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

FORM 10-K

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

For the fiscal year ended December 31, 2025

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from _____ to _____

Commission File Number 001-39531

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.)

601 21st Street, Suite 300 Vero Beach, FL 32960
(Address of Principal Executive Offices, Including Zip Code)

(772) 453-2899
(Registrant's Telephone Number, Including Area Code)

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

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

Securities registered pursuant to Section 12(g) of the Act: **None**.

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	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 management's assessment of the effectiveness of its internal controls over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☐

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2025, 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 $8.1 million.

The number of outstanding shares of the registrant's common stock as of March 13, 2026 was 2,660,039.

DOCUMENTS INCORPORATED BY REFERENCE

Information required in response to Part III of this Annual Report on Form 10-K is hereby incorporated by reference from portions of the registrant's proxy statement for its 2026 annual meeting of stockholders. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2025.

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GLOSSARY OF CERTAIN SCIENTIFIC TERMS

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

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

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

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

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

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

"CMO" means Contract Manufacturing Organization.

"CRO" means Contract Research Organization.

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

"EMA" means the European Medicines Agency.

"FDA" means the Food and Drug Administration.

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

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

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

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our ability to obtain funding for our future clinical trials, preclinical activities and our operations;
- our ability to meet obligations under our license agreements;
- our ability to successfully implement and execute our digital asset treasury strategy, fluctuations in the market price of stablecoin, Chiliz (CHZ) and potentially other digital assets, tokens, and rights of a similar nature ("Digital Assets") that we may acquire;
- the risks of holding Digital Assets on our balance sheet;
- our limited operating history in the digital asset business, risks associated with the current or future regulation of Digital Assets;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- our ability to obtain and maintain regulatory approval of our product;
- the potential market size, opportunity and growth potential for our product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize our product candidates, if approved;

- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;

- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the initiation, timing, progress and results of clinical trials and pre-clinical studies for our NGC drugs;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory filings and approvals and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates by physicians, patients, third-party payors and others in the medical community, if approved;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our financial performance; and
- other risks and uncertainties, including those described under part I, Item 1A. Risk Factors of this Annual Report.

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

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

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

Part I

Item 1. Business

Corporate Information

Processa Pharmaceuticals, Inc. ("Processa," "we" or the "Company") was incorporated under the laws of the State of Delaware on March 29, 2011. Our principal executive office is located at 601 21st Street, Suite 300 Vero Beach, FL 32960. Our telephone number is (772) 453-2899.

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), as well as our Code of Ethics and Code of Conduct. The SEC also maintains a website which provides online access to reports and other information regarding registrants that file electronically with the SEC at: www.sec.gov.

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

Overview

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

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

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

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

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

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

  In 2025, we continued our Phase 2 trial of NGC-Cap in advanced or metastatic breast cancer patients. We have enrolled and dosed the 20 patients required for the planned first formal interim analysis, which is expected to be completed in the first half of 2026.

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

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

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

  We continue to define and explore preclinical and clinical development strategies as well as opportunities to support future development.

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

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

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

- PCS499 is a drug that can be used to treat unmet medical need conditions caused by multiple pathophysiological changes. We are presently defining the development plan for the use of PCS499 in a primary glomerular disease. We believe that PCS499 could be successfully developed in a primary glomerular disease such as focal segmental glomerulosclerosis, or FSGS, and IgA. We met with the FDA to discuss the development program including the next study design. A pathway for the program has been established to include a Phase 2 study followed by a single Phase 3 study. We continue to explore potential partnership opportunities to take the drug to approval.

Our Strategies

Clinical Pipeline Strategy

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

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

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

Clinical Risk

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

Regulatory Risk

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

Commercial Risk

Since the underlying drugs are already heavily used in cancer therapy, we believe that, if our clinical trials are successful in demonstrating better safety-efficacy profile, our NGC therapies will be rapidly and broadly adopted. Why would an oncologist use the older, more toxic drug if the efficacy is no different?

Summary

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

Operating Digital Asset Treasury Strategy

On August 7, 2025, we announced that we were evaluating corporate digital asset treasury strategies as part of our broader financial and growth objectives. We believe that strategic engagement with emerging financial technologies, including select digital assets such as CHZ and other cryptocurrencies, tokens, and rights of a similar nature (collectively referred to as, "Digital Assets") with potential yield-generating capabilities, may offer novel avenues to diversify our capital base and enhance financial flexibility, while providing an opportunity for long-term value creation. One of the potential benefits of a digital asset treasury strategy is the potential of blockchain-based assets to contribute meaningfully to the funding of our clinical development programs.

As of March 13, 2026, we had $1.4 million in CHZ tokens, for which we paid $1.35 million and had an unrealized gain of approximately $77,000. Subject to market conditions, we expect to issue equity or debt securities or engage in other capital raising transactions with the objective of using all or a portion of the proceeds to purchase additional Digital Assets.

Regulatory Science Approach

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

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

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

Our Drug Pipeline

Our oncology pipeline currently consists of NGC-Cap and NGC-Iri (also identified as PCS6422 and PCS11T, respectively) and two non-oncology drugs (PCS12852 and PCS499). We are exploring options for our non-oncology drugs, which may include out-licensing or partnership opportunities. The status of our drug pipeline is set forth below:

NGC-Cap

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

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

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

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

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

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

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

The Phase 1B trial completed enrollment in early 2024 and the last subject completed the study in July 2024. Data from the Phase 1B showed, that although 5-FU exposure at therapeutic doses was 5 to 10 fold greater than for monotherapy, adverse events from 5-FU catabolites were minimal while anabolite associated adverse events for the highest dose cohorts were similar to those reported for monotherapy. In these evaluable subjects with refractory or intolerant cancer, the combination of PCS6422 and capecitabine showed an efficacy with a partial response rate of 11%, stable disease rate of 44%, and a median progression free survival of 93 days. This safety and efficacy data supports the inclusion of the 2 dosage regimens of PCS6422 in combination with capecitabine (from Cohort 3 [75 mg BID] and Cohort 4 [225 mg BID]) in the Phase 2 study. The safety review committee determined the MTD and RP2D as (capecitabine 450 mg/day; 225 mg BID), the Cohort 4 dosing regimen.

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

The IND for the evaluation of NGC-Cap for the treatment of breast cancer was cleared by the FDA on July 24, 2024, and allowed for the Phase 2 trial to be initiated. The Phase 2 study (NCT06568692) is a global multicenter, open-label, adaptive designed safety-efficacy trial comparing two different doses of NGC-Cap to FDA-approved monotherapy capecitabine in approximately 60 to 90 patients with advanced or metastatic breast cancer. The trial is designed to evaluate the safety-efficacy profile of NGC-Cap versus monotherapy capecitabine, to determine the potential optimal dosage regimens of NGC-Cap as required by the FDA Project Optimus Initiative and to evaluate the possibility of personalizing NGC-Cap therapy. The first patient in the trial was dosed on October 2, 2024, and we recently enrolled and dosed our 20th patient. We will conduct our first formal interim analysis to compare safety and preliminary efficacy outcomes between the NGC-Cap and Mono-Cap treatment arms, which is expected to be completed in the first half of 2026. Enrollment in the study is currently on temporary hold until the interim analysis from the 20 patients is completed. Once the data is reviewed the potential addition of a third treatment arm (a second dosage regimen of NGC-Cap) may be added and enrollment of the study will reopen.

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

NGC-Iri

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

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

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

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

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

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

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

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

Non-Oncology Pipeline for Out-licensing or Partnership

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

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

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

On June 17, 2025, we entered into a binding term sheet ("Term Sheet") with Intact Therapeutics ("Intact") granting Intact the exclusive option to license PCS12852, a highly specific and potent 5HT4 irreversible agonist that is Phase 2B ready as potentially the first meaningful treatment for gastroparesis patients We received $50,000 from Intact during their due diligence review, of which $30,000 was provided to Yuhan in accordance with our existing license agreement. On February 12, 2026, the Term Sheet with Intact expired without execution of a definitive license agreement.

In connection with the Term Sheet, Yuhan Corporation executed Amendment No. 1 to our existing license agreement dated August 19, 2020 (the "Yuhan Agreement"), effective June 11, 2025, which, among other things, extended the deadline to dose the first patient in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial from 48 months to 108 months from the effective date of the original agreement.

We are actively speaking to other potential partners to advance the clinical development of PCS12852.

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

  PCS499 was previously evaluated in a Phase 2 trial for the treatment of diabetic nephropathy and successfully demonstrated a positive change in proteinuria. Unfortunately, the primary endpoint for diabetic nephropathy was not proteinuria, so the development was discontinued.

  However, within the last couple of years, FDA has approved drugs based on the change in proteinuria for the primary endpoint in glomerular disease such as IgA. Since diabetic nephropathy is not a primary glomerular disease, diabetic nephropathy is still not a viable indication given the endpoint required and the potential size/cost of a study. In evaluating the previous data, we believe that PCS499 could be successfully developed in a primary glomerular disease such as focal segmental glomerulosclerosis, or FSGS, and IgA. The use of proteinuria for the primary endpoint in FSGS has been accepted by FDA in our protocol discussions. We, therefore, are designing the FSGS development program with a Phase 2 and Phase 3 trial per our discussions with the FDA.

Market Overview

Capecitabine

Market Drivers:

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

Market Size and Growth:

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

Irinotecan / SN-38

Market Size and Growth:

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

Market Segmentation:

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

Key Market Drivers:

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

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Our Team

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

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

Intellectual Property

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

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

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

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

	Sun Pharmaceuticals	Yuhan	Aposense	Elion	Total
U.S. patents	9	6	3	1	18

A provisional patent for NGC-Cap has been filed.

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

License Agreements

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

License Agreement with Elion Oncology, Inc.

On August 23, 2020, we entered into a condition precedent License Agreement with Elion Oncology ("Elion License Agreement"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS6422 globally.

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.

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

License Agreement with Aposense, Ltd.

On May 24, 2020, we entered into a condition precedent License Agreement with Aposense, Ltd. ("Aposense License Agreement"), pursuant to which we were granted Aposense's patent rights and Know-How to develop and commercialize their next generation irinotecan cancer drug, PCS11T. The Aposense License Agreement provides us with an exclusive worldwide license (excluding China), to research, develop and commercialize products comprising or containing PCS11T.

We will pay Aposense development and regulatory milestone payments (up to $3.0 million per milestone) upon the achievement of certain milestones, which primarily consist of having a drug indication approved by a regulatory authority in the United States or another country. In addition, we will pay Aposense one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any sales milestone payments or royalties we receive with Aposense based on any sub-license agreement we may enter.

License Agreement with Yuhan Corporation

On August 19, 2020, we entered into a License Agreement with Yuhan Corporation ("Yuhan License Agreement"), pursuant to which we acquired an exclusive license to develop, manufacture and commercialize PCS12852 globally, excluding South Korea. 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. The milestones primarily consist of dosing a patient in pivotal trials or having a drug indication approved by a regulatory authority in the United States or another country. In addition, we must pay Yuhan one-time sales milestone payments based on the achievement during a calendar year of one or more thresholds for annual sales for products made and pay royalties based on annual licensing sales. We are also required to split any milestone payments received with Yuhan based on any sub-license agreement we may enter.

We are required to use commercially reasonable efforts, at our sole cost and expense, in conjunction with a joint Processa-Yuhan Board to oversee such commercialization efforts, to research, develop and commercialize products in one or more countries. 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 Sun Pharmaceuticals Industries Limited (formerly known as CoNCERT Pharmaceuticals, Inc.)

On March 19, 2018, we entered into a Licensing Agreement with CoNCERT Pharmaceuticals, Inc. (which was later acquired by Sun Pharmaceutical Industries Limited ("Sun Pharma")) ("Sun Pharma License Agreement") for the PCS499 compound.

The Sun Pharma License Agreement provides us with an exclusive (including as to Sun Pharma) royalty-bearing license to Sun Pharma'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 Sun Pharma 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 Sun Pharma 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. Sun Pharma 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 Sun Pharma 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 Sun Pharma Agreement, either party may terminate the agreement provided such breach is not cured in the 90 days following written notice of the breach (which is shortened to 15 days for a payment breach). In addition, either party may terminate the agreement upon an assignment for the benefit of creditors or the filing of an insolvency proceeding by or against the other party that is not dismissed within 90 days of such filing.

Manufacturing and Clinical Supplies

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

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

Competition

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

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

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

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

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

For PCS499, there are currently no FDA-approved drugs for the treatment of patients with FSGS.

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

Government Regulation

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

U.S. Government Regulation

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

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

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

Pre-clinical studies

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

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

Clinical trials

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

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

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

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

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

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

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

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

Marketing Approval

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

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

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

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

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

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

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

Orphan drug designation

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

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

Expedited review and approval

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

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

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

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

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

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

Post-approval requirements

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

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

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

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

- restrictions on the marketing or manufacturing of the product;
- complete withdrawal of the product from the market or product recalls;

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

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

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

Healthcare Reform

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

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

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

Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These enhanced subsidies expired on December 31, 2025. The Trump administration has taken steps to undo certain Biden-era executive orders, including those intended to lower drug costs for beneficiaries, and to freeze funding for federal programs. While the administration's initial freeze has since been rescinded, the administration is likely to make other attempts to reduce federal program expenditures and can generally be expected to oppose increases in ACA and Medicaid enrollment. The IRA also eliminated the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how such challenges, the healthcare reform measures of the Biden administration and the potential rollback of such reform measures by the Trump administration will impact the ACA and our business.

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

Other Regulatory Matters

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

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

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

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

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

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

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

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

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

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

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

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

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

U.S. Patent-Term Restoration and Marketing Exclusivity

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

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

European Union Drug Development

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

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

European Union Drug Review and Approval

In the European Economic Area (EEA), which is comprised of the 27 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.

Digital Assets

The laws and regulations applicable to Digital Assets are evolving and subject to interpretation and change. Governments around the world have reacted differently to Digital Assets; certain governments have deemed them illegal, and others have allowed their use and trade without restriction, while in some jurisdictions, such as the U.S., Digital Assets are subject to overlapping, uncertain and evolving regulatory requirements.

As Digital Assets have grown in both popularity and market size, the U.S. Executive Branch, Congress and a number of U.S. federal and state agencies, including the Financial Crimes Enforcement Network, the Commodity Futures Trading Commission ("CFTC"), the SEC, the Financial Industry Regulatory Authority, the Consumer Financial Protection Bureau, the Department of Justice, the Department of Homeland Security, the Federal Bureau of Investigation, the Internal Revenue Service ("IRS") and state financial regulators, have been examining the operations of digital asset networks, digital asset users and digital asset exchanges, with particular focus on the extent to which Digital Assets can be used to violate state or federal laws, including to facilitate the laundering of proceeds of illegal activities or the funding of criminal or terrorist enterprises, and the safety and soundness and consumer-protective safeguards of exchanges or other service-providers that hold, transfer, trade or exchange Digital Assets for users. Many of these state and federal agencies have issued consumer advisories regarding the risks posed by Digital Assets to investors. In addition, federal and state agencies, and other countries have issued rules or guidance regarding the treatment of digital asset transactions and requirements for businesses engaged in activities related to Digital Assets.

Depending on the regulatory characterization of a particular Digital Asset, our digital asset strategy may be subject to regulation by one or more regulators in the United States and globally. Ongoing and future regulatory actions may alter, to a materially adverse extent, the nature of Digital Assets markets, the participation of industry participants, including service providers and financial institutions in these markets, and our ability to pursue our digital asset strategy. Additionally, U.S. state and federal and foreign regulators and legislatures have taken action against industry participants, including digital assets businesses, and enacted restrictive regimes in response to adverse publicity arising from hacks, consumer harm, or criminal activity stemming from digital assets activity. U.S. federal and state energy regulatory authorities are also monitoring the total electricity consumption of digital asset mining, and the potential impacts of digital asset mining to the supply and dispatch functionality of the wholesale grid and retail distribution systems. Many state legislative bodies have passed, or are actively considering, legislation to address the impact of digital asset mining in their respective states.

The CFTC takes the position that some Digital Assets fall within the definition of a "commodity" under the Commodity Exchange Act (the "CEA"). Under the CEA, the CFTC has broad enforcement authority to police market manipulation and fraud in spot digital assets markets in which we may transact. Beyond instances of fraud or manipulation, the CFTC generally does not oversee cash or spot market exchanges or transactions involving digital asset commodities that do not utilize margin, leverage, or financing. In addition, CFTC regulations and CFTC oversight and enforcement authority apply with respect to futures, swaps, other derivative products and certain retail leveraged commodity transactions involving digital asset commodities, including the markets on which these products trade.

The SEC and its staff have taken the position that certain Digital Assets fall within the definition of a "security" under the U.S. federal securities laws. Public statements made by senior officials and senior members of the staff at the SEC indicate that the SEC does not consider Bitcoin to be a security under the federal securities laws. However, such statements are not official policy statements by the SEC and reflect only the speakers' views, which are not binding on the SEC or any other agency or court and cannot be generalized to any other Digital Assets.

On January 23, 2025, President Trump issued an executive order titled, Strengthening American Leadership in Digital Financial Technology. While the executive order did not mandate the adoption of any specific regulations, the executive order identifies certain key objectives to guide agencies involved in crypto regulation, including (i) protecting the sovereignty of the United States dollar by promoting the development of United States dollar-backed stablecoins, (ii) providing regulatory clarity and certainty built on technology-neutral regulations for individuals and firms involved in digital assets, including through well-defined jurisdictional regulatory boundaries, and (iii) taking measures to protect Americans from the risks of Central Bank Digital Currencies. To achieve these objectives, the executive order established a working group on digital asset markets within the National Economic Council, comprised of representatives from key federal agencies, with a tight timeline for examining existing regulations and proposing a new regulatory framework. This working group released a report on July 30, 2025 that recommended regulatory and legislative proposals to advance the policies established in the executive order. The SEC also established a Crypto Task Force in furtherance of these objectives. Among other things, the Crypto Task Force is charged with helping to draw clear regulatory lines and to appropriately distinguish securities from non-securities. The work of the Crypto Task Force is in its early stages and it is not yet clear whether it will result in material changes to the existing regulatory framework of digital assets. In addition, Congress has considered legislation to establish additional regulation and oversight of the digital asset markets. The GENIUS Act (Guiding and Establishing National Innovation for US Stablecoins Act), which regulates payment stablecoins, was signed into law in July 2025. The Digital Asset Market Clarity Act of 2025 (H.R. 3633), which establishes a framework for digital assets, passed the U.S. House of Representatives in July 2025. This bill distinguishes between digital commodities and digital securities, and provides the CFTC with jurisdiction to oversee digital commodities, exchanges and brokers. The U.S. Senate is also considering its own legislation to establish a framework for digital asset markets.

Human Capital

As of March 13, 2026, we had 12 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 Chief Executive Officer, George Ng and President of Research and Development, David Young, Pharm.D., Ph.D. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements may still allow these employees to leave our employment at any time, for or without cause. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical and scientific personnel.

Item 1A. Risk Factors

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

SUMMARY RISK FACTORS

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

Risks Related to Our Financial Position and Need for Additional Capital

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

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

- Our licenses are subject to termination by the licensor in certain circumstances and any termination of a license agreement would result in a loss of important rights and have a material adverse impact on our business and prospects.
- We currently do not have, and may never develop, any FDA-approved, licensed or commercialized products.
- We depend entirely on the successful development of our product candidates, which have not yet demonstrated efficacy for their target indications in clinical trials. We may never be able to demonstrate efficacy for our product candidates, thus preventing us from licensing, obtaining marketing approval by any regulatory agency, and/or commercializing our product(s).
- We must successfully complete clinical trials for our product candidates before we can apply for marketing approval.
- We have little corporate history of conducting clinical trials. Our planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- Disruptions at the FDA and other government agencies could hinder new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.
- Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully license or commercialize the product and the revenue that we generate from its sales, if any, may be limited.
- We are completely dependent on third parties to manufacture our product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.
- Even if we obtain marketing approval for any of our product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expenses.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.
- Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

- We could face competition from other biotechnology and pharmaceutical companies, and our operating results would suffer if we fail to innovate and compete effectively.
- We rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize any of our product candidates and our business would be substantially harmed.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- Even though we may apply for orphan drug designation for a product candidate, we may not be able to obtain orphan drug marketing exclusivity.
- Although we may pursue expedited regulatory approval pathways for a product candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development, regulatory review or approval process.
- Third-party coverage and reimbursement, health care cost containment initiatives and treatment guidelines may constrain our future revenues.
- Legal, regulatory and legislative changes with respect to reimbursement, pricing and contracting may adversely affect our business and future prospects.
- We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.
- If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.
- We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.
- Changes in U.S. and international trade policies, particularly with respect to China, Europe and India may adversely impact our business and operating results.

Risks Related to our Digital Asset Treasury Strategy

- Investments in Digital Assets are substantially speculative and have a significant risk of resulting in a loss compared to other forms of investment.
- Digital Assets have historically experienced, and are expected to continue to experience, high price volatility which may influence our financial results and the market price of our common stock.
- We may be unable to successfully implement our Digital Asset Strategy.
- Our Digital Asset holdings will be less liquid than existing cash and cash equivalents and may not be able to serve as a source of liquidity to the same extent as cash and cash equivalents.
- If we or our third-party service providers experience a security breach or cyberattack and unauthorized parties obtain access to our Digital Assets, we may lose some or all of our Digital Assets and our financial condition and results of operations could be materially adversely affected.
- We face risks relating to the custody of our Digital Assets, including the loss or destruction of private keys required to access our Digital Assets, and cyberattacks or other data loss relating to our Digital Assets.
- Our custodially-held Digital Assets may become part of the custodian's insolvency estate if one or more of our custodians enters bankruptcy, receivership or similar insolvency proceedings.
- Digital Assets held by us are not subject to FDIC or SIPC protections.
- Digital Assets are novel assets, and are subject to significant legal, commercial, regulatory, and technical uncertainty.
- We could be subject to legal or regulatory action, including fines, in the event the SEC, a foreign regulatory authority, or a court were to determine that a digital asset held by us is a "security" under applicable laws.

Risks Relating to Our Intellectual Property Rights

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

General Company-Related Risks

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

Risks Related to Ownership of Our Common Stock

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

Risks Related to Our Financial Position and Need for Additional Capital

We need to raise additional capital to fund our operations.

We have incurred recurring losses since inception and had an accumulated deficit of approximately $100.8 million at December 31, 2025. At December 31, 2025, we had cash and cash equivalents totaling $5.5 million and prepaid expenses with the clinical research organizations of our Phase 2 trials of $1.0 million. We believe we will need to raise additional capital in the second quarter of 2026 under our current business plan. We will need to raise additional capital to fund our operations and continue our planned development of our NGC drugs in the first half of 2026.

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

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

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

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

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

We have limited cash resources and will require additional financing.

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

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

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

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

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

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

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

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

During the year ended December 31, 2025, we received $20,000 for the binding term sheet with Intact, net of amounts paid to Yuhan in accordance with our licensing agreement. We had no other revenue during the year ended December 31, 2025 or in prior years, and do not have any revenue under contract or any immediate sales prospects. Our primary uses of cash are to fund our planned clinical trials, research and development expenditures and for operating expenses. Cash used to fund operating expenses is impacted by the timing of when we incur and pay these expenses. Our consolidated financial statements have been prepared using U.S. GAAP, and are based on the assumption that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. We face certain risks and uncertainties that are present in many emerging pharmaceutical companies regarding product development, limited working capital, recurring losses and negative cash flow from operations, future profitability, ability to obtain future capital, protection of patents, technologies and property rights, competition, rapid technological change, navigating the domestic and major foreign markets' regulatory and clinical environment, recruiting and retaining key personnel, dependence on third party manufacturing organizations, third party collaboration and licensing agreements, lack of sales and marketing activities. We currently have no customers or pharmaceutical products to sell or distribute. These risks and other factors raise substantial doubt about our ability to continue as a going concern.

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

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

As of December 31, 2025, we had net operating loss (NOL) carryforwards of approximately $54.8 million for federal and state income tax available to offset future taxable income, and federal and state research and development tax credits of approximately $1.2 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended (Section 382). NOL carryforwards prior to 2018 will expire in 2037 if not utilized.

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

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

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Disruptions at the FDA and other government agencies could hinder new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, staffing cuts, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors.

Recent actions by the United States federal government have caused concern in the industry that the FDA will experience staffing reductions and budget cuts. In addition, some senior FDA employees with responsibility for regulation of drugs and biologics have already resigned from the FDA. There are also reports that the United States federal government intends to request Congress reduce FDA funding in upcoming budgets. Such funding cuts may also delay the development and approval of our products.

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

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

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in treatment guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. The law also imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA), into law which, among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These enhanced subsidies expired on December 31, 2025. The Trump administration has taken steps to undo certain Biden-era executive orders, including those intended to lower drug costs for beneficiaries, and to freeze funding for federal programs. While the administration's initial freeze has since been rescinded, the administration is likely to make other attempts to reduce federal program expenditures and can generally be expected to oppose increases in ACA and Medicaid enrollment. The IRA also eliminated the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how such challenges, the healthcare reform measures of the Biden administration and the potential rollback of such reform measures by the Trump administration will impact the ACA and our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China. China and the United States have each imposed tariffs indicating the potential for further trade barriers, including the U.S. Commerce Department adding numerous Chinese entities to its "unverified list," which requires U.S. exporters to go through more procedures before exporting goods to such entities, and China imposing aggressive retaliatory measures. Further, the current administration has imposed tariffs on foreign imports into the United States from China, negotiated and entered into a new trade agreement with India, and has imposed a new 10% global tariff to replace certain previous tariffs struck down by the U.S. Supreme Court in February 2026. It is unknown whether and to what extent new tariffs, export controls, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect our ability to commercialize our product candidates if approved, the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

Risks Related to our Digital Asset Treasury Strategy

Investments in Digital Assets are substantially speculative and have a significant risk of resulting in a loss compared to other forms of investment.

While all investments entail a risk of loss of capital, investments in digital assets such as CHZ and other cryptocurrencies, tokens, and rights of a similar nature (collectively referred to as, "Digital Assets") should be considered substantially more speculative and significantly more likely to result in a loss, including a total loss of capital, than many other forms of investment. The investment characteristics of Digital Assets differ from those of many traditional currencies, commodities, and securities. A particular Digital Asset's status as a "security" in any relevant jurisdiction is subject to a high degree of uncertainty, and if we are unable to properly characterize a Digital Asset, we may be subject to regulatory scrutiny, investigations, fines, and other penalties, which may adversely affect our business, results of operations and/or financial condition.

The legal test for determining whether any given Digital Asset is a security is a highly complex, fact-driven analysis and the outcome is difficult to predict. The SEC generally does not provide advance guidance or confirmation on the status of any particular asset as a security. The classification of a Digital Asset as a security under applicable law has wide-ranging implications for the regulatory obligations that flow from the offer, sale and trading of such assets. For example, a Digital Asset that is a security in the United States may generally only be offered or sold in the United States pursuant to a registration statement filed with the SEC or in an offering that qualifies for an exemption from registration. Persons that effect transactions in assets that are securities in the United States may be subject to registration with the SEC as a "broker" or "dealer." Platforms that bring together purchasers and sellers to trade Digital Assets that are securities in the United States are generally subject to registration as national securities exchanges, or must qualify for an exemption, such as by being operated by a registered broker-dealer as an alternative trading system ("ATS"), in compliance with rules for ATSs. Persons facilitating clearing and settlement of securities may be subject to registration with the SEC as a clearing agency. Foreign jurisdictions may have similar licensing, registration, and qualification requirements. As a result, certain Digital Assets may be deemed to be a "security" under the laws of some jurisdictions but not others. Further, various foreign jurisdictions may, in the future, adopt additional laws, regulations, or directives that affect the characterization of Digital Assets as "securities."

We could be subject to legal or regulatory action in the event the SEC, a foreign regulatory authority, or a court were to determine that a digital asset held by us is a "security" under applicable laws.

Digital Assets have historically experienced, and are expected to continue to experience, high price volatility which may influence our financial results and the market price of our common stock.

Digital Assets have historically experienced, and are expected to continue to experience, high price volatility. Such price fluctuations are likely to influence our financial results and the market price of our common stock. Our financial results and the market price of our common stock would be adversely affected, and our business and financial condition would be negatively impacted, if the price of Digital Assets we hold decrease substantially, including as a result of:

- decreased user and investor confidence in Digital Assets, including due to the various factors described herein;
- investment and trading activities, such as (i) trading activities of highly active retail and institutional users, speculators, miners and investors, (ii) actual or expected significant dispositions of digital assets by large holders, and (iii) actual or perceived manipulation of the spot or derivative markets for digital assets;
- negative publicity, media or social media coverage, or sentiment due to events in or relating to, or perception of, Digital Assets or the broader Digital Assets industry;
- changes in consumer preferences and the perceived value or prospects of Digital Assets;
- competition from other Digital Assets that exhibit better speed, security, scalability, or energy efficiency, that feature other more favored characteristics, that are backed by governments, including the U.S. government, or reserves of fiat currencies, or that represent ownership or security interests in physical assets;
- disruptions, failures, unavailability, or interruptions in service of trading venues for Digital Assets;
- the filing for bankruptcy protection by, liquidation of, or market concerns about the financial viability of digital asset custodians, trading venues, lending platforms, investment funds, or other Digital Asset industry participants;
- regulatory, legislative, enforcement and judicial actions that adversely affect the price, ownership, transferability, trading volumes, legality or public perception of Digital Assets, or that adversely affect the operations of or otherwise prevent digital asset custodians, trading venues, lending platforms or other Digital Assets industry participants from operating in a manner that allows them to continue to deliver services to the Digital Assets industry;
- macroeconomic changes, such as changes in the level of interest rates and inflation, fiscal and monetary policies of governments, trade restrictions, and fiat currency devaluations; and
- developments in mathematics or technology, including in digital computing, algebraic geometry and quantum computing, that could result in the cryptography used by the digital asset blockchain becoming insecure or ineffective.

We may be unable to successfully implement our Digital Asset Strategy.

Our Digital Asset treasury reserve strategy has only been recently approved by our Board. There is no assurance that we will be able to successfully implement this new strategy or operate Digital Asset-related activities at the scale or profitability currently anticipated. Successfully implementing this strategy may present organizational and infrastructure challenges, and we may not be able to fully implement or realize the intended benefits of our strategy. There can be no assurance that we will be successful in implementing its new business strategy. In addition, moving to a new business strategy may result in a loss of established efficiency, which may have a negative impact on our business. We may also face an increased amount of competition as we attempt to expand and grow its business, which may negatively impact our results of operations, cash flows and financial condition.

Our Digital Asset holdings will be less liquid than existing cash and cash equivalents and may not be able to serve as a source of liquidity to the same extent as cash and cash equivalents.

Historically, the Digital Assets markets have been characterized by significant volatility in price, limited liquidity and trading volumes compared to sovereign currencies markets, relative anonymity, a developing regulatory landscape, potential susceptibility to market abuse and manipulation, compliance and internal control failures at exchanges, and various other risks inherent in its entirely electronic, virtual form and decentralized network. During times of market instability, we may not be able to sell our Digital Assets at favorable prices or at all. As a result, our Digital Asset holdings may not be able to serve as a source of liquidity for us to the same extent as cash and cash equivalents. Further, the Digital Assets we intend to hold with our custodians and transact with our trade execution partners does not enjoy the same protections as are available to cash or securities deposited with or transacted by institutions subject to regulation by the Federal Deposit Insurance Corporation or the Securities Investor Protection Corporation. Additionally, we may be unable to enter into term loans or other capital raising transactions collateralized by our unencumbered Digital Assets, or otherwise generate funds using our Digital Asset holdings, including in particular during times of market instability or when the price of a Digital Asset has declined significantly. If we are unable to sell any of our Digital Assets, enter into additional capital raising transactions using any of our Digital Assets as collateral, or otherwise generate funds using our Digital Assets holdings, or if we are forced to sell our Digital Assets at a significant loss, in order to meet our working capital requirements, our business and financial condition could be negatively impacted.

If we or our third-party service providers experience a security breach or cyberattack and unauthorized parties obtain access to our Digital Assets, we may lose some or all of our Digital Assets and our financial condition and results of operations could be materially adversely affected.

Our Digital Assets are or will be held in custody accounts. We could have a high concentration of Digital Assets in one location or with one custodian, which may be prone to losses arising out of hacking, loss of passwords, comprised access credentials, malware, or cyberattacks. Security breaches and cyberattacks are of particular concern with respect to our Digital Asset holdings. Digital Assets and the entities that provide services to participants in the Digital Asset ecosystem have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities. A successful security breach or cyberattack could result in:

- a partial or total loss of our Digital Assets in a manner that may not be covered by insurance or the liability provisions of the custody agreements with the custodians who hold our Digital Assets;
- harm to our reputation and brand;
- improper disclosure of data and violations of applicable data privacy and other laws; or
- significant regulatory scrutiny, investigations, fines, penalties, and other legal, regulatory, contractual and financial exposure.

Further, any actual or perceived data security breach or cybersecurity attack directed at other companies with Digital Assets or companies that operate blockchain networks, regardless of whether we are directly impacted, could lead to a general loss of confidence in the broader blockchain ecosystem or in the use of the digital asset network to conduct financial transactions, which could negatively impact us.

Attacks upon systems across a variety of industries, including industries related to Digital Assets, are increasing in frequency, persistence, and sophistication, and, in many cases, are being conducted by sophisticated, well-funded and organized groups and individuals, including state actors. Any future breach of our operations or those of others in the digital asset industry, including third-party services on which we rely, could materially and adversely affect our financial condition and results of operations.

We face risks relating to the custody of our Digital Assets, including the loss or destruction of private keys required to access our Digital Assets, and cyberattacks or other data loss relating to our Digital Assets.

We hold our Digital Assets with regulated custodians that have duties to safeguard our private keys. Our custodial services contracts do not restrict our ability to reallocate our Digital Assets among our custodians, and our Digital Assets holdings may be concentrated with a single custodian from time to time. In light of the significant amount of Digital Assets we anticipate that we may hold, we continually seek to engage additional custodians to achieve a greater degree of diversification in the custody of our Digital Assets as the extent of potential risk of loss is dependent, in part, on the degree of diversification. If there is a decrease in the availability of Digital Asset custodians that we believe can safely custody our Digital Assets, for example, due to regulatory developments or enforcement actions that cause custodians to discontinue or limit their services in the United States, we may need to enter into agreements that are less favorable than our current agreements or take other measures to custody our Digital Assets, and our ability to seek a greater degree of diversification in the use of custodial services would be materially adversely affected. In addition, holding our Digital Assets with regulated custodians could affect the availability of receiving Digital Assets that may result from "forks" of the blockchain networks if our custodians are unable to support or otherwise provide us with such Digital Assets, thereby reducing the amount of Digital Assets we may hold as a result. While our custodians carry insurance policies to cover losses for commercial crimes, cyber and cold storage, the policy limits vary per provider and would be shared among all of their customers, and subject to various limitations and exclusions (such as if a loss arises due to our failure to protect our login credentials and devices). The insurance that covers losses of our Digital Asset holdings may cover only a small fraction of the value of the entirety of our Digital Asset holdings, and there can be no guarantee that such insurance will be maintained as part of the custodial services we have or that such coverage will cover losses with respect to our Digital Assets. Moreover, our use of custodians exposes us to the risk that the Digital Assets our custodians hold on our behalf could be subject to insolvency proceedings and we could be treated as a general unsecured creditor of the custodian, inhibiting our ability to exercise ownership rights with respect to such Digital Assets. Any loss associated with such insolvency proceedings is unlikely to be covered by any insurance coverage we maintain related to our Digital Assets.

Digital Assets are controllable only by the possessor of both the unique public key and private key(s) relating to the local or online digital wallet in which the assets are held. While the digital asset blockchain ledger requires a public key relating to a digital wallet to be published when used in a transaction, private keys must be safeguarded and kept private in order to prevent a third party from accessing the digital asset held in such wallet. To the extent the private key(s) for a digital wallet are lost, destroyed, or otherwise compromised and no backup of the private key(s) is accessible, neither we nor our custodians will be able to access the digital asset held in the related digital wallet. Furthermore, we cannot provide assurance that our digital wallets, nor the digital wallets of our custodians held on our behalf, will not be compromised as a result of a cyberattack. The digital asset and blockchain ledger, as well as other Digital Assets and blockchain technologies, have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities.

Our custodially-held Digital Assets may become part of the custodian's insolvency estate if one or more of our custodians enters bankruptcy, receivership or similar insolvency proceedings.

If our Digital Assets held by a custodian are considered to be the property of our custodians' estates in the event that any such custodians were to enter bankruptcy, receivership or similar insolvency proceedings, we could be treated as a general unsecured creditor of such custodians, inhibiting our ability to exercise ownership rights with respect to such Digital Asset and this may ultimately result in the loss of the value related to some or all of such Digital Assets. A series of recent high-profile bankruptcies, closures, liquidations, regulatory enforcement actions and other events relating to companies operating in the Digital Asset industry, including the filings for bankruptcy protection by Three Arrows Capital, Celsius Network, Voyager Digital, FTX Trading and Genesis Global Capital, the closure or liquidation of certain financial institutions that provided lending and other services to the Digital Assets industry, including Signature Bank and Silvergate Bank, SEC enforcement actions against Coinbase, Inc. and Binance Holdings Ltd., the placement of Prime Trust, LLC into receivership following a cease-and-desist order issued by Nevada's Department of Business and Industry, and the filing and subsequent settlement of a civil fraud lawsuit by the New York Attorney General against Genesis Global Capital, its parent company Digital Currency Group, Inc., and former partner Gemini Trust Company, have highlighted the counterparty risks applicable to owning and transacting in Digital Assets. Additional bankruptcies, closures, liquidations, regulatory enforcement actions or other events involving participants in the Digital Asset industry in the future may further negatively impact the adoption rate, price, and use of Digital Assets, limit the availability to us of financing collateralized by Digital Assets that we hold, or create or expose additional counterparty risks. Any loss associated with such insolvency proceedings is unlikely to be covered by any insurance coverage we maintain related to our Digital Assets. Even if we are able to prevent our Digital Assets from being considered the property of a custodian's bankruptcy estate as part of an insolvency proceeding, it is possible that we would still be delayed or may otherwise experience difficulty in accessing our Digital Assets held by the affected custodian during the pendency of the insolvency proceedings. Any such outcome could have a material adverse effect on our financial condition and the market price of our common stock.

Digital Assets held by us are not subject to FDIC or SIPC protections.

We will not hold our Digital Assets with a banking institution or a member of the Federal Deposit Insurance Corporation ("FDIC") or the Securities Investor Protection Corporation ("SIPC"), and, therefore, our Digital Assets are not subject to the protections enjoyed by depositors with FDIC or SIPC member institutions. As a result, we may suffer a loss with respect to our Digital Assets that is not covered by insurance, and we may not be able to recover any of our carried value in these Digital Assets if they are lost or stolen or suffer significant and sustained reduction in conversion spot price. If we are not otherwise able to recover damages from a malicious actor in connection with these losses, our business and results of operations may suffer, which may have a material negative impact on our stock price.

Digital Assets are novel assets, and are subject to significant legal, commercial, regulatory, and technical uncertainty.

Digital Assets are relatively novel and are subject to rapidly evolving legal, commercial, regulatory, and technical landscapes. Because the application of federal and state securities and other applicable laws, regulations, and rules ("Applicable Law") remain unsettled in several material respects, there is substantial risk that a governmental or regulatory authority could adopt or interpret Applicable Law in a manner that adversely affects the price of Digital Assets. Increased regulatory scrutiny may result in additional costs for us and may require our management team to devote increased time and attention to regulatory matters, change aspects of our business, or result in limits on the utility of Digital Assets. Moreover, the regulatory landscape with respect to Digital Assets is rapidly changing and we may be required to comply with any new laws, regulations, or interpretations, which may result in heightened regulatory and compliance related costs, litigation, regulatory investigations, and enforcement or other actions. Adverse changes to, or our failure to comply with Applicable Law may have an adverse effect on our reputation, brand, our business, operating results, and financial condition. Further, if any of our Digital Assets are determined to constitute a security for purposes of U.S. federal securities laws, the additional regulatory restrictions imposed by such a determination could adversely affect the market price of the Digital Assets we hold.

The U.S. federal government, states, regulatory agencies, and foreign countries may also enact new laws and regulations, or pursue regulatory, legislative, enforcement or judicial actions, that could materially impact the price of Digital Assets or the ability of individuals or institutions such as us to own or transfer Digital Assets. Regulatory authorities have been evolving in their approach to Digital Assets. It is not possible to predict whether, or when, any of these developments will lead to U.S. Congress granting additional authorities to the SEC or other regulators, or whether any other federal, state, or foreign legislative bodies will take any similar actions. It is also not possible to predict the nature of any such additional authorities, how additional legislation or regulatory oversight might impact the ability of Digital Asset markets to function or the willingness of financial and other institutions to continue to provide services to the Digital Assets industry, nor how any new regulations or changes to existing regulations might impact the value of Digital Assets generally and any Digital Assets we hold specifically. The consequences of increased regulation of Digital Assets and Digital Asset-related activities could adversely affect the market price of any Digital Assets we hold and in turn adversely affect the market price of our common stock.

Moreover, the risks of engaging in a Digital Asset treasury strategy are relatively novel and have created, and could continue to create, complications due to the lack of experience that third parties have with companies engaging in such a strategy, such as increased costs of director and officer liability insurance or the potential inability to obtain such coverage on acceptable terms in the future.

The liquidity of Digital Assets may also be impacted to the extent that changes in Applicable Laws and regulatory requirements negatively impact the ability of exchanges and trading venues to provide services for Digital Assets. The evolving regulatory landscape creates uncertainty for the Company, as new regulations or changes to existing regulations could materially and adversely affect our business operations, financial condition, and results of operations. The effect of any future regulatory change on the Company is impossible to predict, but such change could be substantial and adverse.

We could be subject to legal or regulatory action, including fines, in the event the SEC, a foreign regulatory authority, or a court were to determine that a digital asset held by us is a "security" under applicable laws.

While all investments entail a risk of loss of capital, investments in Digital Assets should be considered substantially more speculative and significantly more likely to result in a loss, including a total loss of capital, than many other forms of investment. The investment characteristics of Digital Assets differ from those of many traditional currencies, commodities, and securities. A particular Digital Asset's status as a "security" in any relevant jurisdiction is subject to a high degree of uncertainty, and if we are unable to properly characterize a Digital Asset, we may be subject to regulatory scrutiny, investigations, fines, and other penalties, which may adversely affect our business, results of operations and/or financial condition.

Risks Relating to Our Intellectual Property Rights

We cannot ensure protection of our licensed intellectual property rights.

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

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

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

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

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

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

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

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

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

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

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

General Company-Related Risks

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

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

On May 10, 2024, we filed a lawsuit against Elion Oncology, Inc. disputing the purported termination of a license agreement, which lawsuit is subject to counterclaims by Elion. On December 3, 2024, two of the investors in our February 2021 private offering filed a lawsuit alleging fraud and negligent misrepresentation in connection therewith and seeking monetary damages.

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

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

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

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

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

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

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

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

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

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

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

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

We have been and may in the future be 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.

In addition, we currently use some artificial intelligence (AI) solutions for certain administrative and other functions. The use of AI by us and/or our business partners creates the additional risk for the potential loss or misuse of personal data or the dissemination of confidential information, either of which may result in significantly increased business and security costs, a damaged reputation, administrative penalties, or costs related to defending legal claims.

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

Risks Related to Ownership of Our Common Stock

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

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

We have in the past received notice from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq as set forth in Nasdaq Listing Rule 5550(a)(2). Although we regained compliance with such requirement as of January 6, 2026, there is no assurance that we will be in compliance in the future.

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

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

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

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

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

Our common stock price is volatile.

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

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

- the introduction of technological innovations or new commercial products by our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- future sales of our common stock by us, our insiders or our other stockholders;
- a negative outcome in any litigation or potential legal proceeding;
- additions and departures of key personnel;
- negative publicity or announcements regarding regulatory developments relating to our products;
- actual or anticipated fluctuations in our financial condition and operating results, including our cash and cash equivalents balance, operating expenses, cash burn rate or revenue levels;
- our filing for protection under federal bankruptcy laws; or
- the other factors described in this "Risk Factors" section.

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

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

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

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

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

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

Cybersecurity Governance and Oversight

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

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

Cybersecurity Incident Reporting and Management

During the years ended December 31, 2024 and 2025, we have not identified any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, we remain vigilant and prepared to respond effectively to any incidents, should they arise.

Item 2. Properties

We maintain our principal executive office at 601 21st Street, Suite 300 Vero Beach, FL 32960 pursuant to a virtual office agreement.

Item 3. Legal Proceedings

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

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

On December 3, 2024, Jason Assad and Marc Gyimesi, two of the investors in our February 2021 private offering, filed a lawsuit that has been assigned to the Commercial Division of the Supreme Court of the State of New York, New York County alleging fraud and negligent misrepresentation in connection therewith regarding alleged company communication and statements and are seeking monetary damages. In addition to being an investor, Mr. Assad was a former investor relations and communications consultant to the Company from September 1, 2021 through June 30, 2024. On April 25, 2025, the Company filed a motion to dismiss the complaint in its entirety. The motion was decided in September 2025. The court dismissed two of the three counts of the complaint (for constructive fraud and negligent misrepresentation) and dismissed that part of the remaining cause of action for fraud to the extent that it related to the retention of Plaintiffs' investment (leaving only the portion of the claim in which Plaintiffs allege they were fraudulently induced to invest in the Company in February 2021). The court also dismissed all claims against Patrick Lin and George Ng. Processa's and David Young's answer was submitted during October 2025. In January 2026, Plaintiffs were granted leave to amend their complaint to add a claim for breach of contract against Processa and David Young based on the same factual allegations. Processa and David Young's responses to the amended complaint were submitted by March 2, 2026. In the meantime, the discovery and deposition phases of the matter are ongoing.

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

Item 4. Mine Safety Disclosures

None.

Part II

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

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

On September 11, 2025, we amended our Certificate of Incorporation to increase the number of authorized shares of our common stock from 100,000,000 to 1,000,000,000. The number of authorized shares of preferred stock remains unchanged at 1,000,000 shares.

On December 17, 2025, we effected a 1-for-25 reverse stock split, reducing the number of our common shares issued on that date from 56,999,223 shares to 2,280,114 shares. There was no corresponding reduction in the number of authorized shares of common stock and no change in the par value per share. All share and per share amounts and conversion and exercise prices presented herein have been adjusted retroactively to reflect this change.

Holders

As of March 13, 2026, there were 2,660,039 shares of common stock outstanding and 187 shareholders of record. One of these holders of record is Cede & Co, a nominee for Depository Trust Company ("DTC"). All of the shares of common stock held by brokerage firms and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder. The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Transfer Agent and Registrar

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

Dividend Policy

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

Recent Sales of Unregistered Securities

None.

Repurchases of Equity Securities

We did not repurchase any shares of our common stock during the year ended December 31, 2025.

Item 6. [Reserved]

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

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

Overview

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

Next Generation Cancer Therapy Pipeline

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

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

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

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

Other Drugs in Our Pipeline

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

PCS499 is a drug that can be used to treat unmet medical need conditions caused by multiple pathophysiological changes. We are presently defining the development plan for the use of PCS499 in a primary glomerular disease. We believe that PCS499 could be successfully developed in a primary glomerular disease such as focal segmental glomerulosclerosis, or FSGS, and IgA. The use of proteinuria for the primary endpoint in FSGS has been accepted by FDA in our protocol discussions. We are designing the FSGS development program with a Phase 2 and Phase 3 trial per our discussions with the FDA. We continue to explore potential partnership opportunities to take the drug to approval.

Recent Developments

Private Placement

[OPEN]

ATM Offering

In May 2024, we filed with the SEC a registration statement on Form S-3 (Registration No. 333-279588) (as amended and supplemented, the "Registration Statement"), including a base prospectus relating to the offering of up to $50,000,000 in the aggregate of the securities identified in the base prospectus from time to time in one or more offerings; and a prospectus supplement relating to the shares of our common stock that may be issued and sold under a sales agreement dated May 21, 2024 (the "Sales Agreement") between us and A.G.P./Alliance Global Partners (the "Sales Agent"), through which we may issue and sell in a registered "at the market offering" shares of our common stock having an aggregate offering price of up to $5.2 million (subject to adjustment) from time to time through or to our Sales Agent (the "ATM Offering"). We expect to use net proceeds, if any, from the ATM Offering over time for continued research and development for our portfolio of drug candidates, especially our oncology products, and working capital and general corporate purposes. The shares under the ATM Offering will be sold and issued pursuant to the Registration Statement. During the year ended December 31, 2025, we received $3.0 million in net proceeds from the sale of 475,905 shares of common stock under the ATM Offering.

Results of Operations

Comparison of the year ended December 31, 2025 and 2024

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

	Year Ended December 31,		
	2025	2024	Change
Operating Expenses			
Research and development costs	$ 7,810,337	$ 7,269,146	$ 541,191
General and administrative expenses	6,178,168	4,782,060	1,396,108
Operating Loss	(13,988,505)	(12,051,206)	
Other Income (Expense)			
Other income	20,000	-	20,000
Unrealized gain on digital assets at fair value	295,180	-	295,180
Interest and dividend income, net	109,491	201,088	(91,597)
Net Loss	$ (13,563,834)	$ (11,850,118)	(1,713,716)

Revenues.

We had no revenue during the years ended December 31, 2025 and 2024. We do not currently have any revenue under contract or any immediate sales prospects.

Research and Development Expenses.

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

Research and development costs for the years ended December 31, 2025 and 2024 were as follows:

	Year ended December 31,	
	2025	2024
Preclinical, clinical trial and other costs	$ 6,240,583	$ 5,450,963
Research and development salaries and benefits	1,569,754	1,818,183
Total	$ 7,810,337	$ 7,269,146

During the year ended December 31, 2025, our research and development expenses increased by $541,000 to $7.8 million when compared to $7.3 million for the year ended December 31, 2024. This was primarily attributable to an increase of approximately $790,000 for ongoing testing and related expenses related to our Phase 1B trial for NGC-Cap and the IND/initiation of our Phase 2 trial for NGC-Cap. Expenses include costs related to contract research organizations, regulatory filing and maintenance fees, drug product testing and stability, consulting, and other clinical fees. The increase was offset by a decrease of $248,000 for salaries and other payroll-related expenses due to a reduction in staff during the year ended December 31, 2025.

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

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

In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related series are recorded as prepaid expenses until the services are rendered. At December 31, 2025, we have recorded $1.0 million in prepaid expenses for advanced payments made to our CRO and other vendors for our NGC-Cap Phase 2 clinical trial.

General and Administrative Expenses.

Our general and administrative expenses for the year ended December 31, 2025 increased by approximately $1.4 million to $6.2 million when compared to $4.8 million for the same period in 2024. This was mostly due to a $474,000 increase in salaries and other payroll-related expenses, a $322,000 increase in employee stock-based compensation, a $313,000 increase in professional fees, a $164,000 increase in franchise taxes, and a $174,000 increase in investment fees, insurance, and other miscellaneous costs. The increases were offset by decreases of $38,000 in office and other miscellaneous expenses and $22,000 in rent expense. We have shared expenses with CorLyst, a related party, and during the years ended December 31, 2025 and 2024, they reimbursed us $100,000 and $110,000, respectively, for rent and other costs we incurred on their behalf.

Other Income.

Net other income for the year ended December 31, 2025 consisted of $295,180 in unrealized gains on our digital asset, $109,491 in interest income, and $20,000 other income from our Term Sheet with Intact. Net other income during the year ended December 31, 2024 solely consisted of interest income.

Income Tax Benefit.

We did not recognize any income tax benefit for the year ended December 31, 2025 or 2024. At December 31, 2025, we recorded deferred tax assets totaling $21.3 million, including $14.5 million of net operating losses that are fully offset by a valuation allowance.

Liquidity and Capital Resources

Sources of Liquidity

At December 31, 2025, we had $5.5 million in cash and cash equivalents. On February 17, 2026, we sold 86,956 shares of our common stock to an accredited investor in a private placement transaction for $200,000.

We have incurred losses and net cash used in our operating activities during the year ended December 31, 2025, which we expect to continue for the foreseeable future. We have incurred losses since our inception, devoting substantially all efforts toward research and development, and have an accumulated deficit of approximately $100.8 million at December 31, 2025. During the year ended December 31, 2025, we generated a net loss of approximately $13.6 million. Based on our current business plans, we believe we will need to raise additional capital in the second quarter of 2026. Our ability to execute our longer-term operating plans, including unplanned future clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions. We plan to continue to actively pursue financing alternatives, but there can be no assurance that we will obtain the necessary funding in the future when needed.

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

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

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

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

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the years ended December 31, 2025 and 2024:

	For the Year Ended December 31,	
	2025	2024
Net cash (used in) provided by:		
Operating activities	$ (11,385,195)	$ (11,245,042)
Investing activities	(850,000)	(3,244)
Financing activities	16,580,825	7,733,414
Net decrease in cash and cash equivalents	$ 4,345,630	$ (3,514,872)

Net cash used in operating activities

We used net cash in our operating activities of $11,385,195 and $11,245,042 during the years ended December 31, 2025 and 2024, respectively. The increase in cash used in operating activities was primarily attributable to increased costs related to our Phase 2 trial for NGC-Cap; increased salaries and other payroll-related expenses; and professional fees during the year ended December 31, 2025. As we continue our Phase 2 trial for NGC-Cap and evaluate NGC-Iri, we anticipate our research and development efforts and ongoing general and administrative costs will continue to generate negative cash flows from operating activities for the foreseeable future.

At December 31, 2025, our prepaid expense and other consisted primarily of $1.0 million for advanced payments we made to the CRO and other vendors related to our Phase 1B and Phase 2 trials of NGC-Cap that have not yet been applied; $42,000 for upcoming patent annuities; $32,000 in various insurance policies, such as directors' and officers' insurance and product liability insurance for conducting our clinical trials; and $16,000 in other miscellaneous general and administrative expenses.

Net cash used in investing activities

We used $850,000 in investing activities to purchase our digital assets during the year ended December 31, 2025 and used $3,244 during year ended December 31, 2024 to purchase equipment.

Net cash provided by financing activities

During the year ended December 31, 2025, we sold 613,639 shares of common stock, pre-funded warrants to purchase up to 828,388 shares of common stock in lieu of shares of common stock, all of which were exercised into shares of our common stock, and warrants to purchase up to 1,603,041 shares of our common stock pursuant to our January 2025 and June 2025 Offerings for net proceeds of $10.6 million. We also sold 476,028 shares of common stock under our ATM Offering for net proceeds of approximately $3.0 million and 218,688 shares of common stock under a Securities Purchase Agreement for net proceeds of $1.2 million. Warrants to purchase 281,749 shares of common stock were also exercised for $1.8 million. We used cash, classified as financing activities, of approximately $10,000 to pay income taxes owed on stock-based compensation and approximately $7,000 for payments owed under a financing lease obligation.

During the year ended December 31, 2024, we sold 19,040 shares of common stock, pre-funded warrants to purchase up to 43,183 shares of common stock in lieu of shares of common stock, all of which were exercised into shares of our common stock, and warrants to purchase up to 62,223 shares of our common stock pursuant to a public offering for net proceeds of $6.3 million. We also sold 32,030 shares of common stock under our ATM Offering for net proceeds of approximately $1.5 million. We used cash, classified as financing activities, of approximately $16,000 to pay income taxes owed on stock-based compensation, approximately $9,000 for the settlement of a stock award, and approximately $5,000 for payments owed under a financing lease obligation.

Contractual Obligations and Commitments

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

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

Off Balance Sheet Arrangements

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

Critical Accounting Policies and Use of Estimates

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

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

Clinical Trial Accruals / Research and Development

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

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

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

Stock-Based Compensation

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

See Note 3 – Stock-Based Compensation for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of warrants granted during the year ended December 31, 2025.

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

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. We have recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets since it was more-likely-than-not that benefits from our deferred tax assets would not be realized. The valuation allowance is reviewed annually and is maintained until sufficient positive evidence exists to support its reversal. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect of changes in tax rates on deferred tax assets and liabilities is recognized in income in the period such changes are enacted. No income tax benefit or expense was recorded for any periods presented nor is expected in the foreseeable future since we expect to generate future taxable net operating losses.

We recognize the impact of an uncertain tax position if the position will more likely than not be sustained upon examination by a taxing authority, based on the technical merits of the position. Our policy is to record interest and penalties related to income taxes as part of its income tax provision. At December 31, 2025, 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.

Valuation and Classification of Digital Assets

We measure our Digital Assets at fair value, with changes in fair value recognized in net income in the period of change. The most critical estimate inherent in the valuation of our Digital Assets is the determination of the principal market under ASC 820, Fair Value Measurement. We evaluate the liquidity, trading volume, and regulatory viability of various exchanges to identify the principal market – the market with the greatest volume and level of activity for the asset that we can access. We have determined that the Coinbase exchange represents the principal market for CHZ. We calculate the fair value of our holdings using the quoted price on the Coinbase exchange as of midnight UTC on the measurement date. The digital asset market is characterized by significant volatility and fragmented liquidity. A change in our determination of the principal market, or the use of a different data source (such as a composite index versus a specific exchange), could result in materially different fair value measurements.

Recent 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, 2025.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

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

Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Processa Pharmaceuticals, Inc. (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes. In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, 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.

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

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred net losses since its inception which has resulted in a cumulative deficit as of December 31, 2025 that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1.

Basis for Opinion

These 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 our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Critical Audit Matter Description

As of December 31, 2025, the Company held digital assets consisting of Chiliz ("CHZ") tokens, which are classified as crypto digital assets. The Company's digital assets are measured at fair value at each reporting date, with changes in fair value recognized in the consolidated statement of operations. We identified the accounting for and valuation of the Company's digital assets as a critical audit matter because of (i) the significant judgment required to determine the appropriate fair value of CHZ tokens, (ii) the high volatility and evolving nature of digital asset markets, (iii) the use of third-party custodians and blockchain-based records to evidence existence and rights, and (iv) the complexity and evolving regulatory environment surrounding digital assets.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the accounting for and valuation of the Company's CHZ digital assets included, among others:

- We evaluated management's accounting conclusions related to the classification and measurement of CHZ tokens, including consistency with the applicable accounting guidance and the Company's disclosed accounting policies.
- We tested the existence of the digital assets by inspecting blockchain records and confirming digital asset balances held in wallets controlled by, or on behalf of, the Company as of the reporting date.
- We evaluated the Company's determination of fair value by assessing the appropriateness of the principal market selected, the pricing sources used, and the consistency of prices with observable market data for CHZ tokens at the measurement date.

/s/ Cherry Bekaert LLP

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

Tampa, Florida
March 18, 2026

Processa Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31, 2025	December 31, 2024
ASSETS		
Current Assets		
Cash and cash equivalents	$ 5,536,955	$ 1,191,325
Prepaid expenses and other	133,919	687,829
Total Current Assets	5,670,874	1,879,154
Digital assets at fair value	1,145,180	-
Prepaid expenses	993,701	1,274,442
Equipment, net	3,812	5,016
Operating lease right-of-use assets, net	-	70,677
Total Assets	$ 7,813,567	$ 3,229,289
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Current maturities of lease liability	$ -	$ 73,020
Accounts payable	1,056,796	880,880
Accrued expenses	1,179,457	578,731
Total Current Liabilities	2,236,253	1,532,631
Non-current lease liability	-	487
Total Liabilities	2,236,253	1,533,118
Commitments and Contingencies	-	-
Stockholders' Equity		
Preferred stock, par value $0.0001, 1,000,000 shares authorized; no shares issued or outstanding at December 31, 2025 or 2024	-	-
Common stock, par value $0.0001, 1,000,000,000 shares authorized; 2,572,114 issued and 2,571,914 outstanding at December 31, 2025 and 148,308 issued and 148,108 outstanding at December 31, 2024	257	15
Additional paid-in capital	106,660,090	89,215,355
Treasury stock, 200 shares at cost	(300,000)	(300,000)
Accumulated deficit	(100,783,033)	(87,219,199)
Total Stockholders' Equity	5,577,314	1,696,171
Total Liabilities and Stockholders' Equity	$ 7,813,567	$ 3,229,289

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2025	2024
Operating Expenses		
Research and development expenses	$ 7,810,337	$ 7,269,146
General and administrative expenses	6,178,168	4,782,060
Operating Loss	(13,988,505)	(12,051,206)
Other Income (Expense)		
Other income	20,000	-
Unrealized gain on digital assets at fair value	295,180	-
Interest and dividend income, net	109,491	201,088
Net Operating Loss Before Income Tax Benefit	(13,563,834)	(11,850,118)
Income Tax Benefit	-	-
Net Loss	$ (13,563,834)	$ (11,850,118)
Net Loss Per Common Share - Basic and Diluted	$ (10.36)	$ (96.78)
Weighted Average Common Shares Used to Compute		
Net Loss Per Common Shares - Basic and Diluted	1,309,271	122,438

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2024 and 2025

	Common Stock		Additional Paid-In	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance, January 1, 2024	51,640	$ 5	$ 80,658,235	(200)	$ (300,000)	$ (75,369,081)	$ 4,989,159
Stock-based compensation	2,521	1	629,513	-	-	-	629,514
Shares issued in connection with capital raises, net of transaction costs	94,253	9	7,763,070	-	-	-	7,763,079
Shares issued in connection with license agreement	200	1	188,999	-	-	-	189,000
Settlement of stock award	-	-	(8,561)	-	-	-	(8,561)
Shares withheld to pay income taxes on stock-based compensation	(306)	(1)	(15,901)	-	-	-	(15,902)
Net loss	-	-	-	-	-	(11,850,118)	(11,850,118)
Balance, December 31, 2024	148,308	15	89,215,355	(200)	(300,000)	(87,219,199)	1,696,171
Stock-based compensation	6,273	1	857,549	-	-	-	857,550
Shares issued in connection with capital raises and warrants, net of transaction costs	2,418,492	242	16,597,589	-	-	-	16,597,831
Shares withheld to pay income taxes on stock-based compensation	(959)	(1)	(10,403)	-	-	-	(10,404)
Net loss	-	-	-	-	-	(13,563,834)	(13,563,834)
Balance, December 31, 2025	2,572,114	$ 257	$ 106,660,090	(200)	$ (300,000)	$ (100,783,033)	$ 5,577,314

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

Processa Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2025	2024
Cash Flows From Operating Activities		
Net Loss	$ (13,563,834)	$ (11,850,118)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,204	782
Non-cash lease expense for right-of-use assets	70,677	87,184
Unrealized gain on digital assets at fair value	(295,180)	-
Stock-based compensation	857,550	629,514
Net changes in operating assets and liabilities:		
Prepaid expenses and other	834,651	(1,030,436)
Operating lease liability	(66,905)	(83,649)
Accounts payable	175,916	569,263
Due from related parties	-	(39)
Accrued expenses	600,726	432,457
Net cash used in operating activities	(11,385,195)	(11,245,042)
Cash Flows From Investing Activities		
Purchase of digital asset	(850,000)	-
Purchase of equipment	-	(3,244)
Net cash used in investing activities	(850,000)	(3,244)
Cash Flows From Financing Activities		
Net proceeds from issuance of common stock	16,597,831	7,763,079
Shares withheld to pay taxes on stock-based compensation	(10,404)	(15,902)
Settlement of stock award	-	(8,561)
Payment of finance lease obligation	(6,602)	(5,202)
Net cash provided by financing activities	16,580,825	7,733,414
Net Increase (Decrease) in Cash and Cash Equivalents	4,345,630	(3,514,872)
Cash and Cash Equivalents - Beginning of Year	1,191,325	4,706,197
Cash and Cash Equivalents - End of Year	$ 5,536,955	$ 1,191,325

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,	
	2025	2024
Supplemental Cash Flow Information:		
Cash paid for interest	$ 5,607	$ 1,204
Cash paid for income taxes	-	-
Non-Cash Financing Activities		
Issuance of 200 shares of common stock in connection with a licensing agreement which had previously been recorded as a due to licensor	$ -	$ 189,000
Right-of-use asset obtained in exchange for financing lease liability	$ -	$ 11,804
Financing lease liability	-	(11,804)
Net	$ -	$ -

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

Note 1 – Organization

Organization

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

On December 17, 2025, we filed a Certificate of Amendment to our Certificate of Incorporation, as amended with the Secretary of State of Delaware that effected a 1-for-25 reverse stock split of our common stock, par value $0.0001 per share (the "Reverse Stock Split"). Pursuant to the Certificate of Amendment, our issued common stock decreased from 56,999,223 shares to 2,280,114 shares and our outstanding common stock decreased from 56,994,223 to 2,279,914. The Reverse Stock Split did not affect our authorized common stock of 1,000,000,000 shares or our common stock par value. All shares of common stock, including common stock underlying warrants, stock options, and restricted stock units, as well as exercise prices and per share information in these consolidated financial statements give retroactive effect to the Reverse Stock Split.

Liquidity

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. We have incurred losses since inception. We are currently devoting substantially all of our efforts toward research and development of our NGC drug product candidates, including conducting a clinical trial and providing general and administrative support for these operations. We have an accumulated deficit of $100.8 million at December 31, 2025. During the year ended December 31, 2025, we generated a net loss of $13.6 million and used $11.4 million in net cash for operating activities from continuing operations. To date, none of our drug candidates have been approved for sale, and therefore we have not generated any product revenue and do not expect positive cash flow from operations in the foreseeable future.

We have financed our operations primarily through public equity issuances, including a private offering we sold on February 17, 2026 where we sold 86,956 shares of our common stock to an accredited investor in a private placement transaction for $200,000. We will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from its operations.

At December 31, 2025, we had cash and cash equivalents totaling $5.5 million. Together with the $200,000 we raised in February 2026, and based on our current business plans, we believe we will need to raise additional capital in the second quarter of 2026. Our ability to execute our longer-term operating plans, including future preclinical studies and clinical trials for our portfolio of drugs depend on our ability to obtain additional funding from the sale of equity and/or debt securities, a strategic transaction or other funding transactions.

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

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

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

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission (the "SEC"), and reflect all of our activities, including those of our wholly-owned subsidiary. All material intercompany accounts and transactions have been eliminated in consolidation. Operating results for the year ended December 31, 2025 are not necessarily indicative of future results.

Use of Estimates

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

Cash and Cash Equivalents

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

Digital Assets

Our digital asset is held in CHZ token and we have accounted for it in accordance with ASC 350-60, Intangibles – Goodwill and Other – Crypto Assets ("ASC 350-60"). We initially recorded the digital asset at cost and then subsequently remeasured at fair value as of the balance sheet date with changes in fair value recognized as unrealized gain or losses in the consolidated statement of operations. We will recognize any realized gains or losses in the consolidated statement of operations based on the fair value of the digital asset on the date of sale or derecognition.

Prepaid Expenses

Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered. The majority of our prepaid expenses relate to advanced payments made to CROs and other vendors for our ongoing clinical trials. We allocate the prepaid expenses between current and non-current assets based on the anticipated timing of utilizing the advances. At December 31, 2025, we determined that $994,000 would not be applied until after December 31, 2026.

Property and Equipment

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

Impairment of Long-Lived Assets and Intangibles Other Than Goodwill

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

Fair Value Measurements and Disclosure

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.

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

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

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

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

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

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

Our digital assets are subject to fair value measurements on a recurring basis and the level of input used for such measurements were as follows:

	December 31, 2025				
		Fair Value			
	Carrying Value	Level 1	Level 2	Level 3	Total
Assets:					
Digital assets	$ -	$ 1,145,180	$ -	$ -	$ 1,145,180
Total assets	$ -	$ 1,145,180	$ -	$ -	$ 1,145,180

Digital assets are measured at fair value on a recurring basis using quoted prices in its principal market (Level 1 inputs). We have designated a principal market based on the market we have access to that has the greatest volume and level of orderly transactions for digital assets. We reassess the principal market when facts and circumstances change, including, but not limited to, when new markets become accessible, or the volume/activity in the current principal market declines.

Stock-based Compensation

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

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

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average common stock outstanding (which excludes unvested RSAs) and vested, but unissued RSUs. Diluted loss per share is computed by dividing our net loss available to common shareholders by the diluted weighted average number of shares of common stock outstanding during the period. Since we have experienced a net loss for all periods presented, basic and diluted net loss per share are the same. As such, diluted loss per share for the years ended December 31, 2025 and 2024 excludes the impact of potentially dilutive common shares related to outstanding stock options, unvested restricted stock awards (RSAs), unvested RSUs and common stock purchase warrants.

Our diluted net loss per share for the years ended December 31, 2025 and 2024 excluded 1,636,573 and 80,537 of potentially dilutive common shares, respectively, related to outstanding stock options, unvested RSUs and warrants since those shares would have had an anti-dilutive effect on loss per share during the years then ended.

Segments

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

Research and Development

Research and development costs are expensed as incurred and consist of direct and overhead-related expenses related primarily to clinical trials, including development personnel salaries and related costs. Expenditures to acquire technologies, including licenses, which are utilized in research and development and that have no alternative future use are expensed as the acquisition of in-process research and development when incurred. Technology we develop for use in our products is expensed as incurred until technological feasibility has been established after which it is capitalized and depreciated. No research and development costs were capitalized during the years ended December 31, 2025 and 2024.

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. As of December 31, 2025 and 2024, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets since it is more-likely-than-not that benefits from our deferred tax assets will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

We recognize the impact of an uncertain tax position if the position will more likely than not be sustained upon examination by a taxing authority, based on the technical merits of the position. Our policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2025, we had no unrecognized tax benefits and as such, no liability, interest or penalties were required to be recorded. We do not expect this to change significantly in the next twelve months.

Recently Adopted Accounting Standard

In December 2023, the FASB issued ASU 2023-09, Improvements to Income Tax Disclosures, which requires public entities to disclose: (1) a tabular reconciliation of its annual effective tax rate using both percentages and amounts, broken out into specific categories with certain reconciling items at or above 5% of the statutory (i.e. expected) tax further broken out by nature and/or jurisdiction and (2) income taxes paid (net of refunds received) disaggregated by federal, state and local to the extent the amount is equal or greater than 5% of total income taxes paid. The disclosure requirements will be applied on a prospective basis. The standard is effective for fiscal years beginning after December 15, 2024. We adopted the new standard during the year ended December 31, 2025.

Recent Accounting Pronouncements

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

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

Note 3 - Stock-based Compensation

The Processa Pharmaceuticals Inc. 2019 Omnibus Equity Incentive Plan (the "2019 Plan") allows us to make grants of stock options, restricted and unrestricted stock and other stock-based awards to employees, including our executive officers, consultants and directors. The 2019 Plan originally provided for the aggregate issuance of 32,000 shares of our common stock. On July 18, 2025, our shareholders approved an increase of shares available under the 2019 Plan, which now provides for the aggregate issuance of 432,000 shares of our common stock. At December 31, 2025, we have 232,521 shares available for future grants.

Stock Compensation Expense

We recorded stock-based compensation expense for the years ended December 31, 2025 and 2024 as follows:

	Year Ended December 31,	
	2025	2024
Research and development	$ 192,630	$ 169,414
General and administrative	664,920	460,100
Total	$ 857,550	$ 629,514

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

Stock Options

The following table summarizes our stock option activity during the years ended December 31, 2024 and 2025:

	Total options Outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2024	302	$ 9,080.65	
Options granted	-		
Forfeited or expired	(190)	8,400.00	
Outstanding as of December 31, 2024	112	10,235.31	3.7
Options granted	136,260	5.03	
Forfeited or expired	-		
Outstanding as of December 31, 2025	136,372	13.43	9.8
Exercisable as of December 31, 2025	112	$ 10,235.31	2.7

During the year ended December 31, 2025, we granted the following stock options:

- On October 1, 2025, we granted stock options for the future purchase of 130,680 shares of common stock to our directors and officers, which vest 1/3 on October 1, 2026, and then ratably monthly afterward. These stock options have an exercise price of $4.96 per share.

- On December 1, 2025, we granted stock options for the future purchase of 5,580 shares of common stock to our employees, which vest 1/3 on December 1, 2026, and then ratably monthly afterward. These stock options have an exercise price of $6.68 per share.

No forfeiture rate was applied to these stock options. The aggregate intrinsic value of outstanding options was $0 at both December 31, 2024 and 2025. No stock options were exercised during the years ended December 31, 2024 or 2025. At December 31, 2025, unrecognized stock-based compensation expense for stock options of $615,000 is expected to be fully recognized over a weighted average period of 2.8 years.

We used the Black-Scholes option pricing model to calculate the grant date fair value of the stock options granted in 2025 with the following assumptions:

Average risk-free rate of interest	4.1%
Expected term (years)	10.0
Expected stock price volatility	138.3%
Dividend yield	0.0%

Restricted Stock Awards

During the year ended December 31, 2024, restricted stock awards (RSA) for 50 shares of common stock vested and were issued. We did not have any other activity related to RSAs during the years ended December 31, 2024 and 2025.

Restricted Stock Units

The following table summarizes our restricted stock unit (RSU) activity during the years ended December 31, 2024 and 2025:

	Number of shares	Weighted-average grant-date fair value per share
Outstanding at January 1, 2024	8,957	$ 1,152.30
Granted	7,704	40.76
Forfeited	(572)	1,821.92
Vested and issued	(695)	2,771.56
Outstanding at December 31, 2024	15,394	498.04
Granted	45,420	5.02
Forfeited	(1,110)	1,324.25
Vested and issued	(3,063)	1,523.96
Outstanding at December 31, 2025	56,641	31.02
Vested and unissued	(10,338)	129.29
Unvested at December 31, 2025	46,303	$ 9.08

During the year ended December 31, 2025, we granted the following RSUs:

- On October 1, 2025, we granted RSUs for the future issuance of 43,560 shares of common stock to our directors and officers, which vest 1/3 on October 1, 2026, and then ratably monthly afterward.

- On December 1, 2025, we granted RSUs for the future issuance of 1,860 shares of common stock to our employees, which vest 1/3 on December 1, 2026, and then ratably monthly afterward.

At December 31, 2025, unrecognized stock-based compensation expense for RSUs of approximately $254,000 is expected to be fully recognized over a weighted average period of 2.7 years. The unrecognized expense excludes $12,250 related to certain RSUs with a performance milestone that is not currently probable of occurring.

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

Warrants

The following table summarizes our warrant activity, excluding pre-funded warrants, during the years ended December 31, 2024 and 2025:

	Total warrants outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2024	6,924	$ 635.29	
Exercisable	300	185.00	
Granted	64,713	113.58	
Expired or cancelled	(900)	1,365.56	
Outstanding and exercisable as of December 31, 2024	71,037	148.87	3.8
Granted	1,647,841	9.22	
Exercised	(281,747)	6.25	
Expired or cancelled	-	-	
Outstanding and exercisable as of December 31, 2025	1,437,131	$ 16.71	3.9

During the years ended December 31, 2024 and 2025, we completed financings that included common warrants to purchase shares of our common stock. See Note 4 for details. We did not have any stock-based compensation expense related to our stock purchase warrants at December 31, 2025.

Note 4 – Stockholders' Equity

Common Stock

Financings

During the year ended December 31, 2025, we issued 2,418,492 shares of our common stock through several capital raising events described below:

- On January 29, 2025, we sold 41,239 shares of our common stock, pre-funded warrants to purchase up to 280,788 shares of our common stock, and accompanying Series A Warrants to purchase up to 322,027 shares of our common stock and Series B Warrants to purchase up to 161,014 shares of our common stock for net proceeds of $4.4 million, after deducting placement agent fees and offering-related expenses under a best efforts public offering (the "January 2025 Offering") at a combined purchase price of $15.38 for institutional investors and $19.94 for the Company's Chief Executive Officer and certain board members who participated in the January 2025 Offering. The Series A and B Warrants both have an exercise price of $16.25 per share of common stock. The Series A Warrants expire on July 18, 2030 and the Series B Warrants expire on January 18, 2027. At December 31, 2025, all pre-funded warrants sold in this offering were exercised and no Series A or B Warrants have been exercised.

- On June 18, 2025, we sold 572,400 shares of our common stock, pre-funded warrants to purchase up to 547,600 shares of our common stock, and accompanying common stock warrants to purchase up to 1,120,000 shares of our common stock for net proceeds of $6.2 million, after deducting placement agent fees and offering-related expenses under a best efforts public offering (the "June 2025 Offering"). We sold one share of our common stock and accompanying common warrant at a combined price of $6.25 per share, and a pre-funded warrant and accompanying common warrant at a combined price of $6.2499 per share. The common warrants have an exercise price of $6.25 per share, are immediately exercisable and expire five years after their original issuance. The pre-funded warrants have an exercise price of $0.0001 and are also immediately exercisable. We issued placement agent warrants to purchase up to 44,800 shares of common stock at an exercise price of $7.81 per share. Warrants to purchase 281,749 shares of common stock for $1.8 million and all pre-funded warrants were exercised during the year ended December 31, 2025.

- On August 4, 2025, we sold 218,688 shares of our common stock at an offering price of $5.75 per share to an accredited investor for net proceeds of $1.2 million, after deducting transaction-related expenses. No warrants were issued as part of this capital raise.

- We sold 476,028 shares at an average price of $6.42 per share for aggregate net proceeds of $3.0 million under our ATM Offering.

During the year ended December 31, 2024, we issued 94,253 shares of our common stock through several capital raising events described below:

- On January 30, 2024, we closed a public offering (the "January 2024 Offering") for the sale of 19,040 shares of common stock, Pre-Funded Warrants to purchase up to 43,183 shares of common stock in lieu of shares of common stock, and Common Warrants to purchase up to 62,223 shares of our common stock. The Common Warrants have an exercise price of $112.50, are immediately exercisable and expire on January 30, 2029. The shares of common stock were offered at a combined public offering price of $112.50 per share and accompanying Common Warrant and $112.4999 per Pre-Funded Warrant and accompanying Common Warrant. The Pre-Funded Warrants had an exercise price of $0.0001 and were exercised in full simultaneously with the closing of the January 2024 Offering in exchange for 43,183 shares of our common stock. We received $6.3 million in net proceeds from the January 2024 Offering, after deducting the fees of the placement agent and other offering-related expenses.

- We sold 32,030 shares at an average price of $48.26 per share for aggregate net proceeds of $1.5 million under our ATM Offering.

We also issued to the placement agent warrants to purchase 2,490 shares of common stock, exercisable at $140.63 per share that expire on February 1, 2027.

Treasury Stock

On February 15, 2026, the Board approved the retirement of the 200 shares held in treasury stock.

Note 5 – Net Loss per Share of Common Stock

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

The computation of net loss per share for the year ended December 31, 2025 and 2024 was as follows:

	2025	2024
Basic and diluted net loss per share:		
Net loss available to common shareholders	$ (13,563,834)	$ (11,850,118)
Weighted-average number of common shares-basic and diluted	1,309,271	122,438
Basic and diluted net loss per share	$ (10.36)	$ (96.78)

	2025	2024
Weighted-average number of common shares outstanding – basic and diluted	1,299,055	116,503
Weighted-average number of vested RSUs– basic and diluted	10,216	5,935
Weighted-average number of common shares-basic and diluted	1,309,271	122,438

As described in Note 3, we issued various equity instruments during the years ended December 31, 2025 and 2024 which impact our EPS calculation. Vested RSUs are included in our computation of the weighted average shares for basic EPS and unvested RSUs are included as dilutive securities. At December 31, 2025 and 2024, 46,303 and 9,388 unvested RSUs, respectively, 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:

	2025	2024
Stock options, unvested RSUs, and purchase warrants	1,636,573	80,537

Note 6 – Digital Assets

The following table sets forth the number of tokens, cost basis and fair value of digital assets held, as shown on the consolidated balance sheet as of December 31, 2025:

	Tokens	Cost basis	Fair value
CHZ	27,101,000	$ 850,000	$ 1,145,180

The following table represents a reconciliation of our assets and (liabilities) related to our digital assets during the year ended December 31, 2025:

	Year ended December 31, 2025
Fair Value, January 1, 2025	$ -
Purchases made with cash and cash equivalents	850,000
Unrealized gains	295,180
Fair Value, December 31, 2025	$ 1,145,180

On January 12, 2026, we purchased 10,416,000 CHZ tokens for $500,000. As of March 13, 2026, we own 37,517,000 CHZ tokens, which had a fair value of $1.4 million.

Note 7 – License Agreements

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

Licensor	Drug Asset	Agreement Date	Amendment Date
Elion Oncology, Inc.	NGC-Cap (PCS6422)	August 23, 2020	May 17, 2022
Aposense, Ltd.	NGC-Iri (PCS11T)	May 24, 2020	N/A
Yuhan Corporation	PCS12852	August 19, 2020	June 11, 2025
Sun Pharmaceutical Industries Limited	PCS499	March 19, 2018	N/A

Under these agreements, we have certain development and regulatory milestone payments payable to each licensor. As of December 31, 2025, no amounts are owed under the license agreements.

Note 8 - Income Taxes

We have incurred net operating losses since inception. At December 31, 2025 and 2024, we had available federal and state net operating loss carryforwards of $54.8 million and $36.0 million, respectively. The federal net operating losses generated in 2018 and later of $54.5 million will carry forward indefinitely. Net operating losses generated prior to 2018 will expire beginning in 2037. We have not recognized any deferred tax assets related to the federal orphan drug or other research and development tax credits as of December 31, 2025 and 2024. The federal research and development tax credits have a 20-year carryforward period. No cash payments were made for income taxes, net of refunds, for the years ended December 31, 2025 and 2024.

Pre-tax loss from continuing operations is disaggregated between U.S. domestic and foreign jurisdictions in accordance with ASU 2023-09 and is presented below:

	December 31,	
	2025	2024
Components of pre-tax loss		
Domestic	$ (13,204,883)	$ (10,992,106)
Foreign	(358,951)	(858,012)
Total loss before income taxes	$ (13,563,834)	$ (11,850,118)

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

The following table is a reconciliation of our effective income tax rate and statutory income tax rate for the years ended December 31, 2025 and 2024 in accordance with the guidance in ASU 2023-09:

	Year Ended December 31,			
	2025		2024	
At federal statutory income tax rate	$ (2,848,405)	21.00%	$ (2,488,525)	21.00%
State tax rate, net of federal benefit	(315,309)	2.32%	(494,140)	4.17%
Change in state tax rate	301,856	(2.23)%	81,784	(0.69)%
Nontaxable or nondeductible items:				
Stock compensation – restricted stock units	1,284,795	(9.47)%	560,835	(4.73)%
Other	155,827	(1.15)%	71,375	(0.60)%
Other – deferred adjustments	-	-	11,319	(0.10)%
Federal orphan drug tax credit	(1,824)	0.01%	(6,247)	0.05%
Change in valuation allowance	1,423,060	(10.48)%	2,263,599	(19.10)%
Total	$ -	0.00%	$ -	0.00%

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

	December 31,	
	2025	2024
Deferred tax assets:		
Non-current:		
Net operating loss carry forward – Federal	$ 11,507,543	$ 7,566,071
Net operating loss carry forward – State	2,957,337	2,074,542
Stock compensation expense and other	1,322,468	2,794,464
Unrealized gain related to digital asset	(75,871)	-
Purchased in-process R&D	2,394,596	2,477,193
Federal orphan drug credits	1,211,026	1,209,202
Capitalized research and development costs	2,008,637	3,781,193
Total non-current deferred tax assets	21,325,736	19,902,665
Valuation allowance for deferred tax assets	(21,325,736)	(19,902,665)
Total deferred tax assets	-	-
Deferred Tax Liabilities:		
Non-current:		
Intangible asset	-	-
Total non-current deferred tax liabilities	-	-
Total deferred tax asset (liability)	$ -	$ -

In 2022, the Tax Cuts and Jobs Act of 2017 (TCJA) eliminated the immediate deduction of research and development (R&D) expenditures, requiring taxpayers to amortize these costs over five or fifteen years pursuant to IRC Section 174. Consequently, we capitalized approximately $3.8 million of research and development expenditures, net of annual amortization during 2024. However, the enactment of the One Big Beautiful Bill Act (OBBBA) reinstated the full deductibility of domestic research and development expenditures effective January 1, 2025. In accordance with the OBBBA's transition rules, we deducted 50% of the remaining unamortized domestic research and development balance in 2025 and plan to deduct the remaining 50% in 2026. We continue to capitalize and amortize foreign research and development expenditures over a 15-year period as required.

A valuation allowance is maintained to reduce deferred tax assets to the amount more-likely-than-not to be realized. In assessing the need for this allowance, we evaluate all available positive and negative evidence, including the timing and extent of future taxable income. Due to significant negative evidence - primarily in the form of cumulative operating losses - we determined that it is not more-likely-than-not that the deferred tax assets will be realized. Consequently, a full valuation allowance has been established. The valuation allowance increased by $1.4 million and $2.3 million for the years ended December 31, 2025 and 2024, respectively.

We evaluate uncertain tax positions through a two-step process in accordance with ASC 740. 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 a tax position will be sustained upon examination, 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 cumulatively greater than 50% likely to be realized upon settlement. We have not recorded any uncertain tax positions. As of December 31, 2025 and 2024, we have no unrecognized tax benefits and have not accrued penalties or interest related to uncertain tax positions.

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

Note 9 – Related Party Transactions

CorLyst, LLC

CorLyst, LLC ("CorLyst") reimburses us for shared costs related to payroll, health insurance and rent based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses in our consolidated statements of operations. We recorded approximately $100,000 and $110,000 in reimbursements during the years ended December 31, 2025 and 2024, respectively. At December 31, 2025, no amounts were due from CorLyst and $47 was due at December 31, 2024. Our President, Research and Development is the Chief Executive Officer of CorLyst, and CorLyst is a shareholder of the Company.

The Chiliz Group

The Chiliz Group (formerly known as 'HX Entertainment Limited') is the issuer of the Chiliz Token. On August 4, 2025, we sold 218,688 restricted shares of our common stock to The Chiliz Group for $1.2 million in net proceeds, and on February 17, 2026, we sold them an additional 86,956 restricted shares of our common stock for $200,000. As of March 13, 2026, The Chiliz Group owned 11.5% of our shares of common stock outstanding.

Note 10 – Litigation

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

On December 3, 2024, Jason Assad and Marc Gyimesi, two of the investors in our February 2021 private offering, filed a lawsuit that has been assigned to the Commercial Division of the Supreme Court of the State of New York County, New York County alleging fraud and negligent misrepresentation in connection therewith and seeking monetary damages. In addition to being an investor, Mr. Assad was a former investor relations and communications consultant to the Company from September 1, 2021 through June 30, 2024. On April 25, 2025, the Company filed a motion to dismiss the complaint in its entirety. The motion was decided in September 2025. The court dismissed two of the three counts of the complaint (for constructive fraud and negligent misrepresentation) and dismissed that part of the remaining cause of action for fraud to the extent that it related to the retention of Plaintiffs' investment (leaving only the portion of the claim in which Plaintiffs allege they were fraudulently induced to invest in the Company in February 2021). The court also dismissed all claims against Patrick Lin and George Ng. Processa's and David Young's answers were submitted during October 2025. The discovery phase of the matter has commenced. In January 2026, Plaintiffs were granted leave to amend their complaint to add a claim for breach of contract against Processa and David Young based on the same factual allegations. Processa and David Young's responses to the amended complaint were submitted by March 2, 2026. In the meantime, the discovery and deposition phases of the matter are ongoing.

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

Note 11 – Segment Reporting

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

The accounting policies of our single operating segment are the same as those described in the summary of significant accounting policies in Note 2. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. In 2025 and 2024, all our long-lived assets were held in the United States. Expenditures for the addition of long-lived assets are reported on the consolidated statements of cash flows as purchases of property and equipment. We do not have intra-entity sales or transfers since our only subsidiary is currently dormant.

The following table presents reportable segment profit and loss, including significant expense categories, attributable to our reportable segment for the years ended December 31, 2025 and 2024:

	Year ended December 31,	
	2025	2024
Preclinical, clinical trial and other costs	$ 6,240,583	$ 5,450,963
Research and development personnel expense[(1)]	1,569,754	1,818,183
General and administrative personnel expense[(2)]	2,786,832	1,981,756
Administrative and facilities expense[(3)]	3,391,336	2,800,304
Other income, net	(424,671)	(201,088)
Total	$ 13,563,834	$ 11,850,118

(1) Research and development personnel costs include employee stock-based compensation expense of $192,630 and $169,414 for the year ended December 31, 2025 and 2024, respectively.

(2) General and administrative personnel costs include employee stock-based compensation expense of $508,644 and $186,925 for the year ended December 31, 2025 and 2024, respectively, and are net of reimbursements received from CorLyst, LLC.

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

Note 12 – Commitments and Contingencies

Purchase Obligations

We enter contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If we terminated a cancellable contract with a specific vendor, we would only be obligated for products or services that we received as of the effective date of the termination and any applicable cancellation fees. As of December 31, 2025, we are contractually obligated to pay up to approximately $11.9 million for future services under the agreements with the CROs for our clinical trials in NGC-Cap. Our actual contractual obligations will also vary depending on the progress and results of the remaining clinical trials.

Note 13 – Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of our cash and cash equivalents. We utilize only well-established banks and financial institutions with high credit ratings. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by our banks at December 31, 2025, exceeded FDIC limits.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

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, 2025, an evaluation was performed by management, with the participation of 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, 2025 to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Inherent Limitations on Effectiveness of Controls

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

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

Management's Annual Report on Internal Control Over Financial Reporting

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

Management assessed our internal control over financial reporting as of December 31, 2025. 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, 2025, our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with GAAP.

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

Changes in Internal Control Over Financial Reporting

There were no changes to our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Rule 10b5-1 Trading Plans

During the quarter ended December 31, 2025, none of our directors or executive officers adopted or terminated a Rule 10b5-1 trading plan or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 of Form 10-K will be included our 2026 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for our 2026 Annual Meeting of Stockholders ("2026 Proxy Statement") is incorporated herein by reference to our 2026 Proxy Statement. The 2026 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates.

Item 11. Executive Compensation

The information required by this Item 11 of Form 10-K is incorporated herein by reference to our 2026 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 2026 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 of Form 10-K is incorporated herein by reference to our 2026 Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 of Form 10-K is incorporated herein by reference to our 2026 Proxy Statement.

Part IV

Item 15. Exhibits and 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
3.1	Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1 to Form S-1 filed on September 17, 2020)
3.1.1	Amendment to Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1.1 to Form S-1 filed on September 17, 2020)
3.1.2	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation dated August 8, 2019 (incorporated by reference to Exhibit 3 to Form 10-Q filed on August 14, 2019)
3.1.3	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. dated June 25, 2020 (incorporated by reference to Exhibit 3.1.4 to Form S-1 filed on September 17, 2020)
3.1.4	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation dated January 1, 2022 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 6, 2022)
3.1.5	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 29, 2023)
3.1.6	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 18, 2024)
3.1.7	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K.A filed September 16, 2025)
3.1.8	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K filed December 15, 2025)

3.2	Amended and Restated Bylaws of Processa Pharmaceuticals, Inc., dated March 18, 2025 (incorporated by reference to Exhibit 3.2 to Form 1-K filed on March 20, 2025)
4.1	Specimen of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form S-1 filed on September 17, 2020)
4.2	Form of Series A Common Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed January 30, 2025)
4.3	Form of Series B Common Warrant (incorporated by reference to Exhibit 4.2 to Form 8-K filed January 30, 2025)
4.4	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.3 to Form 8-K filed January 30, 2025)
4.5	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.5 to Form 10-K filed March 29, 2024)
10.1+	Amended and Restated 2011 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Form S-1 filed on September 17, 2020)
10.2	License Option Agreement with Sun Pharmaceuticals (incorporated by reference to Exhibit 10.2 to Form S-1 filed on September 17, 2020)
10.3	Amendment to License Agreement and Securities Purchase Agreement with Sun Pharmaceuticals (incorporated by reference to Exhibit 10.3 to Form S-1 filed on September 17, 2020)
10.4+	Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.5 to Form S-1 filed on September 17, 2020)
10.5+	Amended and Restated Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Exhibit 4.1 to Form S-8 filed September 22, 2025)
10.6	License Agreement with Aposense, Ltd. dated May 24, 2020 (incorporated by reference to Exhibit 10.9 to Form S-1 filed on September 17, 2020)
10.7	License Agreement with Yuhan Corporation (incorporated by reference to Exhibit 10.11 to Form S-1 filed on September 17, 2020)
10.8	License Agreement with Elion Oncology, Inc. (incorporated by reference to Exhibit 10.13 to Form S-1 filed on September 17, 2020)
10.9	Addendum No. 1 to the Aposense Ltd. License Agreement (incorporated by reference to Exhibit 10.15 to Form 10-K filed on March 25, 2021)
10.10	Sales Agreement, dated May 21, 2024, by and among Processa Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 1.2 to Form S-3 filed on May 21, 2024)
10.11+	Employment Agreement dated March 19, 2025 by and between George Ng and Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.11 to Form 10-K filed on March 20, 2025)
10.12+	Employment Agreement dated March 19, 2025, by and between Russell Skibsted and Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.12 to Form 10-K filed on March 20, 2025)
10.13+	Employment Agreement dated March 19, 2025, by and between Sian Bigora and Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.13 to Form 10-K filed on March 20, 2025)
10.14+	Employment Agreement dated March 19, 2025, by and between Wendy Guy and Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.14 to Form 10-K filed on March 20, 2025)
10.15+	Employment Agreement dated March 19, 2025, by and between Patrick Lin and Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.15 to Form 10-K filed on March 20, 2025)
10.16+	Employment Agreement dated March 19, 2025, by and between David Young and Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.16 to Form 10-K filed on March 20, 2025)
10.17	Amendment No. 1 to License Agreement with Yuhan Corporation (incorporated by reference to Exhibit 10.1 to Form 8-K filed June 30, 2025
19	Insider Trading Policy (incorporated by reference to Exhibit 19 to Form 10-K filed March 20, 2025)
21.1*	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm, Cherry Bekaert, LLP
31.1*	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Processa Pharmaceuticals, Inc. Restatement Clawback Policy (incorporated by reference to Exhibit 97.1 to Form 10-K filed on March 29, 2024)
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PROCESSA PHARMACEUTICALS, INC.

By: */s/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Dated: March 18, 2026

By: */s/ Russell Skibsted*
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: March 18, 2026

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

Name	Capacity	Date
/s/ George Ng George Ng	Chief Executive Officer	March 18, 2026
/s/ Russell Skibsted Russell Skibsted	Chief Financial Officer	March 18, 2026
/s/ David Young David Young	President of Research and Development and Director	March 18, 2026
/s/ Khoso Baluch Khoso Baluch	Director	March 18, 2026
/s/ James Neal James Neal	Director	March 18, 2026
/s/ Geraldine Pannu Geraldine Pannu	Director	March 18, 2026
/s/ Justin Yorke Justin Yorke	Director	March 18, 2026

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (this "Agreement") is dated as of February 13 2026, between Processa Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and each purchaser identified on the signature pages hereto (each, including its successors and assigns, a "Purchaser" and collectively the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to an exemption from the registration requirements of Section 5 of the Securities Act contained in Section 4(a)(2) thereof and/or Regulation D promulgated thereunder, the Company desires to issue and sell to each Purchaser, and each Purchaser, severally and not jointly, desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Acquiring Person" shall have the meaning ascribed to such term in Section 4.5.

"Action" shall have the meaning ascribed to such term in Section 3.1(j).

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

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

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

"Closing" means the closing of the purchase and sale of the Securities pursuant to Section 2.1.

"Closing Date" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchasers' obligations to pay the Subscription Amount and (ii) the Company's obligations to deliver the Securities, in each case, have been satisfied or waived, but in no event later than the first (1st) Trading Day following the date hereof (or the second (2nd) Trading Day following the date hereof if this Agreement is signed on a day that is not a Trading Day or after 4:00 p.m. (New York City time) and before midnight (New York City time) on a Trading Day).

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

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

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

"Company Counsel" means Foley & Lardner LLP, with offices located at 1 Independent Drive, Suite 1300, Jacksonville, FL 32202.

"Evaluation Date" shall have the meaning ascribed to such term in Section 3.1(s).

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

"FCPA" means the Foreign Corrupt Practices Act of 1977, as amended.

"FDA" shall have the meaning ascribed to such term in Section 3.1(hh).

"FDCA" shall have the meaning ascribed to such term in Section 3.1(hh).

"GAAP" shall have the meaning ascribed to such term in Section 3.1(h).

"Indebtedness" shall have the meaning ascribed to such term in Section 3.1(aa).

"Intellectual Property Rights" shall have the meaning ascribed to such term in Section 3.1(p).

"Liens" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"Material Adverse Effect" shall have the meaning assigned to such term in Section 3.1(b).

"Material Permits" shall have the meaning ascribed to such term in Section 3.1(n).

"Per Share Purchase Price" equals $ 2.30 (two US dollars and 30 cents), subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

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

"Pharmaceutical Product" shall have the meaning ascribed to such term in Section 3.1(hh).

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

"Purchaser Party" shall have the meaning ascribed to such term in Section 4.8.

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(h).

"Securities" means the Shares.

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

"Shares" means the shares of Common Stock issued or issuable to each Purchaser pursuant to this Agreement.

"Short Sales" means all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include locating and/or borrowing shares of Common Stock).

"Subscription Amount" means, as to each Purchaser, the aggregate amount to be paid for Shares hereunder as specified below such Purchaser's name on the signature page of this Agreement and next to the heading "Subscription Amount," in United States dollars and in immediately available funds.

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

"Trading Day" means a day on which the principal Trading Market is open for trading.

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

"Transaction Documents" means this Agreement, all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means Continental Stock Transfer & Trust Company, LLC, the current transfer agent of the Company, with a mailing address of 1 State Street, 30th Floor, New York, NY 10004 and an email address of sjones@continentalstock.com, and any successor transfer agent of the Company.

ARTICLE II.
PURCHASE AND SALE

2.1 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, the Company agrees to sell, and the Purchasers, severally and not jointly, agree to purchase, up to an aggregate of $200,000 of Shares. Each Purchaser shall deliver to the Company, via wire transfer or a certified check, immediately available funds equal to such Purchaser's Subscription Amount as set forth on the signature page hereto executed by such Purchaser and the Company shall deliver to each Purchaser its respective Shares as determined pursuant to Section 2.2(a), and the Company and each Purchaser shall deliver the other items set forth in Section 2.2 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.2 and 2.3, the Closing shall occur at the offices of Company Counsel or such other location as the parties shall mutually agree.

2.2 Deliveries.

(a) On or prior to the Closing Date (except as indicated below), the Company shall deliver or cause to be delivered to each Purchaser the following:

(i) this Agreement duly executed by the Company;

(ii) subject to Section 2.1, the Company shall have provided each Purchaser with the Company's wire instructions, on Company letterhead and executed by the Chief Executive Officer or Chief Financial Officer; and

(iii) subject to Section 2.1, a copy of the irrevocable instructions to the Transfer Agent instructing the Transfer Agent to deliver the Shares equal to such Purchaser's Subscription Amount divided by the Per Share Purchase Price, registered in the name of such Purchaser in book-entry form held at the Transfer Agent.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company, the following:

(i) this Agreement duly executed by such Purchaser; and

(ii) such Purchaser's Subscription Amount.

2.3 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) on the Closing Date of the representations and warranties of the Purchasers contained herein (unless as of a specific date therein in which case they shall be accurate in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) as of such date);

(ii) all obligations, covenants and agreements of each Purchaser required to be performed at or prior to the Closing Date shall have been performed; and

(iii) the delivery by each Purchaser of the items set forth in Section 2.2(b) of this Agreement.

(b) The respective obligations of the Purchasers hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein in which case they shall be accurate in all material respects or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) as of such date);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.2(a) of this Agreement;

(iv) there shall have been no Material Adverse Effect with respect to the Company since the date of this Agreement; and

(v) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of such Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. Except as set forth in the SEC Reports, the Company hereby makes the following representations and warranties to each Purchaser:

(a) Subsidiaries. All Subsidiaries of the Company are set forth in the SEC Reports. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse

effect on the results of operations, assets, business or financial condition of the Company and the Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect") and, to the Company's knowledge, no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as would not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.4 of this Agreement, (ii) application(s) to each applicable Trading Market for the listing of the Shares for trading thereon in the time and manner required thereby, and (iii) the filing of Form D with the Commission and such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals").

(f) Issuance of the Securities. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement.

(g) Capitalization. The capitalization of the Company as of the date hereof is as set forth in the SEC Reports. Except as set forth in the SEC Reports, the Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options under the Company's stock option plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. Except as a result of the purchase and sale of the Securities and as set forth in the SEC Reports, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Securities will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person (other than the Purchasers). There are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such

outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any stockholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(h) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the one year preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared, in all material respects, in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(i) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, (i) there has been no event, occurrence or development that has had or that would reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any material liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. The Company does not have pending before the Commission any request for confidential

treatment of information. Except for the issuance of the Securities contemplated by this Agreement or as set forth in the SEC Reports, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made.

(j) Litigation. Except as set forth in the SEC Reports, there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action"). There are no Actions that (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) would, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(k) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which would reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and to the Company's knowledge the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in material compliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(l) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with

notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as would not have or reasonably be expected to result in a Material Adverse Effect.

(m) Environmental Laws. The Company and its Subsidiaries (i) are in compliance, in all material respects, with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "Hazardous Materials") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("Environmental Laws"); (ii) have received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses as currently conducted; and (iii) are in compliance with all terms and conditions of any such permit, license or approval where in each clause (i), (ii) and (iii), the failure to so comply could be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

(n) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits would not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(o) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties. Any real property and

facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance, except for matters which are not expected to result in a Material Adverse Effect.

(p) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all material patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have would have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement. except for matters which are not expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as would not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing material infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(q) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(r) Transactions With Affiliates and Employees. Except as set forth in the SEC Reports, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii)

reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(s) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in material compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002, as amended that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(t) Certain Fees. No brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchasers shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(u) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(v) Registration Rights. Except as set forth in the SEC Reports, no Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(w) Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as set forth in the SEC Reports, the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. Except as set forth in the SEC Reports, the Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(x) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or would become applicable to the Purchasers as a result of the Purchasers and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Securities and the Purchasers' ownership of the Securities.

(y) Disclosure. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, the Company confirms that neither it nor any other Person acting on its behalf has provided any of the Purchasers or their agents or counsel with any information that it believes constitutes material, non-public information. The Company understands and confirms that the Purchasers will rely on the foregoing representation in effecting transactions in securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Purchasers regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(z) No Integrated Offering. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(aa) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, and (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date.

(bb) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(cc) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the

Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA.

(dd) Accountants. The Company's accounting firm is currently Cherry Bekaert LLP. To the knowledge and belief of the Company, such accounting firm (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2025.

(ee) Acknowledgment Regarding Purchasers' Purchase of Securities. The Company acknowledges and agrees that each of the Purchasers is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that no Purchaser is acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by any Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchasers' purchase of the Securities. The Company further represents to each Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(ff) Acknowledgment Regarding Purchaser's Trading Activity. Anything in this Agreement or elsewhere herein to the contrary notwithstanding (except for Sections 3.2(e) and 4.14 hereof), it is understood and acknowledged by the Company that: (i) none of the Purchasers has been asked by the Company to agree, nor has any Purchaser agreed, to desist from purchasing or selling, long and/or short, securities of the Company, or "derivative" securities based on securities issued by the Company or to hold the Securities for any specified term; (ii) past or future open market or other transactions by any Purchaser, specifically including, without limitation, Short Sales or "derivative" transactions, before or after the closing of this or future private placement transactions, may negatively impact the market price of the Company's publicly-traded securities; (iii) any Purchaser, and counter-parties in "derivative" transactions to which any such Purchaser is a party, directly or indirectly, presently may have a "short" position in the Common Stock, and (iv) each Purchaser shall not be deemed to have any affiliation with or control over any arm's length counter-party in any "derivative" transaction. The Company further understands and acknowledges that (y) one or more Purchasers may engage in hedging activities at various times during the period that the Securities are outstanding, and (z) such hedging activities (if any) could reduce the value of the existing stockholders' equity interests in the Company at and after the time that the hedging activities are being conducted. The Company acknowledges that such aforementioned hedging activities do not constitute a breach of any of the Transaction Documents.

(gg) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the

Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company.

(hh) FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration ("FDA") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("FDCA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its Subsidiaries (each such product, a "Pharmaceutical Product"), such Pharmaceutical Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its Subsidiaries, and none of the Company or any of its Subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Pharmaceutical Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Pharmaceutical Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

(ii) Stock Option Plans. Each stock option granted by the Company under the Company's stock option plan was granted (i) in accordance with the terms of the Company's stock option plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options

prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

(jj) Cybersecurity. To the Company's knowledge (i)(x) there has been no security breach or other compromise of or relating to any of the Company's or any Subsidiary's information technology and computer systems, networks, hardware, software, data (including the data of its respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of it), equipment or technology (collectively, "IT Systems and Data") and (y) the Company and the Subsidiaries have not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to its IT Systems and Data; (ii) the Company and the Subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, individually or in the aggregate, have a Material Adverse Effect; (iii) the Company and the Subsidiaries have implemented and maintained commercially reasonable safeguards as the Company believes to be appropriate for a Company of its size to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and Data; and (iv) the Company and the Subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practices as considered reasonably necessary by the Company.

(kk) Compliance with Data Privacy Laws. (i) The Company and the Subsidiaries are, and at all times during the last year were, in compliance in all material respects with all applicable state, federal and foreign data privacy and security laws and regulations, including, without limitation, the European Union General Data Protection Regulation ("GDPR") (EU 2016/679) (collectively, "Privacy Laws"); (ii) the Company and the Subsidiaries have in place, comply with, and take appropriate steps reasonably designed to ensure compliance with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling and analysis of Personal Data (as defined below) (the "Policies"); (iii) the Company provides accurate notice of its applicable Policies to its customers, employees, third party vendors and representatives as required by the Privacy Laws; and (iv) applicable Policies provide accurate and sufficient notice of the Company's then-current privacy practices relating to its subject matter, and do not contain any material omissions of the Company's then-current privacy practices, as required by Privacy Laws. "Personal Data" means (i) a natural person's name, street address, telephone number, email address, photograph, social security number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR; and (iv) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any identifiable data related to an identified person's health or sexual orientation. (i) None of such disclosures made or contained in any of the

Policies have been inaccurate, misleading, or deceptive in violation of any Privacy Laws and (ii) the execution, delivery and performance of the Transaction Documents will not result in a breach of any Privacy Laws or Policies. Neither the Company nor the Subsidiaries (i) to the knowledge of the Company, has received written notice of any actual or potential liability of the Company or the Subsidiaries under, or actual or potential violation by the Company or the Subsidiaries of, any of the Privacy Laws; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation or other corrective action pursuant to any regulatory request or demand pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement by or with any court or arbitrator or governmental or regulatory authority that imposed any obligation or liability under any Privacy Law.

(ll) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC").

(mm) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(nn) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(oo) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no Action or Proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

3.2 Representations and Warranties of the Purchasers. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein, in which case they shall be accurate as of such date):

(a) Organization; Authority. Such Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by such Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Understandings or Arrangements. Such Purchaser is acquiring the Securities as principal for its own account and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities. Such Purchaser is acquiring the Securities hereunder in the ordinary course of its business.

(c) Experience of Such Purchaser. Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. Such Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(d) Access to Information. Such Purchaser acknowledges that it has had the opportunity to review the Transaction Documents (including all exhibits and schedules thereto) and the SEC Reports and has been afforded, (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Securities and the merits and risks of investing in the Securities; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment.

(e) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly

executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that such Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material pricing terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement or to such Purchaser's representatives, including, without limitation, its officers, directors, partners, legal and other advisors, employees, agents and Affiliates, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

(f) Validity. The execution and delivery of the Transaction Documents to which such Purchaser is a party and the consummation by it of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary action on the part of such Purchaser and no further consent or authorization of such Purchaser or its members (or shareholders) is required.

(g) General Solicitation. Such Purchaser is not purchasing the Shares as a result of any advertisement, article, notice or other communication regarding the Shares published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or, to the knowledge of such Purchaser, any other general solicitation or general advertisement.

The Company acknowledges and agrees that the representations contained in this Section 3.2 shall not modify, amend or affect such Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transactions contemplated hereby.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 Transfer Restrictions.

(a) The Shares may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of the Shares other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in

connection with a pledge as contemplated in Section 4.1(b), the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Securities under the Securities Act. As a condition of transfer, any such transferee shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of a Purchaser under this Agreement.

(b) The Purchasers agree to the imprinting, so long as is required by this Section 4.1, of a legend on any of the Shares in the following form:

THESE SHARES OF COMMON STOCK HAVE NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS..

(c) The Company acknowledges and agrees that a Purchaser may from time to time pledge pursuant to a bona fide margin agreement with a registered broker-dealer or grant a security interest in some or all of the Shares to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and, if required under the terms of such arrangement, such Purchaser may transfer pledged or secured the Securities to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the appropriate Purchaser's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of the Securities may reasonably request in connection with a pledge or transfer of the Shares.

(d) Certificates evidencing the Shares shall not contain any legend (including the legend set forth in Section 4.1(b) hereof), (i) while a registration statement covering the resale of such security is effective under the Securities Act, (ii) following any sale of such Shares pursuant to Rule 144, (iii) if such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions, or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission). The Company shall cause its counsel to issue a legal opinion to the Transfer Agent or the Purchaser promptly after the Effective Date if required by the Transfer Agent to effect the removal of the legend hereunder, or if requested by a Purchaser, respectively.

(e) Each Purchaser, severally and not jointly with the other Purchasers, agrees with the Company that such Purchaser will sell any Shares pursuant to either the registration requirements of the Securities Act, including any applicable prospectus delivery requirements, or an exemption therefrom, and that if Securities are sold pursuant to a registration statement, they will be sold in compliance with the plan of distribution set forth therein, and acknowledges that the removal of the restrictive legend from certificates representing Shares as set forth in this Section 4.1 is predicated upon the Company's reliance upon this understanding.

4.2 Furnishing of Information. Until the earliest of the time that no Purchaser owns Securities, the Company covenants to use commercially reasonable efforts to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act even if the Company is not then subject to the reporting requirements of the Exchange Act.

4.3 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.4 Securities Laws Disclosure; Publicity. The Company shall issue a press release disclosing the material terms of the transactions contemplated hereby and/or file a Current Report on Form 8-K, including the Transaction Documents as exhibits thereto, with the Commission within the time required by the Exchange Act.

4.5 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Purchaser is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Purchaser would be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchasers.

4.6 Non-Public Information. Except with respect to the material pricing terms and conditions of the transactions contemplated by the Transaction Documents, which shall be disclosed pursuant to Section 4.4, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide any Purchaser or its agents or counsel with any information that constitutes, or the Company reasonably believes constitutes, material non-public information, unless prior thereto such Purchaser shall have consented in writing to the receipt of such information and agreed in writing with the Company to keep such information confidential. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company. To the extent that the Company, any of its Subsidiaries, or any of their respective officers, directors, agents, employees or Affiliates delivers any material, non-public information to a Purchaser without such Purchaser's consent, the Company hereby covenants and agrees that such Purchaser shall not have any duty of confidentiality to the Company, any of its Subsidiaries, or any of their respective officers,

directors, employees, Affiliates or agents, or a duty to the Company, any of its Subsidiaries or any of their respective officers, directors, employees, Affiliates or agents not to trade on the basis of, such material, non-public information, provided that the Purchaser shall remain subject to applicable law. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously with the delivery of such notice file such notice with the Commission pursuant to a Current Report on Form 8-K. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company.

4.7 Use of Proceeds. The Company shall use the net proceeds from the sale of the Securities hereunder for working capital purposes and shall not use such proceeds: (a) for the satisfaction of any portion of the Company's debt (other than payment of trade payables in the ordinary course of the Company's business and prior practices), (b) for the redemption of any Common Stock or Common Stock Equivalents, (c) for the settlement of any outstanding litigation or (d) in violation of FCPA or OFAC regulations.

4.8 Indemnification of Purchasers. Subject to the provisions of this Section 4.8, the Company will indemnify and hold each Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any stockholder of the Company who is not an Affiliate of such Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is solely based upon a material breach of such Purchaser Party's representations, warranties or covenants under the Transaction Documents or any agreements or understandings such Purchaser Party may have with any such stockholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by such Purchaser Party which is finally judicially determined to constitute fraud, gross negligence or willful misconduct). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and, the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in

the reasonable opinion of counsel a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (y) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (z) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or other agreements in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.8 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.9 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue Shares pursuant to this Agreement.

4.10 Listing of Common Stock. The Company hereby agrees to use commercially reasonable efforts to maintain the listing or quotation of the Common Stock on the Trading Market on which it is currently listed, and concurrently with the Closing, the Company shall apply to list or quote all of the Shares on such Trading Market and promptly secure the listing of all of the Shares on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Shares, and will take such other action as is necessary to cause all of the Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market. The Company agrees to maintain the eligibility of the Common Stock for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

4.11 Equal Treatment of Purchasers. No consideration (including any modification of this Agreement) shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of this Agreement unless the same consideration is also offered to all of the parties to this Agreement. For clarification purposes, this provision constitutes a separate right granted to each Purchaser by the Company and negotiated separately by each Purchaser, and is intended for the Company to treat the Purchasers as a class and shall not in any way be construed as the Purchasers acting in concert or as a group with respect to the purchase, disposition or voting of Securities or otherwise.

4.12 Certain Transactions and Confidentiality. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales

of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company pursuant to the initial press release as described in Section 4.4, such Purchaser will maintain the confidentiality of the existence and terms of this transaction (other than as disclosed to its legal and other representatives). Notwithstanding the foregoing and notwithstanding anything contained in this Agreement to the contrary, the Company expressly acknowledges and agrees that (i) no Purchaser makes any representation, warranty or covenant hereby that it will not engage in effecting transactions in any securities of the Company after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4, (ii) no Purchaser shall be restricted or prohibited from effecting any transactions in any securities of the Company in accordance with applicable securities laws from and after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4 and (iii) no Purchaser shall have any duty of confidentiality or duty not to trade in the securities of the Company to the Company, any of its Subsidiaries, or any of their respective officers, directors, employees, Affiliates, or agent after the issuance of the initial press release as described in Section 4.4. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the covenant set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement.

ARTICLE V.
MISCELLANEOUS

5.1 Termination. This Agreement may be terminated by any Purchaser, as to such Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before the fifth (5th) Trading Day following the date hereof; provided, however, that no such termination will affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and any exercise notice delivered by a Purchaser), stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Shares.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the time of transmission, if such notice or communication is delivered via email attachment at the email address as set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the time of transmission, if such notice or communication is delivered via email attachment at the email address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2^{nd}) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers which purchased at least 50.1% in interest of the Shares based on the initial Subscription Amounts hereunder (or, prior to the Closing, the Company and each Purchaser) or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or multiple Purchasers), the consent of such disproportionately impacted Purchaser (or at least 50.1% in interest of such multiple Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of each Purchaser (other than by merger). Any Purchaser may assign any or all of its rights under this Agreement to any Person to whom such Purchaser assigns or transfers any Securities, provided

that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of the Transaction Documents that apply to the "Purchasers."

5.8 No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Section 4.8.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware, without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the State of Florida. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the State of Florida for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any Action or Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Action or Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If any party shall commence an Action or Proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.8, the prevailing party in such Action or Proceeding shall be reimbursed by the non-prevailing party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Action or Proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such ".pdf" signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever any Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then such Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights.

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchasers and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any Action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to any Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under any Transaction Document are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance or non-performance of the obligations of any other Purchaser under any Transaction Document. Nothing contained herein or in any other Transaction Document, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by the Transaction Documents. Each Purchaser shall be entitled to independently protect and enforce its rights including, without limitation, the rights arising out of this Agreement or out of the other Transaction Documents, and it shall not be necessary for any other Purchaser to be joined as an additional party in any Proceeding for such purpose. Each Purchaser has been represented by its own separate legal counsel in its review and negotiation of the Transaction Documents. The Company has elected to provide all Purchasers with the same terms and Transaction Documents for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement and in each other Transaction Document is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers.

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

5.19 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

(Signature Pages Follow)

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

PROCESSA PHARMACEUTICALS, INC.

By: _____
Name: Wendy Guy
Title: CAO

With a copy to (which shall not constitute notice):

Address for Notice:

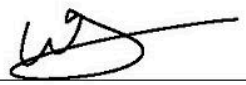
E-Mail:
wguy@processapharma.com

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK
SIGNATURE PAGE FOR PURCHASER FOLLOWS]

[PURCHASER SIGNATURE PAGES TO PCSA SECURITIES PURCHASE AGREEMENT]

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: The Chiliz Group Limited

Signature of Authorized Signatory of Purchaser: 

Name of Authorized Signatory: Alexandre Dreyfus

Title of Authorized Signatory: Director / CEO

Email Address of Authorized Signatory: adreyfus@gmail.com

Address for Notice to Purchaser:

The Chiliz Group Limited
179 Wembley Business Centre Level 6
TRIQ D'ARGENS
MSIDA
MSD 1360
MALTA

Address for Delivery of Shares to Purchaser (if not same as address for notice):

Subscription Amount: $ 200'000 (two hundred thousands US Dollars)

Shares: 86'956

EIN Number: C77290

[SIGNATURE PAGES CONTINUE]

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 inclusion or incorporation by reference of our report, dated March 18, 2026, with respect to the consolidated balance sheets of Processa Pharmaceuticals, Inc. (the "Company") as of December 31, 2025 and 2024 and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, in (i) the Company's Registration Statement on Form S-1 (No. 333-283986 and 333-287997), (ii) the Company's Registration Statements on Form S-3 (No. 333-279588 and No. 333-254983), and (iii) the Company's Registration Statement on Form S-8 (No. 333-290456).

/s/ Cherry Bekaert LLP
Tampa, Florida
March 18, 2026

Exhibit 31.1

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

I, George Ng, certify that:

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

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

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

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

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

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

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

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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 the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 18, 2026

/s/ George Ng
George Ng
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Russell Skibsted, certify that:

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

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

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

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

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

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

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

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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 the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 18, 2026

/s/ Russell Skibsted
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Processa Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2025 (the "Report"), each of George Ng, as Chief Executive Officer of the Company, and Russell Skibsted, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ George Ng
George Ng
Chief Executive Officer
(Principal Executive Officer)
March 18, 2026

/s/ Russell Skibsted
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
March 18, 2026

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.