

## **Charter of the Clinical and Regulatory Committee of the Board of Directors of Protagenic Therapeutics, Inc. (the “Company”)**

### **Purpose**

The purpose of the Clinical and Regulatory 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 clinical testing plans and trials, (ii) interactions with clinical regulatory bodies, especially the U.S. Food and Drug Administration (FDA), and (iii) relationships with clinical investigators and clinical research 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 clinical testing plans and trials, its interactions with clinical regulatory bodies, especially the U.S. Food and Drug Administration (FDA), and its relationships with clinical investigators and clinical research organizations. 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 clinical trial protocol development regarding pharmaceutical product targets in the Company's pipeline.
2. Assist management to identify issues or challenges in a particular regulatory strategy, for the benefit to the Company.
3. Provide guidance to management to evaluate the merits and risks associated with any clinical trial design proposed by a third-party clinical research organization (CRO).
4. Review and evaluate interim data and final outcomes generated by clinical trials.
5. Review and advise on the appropriate structure for agreements with CROs with relation to testing of the company's pharmaceutical assets.
6. Review with management periodically the Company's clinical trial 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 Company-sponsored clinical trials 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 September 1, 2020