that will maintain DPD inhibition throughout capecitabine dosing for each patient treated with this Next Generation Capecitabine. After interacting with the FDA and making protocol modifications, we expect to restart the Phase 1B study in the second quarter of 2022 while defining the Next Generation Capecitabine regimens by the end of 2022. Although we are making modifications to the existing Phase 1B protocol, we expect that our overall timeline has not changed with a Phase 2B or 3 trial starting in 2023-2024 and NDA submission in 2027-2028.

PCS11T

On May 24, 2020, we in-licensed PCS11T (formerly known as ATT-11T) from Aposense, Ltd. ("Aposense"), pursuant to which we were granted Aposense's patent rights and Know-How to develop and commercialize their next generation irinotecan cancer drug, PCS11T.

PCS11T is a novel lipophilic anti-cancer pro-drug that is being developed for the treatment of the same solid tumors as prescribed for irinotecan. This pro-drug is a conjugate of a specific proprietary Aposense molecule connected to SN-38, the active metabolite of irinotecan. The proprietary molecule in PCS11T has been designed to allow PCS11T to bind to cell membranes to form an inactive pro-drug depot on the cell with SN-38 preferentially accumulating in the membrane of tumors cells and the tumor core. This unique characteristic may make the therapeutic window of PCS11T wider than other irinotecan products such that the antitumor effect of PCS11T could occur at a much lower dose with a milder adverse effect profile than irinotecan. Despite the widespread use of commercially marketed irinotecan products in the treatment of metastatic colorectal cancer and other cancers resulting in peak annual sales of approximately $1.1 billion, irinotecan has a narrow therapeutic window and includes an FDA "Black Box" warning for both neutropenia and severe diarrhea. There is, therefore, a substantial unmet need to overcome the limitations of the current commercially marketed irinotecan products, improving efficacy and reducing the severity of treatment emergent AEs. We believe the potential wider therapeutic window of PCS11T will likely lead to more patients responding with less side effects when on PCS11T compared to other irinotecan products.

Pre-clinical studies conducted to date showed that PCS11T demonstrated tumor eradication at much lower doses than irinotecan across various tumor xenograft models. PCS11T does not affect acetyl choline esterase (AChE) activity in human and rat plasma in vitro, which would suggest that PCS11T will show an improved safety profile, compared to irinotecan, which is known for its cholinergic-related side effects.

We are currently planning to manufacture the product at a GMP facility, conduct the required toxicological studies required to file the IND in 2023 and initiate the Phase 1B study in oncology patients with solid tumors.

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 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-label 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 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.

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 PCS3117, 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 PCS6422, 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 PCS11T, 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 PCS11T.

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	4	3	3	6	25

We have filed a provisional patent for PCS6422 and are evaluating another patent for PCS499.

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 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.

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 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 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 the Processa portfolio, and we paid $100,000 cash and issued 825,000 shares of our common stock to Elion. Such shares are subject to a lock-up, with 50% of such shares released from such lock up after six months and the remaining 25% tranches to be released following 9 months and 12 months, respectively.

As part of the Elion License Agreement, we have 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. We issued 100,000 shares on the first anniversary and believe the payment on the second anniversary is probable and represent seller financing since the only condition related to their payment is the passage of time, which management does not believe is substantive. We valued the shares at $4.00 per share based on the underwritten public offering price on October 6, 2020, which is the date the conditions precedent in the license agreement were met.

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.

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 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 the Processa portfolio, and we issued 625,000 shares of our common stock to Aposense. Such shares are subject to a lock-up, with 40% of such shares released from such lock up after six months and the remaining two 30% tranches to be 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.

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.

- 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 also are 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 of 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.

Employees

As of March 24, 2022, 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 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.

Information about our Executive Officers

Our executive officers as of March 24, 2022 are as follows:

Name	Age	Position
Executive Officers:		
David Young, Pharm.D, Ph.D.	69	Chairman of the Board of Directors and Chief Executive Officer
Sian Bigora, Pharm.D.	61	Chief Development Officer
Michael Floyd	66	Chief Operations Officer
Wendy Guy	57	Chief Administrative Officer
Patrick Lin	56	Chief Business and Strategy Officer
James Stanker	64	Chief Financial Officer

David Young, Pharm.D., Ph.D. - Dr. Young has served as our Chairman and Chief Executive Officer since October 4, 2017 and has over 30 years of pharmaceutical research, drug development and corporate experience. He served as our interim CFO from October 4, 2017 to September 1, 2018. From 2006 to 2009, prior to joining the Questcor executive management team, Dr. Young served as an independent Director on the Questcor Board of Directors. As an independent director, Dr. Young, representing Questcor, worked with the FDA in developing a process to obtain approval for Acthar (the only commercial product owned by Questcor) in Infantile Spasms (IS), a deadly and debilitating very rare orphan indication. In 2009, Dr. Young joined the Questcor executive management team as Chief Scientific Officer (CSO) in order to obtain IS FDA approval and market exclusivity by completing the New Drug Application (NDA) process, working with FDA on modernizing the label, and leading all aspects of approval including the Advisory Committee Meeting that voted to approve the NDA for IS. During the eight years that Dr. Young was involved with Questcor as an independent director and as its CSO, Questcor transitioned to an orphan drug specialty pharmaceutical company, moving from an outdated Acthar label and near bankruptcy in 2007 to a modernized Acthar label that helped it to achieve sales greater than $750 million per year and the ultimate sale of the company for approximately $5.6 billion in 2014. While serving on Questcor's Board of Directors, Dr. Young was Executive Director & President, U.S. Operations of AGI Therapeutics plc. Dr. Young has also served as the Executive Vice President of the Strategic Drug Development Division of ICON plc, an international CRO, and was the Founder and CEO of GloboMax LLC, a CRO specializing in FDA drug development, purchased by ICON plc in 2003. Prior to forming GloboMax, Dr. Young was a Tenured Associate Professor at the School of Pharmacy, University of Maryland at Baltimore (UMAB), where he led a group of 30 faculty, scientists, postdocs, graduate students and technicians in evaluating the biological properties of drugs and drug delivery systems in animals and humans.

Dr. Young is an expert in small molecule and protein non-clinical and clinical drug development. He has served on FDA Advisory Committees, was Co-Principal Investigator on an FDA-funded Clinical Pharmacology contract, was responsible for the analytical and pharmacokinetic evaluation of all oral products manufactured in the UMAB-FDA contract which led to the Scale-up and Post-Approval Changes (SUPAC) and in-vitro in-vivo correlation (IVIVC) FDA Guidance, taught FDA reviewers as part of the UMAB-FDA contract for five years, has served on National Institutes of Health (NIH) grant review committees, and was Co-Principal Investigator on a National Cancer Institute contract to evaluate new oncology drugs. Dr. Young has met with the FDA over 100 times on more than 50 drug products and has been a key team member on more than 30 NDA/supplemental NDA approvals. Dr. Young has more than 150 presentations-authored publications-book chapters, including formal presentations to the FDA, FDA Advisory Committees, and numerous invited presentations at both scientific and investment meetings. Dr. Young received his B.S. in Physiology from the University of California at Berkeley, his M.S. in Medical Physics from the University of Wisconsin at Madison, and his Pharm.D. - Ph.D. with emphasis in Pharmacokinetics and Pharmaceutical Sciences from the University of Southern California.

Sian Bigora, Pharm.D. - Dr. Bigora has served as our Chief Development Officer since October 4, 2017 and has over 20 years of pharmaceutical research, regulatory strategy and drug development experience working closely with Dr. Young. From 2009 to 2015 Dr. Bigora was Vice President of Regulatory Affairs at Questcor Pharmaceuticals (acquired by Mallinckrodt Pharmaceuticals in 2014), including leading efforts on modernizing the Acthar Gel label and in obtaining FDA approval in Infantile Spasms, events of material importance to Questcor's subsequent success. During her time at Questcor, she assisted in building an expert regulatory group to address both commercial and development needs for complex products such as Acthar. Dr. Bigora's role at Questcor included heading up the development of a safety pharmacovigilance group and a clinical quality group. Prior to her position at Questcor, Dr. Bigora was Vice President of Clinical and Regulatory Affairs, U.S. Operations of AGI Therapeutics, plc. In this role, she was responsible for the development and implementation of Global Phase 3 studies and interactions with regulatory authorities. Previously, she operated her own consulting company, serving as the regulatory and drug development expert team member for multiple small and mid-sized pharmaceutical companies. Dr. Bigora held multiple positions in regulatory affairs, operations and project management ending as VP of Regulatory Affairs at the Strategic Drug Development Division of ICON, plc, an international CRO, and at GloboMax LLC, a CRO specializing in FDA drug development, purchased by ICON plc in 2003. Prior to GloboMax, she worked in the Pharmacokinetics and Biopharmaceutics Laboratory at the School of Pharmacy, University of Maryland on the FDA funded Clinical Pharmacology contract and UMAB-FDA contract as a clinical scientist and instructor for FDA reviewers. Dr. Bigora received a Pharm.D. from the School of Pharmacy at the University of Maryland at Baltimore. She also completed a Fellowship in Pharmacokinetics and Pediatric Infectious Diseases at the University of Maryland at Baltimore.

Michael Floyd – Mr. Floyd has served as our Chief Operating Officer since October 6, 2020. Mr. Floyd has been a serial entrepreneur with over 15 years of experience with early-stage biopharma businesses in infectious diseases, oncology and rare diseases. In 1996, he founded Neurologic, an early-stage enterprise that in-licensed technology from the National Institutes of Health for a diagnostic test for Alzheimer's disease. Mr. Floyd was the co-author of the plan that created the Blanchette Rockefeller Neurosciences Institute in 1998 with the Honorable Jay Rockefeller and Johns Hopkins University. In 2006, Mr. Floyd was the Chief Executive Officer for the North American subsidiary of Arpida Ltd. where he organized the Phase 3 program for an MRSA drug and organized the NDA submission. Mr. Floyd subsequently led the US efforts to remediate the NDA for Gentium, SpA for defibrotide beginning in 2011. Mr. Floyd was the Founder of Bio-AIM, which is developing monoclonal antibodies for Acinetobacter baumannii and a Co-Founder of Exbaq, which is developing therapies for Gram negative pathogens. In 2016, Mr. Floyd co-founded Elion Oncology and served as its Chief Executive officer until joining Processa. Mr. Floyd received a BSBA in Accounting from Georgetown University and is a Certified Public Accountant (inactive).

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

Patrick Lin - Mr. Lin has served as our Chief Business & Strategy Officer since October 4, 2017 and has over 20 years of financing and investing experience in the Biopharm Sector. He is founder and, for more than 15 years, Managing Partner of Primarius Capital, a family office that manages public and private investments focused on small capitalization companies. For 10 years prior to forming Primarius Capital, Mr. Lin worked at several Wall Street banking and brokerage firms including Robertson Stephens & Co., E*Offering, and Goldman Sachs & Co. Mr. Lin was Co-Founding Partner of E*Offering. Mr. Lin received an MBA from Kellogg Graduate School of Management, a Master of Engineering Management, and a Bachelor of Science in Business Administration from the University of Southern California.

James Stanker - Mr. Stanker has served as our Chief Financial Officer since September 5, 2018. Mr. Stanker has over 30 years of financial and executive leadership experience in the areas of accounting principles and audit standards, regulatory reporting, and fiscal management and strategy. He has served in a financial leadership role as an audit partner at Grant Thornton from February 2000 until his retirement in August 2016. His responsibilities included managing the audit quality in the Atlantic Coast Market Territory. From 2009 to 2012, he served as the Global Head of Audit Quality for Grant Thornton International. Prior to joining Grant Thornton, Mr. Stanker served as the Chief Financial Officer for a Nasdaq listed company and for a privately-held life science company. Mr. Stanker is a Certified Public Accountant. He has a Bachelors degree in Aeronautics from San Jose State University and a Masters in Business Administration from California State University, East Bay. He previously served on the Board of Directors of GSE Systems, Inc. Mr. Stanker is also a visiting professor in the George B. Delaplaine School of Business at Hood College.

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, 2021, the accumulated deficit was approximately $36.8 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 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 existing at-the-market sales agreement and/or our agreement with Lincoln Park, LLC. 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 has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption in the financial and capital markets. We are unable to accurately predict the full impact that the ongoing COVID-19 pandemic will have on our 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.

We have experienced delays in the enrollment of patients in our PCS499 Phase 2B trial due to COVID-19. Potential patients have died of COVID-19 prior to screening and continue to be reluctant to travel to our testing sites for fear of contracting COVID-19. 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 or future pandemics from other viruses will have on our current and future clinical trials.

We have a significant amount of intangible assets related to our acquisition of PCS499 recorded on our balance sheet, which may lead to potentially significant impairment charges in the future.

We review long-lived assets, including intangible assets, for impairment whenever events or changes in estimates and circumstances indicate that the related carrying amounts may not be recoverable based on the existence of certain triggering events. Intangible assets are also subject to an impairment assessment at least annually. The amount of identifiable intangible assets in our consolidated balance sheet is related to our acquisition of PCS499 and our right of use assets. At December 31, 2021, net intangible assets recorded on our consolidated balance sheet was $8.1 million. Any impairment of our assets could have a negative impact on our stock price and ability to seek additional financing.

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 of 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 theses 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, is 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 orphan designation on PCS499 in Necrobiosis Lipoidica (NL), improving the manufacturing of PCS499 final product, receiving FDA IND clearance on one indication for two product candidates, 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, initiating a Phase 2A trial for PCS12852 in gastroparesis patients and conducting a Phase 1B trial for PCS6422 in patients with advanced gastrointestinal tumors. 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 two 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.

Through our IND for PCS499, we are evaluated the safety tolerability of PCS499 in patients with NL in a Phase 2A clinical trial. Based on toxicology studies and healthy human volunteer studies, we administered a PCS499 dose of 1.8 grams/day to patients participating in the study. As anticipated, the 1.8 grams/day of PCS499 was generally well tolerated with no serious adverse events reported. All adverse events reported in the study were mild in severity. As expected, gastrointestinal symptoms were the most frequent adverse events and reported in four patients, all of which resolved within 1-2 weeks of starting dosing. We are currently evaluating the ability of PCS499 to completely close ulcers in patients with NL and better understand the potential response of NL patients on drug and on placebo in a Phase 2 clinical trial.

The FDA also cleared our IND for PCS12852 in October 2021 to proceed with a Phase 2A clinical trial for the treatment of gastroparesis. We anticipate beginning to enroll patients in the first half of 2022, complete enrollment in the second half of 2022 and complete final analysis in the first half of 2023.

We have initiated the Phase 1B trial for PCS6422 in patients with advance GI tumors. This trial will determine the maximum tolerated dose of capecitabine when administered with different dosage regimes of PCS6422. This trial was initiated in the second half of 2021 and is expected to complete enrollment in the second half of 2022.

Some preclinical 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 preclinical studies will translate successfully to our targeted population of patients. It is not uncommon to observe results in human clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical 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 product. 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 expense.

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 increase 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 under 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.

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 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

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 27.0% 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 covers 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.

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 2022.

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 24, 2022, there were 15,843,621 shares of common stock outstanding and 215 shareholders of record.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti 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, 2021.

	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	280,724(1)	$ 11.45	1,899,696
Equity compensation plans not approved by security holders	47,772	19.88	-
Total	328,496		1,899,696(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.

Recent Sales of Unregistered Securities

During the fourth quarter of 2021, we did not issue any securities that were not registered under the Securities Act.

Repurchases of Equity Securities

We did not repurchase any shares of our common stock during the year ended December 31, 2021.

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

Our mission is to develop drug products that improve the survival and/or quality of life for patients with high unmet medical need conditions for which few or no treatment options currently exist. We are a clinical-stage development company, not a discovery company, that seeks to identify and develop drugs for patients who need better treatment options. In order to increase the probability of development success, our pipeline only includes drugs which have previously demonstrated some efficacy in the targeted population or a drug with very similar pharmacological properties that has been shown to be effective in the population.

Our screening criteria for identifying and selecting new candidates include:

- addressing an unmet or underserved clinical need,
- having demonstrated evidence of efficacy in humans, and
- leveraging our regulatory science approach to improve the probability for approval.

In many instances, these clinical candidates have significant pre-clinical and clinical data that we may leverage to high value inflection points while de-risking the programs and adding in optionality to potential future indications. Our regulatory science approach developed by our team over decades of work with regulatory authorities attempts to balance the "benefit/risk" equation to identify a regulatory path with higher clinical benefit and/or lower clinical risk with shorter timelines to deliver better treatment options to patients, physicians and caregivers.

Our pipeline includes drugs that (i) already have clinical proof-of-concept data demonstrating the desired pharmacological activity in humans or, minimally, clinical evidence in the form of case studies or clinical experience demonstrating the drug or a similar drug pharmacologically can successfully treat patients with the targeted indication; (ii) target indications 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 or the present standard of care (e.g., some orphan indications, many serious life-threatening conditions, some serious quality of life conditions); and/or (iii) target indications where the prevalence of the condition and the likelihood of patients enrolling in a study meet the desired timeframe to demonstrate that the drug can, at some level, treat or potentially treat patients with the condition.

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, with our regulatory science approach, 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 and a better return on investment given lower development costs, more efficient development and high commercial value. Given the prior successes of our regulatory science approach, we have selected drugs for our portfolio which may have greater chance for approval in a population of patients who desperately need better treatment options. We have applied rigorous standards to identify drugs for our portfolio, namely:

i. 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,

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

iii. The drug presents opportunities to be developed such that within 2-4 years, critical value-added clinical milestones can be achieved while advancing the drug closer to commercialization and adding to the potential for a high return on investment.

In order to add significant value to our in-licensed drugs within 2 to 4 years, the drugs must be in the clinical development stage and not in discovery stage, and during those 2 to 4 years we must be able to obtain clinical data to support the added value. The additional clinical data could range from a clinical proof-of-concept data to further demonstrate that the proposed pharmacology occurs clinically in the targeted patient population to a pivotal well-designed randomized controlled trial.

Recent Developments

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

Shelf Registration Statement **-** On June 30, 2021, we filed a shelf registration statement on Form S-3, which became effective in July 2021. The shelf registration statement permits the offering, issuance and sale of up to $75.0 million of common stock, preferred stock, warrants and/or units in one or more offerings and in any combination of the foregoing.

"At-the-Market" (ATM) Offering **–** 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 under our shelf registration statement (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 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. During the fourth quarter of 2021, we sold 21,597 shares of our common stock for $174 thousand in net proceeds after paying $5 thousand in commissions to the Sales Agent.

Lincoln Park Capital Fund, LLC Purchase Agreement **-** 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, $0.0001 par value per share ("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. 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. See Note 14 for additional details concerning the Purchase Agreement.

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. We have experienced delays in the enrollment of patients in our PCS499 Phase 2B trial due to COVID-19. Potential patients have died from COVID-19 prior to screening and continue to be reluctant to travel to our testing sites for fear of contracting COVID-19. 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, 2021 and 2020

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

	Year Ended December 31,		
	2021	2020	Change
Operating Expenses			
Research and development costs	$ 6,878,021	$ 3,172,385	$ 3,705,636
Acquisition of in-process research and development	566,583	8,700,000	(8,133,417)
General and administrative expenses	4,688,939	3,264,474	1,424,465
Operating Loss	(12,133,543)	(15,136,859)	
Other Income (Expense)			
Forgiveness of Payroll Protection Program loan and related accrued interest	163,771	-	163,771
Interest expense	(362)	(281,122)	280,760
Interest income	11,989	3,174	8,815
Total other income (expense)	175,398	(277,948)	
Net Operating Loss Before Income Tax Benefit	(11,958,145)	(15,414,807)	3,456,662
Income Tax Benefit	530,611	1,001,019	(470,408)
Net Loss	$ (11,427,534)	$ (14,413,788)	

Revenues.

We had no revenue during the years ended December 31, 2021 and 2020. 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) amortization of the exclusive PCS499 license intangible asset used in research and development activities, (ii) program and testing related expenses including external consulting and professional fees related to the product testing and our development activities, and (iii) internal research and development staff related salaries and other payroll costs including stock-based compensation, payroll taxes and employee benefits. 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, 2021 and 2020 were as follows:

	Year ended December 31,	
	2021	2020
Amortization of intangible assets	$ 790,488	$ 795,328
Preclinical, clinical trial and other costs	4,171,836	972,711
Research and development salaries and benefits	1,915,697	1,404,346
Total	$ 6,878,021	$ 3,172,385

During the year ended December 31, 2021, our research and development expenses increased by $3,705,636 to $6,878,021 when compared to $3,172,385 for the year ended December 31, 2020. The increase was primarily due to an increase in preclinical, clinical trial and other costs of $3,199,125, which are attributable to expenses we incurred as we commenced our Phase 2B clinical trial for PCS499, Phase 1B clinical trial for PCS6422 and for pre-IND costs for PCS12852. Expenses included payments to contract research organizations, for regulatory filings and maintenance fees, drug product testing and stability, consulting and other clinical fees. During the same period in 2020, we were completing the patient portion of our Phase 2A clinical trial for PCS499 and incurring regulatory filing and consulting fees as we prepared for our meeting with the FDA. Additionally, during the year ended December 31, 2021, we experienced increases in payroll and related costs of $511,351 resulting from hiring additional development personnel and increased employee salary rates, when compared to the same period in 2020. These increases were offset by a decrease of $4,840 in amortization expense, as the capitalized software was fully amortized during the year ended December 31, 2021.

We anticipate our research and development costs to continue to increase significantly in 2022 as we: (i) continue our clinical trials for PCS499 and PCS6422 and begin our clinical trial for PCS12852, including the cost of having drug product manufactured; (ii) complete a biomarker assay for PCS3117; and (iii) obtain IND enabling data for PCS11T.

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. As noted above, we anticipate our research and development costs to increase in the future as we conduct the Phase 2B trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL and to continue with an amended Phase 1B clinical trial for PCS6422. On May 19, 2021, we dosed the first patient in our PCS499 randomized, placebo-controlled trial, but have experienced delays in patient enrollment; and while we dosed the first patient in our PCS6422 trial on August 2, 2021, we submitted a modified Phase 1B trial protocol in February 2022 to determine the maximum tolerated dose of capecitabine and provide us with data on the timeline of DPD inhibition and de novo formation. We expect to restart the PCS6422 Phase 1B trial in the second quarter of 2022.

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.

We estimate preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and 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.

Acquisition of In-Process Research and Development.

In connection with the Ocuphire Agreement, we recorded $566,583 of acquired in-process research and development expense in 2021. 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. During the same period in 2020, we recorded $8.7 million of acquired in-process research and development expense in connection with our license agreements with Yuhan, Aposense and Elion. We believe the in-process research and development assets acquired have no alternative future use.

General and Administrative Expenses.

Our general and administrative expenses for the year ended December 31, 2021 increased by $1,424,465 to $4,688,939 when compared to $3,264,474 for the same period in 2020. The majority of the increase was due to increased professional and other consulting fees of $1,086,673 (which includes a $620,793 increase of fees paid in stock compensation); increased payroll and related costs of $174,115 from hiring additional personnel, increased salary rates and health insurance premiums; and a $110,410 increase in employee stock-based compensation. We also experienced an increase in our insurance of $116,024, mostly due to increased insurance premiums; an increase in office and repairs and maintenance expenses of $113,465 as we purchased new/replacement computers for our new and existing employees and replaced outdated hardware and old cabling in the office; and an increase of $10,825 in other miscellaneous expenses. These increased expenses were offset by decreases in depreciation, equipment rent, taxes and travel of $179,724. We share office space with CorLyst, a related party, and during the years ended December 31, 2021 and 2020, they reimbursed us $126,324 and $119,001, 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.

Other Income and (Expense)

Net other income and (expense) was $175,398 and ($277,948) for the years ended December 31, 2021 and 2020, 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 while interest expense in 2020 was related to our $805,000 8% Senior Notes sold in 2019 and 2020 and borrowings on a related party LOC. Included in interest expense is the amortization of debt issuance costs totaling $199,900 for the year ended December 31, 2020.

Income Tax Benefit.

An income tax benefit of $530,611 and $1,001,019 was recognized for the years ended December 31, 2021 and 2020, respectively. A deferred tax liability was created as a result of our acquisition of CoNCERT's license and "Know-How" in exchange for Processa 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*, Processa 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 will be reduced for the effect of the non-deductibility of the amortization of the intangible asset and may be offset by the deferred tax assets resulting from net operating tax losses (see Note 4 – Income Taxes). This offset results in the recognition of a deferred tax benefit shown in the consolidated statements of operations.

Liquidity

At December 31, 2021 we had $16.5 million in cash and cash equivalents.

On February 24, 2021, we closed a private placement for the sale of 1,321,132 shares of our common stock at a purchase price of $7.75 per share to accredited and institutional investors for gross proceeds of $10.2 million. Net proceeds from the offering were $9.9 million. We also completed an underwritten public offering in late 2020 where we raised net proceeds from the offering of approximately $17.1 million.

On August 20, 2021, we entered into the Sales Agreement under which we may issue and sell shares of our common stock in a registered ATM Offering having an aggregate offering price of up to $30.0 million from time to time through or to our Sales Agent. 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 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. During the fourth quarter of 2021, we sold 21,597 shares of common stock under the ATM Offering for net proceeds of $174 thousand. We have not yet sold any shares under the ATM Offering in 2022.

On March 23, 2022, we entered into a Purchase Agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") under which we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15,000,000 of our shares of common stock, par value $0.0001 per share, subject to the terms and conditions in the Purchase Agreement, during the term of the Purchase Agreement as more fully described in Note 14 to the Consolidated Financial Statements.

We have incurred losses and net cash used in our operating activities during the year ended December 31, 2021, which we expect to continue for the foreseeable future. We do not currently nor have since our inception had any sales. We have incurred losses since our inception, devoting substantially all of our efforts toward research and development, and have an accumulated deficit of approximately $36.8 million at December 31, 2021. During the year ended December 31, 2021, we generated a net loss of approximately $11.4 million, of which $4.5 million are non-cash expenses. Based on our current plans, we believe our current cash balance is adequate for at least the next twelve months without considering amounts available from the Lincoln Park Purchase Agreement or potential sales under our ATM Offering. 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 necessary.

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 cost 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. We also plan to develop a biomarker assay for PCS3117 and obtain IND enabling data for PCS11T. 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 clinical trials for PCS499, PCS6422 and PCS12852, and the cost of third-party manufacturing;
- the cost of developing the biomarker assay and clinical trials for PCS3117;
- the delays in patient enrollment due to the COVID-19 pandemic;
- the initiation, progress, timing, costs and results of drug manufacturing, pre-clinical studies, and clinical trials of PCS11T and 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 as our pre-clinical and clinical activities increase;
- 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 also 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 the ATM Offering and the Lincoln Park Purchase Agreement, but there can be no assurance that capital will continue to be available to us on acceptable terms or 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, 2021 and 2020:

	For the Year Ended December 31,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$ (8,717,291)	$ (3,143,196)
Financing activities	9,798,648	17,867,884
Net increase in cash and cash equivalents	$ 1,081,357	$ 14,724,688

Net cash used in operating activities

We used net cash in our operating activities of $8,717,291 and $3,143,196 during the years ended December 31, 2021 and 2020, respectively. The increase in cash used in operating activities during the year ended December 31, 2021 compared to the comparable period in 2020 was primarily related to costs we incurred related to our Phase 2B clinical study for PCS499, Phase 1B clinical study for PCS6422, pre-clinical costs for PCS12852, as well as increased professional fees and salaries. Our prepaid expenses increased by $1.2 million during the year ended December 31, 2021, primarily due to deposits paid to our CROs for clinical trial related costs. Of this amount, $186,491 represents deferred offering costs which impacted net cash provided by financing activities. As a result, the change in prepaid expenses impacting net cash used in operating activities is $1.0 million.

As we continue our clinical trials for PCS499 and PCS6422, begin a Phase 2A clinical trial for PCS12852, and continue to evaluate and develop 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.

Net cash provided by financing activities

During the year ended December 31, 2021, we received $9,875,550 in net proceeds from our February 2021 private placement transaction and $173,987 in net proceeds from the sale of 21,597 shares of our common stock under our ATM Offering. We incurred $186,941 in expenses related to our ATM Offering, $186,493 of which we have capitalized and will amortize as we sell additional shares under our ATM Offering.

Net cash provided by financing activities during the year ended December 31, 2020 of $17,867,884 ($17.1 million in net proceeds) was from our 2020 underwritten public offering, borrowings totaling $700,000 under a related-party LOC Agreement, and $162,459 we received from the Bank of America pursuant to a promissory note under the Paycheck Protection Program.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2021:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	$ 83,754	$ 75,969	$ 7,785	$ -	$ -
Total	$ 83,754	$ 75,969	$ 7,785	$ -	$ -

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 consist of the capitalized costs of $20,500 for a software license and $11,038,929 associated with the exercise of the option to acquire 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. The capitalized costs for the license rights to PCS499, in addition to the fair value of the common stock issued, also includes $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 nominal tax basis 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 as the exclusive license rights represent intangible assets to be used in research and development activities that have future alternative uses.

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.

We determined our intangible assets to have finite useful lives and review them for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

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 granted during the years ended December 31, 2021 and 2020.

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*. Under the asset and liability method, deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss carryforwards. 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. A valuation allowance is provided against net deferred tax assets if recoverability is uncertain on a more likely than not basis. As of December 31, 2021 and 2020, we have established a valuation allowance to offset certain 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, 2021, 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, 2021.

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, 2021 and 2020, 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, 2021 and 2020, 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 Matters

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

Intangible Asset

As discussed in Notes 3 and 10 to the consolidated financial statements, the Company has capitalized costs of $8,056,638 related to the acquisition of the exclusive license rights to PCS499. This intangible asset is tested at least annually for impairment or when events indicate it is more likely than not that the carrying amount of the asset may not be recoverable.

We identified the analysis for potential 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.

Acquisition of In-Process Research and Development

As discussed in Note 10 to the consolidated financial statements, the Company has acquired one additional license in addition to the four licenses acquired in prior years to develop, manufacture and commercialize drugs. The Company determined there were no alternative future use and therefore expensed the cost of acquiring the drug as acquisition of in-process research and development.

We identified the treatment of this license as a critical audit matter due to the materiality of the transaction as well as the added complexity involving the issuance of common stock in conjunction with acquiring the license. To test the appropriateness of expensing the license, we read the agreement and reviewed management's analysis.

/s/ BD & Co.
Owings Mills, MD
March 30, 2022

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

Processa Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
ASSETS		
Current Assets		
Cash and cash equivalents	$ 16,497,581	$ 15,416,224
Due from related party	-	154,730
Due from tax agencies	70,274	77,024
Prepaid expenses and other	1,759,296	554,708
Total Current Assets	18,327,151	16,202,686
Property and Equipment		
Software	19,740	19,740
Office equipment	9,327	9,327
Total Cost	29,067	29,067
Less: accumulated depreciation	29,067	28,583
Property and equipment, net	-	484
Other Assets		
Operating lease right-of-use assets, net	74,181	158,558
Intangible assets, net	8,056,638	8,847,126
Security deposit	5,535	5,535
Total Other Assets	8,136,354	9,011,219
Total Assets	$ 26,463,505	$ 25,214,389
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Note payable – Paycheck Protection Program, current portion	$ -	$ 117,574
Current maturities of operating lease liability	71,078	87,200
Accrued interest	-	950
Accounts payable	218,905	320,694
Due to licensor	400,000	400,000
Due to related parties	1,772	69,858
Accrued expenses	279,265	224,676
Total Current Liabilities	971,020	1,220,952
Non-current Liabilities		
Note payable – Paycheck Protection Program	-	44,885
Non-current operating lease liability	7,385	78,463
Non-current due to licensor	-	400,000
Net deferred tax liability	-	530,611
Total Liabilities	978,405	2,274,911
Commitments and Contingencies		-
Stockholders' Equity		
Common stock, par value $0.0001, 30,000,000 shares authorized; 15,710,246 and 14,181,734 issued and outstanding at December 31, 2021 and 2020, respectively	1,571	1,419
Additional paid-in capital	62,306,861	48,333,857
Accumulated deficit	(36,823,332)	(25,395,798)
Total Stockholders' Equity	25,485,100	22,939,478
Total Liabilities and Stockholders' Equity	$ 26,463,505	$ 25,214,389

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2021	2020
Operating Expenses		
Research and development expenses	$ 6,878,021	$ 3,172,385
Acquisition of in-process research and development	566,583	8,700,000
General and administrative expenses	4,688,939	3,264,474
Operating Loss	(12,133,543)	(15,136,859)
Other Income (Expense)		
Forgiveness of Payroll Protection Program loan and related accrued interest	163,771	-
Interest expense	(362)	(281,122)
Interest income	11,989	3,174
Net Operating Loss Before Income Tax Benefit	(11,958,145)	(15,414,807)
Income Tax Benefit	530,611	1,001,019
Net Loss	$ (11,427,534)	$ (14,413,788)
Net Loss Per Common Share - Basic and Diluted	$ (0.75)	$ (2.54)
Weighted Average Common Shares Used to Compute Net Loss Per Common Shares - Basic and Diluted	15,319,463	7,499,678

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, 2021 and 2020

	Shares	Amount	Additional Paid in Capital	Stock Dividend Payable	Accumulated Deficit	Total
Balance, January 1, 2020	5,486,595	$ 549	$ 18,994,008	$ 3	$ (10,982,010)	$ 8,012,550
Shares issued in connection with our 2020 offering, net of transaction costs of $2,099,363	4,800,000	480	17,100,157	-	-	17,100,637
Shares issued in connection with license agreements	1,950,000	195	7,799,805	-	-	7,800,000
Shares issued due to full-ratchet anti-dilution adjustment	1,156,487	116	(116)	-	-	-
Conversion of LOC Agreement into shares of common stock	199,537	19	718,314	-	-	718,333
Conversion of 8% Senior Convertible Notes into shares of common stock	247,088	25	889,488	-	-	889,513
Stock dividend distributed due to full-ratchet anti-dilution adjustment	28,971	3	-	(3)	-	-
Fair value of warrants issued in the sale of our 2019 Senior Notes	-	-	197,403	-		197,403
Stock-based compensation	336,860	34	2,730,008	-	-	2,730,042
Shares withheld to pay income tax on stock-based compensation	(23,804)	(2)	(95,210)	-		(95,212)
Net loss	-	-	-	-	(14,413,788)	(14,413,788)
Balance, December 31, 2020	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 agreements	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 purchases, net of transaction costs	21,597	2	173,985	-	-	173,987
Net loss	-	-	-	-	(11,427,534)	(11,427,534)
Balance, December 31, 2021	15,710,246	$ 1,571	$ 62,306,861	$ -	$ (36,823,332)	$ 25,485,100

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2021	2020
Cash Flows From Operating Activities		
Net Loss	$ (11,427,534)	$ (14,413,788)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	484	8,446
Non-cash lease expense for right-of-use assets	84,377	78,288
Non-cash acquisition of in-process research and development	300,000	8,600,000
Amortization of debt issuance costs	-	199,900
Amortization of intangible asset	790,488	795,328
Deferred income tax (benefit) expense	(530,611)	(1,001,019)
Stock-based compensation	3,408,015	2,730,042
Forgiveness of Payroll Protection Program loan and related accrued interest	(163,771)	-
Net changes in operating assets and liabilities:		
Prepaid expenses and other	(1,018,095)	(239,103)
Operating lease liability	(87,200)	(77,491)
Accrued interest, including amounts converted into common stock	362	81,894
Accounts payable	(101,789)	245,082
Due (from) to related parties	86,644	(85,188)
Other receivables	6,750	(77,024)
Accrued expenses	(65,411)	11,437
Net cash (used in) operating activities	(8,717,291)	(3,143,196)
Cash Flows From Financing Activities		
Net proceeds from common stock sold	10,049,537	17,100,637
Line of credit payable from related party	-	700,000
Proceeds from our Paycheck Protection Program note payable	-	162,459
Shares withheld to pay taxes on stock based compensation	(64,396)	(95,212)
Other	(186,493)	-
Net cash provided by financing activities	9,798,648	17,867,884
Net Increase in Cash and Cash Equivalents	1,081,357	14,724,688
Cash and Cash Equivalents - Beginning of Year	15,416,224	691,536
Cash and Cash Equivalents - End of Year	$ 16,497,581	$ 15,416,224

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,	
Supplemental Cash Flow Information:	2021	2020
Cash paid for interest	$ -	$ -
Cash paid for income taxes	-	-
Non-Cash Investing and Financing Activities:		
Right-of-use asset obtained in exchange for operating lease liability	$ -	$ (17,772)
Operating lease liability	-	17,772
Net	$ -	$ -
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	$ -
Conversion of $805,000 of Senior Convertible Debt and related accrued interest of $84,513 into 247,088 shares of common stock	$ -	$ 805,000
Conversion of $700,000 of Line of Credit Payable with related party and related accrued interest of $18,333 into 199,537 shares of common stock	$ -	$ 700,000
Issuance of 1,185,458 shares of common stock due to triggering the full-ratchet anti-dilution provision of common stock sold in our 2018 Private Placement Transactions	$ -	$ 119

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 the development of drug products that are intended to provide treatment for patients who have a high unmet medical need condition that effects survival or the patient's quality of life and for which few or no treatment options currently exist. We currently have five drugs: four in various stages of clinical development (PCS499, PCS12852, PCS3117 and PCS6422) and one in nonclinical development (PCS11T). We group our drugs into non-oncology (PCS499 and PCS12852) and oncology (PCS3117, PCS6422 and PCS11T). A summary of each drug is provided below:

- Our most advanced product candidate, PCS499, is an oral tablet that is a deuterated analog of one of the major metabolites of pentoxifylline (PTX or Trental®). We completed a Phase 2A trial for PCS499 in patients with ulcerative and non-ulcerative necrobiosis lipoidica (NL) in late 2020, and in May 2021 we enrolled the first patient in our Phase 2B trial for the treatment of ulcerative NL. We expect to complete our interim analysis and complete enrollment of the Phase 2B trial by the end of 2022; and, depending on the results, begin a pivotal Phase 3 trial in 2023.

- PCS12852 is a highly specific and potent 5HT4 agonist which has already been evaluated in clinical studies in South Korea for gastric emptying and gastrointestinal motility. In October 2021, the FDA cleared our IND application to proceed with a Phase 2A trial for the treatment of gastroparesis. We anticipate beginning to enroll patients in the first half of 2022, complete enrollment in the second half of 2022 and complete final analysis in the first half of 2023.

- PCS3117, which we licensed in June 2021, is a cytosine analog, similar to gemcitabine (Gemzar®) but different enough in chemical structure that some patients are more likely to respond to PCS3117 than gemcitabine. We are evaluating biomarkers to elucidate specifically which patients are more likely to benefit from PCS3117 compared to gemcitabine and other chemotherapy agents to provide a more targeted, precision medicine approach to the treatment of various types of cancer, such as pancreatic and/or non-small cell lung cancer. Over the next 6-12 months, we will be developing, refining and qualifying these biomarker assays for use in our clinical trials as well as define the potential paths to approval for different types of cancer. We anticipate initiating a Phase 2B or adaptive designed Phase 3 in 2023.

- PCS6422 is an orally administered irreversible enzyme inhibitor administered in combination with capecitabine. When combining capecitabine with PCS6422 (the "Next Generation Capecitabine"), capecitabine becomes a more potent cancer chemotherapy agent than current FDA approved 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 and our interim analysis of Cohorts 1 and 2 found no dose-limiting toxicities (DLTs), no drug related adverse events greater than Grade 1, and no hand-foot syndrome. In addition, the interim analysis revealed when PCS6422 inhibits DPD enzyme activity, 5-FU metabolism is significantly decreased (<10% metabolized to F-Bal compared to typically 80%) and the potency of capecitabine is significantly increased (at least 50 times greater 5-FU potency based on systemic exposure per mg of capecitabine administered). The single dose of PCS6422, however, did not sustain the DPD inhibition throughout 7 days of capecitabine dosing which was needed to maintain the improved potency of capecitabine. Therefore, we have modified the existing protocol to obtain more data on DPD inhibition and de novo formation. We anticipate that this additional data will allow us to select PCS6422 dosage regimens that will maintain DPD inhibition for each patient treated with this Next Generation Capecitabine (i.e., combination of PCS6422 and capecitabine). After interacting with the FDA and making protocol modifications, we expect to restart the Phase 1B study in the second quarter of 2022 and complete enrollment while defining the Next Generation Capecitabine regimen (i.e., the PCS6422 regimens and the corresponding capecitabine regimens) by the end of 2022. We expect that our overall timeline has not changed with a Phase 2B or 3 trial starting in 2023-2024 and NDA submission in 2027-2028.

- Our only nonclinical drug candidate is PCS11T, an analog of SN38 (SN38 being the active metabolite of irinotecan) and a next generation irinotecan drug for multiple types of cancers. PCS11T is presently in the IND pre-clinical toxicology stage. We hope to submit an IND in the first half of 2023, followed by a Phase 1B maximum tolerated dose trial.

Impact of COVID-19

We have experienced delays in the enrollment of patients in our PCS499 Phase 2B trial due to COVID-19. Potential patients have died from COVID-19 prior to screening and continue to be reluctant to travel to our testing sites for fear of contracting COVID-19. Delays in enrollment lengthen the time of studies and increase their costs. The COVID-19 pandemic has created uncertainties in the expected timelines for clinical stage biopharmaceutical companies such as ours, including possible delays in clinical trials and disruptions in the supply chain for raw materials used in clinical trial work. Such delays could materially impact our business in future periods. Furthermore, the spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. For more information on the risks associated with COVID-19, refer to Part I, Item 1A, "Risk Factors."

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 research and development, and have an accumulated deficit of approximately $36.8 million at December 31, 2021. During the year ended December 31, 2021, we generated a net loss of approximately $11.4 million and 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 is adequate for at least the next twelve months without considering amounts available from the Lincoln Park Purchase Agreement (see Note 14) or potential sales under our ATM Offering. 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 necessary.

We had no revenue during the year ended December 31, 2021 and do not have any revenue under contract or any immediate sales prospects. Our primary uses of cash are to fund our planned clinical trials, research and development expenditures and operating expenses. Cash used to fund operating expenses is impacted by the timing of when we incur and pay these expenses.

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.

On March 23, 2022, we entered into a Purchase Agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") under which we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15,000,000 of our shares of common stock, par value $0.0001 per share, subject to the terms and conditions in the Purchase Agreement, during the term of the Purchase Agreement. See Note 14 for additional details concerning the Purchase Agreement.

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 (see Note 10). 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, there was no impairment loss recorded during the years ended December 31, 2021 and 2020.

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. We concluded in the third quarter of 2021 that it would be appropriate for us to compute volatility based on the behavior of our own common stock since we have been a public company for more than three years and listed on the Nasdaq Capital Market for one year. As such, we adjusted the expected volatility for new grants issued on or after September 1, 2021 to 74.48%, which is not significantly different from our previous volatility computation of 81.77%.

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, 2021 and 2020 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.

As more fully described in Note 7 and 8, we have determined that each of the underwritten public offering in October 2020 and the sale of the 2019 Senior Notes in late 2019 triggered the full ratchet anti-dilution provision of the common stock we sold in 2018 Private Placement Transactions. For purposes of computing our basic and diluted earnings per share (EPS) for the year ended December 31, 2020, we increased our net loss available for common shareholders by the fair value of the additional shares issued since they did not affect all our common shareholders equally and there were no contingencies related to the issuance of these shares. We also included the related shares in the weighted number of shares of common stock outstanding for the year ended December 31, 2020.

Our diluted net loss per share for the years ended December 31, 2021 and 2020 excluded 822,430 and 816,512 of potentially dilutive common shares, respectively, related to outstanding stock options, unvested RSAs, unvested RSUs and warrants since those shares would have had an anti-dilutive effect on loss per share during the years then ended.

Segments

We 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.

Debt Issuance Costs

We recognized the debt issuance costs incurred related to our 2019 Senior Notes as a reduction of the carrying amount of the 2019 Senior Notes. The debt issuance costs were amortized to interest expense using the straight-line method over the term of the 2019 Senior Notes and at December 31, 2020 were fully amortized.

Research and development

Research and development costs are expensed as incurred and consisted of direct and overhead-related expenses. Research and development costs totaled $6,878,021 and $3,172,385 for the years ended December 31, 2021 and 2020, 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, 2021 and 2020.

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes*. Under the asset and liability method, deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss carryforwards. 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. A valuation allowance is provided against net deferred tax assets if recoverability is uncertain on a more likely than not basis. As of December 31, 2021 and 2020, we have established a valuation allowance to offset certain 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, 2021, 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 evaluated recently issued accounting pronouncements and determined that there is no material impact on our financial position or results of operations.

Note 3 - Intangible Assets

Intangible assets at December 31, 2021 and 2020 consisted of the following:

	2021	2020
Gross intangible assets	$ 11,059,429	$ 11,059,429
Less: accumulated amortization	(3,002,791)	(2,212,303)
Total intangible assets, net	$ 8,056,638	$ 8,847,126

Amortization expense was $790,488 and $795,328 for the years ended December 31, 2021 and 2020, respectively and is included within research and development expense in the accompanying consolidated statements of operations. As of December 31, 2021, estimated amortization expense will be approximately $788,000 per year for the next 10 years.

Our gross intangible assets consist 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 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.

Note 4 - Income Taxes

During the years ended December 31, 2021 and 2020, we incurred financial net operating losses before income tax benefit of $11,958,145 and $15,414,807, respectively, and federal taxable losses of $5,740,342 and $2,648,248, respectively. For the years ended December 31, 2021 and 2020, we did not record any income tax benefits from the following:

- $3,172,746 and $1,345,002 ($807,256 and $370,111 tax effected, respectively) of general and administrative expenses treated as deferred start-up expenditures for tax purposes, respectively;
- $1,580,984 and $383,571 ($415,312 and $105,549 tax effected, respectively) of stock-based compensation, respectively;
- $572,713 and $8,743,517 ($75,073 and $2,405,997 tax effected, respectively) of purchased and expensed in-process research and development costs incurred, respectively; and
- $788,495 for both periods presented ($288,339 and $216,974 tax effected, respectively) related to the intangible asset for the CoNCERT license and Know-How (part of the Section 351 transaction), respectively.

We have recorded the benefit of our 2021 and 2020 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. The benefit associated with the net operating loss carry forward will more-likely-than-not go unrealized unless future operations are successful except for their offset against the deferred tax liability created by the acquired CoNCERT license and Know-How, which will decrease over time leading to an increase to the valuation allowance.

A deferred tax liability was recorded on March 19, 2018 when Processa received CoNCERT's license and Know-How in exchange for Processa 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*, Processa 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. The deferred tax liability has been reduced for the effect of non-deductibility of the amortization of the intangible asset to $2,145,620 at December 31, 2021 and offset by deferred tax assets resulting from net operating tax losses.

For the years ended December 31, 2021 and 2020, we recorded a federal income tax benefit of $530,611 and $1,001,019, respectively, 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.

Our provision (benefit) for income taxes for the years ended December 31, 2021 and 2020 was as follows:

	Year Ended December 31,	
	2021	2020
Current:		
Federal	$ -	$ -
State	-	-
Total deferred tax benefit	-	-
Deferred:		
Federal	(2,853,937)	(3,068,218)
State	(624,844)	(907,504)
Total deferred tax benefit	(3,478,781)	(3,975,722)
Valuation allowance	2,948,170	2,974,703
Net deferred tax benefit	(530,611)	(1,001,019)
Total tax provision (benefit)	$ (530,611)	$ (1,001,019)

A reconciliation of our effective income tax rate and statutory income tax rate for the years ended December 31, 2021 and 2020 is as follows:

	Year Ended December 31,	
	2021	2020
Federal statutory income tax rate	21.00%	21.00%
State tax rate, net	1.05%	1.54%
Permanent differences	(0.18)%	(2.03)%
Federal orphan drug tax credit	3.04%	0.94%
Deferred tax asset valuation allowance	(20.48)%	(14.96)%
Effective income tax rate	4.43%	6.49%

At December 31, 2021 and 2020, we had available federal and state net operating loss carryforwards of approximately $12.5 million and $6.7 million, respectively. The federal net operating loss generated in 2021 and 2020 of $5.7 million and $2.6 million, respectively, will carry forward indefinitely. Net operating losses generated prior to 2018 will expire 2037. We are evaluating our qualified research expenditures for the federal orphan drug credit and the federal and state credit for increasing research activities to offset potential future tax liabilities. The federal research and development tax credits have a 20-year carryforward period. We have not recognized any deferred tax assets related to research and development tax credits as of December 31, 2021 or 2020. All federal and state net operating loss and credit carryforwards listed above are reflected after the reduction for amounts effectively eliminated under Section 382.

We do not recognize other deferred income tax assets at this time because the realization of the assets is not more-likely-than-not that they will be realized. As of December 31, 2021 and 2020, we had deferred tax assets including start-up expenditures, stock-based compensation, purchased in-process research and development expenditures and other deductible expenses for both federal and state income tax purposes of $31,427,925 and $20,361,140, respectively. The benefit associated with the amortization of the deferred start-up expenditures, purchased in-process research and development expenditures and other deductible expenses, including a portion of the net operating loss carry forwards, will more-likely-than-not go unrealized unless future operations are successful. Since the success of future operations is indeterminable, the potential benefits resulting from these deferred tax assets have not been recorded in our consolidated financial statements.

We recorded a valuation allowance during the years ended December 31, 2021 and 2020 equal to the full recorded amount of our net deferred tax assets related to deferred start-up costs, federal orphan drug tax credit and other temporary differences since it is more-likely-than-not that such benefits will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

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

	December 31,	
	2021	2020
Deferred tax assets:		
Non-current:		
Net operating loss carry forward – Federal	$ 2,615,518	$ 1,410,046
Net operating loss carry forward – State	760,897	437,618
Stock compensation expense	593,365	178,053
Depreciation	13,200	12,958
Purchased in-process R&D	2,481,070	2,405,997
Federal orphan drug credits	791,151	427,343
Start-up expenditures and amortization	1,978,418	1,171,162
Total non-current deferred tax assets	9,233,619	6,043,177
Valuation allowance for deferred tax assets	(7,087,999)	(4,139,829)
Total deferred tax assets	2,145,620	1,903,348
Deferred Tax Liabilities:		
Non-current:		
Intangible asset	(2,145,620)	(2,433,959)
Total non-current deferred tax liabilities	(2,145,620)	(2,433,959)
Total deferred tax asset (liability)	$ -	$ (530,611)

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, the projected future taxable income and tax planning strategies in making this assessment. Based on management's analysis, a reserve has been established against the deferred tax assets related to deferred start-up expenditures and certain other deductible expenses. The change in the valuation allowance in 2021 and 2020 was $2,948,170 and $2,974,703, respectively.

Our total deferred tax asset as of December 31, 2021 and 2020 primarily includes $7,428,810 and $4,256,064 ($1,978,418 and $1,171,162 tax effected, respectively) of general and administrative expenses treated as deferred start-up expenditures for tax purposes, respectively, $12,454,846 and $6,714,504 ($3,376,415 and $1,847,664 tax effected, respectively) of tax losses, respectively, resulting in tax loss carryforwards; $2,228,039 and $647,055, respectively, of stock-based compensation expense ($593,365 and $178,053 tax effected, respectively); $9,316,230 and $8,743,517, respectively, of purchased in-process research and development ($2,481,070 and $2,405,997 tax effected, respectively); and $791,151 and $427,343 of federal orphan drug tax credits, respectively. We have had no revenues and recognized cumulative loses since inception. Due to the uncertainty regarding future profitability and recognition of taxable income to utilize the amortization of deferred start-up expenditures, purchased in-process research and development, federal orphan drug tax credits and the tax loss carryforwards, except for their offset against the deferred tax liability created by our acquisition of the CoNCERT license, a valuation allowance against the deferred tax assets has been recognized for the years ended December 31, 2021 and 2020.

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.

We file U.S. Federal income and California and Maryland state tax returns. 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

On June 19, 2019, our stockholders approved, and we adopted the Processa Pharmaceuticals Inc. 2019 Omnibus Equity Incentive Plan (the "2019 Plan"). The 2019 Plan allows us, under the direction of our Board of Directors or a committee thereof, 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 provides for the aggregate issuance of 3,000,000 shares of our common stock, with 1,899,696 shares available for future grants at December 31, 2021.

We recorded stock-based compensation expense for the years ended December 31, 2021 and 2020 as follows:

	Years Ended December 31,	
	2021	2020
Research and development	$ 809,839	$ 863,069
General and administrative	2,598,176	1,866,973
Total	$ 3,408,015	$ 2,730,042

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.

As of December 31, 2021, there was a total of $2,430,142 unrecognized compensation expense, related to the unvested stock options, restricted stock awards (RSAs), restricted stock units (RSUs) and warrants which are expected to be recognized over a weighted average period of 1.7 years, excluding the impact of RSUs for the future issuance of 39,786 shares for which meeting the criteria is not yet probable.

Restricted Stock Awards

During the years ended December 31, 2021 and 2020, we issued 37,500 and 336,860 RSAs, respectively, under the 2019 Omnibus Incentive Plan to our employees and directors. We valued the RSAs based on the closing share price on the date of grant. RSAs are "shares that the recipient receives, but the rights to sell or transfer the shares are restricted until the vesting condition passes." Recipients of RSAs are entitled to voting and dividend rights, even if they have not vested, so we consider these shares to be issued and outstanding once they have been granted.

At December 31, 2021, 281,721 RSAs have vested as follows:

- 214,078 RSAs vested on October 6, 2020 when we successfully completed our underwritten public offering and up-listed to the Nasdaq Capital Market;
- 55,143 RSAs vested on August 5, 2021; and
- 12,500 RSAs vested on October 6, 2021.

During the years ended December 31, 2021 and 2020, 9,176 and 23,804 vested RSAs, respectively, were forfeited to pay for federal, state and local income taxes, and an additional 1,530 unvested RSAs were forfeited upon employment termination during the year ended December 31, 2021. The remaining 91,109 unvested RSAs vest over time with years of employment.

The following table summarizes the information about RSAs outstanding for the years ended December 31, 2020 and 2021.

	Number of shares	**Weighted-average grant-date fair value per share**
Unvested as of January 1, 2020	-	$ -
Granted	336,860	8.33
Vested and Issued	(190,274)	8.50
Forfeited	(23,804)	8.50
Unvested as of December 31, 2020	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

Included in accrued expenses at December 31, 2021 is $120,000 in fees earned by our Directors, which will be satisfied with the issuance of RSAs for 17,572 shares of our common stock in 2022. This expense was accounted for as stock-based compensation in 2021.

Restricted Stock Units

During the year ended December 31, 2021, we granted restricted stock units (RSUs) related to the future issuance of 457,593 shares of our common stock as follows:

- Pursuant to agreements with our Executive team and certain other employees, a portion of their base compensation is paid in RSUs that are granted ratably over the year and vest quarterly. During 2021, we granted RSUs for the future issuance of a total of 144,457 shares of common stock under these agreements. At December 31, 2021, all of these RSUs were vested, but must meet distribution requirements before any shares of common stock will be issued.
- We also granted RSUs to certain other employees and consultants. These awards were communicated via employment letters or consulting agreements. During 2021, we granted RSUs for the future issuance of 110,206 shares of common stock under these agreements. At December 31, 2021, 6,250 of these have vested but must meet distribution requirements before any shares of common stock will be issued, and pursuant to consulting agreements, RSUs for 14,000 shares of common stock vested and were issued.
- On July 1, 2021, we granted RSUs for the future issuance of 202,930 shares of common stock to our employees, 4,000 of which were forfeited upon one employee's voluntary termination of employment. Of the 198,930 RSUs remaining, RSUs for the future issuance of 79,572 shares of common stock contain a service condition that requires continued employment over a two-year period. RSUs for the future issuance of 39,786 shares of common stock vest on July 1, 2022 and the remaining vest on July 1, 2023. RSUs for the future issuance of 119,358 shares of common stock vest upon meeting the following performance criteria: (i) RSUs for the future issuance of 39,786 shares of common stock vest upon the completion of the interim analysis of Cohorts 1 and 2 for our PCS6422 Phase 1B clinical trial; (ii) RSUs for the future issuance of 39,786 shares of common stock vest upon the completion of the interim analysis of our PCS499 Phase 2B clinical trial; and (iii) RSUs for the future issuance of 39,786 shares of common stock vest upon the next capital raise(s) totaling a cumulative amount of at least $30 million. On November 1, 2021, we completed cohort 1 and 2 interim analysis for PCS6422 and the RSUs for the future issuance of 39,786 shares of common stock related to this performance condition vested.

The following table summarizes the information about RSUs outstanding for the year ended December 31, 2021.

	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
Shares issued	(14,000)	7.12
Outstanding at December 31, 2021	439,593	$ 7.76
Vested and unissued	(190,493)	$ 7.41
Unvested at December 31, 2021	249,100	$ 8.03

Holders of our vested RSUs have our promise to issue shares of our common stock upon the earlier to occur of the distribution restrictions contained in their Restricted Stock Unit Award Agreement. The distribution restrictions are different (longer) than the vesting schedule, imposing an additional restriction on the holder. Unlike RSAs, while certain 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. The RSUs contain dividend equivalent rights.

Stock Options

We made one stock option grant to a consultant for the purchase of 30,000 shares during the year ended December 31, 2021 and did not grant any stock options during the same period in 2020.

The fair value of each stock option grant was estimated using the Black-Scholes option-pricing model at the date of grant. We lacked company-specific historical and implied volatility information and therefore, we determined our expected stock volatility based on the historical volatility of a publicly traded set of peer companies. The expected volatility of stock option 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, 2020 and 2021:

	Total options Outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2020	176,962	$ 17.93	
Forfeited	(24,156)	16.80	
Outstanding as of December 31, 2020	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
Exercisable (vested) at December 31, 2021	154,398	$ 17.14	3.6

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, 2021 and 2020 was $1,659,909 and $1,221,952, respectively.

No stock options were exercised during the years ended December 31, 2021 or 2020.

Warrants

The following table summarizes our warrant activity during the years ended December 31, 2021 and 2020. We did not issue any warrants during 2020.

	Total warrants outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2020	534,674	$ 18.34	
Warrants granted	-	-	-
Outstanding as of December 31, 2020	534,674	18.34	
Warrants granted	229,268	8.09	
Forfeited	(460,217)	18.31	
Outstanding as of December 31, 2021	303,725	10.66	1.5
Exercisable (vested) at December 31, 2021	278,725	$ 10.90	1.4

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

On January 26, 2021, we issued a warrant for the purchase of 100,000 shares of our common stock to a consultant in exchange for service to be provided in 2021. The warrant expires on January 11, 2023 and has an exercise price of $7.18 per share. There were no vesting conditions associated with this warrant.

On September 1, 2021, we also issued a warrant for the purchase of 50,000 shares of our common stock 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 warrant vests 12,500 options on each of September 30, 2021, December 31, 2021, March 31, 2022, and June 30, 2022, subject to continued service.

We determined the fair value of the warrants granted at the date of grant to be $321,158 and $139,900, respectively, using the Black-Scholes option pricing model 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 $391,108 related to these warrants during the year ended December 31, 2021.

On February 16, 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 7. These warrants are exercisable for cash at $9.30 per share and expire on February 16, 2023.

Note 6 – Paycheck Protection Program Loan

In May 2020, we entered into a $162,459 Paycheck Protection Promissory Note (the "PPP Loan") with the Bank of America. The PPP Loan was made under, and is subject to the terms and conditions of, the PPP which was established under the CARES Act and is administered by the U.S. Small Business Administration. The original terms of the loan was two years with a maturity date of May 5, 2022 and it contained a favorable fixed annual interest rate of 1.00%. Payments of principal and interest on the PPP Loan were deferred for the first six months of the term of the PPP Loan until November 5, 2020. We used the proceeds of our PPP Loan for payroll costs. On January 18, 2021, we applied for full forgiveness of the loan and in August 2021, we received notice from the Small Business Administration that our loan had been forgiven.

Note 7 – Stockholders' Equity

On January 1, 2022, we amended our Certificate of Incorporation increased 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, 2021 or 2020.

Common Stock

During the year ended December 31, 2021, we had the following grants and issuances:

- 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 10).

- 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) filed on July 30, 2021. 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 for aggregate gross proceeds of approximately $179,831 prior to deducting sales commissions.

- 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. The total fair value of these grants was $743,378. We are amortizing this amount over the related contract lives and in accordance with their vesting schedule.

Also 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.

On December 15, 2020, the holders of all our outstanding 2019 Senior 8% Convertible Notes converted their notes and accrued interest into 247,088 shares of our common stock based on a conversion price of $3.60 per share, which, pursuant to the 2019 Senior Note Agreement, is a 10% discount on the public offering price of $4.00 per share received on our underwritten offering in October 2020.

We closed on our underwritten public offering of 4,800,000 shares of common stock for a public offering price of $4.00 per share on October 6, 2020. Net proceeds from the offering were approximately $17.1 million. The following additional transactions occurred in connection with the closing of our underwritten public offering:

- As a result of closing our public offering, we triggered the full ratchet anti-dilution provision of shares sold in PIPE transactions in 2018 and issued 1,156,487 shares of common stock to those stockholders. The full ratchet anti-dilution provisions expired following the closing of the offering.

- DKBK, our line of credit lender, converted $700,000 principal amount outstanding and related accrued interest into 199,537 shares of common stock on October 6, 2020.

- The conditions for finalizing our agreements with Aposense and Elion were met upon the close of our public offering and up-list to the Nasdaq Capital Market. Pursuant to their respective license agreements, we made a cash payment of $100,000 to Elion and issued 625,000 and 825,000 shares of common stock to Aposense and Elion, respectively.

- We issued 250,000 shares of common stock to Yuhan, in addition to the 250,000 shares issued in August, pursuant to the agreement we entered into with them.

- Restricted stock awards for 214,078 shares of our common stock vested on the completion of our public offering and up-list to the Nasdaq Capital Market on October 6, 2020.

We determined the sale of the 2019 Senior Notes triggered the full ratchet anti-dilution provision of common stock we sold in our 2018 Private Placement Transactions. As a result, those stockholders were entitled to 28,971 shares of common stock in the fourth quarter of 2019, which we issued on June 18, 2020. We had accounted for these shares as a deemed dividend payable at their par value. In connection with our 2019 Senior Notes, we issued warrants with a fair value of $197,403, which was recognized as interest expense during the year ended December 31, 2020.

Note 8 – 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, 2021 and 2020 was as follows:

	2021	2020
Basic and diluted net loss per share:		
Net loss	$ (11,427,534)	$ (14,413,788)
Value of the full ratchet anti-dilution shares	-	(4,625,948)
Net loss available to common shareholders	$ (11,427,534)	$ (19,039,736)
Weighted-average number of common shares-basic and diluted	15,319,463	7,499,678
Basic and diluted net loss per share	$ (0.75)	$ (2.54)

We determined the sale of our common stock in our 2020 underwritten offering and the sale of our 2019 Senior Notes, which are convertible into common stock at a conversion rate of $14.28 per share, both triggered the full ratchet anti-dilution provision in 2020 of the common stock we sold in 2018 Private Placement Transactions. We issued 1,156,487 shares of our common stock in connection with triggering the full-ratchet anti-dilution provisions to shareholders who purchased these shares as a result of closing our underwritten offering in 2020. We valued these shares at $4,625,948, which is the closing price of the offering of $4.00 per share. This increased our weighted-average number of shares shown in the table above by 271,743. We also issued 28,971 shares of common stock to these shareholders in June 2020 related to the deemed dividend we recorded at the end of 2019. We determined the value of these shares at $506,993 based on a price per share of $17.50 which represents the closing price per share on October 18, 2019, the last day investors had to rescind their investment.

For purposes of computing our basic and diluted EPS for the year ended December 31, 2020, we increased our net loss available for common shareholders by the fair value of the additional shares issued related to the anti-dilution provision since they did not affect all our common shareholders equally and there were no contingencies related to the issuance of these shares at December 31, 2020.

As described in Note 5, we issued various equity instruments during the years ended December 31, 2021 and 2020 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, 2021 and 2020, 91,109 and 122,782 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, 2021, 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:

	2021	2020
Stock options, unvested RSAs, unvested RSUs and purchase warrants	822,430	816,512

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, and the if-converted method is used to determine the dilutive effect of the 2019 Senior Notes in 2020.

Note 9 – Leases

We lease our office space under an operating lease agreement. This lease does not have significant rent escalation, concessions, leasehold improvement incentives, or other build-out clauses. Further, the lease does not contain contingent rent provisions. We also lease office equipment under an operating lease. 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. Our leases do not provide an implicit rate and, as such, we have used our incremental borrowing rate of 8% in determining the present value of the lease payments based on the information available at the lease commencement date.

Lease costs included in our consolidated statement of operations totaled $94,263 and $97,545 for the years ended December 31, 2021 and 2020, respectively. The weighted average remaining lease terms and discount rate for our operating leases were as follows at December 31, 2021:

Weighted average remaining lease term (years) for our facility and equipment leases	1.3
Weighted average discount rate for our facility and equipment leases	8.00%

Maturities of our lease liabilities for all operating leases were as follows as of December 31, 2021:

2022	$	75,969
2023		6,228
2024		1,557
Total lease payments		83,754
Less: Interest		(5,291)
Present value of lease liabilities		78,463
Less: current maturities		(71,078)
Non-current lease liability	$	7,385

Note 10 – License Agreements

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.

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).

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 the Processa portfolio, and we paid $100,000 cash and issued 825,000 shares of our common stock to Elion. Such shares are subject to a lock-up, with 50% of such shares released from such lock up after six months and the remaining 25% tranches to be released following 9 months and 12 months, respectively.

As part of the Elion License Agreement, we have 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. We believe the payment of these amounts is probable and represent seller financing since the only condition related to their payment is the passage of time, which management does not believe is substantive. We valued the shares at $4.00 per share based on the underwritten public offering price on October 6, 2020, which is the date the conditions precedent in the license agreement were met.

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. On October 6, 2021, 100,000 shares were issued to Elion for the first milestone payment. 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.

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).

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 the Processa portfolio, and we issued 625,000 shares of our common stock to Aposense. Such shares are subject to a lock-up, with 40% of such shares released from such lock up after six months and the remaining two 30% tranches to be 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.

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 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. There was no change in the total shares issued and outstanding of 5,039,033. 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 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 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 11 – 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 being reimbursed in our consolidated statement of operations. We recorded $126,324 and $119,001 of reimbursements during the years ended December 31, 2021 and 2020, respectively. No amounts were due from CorLyst at December 31, 2021 and 2020. In September 2020, CorLyst prepaid shared expenses to us for the fourth quarter of 2020 through the second quarter of 2021. At December 31, 2021 and 2020, we recognized $1,772 and $69,858 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.

At December 31, 2020, we had $154,730 due from certain employees for federal, state and local income taxes related to the restricted stock awards that vested in October 2020. We did not have a similar receivable at December 31, 2021.

Note 12 – Commitments and Contingencies

Purchase Obligations

We enter into contracts in the normal course of business with CROs 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. At December 31, 2021, we are contractually obligated for up to approximately $5.3 million of future services under the agreements with the CROs, but our actual contractual obligations will vary depending on the progress and results of the clinical trials.

Note 13 – Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of our cash and cash equivalents. We utilize only well-established banks and financial institutions with high credit ratings. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by our banks at December 31, 2021, exceeded FDIC limits.

Note 14 – Subsequent Events

Lincoln Park Capital Fund, LLC Purchase Agreement

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, $0.0001 par value per share, 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. 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.

Beginning on March 23, 2022, 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 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 in no case exceed 3,142,430 shares (subject to proportional adjustments for stock splits, reverse stock splits and similar events as described above), which number of shares 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.

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.

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, 2021, 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, 2021 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, 2021. 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, 2021, 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

Other than those noted below, 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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Material Weaknesses Remediation

In our Annual Report on Form 10-K for our fiscal year ended December 31, 2020, management identified material weaknesses in internal control over financial reporting. During 2021, we took steps to address the internal control deficiencies that contributed to the material weaknesses, including:

- Expanded our risk assessment processes and developed an improved testing plan, along with the related documentation necessary for us to determine that we design, implement and maintain adequate controls over our financial processes and that our controls and procedures are operating effectively;
- Documented and formally assessed our accounting and financial reporting policies and procedures, and implemented additional segregation of duties in key functions including changes to our procurement and cash disbursement processes such as implementing centralized vendor invoice processing procedures and Bank of America's CashPro disbursement system; and
- Improved, and plan to continue to improve, our policies, procedures and process documentation. We adopted several new corporate policies that are available on our website, including our Whistleblower Policy.

We believe implementation of the above remediated our previously reported material weaknesses. However, as part of our commitment to maintaining a strong internal control environment, we plan to continue to strengthen our internal controls over financial reporting during 2022 as follows:

- We recently hired an additional member to our finance team with appropriate experience and GAAP technical accounting expertise, which will allow us to further increase our segregation of duties and expand our review and monitoring controls; and
- We plan to engage a third-party provider to strengthen our internal controls for compliance with the Sarbanes-Oxley Act.

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 2021 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for the Company's 2022 Annual Meeting of Stockholders ("2022 Proxy Statement") is incorporated herein by reference to our 2022 Proxy Statement. The 2022 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 2022 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 2022 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 2022 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 2022 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 16, 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 16, 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 16, 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 16, 2020)
4.1	Specimen of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form S-1 filed on September 16, 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 16, 2020)
4.4	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed herewith)
10.1+	Amended and Restated 2011 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Form S-1 filed on September 16, 2020)
10.2	License Option Agreement with CoNCERT (incorporated by reference to Exhibit 10.2 to Form S-1 filed on September 16, 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 16, 2020)
10.4+	Employment Agreement dated September 5, 2018, between Processa and James Stanker (incorporated by reference to Exhibit 10.4 to Form S-1 filed on September 16, 2020)
10.5+	Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.5 to Form S-1 filed on September 16, 2020)
10.6	Employment Agreement dated October 6, 2020, between Processa and R. Michael Floyd (incorporated by reference to Form 8-K, filed October 13, 2020)
10.7	License Agreement with Aposense, Ltd. dated May 24, 2020 (incorporated by reference to Exhibit 10.9 to Form S-1 filed on September 16, 2020)
10.8	License Agreement with Yuhan Corporation (incorporated by reference to Exhibit 10.11 to Form S-1 filed on September 16, 2020)
10.9	License Agreement with Elion Oncology, Inc. (incorporated by reference to Exhibit 10.13 to Form S-1 filed on September 16, 2020)
10.10	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)
10.11	License Agreement with Ocuphire Pharma, Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed June 17, 2021)
10.12	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)
10.13	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)
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, 2022

By: */s/ James Stanker*
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: March 30, 2022

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	Chief Executive Officer and Director	March 30, 2022
/s/ James Stanker James Stanker	Chief Financial Officer	March 30, 2022
/s/ Khalid Islam Khalid Islam	Director	March 30, 2022
/s/ Geraldine Pannu Geraldine Pannu	Director	March 30, 2022
/s/ Virgil Thompson Virgil Thompson	Director	March 30, 2022
/s/ Justin Yorke Justin Yorke	Director	March 30, 2022

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2021, Processa Pharmaceuticals, Inc. ("we" or "our") had one class of securities, common stock, par value $0.001 per share ("common stock"), registered under Section 12 of the Securities Exchange Act of 1934, as amended. The following description of our common stock is a summary and is subject to, and is qualified in its entirety by reference to, the provisions of our amended and restated certificate of incorporation and amended and restated bylaws. You should also refer to the copies of our amended and restated certificate of incorporation and amended and restated bylaws which have been filed with this Annual Report on Form 10-K.

We have the authority to issue an aggregate of 50,000,000 shares of $0.0001 par value common stock and 1,000,000 shares of $0.0001 par value preferred stock. Our common stock is listed on the Nasdaq Capital Market under the symbol "PCSA." The following is a summary of our common stock:

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

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

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

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

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

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, 2022, relating to the consolidated financial statements of Processa Pharmaceuticals, Inc. for the years ended December 31, 2021 and 2020 included in the Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. for the year ended December 31, 2021.

/s/ BD & Co.

Owings Mills, MD
March 30, 2022

Exhibit 31.1

Certification Pursuant to 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, 2022

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

Exhibit 31.2

Certification Pursuant to 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, 2022

/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, 2021 (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, 2022

/s/ James Stanker
James Stanker
Chief Financial Officer
(Principal Financial and Accounting Officer)
March 30, 2022

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.

A signed original of this written statement required by § 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.