

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

FORM 10-K

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

For fiscal year ended: December 31, 2019

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

(State or other jurisdiction of
incorporation or organization)

**149 Fifth Avenue
New York, New York**

(Address of principal executive offices)

06-1390025

(I.R.S. Employer
Identification No.)

10010

(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
N/A

Name of exchange on which registered
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

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

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 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 No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

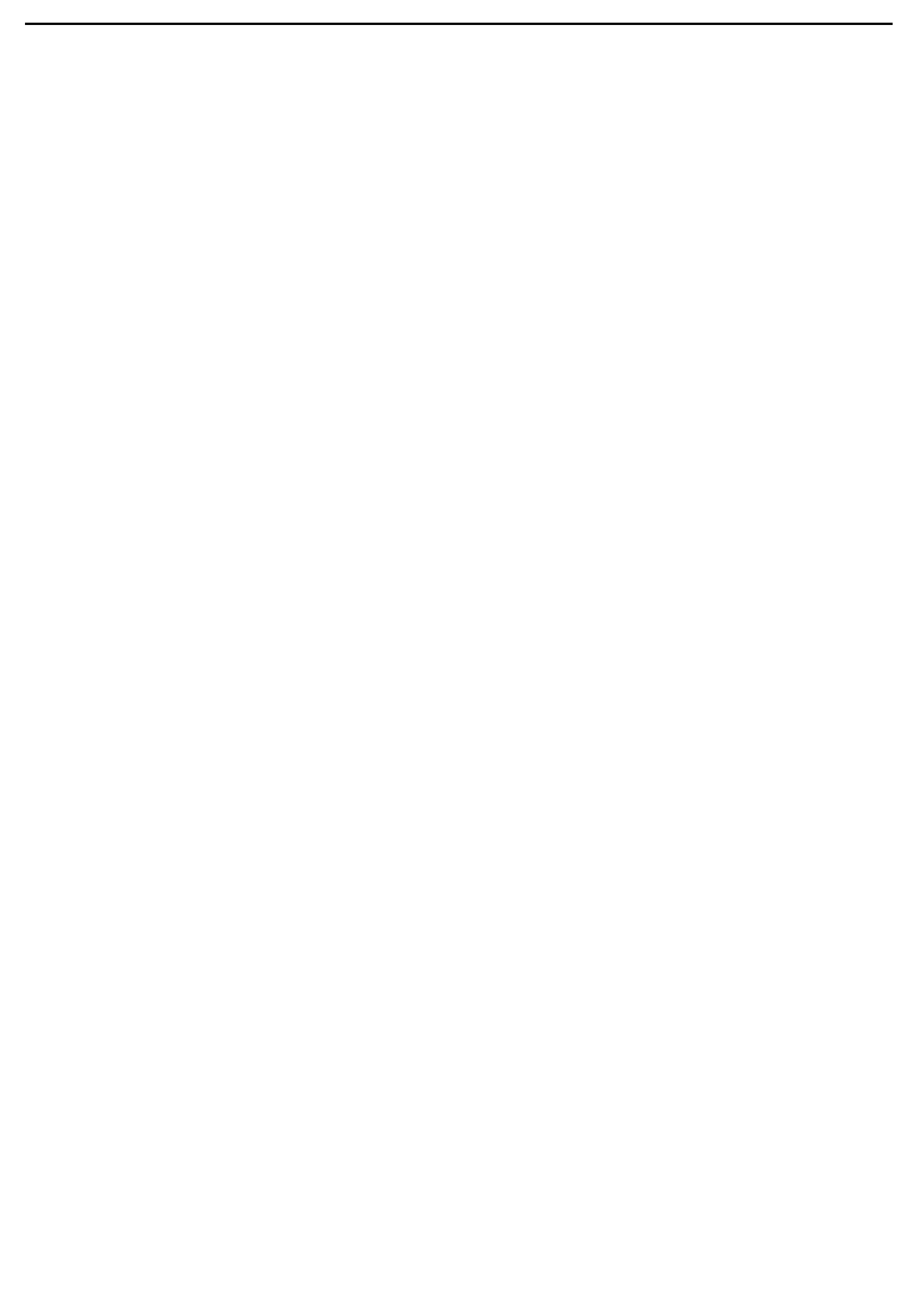
Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2019, based on a closing price as reported on the OTCQB of \$1.50 was approximately \$15,392,129.

As of April 27, 2020, there were 10,261,419 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, 2019
TABLE OF CONTENTS

| | | |
|---------|---|-----------|
| | <u>PART I</u> | 4 |
| Item 1 | <u>Business</u> | 4 |
| Item 1A | <u>Risk Factors</u> | 18 |
| Item 1B | <u>Unresolved Staff Comments</u> | 18 |
| Item 2 | <u>Properties</u> | 18 |
| Item 3 | <u>Legal Proceedings</u> | 18 |
| Item 4 | <u>Mine Safety Disclosures</u> | 18 |
| | <u>PART II</u> | 19 |
| Item 5 | <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 19 |
| Item 6 | <u>Selected Financial Data</u> | 21 |
| Item 7 | <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> | 21 |
| Item 7A | <u>Quantitative and Qualitative Disclosures About Market Risk</u> | 25 |
| Item 8 | <u>Financial Statements and Supplementary Data</u> | 25 |
| Item 9 | <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u> | 25 |
| Item 9A | <u>Controls and Procedures</u> | 25 |
| Item 9B | <u>Other Information</u> | 27 |
| | <u>PART III</u> | 27 |
| Item 10 | <u>Directors, Executive Officers and Corporate Governance</u> | 27 |
| Item 11 | <u>Executive Compensation</u> | 32 |
| Item 12 | <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> | 34 |
| Item 13 | <u>Certain Relationships and Related Transactions, and Director Independence</u> | 44 |
| Item 14 | <u>Principal Accountant Fees and Services</u> | 47 |
| | <u>PART IV</u> | 48 |
| Item 15 | <u>Exhibits and Financial Statement Schedules</u> | 48 |
| | <u>SIGNATURES</u> | 51 |

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.

PART I

Item 1. Business.

Overview

Protagenic Therapeutic, Inc. (together with its subsidiary, “Protagenic,” the “Company,” “we,” “our” or “us”) is a Delaware corporation specializing in the discovery and development of therapeutics to treat central nervous system (CNS) disorders. Our mission is to provide safe and effective treatments for mood, anxiety, depression and neurodegenerative disorders by using novel peptide-based, brain active therapeutics. Our strategy is to develop, test and obtain regulatory approval for various applications of these brain active therapeutics.

Our current business model is designed around the further development of our applications, and to obtain the required regulatory approvals to allow for the commercialization of our neuropeptide-based applications and products (see “Governmental Regulation” below). If approval is obtained, we expect to begin our sales efforts and anticipate generating revenue through both licensing and direct sales of our products. We believe that we can establish and subsequently strengthen our market position in the following ways: (i) working to obtain U.S. Food and Drug Administration (“FDA”) approval of current and future neuropeptide applications; (ii) investigating foreign markets for the use of our current and future products; (iii) securing relationships with strong partners in our field; (iv) entering into license agreements, strategic partnerships and joint ventures for our various applications; and (v) continuing our current research to improve our processes, reduce costs and develop new and innovative applications.

We intend to advance our lead drug candidate, PT00114, through Investigational New Drug (IND)-enabling studies, and enter PT00114 into clinical proof-of-concept studies in Treatment-Resistant Depression (TRD) and/or Post-Traumatic Stress Disorder (PTSD) (preclinical trials started in 2019).

Corporate History

We are currently a Delaware corporation with one subsidiary - Protagenic Therapeutics Canada (2006) Inc. (“PTI Canada”), a corporation formed in 2006 under the laws of the Province of Ontario, Canada.

We were previously known as Atrinsic, Inc., a company that was once a reporting company under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), but that, in 2012 and 2013, reorganized under Chapter 11 of the United States Bankruptcy Code and emerged from bankruptcy. On February 12, 2016, we acquired Protagenic Therapeutics, Inc. through a reverse merger (see “*Corporate History – The Reverse Business Combination (Merger) Transaction*”). On June 17, 2016, Protagenic Therapeutics, Inc. (the then wholly-owned subsidiary of Atrinsic, Inc.) was merged with and into Atrinsic, Inc. Atrinsic, Inc. was the surviving corporation in this merger and changed its name from Atrinsic, Inc. to Protagenic Therapeutics, Inc. (see “*Corporate History – The Subsidiary Merger*”).

The Reverse Business Combination (Merger) Transaction

On February 12, 2016, which we refer to as the Merger Closing Date, we (as Atrinsic, Inc.), Protagenic Therapeutics, Inc. and Protagenic Acquisition Corp., Atrinsic, Inc.’s wholly-owned subsidiary, entered into a merger agreement and completed the merger contemplated by the merger agreement. Pursuant to the merger agreement, on the Merger Closing Date, Protagenic Acquisition Corp. merged with and into Protagenic Therapeutics, Inc., with Protagenic Therapeutics, Inc. remaining as the surviving entity and wholly-owned subsidiary of Atrinsic, Inc. (the “Merger”)

Simultaneously with the Merger, on the Merger Closing Date, all of the issued and outstanding shares of Protagenic common stock converted on a 1-for-1 basis into shares of the Company’s Series B Preferred Stock, par value \$0.000001 per share (“Series B Preferred Stock”). Also on the Merger Closing Date, all of the issued and outstanding options to purchase shares of Protagenic common stock, and all of the issued and outstanding warrants to purchase shares of Protagenic common stock, converted on a 1-for-1 basis into options (the “New Options”) and new warrants (the “New Warrants”) respectively, to purchase shares of our Series B Preferred Stock. The New Options are administered under Protagenic’s 2006 Employee, Director and Consultant Stock Plan (the “2006 Plan”), which the Company assumed and adopted on the Merger Closing Date in connection with the Merger.

On the Merger Closing Date, (i) the former Protagenic common stock was exchanged for the right to receive 6,612,838 shares of Series B Preferred Stock; (ii) New Options to purchase 1,807,744 shares of Series B Preferred Stock granted under the 2006 Plan, having an average exercise price of approximately \$0.87 per share, were issued to optionees pursuant to the assumption of the 2006 Plan; (iii) the holders of options to purchase the common stock of Atrinsic before the Merger (“Predecessor”) were issued options (“Predecessor Options”) to purchase 17,784 shares of Series B Preferred Stock at \$1.25 per share; (iv) 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 Protagenic warrants; and (v) 2,775,000 shares of Series B Preferred Stock were issued to investors at a purchase price of \$1.25 per share in the Private Offering, as defined below. In addition, warrants (“Predecessor Warrants”) to purchase 295,945 shares of Series B Preferred Stock at \$1.25 per share were issued to Strategic Bio Partners, LLC, the designee (the “Designee”) of the holders of Predecessor’s debt, in consideration of the cancellation of debt of \$665,000 in principal and \$35,000 in interest, and Placement Agent Warrants, as such term is defined below, to purchase 127,346 shares of Series B Preferred Stock were issued to the Placement Agent of the Private Offering. The common stockholders of Predecessor before the Merger retained 25,867 shares of our common stock, par value \$0.000001 per share. In addition, upon the effectiveness of the Merger, the holders of the Predecessor’s Series A Preferred Stock exchanged all of the issued and outstanding Series A Preferred Stock for an aggregate of 297,468 shares of Series B Preferred Stock. These shares were issued to the Designee.

The Merger was treated as a recapitalization of Protagenic for financial accounting purposes and the historical financial statements of Protagenic Therapeutics, Inc. are our financial statements as a result of the Merger. The parties to the merger agreement have agreed to take all actions necessary to ensure the Merger is treated as a “plan of reorganization” under Section 368(a) of the Internal Revenue Code of 1986, as amended (the “Code”).

2016 Private Placement

Concurrently with the closing of the Merger, we conducted the first closing of an offering (the “Private Offering”) of our Series B Preferred Stock. At the first closing, we sold 2,775,000 shares of Series B Preferred Stock at a purchase price of \$1.25 per share, for which we received total gross consideration of \$3,468,750. Of this amount, \$350,000 consisted of conversion of outstanding stockholder debt held by Caro H. Armen, our chairman and a member of our board of directors (“Board”), and \$150,000 of legal expenses incurred by Strategic Bio Partners LLC, stockholders of the Predecessor, in conjunction with and as allowed by the merger agreement. On March 2, 2016, we completed the second closing of the Private Offering, at which we issued an additional 913,200 shares of Series B Preferred Stock to accredited investors, for total gross proceeds of \$1,141,500. On April 15, 2016, we completed the final closing of the Private Offering, at which we issued an additional 420,260 shares of Series B Preferred Stock to accredited investors, for total gross proceeds of \$525,325.

We paid Katalyst Securities LLC, our placement agent (the “Placement Agent”) and its selected dealers for the Private Offering a commission of 10% of the funds raised in the Private Offering from investors introduced by the Placement Agent and its selected dealers. In addition, the Placement Agent received \$15,000 to reimburse it for its expenses in the Private Offering, and the Placement Agent and its selected dealers were issued warrants (the “Placement Agent Warrants”) to purchase 127,346 shares of Series B Preferred Stock. The Placement Agent Warrants, which contain a “cashless exercise” provision, are exercisable for a period of five years from the initial closing of the Private Offering at a price of \$1.25 per share.

Pursuant to a registration statement declared effective by the SEC on February 8, 2017, we registered the shares of common stock underlying the Series B Preferred Stock and the Placement Agent Warrants issued in the Private Offering for public resale by the selling stockholders named therein and their assigns. The Company was not required to update and maintain the effectiveness of this registration statement after February 8, 2018.

Split-Off Agreements

At the closing of the Merger, we had a 51% membership interest in MomSpot LLC, and the remaining 49% was held by B.E. Global LLC. Barry Eisenberg was the sole owner of B.E. Global LLC and was the Chief Executive Officer of MomSpot LLC. Immediately after the closing of the Merger, we split off our 51% membership interests in MomSpot LLC. The split-off was accomplished through the transfer of all of our entire interest in MomSpot LLC to B.E. Global LLC.

Immediately after the closing of the Merger, we split off all of our equity interests in 29 wholly-owned subsidiaries. The split-off was accomplished through the sale of all of our equity interests in these wholly-owned subsidiaries to Quintel Holdings, Inc.

Reverse Stock Split

Our stockholders voted at a special meeting held on June 17, 2016 in favor of, and we effectuated, a 1-for-15,463.7183 reverse stock split of our common stock (the "Reverse Split"). As a result of the Reverse Split, 400,000,000 shares of common stock were split into 25,867 shares of common stock. Additionally, as a result of the Reverse Split and in accordance with our certificate of designations for our Series B Preferred Stock, our Series B Preferred Stock immediately and automatically converted into our common stock on a 1-for-1 basis other than any Series B Preferred Stock (i) to the extent (but only to the extent) a Series B Preferred Stock holder would beneficially own greater than 9.99% of our common stock (the "Springing Blocker") and (ii) such holder has notified the Company in writing that it wants the Springing Blocker to apply to such holder. As a result, all share amounts have been adjusted retroactively. On July 27, 2016, 10,146,000 of the Company's 11,018,766 issued and outstanding shares of Series B Preferred Stock were eligible to immediately convert into 10,146,000 shares of the Company's common stock with 872,766 shares of Series B Preferred Stock remaining as a result of one holder exercising the Springing Blocker. As of December 31, 2017, 10,146,000 shares of the Series B Preferred Stock were converted into 10,146,000 shares of common stock on the records of the Company. As of December 31, 2019 and 2018, 872,766 shares of Series B Preferred Stock remained outstanding.

Any Series B Preferred Stock not converted as a result of this provision would automatically convert into common stock as soon as such conversion would not violate the Springing Blocker. Our Series B Preferred Stock will cease to be designated as a separate series of our preferred stock when all of such shares have converted into shares of our common stock.

The Subsidiary Merger

On June 17, 2016, we merged our wholly-owned subsidiary, Protagenic Therapeutics, Inc., with and into the Company and we changed our name from Atrinsic, Inc. to Protagenic Therapeutics, Inc. We are the parent company of PTI Canada.

Mood and Anxiety Disorders

An estimated 340 million people worldwide and 40-60 million people in the United States alone suffer from mental disorders including Major Depressive Disorder, or MDD, which includes treatment-resistant depression or TRD, post-traumatic stress disorder, or PTSD, Bipolar Disorder and various Anxiety Disorders. The global sales of anxiolytic and antidepressant drugs are expected to reach \$ 18.3 billion by 2025 according to Grand View Research, Inc. (Jan 23, 2017 Grand View press release). Yet, up to one-half of mood disorder patients are unresponsive to current treatments. Efficacy of therapy is challenged by non-compliance during the weeks to months required to achieve therapeutic benefit in combination with daily dosing requirements. Major targets in this space include TRD and PTSD, which are both highly resistant to available therapies.

Approximately 37% of those suffering from an MDD that does not respond to the current antidepressant medications constitute a separate group of people suffering from TRD. 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 and lack of efficacy have led to shrinkage or extinction of many pharma or small biotech neuroscience research programs. It is in this TRD market that we intend to focus our PT00114 development efforts.

TRD is the type of MDD that does not respond to standard courses of antidepressant medication. Stress plays a significant role in this illness that affects as many as half of the people diagnosed with depression. 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. As a last resort, this disease is currently managed by invasive treatment, primarily electroconvulsive therapy (ECT). However, the ECT treatment's side effects and high cost prevent millions of people from taking advantage of it.

According to an article titled "Global prevalence of anxiety disorders: a systemic review and meta-regression," written by AJ Baxter et al. (published in *Psychological Medicine* in 2013), PTSD affects an estimated 7.7 million adults (3.5%) in the US, with a disproportionately high prevalence in war veterans. Therapeutic approaches include cognitive therapy in combination with antidepressants, such as selective serotonin reuptake inhibitors (SSRIs). In addition to the vulnerabilities noted above for antidepressant-related treatments, PTSD patients often present with co-morbidities such as addictions or dependencies, which make therapeutic case management difficult.

Protogenic Research

PT00114 is the first known example of a new class of brain-targeted therapies based on a newly-described and highly conserved family of neuropeptides that regulate stress-induced mood and addictive behaviors. PT00114 is believed to act via a novel mechanism of action and is therefore expected to provide an extremely attractive therapeutic and commercial profile, especially for those patients who are not fully responsive to or compliant with current interventions. Based on preclinical data, we believe that PT00114 is well differentiated from other drug candidates on the basis of having:

- dual activity on stress- and addiction-related pathways (as present in TRD and PTSD);
- blood-brain barrier permeability; rapid onset of action and long duration of therapeutic effects;
- restoration of normalcy in stress, anxiety and addiction disorders;
- no adverse effects with little to no accumulation;
- good safety and tolerability profiles;
- convenient dosing route and schedule;
- high potency/low dose; and
- ease of chemical synthesis.

We believe that optimal cellular energy metabolism is fundamental to the biology of the brain, and clinical manifestation of aberrant energy metabolism often manifests in debilitating neurological disorders. PT00114's ability in preclinical models to enhance glucose mobilization and utilization in the brain, maintain energy homeostasis, inhibit stress-related pathways and protect cells from oxidative damage suggests potential therapeutic benefits in a range of indications involving both acute and chronic neurological injury. Potential applications include traumatic brain injury, stroke recovery, and neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease and ALS, among others.

Technology

PT00114 is a synthetic form of the natural peptide sequence TCAP-1.

TCAP-1 was discovered in a genome-wide search for proteins related to corticotropin releasing factor (CRF), a key brain peptide hormone in stress response. While TCAP-1 counteracts stress, it does so by a non-CRF receptor pathway and unlike direct CRF antagonists it does not exhibit negative effects in animal models studied to date.

PT00114 inhibits stress and stress (CRF)-induced actions in clinically-relevant gold-standard animal models of anxiety, depression and addiction at concentrations several magnitudes below current front-line therapeutics. These beneficial effects are maintained for as long as three weeks after treatment. PT00114 promotes neuronal process development, spine density, axon fasciculation and branching in neurons.

PT00114 crosses the blood brain barrier and concentrates in regions of the brain associated with the regulation of mood disorders. Preliminary toxicity assessment (non-GLP) indicates no clear or significant adverse effects, although further toxicity testing is required.

PT00114 is highly soluble and shows excellent stability in several storage conditions. The initial dosage form is intended as a subcutaneous injection but is also amenable to other routes of administration.

Business Plan / Proposed Next Steps

The Company's business plan calls for the following processes during 2020:

Preclinical Efficacy Data

Historically, much of the preclinical efficacy data regarding specific therapeutic benefits of PT00114 had been generated in the lab of our Chief Technology Advisor, Dr. David Lovejoy at the University of Toronto. The Company recognizes that to fully validate its business proposal and persuade potential corporate partners of target-disease efficacy, additional preclinical efficacy data from unaffiliated research organizations would be valuable. Hence, the Company has engaged two contract research organizations (CROs) to conduct preclinical tests of PT00114 for anxiety and depression, as well as alleviation of drug addictive behavior.

Process Development and Manufacturing

In parallel with the Company's external CRO research studies, the Company is pursuing good manufacturing practices (cGMP) synthesis of PT00114. The Company obtained enough TCAP in July 2017 to supply its Phase I human clinical trials anticipated to begin in the second half of 2020. The Company intends to secure at least two supplier relationships for sourcing synthesized human PT00114.

Preclinical Safety & Toxicology

A key part of the Company's preclinical studies for Investigational New Drug, or IND, readiness is the toxicology testing of PT00114 in two animal species. Because these toxicology tests will be carried out with a drug concentration that is a multiple of the intended concentration in the eventual marketable drug, the results are expected to be an important component of the Company's IND application. These tests commenced in 2019, and the Company expects additional results in the first half of 2020.

Pursue Strategic Partnership

The Company believes it would be to its advantage to secure a collaboration with a pharma/biopharma company with a presence in neurological and psychiatric diseases and/or addiction. Therefore, it plans to continue to provide updates to large pharmaceutical companies that could potentially be partners, particularly with the use of preclinical efficacy data generated with the help of CROs.

Compile and File IND

Our most important corporate goal is deploying the working capital we raised in 2019 and which we hope to raise in the future toward the compilation and submission of an investigational new drug (IND) application to the FDA. This is a prerequisite to begin Phase I human testing of PT00114 for any indication. The preclinical efficacy data has been generated at four external CROs. Toxicology tests are in-process. These are the components of this key regulatory submission anticipated in the third quarter of 2020.

Initiate Phase I Clinical Studies

Once the Company's IND application has been filed, the next major milestone is anticipated to be an approval by the Company's FDA review team that the Phase I trial protocol proposed in the IND application is acceptable to begin. The Company believes that this may be achieved in the second half of 2020.

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 and April 10, 2018 and has an expiration date of December 31, 2023.

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. 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, 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, 2019 and 2018 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 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.

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

Manufacturing

We currently do not own any manufacturing facilities, nor have we entered into any agreements with contract manufacturer for the production of PT00114. Currently, we synthesize all of the PT00114 that we use in our development activities.

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.

Major depressive disorder patients that do not respond to the current antidepressant medications constitute a separate group of TRD. 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. According to a May 10, 2016 Zion Research report, the current global depression drug market was valued at approximately \$14.5 billion in 2014, and is expected to generate \$16.8 billion by the end of 2020. The pharmaceutical addiction market is very large but has not yet been quantified because no successful drug has been launched to treat victims. We intend to launch PT00114 into either the TRD, anti-anxiety, or pharmaceutical addiction markets.

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 non-addictive therapeutic drugs for TRD. Competitors include ALKS 5461 (from Alkermes), which is a fixed combination of buprenorphine and samidorphan being developed as a therapy for TRD. Buprenorphine is a mu opioid receptor partial agonist as well as an antagonist of the kappa-opioid receptor (KOR), while samidorphan is an antagonist of mu opioid receptors that essentially works to block the buprenorphine from binding to the mu-receptor. The combination of these mechanisms may result in attenuation of the mu agonist effects of buprenorphine, potentially making this a non-addictive therapy. ALKS 5461 is in Phase III clinical trials as a once-daily therapy administered as a sublingual tablet. It is well tolerated and treatment effects were evident after one week of dosing. We believe that our competitive advantage is that PT00114 targets a different receptor system and, therefore, it is not likely to have a clinical overlap with opioid receptor modulators.

Antipsychotics with antidepressant effects (dopamine receptor modulators)

Brexpiprazole (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 (from Gedeon Richter) 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-like TRD drugs

Drugs that act in a mechanism similar to Ketamine, such as Esketamine nasal spray (from Johnson and Johnson) is the S(+) enantiomer of the drug ketamine acts primarily as a non-competitive NMDA receptor antagonist, but is also a dopamine reuptake inhibitor. This class of candidates has generated excitement but uncertainty due to its use history. It may be a compounding factor in market acceptance. We believe that our competitive advantage is that the toxicity profile is likely to be less favorable when compared with 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. A drug called GLYX 13, an amidated tetrapeptide (with the amino acid sequence Thr-Pro-Pro-Thr-NH₂), is a glycine-site functional partial agonist of the NMDA receptor discovered at Northwestern University, now being developed by Naurex/Allergan, in Phase III U.S. clinical trials. It will be administered by intravenous injection and has a rapid onset. Phase II results have shown that GLYX 13 treatment reduces depression scores in patients with TRD, with no psychotomimetic side effects common to other NMDA receptor modulators. The major peptide candidate in this group, GLYX13, shows a better tolerance profile and even IV dosing once weekly is not a deterrent enough in the clinic so PT00114 peptide with possible subcutaneous delivery would be a much more preferable clinical option. The development of the tetrapeptide and entry into the trials demonstrated room and willingness to accept peptide based therapies in TRD. More candidates are expected to come from this therapeutic class that may present a competitive challenge for PT00114.

Another of Naurex's small molecule candidates, NRX-1074, is an orally active therapy based on GLYX13, in preclinical stages. L-4-Chlorokynurenine, AV-101 (from VistaGen Therapeutics) is a fast acting, orally active small molecule glycine binding site NMDA receptor antagonist. A NIH-funded phase II trial in major depressive disorder has been initiated in the US. CERC-301 (Cerecor) is an orally-active, selective NMDA receptor subunit 2B (NR2B) antagonist which is in phase II an adjunctive therapy for TRD.

PT00114's Competitive Advantages/Disadvantages

We believe PT00114 will be able to compete against each of these drugs based on its core advantages:

- PT00114, once in a patient, had a rapid onset of action (efficacy in animal anxiety and depression models) compared with other TRD drugs which may take longer to take effect.
- 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 from the patient's bloodstream (its "half life" is 5-10min if given intravenously (IV), 20-30 minutes if given subcutaneously (SC)).
- PT00114 naturally crosses the blood brain barrier, while certain other TRD drugs do not naturally do that and therefore must be given at higher doses so that any of them make it into the patient's brain.
- PT00114 is an L-isomer, a naturally modified peptide (by way of pyroGlu, amidation) therefore liver toxicity is not anticipated – resulting in a potentially superior toxicity profile.
- PT00114 is soluble, it can be easily formulated with clinical excipients, and it is stable when lyophilized, making it easy to package into a drug pill form.
- PT00114 will be manufactured by standard solid phase chemistry, which is less expensive than manufacturing processes required by other TRD drugs.
- It counteracts the stress effects associated with corticotropin releasing factor (CRF), a mechanism of action not yet known among today's commercially-available TRD drugs.
- It increases glucose import into brain cells, thus it is potentially effective against diabetes associated depression and anxiety disorders.
- It increases energy metabolism likely by mitochondrial activation in brain cells.

The main competitive disadvantage that PT00114 will have relative to other antidepressant drugs is that it will have fewer marketing resources behind it, assuming that the Company does not consummate a partnership with a large pharmaceutical company during its commercial marketing phase. Beyond this marketing resources disadvantage, the Company acknowledges that PT00114 may have efficacy disadvantages that we are not yet aware of since the drug has not yet been tested in humans. Extrapolating the early results obtained in rodent studies, PT00114 appears to be more effective and with few or no side effects, but this must be treated as an unknown since no human studies have yet been performed, and a new competitive disadvantage could be discovered during the clinical trial phase.

Although we believe PT00114's advantages will allow it to compete effectively against other antidepressant drugs in the TRD market, many of our competitors and potential competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to our programs or advantageous to our business.

Intellectual Property

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

As of December 31, 2019, we have five patents issued by the Governments of the United States, Canada, European Union and Australia and three patent applications pending worldwide including in the U.S. Some 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. Other patent applications were made with various Company personnel as inventors and all rights have either been assigned or are in the process of being assigned from individuals who are legally obligated to assign rights to the Company.

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

We also rely upon trade secrets, confidentiality agreements, proprietary know-how and continuing technological innovation to remain competitive, especially where we do not believe patent protection is appropriate or obtainable. We continue to seek ways to protect our proprietary technology and trade secrets, including entering into confidentiality or license agreements with our employees and consultants, and controlling access to and distribution of our technologies and other proprietary information. While we use these and other reasonable security measures to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors.

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

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

As of December 31, 2019, we controlled the following intellectual property:

| Title | Country | Status | Issue Date |
|---|---|---------------|-------------------|
| 1. Teneurin C-Terminal Associated Peptides (TCAP) and Methods and uses thereof. Serial # 10/510,959 | United States | Patent issued | 01/03/2012 |
| 2. Teneurin C-Terminal Associated Peptides (TCAP) and Methods and uses thereof. Serial # 2003221575. | Australia | Patent issued | 09/23/2011 |
| 3. Teneurin C-Terminal Associated Peptides (TCAP) and Methods and uses thereof. Serial # 2,482,810. | Canada | Patent issued | 06/10/2014 |
| 4. Teneurin C-Terminal Associated Peptides (TCAP) and Methods and uses thereof. Serial # 03717086.7 | European Union. Validated in France, Germany and Great Britain. | Patent issued | 03/12/2014 |
| 5. A Method for Regulating Neurite Growth: Application. Serial # 60/783,821 | United States | Patent issued | 08/01/2017 |
| 6. Method for Modulating Glucose Transport Using Teneurin C-Terminal Associated Peptide (TCAP). Serial # 62/026,346 | United States | Pending | Filed 01/17/2017 |
| 7. Composition, Methods and Uses for Enhancing Muscle Function Using Teneurin C-Terminal Associated Peptide (TCAP). Serial # 62/399,702 | United States | Pending | Filed 09/26/2016 |
| 8. Composition, Methods and Uses for Treating Post-Traumatic Stress Disorder Using Teneurin C-Terminal Associated Peptide (TCAP). Serial # 62/571,616 | United States | Pending | Filed 10/12/2017 |
| 9. Composition, Methods and Uses for Treating Opioid Addiction Using Teneurin C-Terminal Associated Peptide (TCAP). Serial # 62/642,201 | United States | Pending | Filed 03/13/2018 |

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

Governmental Regulation

Our technologies are subject to extensive government regulation, principally by the FDA and state and local authorities in the United States and by comparable agencies in foreign countries. Governmental authorities in the United States extensively regulate the preclinical and clinical testing, safety, efficacy, research, development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceutical products under various federal laws including the Federal Food, Drug and Cosmetic Act, or FFDCA, and under comparable laws by the states and in most foreign countries.

The Company has not commenced its FDA approval application process and does not plan to launch the FDA application process until 2022 or 2023. We cannot commence the FDA application process until we have obtained clinical human data on PT00114 in three phases of clinical trials, none of which have been initiated. Similarly, the Company will be required to obtain regulatory approval in every country or region outside the United States into which it plans to sell its drug products. We may seek approval from authorities outside the United States such as the European Union CE Mark and Japanese Ministry of Health. As of December 31, 2019, the Company has not launched the approval application process for any region in the world because of its lack of clinical human data on PT00114.

Domestic Regulation

In the United States, the FDA, under the FFDCA, the Public Health Service Act and other federal statutes and regulations, subjects pharmaceutical and biologic products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products or product candidates, and we may be criminally prosecuted. The FDA also has the authority to discontinue or suspend manufacture or distribution, require a product withdrawal or recall or revoke previously granted marketing authorizations, if we fail to comply with regulatory standards or if we encounter problems following initial marketing.

FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data demonstrating the product's safety and efficacy as well as detailed information on the manufacture and composition of the product candidate. In most cases, this entails extensive laboratory tests and preclinical and clinical trials. This testing and the preparation of necessary applications and processing of those applications by the FDA are expensive and typically take many years to complete. The FDA may deny our applications or may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing any products we may develop. The FDA also may require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. Regulatory authorities may withdraw product approvals if we fail to comply with regulatory standards or if we encounter problems following initial marketing. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit the products or technologies.

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

- completion of preclinical laboratory tests or trials and formulation studies;
- submission to the FDA of an IND for a new drug or biologic, which must be accepted by FDA before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use; and
- submission and approval of a New Drug Application, or NDA, for a drug, or a Biologic License Application, or BLA, for a biologic.

Preclinical tests include laboratory evaluation of product chemistry formulation and stability, as well as studies to evaluate toxicity. The results of preclinical testing, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The FDA requires a 30-day waiting period after the filing of each IND application before clinical trials may begin, in order to ensure that human research subjects will not be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may halt proposed or ongoing clinical trials, or may authorize trials only on specified terms. The IND application process may become extremely costly and substantially delay development of our products. Moreover, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

The sponsor typically conducts human clinical trials in three sequential phases, which may overlap. These phases generally include the following:

Phase I: The product is usually first introduced into healthy humans or, on occasion, into patients, and is tested for safety, dosage tolerance, absorption, distribution, excretion and metabolism.

Phase II: The product is introduced into a limited patient population to:

- assess its efficacy in specific, targeted indications;
- assess dosage tolerance and optimal dosage; and
- identify possible adverse effects and safety risks.

Phase III: These are commonly referred to as pivotal studies. If a product is found to have an acceptable safety profile and to be potentially effective in Phase II clinical trials, new clinical trials will be initiated to further demonstrate clinical efficacy, optimal dosage and safety within an expanded and diverse patient population at geographically-dispersed clinical study sites.

If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor its safety and effectiveness.

Clinical trials must meet requirements for Institutional Review Board, or IRB, oversight, informed consent and the FDA's Good Clinical Practices. Prior to commencement of each clinical trial, the sponsor must submit to the FDA a clinical plan, or protocol, accompanied by the approval of the committee responsible for overseeing clinical trials at one of the clinical trial sites. The FDA and the IRB at each institution at which a clinical trial is being performed may order the temporary or permanent discontinuation of a clinical trial at any time if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients.

The sponsor must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, in the form of an NDA, or, in the case of a biologic, a BLA. Once the submission has been accepted for filing, the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee.

It is possible that our product candidates will not successfully proceed through this approval process or that the FDA will not approve them in any specific period of time, or at all. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria, or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the product. Satisfaction of FDA pre-market approval requirements for a new biologic is a process that may take several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. The FDA reviews these applications and, when and if it decides that adequate data are available to show that the product is both safe and effective and that other applicable requirements have been met, approves the drug or biologic for marketing. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Upon approval, a product candidate may be marketed only for those indications approved in the BLA or NDA and may be subject to labeling and promotional requirements or limitations, including warnings, precautions, contraindications and use limitations, which could materially impact profitability. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained or if safety, efficacy or other problems occur after the product reaches the marketplace.

The FDA may, during its review of an NDA or BLA, ask for additional test data. If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor the safety and effectiveness of the product. In addition, the FDA may, in some circumstances, impose restrictions on the use of the product, which may be difficult and expensive to administer and may require prior approval of promotional materials.

We have not yet begun the preparation of our IND application to begin Phase I clinical trials. We anticipate doing so in the second half of 2020. We also have not begun to prepare our application for FDA approval which we anticipate will be in 2024 or 2025. The process of collecting the clinical data needed to complete our IND application is the focus of all of our working capital and is expected to consume all of our available capital resources over the next eighteen months. The expenditures necessary to make progress along our IND program are expected to keep our operations in a cash flow negative state for the entire period from now until and after our IND application in the second half of 2024.

Ongoing FDA Requirements

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with the FDA's current Good Manufacturing Practices, or cGMP, requirements which govern the manufacture, holding and distribution of a product. Manufacturers of biologics also must comply with the FDA's general biological product standards. Following approval, the FDA periodically inspects drug and biologic manufacturing facilities to ensure continued compliance with the cGMP requirements. Manufacturers must continue to expend time, money and effort in the areas of production, quality control, record keeping and reporting to ensure full compliance with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, voluntary recall of product, withdrawal of marketing approval or civil or criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or market removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and FTC requirements which include, among others, standards and regulations for direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing the Company to correct deviations from regulatory standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA and enforcement actions that can include seizures, injunctions and criminal prosecution.

Manufacturers are also subject to various laws and regulations governing laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with their research. In each of the above areas, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and deny or withdraw approvals.

HIPAA Requirements

Other federal legislation may affect our ability to obtain certain health information in conjunction with our research activities. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, mandates, among other things, the adoption of standards designed to safeguard the privacy and security of individually identifiable health information. In relevant part, the U.S. Department of Health and Human Services, or HHS, has released two rules mandating the use of new standards with respect to such health information. The first rule imposes new standards relating to the privacy of individually identifiable health information. These standards restrict the manner and circumstances under which covered entities may use and disclose protected health information so as to protect the privacy of that information. The second rule released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards impose requirements on covered entities conducting research activities regarding the use and disclosure of individually identifiable health information collected in the course of conducting the research. As a result, unless they meet these HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

In addition to the statutes and regulations described above, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state and local regulations.

Research and Development

Our research and development efforts with respect to the formulations of PT00114 as our first potential product are exclusively conducted under premises of UT, Ontario, Canada. Much of our scientific research and discovery work is performed by Dr. David A. Lovejoy, our Chief Science Advisor and Dr. Dalia Barsyte, our Chief Technology Advisor. These activities are funded by us under our Sponsored Research agreements with UT. We intend in the future to raise capital in distinct phases, matched to relevant scientific developments. The Company has financed completion of its preclinical proof of principle studies and the solidification of its intellectual property position through private offerings of its securities. In addition, the proceeds of bridge loans from the Company's Chairman were used to fund research, development and the general operating activities of the Company. We anticipate that we will require additional financing through IND-enabling studies, and to support entry into clinical proof-of-concept studies in Treatment-Resistant Depression (TRD) and/or Post-Traumatic Stress Disorder (PTSD). As we intend to develop new product candidates, we may be required to conduct additional scientific, preclinical and as well as clinical studies. We currently have no commitments to provide us with any such additional funding.

We incurred approximately \$807,947 and \$881,186 for research and development activities for the years ended December 31, 2019 and 2018, respectively.

The Company may derive credits from scientific research and experimental development tax credits and/or refunds issued by the Canada Revenue Agency for qualified expenditures. The credits are recognized when the refund is issued. The amounts received are reinvested into the Company's scientific research, experimental development and operational works conducted in Canada.

Subsidiary

PTI Canada was incorporated in 2006 in the Province of 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, 2019 and 2018 of \$23,014 and \$27,130, 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.

Item 1A. Risk Factors.

In December 2019, a novel strain of coronavirus, COVID-19, surfaced in Wuhan, China. This virus continues to spread around the world, resulting in business and social disruption. The coronavirus was declared a Public Health Emergency of International Concern by the World Health Organization on January 30, 2020. The operations and business results of the Company could be materially adversely affected. Employers are also required to prepare and increase as much as possible the capacity and arrangement for employees to work remotely. The extent to which the coronavirus may impact business activity or results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions required to contain the coronavirus or treat its impact, among others.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

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 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 our 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.

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, 2019, 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.

We anticipate that we will expend significant financial and managerial resources in the defense of our intellectual property rights in the future if we believe that our rights have been violated. We also anticipate that we will expend significant financial and managerial resources to defend against claims that our products and services infringe upon the intellectual property rights of third parties.

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.

Trades in our common stock may be subject to Rule 15c-9 of the Exchange Act, which imposes requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, broker/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction before the sale.

The SEC also has rules that regulate broker/dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than \$5.00 (other than securities listed on certain national exchanges, provided that the current price and volume information with respect to transactions in that security is provided by the applicable exchange or system). The penny stock rules require a broker/dealer, before effecting a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing before effecting the transaction, and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for shares of our common stock. As a result of these rules, investors may find it difficult to sell their shares.

Our common stock was quoted on the OTC Pink under the symbol "ATRN" prior to July 27, 2016 and then under the symbol "PTIX" between July 27, 2016 and October 16, 2016. Commencing on October 17, 2016, our common stock is quoted in the OTCQB under the symbol "PTIX". 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.

| | <u>High</u> | <u>Low</u> |
|--------------------|-------------|------------|
| 2018(1) | | |
| First Quarter (1) | \$ 2.20 | \$ 1.76 |
| Second Quarter (1) | \$ 1.76 | \$ 1.76 |
| Third Quarter (1) | \$ 2.50 | \$ 1.25 |
| Fourth Quarter (1) | \$ 2.00 | \$ 1.99 |
| 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 |

(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 April 27, 2020, there are approximately 434 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

From November 2019 through March 2, 2020, the Company held several closings (each, a “Closing”), at which it entered into Convertible Note Purchase Agreements (“Purchase Agreement”) with accredited investors (the “Investors”). Pursuant to the Purchase Agreements, the Company issued and sold unsecured convertible promissory notes (collectively, the “Notes”) to the Investors in the aggregate principal amount of \$950,000, with \$250,000 being from related parties. The Company may issue additional Notes in the future, up to an aggregate of \$2,500,000 principal amount of Notes (the “Note Private Offering”).

The Notes are 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 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 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 will bear interest at the rate of 12% per year (the “Default Rate”) following a default.

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 “Common Stock”). 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 will 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 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 affected at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest 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.

The following events, among others, constitute an event of default under the Notes: (i) failure to pay when due any obligations under the Notes; (ii) any representation or warranty of the Company under the Purchase Agreements and the other documents contemplated by the Purchase Agreement, including the Notes (collectively, the “Loan Documents”) being untrue in any material respect as of the date made; (iii) any breach by the Company of any covenant in the Loan Documents, after a cure period; (iv) a material judgment or judgments are rendered against the Company; (v) the Company makes an assignment for the benefit of creditors; or (vi) an involuntary proceeding in bankruptcy (or similar proceeding) is filed against the Company. Defaults may only be declared by the holders of a majority of the principal amount of the Notes then outstanding (a “Holder Majority”).

If stockholder approval of the issuance of the Notes is required under applicable NASDAQ or other stock exchange listing rules in order for the Company to issue shares of Common Stock upon conversion of the Notes, the Company is obligated to call one or more meetings of the stockholders for purposes of such approval.

The Notes and the shares of Common Stock underlying the Notes have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D thereunder, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

We paid the Placement Agent (the name of which will be disclosed on a subsequent Current Report on Form 8-K) including its sub-agents, a commission of 10% of the funds raised at the Closings from investors introduced by the Placement Agent. In addition, the Placement Agent received warrants (the "Placement Agent 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 at the Third Closing who were introduced by the Placement Agent. As a result of the foregoing arrangement, at the Closing, the Placement Agent (including its sub-agents) was paid aggregate commissions of \$67,000, and will be issued Placement Agent Warrants to purchase an aggregate of 53,600 shares of Common Stock at an exercise price of \$1.25 per share.

Item 6. Selected Financial Data.

Not applicable.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and the related notes and other financial information included elsewhere in this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements."

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.

Historical Background

The Company is a Delaware corporation with one subsidiary named Protagenic Therapeutics Canada (2006) Inc. ("PTI Canada"), which is a corporation formed in 2006 under the laws of the Province of Ontario, Canada.

The Company was formerly known as Atrinsic, Inc., a company that, in 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 June 17, 2016, Protagenic Therapeutics, Inc. (the then wholly-owned subsidiary of Atrinsic, Inc.) was merged with and into Atrinsic, Inc. Atrinsic, Inc. was the surviving corporation in this merger and changed its name from Atrinsic, Inc. to Protagenic Therapeutics, Inc.

Results of Operations

We are a development stage company currently performing clinical trials to obtain FDA approval and commercialization of our product.

During the year ended December 31, 2019, we incurred a loss from operations of \$2,086,130 as compared to \$2,314,217 for the year ended December 31, 2018. The decrease in the loss is due to a decrease in research and development expense of \$73,239 from \$881,186 for the year ended December 31, 2018 to \$807,947 for the year ended December 31, 2019, and a decrease in general and administrative expenses of \$154,299 from \$1,432,941 for the year ended December 31, 2018 to \$1,278,642 for the year ended December 31, 2019 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, 2019, we had cash of \$798,623 and working capital deficit of \$355,292. The Company currently has a derivative liability on the books in the amount of \$332,222 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 deficit to \$23,070. 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 2020. 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 fourth quarter of 2020.

Operating activities used \$487,990 and \$1,071,188 in cash for the years ended December 31, 2019 and 2018, respectively. The use of cash in operating activities during the year ended December 31, 2019, primarily comprised of \$1,750,911 net loss, \$797,761 in stock compensation expense, (\$343,857) of change in the fair value of the derivative liability since December 31, 2018, an increase in prepaid expenses of \$40,044, (\$4,435) from a gain on the sale of marketable securities, amortization of debt discount of \$11,370, and a \$662,158 increase 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 \$250,000 and \$1,045,662 in cash for the years ended December 31, 2019 and 2018, respectively. The cash provided by investing activities consisted of \$250,000 from the sale of marketable securities. The cash provided in investing activities during the year ended December 31, 2018 consisted of the sale of marketable securities of \$3,790,000 and the purchase of marketable securities of \$2,744,338.

Financing activities provided \$670,000 and \$0 in cash for the years ended December 31, 2019 and 2018, respectively. 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.

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.

Our anticipated timeline for reaching the significant milestones in our plan of operations and the costs associated with our plan are set forth in the table below:

| | Estimated Cost |
|---|----------------|
| 2Q 2020 | |
| Final Dosing work for Phase I | \$ 55,000 |
| Final Safety and Toxicology Animal studies | \$ 421,000* |
| 3Q 2020 | |
| Complete Stability and Formulation | \$ 85,000 |
| IND application write-up and filing | \$ 120,000 |
| 4Q 2020 | |
| Site selection, patient enrollment | \$ 850,000* |
| 1H 2021 | |
| Human Safety Data generated from Phase I trial | \$ 450,000 |
| 2H 2021 | |
| Human Efficacy Data generated from Phase II trial | \$ 600,000 |

*We have already paid \$172,000 toward this total.

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 and future plans towards 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 three paid consultants: Andrew Slee, PhD, Development Advisor, Dalia Baryte, PhD, Chief Technology Advisor, David Lovejoy, PhD, Chief Scientific Advisor, and Christina Fam Faragalla, Director of Project Management.

Financing – Capital Needs

In addition to the working capital being generated via the Note Private 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 two years, we anticipate conducting the following research and development activities at the following estimated costs and expense:

| | |
|---|---------------------|
| Basic Science of TCAP-1 | \$ 60,000 |
| Human Efficacy Studies | \$ 1,050,000 |
| Toxicology Studies | \$ 850,000 |
| Stability and Formulation | \$ 85,000 |
| Custom antibodies as an alternative to ELISA | \$ None |
| Tagged antibodies | \$ 104,000 |
| Antibody purification | \$ 24,000 |
| Clinical consultants | \$ 30,000 |
| Medical Writing and IND application compilation | \$ 79,000 |
| Technical Infrastructure | \$ 11,000 |
| Total R&D not including personnel | \$ 2,293,000 |

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 9,070,790 as of December 31, 2019, including common shares issuable under the conversion feature of the preferred shares, options, \$670,000 worth of convertible Notes, which could convert into 536,000 shares of common stock, and warrants issued in the Private Offering and Note Private 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.

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-21 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, 2019, 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 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 among those tasked with preparing the financial statements

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 among those tasked with preparing the financial statements

During the quarter ended December 31, 2019, 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, 2019, 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.

| <u>Name</u> | <u>Age</u> | <u>Position(s)</u> |
|--------------------|------------|--|
| Garo H. Armen | 67 | Executive Chairman of the Board of Directors |
| Alexander K. Arrow | 49 | Chief Financial Officer |
| Robert B. Stein | 69 | Director |
| Khalil Barrage | 55 | Director |
| Brian J. Corvese | 62 | Director |
| Josh Silverman | 49 | Director |

Garo H. Armen, PhD, Executive Chairman, is one of our founders and joined us in September 2004. Garo H. 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 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. Dr. Armen brings to our Board a deep historical and practical knowledge of the business of the Company and its technologies, as well as years of expertise in the financial and biopharmaceutical arenas.

Alexander K. Arrow, MD., CFA –Chief Financial Officer. Dr. Arrow became our Chief Financial Officer in February 2016. Dr. Arrow is also the Chief Executive Officer of Zelegent, Inc., a commercial-stage start-up medical device company launching a minimally invasive snoring alleviation tool, and the Chief Financial Officer of Carlsmed, a personalized medicine spinal implant start-up company. From January 2015 through December 2015, Dr. Arrow also served as a director and acting Chief Operating Officer of Neumedicines, Inc., a clinical-stage private biotechnology company developing protein therapeutics that address unmet clinical and societal needs in Oncology, Hematology and Immunology. Dr. Arrow serves as a director of Medcura, Inc. (formerly Ge-e, Inc.), a wound-care company with an FDA-cleared hemostatic patch product, Paragonix, Inc., a medical device company that provides transplant centers with the world's leading donated organ transplant system, and Singapore-based 8i Enterprises Acquisition Corp (Nasdaq: JFK). Previously, Dr. Arrow served on the board and was the Chairman of both the Audit Committee and Compensation Committee of Biolase, Inc. (NASDAQ: BIOL) from July 2010 through February 2014, and served as the President and Chief Operating Officer of Biolase, Inc. from June 2013 through December 2014. Biolase, Inc. is a medical device manufacturer and the leading provider of lasers to the global dentistry industry. From July 2012 to June 2013 Dr. Arrow was the Chief Medical and Strategic Officer of Circuit Therapeutics, Inc., a company seeking to realize commercial potential in the field of optogenetics. From December 2007 through June 2012, Dr. Arrow was the Chief Financial Officer of Arstasis, Inc., a cardiology device manufacturer. From 2002 to 2007, Dr. Arrow 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, later renamed PLX Systems, Inc., and three years as the publishing life sciences research analyst at Wedbush Morgan Securities. In 1996, Dr. Arrow was a surgical resident at the UCLA Medical Center. 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, joined us effective the closing of the Merger in February, 2016. Dr. Robert B. Stein is Chief Scientific Officer of Agenus Inc. Dr. Robert B. Stein leads Agenus' Research, Preclinical Development and Translational Medicine functions. He helps shape clinical development strategy for vaccines and adjuvants. Additionally, he's leading integration of the 4-Antibody acquisition, which includes the company's fully human antibody drug discovery and optimization technology platform, and portfolio of immune checkpoint antibody programs. Over his 30 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. Dr. Stein bring substantial scientific expertise to our Board.

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 U.S. public equities portfolio, overseeing more than \$2 billion of assets. Mr. Barrage holds a BA from American University of Beirut. Mr. Barrage brings to the Board years of experience in the financial and biopharmaceutical arenas.

Brian J. Corvese, Director, joined us on July 28, 2017. 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. We believe that, with over 30 years of experience in the financial industry, Mr. Corvese brings substantial financial expertise to our Board.

Joshua Silverman, Director, joined us effective the closing of the Merger in February 2016. Mr. Silverman is the Co-founder and Managing Member of Parkfield Funding LLC, and is a former Principal and Managing Partner of Iroquois Capital Management, LLC. Mr. Silverman served as Co-Chief Investment Officer of Iroquois from 2003 until July 2016. From 2000 to 2003, Mr. Silverman served as Co-Chief Investment Officer of Vertical Ventures, LLC, a merchant bank. He also serves as the Chairman of the Board of Neurotrope, Inc. (Nasdaq: NTRP). 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 received his B.A. from Lehigh University in 1992. In the past five years, Mr. Silverman has served as a director of MGT Capital Investments, Inc. and National Holdings Corporation, and in 2016, became a director of WPCS International, Inc. Mr. Silverman brings to our Board years of experience in the financial arena, as well as significant public company experience.

Consultants and Advisors

Dalia Barsyte PhD, Chief Technology 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.

David A. Lovejoy, PhD, Chief 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 3 books in the field and an Associate Editor for a scientific journal and is inventor or co-inventor on all of our intellectual property.

Andrew Slee, PhD, Development Advisor. Andy Slee joined us in April 2016. During his career, he has taken several drugs from inception through all their pre-clinical and early clinical testing. During the past five 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.

Christina Faragalla, Director of Project Management, joined us in June 2016. Ms. Faragalla is responsible for managing communication and timelines in the Company's development projects, as well as being the Company's primary interface with its Contract Research Organizations (CROs). Prior to working with the Company, Ms. Faragalla served in roles both on the sponsor and CRO side. From 2010-2014 she worked with large Pharma clients overseeing late phase CNS programs at PAREXEL. From 2014-2016, she transitioned to exclusively serving emerging biotech clients in early development while at Novella Clinical, a division of Quintiles CRO, running several first-in-man clinical trials. She is an expert in Global Clinical Operations, SOP Development and Harmonization, Translational medicine, POC to Early and Late phase drug development, IND to NDA to large registries and post marketing trials. She holds a MS Clinical Research Administration from George Washington University, and a BS in Biology from Rutgers College.

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.

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. Caro (so long as Mr. Caro 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 attached as an exhibit hereto.

Board Committees

Our Board of Directors has established three standing committees: an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of these committees will operate under a charter that has been approved by our Board of Directors.

Audit Committee. 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 reviews and approves all transactions with affiliated parties. The Audit Committee is comprised of two or more independent directors who are appointed annually and subject to removal by the Board at any time. Each member of the Audit Committee must meet the independence requirements of The NASDAQ Stock Market, LLC, and SEC regulations, as well as any other applicable requirements. The Audit Committee consists of Brian Corvese and Khalil Barrage. 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 provides advice and makes recommendations to the Board in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee also reviews the compensation of our President, Chief Executive Officer, and other officers and makes recommendations in that regard to the Board as a whole. The Compensation Committee is comprised of three or more directors who are 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. Our Board appointed Messrs. Barrage (Committee Chairperson) and Corvese, and Dr. Stein to the Compensation Committee, all of whom are independent.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee nominates individuals to be elected to the full Board by our stockholders. The Nominating and Corporate Governance Committee determines the slate of director nominees for election to the Board, identifies and recommends candidates to fill vacancies occurring between annual stockholder meetings, and reviews 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 Nominating and Corporate Governance Committee is comprised of three or more directors who are 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. The Nominating and Corporate Governance Committee consists of Joshua Silverman (Chair) Garo Armen, Ph.D., and Robert Stein, Ph.D.

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, 2019 and 2018.

Summary Compensation Table

| Name and Principal Position | Year | Salary | Bonus (\$) | Stock Awards (\$) | Option Awards (\$) | Non-Equity Incentive Plan Compensation (\$) | Deferred Compensation (\$) | All Other Compensation (\$) | Total Compensation (\$) |
|--|------|------------|---------------|-------------------------|-----------------------|--|----------------------------------|-----------------------------------|-------------------------------|
| Garo H. Armen, Chairman | 2019 | 0 | 0 | 0 | \$ 0 | 0 | 0 | 0 | \$ 0 |
| | 2018 | 0 | 0 | 0 | \$ 0 | 0 | 0 | 0 | \$ 0 |
| Alexander K. Arrow, Chief Financial Officer | 2019 | \$ 9,094 | \$ 0 | \$ 0 | \$ 81,977(1) | \$ 0 | \$ 0 | N/A | \$ 91,071 |
| | 2018 | \$ 125,000 | \$ 0 | \$ 0 | \$ 0 | \$ 0 | \$ 0 | N/A | \$ 125,000 |

(1) 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 which had 81,977 shares vested by December 31, 2019 valued at U.S. \$1.97 each at December 31, 2019.

Employment Arrangements with Officers and Directors

Dr. Alexander Arrow, our Chief Financial Officer, was receiving base compensation of \$125,000 per year for his part-time work for us, but this cash compensation was suspended effective February 1, 2019 in favor of stock options, given the company's working capital constraints. Dr. Arrow received 100,000 options under the 2006 Plan as a sign-on bonus when he joined us and 140,000 options under the 2016 plan on April 15, 2016. These options have an exercise price of \$1.25 per share, a ten-year term and have vested. On October 16, 2017, we granted Dr. Arrow another ten-year option to purchase 75,000 shares of our common stock at an exercise price of \$1.75 per share, which vests in 35 monthly installments of 2,083 shares and a final installment of 2,095. On February 1, 2019, we granted Dr. Arrow another ten-year option to purchase 41,667 shares of our common stock at an exercise price of \$1.75 per share, which vested immediately. On February 21, 2020, we granted Dr. Arrow another ten-year option to purchase 120,000 shares of our common stock at an exercise price of \$1.75 per share, which vest monthly over 36 months, along with a ten-year option to purchase 187,497 shares of our common stock at an exercise price of \$1.75 per share, which vested immediately. These options were issued to cover Dr. Arrows salary over the period from April 2019 through December 2019. The terms of Dr. Arrow's option grants also include full vesting acceleration upon a change of control. Drs. Arrow and Armen currently are the only executive officers of the Company.

Consultancy Agreements

Dalia Barsyte PhD, Chief Technology Advisor. Our subsidiary, PTI Canada 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 2018. We anticipate signing a similar agreement with her in 2019. 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.

Robert B. Stein, PhD, MD. We entered into a consulting agreement with Dr. Stein effective January 2015. Dr. Stein is responsible for providing us with technical and advisory services related to our research and development efforts. The consulting agreement is effective through January 2020. 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 options vested in increments of 1.667% per month on the first day of each calendar month following January, 2015, such that the shares were fully vested on January 23, 2020. On October 16, 2017, we granted Dr. Stein a ten-year grant to purchase another 200,000 shares of our common stock, at an exercise price of \$1.75 per share, which are also now fully vested.

Christina Faragalla, Director of Project Management. We entered into a consulting agreement with Ms. Faragalla effective June 2016, via her consultancy entitled Lotus Clinical Consulting. She is compensated at the rate \$100 per hour invoices, subject to a 12-month cap of \$100,000. In addition, on October 26, 2016, we granted Ms. Faragalla ten-year options to purchase 25,000 shares of our common stock, at an exercise price of \$1.25 per share. On October 16, 2017, we granted Ms. Faragalla another ten-year option to purchase 30,000 shares of our common stock, at an exercise price of \$1.75 per share, vesting over 48 months, with no cliff. On February 25, 2019, we granted Ms. Faragalla another ten-year option to purchase 59,900 shares of our common stock, at an exercise price of \$1.75 per share, vesting immediately. These options were issued to satisfy an outstanding AP balance of \$29,950.

Director Compensation

During fiscal year 2019 we did not compensate directors who were not employees of the Company.

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 a consulting agreement with Robert B. Stein, PhD, MD, which is described above.

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

Equity Compensation Plans

| Plan category | Equity Compensation Plan Information | | |
|--|--|---|--|
| | (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 | 6,453,887 | \$ 1.18 | 2,327,370 |
| Equity compensation plans not approved by security holders | 0 | 0 | 0 |
| Total | 6,453,887 | \$ 1.18 | 2,327,370 |

In connection with the Merger, we adopted Protagenic's 2006 Employee, Director and Consultant Stock Plan (the "2006 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.

2006 Employee, Director and Consultant Stock 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. Subject to the provisions of the 2006 Plan, the Administrator is authorized to:

- a. Interpret the provisions of the 2006 Plan or of any option or stock grant and to make all rules and determinations which it deems necessary or advisable for the administration of the 2006 Plan;
- b. Determine which employees, directors and consultants shall be granted awards;
- c. Determine the number of Shares for which an award shall be granted;
- d. Specify the terms and conditions upon which an award may be granted; and
- e. Adopt any sub-plans applicable to residents of any specified jurisdiction as it deems necessary or appropriate in order to comply with or take advantage of any tax laws applicable to the us or to 2006 Plan participants or to otherwise facilitate the administration of the 2006 Plan, which sub-plans may include additional restrictions or conditions applicable to options or shares acquired upon exercise of options.

provided, however, that all such interpretations, rules, determinations, terms and conditions shall be made and prescribed in the context of preserving the tax status under Section 422 of the Code of those options which are designated as ISOs. Subject to the foregoing, the interpretation and construction by the Administrator of any provisions of the 2006 Plan or of any award granted under it shall be final.

If permissible under applicable law, the Board of Directors or the Committee may allocate all or any portion of its responsibilities and powers to any one or more of its members and may delegate all or any portion of its responsibilities and powers to any other person selected by it. Any such allocation or delegation may be revoked by the Board of Directors or the Committee at any time.

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 either the consideration payable with respect to the outstanding shares of common stock in connection with the Corporate Transaction or securities of any successor or acquiring entity (provided, that, at the discretion of the Administrator, all unvested options shall be made fully or partially exercisable for purposes of this Subparagraph upon the closing of the Corporate Transaction); 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 originally 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, 2019, 564,378 shares of common stock were added to the 2016 Plan pursuant to this evergreen provision. On February 13, 2020, 564,378 shares of common stock were added to the 2016 Plan pursuant to this evergreen provision. A total of 2,327,370 shares of common stock is currently available for issuance in connection with options and awards granted under the 2016 Plan.

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 Equity Compensation 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, 2019, we had outstanding stock options to purchase 3,835,366 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 2019 and 126,567 nonqualified stock options granted under the 2016 Plan in 2017 to our executive officers and others at an exercise price of \$1.00 per share or \$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 2016-2019 awards to our named executive officers under the 2016 Plan, 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, 2019.

| Name | No. of Securities Underlying Unexercised Options (#) Exercisable | No. of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price | Option Expiration Date |
|------------------------|--|--|--------------------------|---------------------------|
| Garo H. Amen (1) | 500,000 | - | \$ 1.25 | April 15, 2026 |
| Garo H. Amen (2) | 184,028 | 65,972 | \$ 1.75 | October 16, 2027 |
| Alexander K. Arrow (3) | 100,000 | - | \$ 1.25 | February 12, 2026 |
| Alexander K. Arrow (3) | 140,000 | - | \$ 1.25 | April 15, 2026 |
| Alexander K. Arrow (4) | 55,208 | 19,792 | \$ 1.75 | October 16, 2027 |
| Alexander K. Arrow (5) | 41,667 | - | \$ 1.00 | February 1, 2029 |

- (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. Arrow was granted a 100,000 share option grant on February 12, 2016, and a 140,000 share option grant on April 15, 2016
- (4) Dr. Arrow was granted a 75,000 share option grant on October 16, 2017.
- (5) Dr. Arrow was granted a 41,667 share option grant on February 1, 2019.

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 summarizes the beneficial owners of more than 5% of the Company's voting securities and the securities of the Company beneficially owned by the Company's directors and officers as of April 27, 2020.

| Name and address of Beneficial Owner | Amount of Beneficial Ownership | Percent of Beneficial Ownership |
|--|--------------------------------|---------------------------------|
| Caro H. Armen ⁽¹⁾ | 4,741,323(2) | 36% |
| Robert B. Stein ⁽¹⁾ | 502,500(3) | 4% |
| Khalil Barrage ⁽¹⁾ | 380,000(4) | 3% |
| Alexander K. Arrow ⁽¹⁾ | 671,799(5) | 6% |
| Larry N. Feinberg 808 North St., Greenwich, CT 06831 | 800,000(6) | 7% |
| Brian J. Corvese ⁽¹⁾ | 145,000(7) | 1% |
| David A. Lovejoy | 668,037(8) | 6% |
| Josh Silverman ⁽¹⁾ | 140,000(9) | 1% |
| Strategic Bio Partners LLC ⁽¹⁰⁾ 777 Third Avenue 30th Floor New York, NY 10017 | 1,895,945(11) | 17% |
| <i>All directors and executive officers as a group (6 persons)</i> | 6,580,622(12) | 44% |

* Less than 1%

(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 781,944 shares of common stock at an exercise price of \$1.25 or \$1.75 per share. Does not include options to purchase 268,056 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 502,500 shares of common stock at an exercise price of \$1.25 or \$1.75 per share. Does not include options to purchase 87,500 shares in the aggregate that are not exercisable within 60 days of the date of this report.

(4) Includes 50,000 shares of common stock and options to purchase 290,000 shares of common stock at an exercise price of \$1.25 or \$1.75 per share. Does not include options to purchase 70,000 shares in the aggregate that are not exercisable within 60 days of the date of this report. Also includes convertible note of \$50,000 that converts at \$1.25 per share for a total of 40,000 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 553,539 shares of common stock at an exercise price of \$1.25 or \$1.75 per share. Does not include options to purchase 110,625 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 145,000 shares of common stock at an exercise price of \$1.75 per share. Does not include options to purchase 70,000 shares of common stock that are not exercisable within 60 days of the date of this report.

(8) Includes 148,800 shares of common stock held in the name of Dr. Lovejoy and options to purchase 519,237 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 34,063 shares of common stock that are not exercisable within 60 days of the date of this report.

(9) Includes options to purchase 140,000 shares of common stock at an exercise price of \$1.25 or \$1.75 per share. Does not include options to purchase 70,000 shares of common stock that are not exercisable within 60 days of the date of this report.

(10) Hudson Bay Master Fund Ltd. (the "Managing Member") is the managing member of Strategic Bio Partners, LLC ("SBP"). Pursuant to SBP's Limited Liability Company Operating Agreement, the Managing Member has delegated to Hudson Bay Capital Management LP ("HBC") full and sole investment discretion and voting control of SBP's portfolio securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of HBC. Each of SBP, the Managing Member and Sander Gerber disclaims beneficial ownership over these securities.

(11) SBP also holds shares of Series B Preferred Stock convertible into common stock and Predecessor Warrants to purchase common stock. However, the Series B Preferred and the Predecessor Warrants are subject to a “Beneficial Ownership Cap” limitation pursuant to which the holder thereof does not have the right to convert Series B Preferred Stock or exercise the Predecessor Warrants to the extent that such exercise would result in beneficial ownership by the holder thereof, or any of its affiliates and any other persons or entities whose beneficial ownership of common stock would be aggregated with the holder’s for purposes of Section 13(d) of the Exchange Act, of more than 9.99% of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion or exercise. Disregarding the Beneficial Ownership Cap, SBP would own 1,895,945 shares of common stock, including the shares underlying Series B Preferred Stock and Predecessor Warrants.

(12) Includes warrants to purchase 1,253,367 shares of common stock and options to purchase 2,412,983 shares of common stock. Also includes convertible notes of \$250,000 that converts at \$1.25 per share for a total of 200,000 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.

Transactions with Predecessor Shareholders

Split-Off

At the closing of the Merger we had a 51% interest in MomSpot LLC, and the remaining 49% was held by B.E. Global LLC. Barry Eisenberg is the sole owner of B.E. Global LLC and is the Chief Executive Officer of MomSpot LLC. Immediately after the closing of the Merger, we split off our 51% membership interests in MomSpot LLC. The split-off was accomplished through the transfer of all of our membership interests of MomSpot LLC to B.E. Global LLC having nominal value of nominal considerations via a split off agreement.

Secured Convertible Notes/Predecessor Warrants

Between February 11, 2014 and December 9, 2015, Atrinsic issued secured convertible promissory notes (the “Secured Convertible Notes”) in the aggregate principal amount of \$665,000 and \$35,000 in interest to two of its stockholders, of which Secured Convertible Notes in the aggregate principal amount of \$332,500 were issued to Iroquois Master Fund Ltd. (“IMF”). Josh Silverman, who became one of our directors upon the closing of the Merger, is an affiliate of IMF. The Secured Convertible Notes, as revised and amended, had a maturity date of August 31, 2016 and bore interest at the rate of 5.0% per annum, payable at maturity. The outstanding principal and accrued interest of each Secured Convertible Note was convertible, subject to a 4.99% beneficial ownership cap), into shares of Atrinsic’s common stock at an initial conversion price of \$5.00 per share (subject to adjustment), at the option of the respective holders. IMF exchanged the Secured Convertible Notes that it held for 147,972 Predecessor Warrants, which Predecessor Warrants were issued to the Designee at the closing of the Merger, and the instruments by which the Secured Convertible Notes were secured were simultaneously terminated.

Transactions Relating to Protagenic

Caro H. Armen, our Chairman and principal stockholder, purchased shares of Series B Preferred Stock in the Private Offering in exchange for the cancellation of \$350,000 of loans made by him, plus accrued and unpaid interest on these loans.

During 2013 and 2012, Mr. Armen made loans to us in the amount of \$310,000. The proceeds of the loans were used to fund research, development and general operating activity of Protagenic. The loans accrued interest at the rate of 10% per annum. In February 2013, in connection with a capital raise by Protagenic, the loans and accrued interest thereon, totaling \$317,789, were converted into Protagenic warrants to purchase 953,367 shares of Protagenic common stock at an exercise price of \$1.00 per share. Other than with respect to the payment of the purchase price for the securities by the conversion of debt, Mr. Armen participated in this capital raise on the same terms as all other investors.

From April 15, 2015 through October 29, 2015, Mr. Armen made five loans to Protagenic. The proceeds of the loans were used to fund research, development and general operating activity of Protagenic. The loans accrued interest at the rate of 10% per annum. Principal and accrued interest on these loans, totaling approximately \$350,000, were converted into shares of Series B Preferred Stock in the Private Offering at a price of \$1.25 per share.

On December 21, 2015, Dr. Alexander K. Arrow purchased 60,000 shares of common stock of Protagenic from another stockholder at a per share purchase price equal to \$0.50 for an aggregate purchase price of \$30,000. In addition, Dr. Arrow purchased 58,260 shares of Series B Preferred Stock in the Private Offering, on the same terms as all other investors.

Effective December 23, 2015, Mr. Armen entered into an additional loan agreement with Protagenic pursuant to which he agreed to loan Protagenic up to \$150,000. The loans under this Agreement accrued interest at the rate of 10% per year. The principal and interest on these loans is convertible into common stock at a price of \$1.25 per share. On December 23, 2015, Protagenic borrowed \$37,628 of the \$150,000 available Borrowings under the agreement.

Effective June 17, 2016, the Board of Directors, with Caro Armen recused, determined that it was in the best interest of the Company to convert the last remaining portion of debt owed to Dr. Armen into equity, per the terms of the loan agreements. The sum total of remaining debt and accumulated interest as of December 31, 2017 was \$0.

Merger Transaction

On February 12, 2016, which we refer to as the Merger Closing Date, Atrinsic, Inc., Protagenic Therapeutics, Inc. and Protagenic Acquisition Corp., Atrinsic, Inc.'s wholly-owned subsidiary, entered into a merger agreement and completed the merger contemplated by the merger agreement. Pursuant to the merger agreement, on the Merger Closing Date, Protagenic Acquisition Corp. merged with and into Protagenic Therapeutics, Inc., with Protagenic Therapeutics, Inc. remaining as the surviving entity and wholly-owned subsidiary of Atrinsic, Inc. On June 17, 2016, we merged our wholly-owned subsidiary Protagenic Therapeutics, Inc. with and into the Company and we changed our name from Atrinsic, Inc. to Protagenic Therapeutics, Inc.

While we believe that all of these agreements and arrangements are in the best interests of our Company, related parties of the Placement Agent may derive material benefits as the result of these transactions. In addition, related parties of the Placement Agent will have a continuing substantial interest in our Company and will derive substantial benefits from any success of our Company.

Note Private Offering

Caro H. Armen and Khalil Barrage invested \$200,000 and \$50,000, respectively, in the Note Private 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.

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, and Silverman 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) that is a 50% owner of a limited liability company which owns just under 10% 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.

Dr. Stein, a member of the Compensation Committee, is 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, 2019 and 2018.

| | Fiscal Year 2019 | Fiscal Year 2018 |
|--------------------|-----------------------------|-----------------------------|
| Audit fees | \$ 55,000 | \$ 54,550 |
| Audit-related fees | \$ - | \$ - |
| Tax Fees | \$ - | \$ - |
| All other fees | \$ - | \$ - |
| Total | <u>\$ 55,000</u> | <u>\$ 54,550</u> |

Audit Fees: For the fiscal years ended December 31, 2019 and 2018, 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, 2019 and 2018, there were no tax fees, respectively.

All Other Fees: For the fiscal years ended December 31, 2019 and 2018, 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 Marcum LLP’s and Malone Bailey LLP’s independence and has determined that such services for fiscal years 2019 and 2018, 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 financial statements and related notes, together with the reports of Malone Bailey LLP appear at pages 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 |
|------------------------|---|
| 2.1 | <u>Agreement and Plan of Merger and Reorganization, dated as of February 12, 2016, by and among Atrinsic, Inc. a Delaware corporation, Protagenic Acquisition Corp., a Delaware corporation and Protagenic Therapeutics, Inc., a Delaware corporation (Incorporated by reference to Exhibit 2.1 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016).</u> |
| 2.2 | <u>Certificate of Merger as filed with the Delaware Secretary of State effective February 12, 2016 (Incorporated by reference to Exhibit 2.2 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016).</u> |
| 2.3 | <u>Certificate of Ownership and Merger Merging Protagenic Therapeutics, Inc. with and into Atrinsic, Inc. (Incorporated by reference to Exhibit 2.1 to Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2016.)</u> |
| 2.4 | <u>Agreement of Merger of Atrinsic, Inc. and Protagenic Therapeutics, Inc. (Incorporated by reference to Exhibit 2.2 to Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2016.)</u> |
| 3.1 | <u>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).</u> |
| 3.2 | <u>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 4, 2016.)</u> |
| 3.3 | <u>Certificate of Elimination of Series A 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 April 5, 2016.)</u> |
| 3.4 | <u>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 May 31, 2018).</u> |
| 4.1 | <u>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.)</u> |

- 4.2 [Form of Predecessor Warrant of Atrinsic, Inc. \(Incorporated by reference to Exhibit 4.2 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.\)](#)
- 4.3(i) [Warrant of Protagenic Therapeutics, Inc. issued to Garo H. Armen on May 17, 2011. \(Incorporated by reference to Exhibit 4.3\(i\) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.\)](#)
- 4.3(ii) [Warrant of Protagenic Therapeutics, Inc. issued to Garo H. Armen on February 18, 2013 \(Incorporated by reference to Exhibit 4.3\(ii\) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.\)](#)
- 4.4(i) [Warrant of Protagenic Therapeutics, Inc. issued to Gregory H. Ekizian on July 7, 2011. \(Incorporated by reference to Exhibit 4.4\(i\) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.\)](#)
- 4.4(ii) [Warrant of Protagenic Therapeutics, Inc. issued to PENSICO Trust Company, FBO Gregory H. Ekizian on February 18, 2013. \(Incorporated by reference to Exhibit 4.4\(ii\) to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.\)](#)
- 4.5 [Form of Placement Agent Warrant \(Incorporated by reference to Exhibit 4.5 to Company's Current Report on Form 8-K, as filed with the SEC on April 18, 2016.\)](#)
- 4.6 [Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934*](#)
- 10.1 [Indemnity Agreement, effective February 12, 2016, among Atrinsic, Inc., Strategic Bio Partners, LLC, and Iroquois Capital Management LLC and Hudson Bay Capital Management LP as guarantors. \(Incorporated by reference to Exhibit 10.5 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.\)](#)
- 10.2 [Employment Agreement, effective January 1, 2014 between Protagenic Therapeutics Canada \(2006\) Inc. and Dr. Robert Ziroyan \(Incorporated by reference to Exhibit 10.12 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.\)**](#)
- 10.3 [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 [Consulting Agreement, effective January 23, 2015, between Protagenic Therapeutics Inc. and Dr. Robert B. Stein. \(Incorporated by reference to Exhibit 10.15 to Company's Current Report on Form 8-K, as filed with the SEC on February 12, 2016.\)**](#)
- 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 [Form of Indemnification Agreement. \(Incorporated by reference to Exhibit 10.7 to the Company's registration statement on Form 10, as filed with the SEC on July 2, 2014.\)**](#)
- 10.8(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.\)](#)

- 10.8(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.\)](#)
- 10.9(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.\)](#)
- 10.9(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.\)](#)
- 10.10 [Protagenic Therapeutics, Inc. 2016 Equity Compensation Plan. \(Incorporated by reference to Exhibit 10.1 to Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2016.\)**](#)
- 10.11 [Form of Incentive Stock Option Agreement under the Protagenic Therapeutics, Inc. 2016 Equity Compensation Plan. \(Incorporated by reference to Exhibit 10.2 to Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2016.\)**](#)
- 10.12 [Form of Nonqualified Stock Option Grant Agreement under the Protagenic Therapeutics, Inc. 2016 Equity Compensation Plan. \(Incorporated by reference to Exhibit 10.3 to Company's Current Report on Form 8-K, as filed with the SEC on June 20, 2016.\)**](#)
- 10.13 [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 on November 21, 2019 \(the "November 21 Form 8-K"\).](#)
- 10.14 [Form of Convertible Promissory Note \(incorporated by reference to Exhibit 10.2 to the November 21 Form 8-K\).](#)
- 10.15 [Form of Guaranty \(incorporated by reference to Exhibit 10.3 to the November 21 Form 8-K\).](#)
- 23.1 [Consent of Malone Bailey 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 [Charter of the Science Committee of the Board of Directors of the Company.](#)
- [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: April 28, 2020

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.

| <u>Signatures</u> | <u>Title</u> | <u>Date</u> |
|---|---|----------------|
| <u>/s/ Garo H. Armen</u> Garo H. Armen | Director and Chairman of the Board (Principal Executive Officer) | April 28, 2020 |
| <u>/s/ Alexander K. Arrow</u> Alexander K. Arrow | Chief Financial Officer (Principal Financial Officer) | April 28, 2020 |
| <u>/s/ Robert B. Stein</u> Robert B. Stein | Director | April 28, 2020 |
| <u>/s/ Khalil Barrage</u> Khalil Barrage | Director | April 28, 2020 |
| <u>/s/ Brian J. Corvese</u> Brian J. Corvese | Director | April 28, 2020 |
| <u>/s/ Joshua Silverman</u> Joshua Silverman | Director | April 28, 2020 |

PROTAGENIC THERAPEUTICS, INC. AND SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED

DECEMBER 31, 2019 AND 2018

| | <u>Page</u> |
|--|-------------|
| <i>Report of Independent Registered Public Accounting Firm</i> | F-2 |
| Consolidated Balance Sheets | F-3 |
| Consolidated Statements of Operations and Comprehensive Loss | F-4 |
| Consolidated Statements of Stockholders' Equity (Deficit) | F-5 |
| Consolidated Statements of Cash Flows | F-6 |
| Notes to Consolidated Financial Statements | F-7 |

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders 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 subsidiaries (collectively the “Company”) as of December 31, 2019 and 2018, 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, 2019 and 2018, 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.

/s/ MaloneBailey, LLP

www.malonebailey.com

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

Houston, Texas

April 27, 2020

PROTAGENIC THERAPEUTICS, INC., AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

| | December 31, 2019 | December 31, 2018 |
|--|----------------------|----------------------|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash | \$ 798,623 | \$ 362,486 |
| Marketable securities | - | 250,388 |
| Prepaid expenses | 43,354 | 83,399 |
| TOTAL CURRENT ASSETS | 841,977 | 696,273 |
| Equipment - net | 296 | 611 |
| TOTAL ASSETS | \$ 842,273 | \$ 696,884 |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| CURRENT LIABILITIES | | |
| Accounts payable and accrued expenses | 865,047 | 231,688 |
| Derivative liability | 332,222 | 676,079 |
| TOTAL CURRENT LIABILITIES | 1,197,269 | 907,767 |
| PIK convertible notes payable, net of debt discount | 174,821 | - |
| PIK convertible notes payable, net of debt discount - related party | 104,549 | - |
| TOTAL LIABILITIES | 1,476,639 | 907,767 |
| 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, 2019, and December 31, 2018 | 1 | 1 |
| Common stock, \$0.0001 par value, 100,000,000 shares authorized, 10,261,419 shares issued and outstanding at December 31, 2019, and December 31, 2018 | 1,026 | 1,026 |
| Additional paid-in-capital | 14,687,172 | 13,357,920 |
| Accumulated deficit | (15,150,201) | (13,399,290) |
| Accumulated other comprehensive loss | (172,364) | (170,540) |
| TOTAL STOCKHOLDERS' DEFICIT | (634,366) | (210,883) |
| TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT | \$ 842,273 | \$ 696,884 |

See accompanying notes to the consolidated financial statements

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

| | For the year ended December 31, | |
|--|--|-----------------------|
| | 2019 | 2018 |
| OPERATING AND ADMINISTRATIVE EXPENSES | | |
| Research and development | 807,947 | 881,186 |
| General and administrative | 1,278,183 | 1,432,941 |
| TOTAL OPERATING AND ADMINISTRATIVE EXPENSES | 2,086,130 | 2,314,127 |
| LOSS FROM OPERATIONS | (2,086,130) | (2,314,127) |
| OTHER (EXPENSE) INCOME | | |
| Interest income | 2,813 | 2,790 |
| Interest expense | (15,886) | - |
| Realized gain on marketable securities | 4,435 | 4,047 |
| Change in fair value of derivative liability | 343,857 | (250,241) |
| TOTAL OTHER INCOME (EXPENSES) | 335,219 | (243,404) |
| LOSS BEFORE TAX | (1,750,911) | (2,557,531) |
| INCOME TAX EXPENSE | - | - |
| NET LOSS | \$ (1,750,911) | \$ (2,557,531) |
| COMPREHENSIVE LOSS | | |
| Other Comprehensive Loss - net of tax | | |
| Net unrealized loss on marketable securities | - | 6,250 |
| Foreign exchange translation loss | (6,647) | (8,985) |
| TOTAL COMPREHENSIVE LOSS | \$ (1,757,558) | \$ (2,560,266) |
| Net loss per common share - Basic and Diluted | \$ (0.17) | \$ (0.25) |
| Weighted average common shares - Basic and Diluted | 10,261,419 | 10,261,419 |

See accompanying notes to the consolidated financial statements

PROTAGENIC THERAPEUTICS, INC., AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT
For the Fiscal Years Ended December 31, 2019 and 2018

| | Series B Convertible Preferred Stock | | Common Stock | | Additional Paid-in- Capital | Accumulated (Deficit) | Treasury Stock | | Accumulated Other Comprehensive Loss | Stockholders' Deficit) Equity |
|--|--|-------------|-------------------|-----------------|-----------------------------------|--------------------------|----------------|-------------|---|-------------------------------------|
| | Shares | Amount | Shares | Amount | | | Shares | Amount | | |
| BALANCE-December 31, 2017 | <u>872,766</u> | <u>\$ 1</u> | <u>10,261,419</u> | <u>\$ 1,026</u> | <u>\$ 12,227,849</u> | <u>\$ (10,841,759)</u> | <u>-</u> | <u>\$ -</u> | <u>\$ (167,805)</u> | <u>\$ 1,219,312</u> |
| Unrealized gain (loss) on marketable securities | - | - | - | - | - | - | - | - | 6,250 | 6,250 |
| Foreign currency translation gain | - | - | - | - | - | - | - | - | (8,985) | (8,985) |
| Stock compensation - stock options | - | - | - | - | 1,130,071 | - | - | - | - | 1,130,071 |
| Net loss | - | - | - | - | - | (2,557,531) | - | - | - | (2,557,531) |
| BALANCE-December 31, 2018 | <u>872,766</u> | <u>\$ 1</u> | <u>10,261,419</u> | <u>\$ 1,026</u> | <u>\$ 13,357,920</u> | <u>\$ (13,399,290)</u> | <u>-</u> | <u>\$ -</u> | <u>\$ (170,540)</u> | <u>\$ (210,883)</u> |
| 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 | <u>872,766</u> | <u>\$ 1</u> | <u>10,261,419</u> | <u>\$ 1,026</u> | <u>\$ 14,687,172</u> | <u>\$ (15,150,201)</u> | <u>-</u> | <u>\$ -</u> | <u>\$ (172,364)</u> | <u>\$ (634,366)</u> |

See accompanying notes to the consolidated financial statements

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

| | For the year ended December 31, | |
|---|---------------------------------|--------------------|
| | 2019 | 2018 |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net Loss | \$ (1,750,911) | \$ (2,557,531) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation expense | 339 | 347 |
| Stock based compensation | 797,761 | 1,130,071 |
| Change in fair value of the derivative liability | (343,857) | 250,241 |
| Gain on sale of marketable securities | (4,435) | (4,047) |
| Amortization of debt discount | 11,370 | - |
| Loss on settlement of accounts payable | 99,541 | - |
| Changes in operating assets and liabilities | | |
| Prepaid expenses | 40,044 | 11,143 |
| Accounts payable and accrued expenses | 662,158 | 98,588 |
| NET CASH USED IN OPERATING ACTIVITIES | (487,990) | (1,071,188) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Sale of marketable securities | 250,000 | 3,790,000 |
| Purchase of marketable securities | - | (2,744,338) |
| NET CASH PROVIDED BY INVESTING ACTIVITIES | 250,000 | 1,045,662 |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Proceeds from convertible notes | 420,000 | - |
| Proceeds from convertible notes - related party | 250,000 | - |
| NET CASH PROVIDED BY FINANCING ACTIVITIES | 670,000 | - |
| Effect of exchange rate on cash and cash equivalents | 4,127 | (11,675) |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 436,137 | (37,201) |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 362,486 | 399,687 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | \$ 798,623 | \$ 362,486 |
| 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 | \$ (6,250) |
| Debt discount from beneficial conversion feature | \$ 252,000 | \$ - |
| Debt discount from beneficial conversion feature - related party | \$ 150,000 | \$ - |
| Issuance of options for settlement of accounts payable | \$ 29,950 | \$ - |

See accompanying notes to the consolidated financial statements

PROTAGENIC THERAPEUTICS, INC & SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2019 and 2018

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 (which at the time was named Atrinsic, Inc.), 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 a net working capital deficit and 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 2020. Absent generation of sufficient revenue from the execution of the Company’s business plan, the Company will need to obtain debt or equity financing by the fourth quarter of 2020. Management believes that actions presently being taken to obtain additional funding provide the opportunity for the Company to continue as a going concern. 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 SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

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

Principles of consolidation

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

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 the allocation of the fair value of acquired assets and liabilities, 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.

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, 2019 and 2018, 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, 2019 and 2018.

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

During the year ended December 31, 2019, the Company purchased \$0 and sold \$250,000 in marketable securities with a realized gain of \$4,435 and \$4,047 for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019 and 2018, the Company owned marketable securities with a total value of \$0 and \$250,388, respectively. The company recorded an unrealized gain (loss) on marketable securities of \$4,823 and (\$6,250) for the years ended December 31, 2019 and 2018 respectively.

As of 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 maturity of those instruments.

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 as of December 31, 2019.

| | Carrying Value | Fair Value Measurement Using | | | Total |
|---------------------------------|-------------------|------------------------------|---------|--------------|--------------|
| | | Level 1 | Level 2 | Level 3 | |
| Marketable securities | — | — | — | — | — |
| Derivative warrants liabilities | \$ (332,222) | \$ — | \$ — | \$ (332,222) | \$ (332,222) |

The following table provides a summary of financial instruments that are measured at fair value as of December 31, 2018.

| | Carrying Value | Fair Value Measurement Using | | | Total |
|---------------------------------|-------------------|------------------------------|---------|--------------|--------------|
| | | Level 1 | Level 2 | Level 3 | |
| Marketable securities | 250,388 | 250,388 | — | — | 250,388 |
| Derivative warrants liabilities | \$ (676,079) | \$ — | \$ — | \$ (676,079) | \$ (676,079) |

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, 2019 and the year ended December 31, 2018:

| | Fair Value Measurement Using Level 3 Inputs Total |
|---|---|
| Balance, December 31, 2017 | \$ 425,838 |
| Change in fair value of derivative warrants liabilities | 250,241 |
| Balance, December 31, 2018 | 676,079 |
| Change in fair value of derivative warrants liabilities | (343,857) |
| Balance, December 31, 2019 | \$ 332,222 |

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 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 date were calculated using a Black-Scholes option model valued with the following assumptions:

| | December 31, 2018 | December 31, 2019 |
|-------------------------|------------------------------|------------------------------|
| Exercise price | 1.25 | 1.25 |
| Risk free interest rate | 2.46% | 1.59% |
| Dividend yield | 0.00% | 0.00% |
| Expected volatility | 152% | 133% |
| Contractual term | 2.15 Years | 1.15 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 year ended December 31, 2019 and 2018, the Company marked the derivative feature of the warrants to fair value and recorded a loss of \$343,857 and a gain of \$250,241 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 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.

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, 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.

Stock-Based Compensation for Non-Employees

The Company accounts for warrants and options issued to non-employees under AUS 2018-07, *Equity – Equity Based Payments to Non-Employees*, using the Black-Scholes option-pricing model.

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 income statement.

| | Potentially Outstanding Dilutive Common Shares | |
|---|---|---|
| | For the Year Ended December 31, 2019 | For the Year Ended December 31, 2018 |
| Conversion Feature Shares | | |
| Common shares issuable under the conversion feature of preferred shares | 872,766 | 872,766 |
| Stock Options | 3,835,366 | 3,846,299 |
| Warrants | 3,826,658 | 3,826,658 |
| Convertible Notes | 536,000 | - |
| Total potentially outstanding dilutive common shares | 9,070,790 | 8,545,723 |

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 income 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 income 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 statement of income 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:

| | <u>December 31,</u> <u>2019</u> | <u>December 31,</u> <u>2018</u> |
|--------------------------|------------------------------------|------------------------------------|
| Accounting | \$ 36,161 | \$ 52,365 |
| Research and development | 650,584 | 137,114 |
| Legal | 15,273 | 32,161 |
| Other | 163,029 | 10,048 |
| Total | <u>\$ 865,047</u> | <u>\$ 231,688</u> |

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 is to be paid upon the signing of the agreement, 35% of the total price is to be 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 cancellation fee. If the cancellation 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 vendor. As of December 31, 2019, the Company has paid \$0 and there is a balance of \$493,905 due.

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 private 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 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 have a total principle of \$420,000. The notes accrue 6% interest per year, 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. These notes did have a beneficial conversion feature and recorded a debt discount of \$252,000. During the year ended December 31, 2019, the Company amortized \$6,821 of the debt discount. At December 31, 2019, the Company had an unamortized debt discount of \$245,179.

As of December 31, 2019 and 2018, the Company owes \$420,000 and \$0 on the outstanding notes, respectively.

Convertible Notes Payable – Related Party

During the fourth quarter of 2019, the Company entered into a series of unsecured convertible notes with related parties. The convertible notes have a total principle of \$250,000. The notes accrue 6% interest per year, 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. These notes did have a beneficial conversion feature and recorded a debt discount of \$150,000. During the year ended December 31, 2019, the Company amortized \$4,549 of the debt discount. At December 31, 2019, the Company had an unamortized debt discount of \$154,451.

As of December 31, 2019 and 2018, the Company owes \$250,000 and \$0 on the outstanding notes, respectively.

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 and January 1, 2019, 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 this increase, as of December 31, 2019, the aggregate number of shares of common stock available for awards under the 2016 Plan was 4,304,245 shares. Options issued under the 2016 Plan are exercisable for up to ten years from the date of issuance.

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% |

There were 3,846,299 options outstanding as of December 31, 2018. The fair value of each stock option granted was estimated using the Black-Scholes assumptions and or factors as follows:

| | | |
|-------------------------|----|---------------|
| Exercise price | \$ | 1.25 - \$1.75 |
| Expected dividend yield | | 0% |
| Risk free interest rate | | 2.73% - 2.85% |
| Expected life in years | | 3.75-9.40 |
| Expected volatility | | 139% - 146% |

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

| <i>Stock Options</i> | <u>Number</u> | <u>Weighted Average Exercise Price</u> | <u>Weighted Average Remaining Life</u> |
|-------------------------------|-------------------------|--|--|
| Outstanding December 31, 2017 | 3,566,299 | \$ 1.33 | 8.05 |
| Granted | 280,000 | \$ 1.75 | 9.15 |
| Expired | - | | |
| Outstanding December 31, 2018 | <u>3,846,299</u> | <u>\$ 1.36</u> | <u>7.20</u> |
| Granted | 126,567 | \$ 1.15 | 9.20 |
| Expired | (137,500) | \$ 1.75 | |
| Outstanding December 31, 2019 | <u><u>3,835,366</u></u> | <u><u>\$ 1.34</u></u> | <u><u>6.02</u></u> |

A summary of the status of the Company's nonvested options as of December 31, 2019, and changes during the year ended December 31, 2019, is presented below:

| Nonvested Options | Options | Weighted-Average Exercise Price |
|--------------------------------|----------------|--|
| Nonvested at December 31, 2017 | 1,492,861 | \$ 1.54 |
| Granted | 280,000 | \$ 1.75 |
| Vested | (972,651) | \$ 1.29 |
| Forfeited | - | - |
| 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 | <u>204,382</u> | <u>\$ 1.74</u> |

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.

As of December 31, 2019, the Company had 3,846,299 shares issuable under options outstanding at a weighted average exercise price of \$1.36 and an intrinsic value of \$2,150,912.

The total number of options granted during the year ended December, 2019 and 2018 was 126,567 and 280,000, respectively. The exercise price for these options was \$1.00 per share, \$1.25 per share, or \$1.75 per share.

The Company recognized compensation expense related to options issued of \$797,761 and \$1,130,071 during the year ended December 31, 2019 and 2018, respectively, which is included in general and administrative expenses and research and development expenses. For the year ended December 31, 2019, \$562,734 of the stock compensation was related to employees and \$235,027 was related to non-employees.

On January 24, 2018, the Company entered into a consulting agreement (the "Agreement") with NeuroAssets Sàrl ("Consultant"), a Swiss company. As part of the agreement, on February 20, 2018, the Compensation Committee of the Company's Board of Directors approved a grant of 200,000 options under our 2016 Equity Compensation Plan. The options vest over 48 months in equal monthly installments with the first monthly vesting event scheduled to occur on March 20, 2018, have a term of ten years and are exercisable at a price of \$1.75 per share. The vesting of the options will accelerate if a corporate partnership results from an introduction made by Consultant.

During the first quarter of 2018 the Company granted 80,000 stock options to four consultants. 50,000 of these options vest immediately and the remaining 30,000 options vest monthly over 48 months, have an exercise price of \$1.75, and have a term of ten years.

As of December 31, 2019, the unamortized stock option expense was \$287,905 with \$144,423 being related to employees and \$143,482 being related to non-employees. As of December 31, 2019, the weighted average period for the unamortized stock compensation to be recognized is 3.98 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.

Warrants:

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

Simultaneous with the Merger and the Private 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. Placement Agent Warrants to purchase 127,346 shares of Series B Preferred Stock at an exercise price of \$1.25 per share were issued in connection with the Private 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:

| <i>Warrants</i> | <u>Number</u> | <u>Weighted Average Exercise Price</u> | <u>Weighted Average Remaining Life</u> |
|-------------------------------|------------------|--|--|
| Outstanding December 31, 2017 | 3,826,658 | \$ 1.05 | 4.69 |
| Granted | - | - | - |
| Outstanding December 31, 2018 | 3,826,658 | \$ 1.05 | 3.69 |
| Granted | - | - | - |
| Outstanding December 31, 2019 | <u>3,826,658</u> | <u>\$ 1.05</u> | <u>2.69</u> |

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.

As of December 31, 2018 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 \$3,633,335.

NOTE 8 - COLLABORATIVE AGREEMENTS

The Company and the University of Toronto, a stockholder of the Company (the "University") entered into an agreement effective December 14, 2004 (the "Research Agreement") for the performance of a research project titled "Evidence for existence of TCAP receptors in neurons" (the "Project"). The Research Agreement expired on March 31, 2013.

The Company and 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, 2016. 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, 2019, Dr. David Lovejoy of the University has been granted 533,299 stock options, of which 510,903 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 or on October 16, 2027.

The sponsorship research and development expenses pertaining to the Research Agreements were \$63,905 and \$107,868 for the year ended December 31, 2019 and 2018, 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 year ended December 31, 2019 and 2018 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.

NOTE 11 – INCOME TAXES

The components of loss before income taxes are as follows:

| | <u>2019</u> | <u>2018</u> |
|--------------------------|--------------------|--------------------|
| Domestic | (1,698,689) | (2,468,805) |
| Foreign | (52,222) | (88,726) |
| Loss before income taxes | <u>(1,750,911)</u> | <u>(2,557,531)</u> |

The Company had no income tax expense due to operating losses incurred for the years ended December 31, 2019 and 2018.

For the years ended December 31, 2019 and 2018, a reconciliation of the Company's effective tax rate to the statutory U.S. Federal rate is as follows:

| | 2019 | 2018 |
|--|-------------|-------------|
| 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 | (0.6)% | (0.6)% |
| Change in valuation allowance | 30.2% | 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:

| | 2019 | 2018 |
|---|------------------|------------------|
| U.S. net operating loss carryforwards | 2,894,000 | 2,627,000 |
| Stock compensation | 784,000 | 359,000 |
| Canadian Provincial income tax losses | 29,000 | 56,000 |
| Canadian Provincial scientific investment tax credits | (4,000) | - |
| | <u>3,703,000</u> | <u>3,042,000</u> |
| Valuation allowance | (3,703,000) | (3,042,000) |
| Net deferred tax assets | <u>-</u> | <u>-</u> |

As of December 31, 2019 and 2018, the Company had federal net operating loss carryforwards ("NOL") of approximately \$7,161,000 and \$6,617,000, respectively. The losses expire beginning in 2024. The Company has not performed a detailed analysis to determine whether an ownership change under IRC Section 382 has occurred. The effect of an ownership change would be the imposition of annual limitation on the use of NOL carryforwards attributable to periods before the change. Any limitation may result in expiration of a portion of the NOL before utilization. As of December 31, 2019 and 2018, the Company had state and local net operating loss carryforwards of approximately \$7,153,000 and \$6,609,000, respectively, to reduce future state tax liabilities also through 2035.

As of December 31, 2019 and 2018, the Company had Canadian NOL of approximately \$1,111,000 and \$1,070,000, respectively. The Canadian losses expire in stages beginning in 2026. As of December 31, 2019 and 2018, 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, 2019 and 2018 was an increase of \$661,000 and \$457,000, 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, 2019 and 2018.

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, 2014.

NOTE 12 - SUBSEQUENT EVENTS

During 2020, the Company issued 12 convertible notes with a total principle of \$425,000. The notes accrue 6% interest per year, 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 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.

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 exercise price of \$1.25 and are fully vested.

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 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 and the final agreements are in process.

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

The following summary describes the common stock, \$0.0001 par value per share, of Protagenic Therapeutics, Inc. (the "Company", "our", "us", or "we"), which are the only securities of the Company registered under Section 12 of the Securities Exchange Act of 1934, as amended. The following is a summary and does not purport to be complete. The summary is subject to and qualified by the provisions of our Third Amended and Restated Certificate of Incorporation (the "Certificate"), Second Amended and Restated Bylaws (the "Bylaws"), and the Delaware General Corporation Law ("DGCL").

Our Certificate authorizes us to issue 100,000,000 shares of common stock, par value \$0.0001 per share.

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

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

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

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

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

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

Transfer Agent and Registrar

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

Dividends

We have never declared or paid dividends. We do not intend to pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of dividends if any, on our common stock will rest solely within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

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

Our Certificate and Bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of our company. These provisions are as follows:

- they provide that special meetings of stockholders may be called by the board of directors or at the request in writing by stockholders of record owning at least twenty (20%) percent of the issued and outstanding voting shares of common stock;
- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in our board of directors;
- they provide that stockholders seeking to present proposals before our annual meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and, subject to applicable law, will specify requirements as to the form and content of a stockholder's notice; and
- subject to the limitation prescribed by the DGCL, they authorize our Board of Directors to issue, without stockholder approval, preferred stock in one or more series, to establish from time to time the number of shares to be included in each series, and to fix the designation, powers, preferences, and rights of the shares of each series and any of its qualifications, limitations, or restrictions. Any such issuance could adversely affect the rights and powers of the holders of our common stock.

We are subject to the provisions of Section 203 of the DGCL, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the following prescribed manner:

- prior to the time of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and
- on or subsequent to the time of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

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

Stockholder Action by Written Consent

Our Bylaws provide that any action required by law to be taken at any annual or special meeting of the stockholders or any action which may be taken at such a meeting may be taken without a meeting by written consent of the stockholders in lieu of a meeting.

Choice of Forum

Our Certificate provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our Certificate or our Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Market for Common Stock

Our common stock trades on the OTCQB Venture Market under the stock symbol “PTIX.”

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in this Registration Statement on Form S-8 [File No.s 333-214553, 333-214554, 333-217963, 333-232535, 333-237081] of our report dated April 27, 2020 with respect to the audited consolidated financial statements of Protagenic Therapeutics, Inc. for the years ended December 31, 2019 and 2018. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the references to us under the heading "Experts" in such Registration Statement.

/s/ MaloneBailey, LLP

www.malonebailey.com

Houston, Texas

April 27, 2020

9801 Westheimer Road, Suite 1100, Houston, Texas 77042 713.343.4286

Zhongzhou Holdings Financial Center (Tower B) #2205 No. 88, Haide Yi Road, Nanshan District, Shenzhen, P.R. China 518054 86.755.8627.8659

#306-307 Ocean International Center (C Tower) No. 60 Dongsihuan Middle Road, Chaoyang District, Beijing, P.R. China 100025 86.10.5908.1688

www.malonebailey.com

Public Company Accounting Oversight Board Registered AICPA
An Independently Owned and Operated Member of Nexia International



**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.

April 28, 2020

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

**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.

April 28, 2020

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

**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, 2019, 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.

April 28, 2020

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

April 28, 2020

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

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

Purpose

The purpose of the Science Committee (the "Committee") shall be to provide advice, understanding and guidance both to management of the Company and to the Board of Directors on matters involving (i) the Company's development programs and projects, (ii) acquisitions of new technologies or products and other business opportunities of strategic, scientific and commercial importance to the Company, and (iii) relationships with academic and corporate organizations.

Committee Membership and Meetings

The Committee shall consist of two or more members of the Board of Directors. The Board of Directors, upon the recommendation of the Corporate Governance and Nominating Committee, shall appoint the members of the Committee. At least one member of the Committee shall meet the independence requirements of the Nasdaq Stock Market. Members of the Committee shall serve at the pleasure of the Board of Directors and for such term or terms as the Board of Directors may determine. Management of the Company shall also designate one member of management who will be the regular liaison between the Committee and management, and the Committee shall also have access to other members of management and key employees as necessary to carry out its responsibilities hereunder.

The Committee shall meet at such times as it determines to be necessary or appropriate and at such times requested by the Board of Directors and shall report at the next Board of Directors meeting following each such Committee meeting. The Committee may engage external consultants, as required, to provide supplemental expertise to facilitate their performance of their duties, and to determine compensation for such advisors. 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. 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.

Responsibilities

The Committee shall assist the Board of Directors and management of the Company in assessing the progress and performance of the Company's development programs and projects, and identifying, assessing, implementing, and monitoring scientific opportunities that may offer meaningful strategic or commercial benefit to the Company. The role of the Committee will be to leverage the experience and expertise of the Board of Directors to assist management in a dedicated and more intensive manner than can be accomplished through regular board meetings. In particular, the Committee shall:

1. Assist management with pre-clinical research and development of pharmaceutical product targets in the Company's pipeline.
2. Assist management to identify new technologies or products or other business opportunities that may be of strategic, scientific or commercial benefit to the Company.
3. Provide guidance to management to evaluate the merits and risks associated with any such scientific opportunities.
4. Review and evaluate terms for proposed scientific business opportunities proposed to be pursued by management.
5. Review and advise on the appropriate structure for potential strategic transactions of pharmaceutical assets.
6. Review with management periodically the Company's pipeline and product portfolio and strategy, development timelines and progress, and provide the Board with advice regarding same.
7. Provide guidance to the Board of Directors in its review, consideration and oversight of any programs, research studies, or transactions recommended by management.

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; and
- Review such other matters as the Board or the Committee shall deem appropriate.

The Committee shall undertake such additional activities within the scope of its primary functions as the Committee may from time to time determine. Unless the same shall be expressly delegated to the Committee from time to time by the Board of Directors, including under this charter, the Committee shall not have the authority to approve or authorize any matters that would otherwise be the responsibility of the Board of Directors.

Adopted February 24, 2017
