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

FORM 10-K

X ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For fiscal year ended: December 31, 2022

OR

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 000-51353

Protagenic Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**06-1390025**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
149 Fifth Avenue New York, New York	**10010**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(212) 994-8200**

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

Title of each class	Name of exchange on which registered
Common Stock, par value $0.0001, PTIX	Nasdaq Capital Market
Common Stock Purchase Warrant, PTIXW	Nasdaq Capital Market

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, $0.0001 par value
(Title of class)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 X No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted posted 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 and post such files). Yes X No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company X
	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 and attestation to its management's assessment of the effectiveness of its internal control 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. Yes ☐ No X

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2022, based on a closing price as reported on the Nasdaq Capital Market of $0.724 was approximately $12,514,529.

As of March 31 2023, there were 4,321,445 shares of the registrant's common stock, par value $0.0001, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

PROTAGENIC THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2022
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future. The matters discussed in these forward-looking statements are subject to risks, uncertainties and other factors that could cause our actual results to differ materially from those projected, anticipated or implied in the forward-looking statements. As a result, you should not place undue reliance on any forward-looking statements. Except to the limited extent required by applicable law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Risk Factors Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K as part of your evaluation of the risks associated with an investment in our securities.

Risks Related to Our Financial Condition and Capital Requirements

- If we continue to incur operating losses and fail to obtain the capital necessary to fund our operations, we will be unable to advance our development programs, complete our clinical trials, or bring products to market, or may be forced to reduce or cease operations entirely. In addition, any capital obtained by us may be obtained on terms that are unfavorable to us, our investors, or both.
- Unstable market and economic conditions may have serious adverse consequences on our ability to raise funds, which may cause us to cease or delay our operations.
- Covid-19 could adversely impact our business, including our clinical trials, and financial condition.

Risks Related to Clinical Development and Regulatory Approval

- Our results to date provide no basis for predicting whether any of our product candidates will be safe or effective, or receive regulatory approval.
- We may not be able to initiate and complete preclinical studies and clinical trials for our product candidates which could adversely affect our business.
- If we experience delays or difficulties in the enrollment of subjects to our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented, which could materially affect our financial condition.
- If the market opportunities for our current and potential future drug candidates are smaller than we believe they are, our ability to generate product revenues will be adversely affected and our business may suffer.

Risks Related to Our Reliance on Third Parties

- We have no experience in sales, marketing and distribution and may have to enter into agreements with third parties to perform these functions, which could prevent us from successfully commercializing our product candidates.
- Data provided by collaborators and other parties upon which we rely have not been independently verified and could turn out to be inaccurate, misleading, or incomplete.
- We rely on third parties to conduct our non-clinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our current product candidates or any future products, on a timely basis or at all, and our financial condition will be adversely affected.

Risks Related to Commercialization of Our Product Candidates

- We have no experience as a company in commercializing any product. If we fail to obtain commercial expertise, upon product approval by regulatory agencies, our product launch and revenues could be delayed.
- We may not be able to gain market acceptance of our product candidates, which would prevent us from becoming profitable.
- We may not be able to manufacture our product candidates in clinical or commercial quantities, which would prevent us from commercializing our product candidates.
- Disputes under key agreements or conflicts of interest with our scientific advisors or clinical investigators could delay or prevent development or commercialization of our product candidates.

Risks Related to Our Intellectual Property

- We may not be able to maintain our exclusive worldwide license to use and develop PT00114 which could materially affect our business plan.

Risks Related to Our Business Operations and Industry

- If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.
- We may encounter difficulties in managing our growth, which could adversely affect our operations.
- Healthcare reform measures could adversely affect our business.
- Our business and operations are vulnerable to computer system failures, cyber-attacks or deficiencies in our cyber-security, which could increase our expenses, divert the attention of our management and key personnel away from our business operations and adversely affect our results of operations.
- Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.
- If we, our CROs or our IT vendors experience security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of personal data, we may face costs, significant liabilities, harm to our brand and business disruption.
- If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Risks Associated to our Common Stock

- If we fail to comply with the continued minimum closing bid requirements of Nasdaq or other requirements for continued listing, including stockholder equity requirements, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.
- Our common stock is a "Penny Stock" subject to specific rules governing its sale to investors that could impact its liquidity.
- The market price of our common stock may be volatile, which could lead to losses by investors and costly securities litigation.
- If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, investors could lose confidence in our financial reporting and this may decrease the trading price of our stock.
- Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock.
- Our common stock is controlled by insiders.
- We do not intend to pay dividends for the foreseeable future and may never pay dividends.
- Our certificate of incorporation allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

PART I

Item 1. Business.

Overview

Protagenic Therapeutic, Inc. (together with its subsidiary, "Protagenic," the "Company," "we," "our" or "us") are a biopharmaceutical company specializing in the discovery and development of therapeutics to treat stress-related neuropsychiatric and mood disorders. Our proprietary, patent-protected, first-in-class lead compound, PT00114, is a synthetic form of Teneurin Carboxy-terminal Associated Peptide ("TCAP"), an endogenous brain signaling peptide that can dampen overactive stress responses. Our preclinical models have demonstrated efficacy of PT00114 in animal models of depression, anxiety, substance abuse & addiction, and PTSD.

PT00114 leverages a completely novel mechanism of action. Protagenic owns exclusive, worldwide rights to PT00114 through its license agreement with the University of Toronto and has an exclusive right to license additional intellectual property generated by Dr. David Lovejoy's lab at University of Toronto. Additionally, the company is engaged in the research & development of follow-on compounds in the TCAP family. Extensive publications in peer-reviewed scientific journals underline the central role stress plays in the onset and proliferation of neuropsychiatric disorders like depression, anxiety, substance abuse & addiction, and PTSD. The mechanism of action of TCAP suggests that it counterbalances stress overdrive at the cellular level within the brain's stress response cascade. TCAP works to alleviate the harmful behavioral, biochemical, and physiological effects of these disorders, while simultaneously restoring brain health. This mechanism has been corroborated in preclinical animal models of the psychiatric disorders listed above. Previously we anticipated that our preclinical experiments required for IND filing have been completed, and the company will seek to prove the safety and efficacy of PT00114 in humans through its initial clinical studies to commence in the first quarter of 2023. Responding to recent communications from regulatory agencies in the U.S. and in Germany, we are now undertaking to answer questions concerning:

- Stability and sterility additional testing
- Drug substance potency assays
- Cell lines for ELISA to satisfy requests for temperature and stability data

Given the time that we believe will be required to complete these additional tests and data collection, and accounting for expected turnaround time at the U.S. FDA and the German BfArM, we currently anticipate that a Phase I clinical trial of PT00114 in healthy volunteers could commence in the third quarter of 2023.

As Protagenic transitions into a clinical-stage company, we aim to complete certain key strategic and tactical milestones over the coming two years;

- Rapidly advance our lead product candidate, PT00114, through clinical trials in treatment resistant depression, substance use disorder, generalized anxiety disorder, and/or post-traumatic stress disorder.
- Develop additional product candidates from the TCAP family to build out a broad pipeline of assets with differentiated features using our unique expertise with this mechanism.
- Explore efficacy in additional stress-related neuropsychiatric and mood disorders beyond initially targeted indications.
- Facilitate long-term growth by building a nimble R&D, operational, clinical and commercial team.
- Proactively assess strategic partnership opportunities including in important international markets

Continue with our strategy of strengthening our IP position in this important novel field of neuropsychiatry

IND Submission

We currently anticipate re-submitting an investigational new drug (IND) application and initiating a PhaseI/IIa study to evaluate the safety, tolerability, and early activity of PT100114 (TCAP) in healthy volunteers and patients with psychiatric illnesses in the third quarter of 2023. The IND enabling studies, including the preclinical efficacy data generated, as well as the GLP toxicology study, and a summary of the Phase I clinical trial plan, will be among the components of this key regulatory submission.

Clinical Development

The clinical development program will be led by Dr. Maurizio Fava, MD, PhD, a world-leader in psychiatric disorders, the Psychiatrist-in-Chief of the Massachusetts General Hospital and Slater Family Professor of Psychiatry at Harvard Medical School. Dr. Fava was co-principal investigator of STAR*D, the largest research study ever conducted in depression, has coauthored more than 800 medical journal publications, and is one of the top enrolling psychiatry clinicians in the US. Protagenic's Phase I/II clinical study was designed by Dr. Fava, who will be the trial's principal investigator.

We will launch our clinical program with a basket trial designed first to evaluate the safety of TCAP in a small cohort of healthy volunteers, immediately followed by the evaluation of safety, pharmacological and clinical activity in cohorts of patients with stress-related neuropsychiatric disorders including, but not limited to depression, addiction, anxiety, and Post-Traumatic Stress Disorder (PTSD). We will be using this study for both safety and preliminary efficacy to prioritize indications for later phase development that would ultimately support a New Drug Application (NDA) and registration. The four indications were chosen for multiple reasons, including the mechanism of TCAP in reducing biological stress signals, preclinical evidence of efficacy in animal models of these disorders and the high unmet need in these patient populations, which creates significant market opportunity. We believe the basket trial structure offers the most efficient use of capital in early-stage development and will give us insights into which indication we should focus on in advanced clinical trials. Healthy volunteers will be the first cohort and subsequent parallel cohorts will include patients with:

- Major Depressive Disorder (MDD) who have suboptimal response to or poorly tolerated two prior SSRIs / SNRIs
- Generalized Anxiety Disorder (GAD) who have suboptimal response to or poorly tolerated two prior SSRIs /SNRIs
- Opioid Use Disorder (OUD) who are on treatment with Suboxone and have suboptimal response
- Post-Traumatic Stress Disorder (PTSD) who have suboptimal response to or intolerance of sertraline and paroxetine

The trial will use a classic sequential dose escalation design using cohort replication with initial doses estimated from non-clinical data. The study will assess dose ranging through standard and small cohorts with a rules-based approach for dose, safety, efficacy, and biomarkers. Trial participants will have a maximal 28-day exposure. As this will be the first in human study of TCAP, safety and adverse events will be the primary endpoint. Key secondary endpoints were chosen to ascertain efficacy in individual conditions and compare drug impact across disparate diseases. All disease cohorts will be measured for Strengths and Difficulties Questionnaire (SDQ), which is a validated broad self-rated outcome measure that has outperformed the clinician-rated Montgomery–Åsberg Depression Rating Scale (MADRS) scale in previous trials. Patients will also be assessed for stress biomarkers *via* pre- and post-treatment systemic cortisol levels and skin conductance. Each disease cohort (anxiety, depression, PTSD and addiction) will also have disease specific assessments.

Furthermore, although patient populations and their responses to CNS agents can be highly variable in clinical studies, we attempt to mitigate this by stratifying the initial series of cohorts to select for and control for corticosterone levels to enable the broadest window of effect detection. Preclinical studies of TCAP demonstrate that its beneficial actions are most easily observed in stressed animals, which show elevations of plasma corticosterone levels at baseline before TCAP treatment. Anxious or depressed patients have elevated corticosterone levels, providing an opportunity to identify patients more likely to benefit pharmacologically and potentially clinically. This also provides a useful translational bridge between preclinical behavioral models and human clinical studies and enables flexibility in evaluating routes of administration.

Market for Stress-Related Neuropsychiatric Disorders: Depression, Addiction, Anxiety, and PTSD

Humans living in our modern world, in both developed and developing nations, are being exposed to a multitude of life stressors that are progressively taking a toll on our mental health. The recent COVID-19 has exacerbated both near-term and long-term global impacts of stress-induced disorders on modern society. Stress-related mental, mood and behavioral disorders include, but are not limited to: treatment resistant depression (TRD), which is a subgroup of major depressive disorder (MDD); addiction or substance use disorder (SUD); and anxiety, including generalized anxiety disorder (GAD) and post-traumatic stress disorder (PTSD). These disorders are a leading cause of disability worldwide

and also a major contributor to suicide. Yet, a majority of these patients are inadequately served by current therapeutic options, which can have limited efficacy, significant side effects and high treatment burden. We believe these stress-related disorders are suitable indications for the use of Protagenic Therapeutics neuropeptide-based drug candidates.

Major depressive disorder (MDD) is highly prevalent and disabling. The lifetime prevalence is approximately 12% with a past year prevalence of 7.8% of adults in the United States in 2019, translating to over 19 million adults each year. The World Health Organization estimates 264 million people globally suffer from depression, which ranks depression as one of the highest causes of disability and mortality in the world. Stress plays a significant role in this illness and affects as many as half of people diagnosed with depression. MDD is characterized by multiple symptoms, potentially including depressed mood, loss of interest or pleasure, change in appetite or weight, sleep disturbance, fatigue or loss of energy, neurocognitive dysfunction, psychomotor agitation or retardation, feelings of worthlessness or excessive guilt, and suicidal ideation and behavior. MDD is highly treatment resistant, with 45-50% of patients who receive initial treatment for MDD not achieving long term remission, generally referred to as Treatment Resistant Depression (TRD). Patients suffering with TRD are at greater risk of hospitalization for their psychiatric illness and are more likely to abuse drugs and alcohol. These patients have a lower long-term quality of life and are at increased risk of attempting suicide. MDD is also highly recurrent and the estimated rate of recurrence over two years is over 40%, which rises to 75% after two episodes within five years.

Treatment guidelines recommend the combination of pharmacotherapy plus psychotherapy, but pharmacotherapy alone and psychotherapy alone are frequently used. For initial pharmacotherapy with antidepressants, selective serotonin reuptake inhibitors (SSRIs) are recommended. However, several classes of antidepressants are available, including serotonin-norepinephrine reuptake inhibitors (SNRIs), atypical antidepressants, and serotonin modulators, with efficacy generally comparable across and within classes. Drug choice is based on multiple factors, including side effect profile, comorbid illnesses, concurrent medications, patient preference, and cost. Physicians typically cycle through multiple generics if the initial response is suboptimal or patients experience AEs. Efficacy of therapy is challenged by non-compliance during the weeks to months required to achieve therapeutic benefit in combination with daily dosing requirements. However, SSRIs can produce significant quality of life side effects that interfere with medication adherence, including sexual dysfunction, gastrointestinal nausea and diarrhea, insomnia and weight gain. As a last resort, this disease is currently managed by invasive treatment, primarily electroconvulsive therapy (ECT). However, the side effects and high cost prevent widespread adoption.

Several drugs that have launched in recent years validate the market for branded agents in this field, in spite of their marginal improvements in safety or efficacy. Takeda's Trintellix (vortioxetine hydrobromide) launched in 2014 and has grown to $837M 2019 sales, largely due to studies added to the label after original approval showing cognitive function improvement and reduced incidence of treatment emergent sexual dysfunction (TESD). Despite these label additions, sales have lagged original consensus analyst forecasts, which at launch estimated 2019 worldwide sales of ~$1.1B.

Generalized anxiety disorder (GAD) is one of the most common mental disorders in both community and clinical settings. In the United States, the estimated lifetime prevalence of GAD is 5.7% with a past year prevalence of 2.7%, corresponding to 18 million and 9 million individuals, respectively. GAD is characterized by excessive and persistent worrying that causes significant distress or impairment on most days and is hard to control. Other symptoms can include apprehensiveness, irritability, increased fatigue and muscular tension. GAD is also associated with increased rates of substance abuse, posttraumatic stress disorder, and obsessive-compulsive disorder. GAD is a potentially chronic illness, with symptom severity fluctuating over time. A 12-year study of treated patients showed approximately 60% of patients had symptoms resolve, but around one-half of those subsequently relapsed.

Pharmacotherapy for GAD is primarily selective-serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs), which are mildly efficacious. Clinical trials for different SSRIs and SNRIs have shown approximately the same effectiveness, with response rates of approximately 60- 70% for the drug and 40% for placebo. However, SSRIs can produce significant quality of life side effects that interfere with medication adherence, including sexual dysfunction, gastrointestinal nausea and diarrhea, insomnia and weight gain. Thus, choice of agent is often dependent on the patient's side effect profile for individual drugs. Benzodiazepines are efficacious and can reduce emotional and somatic symptoms within hours. However, concerns about dependence risk has contributed to a decline in their use. Buspirone has similar efficacy to benzodiazepines without the risk of dependence but has a time to onset of approximately four weeks. As the majority of these agents are now available as generics, the worldwide market for GAD therapies was only $483M in 2019 and consensus analyst forecasts expect it to decline to $222M in 2026.

Post-traumatic stress disorder (PTSD) is one of the most common psychiatric disorders, with an estimated past-year and lifetime prevalence of 4.7% and 6.1%, translating to 11.5M adults in the US each year. PTSD develops in some patients following exposure to a traumatic event involving actual or threatened injury to themselves or others, such as war, natural disasters, rape or assault. Symptoms can be severe, chronic and disabling, which can include intrusive thoughts, nightmares and flashbacks of past traumatic events, avoidance of reminders of trauma, hypervigilance, and sleep disturbance, all of which lead to significant occupational and social impairment. Currently, PTSD is treated with psychotherapy and/or pharmacotherapy, with psychotherapy as the recommended primary intervention. Logistics and cost often limit access to psychotherapy, which results in many patients needing to rely on pharmacotherapy. Guidelines for pharmacotherapy recommend first-line treatment with sertraline and paroxetine, selective serotonin reuptake inhibitors (SSRI) antidepressants, as these are the only approved medications for PTSD. However, these only treat one aspect of symptomology and efficacy is limited, with fewer than 30% of patients experiencing remission. The side effect profile of these agents results in significant rates of discontinuation, particularly the severe effects such as suicidality and sexual dysfunction. Serotonin-norepinephrine reuptake inhibitors (SNRI) and second-generation antipsychotics are used off-label in some patients, but efficacy is sporadic, and side-effects can make these undesirable therapeutic options. As all of these options are currently generic, branded commercial sales for PTSD is almost non-existent. Given the size of the potential addressable population and limited therapeutic options available, a therapy with a superior therapeutic index could achieve significant market penetration and sales.

Substance use disorders (SUDs) are highly prevalent. According to the 2020 National Survey on Drug Use and Health (NSDUH), 40.3 million Americans, aged 12 or older, had a substance use disorder (SUD) in the past year. The majority of SUDs involve alcohol use disorder (14 million), followed by illicit drug use disorder (8 million). Illicit drug use and nonmedical use of medications alone or in combination with alcohol are associated with a substantial proportion of emergency department visits in the United States. Pharmacologic options to treat SUDs typically have limited efficacy, high treatment burden, with suboptimal side-effect profiles, ultimately leading to limited uptake and high remaining unmet medical need. 40- 60% of patients who receive SUD care experience chronic or relapsing disease course.

The incidence of opioid use disorder (OUD) and overdose deaths have reached epidemic proportions. Opioid use disorder is typically a chronic, relapsing illness, associated with significantly increased rates of morbidity and mortality. Opioid use disorder can be related to misuse of pharmaceutical opioids, heroin, or other opioids such as fentanyl and its analogues. The prevalence of heroin use and heroin use disorder nearly doubled between 2002 and 2018. In 2019, 2.1% of those 12 or older in the US were estimated to have used heroin at some point in their lives, translating 5.7 million people, with 431,000 (0.2%) having reported use in the last month. Opioid use disorders affect over 16 million people worldwide, over 2.1 million in the United States, and there are over 120,000 deaths worldwide annually attributed to opioids.[1]

Unmet needs are particularly high in OUD. First-line treatment for most patients is medication-assisted treatment, consisting of pharmacotherapy with an opioid agonist or antagonist in combination with psychotherapy. Pharmacotherapy can include an opioid agonist (methadone or buprenorphine) and/or an opioid antagonist (e.g. naltrexone). Guidelines for mild opioid use disorder suggest first-line treatment with long-acting injectable naltrexone (e.g. Vivitrol) administered monthly. Guidelines for moderate to severe opioid use disorder suggest initial use of buprenorphine (e.g. Suboxone) due to the higher risk of lethal overdose with methadone. Treatment can allow patients to return to a productive lifestyle but has low success rates and can be extremely burdensome. These therapies require patients remain on maintenance treatment with an opioid agonist for many years as they are physically dependent upon the medications. A minority may be tapered off after a few years, with the taper itself taking several months to years.

The treatment burden and side effect profile of these therapies is substantial. Buprenorphine is classified as a schedule III controlled substance in the United States, with use limited to certified and specially trained physicians. Side effects include sedation, headache, nausea, constipation, insomnia, and sweating. Death is possible if buprenorphine is taken in combination with other substances, especially benzodiazepines and alcohol. Methadone is highly regulated in the United States, where it is classified as a schedule II

drug. Only licensed opioid treatment programs or inpatient hospital units are permitted to dispense. Typical side effects of methadone include constipation, drowsiness, sweating, peripheral edema, reduced libido, and erectile dysfunction, with some patients experiencing severe adverse effects including cardiac arrhythmias, hyperalgesia, and overdose.

[1] National Institutes of Health, June 21, 2022 online report

Alcohol use disorder (AUD) is extraordinarily prevalent. Approximately 30% of adults in the United States use alcohol in an unhealthy manner and may need some form of intervention. The 2019 United States National Survey on Drug Use and Health estimated that of Americans over the age of 12 in the past 30 days, 24% reported binge drinking (five or more drinks on one occasion) and 6% reported heavy drinking (five or more drinks on each of five or more days). The National Institute on Alcohol Abuse and Alcoholism (NIAAA) reports 28% of US adults exceed thresholds for risky use alcohol consumption, with 19% exceeding the daily limit and 9% exceeding both the daily and weekly limits. Rates of diagnosable AUD by DSM-5 criteria from the third National Epidemiologic Survey on Alcohol and Related Conditions showed that 29% had met criteria for an alcohol use disorder in their lifetime and 14% met criteria for a current alcohol use disorder. Worldwide, the World Health Organization estimates that 5% of adults (>283 million people) had alcohol use disorder within the prior 12 months.

AUD is responsible for significant mortality and morbidity. Excessive alcohol consumption is the third leading preventable cause of death in the United States directly causing approximately 85,000 deaths per year, roughly 10% of deaths among working age adults. Nearly 5% of all deaths worldwide (approximately three million each year) have been attributed to alcohol use with 5% of those specifically due to AUD. The economic cost of excessive alcohol use in the United States is estimated to be $249 billion in 2010[2] by the CDC. Therapeutic unmet needs are significant for AUD and the condition is frequently untreated. Psychosocial interventions can be effective for treatment but up to 70% of individuals return to heavy drinking. For patients who met DSM-IV criteria for alcohol abuse, 46% were in remission, 24% continued to meet abuse criteria, and 30% met criteria for alcohol dependence in the future. For patients who met DSM-IV criteria for alcohol dependence, 39% were in remission, 15% met criteria for abuse only, and 46% continued to meet dependence criteria.

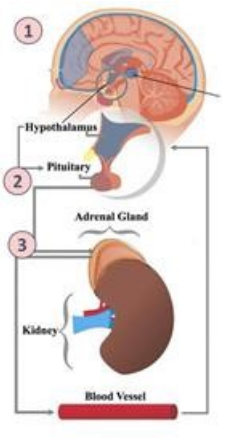
Several medications can be used to treat AUD, which can lead to reduced heavy drinking and increased days of abstinence. For most patients treated with moderate to severe alcohol use disorder, guidelines recommend first-line treatment with naltrexone (e.g. Vivitrol), an opioid antagonist. Vivitrol is an extended-release injectable naltrexone that allows for once monthly dosing that was approved in 2006. Vivitrol is priced at $~1370/month and worldwide sales have grown to $335M. Consensus analyst forecasts for Vivitrol project sales increasing to $419M in 2026, with patent expiry in 2028. Acamprosate (e.g. Campral) is recommended for those in whom naltrexone is contraindicated, such as those taking opioids or with acute hepatitis. Campral (Acamprosate) was approved by the FDA in 2004 and reached peak worldwide sales of $87M in 2008. Acamprosate is currently only available as generic in the US, but is still sold as branded Campral ex-US. Given the overall prevalence of AUD, these relatively low sales numbers indicate the vast majority of patients with AUD are not treated with pharmacotherapy.

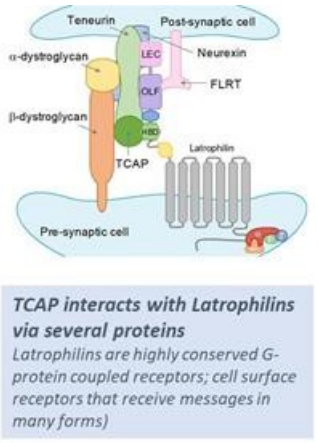
Teneurin Carboxy-terminal Associated Peptide (TCAP) as a Therapy

Our approach to treating stress-related neuropsychiatric and mood disorders is based on research into brain mechanisms conducted over the last 15 years in the laboratory of the company's scientific founder, Dr. David Lovejoy, from the University of Toronto. TCAP was discovered in a genome-wide search for proteins related to corticotropin releasing factor (CRF), an endogenous brain peptide known to be the central mechanism coupling external stress to psychological, behavioral, and endocrine responses. Dr. Lovejoy and his colleagues discovered and characterized Teneurin Carboxy-terminal Associated Peptide (TCAP); their further work revealed that TCAP is of ancient evolutionary origin and plays a central role in maintaining healthy brain structure and function in the face of the negative effects of stress. Although four TCAP peptides were discovered, only TCAP-1 is expressed independent of a larger Teneurin protein and is the primary focus of our development (PT00114).

[2] As of March 2023, these are the most recent data released by the CDC.

TCAP reverses the impact of stress on the Hypothalamic-Pituitary-Adrenal (HPA) axis, the endocrine and behavioral control system which connects environmental stress to behavioral responses via brain levels of Corticotropin Releasing Factor (CRF) and blood levels of the stress hormone cortisol. Stress elevates CRF, which in turn elevates cortisol levels. Studies have demonstrated that TCAP counteracts the effects of either endogenous or pharmacologically-administered CRF via a non-CRF receptor pathway in the brain, that is believed to be evolved over millions of years as a homeostasis-related pathway. There has been strong interest in the pharmaceutical industry for decades to develop drug candidates that block the negative effects of CRF by attempting to directly antagonize the CRF receptor, however clinical results to date with prior CRF receptor antagonists have been disappointing. Because TCAP counteracts the action of CRF by activating separate receptors instead of directly blocking CRF receptors, we believe it is a superior approach to alleviating stress-related neuropsychiatric disorders; TCAP-1 acts by binding to Latrophilin-1 and Latrophilin-3, G-protein-coupled receptors (GPCRs) expressed on nerve cells in the extended amygdala, the region of the brain involved in memory, emotion, and fear. TCAP acts through these receptors to block the effects of CRF and potentially other stress mediators such as Arginine-Vasopressin (AVP). Due to differences in the mechanism of action, TCAP is expected to be efficacious in clinical settings in which earlier studies with CRF receptor antagonists were not. We believe this novel mechanism of action can provide an attractive therapeutic profile for patients who are not fully responsive to currently available therapies.





TCAP interacts with Latrophilins via several proteins

Latrophilins are highly conserved G-protein coupled receptors; cell surface receptors that receive messages in many forms)

Two key effects of TCAP may contribute to its pharmacological activity in reversing or preventing stress-induced behavioral distortions. In settings of stress and depression, the activity of specific neural circuits can be diminished compared to the levels of activity observed in healthy brain tissue. After administration, TCAP crosses the blood brain barrier and concentrates in regions of the brain associated with the regulation of mood disorders. Administered TCAP can lead to increases in activity in some of the neuronal circuitry implicated in depression, demonstrated by increases in the utilization of glucose, a surrogate for cell activity. The fact that the pharmacological effects of TCAP persist after the drug has been cleared aligns with findings that TCAP applied to neurons in culture stabilizes dendritic spines, structures that sprout from the surface of neurons and can form synapses with other neurons to create functional circuitry. Stress and the associated rise in CRF have been reported to cause loss of synapses in animal models. The

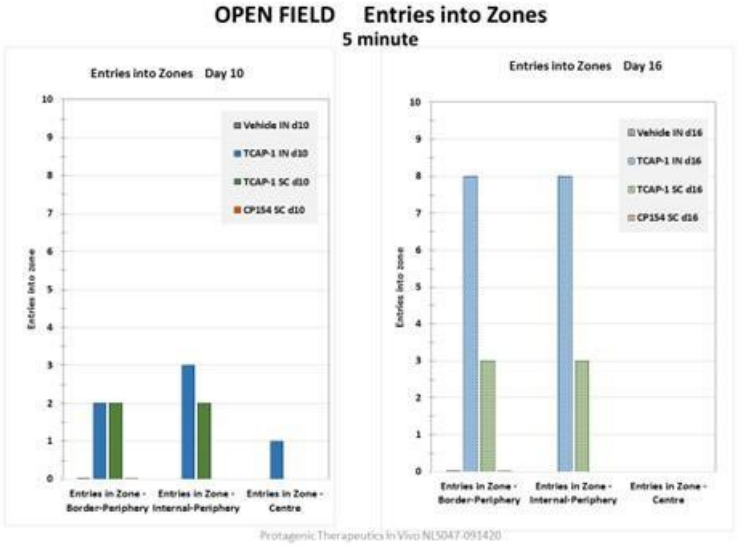
fact that the pharmacological actions of TCAP persist for weeks are consistent with its producing lasting changes in neuronal function by changing patterns of gene expression and thus creating relatively stable changes in neuronal function. In a number of these models, a single subcutaneous dose of TCAP will prevent the behavioral consequences of stress encountered three weeks later. This is especially notable since the administered dose of TCAP is eliminated from the plasma within hours of administration.

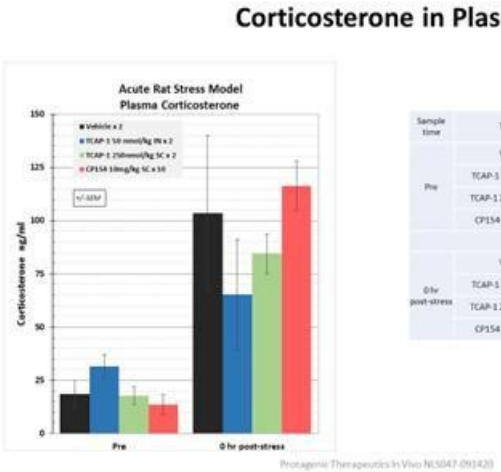
Our lead compound is a 41-residue peptide synthetic TCAP-1, which we have designated PT00114. In addition, we have a portfolio of earlier stage neuropeptides targeting the TCAP pathway that are in preclinical evaluation. The initial dosage form is intended as a subcutaneous injection but is also amenable to other routes of administration including sublingually or intra-nasally. This affords a range of target product profiles and opportunities for lifecycle management.

While many of the initial studies of TCAP had been generated in the lab of Dr. David Lovejoy, we have designed several preclinical studies over the last four years to validate the safety and efficacy of PT00114, for which we hired multiple independent contract research organizations (CROs) to conduct these studies. In preclinical rodent models, administration of PT00114 results in reproducible, dose-dependent reversal of a range of stress-induced behavioral distortions, including depression, stress-exacerbated anxiety, excessive startle, drug seeking, and opioid withdrawal. Stress-induced anxiety was measured by an elevated plus maze, an open field with stressed animals, and acoustic startle in CRF-treated animals. Depression was measured by tail suspension and forced swim. Stress-induced changes in tube-restrained rodents were used as a well-validated model for sub-acute stress. Notably, PT00114 was found to be pharmacologically active in stressed rodents but relatively inactive in non-stressed rodents.

In studies conducted with Charles River Laboratories in Kuopio, Finland, PT00114 showed beneficial effects in Chronic Social Defeat, a murine model of stress-induced behavioral dysfunction that has features of depression. In this model, male mice are placed in cages along with older, dominant male mice. This results in progressively more "resigned" behaviors in the mice experiencing this domineering exposure. This results in a series of behaviors in the cowed mice, termed Chronic Social Defeat. PT00114 reverses many of the component behaviors typically measured in this model, suggesting that it reverses the negative effects of stress in the "defeated" animals.

PT00114 demonstrated efficacy in a variable chronic stress model that has features of anxiety and PTSD. In an open field assessment, mice or rats are stressed by being placed in a tube for several hours, then placed in an open box where their movement is observed for 20 minutes. Control animals exhibit stress response behavior by not moving around much and staying near the edges of the box. Animal receiving PT00114 at the end of the stress condition moved around the open field. Animals receiving multiple administrations of a control small molecule CRH antagonist did not venture into the open field, indicating they were stressed. These results are also reflected in blood cortisol levels, where control mice had increased cortisol levels, which were reduced by treatment with PT00114, but not by the small molecule CRF antagonist.





Sample time	Treatment	Mean	SEM	N	
Pre	Vehicle x 2	19	4	3	
	TCAP-1 50 nmol/kg IN x 2	32	5	3	
	TCAP-1 250nmol/kg SC x 2	18	4	3	
	CP154 10mg/kg SC x 10	13	5	3	
					% inhib
0 hr post-stress	Vehicle x 2	103	36	2	0
	TCAP-1 50 nmol/kg IN x 2	65	26	2	45
	TCAP-1 250nmol/kg SC x 2	84	9	3	22
	CP154 10mg/kg SC x 10	116	12	3	-15

Stress plays a central role in a broad range of addictions, including alcohol and opioids. The ability of PT00114 to blunt excessive stress may be able to provide non-dependence forming treatment of addictions. A series of studies conducted at Porsolt Laboratories in Lavel France support the potential utility of PT00114 as a treatment to help people defeat opioid addiction. In rats addicted to opioids, administering CRF models environmental stress, causing them to frantically seek opioids. PT00114 reduces the opioid seeking behavior in response to CRF administration. Further studies conducted by Porsolt following EMEA guidelines demonstrated that on its own, PT00114 was not addictive and rats did not develop dependence to the peptide after chronic administration.

PT00114 has also demonstrated pre-clinical efficacy in a murine model of opioid withdrawal called the Saleens test. In this test, mice are addicted to opioids and the

animals are then administered the opioid antagonist naloxone, which immediately blocks opioid action and triggers profound stress and opioid withdrawal. This manifests as a behavioral stress response with the mice jumping up to six inches into the air over 70 times in a 20-minute observation period. Administering PT00114 at three different time points within the experiment – before the naloxone-driven withdrawal, before the period of opioid addiction, or up to three weeks before the induced withdrawal – results in a reproducible, dose-dependent restoration to non-stressed behavior and reduced jumping. Significantly, this is not accompanied by any evidence of sedation or reduced activity. This effect appears independent of the opioid used as PT00114 ameliorates this withdrawal-triggered jumping stress behavior in mice experiencing withdrawal from both fentanyl and morphine.

Preclinical Safety and Toxicology

Preclinical safety data for PT00114 demonstrates a robust profile in both rats and non-human primates. As the mechanism is unique and TCAP is a part of healthy brain signaling, we believe PT00114 will have a differentiated side effect profile relative to existing antidepressant and antipsychotic agents. A key aspect of the TCAP mechanism is that it does not completely block the perception of and responses to stress; it rather protects against stress overload. Some perception of environmental stress and a proportionate response to that stress is adaptive behavior and it is not desirable to completely block stress responses. Unlike benzodiazepines that can cause sedation and are prone to dependence, TCAP prevents the maladaptive response to environmental stress without sedation and without developing dependence.

We have completed non-GLP Dose-Range-Finding (DRF) toxicology studies of PT00114 administered subcutaneously daily for five days in rats and non-human primates. The doses tested were substantially above the anticipated clinical doses and were well tolerated and safe, with no dose-limiting toxicities observed at doses at least 50-fold higher than anticipated clinical exposures. No major changes in hematology or clinical chemistries were seen, including prolactin levels or testosterone levels, changes in which may impact libido. Distinct from SSRI's, there was no impact on ambulation, sedation or weight gain. Importantly, further studies conducted following EMEA guidelines, demonstrated that on its own PT00114 was not addictive and rats did not develop dependence to the peptide after chronic administration. The in life 28-day GLP toxicology testing in both the rats and non-human primate have been completed. There have been no changes in clinical chemistries or pathology that would prompt a stop in the program and the therapeutic margin if large. The final audited reports are currently being compiled.

Process Development and Manufacturing

We currently do not own any manufacturing facilities and rely on 3rd party contract manufacturers for synthesis of PT00114. We have sufficient PT00114 synthesized under cGMP conditions to complete GLP toxicology studies and Phase 1 human clinical trials. This material is currently undergoing requisite stability and accelerated stability testing. PT00114 is highly soluble and has shown excellent preliminary stability in several storage conditions, with the material being stable for at least 12 months.

The initial dosage form developed will be a subcutaneous injection. Because PT00114 is also amenable to other routes of administration including sublingually or intra-nasally, we will be doing preliminary process work to develop these formulations, and anticipate using one of these dosage forms in later stage clinical studies.

Technology License Agreement

On July 31, 2005, the Company had entered into a Technology License Agreement ("License Agreement") with the University of Toronto (the "University" or "UT") pursuant to which the University agreed to license to the Company patent rights and other intellectual property, among other things (the "Technologies"). The Technology License Agreement was amended on February 18, 2015. Unless earlier terminated, the term of this License Agreement shall terminate on the expiration or invalidity of the last issued Patent in the License Agreement

Pursuant to the License Agreement and its amendment, the Company obtained an exclusive worldwide license to make, have made, use, sell and import products based upon the Technologies, or to sublicense the Technologies in accordance with the terms of the License Agreement and amendment. In consideration, the Company agreed to pay to the University a royalty payment of 2.5% of net sales of any product based on the Technologies. If the Company elects to sublicense any rights under the License Agreement and amendment, the Company agrees to pay to the University 10% of any up-front sub-license fees for any sub-licenses that occurred on or after September 9, 2006, and, on behalf of the sub-licensee, 2.5% of net sales by the sub-licensee of all products based on the Technologies. The Company had no sales revenue for the year ended December 31, 2021 and therefore was not subject to paying any royalties.

In the event the Company fails to provide the University with semi-annual reports on the progress or fails to continue to make reasonable commercial efforts towards obtaining regulatory approval for products based on the Technologies, the University may convert our exclusive license into a non-exclusive arrangement. Interest on any amounts owed under the License Agreement and amendment will be at 3% per annum. All intellectual property rights resulting from the Technologies or improvements thereon will remain the property of the other inventors and/or Dr. David Lovejoy at the University, and/or the University, as the case may be. The Company has agreed to pay all out-of-pocket filing, prosecution and maintenance expenses in connection with any patents relating to the Technologies. In the case of infringement upon any patents relating to the Technologies, the Company may elect, at its own expense, to bring a cause of action asserting such infringement. In such a case, after deducting any legal expenses the Company may incur, any settlement proceeds will be subject to the 2.5% royalty payment owed to the University under the License Agreement and amendment.

The patent applications were made in the name of Dr. Lovejoy and other inventors, but the Company's exclusive, worldwide rights to such patent applications are included in the License Agreement and its amendment with the University. The Company maintains exclusive licensing agreements and it currently controls the six intellectual patent properties.

Sales and Marketing

We currently have no sales, marketing or distribution capabilities. In order to commercially market PT00114 and any product candidates we develop in the future, we would either need to develop an internal sales team and marketing department or collaborate with third parties who have sales and marketing capabilities. As we currently anticipate entering the clinical trials in the third quarter of 2023, we expect to seek a Market Access expert or consultancy to better understand clinician and payor dynamics in the therapeutic areas we are focused on, so that, as we begin later stage studies, we are working on a deeper commercial assessment in parallel. We have done some high-level benchmarking of pricing based on the current landscape of approved and available therapies for psychiatric disorders we are targeting, both in the generics and on-patent realms.

Competition

The pharmaceutical and biotechnology industries are highly competitive and characterized by rapidly evolving technology and intense research and development efforts. We expect to compete with companies, including major international pharmaceutical companies and other institutions that have substantially greater financial, research and development, marketing and sales capabilities and have substantially greater experience in undertaking preclinical and clinical testing of products, obtaining regulatory approvals and marketing and selling biopharmaceutical products. We will face competition based on, among other things, product efficacy and safety, the timing and scope of regulatory approvals, product ease of use and price.

Despite a large patient population and current treatments that leave much room for improvement, the developmental pipelines are sparse and few novel candidates are in development. The serendipitous discoveries of current drug classes, side effects and lack of efficacy have led to shrinkage or extinction of many pharma or small biotech neuroscience research programs.

Set forth below is a discussion of competitive factors for each of the current drug classes commercially available for TRD, and the competitive advantages that we believe PT00114 may offer. The basis for our beliefs regarding the competitive advantages that PT00114 may offer over its competitors is our own pre-clinical animal studies. We acknowledge that these beliefs and conclusions about competitive advantages must be regarded as theoretical until such time as we have human clinical data that supports and re-affirms the results seen in the pre-clinical animal studies.

Opioid receptor modulators

Opioid receptor modulators have the potential to be therapeutic drugs for TRD but have a high likelihood of abuse and thus regulatory restrictions. We believe that our competitive advantage is that PT00114 targets a different receptor system therefore it is not likely to have a clinical overlap with opioid receptor modulators.

Atypical Antipsychotics with antidepressant effects (dopamine receptor modulators)

Brexpiprazole (Rexulti from Otsuka) is a dopamine (D2 receptor) partial stimulator (agonist) approved as an oral adjunctive TRD therapy. Its side effects include suicidal risk, weight gain and restlessness. Cariprazine (Vraylar from AbbVie) is an oral dopamine D2 and D3 receptor antagonist approved for schizophrenia and bipolar disorder in development for TRD. The most common side effects reported were extrapyramidal symptoms, the urge to move (akathisia), indigestion (dyspepsia), vomiting, drowsiness (somnolence) and restlessness. We believe that our competitive advantage is that PT00114, due to its low toxicity profile, will be clinically preferable to these antipsychotic drugs.

Ketamine and Esketamine

Ketamine and Esketamine (Spratavo nasal spray from Johnson & Johnson) the S(+) enantiomer of the drug ketamine act primarily as a non-competitive NMDA receptor antagonist, but is also a dopamine reuptake inhibitor. Although ketamine is used off-label and Esketamine was recently approved for TRD, limitations and concerns around use limit uptake in a broader population. We believe that our competitive advantage is that the toxicity profile is likely to be less favorable when compared with PT00114.

GABA receptor modulators

GABA receptors, when bound by inhibitory neurotransmitters found throughout the brain, act as a brake on nerve activity. Sage Therapeutics is developing multiple compounds that target this mechanism and more candidates are expected to come from this therapeutic class that may present a competitive challenge for PT00114.

NMDA receptor modulators

The N-methyl-D-aspartate (or "NMDA") receptor is a molecule that appears on the surface of neurons. When "activated" by a drug that binds with it, the NMDA receptor is a potential natural way to counteract TRD. More candidates are expected to come from this therapeutic class that may present a competitive challenge for PT00114.

PT00114's Competitive Advantages

Our preclinical data and the corroborated mechanism of action of PT00114 indicates its advantages as compared to current approved therapies:

- PT00114 has a rapid onset of action in animal anxiety and depression models as compared with other TRD drugs
- PT00114's effects are long-lasting and potent (single 1-10 nmole/kg dose lasts up to one week for glucose/insulin blood-based biomarkers)
- PT00114 is rapidly cleared (its "half-life" is 5-10min if given intravenously (IV), 20-30 minutes if given subcutaneously (SC)
- PT00114 naturally crosses the blood brain barrier
- PT00114 is an L-isomer, a naturally modified peptide, therefore liver toxicities typically associated with other psychiatric therapies are not anticipated
- PT00114 is stable when lyophilized form, making it delivery in an oral or nasal formulation feasible
- PT00114 will be manufactured by standard solid phase chemistry, which is less expensive than manufacturing processes required by other TRD drugs

Studies have demonstrated that the compound does not caused dependency following multiple administrations

Intellectual Property

We believe that patents, trademarks, copyrights and other proprietary rights are important to our business. We also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We seek to protect our intellectual property rights by a variety of means, including obtaining patents, maintaining trade secrets and proprietary know-how, and technological innovation to operate without infringing on the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, actively seeking patent protection in the United States and foreign countries.

As of December 31, 2022, we have four patents issued by the Governments of the United States, Canada, European Union (validated in Germany, France and Great Britain) and Australia on our original platform technology. The patent applications were made in the name of Dr. David A. Lovejoy and inventors, but the Company's exclusive, worldwide rights to such patent applications are included in the License Agreement with UT. We have three further issued patents and ten pending patent applications in related technology that the company has rights in or own.

Our success will depend in part on our ability to maintain our proprietary position through effective patent claims and their enforcement against our competitors. Although we believe our patent applications provide a competitive advantage, the patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. We do not know whether any of our patent applications will result in the issuance of any patents. Those patents that may be issued in the future or those acquired by us may be challenged, invalidated or circumvented, and the rights granted under any issued patent may not provide us with proprietary protection or competitive advantages against competitors with similar technology. In particular, we do not know if competitors will be able to design variations on our treatment methods to circumvent our current and anticipated patent claims. Furthermore, competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized or marketed, any related patent claim may expire or remain in force for only a short period following commercialization, thereby reducing the advantage of the patent.

We also rely upon trade secrets, confidentiality agreements, proprietary know-how and continuing technological innovation to remain competitive, especially where we

do not believe patent protection is appropriate or obtainable. We continue to seek ways to protect our proprietary technology and trade secrets, including entering into confidentiality or license agreements with our employees and consultants, and controlling access to and distribution of our technologies and other proprietary information. While we use these and other reasonable security measures to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors.

Our commercial success will depend in part on our ability to operate without infringing upon the patents and proprietary rights of third parties. It is uncertain whether the issuance of any third-party patents would require us to alter our products or technology, obtain licenses or cease certain activities. Our failure to obtain a license to technology that we may require to discover, develop or commercialize our future products may have a material adverse impact on us. One or more third-party patents or patent applications may conflict with patent applications to which we have rights. Any such conflict may substantially reduce the coverage of any rights that may issue from the patent applications to which we have rights. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention.

We may collaborate in the future with other entities on research, development and commercialization activities. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our subsidiaries, collaborators, partners, licensors and consultants. As a result, we may not be able to maintain our proprietary position.

As of December 31, 2022, we own or have rights in the following intellectual property:

TENEURIN C-TERMINAL ASSOCIATED PEPTIDES (TCAP) AND METHODS AND USES THEREOF*

COUNTRY	FILED	SERIAL#	ISSUED	PATENT#	STATUS
AUSTRALIA	05/02/2003	2003221575	09/23/2011	2003221575	ISSUED
CANADA	05/02/2003	2,482,810	06/10/2014	2,482,810	ISSUED
EUROPEAN PATENT (*Validated in France (FR), Germany (DE) and Great Britain (GB)*	05/02/2003	03717086.7	03/12/2014	1499635	ISSUED
UNITED STATES	11/01/2004	10/510,959	01/03/2012	8,088,889	ISSUED

A METHOD FOR REGULATING NEURITE GROWTH*

COUNTRY	FILED	SERIAL#	ISSUED	PATENT#	STATUS
UNITED STATES	06/19/2012 (Continuation)	13/527,414	08/01/2017	9,718,857	ISSUED

A METHOD FOR MODULATING INSULIN-INDEPENDENT GLUCOSE TRANSPORT USING TENEURIN C-TERMINAL ASSOCIATED PEPTIDE (TCAP)*

COUNTRY	FILED	SERIAL#	ISSUED	PATENT#	STATUS
CANADA	07/21/2015	2,955,410			PENDING
GREAT BRITAIN	07/21/2015(PCT)	1702638.6	07/21/2020	2543996	ISSUED
UNITED STATES	01/17/2017(371c)	15/326,735	04/14/2020	10,617,736	ISSUED

COMPOSITIONS, METHODS AND USES FOR ENHANCING MUSCLE FUNCTION*

COUNTRY	FILED	SERIAL#	ISSUED	PATENT#	STATUS
US	09/26/2017(PCT) / 03/25/2019(371c)	11,446,335	09/20/2022		ISSUED
CA	09/26/2017	3,038,169			PENDING

COMPOSITIONS, METHODS AND USES FOR TREATING POST-TRAUMATIC STRESS DISORDER *

COUNTRY	FILED	SERIAL#	ISSUED	PATENT#	STATUS
UNITED STATES	10/12/2018(PCT) /04/10/2020(371c)	11,426,444	08/30/2022		ISSUED
CANADA	04/14/2020	3,079,724			PENDING

COMPOSITIONS, METHODS AND USES OF A TENEURIN C-TERMINAL ASSOCIATED PEPTIDE-1 (TCAP-1) FOR TREATING OPIOID ADDICTION

COUNTRY	FILED	SERIAL#	ISSUED	PATENT#	STATUS
CANADA	3/13/2019	3,093,841			PENDING
UNITED STATES	3/13/2019(PCT) / 9/11/2010 (371c)	16/980,176			PENDING
EUROPE	10/12/2020	19712494.4			PENDING (Intention to grant 02/24/2023)
HONG KONG (Extended EP Application)	3/13/2019	62021035260.0			PENDING

In the future we may file additional patent applications based on proprietary formulations and novel compounds in the TCAP family.

COVID-19

On January 30, 2020 the World Health Organization declared the COVID-19 coronavirus outbreak a "Public Health Emergency of International Concern" and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The COVID-19 coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographical area in which the Company operates. While it is unknown how long these conditions will last and what the complete financial effect will be to the Company, capital raising efforts and additional development of our technologies may be negatively affected.

Properties

The Company does not currently own any real property. The Company leases office space for its principal executive office located at 149 Fifth Avenue, Suite 500, New York, New York 10010.

Legal Proceedings

From time to time we may be named in claims arising in the ordinary course of business. Currently, no legal proceedings, government actions, administrative actions, investigations or claims are pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition.

Subsidiary

PTI Canada was incorporated in 2006 in the Province on Ontario, Canada. PTI Canada is a wholly-owned subsidiary of Protagenic. It provides operational support and assistance for the implementation of corporate and operational activities conducted in Canada. It also oversees and supports research and development activities conducted under auspices of UT. PTI Canada has three directors: Garo H. Armen (Chairman), Alexander K. Arrow and Vigen Nazarian. PTI Canada also has one part-time consultant, Robert Ziroyan. PTI Canada also benefits through tax incentive programs provided by the governments of Canada and the Province of Ontario. We derived credits from Canadian research and development tax credits for the years ended December 31, 2022 and 2021 of $0 and $0, respectively.

Employees

We currently have two part-time employees. We also engage consultants and temporary employees from time to time to provide services that relate to our research and development activities as well as for general administrative and accounting services. We believe that our current personnel are capable of meeting our operating requirements in the near term. We expect that as our business grows we may hire additional personnel to handle the increased demands on our operations, preclinical and clinical activities.

Corporate and Available Information

Our principal offices are located at 149 Fifth Avenue, New York, New York 10010. Our web address is *www.protagenic.com*.

We make available, free of charge through our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. In addition, you may read and copy any materials we file with the SEC at its Public Reference Room at 100 F Street, NE, Washington, DC 20549, on official business days during the hours of 10:00 am to 3:00 pm. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site, *www.sec.gov* that contains reports, proxy and information statements, and other information that we file electronically with the SEC. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

An investment in our common stock is speculative and illiquid and involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report before purchasing shares of our common stock. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and prospects. If any of the following risks actually materialize, our business, financial condition, prospects and/or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock.

Risks Related to Our Financial Condition and Capital Requirements

The Company's financial statements have been prepared on a going concern basis, and do not include adjustments that might be necessary if the Company is unable to continue as a going concern.

The Company's consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As of December 31, 2022, the Company had incurred significant operating losses since inception, and continues to generate losses from operations, and has an accumulated deficit of $25,777,375. Based on its cash resources as of December 31, 2022, the Company has sufficient resources to fund its operations at least until the end of the third quarter of 2024. The consolidated financial statements included in this report do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

We have a history of losses and expect that losses may continue in the future.

We have generated net losses since we began operations, including $3,555,505 and $4,522,934 for the years ended December 31, 2022 and December 31, 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $25,777,375. We have no approved products and have generated no product revenue. We expect that product development, preclinical and clinical programs will increase losses significantly over the next five years. In order to achieve profitability, we will need to generate significant revenue. We cannot be certain that we will generate sufficient revenue to achieve profitability. We anticipate that we will continue to generate operating losses and negative cash flow from operations and our current cash position is sufficient to fund our current business plan at least until the third quarter of 2024. We cannot be certain that we will ever achieve, or if achieved, maintain profitability. If our revenue grows at a slower rate than we anticipate or if our product development, marketing and operating expenses exceed our expectations or cannot be adjusted accordingly, our business, results of operation and financial condition will be materially adversely affected, and we may be unable to continue operations.

We will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials and receives regulatory approval. As our most advanced product candidates are at an early proof-of-concept stage, we do not expect to receive revenue from any product candidate for the foreseeable future. We may seek to obtain revenue from collaboration or licensing agreements with third parties. We currently have no such agreements which will provide us with material, ongoing future revenue and we may never enter into any such agreements. Even if we eventually generate revenues, we may never be profitable, and if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We need to obtain financing in order to continue our operations.

On a prospective basis, we will require both short-term financing for operations and long-term capital to fund our expected growth. We have no existing bank lines of credit and have not established any definitive sources for additional financing. Additional financing may not be available to us, or if available, then it may not be available upon terms and conditions acceptable to us. If adequate funds are not available, then we may be required to delay, reduce or eliminate product development or clinical programs. Our inability to take advantage of opportunities in the industry because of capital constraints may have a material adverse effect on our business and our prospects. If we fail to obtain the capital necessary to fund our operations, we will be unable to advance our development programs and complete our clinical trials.

In addition, our research and development expenses could exceed our current expectations. This could occur for many reasons, including:

- some or all of our product candidates fail in clinical or preclinical studies and we are forced to seek additional product candidates;
- our product candidates require more extensive clinical or preclinical testing than we currently expect;
- we advance more of our product candidates than expected into costly later stage clinical trials;

- we advance more preclinical product candidates than expected into early stage clinical trials;
- we are required, or consider it advisable, to acquire or license rights from one or more third parties; or
- we determine to acquire or license rights to additional product candidates or new technologies.

While we expect to seek additional funding through public or private financings, we may not be able to obtain financing on acceptable terms, or at all. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock. We may also seek additional funds through arrangements with collaborators or other third parties. These arrangements would generally require us to relinquish rights to some of our technologies, product candidates or products, and we may not be able to enter into such agreements, on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs, including some or all of our product candidates.

If we continue to incur operating losses and fail to obtain the capital necessary to fund our operations, we will be unable to advance our development programs, complete our clinical trials, or bring products to market, or may be forced to reduce or cease operations entirely. In addition, any capital obtained by us may be obtained on terms that are unfavorable to us, our investors, or both.

Developing a new drug and conducting clinical trials and the regulatory review processes involves substantial costs. We have projected cash requirements for the near term based on a variety of assumptions, but some or all of such assumptions are likely to be incorrect and/or incomplete, possibly materially in an adverse direction. Our actual cash needs may deviate materially from those projections, changes in market conditions or other factors may increase our cash requirements, or we may not be successful even in raising the amount of cash we currently project will be required for the near term. We will need to raise additional capital in the future; the amount of additional capital needed will vary as a result of a number of factors, including without limitation the following:

- receiving less funding than we require;
- higher than expected costs to manufacture our product candidates;
- higher than expected costs for preclinical testing;
- an increase in the number, size, duration, and/or complexity of our clinical trials;
- slower than expected progress in developing PT00114, or other product candidates, including without limitation, additional costs caused by program delays;
- higher than expected costs associated with attempting to obtain regulatory approvals, including without limitation additional costs caused by additional regulatory requirements or larger clinical trial requirements;
- higher than expected personnel, consulting or other costs, such as adding personnel or industry expert consultants or pursuing the licensing/acquisition of additional assets; and
- higher than expected costs to protect our intellectual property portfolio or otherwise pursue our intellectual property strategy.

When we attempt to raise additional financing, there can be no assurance that we will be able to secure such additional financing in sufficient quantities or at all. We may be unable to raise additional capital for reasons including, without limitation, our operational and/or financial performance, investor confidence in us and the biopharmaceutical industry, credit availability from banks and other financial institutions, the status of current projects, and our prospects for obtaining any necessary regulatory approvals. Potential investors' capital investments may have shifted to other opportunities with perceived greater returns and/or lower risk thereby reducing capital available to us, if available at all.

In addition, any additional financing might not be available, and even if available, may not be available on terms favorable to us or our then-existing investors. We will seek to raise funds through public or private equity offerings, debt financings, corporate collaboration or licensing arrangements, mergers, acquisitions, sales of intellectual property, or other financing vehicles or arrangements. To the extent that we raise additional capital by issuing equity securities or other securities, our then-existing investors will experience dilution. If we raise funds through debt financings or bank loans, we may become subject to restrictive covenants, our assets may be pledged as collateral for the debt, and the interests of our then-existing investors would be subordinated to the debt holders or banks. In addition, our use of and ability to exploit assets pledged as collateral for debt or loans may be restricted or forfeited. To the extent that we raise additional funds through collaboration or licensing arrangements, we may be required to relinquish significant rights (including without limitation intellectual property rights) to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are not able to raise needed funding under acceptable terms or at all, then we will have to reduce expenses, including the possible options of curtailing operations, abandoning opportunities, licensing or selling off assets, reducing costs to a point where clinical development or other progress is impaired, or ceasing operations entirely.

We have a limited operating history, expect to incur significant operating losses, and have a high risk of never being profitable.

We commenced operations in February 2016 through a reverse merger and have a limited operating history of less than five years. Therefore, there is limited historical financial or operational information upon which to evaluate our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. Many if not most companies in our industry at our stage of development never become profitable and are acquired or go out of business before successfully developing any product that generates revenue from commercial sales or enables profitability.

As of December 31, 2022, we have incurred an accumulated deficit of $25,777,375. We expect to continue to incur substantial operating losses over the next several years for the clinical development of our current and future licensed or purchased product candidates.

The amount of future losses and when, if ever, we will become profitable are uncertain. We do not have any products that have generated any revenues from commercial sales, and do not expect to generate revenues from the commercial sale of products in the near future, if ever. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of the development of our product candidates; obtaining necessary regulatory approvals from the FDA and international regulatory agencies; establishing manufacturing, sales, and marketing arrangements with third parties; obtaining adequate reimbursement by third-party payers; and raising sufficient funds to finance our activities. If we are unsuccessful at some or all of these undertakings, our business, financial condition, and results of operations are expected to be materially and adversely affected.

As a recently established public reporting company, we are subject to SEC reporting and other requirements, which will lead to increased operating costs in order to meet these requirements.

Unstable market and economic conditions may have serious adverse consequences on our ability to raise funds, which may cause us to cease or delay our operations.

From time to time, global and domestic credit and financial markets have experienced extreme disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. Our financing strategy will be adversely affected by any such economic downturn, volatile business environment and continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, it may make a debt or equity financing more difficult to complete, costlier, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms will have a material adverse effect on our business strategy and financial performance, and could require us to cease or delay our operations.

Our financial and operating performance may be adversely affected by the coronavirus pandemic.

The recent outbreak of a strain of coronavirus (Covid-19) in the U.S. has had an unfavorable impact on our business operations. Mandatory closures of businesses imposed by the federal, state and local governments to control the spread of the virus is disrupting the operations of our management, business and finance teams. In addition, the Covid-19 outbreak has adversely affected the U.S. economy and financial markets, which may result in a long-term economic downturn that could negatively affect future performance. The extent to which Covid-19 will impact our business and our consolidated financial results will depend on future developments which are highly uncertain and cannot be predicted at the time of the filing of this Form 10-K, but is expected to result in a material adverse impact on our business, results of operations and financial condition.

COVID-19 may impact our operations.

On January 30, 2020 the World Health Organization declared the COVID-19 coronavirus outbreak a "Public Health Emergency of International Concern" and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The COVID-19 coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographical area in which the Company operates. While it is unknown how long these conditions will last and what the complete financial effect will be to the Company, capital raise efforts and additional development of our technologies may be negatively affected.

Risks Related to Clinical Development and Regulatory Approval

Our results to date provide no basis for predicting whether any of our product candidates will be safe or effective, or receive regulatory approval.

The Company's proprietary portfolio of five new neuropeptide hormones are in various stages of research and preclinical evaluation and their risk of failure is high. It is impossible to predict when or if any of our neuropeptide hormones will prove effective or safe in humans or will receive regulatory approval. These compounds may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory studies, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. If we are unable to discover or successfully develop drugs that are effective and safe in humans, we will not have a viable business.

We may not be able to initiate and complete preclinical studies and clinical trials for our product candidates which could adversely affect our business.

We must successfully initiate and complete extensive preclinical studies and clinical trials for our product candidates before we can receive regulatory approval. Preclinical studies and clinical trials are expensive and will take several years to complete and may not yield results that support further clinical development or product approvals. Conducting clinical studies for any of our drug candidates for approval in the United States requires filing an IND and reaching agreement with the FDA on clinical protocols, finding appropriate clinical sites and clinical investigators, securing approvals for such studies from the independent review board at each such site, manufacturing clinical quantities of drug candidates, supplying drug product to clinical sites and enrolling sufficient numbers of participants. We cannot guarantee that we will be able to successfully accomplish all of the activities necessary to initiate and complete clinical trials.

As a result, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approvals or successfully commercialize our products.

The drug development and approval process is uncertain, time-consuming and expensive.

The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive and uncertain. It also can vary substantially based on the type, complexity, and novelty of the product. We must provide the FDA and foreign regulatory authorities with preclinical and clinical data demonstrating that our products are safe and effective before they can be approved for commercial sale. Clinical development, including preclinical testing, is a long, expensive and uncertain process. It may take us several years to complete our testing, and failure can occur at any stage of testing. Any preclinical or clinical test may fail to produce results satisfactory to the FDA. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, adverse medical events during a clinical trial or safety issues resulting from products of the same class of drug could cause a preclinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful.

The regulatory approval process is costly and lengthy and we may not be able to successfully obtain all required regulatory approvals.

The preclinical development, clinical trials, manufacturing, marketing and labeling of pharmaceuticals are all subject to extensive regulation by numerous governmental authorities and agencies in the United States and other countries. We must obtain regulatory approval for each of our product candidates before marketing or selling any of them. It is not possible to predict how long the approval processes of the FDA or any other applicable federal or foreign regulatory authority or agency for any of our products will take or whether any such approvals ultimately will be granted. The FDA and foreign regulatory agencies have substantial discretion in the drug approval process, and positive results in preclinical testing or early phases of clinical studies offer no assurance of success in later phases of the approval process. Generally, preclinical and clinical testing of products can take many years and require the expenditure of substantial resources, and the data obtained from these tests and trials can be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. If we encounter significant delays in the regulatory process that result in excessive costs, this may prevent us from continuing to develop our product candidates. Any delay in obtaining, or failure to obtain, approvals could adversely affect the marketing of our products and our ability to generate product revenue. The risks associated with the approval process include:

- failure of our product candidates to meet a regulatory agency's requirements for safety, efficacy and quality;
- limitation on the indicated uses for which a product may be marketed;
- unforeseen safety issues or side effects; and
- governmental or regulatory delays and changes in regulatory requirements and guidelines.

Even if we receive regulatory approvals for marketing our product candidates, if we fail to comply with continuing regulatory requirements, we could lose our regulatory approvals, and our business would be adversely affected.

The FDA continues to review products even after they receive initial approval. If we receive approval to commercialize any product candidates, the manufacturing, marketing and sale of these drugs will be subject to continuing regulation, including compliance with quality systems regulations, good manufacturing practices, adverse event requirements, and prohibitions on promoting a product for unapproved uses. Enforcement actions resulting from our failure to comply with government and regulatory requirements could result in fines, suspension of approvals, withdrawal of approvals, product recalls, product seizures, mandatory operating restrictions, criminal prosecution, civil penalties and other actions that could impair the manufacturing, marketing and sale of our potential products and our ability to conduct our business.

Even if we are able to obtain regulatory approvals for any of our product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Even if we receive regulatory approval for our product candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. As a result, regulatory authorities may revoke their approvals; we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

If we experience delays or difficulties in the enrollment of subjects to our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented, which could materially affect our financial condition.

Identifying, screening and enrolling patients to participate in clinical trials of our product candidates is critical to our success, and we may not be able to identify, recruit, enroll and dose a sufficient number of patients with the required or desired characteristics to complete our clinical trials in a timely manner. The timing of our clinical trials depends on our ability to recruit patients to participate as well as to subsequently dose these patients and complete required follow-up periods.

In addition, we may experience enrollment delays related to increased or unforeseen regulatory, legal and logistical requirements at certain clinical trial sites. These delays could be caused by reviews by regulatory authorities and contractual discussions with individual clinical trial sites. Any delays in enrolling and/or dosing patients in our planned clinical trials could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or in termination of the clinical trials altogether.

Patient enrollment may be affected if our competitors have ongoing clinical trials with products for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in our competitors' clinical trials. Patient enrollment may also be affected by other factors, including:

- coordination with clinical research organizations to enroll and administer the clinical trials;
- coordination and recruitment of collaborators and investigators at individual sites;
- size of the patient population and process for identifying patients;
- design of the clinical trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidates under study;
- availability of competing commercially available therapies and other competing products' clinical trials;
- time of year in which the trials are initiated or conducted;
- severity of the diseases under investigation;
- ability to obtain and maintain subject consents;
- ability to enroll and treat patients in a timely manner;
- risk that enrolled subjects will drop out before completion of the trials;
- proximity and availability of clinical trial sites for prospective patients;
- ability to monitor subjects adequately during and after treatment; and
- patient referral practices of physicians.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which could materially affect our financial condition.

New federal laws or regulations on drug importation could make lower cost versions of our future products available, which could adversely affect our revenues, if any.

The prices of some drugs are lower in other countries than in the United States because of government regulation and market conditions. Under current law, importation of drugs into the United States is generally not permitted unless the drugs are approved in the United States and the entity that holds that approval consents to the importation. Various proposals have been advanced to permit the importation of drugs from other countries to provide lower cost alternatives to the products available in the United States. In addition, the MMA requires the Secretary of Health and Human Services to promulgate regulations for drug re-importation from Canada into the United States under some circumstances, including when the drugs are sold at a lower price than in the United States.

If the laws or regulations are changed to permit the importation of drugs into the United States in circumstances that are currently not permitted, such a change could have an adverse effect on our business by making available lower priced alternatives to our future products.

Failure to obtain regulatory and pricing approvals in foreign jurisdictions could delay or prevent commercialization of our products abroad.

If we succeed in developing any products, we intend to market them in the European Union and other foreign jurisdictions. In order to do so, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and additional risks associated with requirements particular to those foreign jurisdictions where we will seek regulatory approval of our products. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

It is uncertain whether product liability insurance will be adequate to address product liability claims, or that insurance against such claims will be affordable or available on acceptable terms in the future.

Clinical research involves the testing of new drugs on human volunteers pursuant to a clinical trial protocol. Such testing involves a risk of liability for personal injury to or death of patients due to, among other causes, adverse side effects, improper administration of the new drug, or improper volunteer behavior. Claims may arise from patients, clinical trial volunteers, consumers, physicians, hospitals, companies, institutions, researchers, or others using, selling, or buying our products, as well as from governmental bodies. In addition, product liability and related risks are likely to increase over time, in particular upon the commercialization or marketing of any products by us or parties with which we enter into development, marketing, or distribution collaborations. Although we are contracting for general liability insurance in connection with our ongoing business, there can be no assurance that the amount and scope of such insurance coverage will be appropriate and sufficient in the event any claims arise, that we will be able to secure additional coverage should we attempt to do so, or that our insurers would not contest or refuse any attempt by us to collect on such insurance policies. Furthermore, there can be no assurance that suitable product liability insurance (at the clinical stage and/or commercial stage) will continue to be available on terms acceptable to us or at all, or that, if obtained, the insurance coverage will be appropriate and sufficient to cover any potential claims or liabilities.

If the market opportunities for our current and potential future drug candidates are smaller than we believe they are, our ability to generate product revenues will be adversely affected and our business may suffer.

Our understanding of the number of people who suffer from stress-related indications, including, but not limited to: treatment resistant depression ("TRD"), which is a subgroup of major depressive disorder ("MDD"); addiction, recidivism, or substance use disorder ("SUD"); anxiety, including generalized anxiety disorder ("GAD"), and post-traumatic stress disorder ("PTSD") is based upon estimates. These estimates may prove to be incorrect, and new studies may demonstrate or suggest a lower estimated incidence or prevalence of this condition. The number of patients in the U.S. or elsewhere may turn out to be lower than expected, may not be otherwise amenable to PT00114 treatment, or treatment-amenable patients may become increasingly difficult to identify and access, all of which would adversely affect our business prospects and financial condition.

Risks Related to Our Reliance on Third Parties

We may not be able to obtain and maintain the third party relationships that are necessary to develop, commercialize and manufacture some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, clinical research organizations, manufacturers and other third parties to support our discovery efforts, to formulate product candidates, to conduct clinical trials for some or all of our product candidates, to manufacture clinical and commercial scale quantities of our product candidates and products and to market, sell, and distribute any products we successfully develop.

We cannot guarantee that we will be able to successfully negotiate agreements for or maintain relationships with collaborators, partners, licensees, clinical investigators, manufacturers and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates, which will in turn adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts of our expenditures will be paid to third parties in these relationships. However, we cannot control the amount or timing of resources our contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all.

We have no experience in sales, marketing and distribution and may have to enter into agreements with third parties to perform these functions, which could prevent us from successfully commercializing our product candidates.

We currently have no sales, marketing or distribution capabilities. To commercialize our product candidates, we must either develop our own sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services for us. If we decide to market any of our products on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, we may not be able to commercialize our product candidates which would adversely affect our business and financial condition.

Data provided by collaborators and other parties upon which we rely have not been independently verified and could turn out to be inaccurate, misleading, or incomplete.

We rely on third-party vendors, scientists, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. We do not independently verify or audit all of such data (including possibly material portions thereof). As a result, such data may be inaccurate, misleading, or incomplete.

In certain cases, we may need to rely on a single supplier for a particular manufacturing material or service, and any interruption in or termination of service by such supplier could delay or disrupt the commercialization of our products.

We rely on third-party suppliers for the materials used to manufacture our compounds. Some of these materials may at times only be available from one supplier. Any interruption in or termination of service by such single source suppliers could result in a delay or disruption in manufacturing until we locate an alternative source of supply. There can be no assurance that we would be successful in locating an alternative source of supply or in negotiating acceptable terms with such prospective supplier.

We rely on third parties to conduct our non-clinical studies and our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our current product candidates or any future products, on a timely basis or at all, and our financial condition will be adversely affected.

We do not have the ability to independently conduct non-clinical studies and clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as contract research organizations or clinical research organizations, to conduct non-clinical studies and clinical trials on our product candidates. The third parties with whom we contract for execution of our non-clinical studies and clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs.

Although we rely on third parties to conduct our non-clinical studies and clinical trials, we remain responsible for ensuring that each of our non-clinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA, EMA and other foreign regulatory authorities require us to comply with regulations and standards, including some regulations commonly referred to as good clinical practices ("GCPs"), for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

In addition, the execution of non-clinical studies and clinical trials, and the subsequent compilation and analyses of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. Under certain circumstances, these third parties may be able to terminate their agreements with us upon short notice. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or 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 trial protocols or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain, on a timely basis or at all, regulatory approval for or to commercialize the product candidate being tested in such trials, and as a result, our financial condition will be adversely affected.

Risks Related to Commercialization of Our Product Candidates

We have no experience as a company in commercializing any product. If we fail to obtain commercial expertise, upon product approval by regulatory agencies, our product launch and revenues could be delayed.

As a company, we have never obtained regulatory approval for, or commercialized, any product. Accordingly, we have not yet begun to build out any sales or marketing capabilities. If we are unable to establish, or contract for, effective sales and marketing capabilities, or if we are unable to enter into agreements with third parties to commercialize our product candidates on favorable terms or on any reasonable terms at all, we may not be able to effectively generate product revenues once our product candidates are approved for marketing. If we fail to obtain commercial expertise or capabilities, upon drug approval, our product launch and subsequent revenues could be delayed and /or fail to reach their commercial potential.

We may not be able to gain market acceptance of our product candidates, which would prevent us from becoming profitable.

We cannot be certain that any of our product candidates will gain market acceptance among physicians, patients, healthcare payers, pharmaceutical companies or others. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. Sales of medical products largely depend on the reimbursement of patients' medical expenses by government healthcare programs and private health insurers. Governments and private insurers closely examine medical products to determine whether they should be covered by reimbursement and if so, the level of reimbursement that will apply. We cannot be certain that third party payers will sufficiently reimburse sales of our products, or enable us to sell our products at profitable prices. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many countries where we plan to market our products, including Europe and Canada, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. Sales of medical products also depend on physicians' willingness to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost-effective. We cannot predict whether physicians, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective relative to competing treatments.

We may not be able to manufacture our product candidates in clinical or commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities by us and third party manufacturers for preclinical studies. If any of our product candidates is approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture it in larger quantities and we intend to use third party manufacturers for commercial quantities. Our third party manufacturers may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or efficient manner, or at all. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate. Our failure or the failure of our third party manufacturers to comply with the FDA's good manufacturing practices and to pass inspections of the manufacturing facilities by the FDA or other regulatory agencies could seriously harm our business.

Our products may not be accepted for reimbursement or properly reimbursed by third-party payers.

The successful commercialization of any products we might develop will depend substantially on whether the costs of our products and related treatments are reimbursed at acceptable levels by government authorities, private healthcare insurers, and other third-party payers, such as health maintenance organizations. Reimbursement rates may vary, depending upon the third-party payer, the type of insurance plan, and other similar or dissimilar factors. If our products do not achieve adequate reimbursement, then the number of physician prescriptions of our products may not be sufficient to make our products profitable.

Comparative effectiveness research demonstrating benefits of a competitor's product could adversely affect the sales of our product candidates. If third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in the product development of that product. In addition, in the U.S. there is a growing emphasis on comparative effectiveness research, both by private payers and by government agencies. To the extent other drugs or therapies are found to be more effective than our products, payers may elect to cover such therapies in lieu of our products or reimburse our products at a lower rate.

New federal legislation may increase the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, expanded Medicare coverage for drug purchases by the elderly and disabled beginning in 2006. The new legislation uses formularies, preferred drug lists and similar mechanisms that may limit the number of drugs that will be covered in any therapeutic class or reduce the reimbursement for some of the drugs in a class. More recently, the Patient Protection and Affordable Care Act of 2010 also contained certain provisions with the potential to affect pricing of pharmaceutical products.

As a result of the expansion of legislation, including recent healthcare insurance 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 could decrease the coverage and price that we receive for our products in the future and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement systems, and any limits on or reductions in reimbursement that occur in the Medicare program may result in similar limits on or reductions in payments from private payers.

Disputes under key agreements or conflicts of interest with our scientific advisors or clinical investigators could delay or prevent development or commercialization of our product candidates.

Any agreements we have or may enter into with third parties, such as collaboration, license, formulation supplier, manufacturing, clinical research organization or clinical trial agreements, may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over rights to ownership or use of intellectual property, the scope and direction of research and development, the approach for regulatory approvals or commercialization strategy. We intend to conduct research programs in a range of therapeutic areas, but our pursuit of these opportunities could result in conflicts with the other parties to these agreements who may be developing or selling pharmaceuticals or conducting other activities in these same therapeutic areas. Any disputes or commercial conflicts could lead to the termination of our agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights or result in costly litigation.

We collaborate with outside scientific advisors and collaborators at academic and other institutions that assist us in our research and development efforts. Our scientific advisors are not our employees and may have other commitments that limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services.

Our competitors and potential competitors may develop products and technologies that make ours less attractive or obsolete.

Many companies, universities, and research organizations developing competing product candidates have greater resources and significantly greater experience in financial, research and development, manufacturing, marketing, sales, distribution, and technical regulatory matters than we have. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Our competitors could commence and complete clinical testing of their product candidates, obtain regulatory approvals, and begin commercial-scale manufacturing of their products faster than we are able to for our products. They could develop products that would render our product candidates, and those of our collaborators, obsolete and noncompetitive. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenues.

Competition in the biotechnology and pharmaceutical industries may result in competing products, superior marketing of other products and lower revenues or profits for us.

There are many companies that are seeking to develop products and therapies for the treatment of mood, anxiety and neurodegenerative disorders. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we do in undertaking preclinical testing and human clinical studies of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products.

Other risks and uncertainties include:

- our ability to successfully complete preclinical and clinical development of our products and services

- our ability to manufacture sufficient amounts of products for development and commercialization activities
- our ability to obtain, maintain and successfully enforce adequate patent and other proprietary rights protection of our products and services
- the scope, validity and enforceability of patents and other proprietary rights held by third parties and their impact on our ability to commercialize our products and services
- the accuracy of our estimates of the size and characteristics of the markets to be addressed by our products and services, including growth projections
- market acceptance of our products and services
- our ability to identify new patients for our products and services
- the accuracy of our information regarding the products and resources of our competitors and potential competitors
- the content and timing of submissions to and decisions made by the US Food and Drug Administration (FDA) and other regulatory agencies
- our ability to obtain reimbursement for our products and services from third-party payors, and the extent of such coverage
- our ability to establish and maintain strategic license, collaboration and distribution arrangements
- the continued funding of our collaborations and joint ventures, if any are ultimately established
- the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of operation of our subsidiaries and our customers, suppliers, distributors, couriers, collaborative partners, licensees and clinical trial sites.

Positive or timely results from preclinical studies and early clinical trials do not ensure positive or timely results in late-stage clinical trials or product approval by the FDA or any other regulatory authority. Product candidates that show positive preclinical or early clinical results often fail in later stage clinical trials. Data obtained from preclinical and clinical activities is susceptible to varying interpretations, which could delay, limit, or prevent regulatory approvals.

We have limited experience in conducting the clinical trials required to obtain regulatory approval. We may not be able to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants, or begin or successfully complete clinical trials in a timely fashion, if at all. Any failure to perform may delay or terminate the trials. Our current clinical trials may be insufficient to demonstrate that our potential products will be active, safe, or effective. Additional clinical trials may be required if clinical trial results are negative or inconclusive, which will require us to incur additional costs and significant delays. If we do not receive the necessary regulatory approvals, we will not be able to generate product revenues and may not become profitable.

Risks Related to Our Intellectual Property

We may not be able to maintain our exclusive worldwide license to use and develop PT00114 which could materially affect our business plan.

On July 21, 2005, we entered into the License Agreement with University of Toronto, or UT, pursuant to which UT agreed to license to us patent rights and other intellectual property related to PT00114, among other things. The Technology License Agreement was amended on February 18, 2015. Unless earlier terminated, the term of this agreement shall terminate on the expiration or invalidity of the last issued Patent in the Agreement

Pursuant to the License Agreement, we obtained an exclusive worldwide license to make, have made, use, sell and import products based upon the Technologies, or to sublicense the Technologies in accordance with the terms of the License Agreement. In the event we fail to provide UT with semi-annual reports on our progress or fail to continue to make reasonable commercial efforts towards obtaining regulatory approval for products based on the Technologies, UT may convert our exclusive license into a non-exclusive one. In such a case, we would lose our competitive advantage in the development of treatments based on PT00114.

We have to sustain and further build our intellectual property rights.

If we fail to sustain and further build our intellectual property rights, competitors will be able to take advantage of our research and development efforts to develop competing products. If we are not able to protect our proprietary technology, trade secrets, and know-how, our competitors may use our inventions to develop competing products. Protagenic has obtained worldwide exclusive rights to PT00114 and related technology that was developed at UT. The Company currently has four patents issued by the Governments of the United States, Canada, European Union and Australia. As of December 31, 2022, we have four patents issued by the Governments of the United States, Canada, European Union (validated in Germany, France and Great Britain) and Australia on our original platform technology. The patent applications were made in the name of Dr. David A. Lovejoy and inventors, but the Company's exclusive, worldwide rights to such patent applications are included in the License Agreement with UT. We have three further issued patents and ten pending patent applications in related technology that the company has rights in or own.

However, our patents and patent applications, even if granted, may not protect us against our competitors. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific and factual questions. The standards which the United States Patent and Trademark Office uses to grant patents, and the standards which courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. In addition, the type and extent of patent claims that will be issued to us in the future is uncertain. Any patents that are issued may not contain claims that permit us to stop competitors from using similar technology.

In addition to our patentable technology, we also rely on unpatented technology, trade secrets, and confidential information. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We generally require each of our employees, consultants, collaborators, and certain contractors to execute a confidentiality agreement at the commencement of an

employment, consulting, collaborative, or contractual relationship with us. However, these agreements may not provide effective protection of our technology or information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

Our patent position is generally uncertain and involves complex legal and factual questions. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and other biotechnology companies have encountered significant problems in protecting and defending their proprietary rights in foreign jurisdictions. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents. In addition, any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated or fail to provide us with any competitive advantages. We may not have the funds available to protect our patents or other technology; such protection is costly and can result in further litigation expenses.

If we do not obtain or we are unable to maintain adequate patent or trade secret protection for our products in the United States, competitors could duplicate them without repeating the extensive testing that we will be required to undertake to obtain approval of the products by the FDA. Regardless of any patent protection, under the current statutory framework the FDA is prohibited by law from approving any generic version of any of our products for three years after it has approved our product. Upon the expiration of that period, or if that time period is altered, the FDA could approve a generic version of our product unless we have patent protection sufficient for us to block that generic version. Without sufficient patent protection, the applicant for a generic version of our product would be required only to conduct a relatively inexpensive study to show that its product is bioequivalent to our product and may not have to repeat the studies that we will need to conduct to demonstrate that the product is safe and effective. In the absence of adequate patent protection in other countries, competitors may similarly be able to obtain regulatory approval in those countries of products that duplicate our products.

We have to comply with our obligations in our intellectual property licenses with third parties.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business**.** We are a party to the License Agreement with UT under which we receive the right to practice and use important third party patent rights. We may enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various diligences, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

We may need to resort to litigation to enforce or defend our intellectual property rights, including any patents issued to us. If a competitor or collaborator files a patent application claiming technology also invented by us, in order to protect our rights, we may have to participate in an expensive and time consuming interference proceeding before the United States Patent and Trademark Office. We cannot guarantee that our product candidates will be free of claims by third parties alleging that we have infringed their intellectual property rights. Third parties may assert that we are employing their proprietary technologies without authorization and they may resort to litigation to attempt to enforce their rights. Third parties may have or obtain patents in the future and claim that the use of our technology or any of our product candidates infringes their patents. We may not be able to develop or commercialize combination product candidates because of patent protection others have. Our business will be harmed if we cannot obtain a necessary or desirable license, can obtain such a license only on terms we consider to be unattractive or unacceptable, or if we are unable to redesign our product candidates or processes to avoid actual or potential patent or other intellectual property infringement. Obtaining, protecting and defending patent and other intellectual property rights can be expensive and may require us to incur substantial costs, including the diversion of management and technical personnel. An unfavorable ruling in patent or intellectual property litigation could subject us to significant liabilities to third parties, require us to cease developing, manufacturing or selling the affected products or using the affected processes, require us to license the disputed rights from third parties, or result in awards of substantial damages against us.

There can be no assurance that we would prevail in any intellectual property infringement action, will be able to obtain a license to any third party intellectual property on commercially reasonable terms, successfully develop non-infringing alternatives on a timely basis, or license non-infringing alternatives, if any exist, on commercially reasonable terms. Any significant intellectual property impediment to our ability to develop and commercialize our products could seriously harm our business and prospects.

Patent litigation or other litigation in connection with our intellectual property rights may lead to publicity that may harm our reputation and the value of our common stock may decline.

During the course of any patent litigation, there may be public announcements of the results of hearings, motions, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the value of our common stock may decline. General proclamations or statements by key public figures may also have a negative impact on the perceived value of our intellectual property.

Protecting and defending against intellectual property claims may have a material adverse effect on our business.

From time to time, we may receive notice that others have infringed on our proprietary rights or that we have infringed on the intellectual property rights of others. There can be no assurance that infringement or invalidity claims will not materially adversely affect our business, financial condition or results of operations. Regardless of the validity or the success of the assertion of claims, we could incur significant costs and diversion of resources in protecting or defending against claims, which could have a material adverse effect on our business, financial condition or results of operations. We may not have the funds or resources available to protect our intellectual property.

Intellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights.

The biopharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation and USPTO post-grant proceedings to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the USPTO to determine the priority and patentability of inventions. The defense and prosecution of intellectual property suits, USPTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or USPTO post-grant and interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Even if a given patent or intellectual property dispute were settled through licensing or similar arrangements, our costs associated with such arrangements may be substantial and could include the payment by us of large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all. Even where we have meritorious claims or defenses, the costs of litigation may prevent us from pursuing these claims or defenses and/or may require extensive financial and personnel resources to pursue these claims or defenses. In addition, it is possible there may be defects of form in our current and future patents that could result in our inability to defend the intended claims. Intellectual property disputes arising from the aforementioned factors, or other factors, may materially harm our business.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents

or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market PT00114 or any future products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U.S. and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our products and technology.

Changes to the patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, as well as other jurisdictions around the world, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

If we fail to comply with our obligations under any license, collaboration or other intellectual property-related agreements, we may be required to pay damages and could lose intellectual property rights that may be necessary for developing, commercializing and protecting our current or future technologies or drug candidates or we could lose certain rights to grant sublicenses.

Any license, collaboration or other intellectual property-related agreements impose, and any future license, collaboration or other intellectual property-related agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license. In spite of our best efforts, any of our future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technologies covered by these license agreements. Any license agreements we enter into may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may seek to obtain licenses from licensors in the future, however, we may be unable to obtain any such licenses at a reasonable cost or on reasonable terms, if at all. In addition, if any of our future licensors terminate any such license agreements, such license termination could result in our inability to develop, manufacture and sell products that are covered by the licensed technology or could enable a competitor to gain access to the licensed technology. Any of these events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and ability to achieve profitability.

Furthermore, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce and defend patents we may in-license, or lose rights to licensed patents or patent applications, our license rights may be reduced or eliminated. In such circumstances, our right to develop and commercialize any of our products or drug candidates that is the subject of such licensed rights could be materially adversely affected. In certain circumstances, our licensed patent rights are subject to our reimbursing our licensors for their patent prosecution and maintenance costs.

Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's intellectual property rights and the amount of any damages or future royalty obligations that would result, if any such claims were successful, would depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, due to such obligations, we may be unable to achieve or maintain profitability.

Risks Related to Our Business Operations and Industry

If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

We are dependent on the members of our management team and our scientific advisors for our business success. An important element of our strategy is to take advantage of the research and development expertise of our current management and to utilize the unique expertise of our scientific advisors. We do not have any employment agreements with our executive officers. The loss of any one of our executive officers or key scientific consultants, including, in particular, Garo Armen, Ph.D., Chairman of the Board, and Dr. David A. Lovejoy, our Chief Scientific Advisor, could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of our product candidates.

To grow, we will eventually need to hire a significant number of qualified commercial, scientific and administrative personnel. However, there is intense competition for human resources, including management in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful development and commercialization of our product candidates. Our inability to attract new employees or to retain existing employees could limit our growth and harm our business.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, reporting systems, and operational, financial,

and management controls. We may not be able to implement improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures which in turn may slow our growth or give rise to inefficiencies that would increase our losses.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any one of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to exploit acquired technologies, or the loss of key employees from either our business or the acquired business.

Healthcare reform measures could adversely affect our business.

The efforts of governmental and third-party payers to contain or reduce the costs of healthcare may adversely affect the business and financial condition of pharmaceutical companies. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. The pendency or approval of such proposals could result in a decrease in our common stock value or limit our ability to raise capital or to enter into collaborations or license rights to our products.

Our business and operations are vulnerable to computer system failures, cyber-attacks or deficiencies in our cyber-security, which could increase our expenses, divert the attention of our management and key personnel away from our business operations and adversely affect our results of operations.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are to damage from: computer viruses; malware; natural disasters; terrorism; war; telecommunication and electrical failures; cyber-attacks or cyber-intrusions over the Internet; attachments to emails; persons inside our organization; or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, and damage to our reputation, and the further development of our product candidates could be delayed. We could be forced to expend significant resources in response to a cyber security breach, including repairing system damage, increasing cyber security protection costs by deploying additional personnel and protection technologies, paying regulatory fines and resolving legal claims and regulatory actions, all of which would increase our expenses, divert the attention of our management and key personnel away from our business operations and adversely affect our results of operations.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

We and our current and any of our future collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws (e.g., the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH")), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation ("GDPR") may also apply to health-related and other personal information obtained outside of the U.S. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the EU, as well as potential fines for non-compliant companies of up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous new requirements for the collection, use, storage and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information (e.g., the right to access, correct and delete their data). In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated.

In addition, California recently enacted the California Consumer Privacy Act ("CCPA"), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA goes into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

If we, our CROs or our IT vendors experience security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of personal data, we may face costs, significant liabilities, harm to our brand and business disruption.

In connection with our drug research and development efforts, we or our CROs may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. Although we have extensive measures in place to prevent the sharing and loss of patient data in our clinical trial processes associated with our developed technologies and drug candidates, any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international laws (e.g., the GDPR). Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business. We may also rely on third-party IT vendors to host or

otherwise process some of our data and that of users, and any failure by such IT vendor to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development and drug candidates and future commercial manufacturing may involve the use of hazardous materials and various chemicals. We currently do not maintain a research laboratory, but we engage third-party research organizations and manufacturers to conduct our preclinical studies, clinical trials and manufacturing. These third-party laboratories and manufacturers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We must rely on the third parties' procedures for storing, handling and disposing of these materials in their facilities to comply with the relevant guidelines of the states in which they operate and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that their safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, this could result in significant delays in our development. We are also subject to numerous environmental, health and workplace safety laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Risks Associated to our Common Stock

If we fail to comply with the continued minimum closing bid requirements of Nasdaq by October 3, 2022 or other requirements for continued listing, including stockholder equity requirements, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is listed for trading on Nasdaq. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum closing bid price requirement of $1.00 per share for 30 consecutive business days. If a company's common stock trades for 30 consecutive business days below the $1.00 minimum closing bid price requirement, Nasdaq will send a deficiency notice, advising that such company has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements. Thereafter, if such a company does not regain compliance with the bid price requirement, a second 180-day compliance period may be available, provided (i) it meets the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on Nasdaq, including stockholder equity requirements, which we may be unable to satisfy (except for the bid price requirement), and (ii) it provides written notice to Nasdaq of its intention to cure this deficiency during the second compliance period by effecting a reverse stock split, if necessary. In the event the company does not regain compliance with Rule 5550(a)(2) prior to the expiration of the initial 180 calendar day period, and if it appears to the Staff of the Listing Qualifications Department of The Nasdaq Stock Market LLC (the "Nasdaq Staff") that the company will not be able to cure the deficiency, or if the company is not otherwise eligible, the Nasdaq Staff will provide the company with written notification that its securities are subject to delisting from Nasdaq. At that time, the company may appeal the delisting determination to a Hearings Panel.

On April 5, 2022, the Nasdaq Staff notified us that we did not comply with the minimum $1.00 per share bid price requirement for continued listing, as set forth in Nasdaq Listing Rule 5550(a)(2), and we had 180 calendar days, or until October 3, 2022, to regain compliance. The closing bid price of our securities must be at least $1.00 per share for a minimum of ten consecutive business days to regain compliance. In September 2022, Nasdaq extended the timeframe by another six months, giving us until April 4, 2023 to comply.

On March 22, 2023, the company underwent a 1-for-4 reverse stock split, to exceed the $1.00 per share minimum bid price and preserving our listing on Nasdaq.

In the future, if we are unable to maintain compliance with the minimum closing bid price requirement, or if we fail to meet any of the other continued listing requirements, including stockholder equity requirements, our securities may be delisted from Nasdaq, which could reduce the liquidity of our common stock materially 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, employees and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock may no longer be recognized as a "covered security" and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock.

Our common stock is a "Penny Stock" subject to specific rules governing its sale to investors that could impact its liquidity.

The SEC has adopted Rule 15g-9 which establishes the definition of a "penny stock," for the purposes relevant to our common stock, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require that a broker or dealer approve a person's account for transactions in penny stocks; and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience objectives of the person; and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination, and states that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors sell shares of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

The market price of our common stock may be volatile, and you could lose all or part of your investment.

The market price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control.

The market price of our common stock may fluctuate substantially and will depend on a number of factors many of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your investment in our common stock since you might be unable to sell your shares at or above the price you pay for the shares. Factors that could cause fluctuations in the market price of our common stock include, but are not necessarily limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;

- volatility in the market prices and trading volumes of pharmaceutical and biotechnology stocks;
- changes in operating performance and stock market valuations of other pharmaceutical and biotechnology companies generally, or those in our industry in particular;
- sales of shares of our common stock by us or our stockholders;
- failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or our failure to meet those projections;
- announcements by us or our competitors of new products or services;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our operating results or fluctuations in our operating results;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Compliance with the reporting requirements of federal securities laws can be expensive.

We are a public reporting company in the United States, and accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, and certain compliance obligations of the Sarbanes-Oxley Act. The costs of preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders are substantial.

Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of its business and its ability to obtain or retain listing of our common stock.

We may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. We may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business and our ability to obtain or retain listing of our shares of common stock on any stock exchange (assuming we elect to seek and are successful in obtaining such listing) could be adversely affected.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, investors could lose confidence in our financial reporting and this may decrease the trading price of our stock.

We must maintain effective internal controls to provide reliable financial reports and detect fraud. We have been assessing our internal controls to identify areas that need improvement and will continue to monitor internal controls to improve them. Failure to implement these changes to our internal controls or any others that it identifies as necessary to maintain an effective system of internal controls could harm our operating results and cause investors to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our stock.

Management has concluded that, during the year-ended December 31, 2022, our internal controls and procedures were not effective to detect the inappropriate application of U.S. GAAP. Management identified the following material weaknesses set forth below in our internal control over financial reporting.

1. We lack the necessary corporate accounting resources to maintain adequate segregation of duties; and
2. We did not perform an effective risk assessment or monitor internal controls over financial reporting.

The price of our common stock may become volatile, which could lead to losses by investors and costly securities litigation.

The trading price of our common stock is likely to be highly volatile and could fluctuate in response to factors such as:

- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- the timing of IDE and/or NDA approval, the completion and/or results of our clinical trials;
- regulatory actions regarding our products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common stock or other securities in the open market; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock.

In the future, we may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for our common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes and some of these issuances may be at a price (or exercise prices) below the price at which shares of our common stock is currently quoted on the NASDAQ Capital Market. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of our common stock.

Our common stock is controlled by insiders

Our officers and directors beneficially own approximately 26% of our outstanding shares of common stock. Such concentrated control of our common stock may adversely affect the price of our common stock. Investors who acquire our common stock may have no effective voice in the management of our operations. Sales by our insiders or affiliates, along with any other market transactions, could affect the market price of our common stock.

We do not intend to pay dividends for the foreseeable future and may never pay dividends.

We have paid no dividends on our common stock to date and it is not anticipated that any dividends will be paid to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of our business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock, and could significantly affect the value of any investment.

There can be no assurance that we will ever provide liquidity to our investors through a sale of our Company.

While acquisitions of pharmaceutical companies like ours are not uncommon, potential investors are cautioned that no assurances can be given that any form of merger, combination, or sale of our Company will take place or that any merger, combination, or sale, even if consummated, would provide liquidity or a profit for our investors. You should not invest in our Company with the expectation that we will be able to sell the business in order to provide liquidity or a profit for our investors.

Our certificate of incorporation allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to issue shares of our preferred stock, with such relative rights and preferences as the board of directors may determine, without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders special and unique rights, including without limitation, a preferred right to our assets upon liquidation, a right to receive dividend payments before dividends are distributed to the holders of common stock and the right to convert into our common stock at a price more favorable then the price at which you acquired our common stock. The issuance of any preferred stock could decrease the value of your common stock and relative voting power of our common stock or result in dilution to our existing stockholders.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from engaging in certain business combinations with us for a prescribed period of time.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

The Company does not currently own any real property. The Company leases office space for its principal executive office located at 149 Fifth Avenue, Suite 500, New York, New York 10010.

Item 3. Legal Proceedings.

From time to time we may be named in claims arising in the ordinary course of business. As of December 31, 2022, no legal proceedings, government actions, administrative actions, investigations or claims are pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business, financial condition, and results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is currently available for trading in the over-the-counter market and is quoted on the Nasdaq Capital Market under the symbol "PTIX." There has been very limited market for our common stock and trading volume has been negligible. There is no guarantee that an active trading market will develop in our common stock. The following table sets forth, for the periods indicated and as reported on the Nasdaq Capital Market, the high and low bid prices for our common stock. Such quotations reflect inter-dealer prices, without retail mark-up, markdown or commission and may not necessarily represent actual transactions.

	High	Low
2021(1)		
First Quarter **(1)**	$ 28.00	$ 4.20
Second Quarter **(1)**	$ 27.00	$ 7.36

Third Quarter **(1)**	$	11.88	$	6.20
Fourth Quarter **(1)**	$	9.40	$	5.32
2022(1)				
First Quarter **(1)**	$	5.80	$	3.20
Second Quarter **(1)**	$	3.68	$	2.60
Third Quarter **(1)**	$	3.20	$	2.28
Fourth Quarter **(1)**	$	2.60	$	1.40

(1) The high and low bid prices for this quarter were reported by the Nasdaq Capital Market. There was negligible trading volume during this period.

Holders

As of March 31, 2023, there are approximately 3,000 record holders of our common stock and zero holders of our Series B Preferred Stock.

Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

Recent Sales of Unregistered Securities

During the year December 31, 2022, $94,985 in principal and interest were converted to 18,912 shares of the Company's common stock.

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 financial statements and the related notes included at the end of this report. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk factors" section of this report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

The discussion and analysis of our financial condition and results of operations are based on Protagenic's financial statements, which Protagenic has prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires Protagenic to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, Protagenic evaluates such estimates and judgments, including those described in greater detail below. Protagenic bases its estimates on historical experience and on various other factors that Protagenic believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value 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 expect to continue to incur significant expenses and minimal positive net cash flows from operations or negative net cash flows from operations for the foreseeable future, and those expenses and losses may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will fluctuate substantially as we:

- continue our ongoing preclinical studies, clinical trials and our product development activities for our pipeline of product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue research and preclinical development and initiate clinical trials of our other product candidates;
- seek to discover and develop additional product candidates either internally or in partnership with other pharmaceutical companies;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio; and
- incur additional legal, accounting and other expenses in operating as a public company.

Results of Operations

We are a development stage company currently performing clinical trials to obtain Food and Drug Administration ("FDA") approval and commercialization of our product.

During the year ended December 31, 2022, we incurred a loss from operations of $3,557,788 as compared to $4,140,413 for the year ended December 31, 2021. The decrease in the loss is due to an increase in research and development expense of $452,449 from $1,136,790 for the year ended December 31, 2021 to $1,589,239 for the year ended December 31, 2022, and a decrease in general and administrative expenses of $1,035,074 from $3,003,623 for the year ended December 31, 2021 to $1,968,549 for the year ended December 31, 2022. The increase in research and development expense is due to additional cost related to the Company's continued research and development efforts. The decrease in general and administrative expenses was due to lower stock compensation expense in the current year.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. To date, we have primarily financed our operations through the public offering of our equity securities and the private placement of our convertible securities.

In April 2021, we completed a public offering of our securities and uplisted to the Nasdaq Capital Market (the "Offering"). Pursuant to the Offering, we issued and sold

795,000 units at a public offering price of $16.60 Each unit consisted of one share of our common stock and one warrant, for a total of 795,000 shares of our common stock and 795,000 warrants to purchase up to an aggregate 795,000 shares of our common stock. Each warrant is exercisable to purchase one share of common stock at an exercise price of $19.92 per share (120% of the public offering price of the unit). The warrants are exercisable at any time from the date of issuance through the fifth anniversary of the date of issuance. The aggregate net proceeds received by the Company from the Offering (before expenses) were $12.1 million. Upon the pricing of the Offering, our common stock was approved for listing on The Nasdaq Capital Market and commenced trading under the ticker symbol "PTIX". At this time, our warrants were also approved for listing and commenced trading under the ticker symbol "PTIXW".

In June 2021, the SEC declared effective a shelf registration statement filed by us. This shelf registration statement allows us to issue any combination of our common stock, preferred stock, debt securities, warrants, or units from time to time for an aggregate initial offering price of up to $100.0 million. In July 2021, we entered into an At Market Issuance Agreement, or the ATM Agreement, with B. Riley Securities, Inc. and EF Hutton, division of Benchmark Investments, LLC, or the Sales Agents, under which we may issue and sell from time to time up to $10.0 million of our common stock through or to the Sales Agents, as agent or principal. Any sale of shares of our common stock under the Sales Agreement will be made under our shelf registration statement on Form S-3. Sales of our common stock under the Sales Agreement are made at market prices by any method that is deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. The Company has not yet sold any shares under the ATM Agreement. Therefore, as of December 31, 2021, $10.0 million of our common stock remained available for sale under the Sales Agreement.

Operating activities used $1,993,814 and $2,798,614 in cash for the years ended December 31, 2022 and 2021, respectively. The use of cash in operating activities during the year ended December 31, 2022, primarily comprised of $3,555,505 net loss, $864,681 in stock compensation expense, a decrease in prepaid expenses and other current assets of $631,728, amortization of debt discount of $110,797, and a $91,596 decrease of accounts payable and accrued expenses, which included payments to legal and accounting professionals, payments to consultants, and other administrative expenses.

Investing activities provided $1,596,974 and used $9,909,601 in cash for the years ended December 31, 2022 and 2021, respectively. The cash provided by investing activities during the year ended December 31, 2022 consisted of $1,632,901 from the sale of marketable securities and ($34,122) in the purchase of marketable securities.

We continually project anticipated cash requirements, predominantly from the ongoing funding requirements of our neuropeptide drug development program. The majority of these expenses relate to paying external vendors such as Contract Research Organizations (CROs) and peptide synthesizer companies. They could also include business combinations, capital expenditures, and new drug development working capital requirements. As of December 31, 2022, we had cash of $215,189 and working capital of $6,915,783.

We anticipate that losses will continue for the foreseeable future. Based on our current operating plans, we believe that our cash resources will be sufficient to fund its operations until approximately the end of the third quarter of 2024. In order to continue our operations beyond our forecasted runway we will need to raise additional capital, and we have no committed sources of additional capital at this time. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors. We have based our estimates on assumptions that may prove to be wrong, and our expenses could prove to be significantly higher than we currently anticipate. Management does not know whether additional financing will be on terms favorable or acceptable to us when needed, if at all. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for further development of our product candidates, management may need to curtail its development efforts and planned operations.

Contractual Obligations

The following table sets forth certain information concerning the future contractual obligations under our convertible notes at December 31, 2022.

	Payments due by period				
Contractual obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-Term PIK convertible notes payable	$ 230,000	$ 230,000	$ -	$ -	$ -
Long-Term PIK convertible notes payable– Related Party	$ 200,000	$ 200,000	$ -	$ -	$ -
Total	$ 430,000	$ 430,000	$ -	$ -	$ -

Plan of Operations

Business Overview

The Company is in its developmental stage, with encouraging but not conclusive evidence that its lead drug candidate, PT00014, may be effective as an anti-anxiety and/or anti-depression drug. It is focused on confirming the efficacy of this drug candidate, along with performing the other preclinical steps needed to progress along the pathway to bring this drug candidate into human clinical trials and eventually, to the global market to provide a new pharmaceutical for patients suffering from anxiety or treatment-resistant depression.

If we are able to successfully develop our drug, PT00114, and obtain FDA approval, we could then begin marketing and selling it in the United States and generate revenue. FDA approval to begin commercial sales is the singular gating item that will allow us to begin generating sales revenue in the U.S., so it will have an enormous impact on our business plan and our financial condition. It is anticipated that the sale of our drug will allow the Company to generate enough sales revenue to support all of our operations and to generate a profit. However, given the stage of development, even if FDA Approval is obtained, we do not anticipate generating any revenue from sales prior to 2026.

Development Milestones Currently Anticipated

Recent communications with the U.S. FDA has resulted in following revised guidance for clinical timelines.

- The Company in the process of refiling its IND application for PT00114 addressing the questions raised by regulators.
- Anticipate Q3 2023: Initiation of Phase I/IIa study for PT00114

Human Resources (current state of employees)

The Company has two part-time employees: Garo H. Armen, PhD, the Executive Chairman, and Alexander K. Arrow, MD, the Chief Financial Officer, and one full-time employee, Lauren Mueller, PhD, a Senior Research Scientist. The Company also has six paid consultants: Andrew Slee, PhD, Chief Operating Officer, Robert S. Stein, MD, PhD, Chief Medical Officer, Dalia Barsyte, PhD, Scientific Advisor, David Lovejoy, PhD, Scientific Advisor, and Zack Armen, Strategic Advisor.

Financing Activities

Financing activities provided $0 and $12,577,664 in cash for the years ended December 31, 2022 and 2021, respectively. The cash provided by financing consisted of $100,000 in proceeds from convertible notes, ($100,000) from the repayment of convertible notes, $327,125 from the exercise of warrants, $542,500 from the exercise of options, and $11,708,039 from the sale of shares and warrants, net of offering costs, for the year ended December 31, 2021.

Off Balance Sheet Arrangements

We have no material off-balance sheet arrangements that are likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital resources, or capital expenditures.

Critical accounting policies and estimates

Our discussion and analysis of financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The notes to the consolidated financial statements contained in this Annual Report describe our significant accounting policies used in the preparation of the consolidated financial statements. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. We continually evaluate our critical accounting policies and estimates.

COVID-19

On January 30, 2020, the World Health Organization declared the COVID-19 novel coronavirus outbreak a "Public Health Emergency of International Concern" and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The COVID-19 coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographical area in which the Company operates. While it is unknown how long these conditions will last and what the financial impact will be to the Company, it is reasonably possible that future capital raising efforts and additional development of our technologies may be negatively affected.

Recently Issued Accounting Pronouncements

None

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

See pages F-1 through F-20 following the Exhibit Index of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Assessment of the Effectiveness of Internal Controls over Financial Reporting

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework published in 2013. Based on its evaluation, our management concluded that our internal control over financial reporting was not effective as of the end of the period covered by this Annual Report on Form 10-K.

(a) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. 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 the transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with the authorization of management and/or our Board of Directors; and

(iii) provide reasonable assurance regarding the prevention or timely detection of any unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2022, management has completed a proper evaluation, risk assessment and monitoring of the Company's internal controls over financial reporting based on the 2013 Committee of Sponsoring Organizations (COSO) framework. Management concluded that, during the period covered by this report, our internal controls and procedures were not effective to detect the inappropriate application of GAAP. Management identified the following material weaknesses and concluded that the internal controls over financial reporting were not effective.

1. We lack the necessary corporate accounting resources to maintain adequate segregation of duties. We currently rely heavily on our Executive Chairman, for almost every

key financial duty and he has access to materially all of our financial information. Such a lack of segregation of duties is typical in a company with limited resources. Although the Company's Executive Chairman and Board of Directors review the financial statements and would most likely discover any misappropriation of funds, this cannot be assured by the existing system.

2. Limited level of multiple reviews in connection with the financial reporting process.

This annual report does not include an attestation report by our independent registered public accounting firm regarding internal control over financial reporting. As we are neither a large accelerated filer nor an accelerated filer, our management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

(b) Evaluation of Disclosure Controls and Procedures

Pursuant to Rule 13a–15(b) under the Exchange Act, the Company carried out an evaluation, with the participation of the Company's management, including the Company's Board of Directors, the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the Company's disclosure controls and procedures (as defined under Rule 13a–15(e) under the Exchange Act) as of the end of the period covered by this Report. Based upon that evaluation, the Company's management concluded that the Company's disclosure controls and procedures were not effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits 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 the Company's management to allow timely decisions regarding required disclosure due to the following:

1. We do not have sufficient segregation of duties within accounting functions, which is a basic internal control. Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Management evaluated the impact of our failure to have segregation of duties on our assessment of our disclosure controls and procedures and has concluded that the control deficiency that resulted represented a material weakness.
2. Limited level of multiple reviews among those tasked with preparing the financial statements.

During the quarter ended December 31, 2022, the Company analyzed and documenting accounting policies and procedures. In addition, management implemented certain policies and procedures but concluded that material weaknesses still exist and that such controls are not effective under the COSO framework. These material weaknesses could result in a material misstatement to the annual or interim condensed consolidated financial statements that would not be prevented or detected.

Remediation Plan

To address the material weakness described above, we have engaged an independent third party to enhance our segregation of duties.

Since we remain a small Company, with limited segregation of duties, the third party has identified certain areas where we can layer in added controls and procedures. Management intends to implement such controls and procedures in the future.

Limitations on the Effectiveness of Controls. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived 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 controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

(c) Changes in Internal Control over Financial Reporting

Other than as discussed above, there were no changes in our internal controls over financial reporting (as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Nasdaq Deficiency Notice

On April 5, 2022, we received a deficiency letter from the Nasdaq Staff notifying the Company that, for the last 30 consecutive business days, the closing bid price for our common stock had been below the minimum $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were given 180 calendar days, or until October 3, 2022, to regain compliance with Rule 5550(a)(2). On October 4, 2022, we received a letter from Nasdaq notifying us that we had been granted the Second 180 Day Compliance Period or until April 5, 2022, to regain compliance with the minimum $1.00 bid price per share requirement of the Rule. On March 22, 2023, the company underwent a 1-for-4 reverse stock split, to exceed the $1.00 per share minimum bid price and preserve our listing on Nasdaq.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

[Not applicable].

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following sets forth certain information with respect to our executive officers and directors.

Name	Age	Position(s)
Garo H. Armen	70	Executive Chairman of the Board of Directors

Alexander K. Arrow	52	Chief Financial Officer
Robert B. Stein	72	Director, Chief Medical Officer
Andrew Slee	73	Chief Operating Officer
Khalil Barrage	58	Director
Timothy Wright	65	Director
Brian Corvese	65	Director
Jennifer Buell	48	Director

Garo H. Armen, PhD, Executive Chairman, is one of our founders and joined us in September 2004. Dr. Armen is Chairman and Chief Executive Officer of Agenus Inc., a biotechnology company he co-founded in 1994. From mid-2002 through 2004, he also served as Chairman of the Board of directors of the biopharmaceutical company Elan Corporation, plc, which he successfully restructured. Prior to Agenus Inc., Dr. Armen established Armen Partners, a money management firm specializing in biotechnology and pharmaceutical companies, and was the architect of the widely publicized creation of the Immunex Lederle oncology business in 1993. Earlier, he was a senior vice president of research at Dean Witter Reynolds, having begun his career on Wall Street as an analyst and investment banker at EF Hutton. In 2002, Dr. Armen founded the Children of Armenia Fund, a nonprofit organization dedicated to significantly rebuilding and revitalizing impoverished rural Armenian towns to provide immediate and sustainable benefits to children and youth. He received the Ellis Island Medal of Honor in 2004 for his humanitarian efforts, and received the Sabin Humanitarian Award from the Sabin Vaccine Institute in 2006 for his achievements in biotechnology and progressing medical research. Dr. Armen was also the Ernst & Young 2002 New York City Biotechnology Entrepreneur of the Year, and received a Wings of Hope Award in 2005 from The Melanoma Research Foundation for his ongoing commitment to the melanoma community. Dr. Armen received a PhD in physical chemistry from the Graduate Center, City University of New York, after which he worked as a research fellow at Brookhaven National Laboratories in Long Island, NY.

Alexander K. Arrow, M.D., CFA, Chief Financial Officer. Dr. Arrow became our Chief Financial Officer in February 2016. Dr. Arrow is the Chief Financial Officer of Carlsmed, Inc, a spinal implant manufacturer whose mission is to improve outcomes and decrease the cost of healthcare for spine surgery and beyond. He serves on the Boards of Zelegent, Inc., a medical device company selling a minimally-invasive snoring alleviation tool, and Paragonix Technologies, the supplier of the leading solid organ transportation device. Previously, Dr. Arrow served as a director of Neumedicines, Inc., a company developing protein therapeutics in Oncology, Hematology and Immunology. Dr. Arrow served as a director and as Chairman of the Audit and Compensation Committees of Biolase, Inc. (NASDAQ: BIOL) from 2010 through 2014, and served as the President and Chief Operating Officer. Biolase, Inc. is the leading manufacturer of dental lasers. Before Biolase, he was the Chief Medical and Strategic Officer of Circuit Therapeutics, Inc., in the field of optogenetics. From 2007 through 2012, Dr. Arrow was the Chief Financial Officer of Arstasis, Inc., a cardiology device manufacturer. From 2002 to 2007, he headed medical technology equity research at the global investment bank Lazard Capital markets, LLC. Dr. Arrow spent two years 1999-2001 as Chief Financial Officer of the Patent & License Exchange Inc., and three years as the life sciences research analyst at Wedbush Morgan Securities. Dr. Arrow received his CFA in 1999. He was awarded an M.D. from Harvard Medical School in 1996 and a B.A. in Biophysics, *magna cum laude*, from Cornell University in 1992.

Robert B. Stein, PhD. MD, Director, Chief Medical Officer, joined us effective the closing of the Merger in February, 2016. Dr. Robert B. Stein retired as President of R&D at Agenus Inc. in April 2017. He continues as Senior Advisor, R&D for both Agenus, Inc. and its cell therapy partially-owned subsidiary MiNK Therapeutics (Nasdaq: INKT). Dr. Robert B. Stein lead Agenus' Research, Preclinical Development and Translational Medicine functions. He helps shape clinical development strategy for vaccines and adjuvants. Additionally, he lead integration of the 4-Antibody, PhosImmune, and Xoma Pilot Plant acquisitions, which includes the company's fully human antibody drug discovery and optimization technology platform, and portfolio of immune checkpoint antibody programs. Over his 35 years of experience in the biopharmaceutical industry he played a pivotal role in bringing to the market Sustiva®, Fablyn®, Viviant®, PanRetin®, TargRetin®, Promacta® and Eliquis®. Prior to joining Agenus, he held executive management positions at Ligand Pharmaceuticals, DuPont Merck, Incyte Pharmaceuticals, Roche Palo Alto and KineMed. Dr. Stein began his career at Merck, Sharp and Dohme. He holds an MD and a PhD in Physiology & Pharmacology from Duke University. Dr. Stein filed a personal voluntary bankruptcy petition under Chapter 7 in August of 2012 and the bankruptcy was discharged in May 2013.

Andrew Slee, PhD, Chief Operating Officer. Dr. Andy Slee joined us in April 2016. During his 37-year pharmaceutical career, Mr. Slee has taken several drugs from inception through all their pre-clinical and early clinical testing. During the past 37 years, he has worked for Preclinical CROs, immune-oncology companies and natural product companies focusing on anti-infectives, cancer, CNS, diabetes and inflammatory diseases. Spreading his influence beyond a single company, he created and ran his own Contract Research Organization (CRO), VivoSource Laboratories, which for ten years from 2003 to 2013 provided preclinical proof of concept catering to biopharmaceutical companies. For the 18 years before that, Mr. Slee shepherded multiple pharma targets in several therapeutic areas from inception onward at DuPont Pharmaceuticals. He is a graduate of Syracuse University and Leeds University.

Khalil Barrage, Director, joined us in July, 2007. Mr. Khalil Barrage has served as a Managing Director of The Invus Group, LLC since 2003, in charge of the Public Equities Group that he set up in September 2003. Invus manages over $3B of capital, with a primary focus is on private equity investments, biotechnology and health care. In addition, Invus manages a fund-of-funds liquid alternative investment and, most recently, the newly established public equities portfolio activity. Mr. Barrage is a value investor. He started his career in 1988 with The Olayan Group, a multibillion private group. He was in charge of the group's US public equities portfolio, overseeing more than $2 billion of assets. Mr. Barrage holds a BA from American University of Beirut.

Brian J. Corvese, Director, joined us on July 28, 2017, filling the open board seat vacated by Gregory H. Ekizian. Since 1999, Mr. Corvese has been the President and Founder of Vencor Capital ("Vencor"), a private equity firm with telecommunications and technology investments in the Middle East and Mediterranean regions. Prior to working at Vencor, Mr. Corvese worked on investments in the U.S. and global equity markets as a Managing Director and partner at Soros Fund Management, the largest hedge fund in the world at the time. From 1988 to 1996, Mr. Corvese was a partner at Chancellor Capital Management ("Chancellor"), a $25 billion money management firm. While at Chancellor, Mr. Corvese was a Portfolio Manager with responsibility for investments made in basic industries, restructurings, and special situations, corporate governance investments, as well as founded and managed his own hedge fund. From 1981 to 1988, Mr. Corvese was with Drexel Burnham Lambert ("Drexel") as an equity analyst following the chemical and specialty chemical industries and participated in a significant number of merger and acquisition activities. While at Drexel, Mr. Corvese was a member of the top chemical and specialty chemical research team, as ranked by Institutional Investor. Mr. Corvese currently serves on the board of directors of Agenus Inc. and the National Telecommunications Corporation, based in Cairo, Egypt. Mr. Corvese earned degrees in finance and political science from The University of Rhode Island and attended New York University Graduate School. With over 30 years of experience in the financial industry, Mr. Corvese brings substantial financial expertise to our Board.

Timothy Wright, Director, Mr. Wright is the Chief Executive Officer of MiMedX Group, Inc., a position that he has held since May 2019. MiMedX is an advanced wound care and emerging therapeutic biologics company. Mr. Wright also currently serves on the board of directors of Agenus Inc., which he has served on since 2006. Mr. Wright also serves as a Partner at Signal Hill Advisors, LLC, a position he has held since February 2011. In addition, Mr. Wright serves as Chairman of The Ohio State University Comprehensive Cancer Center Drug Development Institute and Director of the Ohio State University Innovation Foundation. Mr. Wright previously held several executive roles at Covidien (now Medtronic), Teva Pharmaceuticals Industries Ltd., DuPont Merck, Elan Bio-Pharmaceuticals, M2Gen Corp. and Curaxis Pharmaceuticals Corporation. As our Lead Director, Mr. Wright brings 30 years of experience on boards of companies in North America, Europe, Asia and Japan.

Jennifer Buell, PhD, Director, joined our board in July 2020. Dr. Buell is the President and Chief Operating Officer of Agenus, Inc., where she has previously served as served as the Head of Global R&D operations, Head of Research, and Chief Communications and External Affairs Officer. She is also the president of Agenus' cell therapy partially-owned subsidiary MiNK Therapeutics, Inc, (Nasdaq: INKT). With 20 years of biopharmaceutical R&D experience, Dr. Buell has extensive knowledge in advancing discovery candidates through development and experience communicating with external stakeholders including regulators, investors, and collaborators. She has a proven record of success in R&D leadership, most recently at Agenus, where she led high performing teams in advancing candidates into the clinic and delivered on key alliance collaborations. Prior to joining Agenus, Dr. Buell held leadership positions in R&D operations at Bristol-Myers Squibb and later was responsible for Program and Alliance Management at Harvard

Clinical Research Institute (Baim), where she was involved in the development strategy and operations for a portfolio of industry and government sponsored clinical programs. Dr. Buell obtained her PhD in Cellular, Biochemical, and Molecular Biochemistry with an MS in Biostatistics from Tufts University in Boston.

Consultants and Advisors

David A. Lovejoy, PhD, Scientific Advisor, is one of our founders and joined us in September 2004. He holds a PhD in Neuroendocrinology from the University of Victoria (Victoria, BC) and spent three years at the Clayton Foundation Laboratories for Peptide Biology at the Salk Institute (San Diego, CA) as a postdoctoral fellow. Dr. Lovejoy took his first academic appointment at the University of Manchester (Manchester, UK), one of the United Kingdom's top-ranking research universities. He joined the University of Toronto (Toronto, Ontario) in 2000 and is currently Professor of Neuroendocrinology in the Department of Cell and Systems Biology at the University of Toronto. He is the author of more than 210 scientific publications including three books in the field and an Associate Editor for a scientific journal and is inventor or co-inventor on all of our intellectual property.

Dalia Barsyte PhD, Scientific Advisor. Dr. Dalia Barsyte received her PhD in molecular and cellular biology from the University of Manchester, UK. She did the postdoctoral training at the University of Manchester and Ontario Cancer Institute, and currently is a scientist at the University of Toronto, Structural Genomics Consortium, where she has been employed since 2009. Dr. Barsyte is an inventor on one of the key Protagenic patents and author of over 50 scientific publications in oncology and neuroscience. Dr. Barsyte's scientific interests include exploring chemical biology in therapeutic target validation through peptide or small molecule chemical probe compounds as well as novel in vitro models of disease based on patient derived cell culture.

Zack Armen, Strategic Advisor. Mr. Armen became involved with Protagenic in Fall 2018, and brings experience in strategic finance and life sciences venture investing to the company through roles at Goldman Sachs, Flagship Pioneering, CiBO Technologies, and his current role as Director of Corporate Development at Valo Health.

Mark Berg, Strategic Consultant. Mr. Berg became a strategic consultant to Protagenic in January 2022. He brings several decades of perspective regarding publicly-traded biotechnology companies' perceptions by investors.

Director Independence

Each of Messrs. Corvese, Silverman, and Barrage, and Dr. Buell are "independent" members of our board of directors as "independence" is defined in Nasdaq Marketplace Rule 5605(a)(2).

Family Relationships

There are no family relationships between or among the directors, executive officers or persons nominated or chosen by our stockholders or us to become directors or executive officers. There is one family relationship between Strategic Advisor Zack Armen and our Executive Chairman, Garo Armen (Garo Armen is Zack Armen's father).

Former Voting Agreement

On February 12, 2016, the Company and certain of its stockholders (then representing approximately 43% of the Company's issued and outstanding common stock), including Drs. Armen, Arrow and former director Mr. Greg Ekizian and former shareholder Strategic Bio Partners, LLC, entered into a voting agreement whereby these stockholders agreed to vote in favor of setting and maintaining the size of the Board at five directors (unless increased by the Board), the election of one director designated by Strategic Bio Partners, LLC (Mr. Silverman) and the election of four directors designated by Dr. Armen (so long as Dr. Armen is an officer or director of the Company). The voting agreement terminated on February 12, 2019.

Involvement in Certain Legal Proceedings

To our knowledge, during the past ten years, none of our directors, executive officers, promoters, control persons, or nominees has:

been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

except as set forth above with respect to Dr. Stein, had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;

been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;

been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Code of Business Conduct and Ethics

On February 24, 2017, we adopted a written Code of Business Conduct and Ethics. Guidelines on Significant Governance Issues, and Process for Security Holder Communications with Directors, each of which is filed as an exhibit to this annual report.

Board Committees

Our board of directors has established five standing committees: an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee, a Science Committee and a Clinical and Regulatory Committee. Each of these committees will operate under a charter that has been approved by our board of directors.

Audit Committee. The Audit Committee will oversee and monitor our financial reporting process and internal control system, review and evaluate the audit performed by our registered independent public accountants and reports to the Board any substantive issues found during the audit. The Audit Committee will be directly responsible for the

appointment, compensation and oversight of the work of our registered independent public accountants. The Audit Committee will review and approve all transactions with affiliated parties. The Audit Committee shall be comprised on two or more independent directors who shall be appointed annually and subject to removal by the Board at any time. Each member of the Audit Committee shall meet the independence requirements of The NASDAQ Stock Market, LLC, and SEC regulations, as well as any other applicable requirements. Messrs. Corvese (Committee Chairperson), Wright, and Barrage comprise the Audit Committee, each of whom meets the independence requirements. In addition, the Board also designated Brian Corvese as an "audit committee financial expert," as that term is defined by the NSADAQ Listing Rules and SEC regulations.

Compensation Committee. The Compensation Committee will provide advice and make recommendations to the board in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee will also review the compensation of our President, Chief Executive Officer, and other officers and make recommendations in that regard to the board as a whole. The Compensation Committee shall be comprised on three or more directors who shall be appointed annually and subject to removal by the Board at any time. The Compensation Committee must have at least two members, and must consist solely of independent directors. Messrs. Barrage, Corvese, and Wright comprise the Compensation Committee and are all independent.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee will nominate individuals to be elected to the full board by our stockholders. The Nominating and Corporate Governance Committee will determine the slate of director nominees for election to the Board, to identify and recommend candidates to fill vacancies occurring between annual stockholder meetings, to review the Company's policies and programs that relate to matters of corporate responsibility, including public issues of significance to the Company and its stockholders. The Compensation Committee shall be comprised on three or more directors who shall be appointed annually and subject to removal by the Board at any time. Each member of the Nominating and Corporate Governance Committee may or may not meet the independence requirements of The NASDAQ Stock Market, LLC and SEC regulations. Messrs. Wright (Committee Chairperson), and Drs. Armen and Stein comprise the Nominating and Corporate Governance Committee.

Science Committee. The Science Committee will meet regularly to review the strategic direction being taken by Management with respect to developing the Company's scientific assets. A key function of the Science Committee is to ensure that the Company is targeting disease indications for its drug candidates that take full advantage of the drug candidates' potential, within the constraints of the working capital available to the Company. This process is expected to continually necessitate difficult choices concerning how many disease targets to pursue. The Science Committee will be directly responsible for the appointment, compensation and oversight of the Company's top scientific staff. The Science Committee will review and approve all major contractual agreements with contract research organizations. The Science Committee shall be comprised on two or more directors who shall be appointed annually and subject to removal by the Board at any time. Drs. Stein (Committee Chairperson) and Armen comprise the Science Committee.

Clinical and Regulatory Committee: The Clinical and Regulatory committee will meet at least once per year to review progress of the clinical trial programs of the Company. The Clinical and Regulatory committee was created in July 2020 and Dr. Jennifer Buell was appointed as its chair.

Limitation of Directors Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Delaware law.

We have director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act. Our certificate of incorporation and bylaws also provide that we will indemnify our directors and officers who, by reason of the fact that he or she is one of our officers or directors of our company, is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative related to their board role with the company.

We have entered into indemnification agreements with each of our directors and executive officers. It is anticipated that future directors and officers will enter into an Indemnification Agreement with us in substantially similar form. The Indemnification Agreement provides, among other things, that we will indemnify and hold harmless each person subject to an Indemnification Agreement (each, an "Indemnified Party") to the fullest extent permitted by applicable law from and against all losses, costs, liabilities, judgments, penalties, fines, expenses and other matters that may result or arise in connection with such Indemnified Party serving in his or her capacity as a director of ours or serving at our direction as a director, officer, employee, fiduciary or agent of another entity. The Indemnification Agreement further provides that, upon an Indemnified Party's request, we will advance expenses to the Indemnified Party to the fullest extent permitted by applicable law. Pursuant to the Indemnification Agreement, an Indemnified Party is presumed to be entitled to indemnification and we have the burden of proving otherwise. The Indemnification Agreement also requires us to maintain in full force and effect directors' liability insurance on the terms described in the Indemnification Agreement. If indemnification under the Indemnification Agreement is unavailable to an Indemnified Party for any reason, we, in lieu of indemnifying the Indemnified Party, will contribute to any amounts incurred by the Indemnified Party in connection with any claim relating to an indemnifiable event in such proportion as is deemed fair and reasonable in light of all of the circumstances to reflect the relative benefits received or relative fault of the parties in connection with such event.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

Item 11. Executive Compensation.

The following table sets forth information regarding each element of compensation that we paid or awarded to our named executive officers and for fiscal years ended December 31, 2022 and 2021.

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total Compensation ($)
Garo H. Armen,	2022	0	0	0	$ 0	0	0	0	$ 0

Chairman	2021		0		0		0	$	0		0		0		0	$	0
Alexander K. Arrow,	2022	$	150,000	$	0	$	0	$	0	$	0	$	0		0	$	150,000
Chief Financial Officer	2021	$	136,538	$	0	$	0	$	0	$	0	$	0		0		$136,538,

Employment Arrangements with Officers and Directors

Dr. Alexander Arrow, our Chief Financial Officer, receives base compensation of $150,000 per year for his part-time work for us, an increase from the $125,000 he received until July 1, 2021, except for an 18-month period from February 2019 through August 2020 during which he received zero cash salary and three grants totaling 88,541 options in lieu of cash salary. From 2016 through 2020, cumulatively, Dr. Arrow received 25,000 options under the 2006 Plan and three grants totaling 335,000 incentive options in the aggregate under the 2016 plan with exercise prices of $5.00 and $7.00 per share. The terms of Dr. Arrow's option grants include full vesting acceleration upon a change of control.

Consulting Agreements

Andrew Slee, PhD, Chief Operating Officer. In December 2020, we entered into a consulting agreement with Dr. Slee to act as our Chief Operating Officer. We granted Dr. Slee (i) 25,000 options on April 15, 2016, at an exercise price of $5.00 per option, (ii) 18,750 options on October 16, 2017, at an exercise price of $7.00 per option, (iii) 18,750 options on July 18, 2020, at an exercise price of $5.00 per option, (iv) 37,500 options on February 13, 2020, at an exercise price of $7.00 per option, and (v) 12,500 options on February 25, 2021, at an exercise price of $22.40.

Dalia Barsyte PhD, Scientific Advisor. Our subsidiary, Protagenic Therapeutics Canada (2006) Inc., entered into a consulting agreement with Dr. Dalia Barsyte. Dr. Barsyte is responsible for overseeing i) design and development of ELISA assays for measuring TCAP, ii) evaluation of TCAP exposure biomarker assay, iii) development of pipeline peptides, iv) development of clinically compatible formulations for TCAP, as well as all of the bench research and development of formulation and extraction methods. Her consulting agreement is effective through December 2017. She is compensated at the rate of up to $3,000 (Canadian) per month, if she works at least 20 hours on behalf of the Company. As well, we have granted Dr. Barsyte 2,500 shares of our common stock and ten-year options to purchase 37,500 shares of our common stock. Options to purchase 25,000 shares of common stock, at an exercise price of $4.00 per share, have fully vested; the options to purchase the remaining 12,500 shares of common stock, at an exercise price of $5.00 per share, vested in March 2016. On October 16, 2017, we granted Dr. Barsyte another ten-year option to purchase 5,000 shares of our common stock at an exercise price of $7.00 per share. On February 13, 2020, we granted Dr. Barsyte ten-year option to purchase 2,500 shares of our common stock at an exercise price of $7.00 per share.

Robert B. Stein, PhD, MD, Director, Chief Medical Officer. We entered into a consulting agreement with Dr. Stein effective January 2015, and amended and restated this consulting agreement in December 2020 to appoint Dr. Stein as our Chief Medical Officer. Dr. Stein is responsible for providing us with technical and advisory services related to our research and development efforts. On January 23, 2015, we granted Dr. Stein ten-year options to purchase 50,000 shares of our common stock, at an exercise price of $5.00 per share (the "January Options"). The January Options are fully vested. We granted Dr. Stein (i) 10,000 options on April 15, 2016, at an exercise price of $5.00 per option, (ii) 50,000 options on October 16, 2017, at an exercise price of $7.00 per option, (iii) 37,500 options on February 13, 2020, at an exercise price of $5.00 per option, and (iv) 12,500 options on February 25, 2021, at an exercise price of $22.40 per option.

Jennifer Buell, PhD, Clinical and Regulatory Development Advisor. We entered into a consulting agreement with Dr. Buell effective February 2021, providing for her to do three things: (1) advise the Company's clinical and regulatory development plan to support the Company's lead product candidate, PT00114, in support of an IND application to the U.S. Food and Drug Administration and demonstration of safety and clinical activity in early phase clinical trials, (2) develop a panel of experts to prepare a clinical development plan and operational plan that would enable the evaluation of safety and clinical activity of the companies lead therapeutic, PT00114, and (3) determine the fastest development pathway of PT00114 in four key indications as defined by the Company Management. We granted Dr. Buell 50,000 nonstatutory stock options (" NSOs") on February 25, 2021 at an exercise price of $22.40 per share, and 36,250 options on July 18, 2020 at an exercise price of $7.00 per share.

Mark Berg, Strategic Advisor. We entered into a consulting agreement with Mr. Berg effective January 2022, providing for him to provide strategic consulting services to the company, none of which involves direct contact with investors. We granted Mr. Berg 12,500 nonstatutory stock options (" NSOs") on January 26, 2022 at an exercise price of $4.84 per share.

Director Compensation

During fiscal year 2021 we issued 50,000 options with an exercise price of $22.40 to Dr. Buell for her services on the Board.

Going forward, on April 15 of each fiscal year, we plan to grant each non-employee director an option under the 2016 Plan to purchase 10,000 shares of common stock, as well as an option to purchase 1,250 shares for each committee which they chair. No additional options shall be granted for serving on a committee without being its chair. All options will be granted at fair market value, as defined in the 2016 Plan, on the date of grant, and will vest over a three-year period in equal monthly installments. Vesting will accelerate in certain circumstances, such as a change of control of the Company, and unvested options will terminate upon the cessation of an individual's service to us as a director.

Non-employee directors may be reimbursed for their reasonable expenses in attending Board and committee meetings.

We entered into an amended and restated consulting agreement during fiscal year 2020 with Robert B. Stein, PhD, MD, under which we issued 137,500 options on February 13, 2020, at an exercise price of $5.00 per option. During fiscal year 2021 with Robert B. Stein, PhD, MD, under which we issued 12,500 options on February 20, 2021, at an exercise price of $22.40 per option.

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

Equity Compensation Plans

Equity Compensation Plan Information

Plan category	(a) No. of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) No. of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
Equity compensation plans approved by security holders	2,894,624	$ 10.54	48,719

Equity compensation plans not approved by security holders	0		0	0
Total	2,894,624	$	10.54	48,719

2006 Employee, Director and Consultant Stock Plan

On June 17, 2016, our stockholders adopted our 2016 Equity Compensation Plan and, as a result, we terminated the 2006 Plan. We will not grant any further awards under the 2006 Plan. All outstanding grants under the 2006 Plan will continue in effect in accordance with the terms of the particular grant and the 2006 Plan.

The following description of the pertinent terms of the 2006 Plan is a summary and is qualified in its entirety by the full text of the 2006 Plan.

Administration. The administrator (the "**Administrator**") of the 2006 Plan is the Board of Directors, except to the extent the Board of Directors delegates its authority to the Compensation committee (the "**Committee**") of the Board, in which case the Committee shall be the Administrator.

Terms and Conditions of Options. Options granted under the 2006 Plan may be either "incentive stock options" that are intended to meet the requirements of Section 422 of the Code or "nonqualified stock options" that do not meet the requirements of Section 422 of the Code. The Administrator will determine the exercise price of options granted under the 2006 Plan. The exercise price of stock options may not be less than the fair market value per share of our common stock on the date of grant (or 110% of fair market value in the case of incentive stock options granted to a ten-percent stockholder).

If on the date of grant the common stock is listed on a stock exchange or national market system, the fair market value will generally be the closing sale price on the date of grant. If the common stock is not traded on a stock exchange or national market system on the date of grant, the fair market value will generally be the mean between the bid and the asked price for the common stock at the close of trading in the over-the-counter market for the trading day on which common stock was traded immediately preceding the applicable date. If no such prices are available, the fair market value shall be determined in good faith by the Administrator.

No option intended to qualify as an ISO may be exercisable for more than ten years from the date of grant (five years in the case of an incentive stock option granted to a ten-percent stockholder). Options granted under the 2006 Plan will be exercisable at such time or times as the Administrator prescribes at the time of grant. No employee may receive incentive stock options that first become exercisable in any calendar year in an amount exceeding $100,000.

Generally, the exercise price of an option may be paid (a) in cash or by certified bank check, (b) at the discretion of the Administrator, through delivery of shares of our common stock held for at least six months having a fair market value equal to the purchase price, (c) at the discretion of the Administrator, by delivery of the grantee's personal note, for full, partial or no recourse, bearing interest payable not less than annually at market rate on the date of exercise and at no less than 100% of the applicable Federal rate, as defined in Section 1274(d) of the Code, with or without the pledge of such shares as collateral, or (d) at the discretion of the Administrator, in accordance with a cashless exercise program established with a securities brokerage firm, and approved by the Administrator, or (e) at the discretion of the Administrator, by any combination of the above methods.

No option may be transferred other than by will or by the laws of descent and distribution, and during a recipient's lifetime an option may be exercised only by the recipient. The Administrator will determine the extent to which a holder of a stock option may exercise the option following termination of service with us.

The Administrator will determine the extent to which a holder of a stock option may exercise the option following termination of service with us.

Effect of Certain Corporate Transactions. If the Company is to be consolidated with or acquired by another entity in a merger, sale of all or substantially all of the Company's assets other than a transaction to merely change the state of incorporation (a "**Corporate Transaction**"), the Administrator or the board of directors of any entity assuming the obligations of the Company hereunder (the "**Successor Board**"), shall, as to outstanding options, either (i) make appropriate provision for the continuation of such options by substituting on an equitable basis for the Shares then subject to such options; or (ii) upon written notice to the participants, provide that all options must be exercised (either to the extent then exercisable or, at the discretion of the Administrator, all options being made fully or partially exercisable), within a specified number of days of the date of such notice, at the end of which period the options shall terminate; or (iii) terminate all options in exchange for a cash payment equal to the excess of the fair market value of the shares of common stock subject to such options (either to the extent then exercisable or, at the discretion of the Administrator, all options being made fully or partially exercisable) over the exercise price thereof.

Tax Withholding. As and when appropriate, we shall have the right to require each optionee purchasing shares of common stock and each grantee receiving an award of shares of common stock under the 2006 Plan to pay any federal, state or local taxes required by law to be withheld.

2016 Equity Compensation Plan

The following description of the principal terms of the 2016 Plan is a summary and is qualified in its entirety by the full text of the 2016 Plan.

Administration. The 2016 Plan is administered by the Compensation Committee of our Board of Directors, provided that the entire Board of Directors may act in lieu of the Compensation Committee on any matter, subject to certain requirements set forth in the 2016 Plan. The Compensation Committee may grant options to purchase shares of our common stock, stock appreciation rights, stock units, restricted shares of our common stock, performance shares, performance units, incentive bonus awards, other cash-based awards and other stock-based awards. The Compensation Committee also has broad authority to determine the terms and conditions of each option or other kind of award, and adopt, amend and rescind rules and regulations for the administration of the 2016 Plan. Subject to applicable law, the Compensation Committee may authorize one or more reporting persons (as defined in the 2016 Plan) or other officers to make awards (other than awards to reporting persons, or other officers whom the Compensation Committee has specifically authorized to make awards). No awards may be granted under the 2016 Plan on or after the ten-year anniversary of the adoption of the 2016 Plan by our Board of Directors, but awards granted prior to such tenth anniversary may extend beyond that date.

Eligibility. Awards may be granted under the 2016 Plan to any person who is an employee, officer, director, consultant, advisor or other individual service provider of the Company or any subsidiary, or any person who is determined by the Compensation Committee to be a prospective employee, officer, director, consultant, advisor or other individual service provider of the Company or any subsidiary.

Shares Subject to the 2016 Plan. The aggregate number of shares of common stock proposed to be available for issuance in connection with options and awards granted under the 2016 Plan is 750,000 shares. Incentive Stock Options may, but need not be, granted with respect to all of the shares available for issuance under the 2016 Plan; provided, however, that the maximum aggregate number of shares of common stock which may be issued in respect of Incentive Stock Options (after giving effect to any increases pursuant to the "evergreen" provisions of the 2016 Plan discussed below) shall not exceed 1,500,000 shares, subject to adjustment in the event of stock, splits and similar transactions. If any award granted under the 2016 Plan payable in shares of common stock is forfeited, cancelled, or returned for failure to satisfy vesting requirements, otherwise terminates without payment being made, or if shares of common stock are withheld to cover withholding taxes on options or other awards, the number of shares of common stock as to which such option or award was forfeited, or which were withheld, will be available for future grants under the 2016 Plan.

In addition, the 2016 Plan contains an "evergreen" provision allowing for an annual increase in the number of shares of our common stock available for issuance under the 2016 Plan on January 1 of each year during the period beginning January 1, 2017, and ending on (and including) January 1, 2026. The annual increase in the number of shares shall be equal to (i) five point five percent (5.5%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, or (ii) with respect to shares of common stock which may be issued under the 2016 Plan other than in respect to Incentive Stock Options, the difference between (x) eighteen percent (18%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, and (y) the total number of shares of common stock reserved under the 2016 Plan on December 31st of such preceding calendar year (including shares subject to outstanding awards, issued pursuant to awards or available for future awards) if such amount is greater than the amount determined in (i) immediately above; provided, however, that our Board may act prior to the first day of any calendar year to provide that there shall be no increase such calendar year, or that the increase shall be a lesser number of shares of common stock than would otherwise occur. On January 1, 2017, 2019, and 2020, each year 141,095 shares of common stock were added to the 2016 Plan pursuant to this evergreen provision. On January 1, 2021, 142,457 shares of common stock were added to the 2016 Plan pursuant to this evergreen provision. On January 1, 2022, 184,260 additional shares of common stock are available for issuance under the 2016 Plan as a result of operation of the evergreen provision: (a) 141,070 shares resulting from operation of the evergreen provision in 2019, which were never previously registered and (b) 43,191 shares resulting from operation of the evergreen provision in 2022.

Terms and Conditions of Options. Options granted under the 2016 Plan may be either "incentive stock options" that are intended to meet the requirements of Section 422 of the Code or "nonqualified stock options" that do not meet the requirements of Section 422 of the Code. The Compensation Committee will determine the exercise price of options granted under the 2016 Plan. The exercise price of stock options may not be less than the fair market value, on the date of grant, per share of our common stock issuable upon exercise of the option (or 110% of fair market value in the case of incentive options granted to a ten-percent stockholder).

If on the date of grant the common stock is listed on a stock exchange or national market system, the fair market value shall generally be the closing sale price as of such date, or if there were no trades recorded on such date, then the most recent date preceding such date on which trades were recorded. If on the date of grant the common stock is traded in an over-the-counter market, the fair market will generally be the average of the closing bid and asked prices for the shares of common stock as of such date, or, if there are no closing bid and asked prices for the shares of common stock on such date, then the average of the bid and asked prices for the shares of common stock on the most recent date preceding such date on which such closing bid and asked prices are available. If the common stock is not listed on a national securities exchange or national market system or traded in an over-the-counter market, the fair market value shall be determined by the Compensation Committee in a manner consistent with Section 409A of the Code. Notwithstanding the foregoing, if on the date of grant the common stock is listed on a stock exchange or is quoted on a national market system, or is traded in an over-the-counter market, then solely for purposes of determining the exercise price of any grant of a stock option or the base price of any grant of a stock appreciation right, the Compensation Committee may, in its discretion, base fair market value on the last sale before or the first sale after the grant, the closing price on the trading day before or the trading day of the grant, the arithmetic mean of the high and low prices on the trading day before or the trading day of the grant, or any other reasonable method using actual transactions of the common stock as reported by the exchange or market on which the common stock is traded. In addition, the determination of fair market value also may be made using any other method permitted under Treasury Regulation section 1.409A-1(b)(5)(iv).

No option may be exercisable for more than ten years from the date of grant (five years in the case of an incentive stock option granted to a ten-percent stockholder). Options granted under the 2016 Plan will be exercisable at such time or times as the Compensation Committee prescribes at the time of grant. No employee may receive incentive stock options that first become exercisable in any calendar year in an amount exceeding $100,000. The Compensation Committee may, in its discretion, permit a holder of a nonqualified stock option to exercise the option before it has otherwise become exercisable, in which case the shares of our common stock issued to the recipient will continue to be subject to the vesting requirements that applied to the option before exercise.

Generally, the option price may be paid in cash or by bank check, or such other means as the Compensation Committee may accept. As set forth in an award agreement or otherwise determined by the Compensation Committee, in its sole discretion, at or after grant, payment in full or part of the exercise price of an option may be made (a) in the form of shares of common stock that have been held by the participant for such period as the Compensation Committee may deem appropriate for accounting purposes or otherwise, valued at the fair market value of such shares on the date of exercise; (ii) by surrendering to the Company shares of common stock otherwise receivable on exercise of the option; (iii) by a cashless exercise program implemented by the Compensation Committee in connection with the 2016 Plan; and/or (iv) by such other method as may be approved by the Compensation Committee and set forth in an award agreement.

No option may be transferred other than by will or by the laws of descent and distribution, and during a recipient's lifetime an option may be exercised only by the recipient or the recipient's guardian or legal representative. However, the Compensation Committee may permit the transfer of a nonqualified stock option, share-settled stock appreciation right, restricted stock award, performance share or share-settled other stock-based award either (a) by instrument to the participant's immediate family (as defined in the 2016 Plan), (b) by instrument to an inter vivos or testamentary trust (or other entity) in which the award is to be passed to the participant's designated beneficiaries, or (c) by gift to charitable institutions. The Compensation Committee will determine the extent to which a holder of a stock option may exercise the option following termination of service.

Stock Appreciation Rights. The Compensation Committee may grant stock appreciation rights independent of or in connection with an option. The Compensation Committee will determine the terms applicable to stock appreciation rights. The base price of a stock appreciation right will be determined by the Compensation Committee, but will not be less than 100% of the fair market value of a share of our common stock with respect to the date of grant of such stock appreciation right. The maximum term of any SAR granted under the 2016 Plan is ten years from the date of grant. Generally, each SAR stock appreciation right will entitle a participant upon exercise to an amount equal to:

- the excess of the fair market value of a share of common stock on the date of exercise of the stock appreciation right over the base price of such stock appreciation right, multiplied by
- the number of shares as to which such stock appreciation right is exercised.

Payment may be made in shares of our common stock, in cash, or partly in common stock and partly in cash, all as determined by the Compensation Committee.

Restricted Stock and Stock Units. The Compensation Committee may award restricted common stock and/or stock units under the 2016 Plan. Restricted stock awards consist of shares of stock that are transferred to a participant subject to restrictions that may result in forfeiture if specified conditions are not satisfied. Stock units confer the right to receive shares of our common stock, cash, or a combination of shares and cash, at a future date upon or following the attainment of certain conditions specified by the Compensation Committee. The Compensation Committee will determine the restrictions and conditions applicable to each award of restricted stock or stock units, which may include performance-based conditions. Dividends with respect to restricted stock may be paid to the holder of the shares as and when dividends are paid to stockholders or at the times of vesting or other payment of the restricted stock award. Stock unit awards may be granted with dividend equivalent rights, which may be accumulated and may be deemed reinvested in additional stock units, as determined by the Compensation Committee in its discretion. If any dividend equivalents are paid while a stock unit award is subject to restrictions, the dividend equivalents shall be subject to the same restrictions on transferability as the underlying stock units, unless otherwise set forth in an award agreement. Unless the Compensation Committee determines otherwise, holders of restricted stock will have the right to vote the shares.

Performance Shares and Performance Units. The Compensation Committee may award performance shares and/or performance units under the 2016 Plan. Performance shares and performance units are awards which are earned during a specified performance period subject to the attainment of performance criteria, as established by the Compensation Committee. The Compensation Committee will determine the restrictions and conditions applicable to each award of performance shares and performance units.

Incentive Bonus Awards. The Compensation Committee may award Incentive Bonus Awards under the 2016 Plan. Incentive Bonus Awards may be based upon the

attainment of specified levels of Company or subsidiary performance as measured by pre-established, objective performance criteria determined at the discretion of the Compensation Committee. Incentive Bonus Awards will be paid in cash or common stock, as set forth in an award agreement.

Other Stock-Based and Cash-Based Awards. The Compensation Committee may award other types of equity-based or cash-based awards under the 2016 Plan, including the grant or offer for sale of unrestricted shares of our common stock and payment in cash or otherwise of amounts based on the value of shares of common stock.

Section 162(m) Compliance. If stock or cash-based awards are intended to satisfy the conditions for deductibility under Section 162(m) of the Code as "performance-based compensation," the performance criteria will be selected from among the following, which may be applied to our Company as a whole, any subsidiary or any division or operating unit thereof: (a) pre-tax income; (b) after-tax income; (c) net income; (d) operating income or profit; (e) cash flow, free cash flow, cash flow return on investment, net cash provided by operations, or cash flow in excess of cost of capital; (f) earnings per share; (g) return on equity; (h) return on sales or revenues; (i) return on invested capital or assets; (j) cash, funds or earnings available for distribution; (k) appreciation in the fair market value of the common stock; (l) operating expenses; (m) implementation or completion of critical projects or processes; (n) return on investment; (o) total return to stockholders; (p) dividends paid; (q) net earnings growth; (r) related return ratios; (s) increase in revenues; (t) the Company's published ranking against its peer group of pharmaceutical companies based on total stockholder return; (u) net earnings; (v) changes (or the absence of changes) in the per share or aggregate market price of the common stock; (w) number of securities sold; (x) earnings before or after any one or more of the following items: interest, taxes, depreciation or amortization, as reflected in the Company's financial reports for the applicable period; (y) total revenue growth; (z) economic value created; (aa) operating margin or profit margin; (bb) share price or total stockholder return; (cc) cost targets, reductions and savings, productivity and efficiencies; (dd) strategic business criteria, consisting of one or more objectives based on meeting objectively determinable criteria: specified market penetration, geographic business expansion, progress with research and development activities, investor satisfaction, employee satisfaction, human resources management, supervision of litigation, information technology, and goals relating to acquisitions, divestitures, joint ventures and similar transactions, and budget comparisons; (ee) objectively determinable personal or professional objectives, including any of the following performance goals: the implementation of policies and plans, the negotiation of transactions, the development of long term business goals, formation of joint ventures, research or development collaborations, and the completion of other corporate transactions, and (ff) any combination of, or a specified increase or improvement in, any of the foregoing.

At the end of the performance period established in connection with any award, the Compensation Committee will determine the extent to which the performance goal or goals established for such award have been attained, and shall determine, on that basis, the number of performance shares or performance units included in such award that have been earned and as to which payment will be made. The Compensation Committee will certify in writing the extent to which it has determined that the performance goal or goals established by it for such award have been attained.

With respect to awards intended to be performance-based compensation under Section 162(m) of the Code, no participant of the 2016 Plan may receive in any one fiscal year (a) options or stock appreciation rights relating to more than 250,000 shares of our common stock, and (b) stock units, restricted shares, performance shares, performance units or other stock-based awards that are denominated in shares of common stock relating to more than 250,000 shares of our common stock in the aggregate. The maximum dollar value payable to any participant for a fiscal year of the Company with respect to stock units, performance units or incentive bonus awards or other stock-based awards that may be settled in cash or other property (other than common stock) is $1,500,000.

Effect of Certain Corporate Transactions. The Compensation Committee may, at the time of the grant of an award, provide for the effect of a change in control (as defined in the 2016 Plan) on any award, including (i) accelerating or extending the time periods for exercising, vesting in, or realizing gain from any award, (ii) eliminating or modifying the performance or other conditions of an award, (iii) providing for the cash settlement of an award for an equivalent cash value, as determined by the Compensation Committee, or (iv) such other modification or adjustment to an award as the Compensation Committee deems appropriate to maintain and protect the rights and interests of participants upon or following a change in control. The Compensation Committee may, in its discretion and without the need for the consent of any recipient of an award, also take one or more of the following actions contingent upon the occurrence of a change in control: (a) cause any or all outstanding options and stock appreciation rights to become immediately exercisable, in whole or in part; (b) cause any other awards to become non-forfeitable, in whole or in part; (c) cancel any option or stock appreciation right in exchange for a substitute option; (d) cancel any award of restricted stock, stock units, performance shares or performance units in exchange for a similar award of the capital stock of any successor corporation; (e) redeem any restricted stock, stock unit, performance share or performance unit for cash and/or other substitute consideration with a value equal to the fair market value of an unrestricted share of our common stock on the date of the change in control; (f) cancel any option or stock appreciation right in exchange for cash and/or other substitute consideration based on the value of our common stock on the date of the change in control, and cancel any option or stock appreciation right without any payment if its exercise price exceeds the value of our common stock on the date of the change in control; (g) cancel any stock unit or performance unit held by a participant affected by the change in control in exchange for cash and/or other substitute consideration with a value equal to the fair market value per share of common stock on the date of the change in control, or (h) make such other modifications, adjustments or amendments to outstanding awards as the Compensation Committee deems necessary or appropriate.

Amendment, Termination. The 2016 Plan will remain in effect until March 2026, or, if earlier, when awards have been granted covering all available shares under the 2016 Plan or the 2016 Plan is otherwise terminated by the Board. The Board may amend the terms of awards in any manner not inconsistent with the 2016 Plan, provided that no amendment shall adversely affect the rights of a participant with respect to an outstanding award without the participant's consent. In addition, our Board of Directors may at any time amend, suspend, or terminate the 2016 Plan, provided that (i) no such amendment, suspension or termination shall materially and adversely affect the rights of any participant under any outstanding award without the consent of such participant and (ii) to the extent necessary and desirable to comply with any applicable law, regulation, or stock exchange rule, the 2016 Plan requires us to obtain stockholder consent. Stockholder approval is required for any plan amendment that increases the number of shares of common stock available for issuance under the 2016 Plan or changes the persons or classes of persons eligible to receive awards.

Tax Withholding. The Company has the power and right to deduct or withhold, or require a participant to remit to the Company, the minimum statutory amount to satisfy federal, state, and local taxes, domestic or foreign, required by law or regulations to be withheld.

Recoupment Policy. Awards granted under the 2016 Plan will be subject to any provisions of applicable law providing for the recoupment or clawback of incentive compensation, such as provisions imposed pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act; the terms of any Company recoupment, clawback or similar policy in effect at the time of grant of the award; and any recoupment, clawback or similar provisions that may be included in the applicable award agreement.

Federal Income Tax Consequences. The following is a brief summary of the U.S. federal income tax consequences applicable to awards granted under the 2016 Plan based on the federal income tax laws in effect on the date of this report. This summary is not intended to be exhaustive and does not address all matters relevant to a particular participant based on his or her specific circumstances. The summary expressly does not discuss the income tax laws of any state, municipality, or non-U.S. taxing jurisdiction, or the gift, estate, excise (including the rules applicable to deferred compensation under Code Section 409A), or other tax laws other than federal income tax law. The following is not intended or written to be used, and cannot be used, for the purposes of avoiding taxpayer penalties. Because individual circumstances may vary, the Company advises all participants to consult their own tax advisor concerning the tax implications of awards granted under the 2016 Plan.

A recipient of a stock option or stock appreciation right will not have taxable income upon the grant of the stock option or stock appreciation right. For non-statutory stock options and stock appreciation rights, the participant will recognize ordinary income upon exercise in an amount equal to the difference between the fair market value of the shares and the exercise price on the date of exercise. Any gain or loss recognized upon any later disposition of the shares generally will be a capital gain or loss.

The acquisition of shares upon exercise of an incentive stock option will not result in any taxable income to the participant, except, possibly, for purposes of the alternative minimum tax. The gain or loss recognized by the participant on a later sale or other disposition of such shares will either be long-term capital gain or loss or ordinary

income, depending upon whether the participant holds the shares for the legally-required period (two years from the date of grant and one year from the date of exercise). If the shares are not held for the legally-required period, the participant will recognize ordinary income equal to the lesser of (i) the difference between the fair market value of the shares on the date of exercise and the exercise price, or (ii) the difference between the sales price and the exercise price, and the balance of the gain, if any, will be afforded capital gain treatment.

For awards of stock grants, the participant will not have taxable income upon the receipt of the award (unless the participant elects to be taxed at the time of the stock is granted rather than when it becomes vested). The stock grants will generally be subject to tax upon vesting as ordinary income equal to the fair market value of the shares at the time of vesting less the amount paid for such shares (if any).

A participant is not deemed to receive any taxable income at the time an award of restricted stock units is granted. When vested restricted stock units (and dividend equivalents, if any) are settled and distributed, the participant will recognize ordinary income equal to the amount of cash and/or the fair market value of shares received less the amount paid for such restricted stock units (if any).

If the participant is an employee or former employee, the amount a participant recognizes as ordinary income in connection with any award is subject to withholding taxes (not applicable to incentive stock options) and the Company is allowed a tax deduction equal to the amount of ordinary income recognized by the participant. In addition, Code Section 162(m) contains special rules regarding the federal income tax deductibility of compensation paid to the Company's chief executive officer and to certain of the Company's other executive officers. The general rule is that annual compensation paid to any of these specified executives will be deductible only to the extent that it does not exceed $1,000,000. However, the Company can preserve the deductibility of certain compensation in excess of $1,000,000 if such compensation qualifies as "performance-based compensation" by complying with certain conditions imposed by the Code Section 162(m) rules (including the establishment of a maximum number of shares with respect to which awards may be granted to any one employee during one fiscal year).

Option Grants and Stock Awards

As of December 31, 2022, we had outstanding stock options to purchase 1,357,466 shares at an average exercise price of approximately $7.39 per share. Included in the total outstanding stock options were 0 stock options granted under the 2006 Plan in 2022 and 12,500 nonqualified stock options granted under the 2016 Plan in 2022 to our executive officers and others at an exercise price of $4.84 per share.

All awards to be made under the 2016 Plan are discretionary, subject to the terms of the 2016 Plan. Therefore, the benefits and amounts that will be received or allocated under the 2016 Plan are generally not determinable at this time. The equity grant program for our non-employee directors is described under the Compensation of Directors section in this proxy statement. The following table summarizes these 2016 awards to our named executive officers, all executive officers and the non-executive officer employees and consultants.

Outstanding Equity Awards at Fiscal Year End

The following table summarizes the equity awards made to our named executive officers that were outstanding at December 31, 2022.

Name	No. of Securities Underlying Unexercised Options (#) Exercisable	No. of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date
Garo H. Armen (1)	125,000	-	$ 5.00	April 15, 2026
Garo H. Armen (2)	62,500	-	$ 7.00	October 16, 2027
Garo H. Armen (3)	41,667	33,333	$ 7.00	February 13, 2030
Alexander K. Arrow (4)	25,000	-	$ 5.00	February 12, 2026
Alexander K. Arrow (4)	35,000	-	$ 5.00	April 15, 2026
Alexander K. Arrow (5)	18,750	-	$ 7.00	October 16, 2027
Alexander K. Arrow (6)	10,417	-	$ 5.00	February 1, 2029
Alexander K. Arrow (7)	16,667	13,333	$ 7.00	February 13, 2030
Alexander K. Arrow (8)	46,874	-	$ 7.00	February 13, 2030
Alexander K. Arrow (9)	31,250	-	$ 7.00	July 18, 2030
Andrew Slee (10)	25,000	-	$ 5.00	April 15, 2026
Andrew Slee (11)	18,750	-	$ 7.00	October 16, 2027
Andrew Slee (12)	21,875	15,625	$ 7.00	February 13, 2030
Andrew Slee (13)	12,500	6,250	$ 5.00	July 18, 2030
Andrew Slee (14)	9,896	2,604	$ 22.60	February 25, 2031
Robert B. Stein (15)	50,000	-	$ 5.00	January 22, 2025
Robert B. Stein (16)	10,000	-	$ 5.00	April 15, 2026
Robert B. Stein (17)	50,000	-	$ 7.00	October 16, 2027
Robert B. Stein (18)	37,500	-	$ 7.00	February 13, 2030
Robert B. Stein (19)	9,896	2,604	$ 22.40	February 25, 2031

(1) Dr. Armen was granted a 125,000 share option grant on April 15, 2016

(2) Dr. Armen was granted a 62,500 share option grant on October 16, 2017.

(3) Dr. Armen was granted a 75,000 share option grant on February 13, 2020.

(4) Dr. Arrow was granted a 25,000 share option grant on February 12, 2016, and a 35,000 share option grant on April 15, 2016

(5) Dr. Arrow was granted a 18,750 share option grant on October 16, 2017.

(6) Dr. Arrow was granted a 10,417 share option grant on February 1, 2019.

(7) Dr. Arrow was granted a 30,000 share option grant on February 13, 2020.

(8) Dr. Arrow was granted a 46,874 share option grant on February 13, 2020.

(9) Dr. Arrow was granted a 31,250 share option grant on July 18, 2020.

(10) Dr. Slee was granted a 25,000 shares option grant on April 15, 2016.

(11) Dr. Slee was granted a 18,750 shares option grant on October 16, 2017.

(12) Dr. Slee was granted a 37,500 shares option grant on February 13, 2020.

(13) Dr. Slee was granted a 18,750 shares option grant on July 18, 2020.

(14) Dr. Slee was granted a 12,500 shares option grant on February 25, 2021.

(15) Dr. Stein was granted a 50,000 shares option grant on January 22, 2015.

(16) Dr. Stein was granted a 10,000 shares option grant on April 15, 2016.

(17) Dr. Stein was granted a 50,000 shares option grant on October 16, 2017.

(18) Dr. Stein was granted a 37,500 shares option grant on February 13, 2020.

(19) Dr. Stein was granted a 12,500 shares option grant on February 25, 2021.

For Drs. Armen and Arrow, following a qualified Change of Control, a resignation for Good Reason, or an involuntary termination other than For Cause, 100% of the executives' then-unvested options shall become immediately vested.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership of the Common Stock as of March 26, 2023, unless otherwise indicated, by (1) each person known by the Company to be the beneficial owner of more than 5% of the outstanding shares of common stock, (2) each director of the Company, (3) the Company's current executive officers, and (4) all current directors and executive officers of the Company as a group. The persons and entities named in the table have sole voting and investment power with respect to all such shares owned by them, unless otherwise indicated.

Name and address of Beneficial Owner*	Amount and Nature of Beneficial Ownership	Percent of Class
Garo H. Armen(1)	1,239,331(2)	26%
Robert B. Stein(1)	154,5315(3)	3%
Khalil Barrage(1)	187,500(4)	4%
Alexander K. Arrow(1)	197,291(5)	4%
Larry N. Feinberg	75,000(6)	2%
Brian J. Corvese(1)	53,750(7)	1%
David A. Lovejoy	105,929(8)	2%
Jennifer Buell(1)	55,860(9)	1%
Andrew Slee(1)	92,578(10)	2%
All directors and executive officers as a group (7 persons)	1,980,840(11)	36%

* Address for each party listed in the above table is c/o Protagenic Therapeutics, Inc., 149 Fifth Avenue, Suite 500, New York, NY 10010.

(1) Executive officer and/or director.

(2) Includes warrants to purchase 238,342 shares of common stock at an exercise price of approximately $4.00 per share. Includes 675,989 shares held in the name of Dr.

Armen and 62,500 shares held in the name of the Garo H. Armen IRA, as to which Dr. Armen has sole voting and dispositive power. Also includes options to purchase 262,500 shares of common stock at an exercise price of $5.00 or $7.00 per share.

(3) Represents options to purchase 154,531 shares of common stock at an exercise price of $5.00, $7.00, or $22.40 per share. Does not include options to purchase 5,469 shares that are not exercisable within 60 days of the date of this report.

(4) Includes 102,500 shares of common stock and options to purchase 45,000 shares of common stock at an exercise price of $14.60 per share. Also includes convertible note of $200,000 that converts at $5.00 per share for a total of 40,000 shares of common stock.

(5) Includes options to purchase 197,291 shares of common stock at an exercise price of $4.00, $5.00 or $7.00 per share.

(6) Includes warrants to purchase 75,000 shares of common stock at an exercise price of $4.00 per share.

(7) Includes options to purchase 53,750 shares of common stock at an exercise price of $7.00 per share.

(8) Includes options to purchase 105,929 shares of common stock in the aggregate with an exercise price ranging from $4.00 to $5.00 per share. Does not include options to purchase 1,146 shares of common stock that are not exercisable within 60 days of the date of this report.

(9) Includes options to purchase 55,859 shares of common stock at an exercise price of $7.00 or $22.40 per share. Does not include options to purchase 30,391 shares of common stock that are not exercisable within 60 days of the date of this report.

(10) Includes options to purchase 92,578 shares of common stock at an exercise price of $5.00, $7.00, or $22.40 per share. Does not include options to purchase 19,922 shares of common stock that are not exercisable within 60 days of the date of this report.

(11) Includes warrants to purchase 238,342 shares of common stock and options to purchase 861,509 shares of common stock. Also includes convertible notes of $200,000 that converts at $5.00 per share for a total of 40,000 shares of common stock.

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

Certain Relationships and Related Party Transactions

Other than compensation arrangements for our named executive officers and directors, we describe below each transaction or series of similar transactions, since January 1, 2016, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and directors are described in Item 11, Executive Compensation.

Our principal offices are located at 149 Fifth Avenue, Suite 500, New York, New York 10010, in a conference room of Agenus, Inc. We utilize our principal office for quarterly board meetings and our annual shareholder meeting at no cost. Our personnel and consultants all work remotely, the Company's basic science laboratory work is conducted in the Lovejoy Lab at the University of Toronto, and its preclinical efficacy work is conducted at CROs. Hence the Company does not have the need for a day-to-day physical office location other than a mailing address and conference room facility for meetings. For that reason, the Agenus conference room suits its purposes without imposing any inconveniences upon Agenus. Dr. Armen, our Executive Chairman, is also the Chairman and Chief Executive Officer of Agenus Inc.

2019-2020 Convertible Note Offering

Garo H. Armen and Khalil Barrage invested $200,000 and $200,000, respectively, in the Convertible Note Offering on the same terms as all other Investors.

Zack Armen

During the latter part of 2018 and the first quarter of 2019, Zack Armen, the son of our Executive Chairman, Garo H. Armen, Ph.D., assisted us in the development of slide deck presentations and summaries, video editing, and forecasting and market size projections that were incorporated into presentations to investors and others. We have included these presentations in various Current Reports on Form 8-K which we filed with the Securities and Exchange Commission. On June 17, 2019, the Compensation and Audit Committees of the Board authorized the issuance to Mr. Zack Armen of 6,250 stock options under the 2016 Plan in consideration for his services. These options vested in their entirety on issuance, have a ten-year term and are exercisable at a price of $7.00 per share. On February 21, 2020 Mr. Zack Armen was also issued an additional 12,500 stock options that vest over 48 months and are exercisable at a price of $7.00 per share. On July 18, 2020 Mr. Zack Armen was also issued an additional 7,500 stock options that vest over 48 months and are exercisable at a price of $7.00 per share.

Policies and Procedures for Related Party Transactions

We have adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest, which we refer to collectively as related parties, are not permitted to enter into a transaction with us without the prior consent of our Board of Directors acting through the audit committee or, in certain circumstances, the chairman of the audit committee. Any request for us to enter into a transaction with a related party, in which the amount involved exceeds $100,000 and such related party would have a direct or indirect interest must first be presented to our audit committee, or in certain circumstances the chairman of our audit committee, for review, consideration and approval. In approving or rejecting any such proposal, our audit committee, or the chairman of our audit committee, is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related party's interest in the transaction.

Director Independence

We are not currently listed on any national securities exchange or in an inter-dealer quotation system that has a requirement that the Board of Directors be independent. However, in evaluating the independence of our members and the composition of the committees of our Board of Directors, our Board utilizes the definition of "independence" as

that term is defined by applicable listing standards of the NASDAQ Stock Market and SEC rules, including the rules relating to the independence standards of an audit committee and the non-employee director definition of Rule 16b-3 promulgated under the Exchange Act.

Our Board of Directors expects to continue to evaluate its independence standards and whether and to what extent the composition of the Board and its committees meets those standards. We ultimately intend to appoint such persons to our Board and committees of our Board as are expected to be required to meet the corporate governance requirements imposed by a national securities exchange. Therefore, we intend that a majority of our directors will be independent directors of which at least one director will qualify as an "audit committee financial expert," within the meaning of Item 407(d)(5) of Regulation S-K, as promulgated by the SEC.

We believe that Messrs. Barrage, Corvese, Wright, and Dr. Buell are each an "independent" director as that term is defined by the NASDAQ Stock Market, Inc. Marketplace Rules and SEC Regulations. In addition, the Board also designated Brian Corvese as an "audit committee financial expert," as that term is defined by the NASDAQ Listing Rules and SEC regulations.

With regard to Mr. Wright's independent status, the Board considered the fact that he is a current CEO of a publicly-traded biopharmaceutical company (MiMedX Group, Inc.) and that he is as a Partner at an investment firm (Signal Hill Advisors, LLC). He also serves on the Board of Directors of Agenus, Inc., a publicly-traded company for which Dr. Armen is the Chairman and CEO.

With regard to Mr. Corvese's independent status, the Board considered the fact that he has no business relationship with the Company.

With regard to Mr. Barrage's independent status, the Board considered the fact that he has no business relationship with the Company.

With regard to Dr. Buell's independent status, the Board considered the fact that she has no business relationship with the Company except her consulting role assisting with clinical trial design and that she reports to Dr. Armen in the course of her primary roles, as president of Agenus, Inc and MiNK Therapeutics, Inc, and is therefore not considered "independent.".

Dr. Stein, a member of the Science and Clinical & Regulatory Committees, serves as our Chief Medical Officer, and is therefore not considered "independent."

Dr. Armen, a member of the Science and Clinical & Regulatory Committees, serves as our Executive Chairman, and is therefore not considered "independent."

Our principal offices are located at 149 Fifth Avenue, Suite 500, New York, New York 10010, in a conference room of Agenus, Inc. We utilize our principal office for quarterly board meetings and our annual shareholder meeting on a month to month basis at a nominal value. Dr. Armen, our Executive Chairman, is also the Chairman and Chief Executive Officer of Agenus Inc.

Item 14. Principal Accounting Fees and Services.

The following table sets forth the fees for services provided and reasonably expected to be billed by Malone Bailey LLP. The following is a summary of the fees billed to the Company for professional services rendered for the fiscal years ended December 31, 2022 and 2021.

	Fiscal Year 2022	Fiscal Year 2021
Audit fees	$ 85,000	$ 68,000
Audit-related fees	$ -	$ 62,750
Tax Fees	$ -	$ -
All other fees	$ -	$ -
Total	$ 85,000	$ 130,750

Audit Fees: For the fiscal years ended December 31, 2022 and 2021, the aggregate audit fees billed by our independent auditors were for professional services rendered for audits and quarterly reviews of our consolidated financial statements, and assistance with reviews of registration statements and documents filed with the SEC.

Audit-Related Fees: Audit-related fees are for assurance and other activities not explicitly related to the audit of our financial statements.

Tax Fees: For the fiscal years ended December 31, 2022 and 2021, there were no tax fees, respectively.

All Other Fees: For the fiscal years ended December 31, 2022 and 2021, there were $0 and $0, respectively

Audit Committee Pre-Approval Policies and Procedures. The Audit Committee oversees and monitors our financial reporting process and internal control system, reviews and evaluates the audit performed by our registered independent public accountants and reports to the Board any substantive issues found during the audit. The Audit Committee is directly responsible for the appointment, compensation and oversight of the work of our registered independent public accountants. The Audit Committee convenes on a quarterly basis to approve each quarterly filing, and an annual basis to review the engagement of the Company's external auditor.

The Audit Committee has considered whether the provision of Audit-Related Fees, Tax Fees, and all other fees as described above is compatible with maintaining MaloneBailey, LLP's independence and has determined that such services for fiscal years 2022 and 2021, respectively, were compatible. All such services were approved by the Audit Committee pursuant to Rule 2-01 of Regulation S-X under the Exchange Act to the extent that rule was applicable.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) List of Documents filed as part of this Report

(1) Consolidated Financial Statements

The F-1 through F-20 following the Exhibit List as required by Part II, Item 8 "Financial Statements and Supplementary Data" of this Form 10-K.

(2) Financial Statement Schedules.

Schedules are omitted because they are either not required, not applicable, or the information is otherwise included.

(3) Exhibits

The Company has filed with this report or incorporated by reference herein certain exhibits as specified below pursuant to Rule 12b-32 under the Exchange Act. See Exhibit Index following the signature page to this report for a complete list of documents filed with this report.

Exhibit No.	Description
3.1	Third Amended and Restated Certificate of Incorporation of Protagenic Therapeutics, Inc. (Incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2016).
3.2	Certificate of Designations, Powers, Preferences and Other Rights of Preferred Stock and Qualifications, Limitations and Restrictions Thereof of Series B Convertible Preferred Stock of Atrinsic, Inc. (Incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K, as filed with the SEC on February 5, 2016.)
3.3	Second Amended and Restated Bylaws Protagenic Therapeutics, Inc., (Incorporated by reference to Exhibit 3.1 to Company's Current Report on Form 8-K, as filed with the SEC on June 1, 2018).
4.1	Description of Securities*
4.2	Form of Warrant of Protagenic Therapeutics, Inc. (Incorporated by reference to Exhibit 4.1 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)
4.3(i)	Warrant of Protagenic Therapeutics, Inc. issued to Garo H. Armen on May 17, 2011. (Incorporated by reference to Exhibit 4.3(i) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)
4.3(ii)	Warrant of Protagenic Therapeutics, Inc. issued to Garo H. Armen on February 18, 2013 (Incorporated by reference to Exhibit 4.3(ii) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)
4.4(i)	Warrant of Protagenic Therapeutics, Inc. issued to Gregory H. Ekizian on July 7, 2011. (Incorporated by reference to Exhibit 4.4(i) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)

4.4(ii)	Warrant of Protagenic Therapeutics, Inc. issued to PENSCO Trust Company, FBO Gregory H. Ekizian on February 18, 2013. (Incorporated by reference to Exhibit 4.4(ii) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)
4.5	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.5 to Company's Current Report on Form 8-K, as filed with the SEC on April 18, 2016).
10.1	Employment Agreement, effective January 1, 2014 between Protagenic Therapeutics Canada (2006) Inc. and Dr. Robert Ziroyan (Incorporated by reference to Exhibit 10.12 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)**
10.2	Consulting Agreement, effective December 18, 2020, between Protagenic Therapeutics Inc. and Dr. Andrew Slee. (Incorporated by reference to Exhibit 10.2 to Company's Annual Report on Form 10-K, as filed with the SEC on March 25, 2021.)* **
10.3	Consulting Agreement, as amended, between Protagenic Therapeutics Canada (2006) Inc. and Dr. Dalia Barsyte (Incorporated by reference to Exhibit 10.13 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)**
10.4	Amended and Restated Consulting Agreement, effective December 18, 2020, between Protagenic Therapeutics Inc. and Dr. Robert B. Stein. (Incorporated by reference to Exhibit 10.4 to Company's Annual Report on Form 10-K, as filed with the SEC on March 25, 2021.)* **
10.5	Protagenic Therapeutics, Inc. 2006 Employee, Director and Consultant Stock Plan (Incorporated by reference to Exhibit 10.16 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)**
10.6	Form of Nonqualified Stock Option Award Agreement under the 2006 Employee, Director and Consultant Stock Plan. (Incorporated by reference to Exhibit 10.17 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.) **
10.7(i)	Technology License Agreement, effective July 21, 2005, between The University of Toronto Innovations Foundation and Protagenic Therapeutics, Inc. (Incorporated by reference to Exhibit 10.19(i) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)
10.7(ii)	First Amendment to Technology License Agreement, effective February 18, 2015, between the Governing Council of the University of Toronto and Protagenic Therapeutics, Inc. (Incorporated by reference to Exhibit 10.19(ii) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)
10.8(i)	Sponsored Research Agreement, effective April 1, 2014, between the Governing Council of the University of Toronto and Protagenic Therapeutics Canada (2006), Inc., Protagenic Therapeutics, Inc. (Incorporated by reference to Exhibit 10.20(i) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)
10.8(ii)	Amendment to the Sponsored Research Agreement, effective April 1, 2015, between the Governing Council of the University of Toronto and Protagenic Therapeutics Canada (2006), Inc., Protagenic Therapeutics, Inc. (Incorporated by reference to Exhibit 10.20(ii) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.)
10.9	Protagenic Therapeutics, Inc. 2016 Equity Compensation Plan. (Incorporated by reference to Exhibit 10.1 to Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2016.)**
10.10	Form of Incentive Stock Option Agreement under the Protagenic Therapeutics, Inc. 2016 Equity Compensation Plan. (Incorporated by reference to Exhibit 10.2 to Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2016.) **
10.11	Form of Nonqualified Stock Option Grant Agreement under the Protagenic Therapeutics, Inc. 2016 Equity Compensation Plan. (Incorporated by reference to Exhibit 10.3 to Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2016.) **

10.12	Form of Convertible Note Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 21, 2019)
10.13	Form of Convertible Promissory Note (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on November 21, 2019)
10.14	Form of Guaranty (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on November 21, 2019)
14.1	Protagenic Therapeutics, Inc. Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 to the Current Report on Form 10-K, as filed with the SEC on April 18, 2017).
14.2	Protagenic Therapeutics, Inc. Guideline on Significant Corporate Governance Issues (incorporated by reference to Exhibit 14.2 to the Current Report on Form 10-K, as filed with the SEC on April 18, 2017).
14.3	Protagenic Therapeutics, Inc. Process for Security Holder Communications with Directors (incorporated by reference to Exhibit 14.3 to the Current Report on Form 10-K, as filed with the SEC on April 18, 2017).
21.1	Subsidiaries *
31.1	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)*.
31.2	Certification of Chief Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b)*.
99.1	Audit Committee Charter adopted by Board of Directors of Protagenic Therapeutics, Inc. on March 7, 2017*.
99.2	Compensation Committee Charter adopted by Board of Directors of Protagenic Therapeutics, Inc. on March 7, 2017*.
99.3	Governance and Nominating Committee Charter adopted by Board of Directors of Protagenic Therapeutics, Inc. on March 7, 2017*.
99.4	Science Committee Charter adopted by the Board of Directors of Protagenic Therapeutics, Inc. (Incorporated by reference to Exhibit 99.1 to the Company's Annual Report on Form 10-K, as filed with the SEC on April 29, 2020)
[100.1]	[XBRL-related documents]
[101.1]	[Interactive Data Files]
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 Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith
** Designates management contracts and compensation plans
† Furnished herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of 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.

PROTAGENIC THERAPEUTICS, INC.

Date: March 31, 2023

By: */s/ Garo H. Armen*
Garo H. Armen
Chairman (Principal Executive Officer and Duly Authorized Officer)

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

Signatures	Title	Date
/s/ Garo H. Armen Garo H. Armen	Director and Chairman of the Board (Principal Executive Officer)	March 31, 2023
/s/ Alexander K. Arrow Alexander K. Arrow	Chief Financial Officer (Principal Financial Officer)	March 31, 2023
/s/ Robert B. Stein Robert B. Stein	Director	March 31, 2023
/s/ Khalil Barrage Khalil Barrage	Director	March 31, 2023

/s/ Brian J. Corvese Brian J. Corvese	Director	March 31, 2023
/s/ Timothy Wright Timothy Wright	Director	March 31, 2023
/s/ Jennifer Buell Jennifer Buell	Director	March 31, 2023

PROTAGENIC THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED

DECEMBER 31, 2022 AND 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Protagenic Therapeutics, Inc.

Opinion on the Financial Statements

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

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our 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 financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

/s/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor since 2017.
Houston, Texas
March 31, 2023

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash	$ 215,189	$ 541,171
Marketable securities	7,763,517	9,830,085
Prepaid expenses	56,939	688,667
TOTAL CURRENT ASSETS	8,035,645	11,059,923
Equipment - net	1,775	-
TOTAL ASSETS	$ 8,037,420	$ 11,059,923
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 669,704	$ 499,535
Accounts payable and accrued expenses - related party	105,928	300,000
PIK convertible notes payable, net of debt discount	150,591	-
PIK convertible notes payable, net of debt discount - related parties	193,639	-
TOTAL CURRENT LIABILITIES	1,119,862	799,535
PIK convertible notes payable, net of debt discount	-	132,284
PIK convertible notes payable, net of debt discount - related parties	-	186,149
TOTAL LIABILITIES	1,119,862	1,117,968
STOCKHOLDERS' EQUITY		
Preferred stock, $0.000001 par value; 20,000,000 shares authorized; none shares issued and outstanding in the following classes:		
Preferred stock; par value $0.000001; 2,000,000 shares authorized; none issued and outstanding	-	-
Series B convertible preferred stock, $0.000001 par value; 18,000,000 shares authorized; 0 and 0 shares issued and outstanding at December 31, 2022, and December 31, 2021	-	-
Common stock, $.0001 par value, 100,000,000 shares authorized, 4,321,315 and 4,302,403 shares issued and outstanding at December 31, 2022, and December 31, 2021	434	432
Additional paid-in-capital	33,371,406	32,411,742
Accumulated deficit	(25,777,375)	(22,221,870)
Accumulated other comprehensive loss	(676,907)	(248,349)
TOTAL STOCKHOLDERS' EQUITY	6,917,558	9,941,955
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 8,037,420	$ 11,059,923

See accompanying notes to the consolidated financial statements

PROTAGENIC THERAPEUTICS, INC., AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the years ended December 31,	
	2022	2021
OPERATING AND ADMINISTRATIVE EXPENSES		
Research and development	$ 1,589,239	$ 1,136,790
General and administrative	1,968,549	3,003,623
TOTAL OPERATING AND ADMINISTRATIVE EXPENSES	3,557,788	4,140,413
LOSS FROM OPERATIONS	(3,557,788)	(4,140,413)
OTHER (EXPENSE) INCOME		
Interest income	185,790	33,207
Interest expense	(137,456)	(4,96,912)
Realized loss on marketable securities	(46,051)	(2,486)
Change in fair value of derivative liability	-	83,670
TOTAL OTHER INCOME (EXPENSES)	2,283	(382,521)
LOSS BEFORE TAX	(3,555,505)	(4,522,934)
INCOME TAX EXPENSE	-	-

NET LOSS	$ (3,555,505)	$ (4,522,934)
COMPREHENSIVE LOSS		
Other Comprehensive Loss - net of tax		
Net unrealized loss on marketable securities	(421,738)	(77,029)
Foreign exchange translation income (loss)	(6,820)	266
TOTAL COMPREHENSIVE LOSS	$ (3,984,063)	$ (4,599,697)
Net loss per common share - Basic and Diluted	$ (0.82)	$ (1.24)
Weighted average common shares - Basic and Diluted	4,317,875	3,685,206

See accompanying notes to the consolidated financial statements

PROTAGENIC THERAPEUTICS, INC., AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGE IN STOCKHOLDERS' EQUITY
For the Year Ended December 31, 2022 and 2021

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-in-	Accumulated	Accumulated Other Comprehensive	Stockholders'
	Shares	Amount	Shares	Amount	Capital	(Deficit)	Loss	Equity
BALANCE-December 31, 2020	872,766	$ 1	2,590,120	$ 260	$ 16,720,525	$ (17,698,936)	$ (171,586)	$ (1,149,736)
Foreign currency translation gain	-	-	-	-	-	-	266	266
Unrealized gain on marketable securities	-	-	-	-	-	-	(77,029)	(77,029)
Stock compensation - stock options	-	-	-	-	1,518,756	-	-	1,518,756
Exercise of options	-	-	92,500	9	542,491	-	-	542,500
Exercise of warrants	-	-	269,170	27	327,098	-	-	327,125
Issuance of shares and warrants from offering, net of offering costs	-	-	795,000	80	11,707,959	-	-	11,708,039
Conversion of preferred stock	(872,766)	(1)	218,192	22	(21)	-	-	-
Conversion of notes and interest	-	-	317,546	32	1,594,936	-	-	1,594,968
Stock issued for underwriter	-	-	19,875	2	(2)	-	-	-
Net loss	-	-	-	-	-	(4,522,934)	-	(4,522,934)
BALANCE-December 31, 2021	-	$ -	4,302,403	$ 432	$ 32,411,742	$ (22,221,870)	$ (248,349)	$ 9,941,955
Foreign currency translation gain	-	-	-	-	-	-	(6,820)	(6,820)
Unrealized gain on marketable securities	-	-	-	-	-	-	(421,738)	(421,738)
Stock compensation - stock options	-	-	-	-	844,248	-	-	844,248
Stock compensation - warrants	-	-	-	-	20,433	-	-	20,433
Conversion of notes and interest	-	-	18,912	2	94,893	-	-	94,985
Net loss	-	-	-	-	-	(3,555,505)	-	(3,555,505)
BALANCE-December 31, 2022	-	$ -	4,321,315	$ 434	$ 33,371,406	$ (25,777,375)	$ (676,907)	$ 6,917,558

See accompanying notes to the consolidated financial statements

PROTAGENIC THERAPEUTICS, INC., AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the year ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (3,555,505)	$ (4,522,934)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation expense	30	-
Stock-based compensation	864,681	1,518,756
Change in fair value of the derivative liability	-	(83,670)
Realized loss on sale of marketable securities	46,051	2,486
Amortization of debt discount	110,797	427,137
Changes in operating assets and liabilities		
Prepaid expenses	631,728	(480,510)
Accounts payable and accrued expenses	(91,596)	340,121
NET CASH USED IN OPERATING ACTIVITIES	(1,993,814)	(2,798,614)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from sale of marketable securities	1,632,901	485,946
Purchase of marketable securities	(34,122)	(10,395,547)

Purchase of fixed assets	(1,805)	-
NET CASH PROVIDED BY INVESTING ACTIVITIES	1,596,974	(9,909,601)
CASH FLOWS FROM FINANCING ACTIVITIES		
Exercise of warrants for cash	-	327,125
Exercise of options for cash	-	542,500
Issuance of shares and warrants from offering, net of offering costs	-	11,708,039
Proceeds from notes payable	-	100,000
Repayment of notes payable	-	(100,000)
NET CASH PROVIDED BY FINANCING ACTIVITIES	-	12,577,664
Effect of exchange rate changes on cash	70,858	631
NET CHANGE IN CASH	(325,982)	(129,920)
CASH, BEGINNING OF THE PERIOD	541,171	671,091
CASH, END OF THE PERIOD	$ 215,189	$ 541,171
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Cash paid for interest expense	$ -	$ -
Cash paid for income taxes	$ -	$ -
NONCASH FINANCING AND INVESTING TRANSACTIONS		
Shares issued for conversion of notes and interest	$ 94,985	$ 1,594,968
Unrealized loss on marketable securities	$ 421,738	$ 77,029

See accompanying notes to the consolidated financial statements

PROTAGENIC THERAPEUTICS, INC. & SUBSIDIARY
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2022

NOTE 1 – ORGANIZATION AND NATURE OF BUSINESS

Company Background

Protagenic Therapeutics, Inc. ("we," "our," "Protagenic" or "the Company"), formerly known as Atrinsic, Inc., is a Delaware corporation with one subsidiary named Protagenic Therapeutics Canada (2006) Inc. ("PTI Canada"), a corporation formed in 2006 under the laws of the Province of Ontario, Canada.

We are a biopharmaceutical company specializing in the discovery and development of therapeutics to treat stress-related neuropsychiatric and mood disorders.

Reverse Stock Split

On March 22, 2023, the Company effectuated a 1 for 4 reverse stock split (the "Reverse Split"). The Company's stock began trading on a split-adjusted basis effective on the Nasdaq Stock Market on March 22, 2023. There was no change to the number of authorized shares of the Company's common stock. All share and per share information in these financial statements are adjusted to reflect the Reverse Split.

NOTE 2 - LIQUIDITY

As shown in the accompanying consolidated financial statements, the Company has incurred significant recurring losses resulting in an accumulated deficit. The Company anticipates further losses in the development of its business. The Company also had negative cash flows used in operations. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Based on its cash resources and positive working capital as of December 31, 2022, the Company has sufficient resources to fund its operations at least until the end of the third quarter of 2024. The positive working capital as of December 31, 2022 was due to funds raised by the Company from its equity offering during the year ended December 31, 2021. Absent generation of sufficient revenue from the execution of the Company's business plan, the Company will need to obtain debt or equity financing by the third quarter of 2024. Because the Company has sufficient resources on hand to fund operations through the next twelve months from the date these consolidated financial statements are available to be issued, the Company believes that this alleviates the substantial doubt in connection with its ability to continue as a going concern.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC").

Principles of consolidation

The consolidated financial statements include the accounts of Protagenic Therapeutics, Inc., and its wholly owned Canadian subsidiary, PTI Canada. All significant intercompany balances and transactions have been eliminated.

Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expense during the reporting period. Actual results could differ from those estimates. Significant estimates underlying the consolidated financial statements include valuation of stock options and warrants and assessment of deferred tax asset valuation allowance.

Concentrations of Credit Risk

The Company maintains its cash accounts at financial institutions which are insured by the Federal Deposit Insurance Corporation. At times, the Company may have deposits in excess of federally insured limits. As of December 31, 2022, the Company has bank balances that exceeds the federally insured limits. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of December 31, 2022 and December 31, 2021 the Company did not have any cash equivalents.

Marketable Securities

The Company accounts for marketable debt securities, the only type of securities it owns, in accordance with the FASB Accounting Standards Codification 320, Investments – Debt and Equity Securities ("ASC 320").

Pursuant to ASC 320-10-35-1, investments in debt securities that are classified as available for sale shall be measured subsequently at fair value in the consolidated balance sheets at each balance sheet date. Unrealized holding gains and losses for available-for-sale securities (including those classified as current assets) shall be excluded from earnings and reported in other comprehensive income until realized.

During the year ended December 31, 2022 the Company purchased $34,122 and sold $1,632,901 in marketable securities with a realized loss of $46,051 and an unrealized loss of $421,738. As of December 31, 2022 and December 31, 2021, the Company owned marketable securities with a total value of $7,763,517 and $9,830,085, respectively.

Equipment

Equipment is stated at cost less accumulated depreciation. Cost includes expenditures for computer equipment. Maintenance and repairs are charged to expense as incurred. When assets are sold, retired, or otherwise disposed of, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in operations. The cost of equipment is depreciated using the straight-line method over the estimated useful lives of the related assets which is three years. Depreciation expense was not material for the year ended December 31, 2022.

Fair Value Measurements

ASC 820, "Fair Value Measurements and Disclosure," defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, not adjusted for transaction costs. ASC 820 also establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels giving the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels are described below:

Level 1 Inputs – Unadjusted quoted prices in active markets for identical assets or liabilities that is accessible by the Company;

Level 2 Inputs – Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly;

Level 3 Inputs – Unobservable inputs for the asset or liability including significant assumptions of the Company and other market participants.

The carrying amount of the Company's financial assets and liabilities, such as cash, accounts payable and accrued expenses approximate their fair value because of the short term maturity of those instruments. The carrying value of long-term debt approximates fair value since the related rates of interest approximate current market rates.

Transactions involving related parties cannot be presumed to be carried out on an arm's-length basis, as the requisite conditions of competitive, free-market dealings may not exist. Representations about transactions with related parties, if made, shall not imply that the related party transactions were consummated on terms equivalent to those that prevail in arm's-length transactions unless such representations can be substantiated.

The assets 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. The following table provides a summary of financial instruments that are measured at fair value on a recurring basis as of December 31, 2022.

	Carrying Value	Fair Value Measurement Using			
		Level 1	Level 2	Level 3	Total
Marketable securities	$ 7,763,517	$ 7,763,517	$ —	$ —	$ 7,763,517

The following table provides a summary of financial instruments that are measured at fair value on a recurring basis as of December 31, 2021.

	Carrying Value	Fair Value Measurement Using			
		Level 1	Level 2	Level 3	Total
Marketable securities	$ 9,830,085	$ 9,830,085	$ —	$ —	$ 9,830,085

Stock-Based Compensation

The Company accounts for stock based compensation costs under the provisions of ASC 718, "Compensation—Stock Compensation", which requires the measurement and recognition of compensation expense related to the fair value of stock based compensation awards that are ultimately expected to vest. Stock based compensation expense recognized includes the compensation cost for all stock based payments granted to employees, officers, non-employees, and directors based on the grant date fair value estimated in accordance with the provisions of ASC 718. ASC. 718 is also applied to awards modified, repurchased, or cancelled during the periods reported.

If any award granted under the Company's 2016 Equity Compensation Plan (the "2016 Plan") payable in shares of common stock is forfeited, cancelled, or returned for failure to satisfy vesting requirements, otherwise terminates without payment being made, or if shares of common stock are withheld to cover withholding taxes on options or other awards, the number of shares of common stock as to which such option or award was forfeited, or which were withheld, will be available for future grants under the 2016 Plan. The Company recognizes the impact of forfeitures when they occur.

Basic and Diluted Net (Loss) per Common Share

Basic (loss) per common share is computed by dividing the net (loss) by the weighted average number of shares of common stock outstanding for each period. Diluted (loss) per share is computed by dividing the net (loss) by the weighted average number of shares of common stock outstanding plus the dilutive effect of shares issuable through the common stock equivalents. The effect of dilution on net loss becomes anti-dilutive and therefore is not reflected on the consolidated statements of operations and comprehensive loss.

	Potentially Outstanding Dilutive Common Shares	
	For the Years Ended December 31, 2022	For the Years Ended December 31, 2021
Conversion Feature Shares		
Stock Options	1,357,466	1,380,215
Warrants	1,537,158	1,533,158
Convertible Notes	86,000	103,000
Total potentially outstanding dilutive common shares	2,980,624	3,016,373

Research and Development

Research and development expenses are charged to operations as incurred.

Foreign Currency Translation

The Company follows ASC 830, *Foreign Currency Matters* ("ASC 830") for foreign currency translation to translate the financial statements of the foreign subsidiary from the functional currency, generally the local currency, into U.S. Dollars. ASC 830-10-45 sets out the guidance relating to how a reporting entity determines the functional currency of a foreign entity (including of a foreign entity in a highly inflationary economy), re-measures the books of record (if necessary), and characterizes transaction gains and losses. Pursuant to ASC 830-10-45, the assets, liabilities, and operations of a foreign entity shall be measured using the functional currency of that entity. An entity's functional currency is the currency of the primary economic environment in which the entity operates; normally, that is the currency of the environment, or local currency, in which an entity primarily generates and expends cash.

The functional currency of each foreign subsidiary is determined based on management's judgment and involves consideration of all relevant economic facts and circumstances affecting the subsidiary. Generally, the currency in which the subsidiary transacts a majority of its transactions, including billings, financing, payroll and other expenditures, would be considered the functional currency, but any dependency upon the parent and the nature of the subsidiary's operations must also be considered. If a subsidiary's functional currency is deemed to be the local currency, then any gain or loss associated with the translation of that subsidiary's financial statements is included in accumulated other comprehensive income. However, if the functional currency is deemed to be the U.S. Dollar, then any gain or loss associated with the re-measurement of these financial statements from the local currency to the functional currency would be included in the condensed consolidated statements of operations and comprehensive income (loss). If the Company disposes of foreign subsidiaries, then any cumulative translation gains or losses would be recorded into the condensed consolidated statements of operations and comprehensive income (loss). If the Company determines that there has been a change in the functional currency of a subsidiary to the U.S. Dollar, any translation gains or losses arising after the date of change would be included within the condensed consolidated statements of operations and comprehensive loss.

Based on an assessment of the factors discussed above, the management of the Company determined its subsidiary's local currency (i.e. the Canadian dollar) to be the functional currency for its foreign subsidiary.

Recent Accounting Pronouncements

Management does not believe that any recently issued, but not effective, accounting standards, if currently adopted, would have a material effect on the Company's financial statements.

NOTE 4 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following at:

	December 31, 2022	December 31, 2021
Accounting	$ 36,750	$ 68,151
Research and development	557,934	375,427
Legal	25,462	77,000
Other	155,486	278,957
Total	$ 775,632	$ 799,535

NOTE 5 – NOTE PAYABLE AND CONVERTIBLE NOTE PAYABLE (PIK NOTES)

Convertible Notes Payable

During the years ended December 31, 2022 and 2021, the Company amortized $110,797 and $333,400 of the debt discount, respectively. At December 31, 2022 and December 31, 2021, the Company had an unamortized debt discount of $79,409 and $182,716, respectively.

During the year ended December 31, 2022, a total of 18,912 shares of the Company's common stock was issued for the conversion of notes and interest. A total of $85,000 in principal and $9,985 in accrued interest was converted.

As of December 31, 2022 and December 31, 2021, the Company owes $230,000 and $315,000 on the outstanding Convertible Notes, respectively. These convertible notes have a maturity date of November 6, 2023.

Convertible Notes Payable – Related Parties

During the years ended December 31, 2022 and 2021, the Company amortized $7,490 and $93,737 of the debt discount, respectively. At December 31, 2022 and December 31, 2021, the Company had an unamortized debt discount of $6,361 and $13,851, respectively.

As of December 31, 2022 and December 31, 2021, the Company owes $200,000 and $200,000 on the outstanding Convertible Notes, respectively. These convertible notes have a maturity date of November 6, 2023.

NOTE 6 - STOCKHOLDERS' DEFICIT

Common Stock

During the years ended December 31, 2022, the Company issued 18,911 shares of common stock for the conversion of notes and interest. (See Note 5).

Stock-Based Compensation

The Company adopted an Employee, Director and Consultant Stock Plan on June 17, 2016 (the "2016 Plan"). Pursuant to the 2016 Plan, the Company's Compensation Committee may grant awards to any employee, officer, director, consultant, advisor or other individual service provider of the Company or any subsidiary. Due to an annual "evergreen" provision in the 2016 Plan, the number of shares reserved for future grants was increased by 184,260 and 142,457 in 2022 and 2021, respectively. As a result of these increases, as of December 31, 2022 and December 31, 2021, the aggregate number of shares of common stock available for awards under the 2016 Plan was 1,543,872 shares and 1,359,612 shares, respectively. Options issued under the 2016 Plan are exercisable for up to ten years from the date of issuance.

There were 1,357,466 options outstanding as of December 31, 2022. The fair value of each stock option granted during the year ended December 31, 2022 was estimated using the Black-Scholes assumptions and or factors as follows:

Exercise price	$ 4.84
Expected dividend yield	0%
Risk free interest rate	1.73%
Expected life in years	10
Expected volatility	146%

There were 1,380,216 options outstanding as of December 31, 2021. The fair value of each stock option granted was estimated using the Black-Scholes assumptions and or factors as follows:

Exercise price	$ 7.84-22.40
Expected dividend yield	0%
Risk free interest rate	0.81%-1.58%
Expected life in years	5-10
Expected volatility	147%-158%

The following is an analysis of the stock option grant activity under the Plan:

	Number	Weighted Average Exercise Price	Weighted Average Remaining Life
Stock Options			
Outstanding December 31, 2020	1,399,466	$ 5.88	6.48
Granted	145,750	$ 19.08	9.12
Expired	(72,500)	$ 4.00	-
Exercised	(92,500)	$ 5.92	-
Outstanding December 31, 2021	1,380,216	$ 7.36	6.32
Granted	12,500	$ 4.84	9.02
Expired	(35,250)	$ 6.09	-
Exercised	-	$ -	-
Outstanding December 31, 2022	1,357,466	$ 7.39	5.41

A summary of the status of the Company's nonvested options as of December 31, 2022, and changes during the years ended December 31, 2022 and 2021, is presented below:

Nonvested Options	Options	Weighted-Average Exercise Price
Nonvested at December 31, 2020	215,708	$ 7.00
Granted	145,750	$ 19.08
Vested	158,875	$ 12.28
Forfeited	-	$ -
Nonvested at December 31, 2021	202,583	$ 12.32
Granted	12,500	$ 4.84
Vested	(96,896)	$ 10.44
Forfeited	-	$ -
Nonvested at December 31, 2022	118,187	$ 13.07

As of December 31, 2022, the Company had 1,357,466 shares issuable under options outstanding at a weighted average exercise price of $7.39 and an intrinsic value of $0.

The total number of options granted during the years ended December 31, 2022 and 2021 was 12,500 and 145,750, respectively. The exercise price for these options ranges from $4.84 to $22.40 per share.

The Company recognized compensation expense related to options issued of $844,248 and $1,518,756 for the years ended December 31, 2022 and 2021, respectively, in which $747,830 and $1,513,835 is included in general and administrative expenses and $96,418 and $4,921 in research and development expenses, respectively. For the years ended December 31, 2022 and 2021, $182,748 and $769,479 of the stock compensation was related to employees and $661,500 and $749,277 was related to non-employees, respectively.

As of December 31, 2022, the unamortized stock option expense was $1,342,673 with $8,566 being related to employees and $1,334,107 being related to non-employees. As of December 31, 2022, the weighted average period for the unamortized stock compensation to be recognized is 3.37 years.

On January 6, 2022, the Company issued a total of 12,500 options to purchase shares of the Company's common stock to a consultant. These options had a grant date fair value of $68,614. These options have an exercise price of $4.84, a term of 10 years, and vest over four years.

Warrants:

A summary of warrant issuances are as follows:

	Number	Weighted Average Exercise Price	Weighted Average Remaining Life
Warrants			
Outstanding December 31, 2020	1,001,765	4.24	1.86
Granted	914,250	19.92	4.83
Expired	(37,562)	5.00	-
Exercised	(345,295)	4.52	-
Outstanding December 31, 2021	1,533,158	$ 13.52	3.15
Granted	4,000	5.00	4.02
Expired	-	-	-
Exercised	-	-	-
Outstanding December 31, 2022	1,537,158	$ 13.49	2.15

As of December 31, 2022, the Company had 1,537,158 shares issuable under warrants outstanding at a weighted average exercise price of $13.49 and an intrinsic value of $0.

The Company recognized compensation expense related to warrants issued of $20,433 and $0 during the years ended December 31, 2022 and 2021, respectively.

On January 6, 2022, the Company cancelled 4,000 options and replaced them with 4,000 warrants with a 5-year term and an exercise price of $5.00.

NOTE 7 - COLLABORATIVE AGREEMENTS

The Company and the University of Toronto (the "University") entered into an agreement effective April 1, 2014 (the "New Research Agreement") for the performance of a research project titled "Teneurin C-terminal Associated Peptide ("TCAP") mediated stress attenuation in vertebrates: Establishing the role of organismal and intracellular energy and glucose regulation and metabolism" (the "New Project"). The New Project is to perform research related to work done by Dr. David A. Lovejoy, a professor at the University and stockholder of the Company, in regard to TCAP mediated stress attenuation in vertebrates: Establishing the role of organismal and intracellular energy and glucose regulation and metabolism. In addition to the New Research Agreement, Dr. Lovejoy entered into an agreement with the University in order to commercialize certain technologies. The New Research Agreement expired on March 30, 2016. In February 2017, the New Research Agreement was extended to December 31, 2017. The extension allowed for further development of the technologies and use of their applications. On April 10, 2018, the agreement was amended and the research agreement has been further extended to December 31, 2023.

Prior to January 1, 2016, the University has been granted 6,250 stock options which are fully vested at the exercise price of $4.00 exercisable over a ten year period which ended on April 1, 2022. As of December 31, 2022, Dr. David Lovejoy of the University has been granted 138,325 stock options, of which 113,325 are fully vested and 25,000 have expired. These have an exercise price of $4.00, $5.00 or $7.00 and are exercisable over a period ranging from 10 to 13 years.

The sponsorship research and development expenses pertaining to the Research Agreements were $28,645 and $0 for the years ended December 31, 2022 and 2021, respectively.

NOTE 8 - COMMITMENTS AND CONTINGENCIES

Licensing Agreements

On July 31, 2005, the Company had entered into a Technology License Agreement ("License Agreement") with the University pursuant to which the University agreed to license to the Company patent rights and other intellectual property, among other things (the "Technologies"). The Technology License Agreement was amended on February 18, 2015 and currently does not provide for an expiration date.

Pursuant to the License Agreement and its amendment, the Company obtained an exclusive worldwide license to make, have made, use, sell and import products based upon the Technologies, or to sublicense the Technologies in accordance with the terms of the License Agreement and amendment. In consideration, the Company agreed to pay to the University a royalty payment of 2.5% of net sales of any product based on the Technologies. If the Company elects to sublicense any rights under the License Agreement and amendment, the Company agrees to pay to the University 10% of any up-front sub-license fees for any sub-licenses that occurred on or after September 9, 2006, and, on behalf of the sub-licensee, 2.5% of net sales by the sub-licensee of all products based on the Technologies. The Company had no sales revenue for the years ended December 31, 2022 and 2021 and therefore was not subject to paying any royalties.

In the event the Company fails to provide the University with semi-annual reports on the progress or fails to continue to make reasonable commercial efforts towards obtaining regulatory approval for products based on the Technologies, the University may convert our exclusive license into a non-exclusive arrangement. Interest on any

amounts owed under the License Agreement and amendment will be at 3% per annum. All intellectual property rights resulting from the Technologies or improvements thereon will remain the property of the other inventors and/or Dr. Lovejoy, and/or the University, as the case may be. The Company has agreed to pay all out-of-pocket filing, prosecution and maintenance expenses in connection with any patents relating to the Technologies. In the case of infringement upon any patents relating to the Technologies, the Company may elect, at its own expense, to bring a cause of action asserting such infringement. In such a case, after deducting any legal expenses the Company may incur, any settlement proceeds will be subject to the 2.5% royalty payment owed to the University under the License Agreement and amendment.

The patent applications were made in the name of Dr. Lovejoy and other inventors, but the Company's exclusive, worldwide rights to such patent applications are included in the License Agreement and its amendment with the University. The Company maintains exclusive licensing agreements and it currently controls the five intellectual patent properties.

Legal Proceedings

From time to time we may be named in claims arising in the ordinary course of business. Currently, no legal proceedings, government actions, administrative actions, investigations or claims are pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition.

NOTE 9 – RELATED PARTY TRANSACTIONS

The Company is provided free office space consisting of a conference room by the Company Executive Chairman, Dr. Armen. The Company does not pay any rent for the use of this space. This space is used for quarterly board meetings and our annual shareholder meeting.

During the year ended December 31, 2021, the Company engaged Agenus Inc., a related party, to perform research and development services. Agenus Inc. is a related party due to the Company's Director and Chairman of the Board being the CEO and Chairman of the Board for Agenus Inc. The Company accrued $300,000 in expenses related to these services during the year ended December 31, 2021. The Company accrued $105,928 in expenses related to these services during the year ended December 31, 2022. As of December 31, 2022, the balance on these accrued expenses is $105,928.

During the year ended December 31, 2022, the Company engaged CTC North, GmbH ("CTC") to perform research and development services. CTC is a related party due to the Company's Director and Chairman of the Board being the CEO and Chairman of the Board for Agenus Inc, CTC's parent company. The total commitment for this agreement is $1.3 million. For the year ended December 31, 2022, the Company has incurred a total of $105,801 in expenses related to this agreement. As of December 31, 2022, there is $0 owed to CTC in connection with this agreement.

NOTE 10 – INCOME TAXES

The components of loss before income taxes are as follows:

	2022	2021
Domestic	(3,522,834)	(4,522,862)
Foreign	(32,671)	(72)
Loss before income taxes	(3,555,505)	(4,522,934)

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2022 and 2021.

For the years ended December 31, 2022 and 2021, a reconciliation of the Company's effective tax rate to the statutory U.S. Federal rate is as follows:

	2022	2021
Income taxes at Federal statutory rate	(21.0)%	(21.0)%
State income taxes, net of Federal income tax effect	(8.8)%	(8.9)%
Perm difference	0.0%	0.0%
Foreign tax rate differential	(0.2)%	0.0%
Change in valuation allowance	30.0%	29.9%
Other	0.0%	0.0%
Income tax provision	0.0%	0.0%

The tax effects of temporary differences that give rise to the Company's deferred tax assets and liabilities are as follows:

	2022	2021
U.S. net operating loss carryforwards	3,620,000	3,779,000
Stock compensation	1,931,000	1,672,000
Canadian Provincial income tax losses	7,000	(3,000)
Canadian Provincial scientific investment tax credits	-	(27,000)
	5,558,000	5,421,000
Valuation allowance	(5,558,000)	(5,421,000)
Net deferred tax assets	-	-

As of December 31, 2022 the Company had federal net operating loss carryforwards ("NOL") of approximately $10.8 million. The 2017 Tax Cuts and Jobs Act ("TCJA") will generally allow losses incurred after 2017 to be carried over indefinitely, but will generally limit the net operating loss deduction to the lesser of the net operating loss carryover or 80% of a corporation's taxable income (subject to Section 382 of the Internal Revenue Code of 1986, as amended). Also, there will be no carryback for losses incurred after 2017. Losses incurred prior to 2018 will generally be deductible to the extent of the lesser of a corporation's net operating loss carryover or 100% of a corporation's taxable income and be available for twenty years from the period the loss was generated. The federal net operating losses generated prior to 2018 of $0.1 million will expire at various dates through 2037. As of December 31, 2022 and 2021, the Company had state and local net operating loss carryforwards of approximately $9,568,415 and $6,921,574, respectively, to reduce future state tax liabilities also through 2035.

As of December 31, 2022 and 2021, the Company had Canadian NOL of approximately $1,413,000 and $1,446,000, respectively. The Canadian losses expire in stages beginning in 2026. As of December 31, 2022 and 2021, the Company also has unclaimed Canadian federal scientific research and development investment tax credits, which are available to reduce future federal taxes payable of approximately $0 and $0 respectively.

As a result of losses and uncertainty of future profit, the net deferred tax asset has been fully reserved. The net change in the valuation allowance during the years ended December 31, 2022 and 2021 was an increase of $137,000 and $1,300,000, respectively.

Foreign earnings are assumed to be permanently reinvested. U.S. Federal income taxes have not been provided on undistributed earnings of our foreign subsidiary.

The Company recognizes interest and penalties related to uncertain tax positions in selling, general and administrative expenses. The Company has not identified any uncertain tax positions requiring a reserve as of December 31, 2022 and 2021.

The Company is required to file U.S. federal and state income tax returns. These returns are subject to audit by tax authorities beginning with the year ended December 31, 2017.

Exhibit 4.1

DESCRIPTION OF SECURITIES
PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 11934

The following description is intended as a summary of our third amended and restated certificate of incorporation (which we refer to as our "charter") and our bylaws, and to the applicable provisions of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our charter and bylaws.

Our current certificate of incorporation authorizes us to issue:

- 100,000,000 shares of common stock, par value $0.0001 per share; and
- 20,000,000 shares of Preferred Stock, par value $0.000001 per share, of which 18,000,000 shares have been designated as Series B preferred stock and the remainder of which have not been designated.

As of March 31, 2023, there were 4,321,445 shares of common stock outstanding and 0 shares of Series B Preferred Stock outstanding.

Common Stock

Voting. The holders of our common stock are entitled to one vote for each share held of record on all matters on which the holders are entitled to vote (or consent pursuant to written consent).

Dividends. The holders of our common stock are entitled to receive, ratably, dividends only if, when and as declared by our board of directors out of funds legally available therefor and after provision is made for each class of capital stock having preference over the common stock.

Liquidation Rights. In the event of our liquidation, dissolution or winding-up, the holders of our common stock are entitled to share, ratably, in all assets remaining available for distribution after payment of all liabilities and after provision is made for each class of capital stock having preference over the common stock.

Conversion Rights. The holders of our common stock have no conversion rights.

Preemptive and Similar Rights. The holders of our common stock have no preemptive or similar rights.

Redemption/Put Rights. There are no redemption or sinking fund provisions applicable to the common stock. All of the outstanding shares of our common stock are fully-paid and non-assessable.

Preferred Stock

We are authorized to issue up to 20,000,000 shares of "blank check" preferred, which may be issued from time to time in one or more series upon authorization by our board of directors. Our board of directors, without further approval of the stockholders, is authorized to fix the dividend rights and terms, conversion rights, voting rights, redemption rights and terms, liquidation preferences, and any other rights, preferences, privileges and restrictions applicable to each series of preferred stock. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting, or other rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying or preventing a change in control of our company, all without further action by our stockholders. Our board of directors has designated 18,000,000 of our preferred stock as Series B Preferred Stock.

Series B Preferred Stock

Voting. The holders of our Series B Preferred Stock are entitled to vote together with our common stock as a single class, on all matters on which the holders of the common stock are entitled to vote (or consent pursuant to written consent) Each share of Series B Preferred Stock will have a number of votes equal to one share of common stock.

Dividends. The holders of Series B Preferred Stock are entitled to share, ratably and on an as-converted basis, in all dividends declared by our board of directors and paid to the holders of our common stock.

Liquidation. In the event of any liquidation, dissolution or winding up of our company, the assets available for distribution to our stockholders will be distributed among the holders of our Series B Preferred Stock and the holders of our common stock, pro rata, on an as-converted-to-common stock basis.

Conversion Rights. Under the terms of the Series B Preferred Stock, each share of Series Preferred B Stock was to convert into one share of our common stock upon the Reverse Split unless (i) to the extent (but only to the extent) such conversion for a Series B Preferred Stock holder would violate the Springing Blocker and (ii) such holder has notified the Company in writing that it wants the Springing Blocker to apply to such holder. We had only one holder of our Series B Preferred Stock that notified the Company that it wanted the Springing Blocker to apply. Any Series B Preferred Stock not converted as a result of this provision would automatically convert into common stock as soon as such conversion would not violate the Springing Blocker. Our Series B Preferred Stock will cease to be designated as a separate series of our preferred stock when all of such shares have converted into shares of our common stock.

Preemptive and Similar Rights. The holders of our Series B Preferred Stock have no preemptive or similar rights.

Redemption/Put Rights. There are no redemption or sinking fund provisions applicable to our Series B Preferred Stock. All of the outstanding shares of our Series B Preferred Stock are fully-paid and non-assessable.

Transfer Agent and Registrar

American Stock Transfer & Trust Company, LLC is the transfer agent and registrar for our common stock.

Dividends

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

Anti-Takeover Effect of Delaware Law, Certain Charter and Bylaw Provisions

In addition to the provisions included in our Amended and Restated Certificate and Bylaws, we are subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the following prescribed manner:

- prior to the time of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

- on or subsequent to the time of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, for purposes of Section 203, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, owned 15% or more of a corporation's outstanding voting securities.

Public Warrants

General. Each warrant is exercisable to purchase one share of common stock at an exercise price of $9.92 per share. This exercise price will be adjusted if specific events, summarized below, occur. A holder of warrants will not be deemed a holder of the underlying stock for any purpose until the warrant is exercised.

Form and Exchange Listing. The warrants are listed on The NASDAQ Capital Market under the symbol "PTIXW".

Warrant Agent. The warrants were issued in registered form under a warrant agency agreement between American Stock Transfer & Trust Company, LLC, as warrant agent, and us.

Exercisability. The warrants are exercisable at any time after their original issuance and at any time up to the date that is five years after their original issuance. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of Common Stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the issuance of the shares of Common Stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the warrant. No fractional shares of Common Stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Price. The exercise price per share of common stock purchasable upon exercise of the warrants is $4.98 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Redemption. Beginning July 25, 2021, the warrants became redeemable at our option, in whole or in part, at a redemption price equal to $0.10 per warrant upon 30 days' prior notice (which may be made via publication of a press release), at any time after the date on which the closing price of our common stock has equaled or exceeded $29.04 for at least five consecutive trading days, provided we have a current and effective registration statement available covering the exercise of the warrants. Notice of redemption may be made via publication of a press release or any other lawful means. If notice of redemption is made via publication of a press release, no other form of notice or publication will be required. If we call the warrants for redemption, the holders of the warrants will then have to decide whether to sell warrants, exercise them before the close of business on the business day preceding the specified redemption date or hold them for redemption.

Adjustments in Certain Events. We will make adjustments to the terms of the warrants if certain events occur as described below. If prior to the exercise of any warrants, we effect one or more stock splits, stock dividends or other increases or reductions of the number of shares of our common stock outstanding without receiving compensation therefor in money, services or property, the number of shares of common stock subject to the warrants shall (i) if a net increase shall have been effected in the number of outstanding shares of common stock, be proportionately increased, and the exercise price payable per share of common stock subject to the warrant shall be proportionately reduced, and, (ii) if a net reduction shall have been effected in the number of outstanding shares of the common stock, be proportionately reduced and the exercise price payable per share of common stock subject to the warrant shall be proportionately increased. We may, in our sole discretion, lower the exercise price per share of common stock subject to the warrant at any time prior to the expiration date for a period of not less than 20 days.

In the event of a capital reorganization or reclassification of our common stock, the warrants will be adjusted so that thereafter each warrant holder will be entitled to receive upon exercise the same number and kind of securities that such holder would have received if the warrant had been exercised before the capital reorganization or reclassification of our common stock.

If we merge or consolidate with another corporation, or if we sell our assets as an entirety or substantially as an entirety to another corporation, we will make provisions so that warrantholders will be entitled to receive upon exercise of a warrant the kind and number of securities, cash or other property that would have been received as a result of the transaction by a person who was our stockholder immediately before the transaction and who owned the same number of shares of common stock for which the warrant was exercisable immediately before the transaction. No adjustment to the warrants will be made, however, if a merger or consolidation does not result in any reclassification or change in our outstanding common stock.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Exhibit 21.1

SUBSIDIARIES OF PROTAGENIC THERAPEUTICS, INC.

Subsidiary	Jurisdiction of Organization/Incorporation
Protagenic Therapuetics Canada (2006) Inc.	Canada

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Garo H. Armen, PhD, certify that:

1. I have reviewed this annual report on Form 10-K of Protagenic Therapeutics, Inc..

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 (the registrant's fourth fiscal quarter in the case of an annual report) 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.

March 31, 2023

/s/ Garo H. Armen

Name: Garo H. Armen, Ph.D.
Title: Executive Chairman

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Alexander K. Arrow, MD, certify that:

1. I have reviewed this annual report on Form 10-K of Protagenic Therapeutics, Inc.;

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 (the registrant's fourth fiscal quarter in the case of an annual report) 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.

March 31, 2023

/s/ Alexander K. Arrow

Name: Alexander K. Arrow, MD
Title: Chief Financial Officer

Charter of the Audit Committee of the
Board of Directors of Protagenic Therapeutics, Inc.

Purpose

The principal purpose of the Audit and Finance Committee (the "Committee") is to assist the Board of Directors (the "Board") of Protagenic Therapeutics, Inc. (the "Company") in fulfilling its responsibility to oversee the Company's accounting and financial reporting processes and audits of the Company's financial statements, including by reviewing the financial reports and other financial information provided by the Company, the Company's disclosure controls and procedures and internal accounting and financial controls, and the annual independent audit process.

In discharging its oversight role, the Committee is granted the authority to investigate any matter brought to its attention with full access to all books, records, facilities and personnel of the Company and the authority to engage independent counsel and other advisors, as it determines necessary to carry out its duties. The Committee also is authorized to approve the use of Company funds to the extent it deems such expenditures necessary or appropriate in carrying out the responsibilities of the Committee.

The Committee shall be responsible for the appointment (and where appropriate, replacement), compensation, retention and oversight of the work of the Company's outside auditor in preparing or issuing an audit report or related work, including resolving any disagreements between management and the outside auditor regarding financial reporting. The Committee shall receive direct reports from the outside auditor. The Committee shall be responsible for overseeing the independence of the outside auditor and for approving all auditing services and permitted nonaudit services provided by the outside auditor.

This Charter shall be reviewed for adequacy on an annual basis by the Committee and any changes thereto shall be submitted to the Board for approval.

Membership

The Committee shall be comprised of not less than two members of the Board, and the Committee's composition will meet the Nasdaq Audit Committee requirements. Accordingly, subject to the paragraph below, all of the members will be directors:

- Who are "independent" as defined by applicable Nasdaq rules, who meet the criteria for independence set forth in Rule 10A-3(b)(1) under the Securities Exchange Act of 1934, as amended (subject to the exemptions provided in Rule 10A-3(c)), and who have not participated in the preparation of the financial statements of the Company or any current subsidiary of the Company at any time during the past three years. In order to ensure the independence of the Committee members, the Committee's members must be monitored throughout the year to confirm that they all remain independent as required by Nasdaq rules. In addition, it must be considered whether any members of the Committee have relationships with the Company that may create the appearance of a lack of independence, even though such relationships do not automatically disqualify the person from being "independent" under applicable laws and listing rules;

- Who do not receive any consulting, advisory or other compensatory fee from the Company, other than in the member's capacity as a member of the Board or any of its committees; and
- Who must be able to read and understand fundamental financial statements, including the Company's balance sheet, income statement, and cash flow statement. In addition, at least one member must have past employment experience in finance or accounting, requisite professional certification in accounting, or any other comparable experience or background which results in the individual's financial sophistication, including being or having been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities. Unless otherwise determined by the Board (in which case disclosure of such determination shall be made in the Company's annual report filed with the SEC), at least one member of the Committee shall be an "audit committee financial expert" (as defined by applicable SEC rules).

Except under exceptional circumstances approved by the Board, no member of the Committee may serve simultaneously on the audit committee of more than three other public companies. Subject to applicable law and regulations, the Board may appoint one member who does not meet the independence requirements set forth above and who is not a current employee of the Company or an immediate family member of such employee if the Board, under exceptional and limited circumstances, determines that membership on the Committee by the individual is required in the best interests of the Company and its shareholders. Such member may not serve for more than two years, and may not serve as the Committee chair. The Board shall disclose in the next proxy statement after such determination the nature of the relationship and the reasons for the determination.

In order to fulfill its role, the Committee shall be organized and governed in the following manner:

- Committee members and the Committee chair will be recommended by the Corporate Governance and Nominating Committee and appointed and removed, with or without cause, by the Board;
- Action may be taken by the Committee (or any subcommittee of the Committee) upon the affirmative vote of a majority of the members of the Committee (or subcommittee);
- Any member of the Committee may call a meeting of the Committee upon due notice to each other member at least twenty-four hours prior to the meeting (provided that participation in any meeting shall be deemed to constitute waiver of any deficiency in such notice);
- Action may be taken by the Committee without a meeting if all of the members of the Committee indicate their approval thereof in writing or by electronic transmission;
- The Committee shall have the authority to delegate to subcommittees of the Committee any responsibilities of the full Committee; and
- The Committee shall periodically perform an evaluation of the performance of the Committee and report to the Board on the results of such evaluation.

Key Responsibilities

The Committee's role is one of oversight, and it is recognized that the Company's management is responsible for preparing the Company's financial statements and that the outside auditor is responsible for auditing those financial statements.

The following functions shall be the common recurring activities of the Committee in carrying out its oversight function. The functions are set forth as a guide and may be varied from time to time as appropriate under the circumstances.

- The Committee shall review with management and the outside auditor the audited financial statements to be included in the Company's Annual Report on Form 10-K and the Annual Report to Stockholders, including the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations," and shall review and consider with the outside auditor the matters required to be discussed under generally accepted auditing standards, including Auditing Standard No. 16, or other such requirements established by the Public Company Accounting Oversight Board.
- As a whole, or through the Committee chair, the Committee shall review with the outside auditor, prior to filing with the SEC, the Company's interim financial information to be included in the Company's Quarterly Reports on Form 10-Q and the matters required to be discussed by SAS No. 61 or other such requirements established by the Public Company Accounting Oversight Board.

- The Committee shall recommend to the Board whether, based on the reviews and discussions referred to above, the financial statements should be included in the
- Company's Annual Report on Form 10-K.
- The Committee shall periodically discuss with management and the outside auditor the effectiveness and adequacy of the Company's internal controls and internal auditing procedures, including any significant deficiencies or material weaknesses in the design or operation of those controls which could adversely affect the Company's ability to record, process, summarize and report financial data and any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls, and discuss with the outside auditor how the Company's financial systems and controls compare with industry practices.
- The Committee shall periodically review with management and the outside auditor the quality, as well as acceptability, of the Company's accounting policies, and discuss with the outside auditor how the Company's accounting policies compare with those in the industry and all alternative treatments of financial information within generally accepted accounting principles that have been discussed with management, the ramifications of use of such alternative disclosures and treatments and the treatment preferred by the outside auditor.

- The Committee shall periodically discuss with the outside auditor whether all material correcting adjustments identified by the outside auditor in accordance with generally accepted accounting principles and the rules of the SEC are reflected in the Company's financial statements.
- The Committee shall review with management and the outside auditor any material financial or other arrangements of the Company which do not appear on the Company's financial statements and any transactions or courses of dealing with third parties that are significant in size or involve terms or other aspects that differ from those that would likely be negotiated with independent parties, and which arrangements or transactions are relevant to an understanding of the Company's financial statements.
- The Committee shall review with management and the outside auditor the Company's critical accounting policies and practices.
- The Committee shall review with the outside auditor all material communications between the outside auditor and management, such as any management letter or schedule of unadjusted differences.
- The Committee shall (i) request from the outside auditor annually a formal written statement delineating all relationships between the auditor and the Company consistent with other requirements as may be consistent with requirements established by the Public Company Accounting Oversight Board; (ii) discuss with the outside auditor any such disclosed relationships or services and their impact on the outside auditor's independence; and (iii) take appropriate action to oversee the independence of the outside auditor.
- The Committee shall approve the engagement of the outside auditor and shall approve, in advance, all audit services and all permitted non-audit services to be provided to the Company by the outside auditor. The committee may also delegate this responsibility (for services up to $50,000) to the chairman in between meetings, with those actions disclosed to the full committee at the next regularly scheduled meeting.
- The Committee shall approve a code of ethics, as required by rules of the SEC, for senior financial officers and such other employees and agents of the Company as it determines.
- The Committee shall ensure that this charter is posted to the Company's Web site in accordance with the rules and regulations of the SEC or the exchanges.
- The Committee shall review and approve all transaction required to be disclosed in the Company's filings with the SEC pursuant to Item 404 of Regulation S-K (each, a "Related Party Transaction"). In considering any Related Party Transaction, the Committee shall consider the facts and circumstances regarding such transaction, including, among other things, the amounts involved (including whether the transaction amount exceeds $120,000), the relationship of the related person (including those persons identified in the instructions to Item 404(a) of Regulation S-K) with the Company and the terms that would be available in a similar transaction with an unaffiliated third-party. The Committee shall also consider its fiduciary duties, the Company's obligations under applicable securities law, including disclosure obligations and director independence rules, and other applicable law in evaluating any Related Party Transaction.

Complaint Procedures

Any issue of significant financial misconduct shall be brought to the attention of the Committee for its consideration. In this connection, the Committee shall establish procedures for (i) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and (ii) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.

Adopted March 25, 2016
To be amended in May 2016 following expected corporate name change to Protagenic
Therapeutics, Inc.

Amended March 7, 2017

Charter of the Compensation Committee of the
Board of Directors of Protagenic Therapeutics, Inc. (the "Company")

Purpose

The principal purpose of the Compensation Committee (the "Committee") of the Board of Directors (the "Board") is to approve, administer and interpret the Company's executive and key employee compensation and benefit policies, including the Company's equity incentive plans. The Committee shall ensure that the Company's executive and key employee compensation and benefit program is consistent with the Company's compensation philosophy and the Company's Guidelines on Significant Corporate Governance Issues, and determine the executive compensation packages offered to the Company's executive officers.

The Committee's responsibilities and authority include the following:

- The Committee shall review and approve corporate goals and objectives relevant to, and incentives for risk-taking created by, executive officer compensation, and evaluate the performance of executive officers in light of those goals, objectives and incentives;
- The Committee shall determine the compensation of the Chief Executive Officer and/or Executive Chairman; provided that the Chief Executive Officer or Executive Chairman may not be present during voting or deliberations on his or her compensation; provided, further, that in evaluating and determining the compensation of the Chief Executive Officer or Executive Chairman, the Committee shall consider the results of the most recent stockholder advisory vote on executive compensation ("Say on Pay Vote") required by Section 14A of the Securities Exchange Act of 1934, as amended (the "Exchange Act");
- The Committee shall review and approve the compensation of other executive officers and key employees; provided that in evaluating and determining the compensation of other executive officers and key employees, the Committee shall consider the results of the most recent Say on Pay Vote;
- The Committee shall review and recommend compensation for members of the Board and Board committees; provided that no adoption, amendment or termination of any compensation plan under which a member of the Board who is not an employee of the Company may be a participant shall be effective unless the same shall be approved by the Board and, to the extent required by law or the rules of the Nasdaq Stock Market, by the Company's stockholders;
- The Committee shall review and discuss with management the compensation discussion and analysis required to be included in the Company's filings with the Securities and Exchange Commission and, based on such review and discussion, in the case of compensation discussion and analysis proposed to be included in the Company's annual report on Form 10-K or proxy statement, recommend to the Board whether the compensation discussion and analysis should be included in such annual report or proxy statement;

- The Committee shall review and consider the outcome of stockholder advisory votes on the compensation of the Company's named executive officers when considering future executive compensation arrangements;
- The Committee shall make recommendations to the Board regarding the adoption of new incentive compensation plans and equity-based plans and administer the Company's existing incentive compensation plans and equity-based plans, including reviewing and approving stock option grants. To the extent permitted by applicable law and the provisions of a given equity-based plan, and consistent with the requirements of applicable law and such equity-based plan, the Committee may delegate to one or more executive officers of the Company the power to grant options or other stock awards pursuant to such equity-based plan to employees of the Company or any subsidiary of the Company who are not directors or executive officers of the Company;
- The Committee shall have authority to adopt, amend or terminate compensation plans applicable to any class of employees of the Company and/or any subsidiary of the Company;
- The Committee shall consider and take actions with respect to the adoption, amendment, administration and termination of compensation, welfare, benefit, pension and other plans related to compensation of employees of the Company, in each case taking into account appropriate industry benchmarks and, as appropriate, the compensation policies pursued by companies similarly situated to the Company;
- The Committee shall establish and review the Company's policies concerning perquisites provided to the Company's executive officers, including benefits provided upon retirement or other termination of employment;
- The Committee shall review and recommend to the Board the frequency with which the Company will conduct Say on Pay Votes, taking into account, among other things, the results of the most recent stockholder advisory vote on frequency of Say on Pay Votes required by Section 14A of the Exchange Act;
- The Committee may, in its sole discretion, retain or obtain the advice of any compensation consultants, legal counsel or other advisers;
- The Committee shall be directly responsible for the appointment, compensation and oversight of the work of any compensation consultant, legal counsel and other adviser retained by the Committee;
  The Company must provide for appropriate funding, as determined by the Committee, for payment of reasonable compensation to a compensation consultant, legal counsel or any other adviser retained by the Committee;
- The Committee may select, or receive advice from, a compensation consultant, legal counsel or other adviser to the Committee, other than in-house legal counsel, only after taking into consideration the following factors:
  - the provision of other services to the Company by the person that employs the compensation consultant, legal counsel or other adviser;
  - the amount of fees received from the Company by the person that employs the compensation consultant, legal counsel or other adviser, as a percentage of the total revenue of the person that employs the compensation consultant, legal counsel or other adviser;

  - the policies and procedures of the person that employs the compensation consultant, legal counsel or other adviser that are designed to prevent conflicts of interest;
  - any business or personal relationship of the compensation consultant, legal counsel or other adviser with a member of the Committee;
  - any stock of the Company owned by the compensation consultant, legal counsel or other adviser; and
  - any business or personal relationship of the compensation consultant, legal counsel, other adviser or the person employing the adviser with an executive officer of the Company.

- The Committee shall, not less than annually, review and assess the adequacy of this charter and submit any changes to the Board for approval;
- The Committee shall, not less than annually, perform an evaluation of the performance of the Committee and report to the Board on the results of such evaluation; and
- The Committee shall review such other matters as the Board or the Committee shall deem appropriate.

Membership

The Committee shall be composed of at least three directors, at least two of which shall satisfy the independence and eligibility requirements of the Nasdaq Stock Market and be appointed by the Board on the recommendation of the Corporate Governance and Nominating Committee. In addition, at least two members of the Committee shall qualify as "outside directors" within the meaning of Section 162(m) of the Internal Revenue Code, as amended, and shall be a "nonemployee director" within the meaning of Rule 16b-3 under the Exchange Act. Subject to applicable law and regulations, if the Committee consists of three or more members, the Board may appoint, for a period not to exceed two (2) years, one or more members who do not meet the independence requirements of the Nasdaq Stock Market and as otherwise set forth above and who is not a current employee of the Company or an immediate family member of such employee if the Board, under exceptional and limited circumstances, determines that membership on the Committee by the

individual or individuals is required in the best interests of the Company and its shareholders. The Board shall disclose in the next proxy statement after such determination the nature of the relationship and the reasons for the determination.

In order to fulfill its role, the Committee shall be organized and governed in the following manner:

- Committee members will be appointed and removed by the Board on the recommendation of the Corporate Governance and Nominating Committee;
- Action may be taken by the Committee (or any subcommittee of the Committee) upon the affirmative vote of a majority of the members of the Committee (or subcommittee) provided, however, at any time the Committee consists of two members, if one member recuses himself or herself due to a potential conflict of interest, action may be taken by the other member;
- Any member of the Committee may call a meeting of the Committee upon due notice to each other member at least twenty-four hours prior to the meeting (provided that participation in any meeting shall be deemed to constitute waiver of any deficiency in such notice);
- Action may be taken by the Committee without a meeting if all of the members of the Committee indicate their approval thereof in writing or electronic submission; and
- The Committee shall have the authority to delegate to subcommittees of the Committee any of the responsibilities of the full Committee.

Adopted March 25, 2016
To be amended May 2016 following expected corporate name change to Protagenic Therapeutics, Inc.

Amended March 7, 2017

Exhibit 99.3

Charter of the Corporate Governance and Nominating Committee of the Board of Directors of Protagenic Therapeutics, Inc. (the "Company")

Function

The Corporate Governance and Nominating Committee (the "Committee") shall, among other things, review and recommend policies to the Board of Directors of the Company (the "Board") regarding Board procedures, Board leadership, the process for annual evaluations of the performance of the Board, the Chairman of the Board, the Executive Chairman, and/or the Chief Executive Officer and issues of corporate public responsibility, including charitable contributions; evaluate the independence of Board members and serve as the Company's nominating committee to review the requisite skills and criteria for new Board members as well as the composition of the Board as a whole, recommend a slate of director nominees to be proposed by the Board to the Company's stockholders, recommend any director nominees to be elected by the Board to fill interim vacancies and recommend directors for membership on the Board committees. If a director believes that a significant issue exists that implicates corporate governance at the Company, that director should promptly bring such issue directly to the attention of the Committee; absent unusual circumstances, discussion with the Committee should occur prior to raising the matter with other directors or members of management.

Organization and Governance

The Committee shall consist of not less than two members appointed by the Board at the recommendation of the Committee who may or may not satisfy the independence and eligibility requirements of the Nasdaq Stock Market.

In order to fulfill its role, the Committee shall be organized and governed in the following manner:

- Committee members will be appointed and removed, with or without cause, by the Board;
- Action may be taken by the Committee (or any subcommittee of the Committee) upon the affirmative vote of a majority of the members of the Committee (or subcommittee); provided, however, at any time the Committee consists of two members, if one member recuses himself or herself due to a potential conflict of interest, action may be taken by the other member;
- Any member of the Committee may call a meeting of the Committee upon due notice to each other member at least twenty-four hours prior to the meeting (provided that participation in any meeting shall be deemed to constitute waiver of any deficiency in such notice);
- Action may be taken by the Committee without a meeting if all of the members of the Committee indicate their approval thereof in writing or by electronic transmission; and
- The Committee shall have the authority to delegate to subcommittees of the Committee any responsibilities of the full Committee.

Management Oversight

The Committee shall oversee the development and presentation to the Board of management's plans for succession to senior management positions in the Company, including the position of Chief Executive Officer.

Other

The Committee shall:

- Periodically review and assess the adequacy of this charter and submit any changes to the Board for approval;
- Periodically perform an evaluation of the performance of the Committee and report to the Board on the results of such evaluation;
- Periodically evaluate the Company's Code of Business Conduct and Ethics (including the Company's Policy Statement on Insider Trading and Disclosure by Company Personnel, Directors and Executive Officers) and, if appropriate, recommend changes thereto; and
- Review such other matters as the Board or the Committee shall deem appropriate.

Powers of the Corporate Governance and Nominating Committee

In order to fulfill its role, the Committee shall have the authority to retain and terminate a search firm to assist in the identification of director candidates, and have the authority to approve the search firm's fees and other retention terms. The Committee shall also have the authority to obtain advice and assistance from internal or external legal, accounting or other advisors and to authorize payment of such advisors with Company funds.

Adopted March 25, 2016
To be amended May 2016 following expected corporate name change to Protagenic Therapeutics, Inc.

Amended March 7, 2017
