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, 2020

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
N/A	N/A

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, 2020, based on a closing price as reported on the OTCQB of $1.17 was approximately $12,005,860.

As of March 17, 2021, there were 10,521,506 shares of the registrant's common stock, par value $0.0001, issued and outstanding, and 872,766 shares of the registrant's Series B Preferred Stock, par value $0.000001, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

PROTAGENIC THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2020
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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

- 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.
- 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

- Our common stock is a “Penny Stock” subject to specific rules governing its sale to investors that could impact its liquidity.
- There is no recent trading activity in our common stock and there is no assurance that an active market will develop in the future.
- Our ability to list on Nasdaq will require raising significant capital; failure to qualify to trade on Nasdaq will make it more difficult to raise capital.
- 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. 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 by midyear 2021.

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 anticipate submitting an investigational new drug (IND) application in early 2021 to evaluate the safety, tolerability, and early activity of PT100114 (TCAP) in healthy volunteers and patients with psychiatric illnesses. 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, with ~7.2% of individuals age 12 or over having a diagnosable SUD in 2017, translating to ~20 million people in the United States. 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. This resulted in an increase in heroin-related overdose deaths, with ~15,000 in the US in 2018. Approximately 65% of people who primarily use heroin have been reported to additionally use prescription opioids and heroin use is increasing for persons who begin by first having nonmedical use/abuse of prescription opioid analgesics. These prescription opioids can be obtained from a relative, friend or directly from a clinician. In 2015, 3.8 million people aged 12 and older in the US reported past month misuse of a prescription pain medication, 2 million of whom qualified for a disorder of opioid use or dependence.

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.

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.

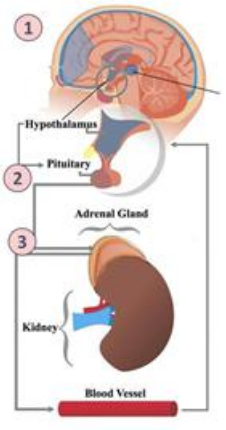
AUD is responsible for significant mortality and morbidity. Excessive alcohol consumption is the third leading preventable cause of death in the United States directly causing approximately 85,000 deaths per year, roughly 10% of deaths among working age adults. Nearly 5% of all deaths worldwide (approximately 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 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.

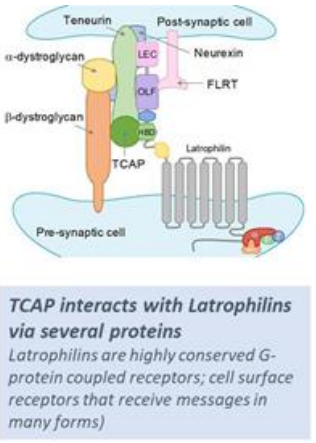
Several medications can be used to treat AUD, which can lead to reduced heavy drinking and increased days of abstinence. For most patients treated with moderate to severe alcohol use disorder, guidelines recommend first-line treatment with naltrexone (e.g. Vivitrol), an opioid antagonist. Vivitrol is 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).

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)

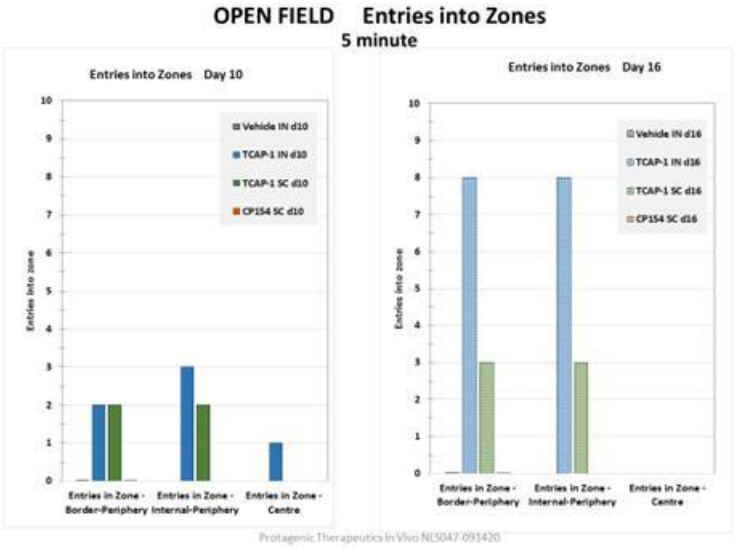
Two key effects of TCAP may contribute to its pharmacological activity in reversing or preventing stress-induced behavioral distortions. In settings of stress and depression, the activity of specific neural circuits can be diminished compared to the levels of activity observed in healthy brain tissue. 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.

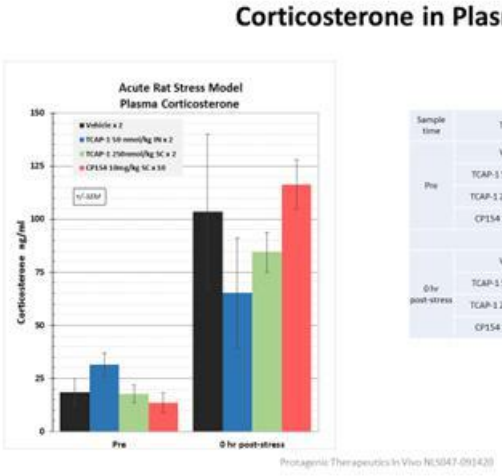
Our lead compound is a 41-residue peptide synthetic TCAP-1, which we have designated PT00114. In addition, we have a portfolio of earlier stage neuropeptides targeting the TCAP pathway that are in preclinical evaluation. The initial dosage form is intended as a subcutaneous injection but is also amenable 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	34	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, 2016 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 enter the clinic in 2021, we anticipate working with 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 15, 2020, 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 8 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 15, 2020, 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	1702638.6	07/21/2020	2543996	ISSUED
UNITED STATES	01/17/2017	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	03/25/2019	16/336,334			PENDING
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	04/10/2020	16/755,372			PENDING
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	09/11/2020	3,093,841			PENDING
UNITED STATES		16/980,176			PENDING
EUROPE	10/12/2020	19712494.4			PENDING

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

COVID-19

On March 11, 2020, the World Health Organization ("WHO") declared the Covid-19 outbreak to be a global pandemic. In addition to the devastating effects on human life, the pandemic is having a negative ripple effect on the global economy, leading to disruptions and volatility in the global financial markets. Most U.S. states and many countries have issued policies intended to stop or slow the further spread of the disease. Covid-19 and the U.S. response to the pandemic are significantly affecting the economy. There are no comparable events that provide guidance as to the effect the Covid-19 pandemic may have, and, as a result, the ultimate effect of the pandemic is highly uncertain and subject to change. We do not yet know the full extent of the effects on the economy, the markets we serve, our business, or our operations.

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, 2020 and 2019 of $16,830 and $23,014, 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, 2020, the Company had incurred significant operating losses since inception, and continues to generate losses from operations, and has an accumulated deficit of $17,698,936. These matters raise substantial doubt about the Company's ability to continue as a going concern. 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 $2,548,735 and $1,750,911 for the years ended December 31, 2020 and December 31, 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $17,698,936. 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 second 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, 2020, we have incurred an accumulated deficit of $17,698,936. 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 could adversely impact our business, including our clinical trials, and financial condition.

We are subject to risks related to public health crises such as the global pandemic associated with Covid-19. In December 2019, a novel strain of coronavirus, was reported to have surfaced in Wuhan, China. Since then, Covid-19 has spread to most countries and all 50 states within the United States, including countries and states in which

we have planned or active clinical trial sites. As Covid-19 continues to spread around the globe, we have and/or will likely experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire Covid-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving authorizations from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- changes in local regulations as part of a response to the Covid-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruptions or delays in preclinical studies due to restricted or limited operations at our research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of Covid-19. Starting in mid-March 2020, the governor of New York, where our corporate operations are based, issued "shelter-in-place" or "stay at home" orders restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Similar orders and restrictions have been imposed in California and Massachusetts, and such orders or restrictions have resulted in our office closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. In addition, even after the "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of Covid-19 are lifted, we may continue to experience disruptions to our business.

The global pandemic of Covid-19 continues to rapidly evolve. The extent to which Covid-19 may impact our business, including our clinical trials, and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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 15, 2020, 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 eight 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

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.

There is no recent trading activity in our common stock and there is no assurance that an active market will develop in the future.

Although our common stock is currently quoted on the OTCQB (an interdealer electronic quotation system operated by OTC Markets Group, Inc.) under the symbol "PTIX", trading of our common stock may be extremely sporadic. For example, several days may pass before any shares may be traded. As a result, an investor may find it difficult to dispose of, or to obtain accurate quotations of the price of our common stock. There can be no assurance that a more active market for our common stock will develop, or if one should develop, there is no assurance that it will be sustained. This severely limits the liquidity of our common stock, and would likely have a material adverse effect on the market price of our common stock and on our ability to raise additional capital.

Our ability to list on Nasdaq will require raising significant capital; failure to qualify to trade on Nasdaq will make it more difficult to raise capital.

We have applied to list our common stock on The Nasdaq Capital Market ("Nasdaq"), a national securities exchange. If we are listed on Nasdaq, we will need to raise significant additional funding in the coming months to start our clinical trial programs. We believe that if our stock is trading on Nasdaq's Capital Market it will enable better access to capital. Nasdaq has listing requirements for inclusion of securities for trading on the Nasdaq Capital Market, including stockholders equity of $4 million (market value standard) or $5 million (equity standard), market value of publicly held shares of $15 million, an operating history of 2 years under the equity standard or a market value of listed securities of $50 million under the market value standard, 1 million publicly held shares, 300 shareholders, three market makers and a $4 bid price or a closing price of $3 (equity standard) or $2 (market value standard). If we are unable to maintain our listing on Nasdaq, it could make it harder for us to raise capital in both the immediate time frame and in the long-term. If we are unable to raise capital when needed in the future, we may have to cease or reduce operations. There can be no assurance that we will be successful in including our common

stock for trading on Nasdaq, maintain the listing or that a market will develop for our common stock.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.

If after qualifying for initial listing on Nasdaq, we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, the Nasdaq Stock Market may take steps to de-list our common stock. Such a de-listing or the announcement of such de-listing will have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with the Nasdaq listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the Nasdaq listing requirements.

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, 2020, 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 OTCQB. 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, 2020, 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 OTCQB 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 OTC Markets, 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
2019(1)		
First Quarter **(1)**	$ 2.30	$ 2.00
Second Quarter **(1)**	$ 2.00	$ 1.50
Third Quarter **(1)**	$ 1.50	$ 1.40
Fourth Quarter **(1)**	$ 3.80	$ 1.40
2020(1)		
First Quarter **(1)**	$ 1.72	$ 1.16
Second Quarter **(1)**	$ 2.00	$ 1.15
Third Quarter **(1)**	$ 2.00	$ 1.17
Fourth Quarter **(1)**	$ 1.22	$ 1.05

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

Holders

As of March 17, 2021, there are approximately 331 record holders of our common stock and three 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

2019-2020 Convertible Note Offering

From November 21, 2019 through July 8, 2020, Protagenic Therapeutics, Inc. (the "Company") entered into a Convertible Note Purchase Agreement ("Purchase Agreement") with accredited investors (the "Investors"), pursuant to which the Company issued and sold unsecured convertible promissory notes (collectively, the "Notes") to the Investors in the aggregate principal amount of $1,570,000 (the "Convertible Note Offering"), as reported in Current Reports on Form 8-K filed on November 21, 2019, December 4, 2019, December 23, 2019, January 29, 2020, March 3, 2020, May 14, 2020, and July 8, 2020.

On August 11, 2020, the Company notified investors in a conference call that it was re-opening the convertible note financing, with identical terms to the previous round, except for the closing date, which has now been set at Friday, August 21st, at 5:00 pm.

On August 28, 2020, the "Company" entered into a Convertible Note Purchase Agreement with certain accredited investors, pursuant to which the Company issued and sold unsecured convertible promissory notes to the Investors in the aggregate principal amount of $427,500.

For both sets of Notes, the Notes will be due on November 6, 2023 (the "Maturity Date") and accrue simple interest at an annual rate of 6% on the aggregate unconverted and outstanding principal amount, payable annually, beginning October 31, 2020. The Notes have the same Maturity Date and interest rate as the set of convertible notes with an aggregate principal amount of $1,570,000 that the Company previously issued and reported in the Current Reports on Form 8-K filed respectively on November 21, 2019, December 4, 2019, December 23, 2019, January 29, 2020, March 3, 2020, May 14, 2020, and July 8, 2020. The Company will pay (a "PIK Payment") the interest due by adding such interest (including interest at the Default Rate, as defined below, if any) to the then-outstanding principal amount of the Notes on each interest payment date and on the Maturity Date. Each PIK Payment will be preceded by written notice from the Company to each holder of the Notes setting forth in reasonable detail the amount of such PIK Payment and the principal amount of the Notes following such PIK Payment. The Notes will bear interest at the rate of 12% per year (the "Default Rate") following a Default (as defined below).

Holders may convert their Notes (including accrued interest) at their option, in whole or in part, at any time prior to the Maturity Date, at a conversion price (the "Conversion Price") of $1.25 per share of the Company's common stock, par value $0.0001 per share. The Conversion Price is subject to adjustment for any stock dividend, stock split, combination or other similar recapitalization event. On the Maturity Date, the Company is required to repay the Notes (including accrued interest) in their entirety in cash or, at its option, in shares of common stock at the Conversion Price.

The Company may redeem for cash or shares of common stock all or any portion of the Notes, at its option, on or after November 5, 2021 if the last reported sale price of its common stock has been at least 120% of the Conversion Price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which it provides notice of redemption. The redemption will be effected at a redemption price equal to 100% of the outstanding principal amount of the Notes to be redeemed, plus accrued and unpaid interest up to, but excluding, the redemption date. Any such redemption

must be applied ratably among all Convertible Notes in proportion to their respective outstanding principal balances, plus accrued and unpaid interest. Other than pursuant to this redemption right, the Company may not pre-pay the Notes.

Item 6. Selected Financial Data.

Not applicable.

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, 2020, we incurred a loss from operations of $2,551,611 as compared to $2,086,130 for the year ended December 31, 2019. The increase in the loss is due to a decrease in research and development expense of $108,150 from $807,947 for the year ended December 31, 2019 to $699,797 for the year ended December 31, 2020, and an increase in general and administrative expenses of $573,631 from $1,278,183 for the year ended December 31, 2019 to $1,851,814 or the year ended December 31, 2020 due to an increase in stock compensation expense.

Liquidity and Going Concern

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, 2020, we had cash of $671,091 and working capital of $224,060. The Company currently has a derivative liability on the books in the amount of $83,670 and we don't expect to settle this liability in cash. Removing the derivative liability from the working capital calculation would increase our working capital to $307,730. We anticipate further losses in the development of our business. Based on its current forecast and budget, Management believes that its cash resources will be sufficient to fund its operations at least until the end of the third quarter of 2021. Absent generation of sufficient revenue from the execution of the Company's business plan, it will need to obtain debt or equity financing by the third quarter of 2021.

Operating activities used $1,348,779 and $487,990 in cash for the years ended December 31, 2020 and 2019, respectively. The use of cash in operating activities during the year ended December 31, 2020, primarily comprised of $2,548,735 net loss, $1,654,754 in stock compensation expense, ($248,552) of change in the fair value of the derivative liability since December 31, 2019, a decrease in prepaid expenses of $164,802, amortization of debt discount of $154,899, and a ($196,629) decrease of accounts payable and accrued expenses, which included payments to tax penalties, legal and accounting professionals, payments to consultants, and other administrative expenses.

Investing activities provided $0 and $250,000 in cash for the years ended December 31, 2020 and 2019, respectively. The cash provided by investing activities during the year ended December 31, 2019 consisted of $250,000 from the sale of marketable securities.

Financing activities provided $1,223,410 and $670,000 in cash for the years ended December 31, 2020 and 2019, respectively. The cash provided by financing consisted of $1,177,500 in proceeds from convertible notes, $150,000 in proceeds from convertible notes from related parties, and ($104,090) in payment of debt issuance costs of convertible notes for the year ended December 31, 2020. The cash provided by financing consisted of $420,000 in proceeds from convertible notes and $250,000 in proceeds from convertible notes from related parties for the year ended December 31, 2019.

Contractual Obligations

The following table sets forth certain information concerning the future contractual obligations under our convertible notes at December 31, 2020.

	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	$ 1,597,500	$ -	$ -	$ 1,597,500	$ -
Long-Term PIK convertible notes payable– Related Party	$ 400,000	$ -	$ -	$ 400,000	$ -

Total	$	1,997,500	$	-	$	-	$	1,997,500	$	-

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.

We anticipate $4,225,000 in capital expenditures in FY 2021 to implement our current plan of operations in connection with the development of PT00114.

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 2024.

Development Milestones (upcoming developmental milestones)

Upcoming development milestones include confirming efficacy of our lead drug candidate in an animal model in a CRO, conducting toxicology testing in two animal species, and filing an IND application to begin human clinical trials.

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. 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 – Capital Needs

In addition to the working capital being generated via the Convertible Note Offering, the Company anticipates that it will need to raise additional capital in the next year or so to support its research and development activities as it prepares to commence and commences human clinical trials. The Company does not have any commitments for such additional capital.

Over the next three years, we currently anticipate capital expenditures of $4,225,00 in 2021, $6,278,000 in 2022, and $12,215,000 in 2023. These expenditures are anticipated to be focused on conducting research and development activities in connection with our lead drug candidate as well as other potential drug candidates.

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.

We believe the critical accounting policies listed below reflect significant judgments, estimates and assumptions used in the preparation of our consolidated financial statements.

Foreign Currency Translation and Transactions. The assets and liabilities of our foreign subsidiary PTI Canada are translated into U.S. dollars from the functional currency using the exchange rate in effect at the balance sheets date. Additionally, the accounts on the statements of operations are translated using exchange rates approximating average rates prevailing during the years. Equity accounts are translated at historical exchange rates. Translation adjustments that arise from translating its financial statements from the local currency to the U.S. dollar are accumulated and reflected as a separate component of stockholders' equity (deficit). The current year effects of the transaction adjustments are included on the statement of operations as a realized gain (loss) on foreign transaction exchange.

Use of Estimates. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses as well as the disclosure of contingent assets and liabilities. Management continually evaluates its estimates and judgments including those related to accruals, contingencies, valuation allowance for deferred tax assets, and valuation of stock options and warrants. Management bases its estimates and judgments on historical experience and other factors that are believed to be reasonable in the circumstances. Actual results may differ from those estimates. Macroeconomic conditions may directly, or indirectly through our business partners and vendors, impact our financial performance and available resources. Such conditions may, in turn, impact the aforementioned estimates and assumptions.

Fair Value Measurements. Accounting Standards Codification 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.

Derivative Liability. The Company evaluates its options, warrants or other contracts, if any, to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC 815-10-05-4 and 815-40-25. The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market each balance sheet date and recorded as either an asset or a liability. In the event that the fair value is recorded as a liability, the change in fair value is recorded in the consolidated statement of operations as other income or expense. Upon conversion, exercise or cancellation of a derivative instrument, the instrument is marked to fair value at the date of conversion, exercise or cancellation and then the related fair value is reclassified to equity.

The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities will be classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within 12 months of the balance sheet date.

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. Potentially dilutive securities consisting of options, warrants, and convertible notes aggregating 11,085,039 as of December 31, 2020, including common shares issuable under the conversion feature of the preferred shares, options, $1,997,500 worth of convertible Notes, which could convert into 1,598,000 shares of common stock, and warrants issued in the Private Offering and Convertible Note Offering closings and merger transactions were not included in the calculation of weighted-average shares of common stock outstanding as they were determined to be anti-dilutive.

COVID-19

On March 11, 2020, the World Health Organization ("WHO") declared the Covid-19 outbreak to be a global pandemic. In addition to the devastating effects on human life, the pandemic is having a negative ripple effect on the global economy, leading to disruptions and volatility in the global financial markets. Most U.S. states and many countries have issued policies intended to stop or slow the further spread of the disease. Covid-19 and the U.S. response to the pandemic are significantly affecting the economy. There are no comparable events that provide guidance as to the effect the Covid-19 pandemic may have, and, as a result, the ultimate effect of the pandemic is highly uncertain and subject to change. We do not yet know the full extent of the effects on the economy, the markets we serve, our business, or our operations.

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, 2020, 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. Lack of Segregation of Duties; Management is aware that there is a lack of segregation of accounting duties as a result of limited personnel.
2. Limited level of multiple reviews in connection with the financial reporting process.

During the quarter ended December 31, 2020, 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.

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

There were no changes in our internal control 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, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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	68	Executive Chairman of the Board of Directors
Alexander K. Arrow	50	Chief Financial Officer
Robert B. Stein	70	Director, Chief Medical Officer
Andrew Slee	71	Chief Operating Officer
Khalil Barrage	56	Director
Josh Silverman	50	Director
Brian Corvese	63	Director
Jennifer Buell	46	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 complex 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 subsidiary AgenTus. 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.

Joshua Silverman, Director, Mr. Silverman currently serves as the managing member of Parkfield Funding LLC. Mr. Silverman was the co-founder, and a principal and managing partner of Iroquois Capital Management, LLC ("Iroquois"), an investment advisory firm. Since its inception in 2003 until July 2016, Mr. Silverman served as co-chief investment officer of Iroquois. While at Iroquois, he designed and executed complex transactions, structuring and negotiating investments in both public and private companies and has often been called upon by the companies solve inefficiencies as they relate to corporate structure, cash flow, and management. From 2000 to 2003, Mr. Silverman served as co-chief investment officer of Vertical Ventures, LLC, a merchant bank. Prior to forming Iroquois, Mr. Silverman was a director of Joele Frank, a boutique consulting firm specializing in mergers and acquisitions. Previously, Mr. Silverman served as assistant press secretary to the president of the United States. Mr. Silverman currently serves as a director of Akers Biosciences, Inc., AYRO, Inc., Protagenic Therapeutics, Petros Pharmaceuticals, Inc. and Synaptogenix, Inc. all of which are public companies. He previously served as a director of National Holdings Corporation from July 2014 through August 2016 and as a director of Marker Therapeutics, Inc. from August 2016 until October 2018. Mr. Silverman received his B.A. from Lehigh University in 1992.

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. 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 Zack 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.

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).

Voting Agreement

On February 12, 2016, the Company and certain of its stockholders (currently representing approximately 43% of the Company's issued and outstanding common stock), including Messrs. Armen, Arrow and Ekizian and 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 Mr. Garo (so long as Mr. Garo 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) 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 Silverman 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. Silverman (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), Armen and Mr. Silverman 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, 2020 and 2019.

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,	2020	0	0	0	$ 411,185(1)	0	0	0	$ 411,185
Chairman	2019	0	0	0	$ 0	0	0	0	$ 0
Alexander K. Arrow,	2020	$ 38,462	$ 0	$ 0	$ 564,067(2)	$ 0	$ 0	0	$ 602,529
Chief Financial Officer	2019	$ 9,094	$ 0	$ 0	$ 81,977(2)	$ 0	$ 0	0	$ 91,071

(1) We use the Black-Scholes option pricing model to value the options granted. On February 13, 2020, Dr. Armen was granted 300,000 options (exercise price of $1.75/option) under the 2016 Equity Compensation Plan.

(2) We use the Black-Scholes option pricing model to value the options granted. On February 1, 2019, Dr. Arrow was granted 41,667 options (exercise price of $1.75/option) under the 2016 Equity Compensation Plan in lieu of two months cash salary. On February 13, 2020, Dr. Arrow was granted 120,000 options (exercise price $1.75/option) under the 2016 Equity Compensation Plan. On February 13, 2020, he was granted 187,497 options (exercise price of $1.75/option) in lieu of nine months of cash salary. On July 18, 2020, he was granted 124,998 options (exercise price $1.75/option) in lieu of six months of cash salary.

Employment Arrangements with Officers and Directors

Dr. Alexander Arrow, our Chief Financial Officer, receives base compensation of $125,000 per year for his part-time work for us, except for an 18-month period from February 2019 through August 2020 during which he received zero cash salary and three grants totaling 354,162 options in lieu of cash salary. From 2016 through 2020, cumulatively, Dr. Arrow received 100,000 options under the 2006 Plan and three grants totaling 335,000 incentive options in the aggregate under the 2016 plan with exercise prices of $1.25 and $1.75 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) 100,000 options on April 15, 2016, at an exercise price of $1.25 per option, (ii) 75,000 options on October 16, 2017, at an exercise price of $1.75 per option, (iii) 75,000 options on July 18, 2020, at an exercise price of $1.25 per option, and (iv) 150,000 options on February 13, 2020, at an exercise price of $1.75 per option.

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 10,000 shares of our common stock and ten-year options to purchase 150,000 shares of our common stock. Options to purchase 100,000 shares of common stock, at an exercise price of $1.00 per share, have fully vested; the options to purchase the remaining 50,000 shares of common stock, at an exercise price of $1.25 per share, vested in March 2016. On October 16, 2017, we granted Dr. Barsyte another ten-year option to purchase 20,000 shares of our common stock at an exercise price of $1.75 per share. On February 13, 2020, we granted Dr. Barsyte ten-year option to purchase 10,000 shares of our common stock at an exercise price of $1.75 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 200,000 shares of our common stock, at an exercise price of $1.25 per share (the "January Options"). The January Options are fully vested. We granted Dr. Stein (i) 40,000 options on April 15, 2016, at an exercise price of $1.25 per option, (ii) 200,000 options on October 16, 2017, at an exercise price of $1.75 per option, and (iii) 150,000 options on February 13, 2020, at an exercise price of $1.25 per option, bringing Dr. Stein's total to 590,000 options.

Director Compensation

During fiscal year 2020 we issued 45,000 options with an exercise price of $1.75 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 40,000 shares of common stock, as well as an option to purchase 5,000 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 150,000 options on February 13, 2020, at an exercise price of $1.25 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	10,477,685	$ 1.27	1,122,918
Equity compensation plans not approved by security holders	0	0	0
Total	10,477,685	$ 1.27	1,122,918

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 3,000,000 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 6,000,000 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 564,378 shares of common stock were added to the 2016 Plan pursuant to this evergreen provision.

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 1,000,000 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 1,000,000 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, 2020, we had outstanding stock options to purchase 5,597,861 shares at an average exercise price of approximately $1.34 per share. Included in the total outstanding stock options were 0 stock options granted under the 2006 Plan in 2020 and 1,762,495 nonqualified stock options granted under the 2016 Plan in 2020 to our executive officers and others at an exercise price of $1.75 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, 2020.

	No. of Securities Underlying Unexercised	No. of Securities Underlying Unexercised	Option	Option

Name	Options (#) Exercisable	Options (#) Unexercisable	Exercise Price	Expiration Date
Garo H. Armen (1)	500,000	-	$ 1.25	April 15, 2026
Garo H. Armen (2)	250,000	-	$ 1.75	October 16, 2027
Garo H. Armen (3)	300,000	-	$ 1.75	February 13, 2030
Alexander K. Arrow (4)	100,000	-	$ 1.25	February 12, 2026
Alexander K. Arrow (4)	140,000	-	$ 1.25	April 15, 2026
Alexander K. Arrow (5)	75,000	-	$ 1.75	October 16, 2027
Alexander K. Arrow (6)	41,667	-	$ 1.00	February 1, 2029
Alexander K. Arrow (7)	120,000	-	$ 1.75	February 13, 2030
Alexander K. Arrow (8)	187,497	-	$ 1.75	February 13, 2030
Alexander K. Arrow (9)	124,998	-	$ 1.75	July 18, 2030
Andrew Slee (10)	100,000	-	$ 1.25	April 15, 2026
Andrew Slee (11)	75,000	-	$ 1.75	October 16, 2027
Andrew Slee (12)	150,000	-	$ 1.75	February 13, 2030
Andrew Slee (13)	75,000	-	$ 1.25	July 18, 2030
Robert B. Stein (14)	200,000	-	$ 1.25	January 22, 2025
Robert B. Stein (15)	40,000	-	$ 1.25	April 15, 2026
Robert B. Stein (16)	200,000	-	$ 1.75	October 16, 2027
Robert B. Stein (17)	150,000	-	$ 1.75	February 13, 2030

(1) Dr. Armen was granted a 500,000 share option grant on April 15, 2016

(2) Dr. Armen was granted a 250,000 share option grant on October 16, 2017.

(3) Dr. Armen was granted a 300,000 share option grant on February 13, 2020.

(4) Dr. Arrow was granted a 100,000 share option grant on February 12, 2016, and a 140,000 share option grant on April 15, 2016

(5) Dr. Arrow was granted a 75,000 share option grant on October 16, 2017.

(6) Dr. Arrow was granted a 41,667 share option grant on February 1, 2019.

(7) Dr. Arrow was granted a 120,000 share option grant on February 13, 2020.

(8) Dr. Arrow was granted a 187,497 share option grant on February 13, 2020.

(9) Dr. Arrow was granted a 124,998 share option grant on July 18, 2020.

(10) Dr. Slee was granted a 100,000 shares option grant on April 15, 2016.

(11) Dr. Slee was granted a 75,000 shares option grant on October 16, 2017.

(12) Dr. Slee was granted a 150,000 shares option grant on February 13, 2020.

(13) Dr. Slee was granted a 75,000 shares option grant on July 18, 2020.

(14) Dr. Stein was granted a 200,000 shares option grant on January 22, 2015.

(15) Dr. Stein was granted a 40,000 shares option grant on April 15, 2016.

(16) Dr. Stein was granted a 200,000 shares option grant on October 16, 2017.

(17) Dr. Stein was granted a 150,000 shares option grant on February 13, 2020.

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 17, 2021, 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)	4,832,295(2)	35%
Robert B. Stein(1)	590,000(3)	5%
Khalil Barrage(1)	570,000(4)	5%
Alexander K. Arrow(1)	830,755(5)	7%
Larry N. Feinberg	800,000(6)	7%
Brian J. Corvese(1)	215,000(7)	2%
David A. Lovejoy	680,745(8)	6%
Josh Silverman(1)	210,000(9)	2%
Jennifer Buell(1)	40,833(10)	0%
Andrew Slee(1)	216,406(11)	2%
Hudson Bay Master Fund	949,530(12)	8%
Iroquois Master Fund	832,755	7%
All directors and executive officers as a group (8 persons)	7,505,289(13)	46%

* 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 1,253,367 shares of common stock at an exercise price of approximately $1.00 per share. Includes 2,296,012 shares held in the name of Dr. Armen and 250,000 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 872,916 shares of common stock at an exercise price of $1.25 or $1.75 per share. Does not include options to purchase 177,084 shares that are not exercisable within 60 days of the date of this report. Also includes convertible note of $200,000 that converts at $1.25 per share for a total of 160,000 shares of common stock.

(3) Represents options to purchase 590,000 shares of common stock at an exercise price of $1.25 or $1.75 per share.

(4) Includes 50,000 shares of common stock and options to purchase 360,000 shares of common stock at an exercise price of $1.25 or $1.75 per share. Also includes convertible note of $200,000 that converts at $1.25 per share for a total of 160,000 shares of common stock.

(5) Includes 100,000 shares held in the name of Dr. Arrow and 18,260 shares held in the name of the Alexander K. Arrow IRA, as to which Dr. Arrow has sole voting and dispositive power. Also includes options to purchase 712,495 shares of common stock at an exercise price of $1.00, $1.25 or $1.75 per share. Does not include options to purchase 76,667 shares of common stock in the aggregate that are not exercisable within 60 days of the date of this report.

(6) Includes 200,000 shares of common stock held in the name of Mr. Feinberg and warrants to purchase 600,000 shares of common stock at an exercise price of $1.00 per share.

(7) Includes options to purchase 215,000 shares of common stock at an exercise price of $1.75 per share.

(8) Includes 148,800 shares of common stock held in the name of Dr. Lovejoy and options to purchase 531,945 shares of common stock in the aggregate with an exercise price ranging from $1.00 to $1.75 per share. Does not include options to purchase 21,354 shares of common stock that are not exercisable within 60 days of the date of this report.

(9) Includes options to purchase 210,000 shares of common stock at an exercise price of $1.25 or $1.75 per share.

(10) Includes options to purchase 40,833 shares of common stock at an exercise price of $1.75 per share. Does not include options to purchase 104,167 shares of common stock that are not exercisable within 60 days of the date of this report.

(11) Includes options to purchase 216,406 shares of common stock at an exercise price of $1.25 or $1.75 per share. Does not include options to purchase 183,594 shares of common stock that are not exercisable within 60 days of the date of this report.

(12) Hudson Bay Master Fund Ltd. (the "Managing Member"). Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of HBC. Each of HBC, the Managing Member and Sander Gerber disclaims beneficial ownership over these securities.

(13) Includes warrants to purchase 1,253,367 shares of common stock and options to purchase 3,217,650 shares of common stock. Also includes convertible notes of $400,000 that converts at $1.25 per share for a total of 320,000 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 25,000 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 $1.75 per share. On February 21, 2020 Mr. Zack Armen was also issued an additional 50,000 stock options that vest over 48 months and are exercisable at a price of $1.75 per share. On July 18, 2020 Mr. Zack Armen was also issued an additional 30,000 stock options that vest over 48 months and are exercisable at a price of $1.75 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, Silverman, 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. Silverman's independent status, the Board considered the fact that he is an ex-CEO of one of the institutional funds (Iroquois Asset Management) owns just under 5% of the Company's common stock. The Board noted that Mr. Silverman is no longer the CEO of Iroquois Asset Management, and as such, he does not represent a major single shareholder.

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.

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, 2020 and 2019.

	Fiscal Year 2020	Fiscal Year 2018
Audit fees	$ 55,800	$ 55,000
Audit-related fees	$ -	$ -
Tax Fees	$ -	$ -
All other fees	$ -	$ -
Total	$ 55,800	$ 55,000

Audit Fees: For the fiscal years ended December 31, 2020 and 2019, 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, 2020 and 2019, there were no tax fees, respectively.

All Other Fees: For the fiscal years ended December 31, 2020 and 2019, 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 2020 and 2019, 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	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.)
4.2(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.)
4.2(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.)
4.3(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.)
4.3(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.)

4.4	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.* **
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.* **
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 *
23.1	Consent of MaloneBailey, LLP*
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)*.
32.1	Section 1350 Certifications †
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]

* 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 25, 2021

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 25, 2021
/s/ Alexander K. Arrow Alexander K. Arrow	Chief Financial Officer (Principal Financial Officer)	March 25, 2021
/s/ Robert B. Stein Robert B. Stein	Director	March 25, 2021
/s/ Khalil Barrage Khalil Barrage	Director	March 25, 2021
/s/ Brian J. Corvese Brian J. Corvese	Director	March 25, 2021
/s/ Joshua Silverman Joshua Silverman	Director	March 25, 2021
/s/ Jennifer Buell Jennifer Buell	Director	March 25, 2021

PROTAGENIC THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED

DECEMBER 31, 2020 AND 2019

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, 2020 and

2019, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' deficit, 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, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 23, 2021

PROTAGENIC THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash	$ 671,091	$ 798,623
Prepaid expenses	208,156	43,354
TOTAL CURRENT ASSETS	879,247	841,977
Equipment - net	-	296
TOTAL ASSETS	$ 879,247	$ 842,273
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	571,517	865,047
Derivative liability	83,670	332,222
TOTAL CURRENT LIABILITIES	655,187	1,197,269
PIK convertible notes payable, net of debt discount	1,081,384	174,821
PIK convertible notes payable, net of debt discount - related parties	292,412	104,549
TOTAL LIABILITIES	2,028,983	1,476,639
STOCKHOLDERS' DEFICIT		
Preferred stock, $0.000001 par value; 20,000,000 shares authorized; 872,766 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;		
872,766 shares issued and outstanding at December 31, 2020, and December 31, 2019	1	1
Common stock, $.0001 par value, 100,000,000 shares authorized, 10,360,480 and 10,261,419 shares issued and		

outstanding at December 31, 2020, and December 31, 2019	1,036	1,026
Additional paid-in-capital	16,719,749	14,687,172
Accumulated deficit	(17,698,936)	(15,150,201)
Accumulated other comprehensive loss	(171,586)	(172,364)
TOTAL STOCKHOLDERS' DEFICIT	(1,149,736)	(634,366)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 879,247	$ 842,273

See accompanying notes to the consolidated financial statements

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

	For the year ended December 31,	
	2020	**2019**
OPERATING AND ADMINISTRATIVE EXPENSES		
Research and development	699,797	807,947
General and administrative	1,851,814	1,278,183
TOTAL OPERATING AND ADMINISTRATIVE EXPENSES	2,551,611	2,086,130
LOSS FROM OPERATIONS	(2,551,611)	(2,086,130)
OTHER (EXPENSE) INCOME		
Interest income	502	2,813
Interest expense	(246,178)	(15,886)
Realized gain on marketable securities	-	4,435
Change in fair value of derivative liability	248,552	343,857
TOTAL OTHER INCOME (EXPENSES)	2,876	335,219
LOSS BEFORE INCOME TAX	(2,548,735)	(1,750,911)
INCOME TAX EXPENSE	-	-
NET LOSS	$ (2,548,735)	$ (1,750,911)
COMPREHENSIVE LOSS		
Other Comprehensive Loss - net of tax		
Foreign exchange translation gain (loss)	778	(6,647)
TOTAL COMPREHENSIVE LOSS	$ (2,547,957)	$ (1,757,558)
Net loss per common share - Basic and Diluted	$ (0.25)	$ (0.17)
Weighted average common shares - Basic and Diluted	10,339,071	10,261,419

See accompanying notes to the consolidated financial statements

PROTAGENIC THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
For the Fiscal Years Ended December 31, 2020 and 2019

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-in-	Accumulated	Treasury Stock		Accumulated Other Comprehensive	Stockholders'
	Shares	Amount	Shares	Amount	Capital	(Deficit)	Shares	Amount	Loss	Deficit)
BALANCE-December 31, 2018	872,766	$ 1	10,261,419	$ 1,026	$ 13,357,920	$ (13,399,290)	-	$ -	$ (170,540)	$ (210,883)
Unrealized gain (loss) on marketable securities	-	-	-	-	-	-	-	-	4,823	4,823
Foreign currency translation gain	-		-	-					(6,647)	(6,647)
Stock compensation - stock options	-	-	-	-	797,761	-		-	-	797,761
Debt discount from beneficial conversion feature	-	-	-	-	402,000	-	-	-	-	402,000
Issuance of options for settlement of accounts payable	-	-	-	-	129,491	-	-	-	-	129,491
Net loss	-	-	-	-	-	(1,750,911)	-	-	-	(1,750,911)

BALANCE - December 31, 2019	872,766	$ 1	10,261,419	$ 1,026	$ 14,687,172	$ (15,150,201)	-	$ -	$ (172,364)	$ (634,366)
Foreign currency translation gain	-	-	-	-	-	-	-	-	778	778
Stock compensation - stock options	-	-	-	-	1,427,084	-	-	-	-	1,427,084
Stock compensation - warrants	-	-	-	-	107,670	-	-	-	-	107,670
Debt discount from beneficial conversion feature	-	-	-	-	104,204	-	-	-	-	104,204
Issuance of options for settlement of accrued payroll	-	-	-	-	93,950	-	-	-	-	93,950
Stock issued for services	-	-	99,061	10	119,990	-	-	-	-	120,000
Debt discount from warrants issued to placement agents	-	-	-	-	179,679	-	-	-	-	179,679
Net loss	-	-	-	-	-	(2,548,735)	-	-	-	(2,548,735)
BALANCE - December 31, 2020	872,766	$ 1	10,360,480	$ 1,036	$ 16,719,749	$ (17,698,936)	-	$ -	$ (171,586)	$ (1,149,736)

See accompanying notes to the consolidated financial statements

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

	For the year ended December 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (2,548,735)	$ (1,750,911)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation expense	286	339
Stock based compensation	1,654,754	797,761
Change in fair value of the derivative liability	(248,552)	(343,857)
Gain on sale of marketable securities	-	(4,435)
Amortization of debt discount	154,899	11,370
Loss on settlement of accounts payable	-	99,541
Changes in operating assets and liabilities		
Prepaid expenses	(164,802)	40,044
Accounts payable and accrued expenses	(196,629)	662,158
NET CASH USED IN OPERATING ACTIVITIES	(1,348,779)	(487,990)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sale of marketable securities	-	250,000
NET CASH PROVIDED BY INVESTING ACTIVITIES	-	250,000
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of debt issuance costs	(104,090)	-
Proceeds from convertible notes	1,177,500	420,000
Proceeds from convertible notes - related party	150,000	250,000
NET CASH PROVIDED BY FINANCING ACTIVITIES	1,223,410	670,000
Effect of exchange rate on cash and cash equivalents	(2,163)	4,127
NET INCREASE (DECREASE) IN CASH	(127,532)	436,137
CASH, BEGINNING OF YEAR	798,623	362,486
CASH, END OF YEAR	$ 671,091	$ 798,623
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Cash paid for interest expense	$ -	$ -
Cash paid for income taxes	$ -	$ -
NONCASH FINANCING AND INVESTING TRANSACTIONS		
Unrealized (gain) loss on marketable securities	$ -	$ 4,823
Debt discount from beneficial conversion feature	$ 104,204	$ 252,000
Debt discount from beneficial conversion feature - related parties	$ -	$ 150,000
Debt discount from warrants issued to placement agents	$ 179,679	$ -
Issuance of options for settlement of accounts payable	$ 93,950	$ 29,950

See accompanying notes to the consolidated financial statements

NOTE 1 – ORGANIZATION AND NATURE OF BUSINESS

Company Background

Protagenic Therapeutics, Inc. ("we," "our," "Protagenic" or "the Company"), 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.

The Company was previously known as Atrinsic, Inc., a company that was once a reporting company under the Securities Exchange Act of 1934, but that, in 2012 and 2013, reorganized under Chapter 11 of the United States Bankruptcy Code and emerged from bankruptcy. On February 12, 2016, the Company acquired Protagenic Therapeutics, Inc. ("Prior Protagenic") through a reverse merger.

On February 12, 2016, Protagenic Acquisition Corp., a wholly-owned subsidiary of the Company, merged (the "Merger") with and into Prior Protagenic. Prior Protagenic was the surviving corporation of the Merger. As a result of the Merger, the Company acquired the business of Prior Protagenic and has continued the existing business operations of Prior Protagenic as a wholly-owned subsidiary. On June 17, 2016, Prior Protagenic merged with and into the Company with the Company as the surviving corporation in the merger. Immediately thereafter, the Company changed its name from Atrinsic, Inc. to Protagenic Therapeutics, Inc.

NOTE 2 - GOING CONCERN

As shown in the accompanying consolidated financial statements, the Company has incurred significant reoccurring losses resulting in an accumulated deficit. The Company anticipates further losses in the development of its business. The Company 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 current forecast and budget, management believes that its cash resources will be sufficient to fund its operations at least until the end of the third quarter of 2021. Absent generation of sufficient revenue from the execution of the Company's business plan and sales revenue is not anticipated before 2024, the Company will need to obtain debt or equity financing by the third quarter of 2021. Management believes that actions presently being taken to obtain additional funding provide the opportunity for the Company to continue as a going concern, however, management cannot be certain that such plans can be achieved. The accompanying financial statements have been prepared assuming the Company will continue as a going concern; no adjustments to the financial statements have been made to account for this uncertainty.

NOTE 3 - SUMMARY OF SIGNFICANT 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 in the consolidated financial statements.

Reclassifications:

Reclassifications of prior periods have been made to conform with current year presentation

Use of estimates

The preparation of 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 income tax provisions, 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. 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. While the Company's marketable securities are cash equivalents it is the Company's policy to present them separately on the balance sheet. As of December 31, 2020 and December 31, 2019, the Company did not have any cash equivalents.

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 nominal for the years ended December 31, 2020 and 2019.

Marketable Securities

The Company accounts for marketable debt securities, the only type of securities it owns, in accordance with sub-topic 320-10 of the FASB Accounting Standards Codification ("Sub-topic 320-10").

Pursuant to Paragraph 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 debt securities (including those classified as current assets) shall be excluded from earnings and reported in other comprehensive income until realized.

During the years ended December 31, 2020 and 2019, the Company purchased $0 and sold $250,000 in marketable securities, respectively.

As of December 31, 2020 and December 31, 2019, the Company owned marketable securities with a total value of $0 and $0, respectively. The Company recorded a realized gain on marketable securities of $0 and $4,435 for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020 and December 31, 2019, the Company held no marketable securities.

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, 2020.

	Carrying Value	Fair Value Measurement Using			
		Level 1	Level 2	Level 3	Total
Derivative warrants liabilities	$ 83,670	$ —	$ —	$ 83,670	$ 83,670

The following table provides a summary of financial instruments that are measured at fair value on a recurring basis as of December 31, 2019.

	Carrying Value	Fair Value Measurement Using			
		Level 1	Level 2	Level 3	Total
Derivative warrants liabilities	$ 332,222	$ —	$ —	$ 332,222	$ 332,222

The table below provides a summary of the changes in fair value, including net transfers in and/or out, of all financial assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the year ended December 31, 2020 and the year ended December 31, 2019:

	Fair Value Measurement Using Level 3 Inputs Total
Balance, December 31, 2018	$ 676,079
Change in fair value of derivative warrants liabilities	(343,857)
Balance, December 31, 2019	$ 332,222
Change in fair value of derivative warrants liabilities	(248,552)
Balance, December 31, 2020	$ 83,670

The fair value of the derivative feature of the 127,346 and 295,945 warrants issued to the placement agent of the Company's 2016 private offering (the "2016 Offering") and to a holder of its debt for debt cancellation in connection with the Merger, respectively on the issuance dates and at the balance sheet dates were calculated using a Black-Scholes option model valued with the following assumptions:

	December 31, 2019	December 31 2020
Exercise price	1.25	1.25
Risk free interest rate	1.59%	0.09%
Dividend yield	0.00%	0.00%
Expected volatility	133%	169%
Contractual term	1.15 Years	0.14 Years

Risk-free interest rate: The Company uses the risk-free interest rate of a U.S. Treasury Note with a similar expected term on the date of measurement.

Dividend yield: The Company uses a 0% expected dividend yield as the Company has not paid dividends to date and does not anticipate declaring dividends in the near future.

Volatility: The Company calculates the expected volatility of the stock price based on the corresponding volatility of the Company's peer group stock price for a period consistent with the warrants' expected term.

Expected term: The Company's expected term is based on the remaining contractual maturity of the warrants.

During the years ended December 31, 2020 and 2019, the Company marked the derivative feature of the warrants to fair value and recorded a gain of $248,552 and a gain of $343,857 relating to the change in fair value, respectively.

Derivative Liability

The Company evaluates its options, warrants or other contracts, if any, to determine if those contracts or embedded components of those contracts qualify as derivatives to be separately accounted for in accordance with ASC 815-10-05-4 and 815-40-25. The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market each balance sheet date and recorded as either an asset or a liability. In the event that the fair value is recorded as a liability, the change in fair value is recorded in the consolidated statements of operations as other income or expense. Upon conversion, exercise or cancellation of a derivative instrument, the instrument is marked to fair value at the date of conversion, exercise or cancellation and then the related fair value is reclassified to equity.

The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. Equity instruments that are initially classified as equity that become subject to reclassification are reclassified to liability at the fair value of the instrument on the reclassification date. Derivative instrument liabilities will be classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is expected within 12 months of the balance sheet date.

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 canceled 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.

	Potentially Outstanding Dilutive Common Shares	
	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Conversion Feature Shares		
Common shares issuable under the conversion feature of preferred shares	872,766	872,766
Stock Options	5,597,861	3,835,366
Warrants	4,007,058	3,826,658
Convertible Notes	1,598,000	536,000
Total potentially outstanding dilutive common shares	12,075,685	9,070,790

Research and Development

Research and development expenses are charged to operations as incurred.

Foreign Currency Translation

The Company follows Section 830-10-45 of the FASB Accounting Standards Codification ("Section 830-10-45") 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. Section 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 Section 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 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 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 consolidated statements of operations and comprehensive income (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.

Leases

In February 2016, FASB issued Accounting Standards Update ("ASU") 2016-02: Leases (Topic 842). The new guidance generally requires an entity to recognize on its balance sheet operating and financing lease liabilities and corresponding right-of-use assets. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The new standard requires a modified retrospective transition for existing leases to each prior reporting period presented or entered into after, the beginning of the earliest comparative period presented in the financial statements. This standard was adopted by the Company on January 1, 2018. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward the historical lease classification. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

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, 2020	December 31, 2019
Accounting	$ 36,161	$ 36,161
Research and development	393,496	650,584
Legal	-	15,273
Other	141,860	163,029
Total	$ 571,517	$ 865,047

On October 1, 2019, the Company entered into an agreement with a consultant for toxicology studies. The consultant quoted a commitment of approximately $988,000 as an estimate for the study. 50% of the total price was paid upon the signing of the agreement, 35% of the total price is to be paid upon completion of the in-life study, and the remaining 15% of the total price is to be paid upon the issuance of the report. If the Company cancels the study the Company will be required to pay a cancelation fee. If the cancelation happens prior to the arrival of the test animals then the Company will need to pay between 20% and 50% of the animal fees depending on when the cancellation happens. If the cancellation occurs after the animals arrive but before the study begins then the Company will be responsible for paying 50% of the protocol price plus a fee of $7,000 per room/week for animal husbandry until the animals can be relocated or disposed of. If the Company cancels the study after it has begun then the Company will need to pay any fees for procured items for the study and any nonrecoverable expenses incurred by the consultant. As of December 31, 2020 and December 31, 2019, the Company has paid $174,106 and $0 and there is a balance of $319,799 and $493,905 due, respectively.

On February 13, 2020, the Company issued 187,497 options to the Company's CFO to settle $93,950 in accrued compensations. The difference between the fair value of the options and the liability settled of $163,036 was charged to stock compensation expense during the year ended December 31, 2020. The options are fully vested on issuance, have an exercise price of $1.75, and expire in 10 years from issuance.

NOTE 5 - DERIVATIVE LIABILITIES

Upon closing of the private placement transactions in 2016, the Company issued 127,346 and 295,945 warrants, respectively, to the placement agent of the 2016 Offering and to Strategic Bio Partners, a holder of the Company's debt, for debt cancellation, respectively, to purchase the Company's Series B Preferred Stock with an exercise price of $1.25 and a five-year term. Upon the effectiveness of our reverse stock split in July 2016, these became warrants to purchase our common stock on the same terms and conditions. The warrants, if exercised under the cashless provision, do not have an explicit limit on the number of shares that will be issued. The warrants have a cashless exercise feature that requires the Company to classify the warrants as a derivative liability.

NOTE 6 – CONVERTIBLE NOTE PAYABLE (PIK NOTES)

Convertible Notes Payable

During the fourth quarter of 2019, the Company entered into a series of unsecured convertible notes (the "Convertible Notes"). The Convertible Notes have a total principal amount of $420,000. The Convertible Notes accrue 6% interest per year payable on October 31, 2020 and on the end of each calendar year thereafter, payable by a corresponding increase in the principal amount of each Convertible Note that increases to 12% per year (the Default Rate") in the case a default. The Company will pay (a "PIK Payment") the interest due by adding such interest (including interest at the Default Rate) to the then-outstanding principal amount of the Convertible Notes on each interest payment date and on the maturity date. Each PIK Payment will be preceded by written notice from the Company to the Convertible Note holder setting forth in reasonable detail the amount of such PIK Payment and the principal amount of the Convertible Note following such PIK Payment. The Convertible Notes are due on November 6, 2023. The Convertible Notes are convertible into shares of the Company's common stock with a conversion price of $1.25 per share, subject to adjustment in certain circumstances.

During the second quarter of 2020, the Company issued additional unsecured Convertible Notes in the aggregate principal amount of $850,000. The notes accrue 6% interest per year payable on October 31, 2020 and on the end of each calendar year thereafter, payable by a corresponding increase in the principal amount of each note that increases to 12% per year in the case of the notes entering default. The Company will pay (a "PIK Payment") the interest due by adding such interest (including interest at the Default Rate) to the then-outstanding principal amount of the Notes on each interest payment date and on the Maturity Date. Each PIK Payment will be preceded by written notice from the Company to the Note holder setting forth in reasonable detail the amount of such PIK Payment and the principal amount of the Note following such PIK Payment. The notes are due on November 6, 2023. The notes are convertible into shares of the Company's common stock with an exercise price of $1.25 per share.

During the third quarter of 2020, the Company issued additional unsecured Convertible Notes in the aggregate principal amount of $327,500. The notes accrue 6% interest per year payable on October 31, 2020 and on the end of each calendar year thereafter, payable by a corresponding increase in the principal amount of each note that increases to 12% per year in the case of the notes entering default. The Company will pay (a "PIK Payment") the interest due by adding such interest (including interest at the Default Rate) to the then-outstanding principal amount of the Notes on each interest payment date and on the Maturity Date. Each PIK Payment will be preceded by written notice from the Company to the Note holder setting forth in reasonable detail the amount of such PIK Payment and the principal amount of the Note following such PIK Payment. The notes are due on November 6, 2023. The notes are convertible into shares of the Company's common stock with an exercise price of $1.25 per share.

The Company has evaluated the terms of the Convertible Notes and determined that there are no derivative features in the Convertible Notes. These Convertible Notes do have a beneficial conversion feature and recorded a total debt discount of $356,204 with $104,204 being recorded in the year ended December 31, 2020.

Katalyst Securities LLC acted as the Company's placement agent (the "Placement Agent") for the sale of the Convertible Notes. The Company paid the Placement Agent, including its sub-agents, a commission of 10% of the funds raised from the investors introduced by the Placement Agent. In addition, the Placement Agent will receive warrants to purchase a number of shares of Common Stock equal to 10% of the shares of Common Stock issuable upon conversion of the Notes sold to the investors who were introduced to us by the Placement Agent (See note 7). The Company recognized $104,090 in expenses related to the Placement Agent commission for this offering which were recorded as a debt discount. This debt discount and the fair value of the warrants issued to the placement agent of $179,679 are being amortized over the life of the notes from the private placement.

During the years ended December 31, 2020 and 2019, the Company amortized $117,036 and $6,821 of the debt discount, respectively. At December 31, 2020 and December 31, 2019, the Company had an unamortized debt discount of $516,116 and $245,179, respectively.

As of December 31, 2020 and December 31, 2019, the Company owes $1,597,500 and $420,000 on the outstanding Convertible Notes, respectively.

Maturity Date of Notes for Twelve Months Ending December 31,	Amount due
2021	$ -
2022	-
2023	1,597,500
2024	-
2025	-
Total	$ 1,597,500

Convertible Notes Payable – Related Party

During the fourth quarter of 2019, the Company issued unsecured Convertible Notes in the aggregate principal amount of $250,000 to related parties. The notes accrue 6% interest per year payable on October 31, 2020 and on the end of each calendar year thereafter, payable by a corresponding increase in the principal amount of each Convertible Note that increases to 12% per year in the case of the notes entering default. The Company will pay (a "PIK Payment") the interest due by adding such interest (including interest at the Default Rate) to the then-outstanding principal amount of the Notes on each interest payment date and on the Maturity Date. Each PIK Payment will be preceded by written notice from the Company to the Note holder setting forth in reasonable detail the amount of such PIK Payment and the principal amount of the Note following such PIK Payment. The notes are due on November 6, 2023. The notes are convertible into shares of the Company's common stock with an exercise price of $1.25 per share.

During the second quarter of, 2020, the Company issued additional unsecured Convertible Notes in the aggregate principal amount of $50,000. The notes accrue 6% interest per year payable on October 31, 2020 and on the end of each calendar year thereafter, payable by a corresponding increase in the principal amount of each note that increases to 12% per year in the case of the notes entering default. The Company will pay (a "PIK Payment") the interest due by adding such interest (including interest at the Default Rate) to the then-outstanding principal amount of the Notes on each interest payment date and on the Maturity Date. Each PIK Payment will be preceded by written notice from the Company to the Note holder setting forth in reasonable detail the amount of such PIK Payment and the principal amount of the Note following such PIK Payment. The notes are due on November 6, 2023. The notes are convertible into shares of the Company's common stock with an exercise price of $1.25 per share.

During the third quarter of, 2020, the Company issued additional unsecured Convertible Notes in the aggregate principal amount of $100,000. The notes accrue 6% interest per year payable on October 31, 2020 and on the end of each calendar year thereafter, payable by a corresponding increase in the principal amount of each note that increases to 12% per year in the case of the notes entering default. The Company will pay (a "PIK Payment") the interest due by adding such interest (including interest at the Default Rate) to the then-outstanding principal amount of the Notes on each interest payment date and on the Maturity Date. Each PIK Payment will be preceded by written notice from the Company to the Note holder setting forth in reasonable detail the amount of such PIK Payment and the principal amount of the Note following such PIK Payment. The notes are due on November 6, 2023. The notes are convertible into shares of the Company's common stock with an exercise price of $1.25 per share.

The Company has evaluated the terms of the notes and determined that there are no derivative features in the note. The Convertible Notes issued to related parties have a beneficial conversion feature and, accordingly, the Company recorded a debt discount of $150,000 during the year ended December 31, 2019. No debt discount was recorded during the year ended December 31, 2020. During the year ended December 31, 2020 and 2019, the Company amortized $37,863 and $4,549 of the debt discount, respectively, on Convertible Notes issued to related parties. Additionally, a fee of $9,000 was expensed related to the notes. At December 31, 2020 and December 31, 2019, the Company had an unamortized debt discount of $107,588 and $145,451, respectively, on Convertible Notes issued to related parties.

As of December 31, 2020 and December 31, 2019, the Company owes $400,000 and $250,000 on the outstanding notes, respectively, held by related parties.

Maturity Date of Notes for Twelve Months Ending December 31,	Amount due
2021	$ -
2022	-
2023	400,000
2024	-
2025	-
Total	$ 400,000

NOTE 7 - STOCKHOLDERS' DEFICIT

Stock-Based Compensation

In connection with the consummation of the Merger completed on February 12, 2016, we adopted Prior Protagenic's 2006 Employee, Director and Consultant Stock Plan (the "2006 Plan"). On June 17, 2016, our stockholders adopted the 2016 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.

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. On each of January 1, 2017, January 1, 2019 and January 1, 2020, pursuant to an annual "evergreen" provision contained in the 2016 Plan, the number of shares reserved for future grants was increased by 564,378 shares, or a total of 1,693,134 shares. As a result of these increases, as of December 31, 2019 and December 31, 2020, the aggregate number of shares of common stock available for awards under the 2016 Plan was 4,304,245 shares and 4,868,623 shares, respectively. Options issued under the 2016 Plan are exercisable for up to ten years from the date of issuance.

There were 5,597,861 options outstanding as of December 31, 2020. The fair value of each stock option granted was estimated using the Black-Scholes assumptions and or factors as follows:

Exercise price	$	1.75
Expected dividend yield		0%
Risk free interest rate		0.64%-1.61%
Expected life in years		10
Expected volatility		140%-146%

There were 3,835,366 options outstanding as of December 31, 2019. The fair value of each stock option granted was estimated using the Black-Scholes assumptions and or factors as follows:

Exercise price	$	1.00 - $1.75
Expected dividend yield		0%
Risk free interest rate		2.09%-2.70%
Expected life in years		10
Expected volatility		137%-140%

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, 2018	3,846,299	$	1.36	7.20
Granted	126,567	$	1.15	9.20
Expired	(137,500)	$	1.75	
Outstanding December 31, 2019	3,835,366	$	1.34	6.02
Granted	1,762,495	$	1.75	8.01
Expired	-	$	-	
Outstanding December 31, 2020	5,597,861	$	1.47	6.48

A summary of the status of the Company's nonvested options as of December 31, 2020, and changes during the year ended December 31, 2020, is presented below:

Nonvested Options	**Options**		**Weighted-Average Exercise Price**
Nonvested at December 31, 2018	800,210	$	1.63
Granted	126,567	$	1.15
Vested	(584,895)	$	1.46
Forfeited	(137,500)	$	1.75
Nonvested at December, 2019	204,382	$	1.74
Granted	1,762,495	$	1.75
Vested	(1,104,044)	$	1.75
Forfeited	-	$	-
Nonvested at December 31, 2020	862,833	$	1.75

As of December 31, 2020, the Company had 5,597,861 shares issuable under options outstanding at a weighted average exercise price of $1.47 and an intrinsic value of $38,328.

As of December 31, 2019, the Company had 3,835,366 shares issuable under options outstanding at a weighted average exercise price of $1.34 and an intrinsic value of $635,536.

The total number of options granted during the years ended December 31, 2020 and 2019 was 1,762,495 and 126,567, respectively. The exercise price for these options was $1.00 per share or $1.75 per share.

The Company recognized compensation expense related to options issued of $1,427,084 and $797,761 during the years ended December 31, 2020 and 2019, respectively, in which $1,354,750 and $698,293 is included in general and administrative expenses and $72,334 and $99,468 in research and development expenses, respectively. For the year ended December 31, 2020, $1,046,795 of the stock compensation was related to employees and $380,289 was related to non-employees.

As of December 31, 2020, the unamortized stock option expense was $898,665 with $305,527 being related to employees and $593,138 being related to non-employees. As of December 31, 2020, the weighted average period for the unamortized stock compensation to be recognized is 2.99 years.

On February 25, 2019, the Company granted 101,567 options with an exercise price of $1.00 and a ten year term. 59,900 of these options vest immediately and 41,667 vest bi-weekly over two months. These options have a Black-Scholes value of $199,807. The Company issued 59,900 options for settlement of accounts payable totaling $29,850 and recorded a loss of $99,541 on the settlement of the accounts payable.

On June 17, 2019, the Company granted 25,000 options with an exercise price of $1.75 and a ten year term. These options vest immediately and have a Black-Scholes value of $36,374.

On February 21, 2020, the Company issued a total of 1,387,497 options to purchase shares of the Company's common stock to sixteen individuals with 1,362,497 option going to twelve related parties. These options had a grant date fair value of $1,901,724. From these options, 187,497 options were used to settle $93,950 in accrued compensations.

These options have an exercise price of $1.75. 187,497 of the options vest immediately, 510,000 of the options vest monthly over 12 months, 5,000 of the options vest monthly over 24 months, 420,000 of the options vest monthly over 36 months, and 265,000 of the options vest monthly over 48 months. These options were approved by the board of directors on February 13, 2020.

On July 18, 2020, the Company issued 124,998 options to a related party. These options have an exercise price of $1.75 and a term of ten years. These options vest immediately and the grant date fair value of these options was $142,607.

On July 18, 2020, the Company issued 105,000 options to consultants. These options have an exercise price of $1.75 and a term of ten years. These options vest monthly over four years and the grant date fair value of these options was $119,792.

On July 18, 2020, the Board of Directors increased the size of the Board from five directors to six directors and appointed Jennifer Buell, Ph.D. as a member of the Board, effective immediately, to fill the vacancy created by such increase and to serve until the next annual meeting of shareholders. Dr. Buell was issued options to purchase 100,000 shares of the Company's common stock at an exercise price of $1.75 per share. The options vest as follows: monthly over 48 months. In recognition of her upcoming service as a Director of the Company, Dr. Buell was issued 45,000 options that vest monthly over 12 months. In each case the vesting commenced on the date of grant, July 18, 2020. These options had a grant date fair value of $165,426.

Warrants:

In connection with the Merger, all of the issued and outstanding warrants to purchase shares of Prior Protagenic common stock converted, on a 1 for 1 basis, into new warrants (the "New Warrants") to purchase shares of our Series B Preferred Stock.

Simultaneously with the Merger and the 2016 Offering, New Warrants to purchase 3,403,367 shares of Series B Preferred Stock at an average exercise price of approximately $1.05 per share were issued to holders of Prior Protagenic warrants; additionally, the holder of $665,000 of our debt and $35,000 of accrued interest exchanged such debt for five-year warrants to purchase 295,945 shares of Series B Preferred Stock at $1.25 per share. Warrants to purchase 127,346 shares of Series B Preferred Stock at an exercise price of $1.25 per share were issued to the placement agent in connection with the 2016 Offering. These warrants to purchase 423,291 shares of Series B Preferred Stock have been recorded as derivative liabilities. All of these warrants automatically converted into warrants to purchase our common stock upon the effectiveness of our reverse stock split in July 2016. See Note 5.

A summary of warrant issuances are as follows:

	Number	Weighted Average Exercise Price	Weighted Average Remaining Life
Warrants			
Outstanding December 31, 2018	3,826,658	$ 1.05	3.69
Granted	-	-	-
Outstanding December 31, 2019	3,826,658	$ 1.05	2.69
Granted	180,400	1.25	4.53
Outstanding December 31, 2020	4,007,058	$ 1.06	1.86

As of December 31, 2020, the Company had 4,007,058 shares issuable under warrants outstanding at a weighted average exercise price of $1.06 and an intrinsic value of $782,668.

As of December 31, 2019, the Company had 3,826,658 shares issuable under warrants outstanding at a weighted average exercise price of $1.05 and an intrinsic value of $1,375,990.

On February 21, 2020, the Company extended the expiration date for 100,000 warrants to purchase shares of the Company's common stock. The expiration date was extended by two years from January 2, 2020 to January 2, 2022. These warrants have an exercise price of $1.25 and are fully vested. The Company recognized $95,187 in stock compensation as part of this modification.

On June 30, 2020, the Company issued 81,600 warrants to purchase shares of the Company's common stock. These warrants vest immediately, had an exercise price of $1.25 and a term of 5 years. These warrants have a Black-Scholes value of $86,968, which is being amortized over the life of the notes from the private placement. These warrants were issued as compensation to the placement agents in connection with the Company's private placement offering of debt in which $6,643 was recorded as stock compensation expense and $80,325 recorded as a debt discount.

During the third quarter of 2020, the Company issued 98,800 warrants to purchase shares of the Company's common stock. These warrants vest immediately, had an exercise price of $1.25 and a term of 5 years. These warrants have a Black-Scholes value of $105,194 which is being amortized over the life of the notes from the private placement. These warrants were issued as compensation to the placement agents in connection with the Company's private placement offering in which $5,840 was recorded as stock compensation expense and $99,354 recorded as a debt discount.

NOTE 8 - 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 25,000 stock options which are fully vested at the exercise price of $1.00 exercisable over a ten year period which ends on April 1, 2022. As of December 31, 2020, Dr. David Lovejoy of the University has been granted 553,299 stock options, of which 527,570 are fully vested. These have an exercise price of $1.00, $1.25 or 1.75 and are exercisable over ten or thirteen year periods which end either on March 30, 2021, December 1, 2022, April 15, 2026, March 1, 2027, October 16, 2027 or on February 13, 2030.

The sponsorship research and development expenses pertaining to the Research Agreements were $0 and $63,905 for the years ended December 31, 2020 and 2019, respectively.

NOTE 9 - 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, 2020 and 2019 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 10 – 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.

On February 13, 2020, the Company issued 50,000 options to purchase common stock to a related party. These options had an exercise price of $1.75 and a term of 48 months. (See Note 7)

NOTE 11 – INCOME TAXES

The components of loss before income taxes are as follows:

	2020	2019
Domestic	(2,542,428)	(1,698,689)
Foreign	(6,307)	(52,222)
Loss before income taxes	(2,548,735)	(1,750,911)

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2020 and 2019.

For the years ended December 31, 2020 and 2019, a reconciliation of the Company's effective tax rate to the statutory U.S. Federal rate is as follows:

	2020	2019
Income taxes at Federal statutory rate	(21.0)%	(21.0)%
State income taxes, net of Federal income tax effect	(8.6)%	(8.6)%
Perm difference	0.0%	0.0)%
Foreign tax rate differential	(0.4)%	(0.6)%
Change in valuation allowance	30.0%	30.2%
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:

	2020	2019
U.S. net operating loss carryforwards	2,907,000	2,894,000
Stock compensation	1,217,000	784,000
Canadian Provincial income tax losses	7,000	29,000
Canadian Provincial scientific investment tax credits	(10,000)	(4,000)
	4,121,000	3,703,000
Valuation allowance	(4,121,000)	(3,703,000)
Net deferred tax assets	-	-

As of December 31, 2020 and 2019, the Company had federal net operating loss carryforwards ("NOL") of approximately $7,550,000 and $7,161,000, respectively. 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. The CARES Act temporarily allows the Company to carryback net operating losses arising in 2018, 2019 and 2020 to the five prior tax years. In addition, net operating losses generated in these years could fully offset prior year taxable income without the 80% of the taxable income limitation under the TCJA which was enacted on December 22, 2017. The Company has been generating losses since its inception, as such the net operating loss carryback provision under the CARES Act is not applicable to the Company. As of December 31, 2020 and 2019, the Company had state and local net operating loss carryforwards of approximately $7,540,000 and $7,153,000, respectively, to reduce future state tax liabilities also through 2035.

As of December 31, 2020 and 2019, the Company had Canadian NOL of approximately $1,115,000 and $1,111,000, respectively. The Canadian losses expire in stages beginning in 2026. As of December 31, 2020 and 2019, 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, 2020 and 2019 was an increase of $418,000 and $661,000, 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, 2020 and 2019.

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.

NOTE 12 - SUBSEQUENT EVENTS

On February 25, 2021, the Company issued 366,000 options to purchase share of the Company's common stock. 350,000 of these options vest over 48 months and have a term of ten years and the remaining 16,000 options vest immediately and have a term of five years. All of these options have an exercise price of $5.60.

During the first quarter of 2021, a total of 268,233 warrants were exercised for a total of 161,026 shares of the Company's common stock.

Confidential

CONSULTING AGREEMENT

This Consulting Agreement (the "Agreement"), effective as of December 18, 2020 (the "Effective Date") is made between Protagenic Therapeutics Inc., a Delaware corporation, having an address at 149 Fifth Avenue, Suite 500, New York, NY 10010 ("Protagenic"), and Dr. Andrew Slee, an individual having an address at _____ (the "Consultant") (each a "Party" and collectively the "Parties").

WHEREAS, Protagenic desires to retain the services of Consultant, and Consultant desires to perform certain services for Protagenic;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Protagenic and Consultant hereby agree as follows:

1. Services.

1.1 Description of Services. Subject to the terms and conditions of this Agreement, Protagenic or its designee hereby retains Consultant to perform for Protagenic and/or its Affiliates (as hereinafter defined) the services specified in one or more attachments (the "Attachment") to this Agreement executed by the Parties (the "Services"). Consultant shall perform the Services promptly and in compliance with the provisions of this Agreement and all applicable laws, rules and regulations, including if applicable, laws and regulations administered by the U.S. Food and Drug Administration ("FDA") regarding the promotion and marketing of pharmaceutical products. Consultant shall ensure that the Services are performed promptly and diligently.

As used in this Agreement "Affiliate" means any corporation, firm, partnership or other entity, which controls, is controlled by or is under common control with a Party. As used in this Agreement, "control" means direct or indirect ownership of fifty percent (50%) or more of the outstanding stock or other voting rights entitled to elect directors thereof or the ability to otherwise control the management of the corporation, firm, partnership or other entity.

1.2 Non-Solicitation. Consultant agrees that during the term of this Agreement and for a period of one (1) year thereafter, Consultant shall not, directly or indirectly, (i) solicit, divert, or take away, or attempt to divert or take away, the business or patronage of any actual or prospective clients, customers, or accounts of Protagenic, or (ii) recruit, solicit, or hire any employee of Protagenic, or induce or attempt to induce any employee of Protagenic, to discontinue his or her relationship with Protagenic.

1.3 Third Party Obligations. Consultant represents and warrants to Protagenic that none of his or her past or current obligations conflict with this Agreement or prevent the Consultant from providing the Services hereunder. During the Term of this Agreement, Consultant covenants not to enter into any such conflicting agreement or incur any such conflicting obligation without the prior written consent of Protagenic. Consultant further covenants that the performance of the Services will not breach any agreement or obligation with

any third party, including without limitation any obligation to refrain from engaging in activities that may compete with such party.

1.4 No Disparagement. Consultant agrees not disparage Protagenic or any of its Affiliates, or their respective directors, officers, employees, consultants, or agents, or otherwise make any statement or take any actions that would be materially harmful to the business, interests or reputation of Protagenic or any of its Affiliates, or their respective directors, officers, employees, consultants, or agents.

2. Compensation.

2.1 Compensation. In exchange for the timely completion of Services during the Term, Protagenic shall pay to Consultant compensation as set forth on Exhibit A hereto. Fees (as defined on Exhibit A) will be paid upon documented completion of the Services in accordance with the requirements set forth on Exhibit A. All compensation and expense reimbursements to be paid under this Agreement shall be paid to Consultant in U.S. Dollars. Consultant acknowledges and agrees that payments made hereunder are for Services performed by Consultant. No payments shall be passed through to third parties on behalf of Protagenic without a valid invoice or other written documentation between the Parties evidencing such payment arrangement. Except as otherwise set forth herein, no other Fees shall be due and payable to Consultant hereunder for the Services.

2.2 Reimbursement of Expenses. Protagenic shall reimburse Consultant for reasonable travel and other out-of-pocket expenses pre-approved by Protagenic in writing, and incurred by Consultant in performance of the Services and in accordance with Protagenic's Travel & Expense Policy and Procedures, as may be amended from time to time by Protagenic. Consultant shall sumbit to Protagenic written expense statements and other supporting documentation in a form that is reasonably satisfactory to Protagenic. Protagenic shall provide Consultant with a check for any reimbursement amounts due under this Section 2.2 within forty-five (45) days after Protagenic receives satisfactory documentation.

2.3 Independent Contractor. Consultant is an independent contractor of Protagenic. Consultant acknowledges and agrees that Protagenic will not provide Consultant with any benefits. Without in any way limiting the generality of the foregoing, Consultant acknowledges and agrees that he or she has no right to participate in any Protagenic equity plan(s). Consultant is also responsible for the payment and the withholding of all applicable taxes, levies and/or duties applicable to any compensation or reimbursements paid to Consultant hereunder in accordance with all applicable laws, rules and regulations.

2.4 No Additional Obligation/Fair Market Value. Consultant acknowledges and agrees that the compensation payable hereunder represents Protagenic's full and complete obligation for any and all Services to be rendered by Consultant under this Agreement. Consultant further represents to Protagenic that the compensation paid hereunder represents fair market value for Consultant's time and the Services hereunder and is consistent with fees paid to Consultant for similar time and services provided by Consultant to others. Both Parties acknowledge that the compensation is not determined in a manner that takes into account the volume or value of any future business that might be generated between the Parties. In addition,

Consultant and Protagenic acknowledge that nothing in this Agreement shall be construed to require Consultant to promote, purchase, prescribe, or otherwise recommend any Protagenic products being marketed or under development.

3. Term and Termination.

3.1 Term. This Agreement shall commence on the Effective Date and shall remain in effect indefinitely (the "Term").[1]

3.2 General Termination by Protagenic. Protagenic may terminate this Agreement with or without cause upon seven (7) days prior written notice to Consultant with no further obligation to Consultant, other than payment of compensation in accordance with Article 2 for Services rendered in accordance with this Agreement prior to the termination of this Agreement.

3.3 Immediate Termination by Protagenic. In addition, Protagenic may terminate this Agreement immediately upon written notice to Consultant (or his/her legal representative) in the event (i) of the death or legal incapacity of Consultant or (ii) that Consultant is otherwise no longer able to perform the Services or (iii) if Consultant breaches or threatens to breach any provision of Sections 1.2, 1.3, 1.4, 6.3 or Articles 4, 5 or 6.

3.4 Termination by Consultant. In the event that Protagenic commits a material breach of its obligations under this Agreement, which is not cured within fifteen (15) business days of Protagenic's receipt of notice from Consultant of such material breach, Consultant may terminate this Agreement upon fifteen (15) days prior written notice to Protagenic, unless the breach is cured within such fifteen (15) business day notice period.

3.5 Survival. The following provisions shall survive the expiration or termination of this Agreement: Articles 4, 5 and **Error! Reference source not found.**; Sections 1.2, 1.4, 6.3 through 6.10, and this Section 3.5.

4. Confidential Information.

4.1 Definition of Confidential Information. Confidential Information shall mean any technical or business information furnished by or on behalf of Protagenic to Consultant in connection with this Agreement or developed by Consultant in the course of performing the Services, regardless of whether such Confidential Information is in oral, electronic or written form. Such Confidential Information may include, without limitation, trade secrets, know-how, inventions, technical data or specifications, testing methods, business or financial information,

[1] NTD: Consider having a termination date with an automatic renewal in place of this provision.

research and development activities, product and marketing plans, and customer and supplier information (collectively, "Confidential Information").

4.2 Obligations. Consultant shall

(a) maintain all Confidential Information in strict confidence; and

(b) use all Confidential Information solely for the purpose of providing the Services as requested by Protagenic; and

(c) reproduce the Confidential Information only to the extent necessary for providing the Services as requested by Protagenic, with all such reproductions being considered Confidential Information;

(d) disclose the Confidential Information only as expressly permitted in order to perform the Services; and

(e) not disclose or publish any Confidential Information to any third party without the express prior written consent of Protagenic, in each case in Protagenic's sole discretion.

4.3 Exceptions. The obligations of Consultant under Section 4.2 shall not apply to the extent that Consultant can demonstrate that certain information:

(a) was in the public domain prior to the time of its disclosure or development under this Agreement;

(b) entered the public domain after the time of its disclosure or development under this Agreement other than due to an act or omission by Consultant;

(c) was independently developed by Consultant prior to the time of its disclosure or development under this Agreement and without access to Confidential Information; or

(d) is or was disclosed to Consultant at any time prior to its disclosure or development under this Agreement, without restriction, by a third party having no fiduciary relationship with Protagenic and having no obligation of confidentiality with respect to such Confidential Information.

4.4 Required Disclosures. In addition, Consultant may disclose Confidential Information to the extent necessary to comply with applicable laws or regulations, or with a court or administrative order, provided that Consultant (i) gives Protagenic prompt written notice of such requirement, (ii) takes all reasonable and lawful actions to obtain confidential treatment for such disclosure and, if possible, to minimize the extent of such disclosure, and (iii) discloses only the Confidential Information strictly required to comply with such legal obligation, as determined by legal counsel.

4.5 Return of Confidential Information; Survival of Obligations. Upon the termination of this Agreement, or earlier at the request of Protagenic, Consultant shall return to Protagenic all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information in the possession or control of Consultant. The obligations set forth in this Article 4 shall remain in effect for a period of five (5) years after termination of this Agreement, except that the obligations of Consultant to return Confidential Information shall survive until fulfilled. Consultant acknowledges and agrees that the Confidential Information is of extreme value to Protagenic, and any use or disclosure thereof other than as expressly allowed under this Agreement would cause irreparable harm to Protagenic for which Protagenic could obtain relief as contemplated in Section 6.9 of this Agreement, and that such unauthorized disclosure may represent Consultant's violation of U.S. securities laws.

5. Developments; Third Party IP; Avoidance of Claims.

5.1 Developments. "Developments" shall mean any and all inventions, developments, data, discoveries, improvements, ideas, or concepts, and related documentation, and any other works of invention or authorship (whether or not patentable or copyrightable) which Consultant has conceived, discovered, developed, or reduced to practice or tangible medium in the course of providing the Services, or which arise from access to and/or use of Confidential Information, and any and all intellectual property rights in any of the foregoing. Consultant shall promptly disclose to Protagenic any and all Developments. Consultant acknowledges and agrees that all Confidential Information and Developments is and shall remain the exclusive property of Protagenic or the third party entrusting any Confidential Information to Protagenic. Consultant shall and hereby assigns, conveys, and grants to Protagenic, all of his or her right, title, and interest in and to any and all Developments.

5.4 Third-Party Intellectual Property. Consultant acknowledges that Protagenic does not desire to acquire any trade secrets, know-how, confidential information, or other intellectual property that Consultant may have acquired from or developed for any third party ("Third-Party IP"). Consultant agrees that in the course of providing the Services, Consultant shall not improperly use or disclose any Third-Party IP.

5.5 Avoidance of Claims by Third-Parties. Unless covered by an appropriate agreement between any third party and Protagenic, Consultant shall not engage in any activities or use any facilities, funds or equipment, in the course of providing Services, which could result in claims of ownership to any Developments by such third party.

5.6 FCPA. Consultant understands that Protagenic is an issuer of securities in the United States and is subject to the provisions of the U. S. Foreign Corrupt Practices Act, 15 U.S.C. §§ 78m, 78dd-1 through 78dd-3 ("FCPA"). This law prohibits making, promising or offering to make corrupt payments to foreign officials, political parties or candidates, or making payments to other persons who will offer or make payments to any of the aforementioned parties

in order to obtain business, retain business or gain an improper advantage. Consultant represents and warrants to Protagenic that Consultant is familiar with and understands the FCPA.

5.7 Representations. Consultant represents and warrants to Protagenic that throughout the period in which Consultant provides Services to Protagenic, neither Consultant, nor any person performing Services on behalf of Consultant will engage in any activity that could cause a violation of any provision of the FCPA by Protagenic. Consultant represents and warrants that Consultant has not made, promised to make, or arranged for any third party to make any payments or gifts to foreign officials in connection with Consultant's engagement by Protagenic. Further, Consultant represents and warrants to Protagenic that Consultant has not violated any anti-corruption law and further that Consultant is not involved in, or the subject of, any investigation involving bribery, corruption or improper payments to foreign government officials, as defined in the FCPA. Consultant agrees to update these representations and warranties on a periodic basis as required by Protagenic in a format prescribed by Protagenic.

5.8 Notice of Violation. Consultant agrees to notify Protagenic immediately in writing if Consultant or any person who is performing Services hereunder on behalf of Consultant is suspected of violating any anti-corruption law or becomes involved in, or a subject of, an investigation or law enforcement inquiry into possible improper payments to foreign officials or possible violations of anti-corruption laws. Consultant further agrees to provide such notification if Consultant or any person performing Services hereunder on behalf of Consultant becomes involved in any action, suit, claim, investigation or proceeding that is pending, or to the knowledge of Consultant threatened, relating to a potential violation of any anti-corruption laws, including the FCPA.

5.9 Audits. Consultant agrees to grant Protagenic the right to audit Consultant's books and records regarding the receipt and disposition of any payments made to Consultant by Protagenic, and Consultant further agrees to cooperate with Protagenic in connection with such audits.

5.10 Material Provision. It is agreed between Consultant and Protagenic that this Article 5 is deemed by the Parties to be a material provision of this Agreement.

5.11 Consultant has received a copy of Protagenic's Code of Conduct and FCPA Compliance Memorandum (each a "Policy"). Consultant represents and warrants that Consultant has had the opportunity to review the Policy, understands the Policy, and will comply with it.

6. Miscellaneous.

6.1 Counterparts. This Agreement may be executed in counterparts, which, when taken together, shall constitute one agreement. If any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

6.2 Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party, except that Protagenic may assign this Agreement to an

affiliate or in connection with the merger, consolidation, or sale of all or substantially all of its business or assets relating to this Agreement. This Agreement shall inure to the benefit of and be binding upon the Parties and their respective lawful successors, assigns, heirs, and personal representatives.

6.3 Insider Trading. Consultant acknowledges that Consultant may receive material, non-public information about Protagenic and its business in the course of providing the Services, that this information must be maintained in strict confidence, and that the U.S. securities laws restrict trading on the basis of such information or providing such information to third parties who may trade on such information.

6.4 Publicity. Consultant consents to use by Protagenic of Consultant's name and likeness in written materials or oral presentations to current or prospective customers, investors or others, provided that such materials or presentations accurately describe the nature of Consultant's relationship with or contribution to Protagenic.

6.5 Notices. Any notice or other communication required or permitted hereunder shall be in writing and shall be deemed given (a) when delivered personally, (b) upon confirmation of delivery by email if sent during normal business hours, and otherwise on the next business day, (c) on the next business day after timely delivery to an overnight courier (postage prepaid), or (d) on the third business day after deposit in the United States mail (certified or registered mail return receipt requested, postage prepaid), to the addresses of the Parties set forth in the first paragraph of this Agreement, and in the case of correspondence to Protagenic, with a copy to "Legal Department" at the same address. Either Party may change its designated address by notice to the other Party in the manner provided in this Section 6.5.

6.6 Entire Agreement; Amendment. This Agreement, including Exhibit A, constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes any and all prior or contemporaneous oral and prior written agreements and understandings. This Agreement, including Exhibit A, may be modified, amended, or supplemented only by means of a written instrument signed by both Parties. Any waiver of any rights or failure to act in a specific instance shall relate only to such instance and shall not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

6.7 Governing Law. This Agreement has been drafted in the English Language and the English language shall govern its interpretation. This Agreement shall be governed by and construed in accordance with the laws of the State of New York irrespective of any conflict of laws principles.

6.8 Severability. In the event that any provision of this Agreement shall, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid or unenforceable provision had not been included herein. If any provision hereof shall, for any reason, be held by a court to be excessively broad as to duration, geographical scope, activity, or subject matter, it shall be construed by limiting and reducing it to make it enforceable to the extent compatible with applicable law as then in effect. To the extent this Agreement may

be construed in accordance with the laws of any state that limits the assignability to Protagenic of certain Developments, the provisions of this Agreement shall be modified to conform to such state limitation while most closely effectuating the original intention of the Parties (e.g., by providing for fully paid up license rights, or the like).

6.9 Equitable Relief. Consultant acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of Protagenic and are reasonable for such purpose. Consultant agrees that any breach or threatened breach of his or her obligations under this Agreement will cause irreparable harm to Protagenic. Therefore, in addition to any other remedies that may be available to Protagenic, Protagenic may apply for and obtain immediate injunctive relief in any court of competent jurisdiction to restrain the breach or threatened breach of, or otherwise to specifically enforce, any obligations of Consultant under this Agreement.

6.10 Massachusetts Information Security Regulations Compliance. Massachusetts Information Security Regulations, 201 Code of Mass. Regs. 17.00 et seq. (the "IS Regulations") mandate procedures to safeguard the "Personal Information," as defined in the IS Regulations, of Massachusetts residents. Because Consultant may have access to the Personal Information of Protagenic's employees, contractors, business associates, or customers who are Massachusetts residents ("Protected Information"), the IS Regulations require Consultant to certify compliance with the IS Regulations. Accordingly, Consultant agrees that, as long as Consultant has access to or maintains copies of Protected Information Consultant will: (a) comply with the IS Regulations with respect to the Protected Information, (b) promptly notify Protagenic of any suspected or actual data breach involving Protected Information, and (c) cooperate with Protagenic to investigate and remediate any suspected or actual data breach involving Protected Information.

6.11 Whistleblower Notice. Pursuant to 18 USC § 1833(b), an individual may not be held criminally or civilly liable under any federal or state trade secret law for disclosure of a trade secret: (i) made in confidence to a government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law; and/or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Accordingly, the Parties to this Agreement have the right to disclose in confidence trade secrets to Federal, State, and local government officials, or to an attorney, for the sole purpose of reporting or investigating a suspected violation of law. The Parties also have the right to disclose trade secrets in a document filed in a lawsuit or other proceeding, but only if the filing is made under seal and protected from public disclosure.

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EXHIBIT A

Consulting Services

Description of Services

Consultant shall continue to provide Services to Protagenic Therapeutics Inc. ("Protagenic") related to Preclinical & Clinical Development of the Company's drug portfolio, as Chief Operating Officer of the Company.

Compensation

Protagenic shall compensate Consultant for Services via an Equity Grant of 50,000 nonstatutory stock options ("NSOs") at an exercise price equal to the fair market value of a PTIX share, to be proposed at the next meeting of the Company's Board of Directors, exercisable until December 19, 2030. The NSOs shall (i) contain usual and customary provisions, and (ii) vest on a four-year vesting schedule. Upon the one year anniversary of the Effective Date of this Agreement, the Company and Consultant shall make any adjustments as agreed to between both Parties, in good faith, based upon Consultants contribution to the Company.

IN WITNESS WHEREOF, the Parties each have caused this Agreement to be executed by their duly respective authorized representative as of the Effective Date.

PROTAGENIC INC.	CONSULTANT
Name: Dr. Garo Armen	Name: Dr. Andrew Slee
Title: Executive Chairman	Title: Chief Operating Officer
Date:	Date: 03/1/2021

Confidential

CONSULTING AGREEMENT

This Consulting Agreement (the "Agreement"), effective as of December 18, 2020 (the "Effective Date") is made between Protagenic Therapeutics Inc., a Delaware corporation, having an address at 149 Fifth Avenue, Suite 500, New York, NY 10010 ("Protagenic"), and Dr. Robert Stein, an individual having an address at 3000 S. Cherokee Lane, (the "Consultant") (each a "Party" and collectively the "Parties").

WHEREAS, Protagenic desires to retain the services of Consultant, and Consultant desires to perform certain services for Protagenic;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Protagenic and Consultant hereby agree as follows:

1. Services.

1.1 Description of Services. Subject to the terms and conditions of this Agreement, Protagenic or its designee hereby retains Consultant to perform for Protagenic and/or its Affiliates (as hereinafter defined) the services specified in one or more attachments (the "Attachment") to this Agreement executed by the Parties (the "Services"). Consultant shall perform the Services promptly and in compliance with the provisions of this Agreement and all applicable laws, rules and regulations, including if applicable, laws and regulations administered by the U.S. Food and Drug Administration ("FDA") regarding the promotion and marketing of pharmaceutical products. Consultant shall ensure that the Services are performed promptly and diligently.

As used in this Agreement "Affiliate" means any corporation, firm, partnership or other entity, which controls, is controlled by or is under common control with a Party. As used in this Agreement, "control" means direct or indirect ownership of fifty percent (50%) or more of the outstanding stock or other voting rights entitled to elect directors thereof or the ability to otherwise control the management of the corporation, firm, partnership or other entity.

1.2 Non-Solicitation. Consultant agrees that during the term of this Agreement and for a period of one (1) year thereafter, Consultant shall not, directly or indirectly, (i) solicit, divert, or take away, or attempt to divert or take away, the business or patronage of any actual or prospective clients, customers, or accounts of Protagenic, or (ii) recruit, solicit, or hire any employee of Protagenic, or induce or attempt to induce any employee of Protagenic, to discontinue his or her relationship with Protagenic.

1.3 Third Party Obligations. Consultant represents and warrants to Protagenic that none of his or her past or current obligations conflict with this Agreement or prevent the Consultant from providing the Services hereunder. During the Term of this Agreement, Consultant covenants not to enter into any such conflicting agreement or incur any such conflicting obligation without the prior written consent of Protagenic. Consultant further covenants that the performance of the Services will not breach any agreement or obligation with

any third party, including without limitation any obligation to refrain from engaging in activities that may compete with such party.

1.4 No Disparagement. Consultant agrees not disparage Protagenic or any of its Affiliates, or their respective directors, officers, employees, consultants, or agents, or otherwise make any statement or take any actions that would be materially harmful to the business, interests or reputation of Protagenic or any of its Affiliates, or their respective directors, officers, employees, consultants, or agents.

2. Compensation.

2.1 Compensation. In exchange for the timely completion of Services during the Term, Protagenic shall pay to Consultant compensation as set forth on Exhibit A hereto. Fees (as defined on Exhibit A) will be paid upon documented completion of the Services in accordance with the requirements set forth on Exhibit A. All compensation and expense reimbursements to be paid under this Agreement shall be paid to Consultant in U.S. Dollars. Consultant acknowledges and agrees that payments made hereunder are for Services performed by Consultant. No payments shall be passed through to third parties on behalf of Protagenic without a valid invoice or other written documentation between the Parties evidencing such payment arrangement. Except as otherwise set forth herein, no other Fees shall be due and payable to Consultant hereunder for the Services.

2.2 Reimbursement of Expenses. Protagenic shall reimburse Consultant for reasonable travel and other out-of-pocket expenses pre-approved by Protagenic in writing, and incurred by Consultant in performance of the Services and in accordance with Protagenic's Travel & Expense Policy and Procedures, as may be amended from time to time by Protagenic. Consultant shall sumbit to Protagenic written expense statements and other supporting documentation in a form that is reasonably satisfactory to Protagenic. Protagenic shall provide Consultant with a check for any reimbursement amounts due under this Section 2.2 within forty-five (45) days after Protagenic receives satisfactory documentation.

2.3 Independent Contractor. Consultant is an independent contractor of Protagenic. Consultant acknowledges and agrees that Protagenic will not provide Consultant with any benefits. Without in any way limiting the generality of the foregoing, Consultant acknowledges and agrees that he or she has no right to participate in any Protagenic equity plan(s). Consultant is also responsible for the payment and the withholding of all applicable taxes, levies and/or duties applicable to any compensation or reimbursements paid to Consultant hereunder in accordance with all applicable laws, rules and regulations.

2.4 No Additional Obligation/Fair Market Value. Consultant acknowledges and agrees that the compensation payable hereunder represents Protagenic's full and complete obligation for any and all Services to be rendered by Consultant under this Agreement. Consultant further represents to Protagenic that the compensation paid hereunder represents fair market value for Consultant's time and the Services hereunder and is consistent with fees paid to Consultant for similar time and services provided by Consultant to others. Both Parties acknowledge that the compensation is not determined in a manner that takes into account the volume or value of any future business that might be generated between the Parties. In addition,

Consultant and Protagenic acknowledge that nothing in this Agreement shall be construed to require Consultant to promote, purchase, prescribe, or otherwise recommend any Protagenic products being marketed or under development.

3. Term and Termination.

3.1 Term. This Agreement shall commence on the Effective Date and shall remain in effect indefinitely (the "Term").[1]

3.2 General Termination by Protagenic. Protagenic may terminate this Agreement with or without cause upon seven (7) days prior written notice to Consultant with no further obligation to Consultant, other than payment of compensation in accordance with Article 2 for Services rendered in accordance with this Agreement prior to the termination of this Agreement.

3.3 Immediate Termination by Protagenic. In addition, Protagenic may terminate this Agreement immediately upon written notice to Consultant (or his/her legal representative) in the event (i) of the death or legal incapacity of Consultant or (ii) that Consultant is otherwise no longer able to perform the Services or (iii) if Consultant breaches or threatens to breach any provision of Sections 1.2, 1.3, 1.4, 6.3 or Articles 4, 5 or 6.

3.4 Termination by Consultant. In the event that Protagenic commits a material breach of its obligations under this Agreement, which is not cured within fifteen (15) business days of Protagenic's receipt of notice from Consultant of such material breach, Consultant may terminate this Agreement upon fifteen (15) days prior written notice to Protagenic, unless the breach is cured within such fifteen (15) business day notice period.

3.5 Survival. The following provisions shall survive the expiration or termination of this Agreement: Articles 4, 5 and **Error! Reference source not found.**; Sections 1.2, 1.4, 6.3 through 6.10, and this Section 3.5.

4. Confidential Information.

4.1 Definition of Confidential Information. Confidential Information shall mean any technical or business information furnished by or on behalf of Protagenic to Consultant in connection with this Agreement or developed by Consultant in the course of performing the Services, regardless of whether such Confidential Information is in oral, electronic or written form. Such Confidential Information may include, without limitation, trade secrets, know-how, inventions, technical data or specifications, testing methods, business or financial information,

[1] NTD: Consider having a termination date with an automatic renewal in place of this provision.

research and development activities, product and marketing plans, and customer and supplier information (collectively, "Confidential Information").

4.2 Obligations. Consultant shall

(a) maintain all Confidential Information in strict confidence; and

(b) use all Confidential Information solely for the purpose of providing the Services as requested by Protagenic; and

(c) reproduce the Confidential Information only to the extent necessary for providing the Services as requested by Protagenic, with all such reproductions being considered Confidential Information;

(d) disclose the Confidential Information only as expressly permitted in order to perform the Services; and

(e) not disclose or publish any Confidential Information to any third party without the express prior written consent of Protagenic, in each case in Protagenic's sole discretion.

4.3 Exceptions. The obligations of Consultant under Section 4.2 shall not apply to the extent that Consultant can demonstrate that certain information:

(a) was in the public domain prior to the time of its disclosure or development under this Agreement;

(b) entered the public domain after the time of its disclosure or development under this Agreement other than due to an act or omission by Consultant;

(c) was independently developed by Consultant prior to the time of its disclosure or development under this Agreement and without access to Confidential Information; or

(d) is or was disclosed to Consultant at any time prior to its disclosure or development under this Agreement, without restriction, by a third party having no fiduciary relationship with Protagenic and having no obligation of confidentiality with respect to such Confidential Information.

4.4 Required Disclosures. In addition, Consultant may disclose Confidential Information to the extent necessary to comply with applicable laws or regulations, or with a court or administrative order, provided that Consultant (i) gives Protagenic prompt written notice of such requirement, (ii) takes all reasonable and lawful actions to obtain confidential treatment for such disclosure and, if possible, to minimize the extent of such disclosure, and (iii) discloses only the Confidential Information strictly required to comply with such legal obligation, as determined by legal counsel.

4.5 Return of Confidential Information; Survival of Obligations. Upon the termination of this Agreement, or earlier at the request of Protagenic, Consultant shall return to Protagenic all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information in the possession or control of Consultant. The obligations set forth in this Article 4 shall remain in effect for a period of five (5) years after termination of this Agreement, except that the obligations of Consultant to return Confidential Information shall survive until fulfilled. Consultant acknowledges and agrees that the Confidential Information is of extreme value to Protagenic, and any use or disclosure thereof other than as expressly allowed under this Agreement would cause irreparable harm to Protagenic for which Protagenic could obtain relief as contemplated in Section 6.9 of this Agreement, and that such unauthorized disclosure may represent Consultant's violation of U.S. securities laws.

5. Developments; Third Party IP; Avoidance of Claims.

5.1 Developments. "Developments" shall mean any and all inventions, developments, data, discoveries, improvements, ideas, or concepts, and related documentation, and any other works of invention or authorship (whether or not patentable or copyrightable) which Consultant has conceived, discovered, developed, or reduced to practice or tangible medium in the course of providing the Services, or which arise from access to and/or use of Confidential Information, and any and all intellectual property rights in any of the foregoing. Consultant shall promptly disclose to Protagenic any and all Developments. Consultant acknowledges and agrees that all Confidential Information and Developments is and shall remain the exclusive property of Protagenic or the third party entrusting any Confidential Information to Protagenic. Consultant shall and hereby assigns, conveys, and grants to Protagenic, all of his or her right, title, and interest in and to any and all Developments.

5.4 Third-Party Intellectual Property. Consultant acknowledges that Protagenic does not desire to acquire any trade secrets, know-how, confidential information, or other intellectual property that Consultant may have acquired from or developed for any third party ("Third-Party IP"). Consultant agrees that in the course of providing the Services, Consultant shall not improperly use or disclose any Third-Party IP.

5.5 Avoidance of Claims by Third-Parties. Unless covered by an appropriate agreement between any third party and Protagenic, Consultant shall not engage in any activities or use any facilities, funds or equipment, in the course of providing Services, which could result in claims of ownership to any Developments by such third party.

5.6 FCPA. Consultant understands that Protagenic is an issuer of securities in the United States and is subject to the provisions of the U. S. Foreign Corrupt Practices Act, 15 U.S.C. §§ 78m, 78dd-1 through 78dd-3 ("FCPA"). This law prohibits making, promising or offering to make corrupt payments to foreign officials, political parties or candidates, or making payments to other persons who will offer or make payments to any of the aforementioned parties

in order to obtain business, retain business or gain an improper advantage. Consultant represents and warrants to Protagenic that Consultant is familiar with and understands the FCPA.

5.7 Representations. Consultant represents and warrants to Protagenic that throughout the period in which Consultant provides Services to Protagenic, neither Consultant, nor any person performing Services on behalf of Consultant will engage in any activity that could cause a violation of any provision of the FCPA by Protagenic. Consultant represents and warrants that Consultant has not made, promised to make, or arranged for any third party to make any payments or gifts to foreign officials in connection with Consultant's engagement by Protagenic. Further, Consultant represents and warrants to Protagenic that Consultant has not violated any anti-corruption law and further that Consultant is not involved in, or the subject of, any investigation involving bribery, corruption or improper payments to foreign government officials, as defined in the FCPA. Consultant agrees to update these representations and warranties on a periodic basis as required by Protagenic in a format prescribed by Protagenic.

5.8 Notice of Violation. Consultant agrees to notify Protagenic immediately in writing if Consultant or any person who is performing Services hereunder on behalf of Consultant is suspected of violating any anti-corruption law or becomes involved in, or a subject of, an investigation or law enforcement inquiry into possible improper payments to foreign officials or possible violations of anti-corruption laws. Consultant further agrees to provide such notification if Consultant or any person performing Services hereunder on behalf of Consultant becomes involved in any action, suit, claim, investigation or proceeding that is pending, or to the knowledge of Consultant threatened, relating to a potential violation of any anti-corruption laws, including the FCPA.

5.9 Audits. Consultant agrees to grant Protagenic the right to audit Consultant's books and records regarding the receipt and disposition of any payments made to Consultant by Protagenic, and Consultant further agrees to cooperate with Protagenic in connection with such audits.

5.10 Material Provision. It is agreed between Consultant and Protagenic that this Article 5 is deemed by the Parties to be a material provision of this Agreement.

5.11 Consultant has received a copy of Protagenic's Code of Conduct and FCPA Compliance Memorandum (each a "Policy"). Consultant represents and warrants that Consultant has had the opportunity to review the Policy, understands the Policy, and will comply with it.

6. Miscellaneous.

6.1 Counterparts. This Agreement may be executed in counterparts, which, when taken together, shall constitute one agreement. If any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

6.2 Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party, except that Protagenic may assign this Agreement to an

affiliate or in connection with the merger, consolidation, or sale of all or substantially all of its business or assets relating to this Agreement. This Agreement shall inure to the benefit of and be binding upon the Parties and their respective lawful successors, assigns, heirs, and personal representatives.

6.3 Insider Trading. Consultant acknowledges that Consultant may receive material, non-public information about Protagenic and its business in the course of providing the Services, that this information must be maintained in strict confidence, and that the U.S. securities laws restrict trading on the basis of such information or providing such information to third parties who may trade on such information.

6.4 Publicity. Consultant consents to use by Protagenic of Consultant's name and likeness in written materials or oral presentations to current or prospective customers, investors or others, provided that such materials or presentations accurately describe the nature of Consultant's relationship with or contribution to Protagenic.

6.5 Notices. Any notice or other communication required or permitted hereunder shall be in writing and shall be deemed given (a) when delivered personally, (b) upon confirmation of delivery by email if sent during normal business hours, and otherwise on the next business day, (c) on the next business day after timely delivery to an overnight courier (postage prepaid), or (d) on the third business day after deposit in the United States mail (certified or registered mail return receipt requested, postage prepaid), to the addresses of the Parties set forth in the first paragraph of this Agreement, and in the case of correspondence to Protagenic, with a copy to "Legal Department" at the same address. Either Party may change its designated address by notice to the other Party in the manner provided in this Section 6.5.

6.6 Entire Agreement; Amendment. This Agreement, including Exhibit A, constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes any and all prior or contemporaneous oral and prior written agreements and understandings. This Agreement, including Exhibit A, may be modified, amended, or supplemented only by means of a written instrument signed by both Parties. Any waiver of any rights or failure to act in a specific instance shall relate only to such instance and shall not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

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6.8 Severability. In the event that any provision of this Agreement shall, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid or unenforceable provision had not been included herein. If any provision hereof shall, for any reason, be held by a court to be excessively broad as to duration, geographical scope, activity, or subject matter, it shall be construed by limiting and reducing it to make it enforceable to the extent compatible with applicable law as then in effect. To the extent this Agreement may

be construed in accordance with the laws of any state that limits the assignability to Protagenic of certain Developments, the provisions of this Agreement shall be modified to conform to such state limitation while most closely effectuating the original intention of the Parties (e.g., by providing for fully paid up license rights, or the like).

6.9 Equitable Relief. Consultant acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of Protagenic and are reasonable for such purpose. Consultant agrees that any breach or threatened breach of his or her obligations under this Agreement will cause irreparable harm to Protagenic. Therefore, in addition to any other remedies that may be available to Protagenic, Protagenic may apply for and obtain immediate injunctive relief in any court of competent jurisdiction to restrain the breach or threatened breach of, or otherwise to specifically enforce, any obligations of Consultant under this Agreement.

6.10 Massachusetts Information Security Regulations Compliance. Massachusetts Information Security Regulations, 201 Code of Mass. Regs. 17.00 et seq. (the "IS Regulations") mandate procedures to safeguard the "Personal Information," as defined in the IS Regulations, of Massachusetts residents. Because Consultant may have access to the Personal Information of Protagenic's employees, contractors, business associates, or customers who are Massachusetts residents ("Protected Information"), the IS Regulations require Consultant to certify compliance with the IS Regulations. Accordingly, Consultant agrees that, as long as Consultant has access to or maintains copies of Protected Information Consultant will: (a) comply with the IS Regulations with respect to the Protected Information, (b) promptly notify Protagenic of any suspected or actual data breach involving Protected Information, and (c) cooperate with Protagenic to investigate and remediate any suspected or actual data breach involving Protected Information.

6.11 Whistleblower Notice. Pursuant to 18 USC § 1833(b), an individual may not be held criminally or civilly liable under any federal or state trade secret law for disclosure of a trade secret: (i) made in confidence to a government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law; and/or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Accordingly, the Parties to this Agreement have the right to disclose in confidence trade secrets to Federal, State, and local government officials, or to an attorney, for the sole purpose of reporting or investigating a suspected violation of law. The Parties also have the right to disclose trade secrets in a document filed in a lawsuit or other proceeding, but only if the filing is made under seal and protected from public disclosure.

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EXHIBIT A

Consulting Services

Description of Services

Consultant shall continue to provide Services to Protagenic Therapeutics Inc. ("Protagenic") related to Preclinical & Clinical Development of the Company's drug portfolio, as Chief Medical Officer of the Company.

Compensation

Protagenic shall compensate Consultant for Services via an Equity Grant of 50,000 non-statutory stock options ("NSOs") at an exercise price equal to the fair market value per PTIX share, to be proposed at the next meeting of the Board of Directors, exercisable until December 19, 2030. The NSOs shall (i) contain usual and customary provisions, and (ii) vest on a four-year vesting schedule. Upon the one year anniversary of the Effective Date of this Agreement, the Company and Consultant shall make any adjustments as agreed to between both Parties, in good faith, based upon Consultants contribution to the Company.

IN WITNESS WHEREOF, the Parties each have caused this Agreement to be executed by their duly respective authorized representative as of the Effective Date.

PROTAGENIC THERPEUTICS INC.	CONSULTANT
Name: Dr. Garo Armen	Name: Dr. Robert Stein
Title: Executive Chairman	Title: Chief Medical Officer
Date: _____	Date: February 23, 2021

Exhibit 21.1

SUBSIDIARIES OF PROTAGENIC THERAPEUTICS, INC.

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Forms S-8 (File Nos. 333-214553, 333-214554, 333-217963, 333-232535, 333-237081, 333-254112) of our report dated March 23, 2021 with respect to the consolidated financial statements of Protagenic Therapeutics, Inc. (the "Company") appearing in this Annual Report on Form 10-K for the year ended December 31, 2020. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ MaloneBailey, LLP

www.malonebailey.com
Houston, Texas
March 23, 2021

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 25, 2021

/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 25, 2021

/s/ Alexander K. Arrow

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

Exhibit 32.1

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

In connection with the annual Report of Protagenic Therapeutics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Garo H. Armen, Executive Chairman, and Alexander K. Arrow, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, that:

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

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

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

March 25, 2021

By: */s/ Garo H. Armen*
Garo H. Armen, PhD
Executive Chairman
(Principal Executive Officer)

March 25, 2021

By: */s/ Alexander K. Arrow*
Alexander K. Arrow, MD, CFA
Chief Financial Officer
(Principal Financial Officer)

Exhibit 99.1

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

Exhibit 99.2

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