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

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**FORM 8-K**

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**CURRENT REPORT**

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

**December 20, 2011**

Date of Report (Date of earliest event reported)

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**GALECTIN THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

**NEVADA**  
(State or other jurisdiction of incorporation)

**000-32877**  
(Commission File Number)

**04-3562325**  
(IRS Employer Identification No.)

**7 WELLS AVENUE  
NEWTON, MASSACHUSETTS  
02459**  
(Address of principal executive offices) (Zip Code)

**(617) 559-0033**  
(Registrant's telephone number, including area code)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01 Other Events**

Exhibit 10.2 to our Form 10-Q Quarterly Report filed on November 10, 2011, is a copy of our Collaboration, Supply, Marketing and Distribution Agreement with Procaps S.A. (the “Agreement”) that was redacted to omit certain information as to which we requested confidential treatment from the Securities and Exchange Commission. Attached as Exhibit 10.2 to this report is the same document except that in Section 18 thereof we have restored information as to the term of the Agreement.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

10.2. Collaboration, Supply, Marketing and Distribution Agreement between Galectin Therapeutics Inc. and Procaps S.A. dated as of October 18, 2011 (subject to an application requesting confidential treatment of the portions indicated by [\*\*\*\*] submitted to the Secretary of the Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended)

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Galectin Therapeutics Inc.**

By: /s/ Anthony D. Squeglia  
Anthony D. Squeglia  
Chief Financial Officer

Date: December 20, 2011

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## Exhibit Index

### Exhibit No.:

10.2. Collaboration, Supply, Marketing and Distribution Agreement between Galectin Therapeutics Inc. and Procaps S.A. dated as of October 18, 2011 (subject to an application requesting confidential treatment of the portions indicated by [\*\*\*\*] submitted to the Secretary of the Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended)

## COLLABORATION, SUPPLY, MARKETING AND DISTRIBUTION AGREEMENT

This Collaboration, Supply, Marketing and Distribution Agreement (this “Agreement”) is made as of October 18, 2011 (the “Effective Date”) by and between Galectin Therapeutics, Inc. (f/k/a Pro-Pharmaceuticals, Inc.), a Nevada corporation, having a principal place of business at 7 Wells Avenue, Newton, MA 02459, USA (“Galectin Therapeutics”) and Procaps S.A., a Colombian Company, having offices at Calle 80, Bo. 78B – 201, Barranquilla, Colombia (“Procaps”). Galectin Therapeutics and Procaps are each a “Party” and are collectively referred to as the “Parties.”

WHEREAS, Galectin Therapeutics is in the business of developing and commercializing drug therapies for cancer, as well as other diseases;

WHEREAS, Procaps is in the business of importing, seeking approval for, obtaining pricing reimbursement approval for, distributing, marketing and commercializing pharmaceutical products in the Territory (as defined below) and providing related services; and

WHEREAS, Procaps has offered to import, seek approval for, distribute, market and commercialize Galectin Therapeutics’ GM-CT-01 (DAVANAT®) product in the Territory and provide related services, and Galectin Therapeutics is willing to engage Procaps, in accordance with this Agreement;

NOW THEREFORE, in consideration of the foregoing and the mutual promises and covenants contained herein, the adequacy of which each Party hereby accepts, the Parties mutually agree as follows:

### 1. DEFINITIONS

1.1. “Affiliate” means, with respect to any Person, a Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, the first mentioned Person.

1.2. “Approval Plan” has the meaning set forth in Section 4.2.

1.3. “Business Day” means any day where the banks in New York, NY, USA are open.

1.4. “Clinical Approvals” means any approval of any applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product in any country or regulatory jurisdiction in the Territory, excluding any separate pricing or reimbursement approvals that may be required in any country or regulatory jurisdiction in the Territory.

1.5. “Combination Product” means any unified dose (e.g., not a kit of two separate and distinct drug dosage forms) of pharmaceutical product which is comprised of the Product and other therapeutically active compound(s) and/or ingredient(s).

1.6. “Compound” means Galectin Therapeutics’ oncology product GM-CT-01 (DAVANAT®) which will be renamed for distribution in Colombia and Latin America.

1.7. “Confidential Information” has the meaning set forth in Section 15.1.

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Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company’s application requesting confidential treatment under Rules 24b-2 of the Securities Exchange Act of 1934, as amended.

1.8. “Diligent Efforts” means, with respect to Procaps’ obligations under this Agreement to Pursue Approval or Market and Distribute the Product, the carrying out of such obligations or tasks in a sustained and diligent manner consistent with the reasonable best practices of the pharmaceutical industry for the approval or marketing and distribution of a high priority pharmaceutical product at a similar stage of development or commercialization.

1.9. “Excess Amount” has the meaning set forth in Section 8.1.

1.10. “Field” means the treatment of cancer using a regimen containing 5-FU.

1.11. “First Commercial Sale” has the meaning set forth in Section 11.2.

1.12. “Formulated Dose” means the dose for the Product, which shall be a single unit, 10ml sterile vial (60mg/ml).

1.13. “Galectin Therapeutics Patents” means all patents and patent applications that (a) are controlled as of the Effective Date or are filed or granted during the term of the Agreement by Galectin Therapeutics or its Affiliates and that claim the composition of matter, manufacture, or use of the Compound or Product, (b) are substitutions, divisions, continuations, continuations-in-part (to the extent directed to the subject matter disclosed in a patent or patent application described in (a)) and requests for continued examination of any of the foregoing, (c) are patents arising from or claiming priority to any of the foregoing, (d) are reissues, renewals, registrations, confirmations, re-examinations, extensions, and supplementary protection certificates of any of the foregoing, and/or (e) all foreign equivalents of any of the foregoing. For the avoidance of doubt, the Galectin Therapeutics Patents shall include any patent or application claiming Product Related IP Rights to the extent that such patent or patent application claims the composition of matter, manufacture, or use of the Compound or Product.

1.14. “Initial Approval Plan” has the meaning set forth in Section 4.3.

1.15. “Licensed Marks” means the trademarks, trade names, names, brands, logos, symbols, and other proprietary designations of Galectin Therapeutics as set forth on Exhibit A, as may be updated from time to time by Galectin Therapeutics.

1.16. “Market and Distribute” (and its other forms including Markets and Distributes, Marketing and Distributing, Marketing and Distribution, etc.) means to sell, market, promote and/or distribute Product and obtain remittance for said Product in the Field in the Territory.

1.17. “Marketing and Distribution Plan” means a written Marketing and Distribution plan setting forth anticipated Marketing and Distribution activities to be performed with respect to the Product in the Field in the Territory by Procaps or on its behalf by approved contractors (including without limitation market studies, launch plans, detailing and promotion), as well as projected timelines for such activities.

1.18. “Maximum Amount” means one hundred twenty percent (120%) of the amount of Compound forecasted by Procaps to be needed by it as set forth in the then current Marketing and Distribution Plan.

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1.19. "Net Sales" means the gross amount invoiced by Procaps or its Affiliates for sales of the Product in the Territory to a Third Party, less: (a) financial discounts to recover receipts; (b) recalls and (c) returns; in each case actually taken and provided that any deductions for items (a), (b) and (c) above shall not exceed ten percent (10%) of the Sales Price. Net Sales shall be calculated in United States dollars pursuant to Section 11.4. A credit will be given on the subsequent order for any amounts owing for deductions due to (a), (b) or (c) above.

With respect to any sale or other disposal of any Product for any consideration other than exclusively monetary consideration on arm's length terms, for purposes of calculating the gross sales amount necessary to calculate the Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sale price charged to Third Parties for cash sales during the applicable reporting period.

Net Sales shall be determined in accordance with generally accepted accounting principles in the United States.

1.20. "Person" means an individual, corporation, partnership, association, trust, unincorporated organization or other entity.

1.21. "Procaps" has the meaning set forth in the first paragraph of this Agreement.

1.22. "Product" means the final formulation of the Compound, including fill and finish, for which Regulatory Approval has been received, and any accompanying instructions for use and any other documentation and materials provided by Galectin Therapeutics as a package with, or for use with, such product, as may be modified by Galectin Therapeutics.

1.23. "Product Order" has the meaning set forth in Section 10.1.

1.24. "Product Related IP Rights" has the meaning set forth in Section 14.1

1.25. "Purchaser" shall mean a doctor, hospital, clinic or any other entity purchasing the Product from Procaps for administration to patients.

1.26. "Pursue Approval" (and its other forms including Pursues Approval, Pursuing Approval, Approval Pursuit, etc.) means all activities that relate to (a) obtaining, maintaining or expanding Regulatory Approval of the Product or (b) developing the ability to formulate, fill and finish commercial quantities of the Product. This includes, without limitation, (i) formulation and manufacturing-related technology development; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a governmental authority to obtain, maintain and/or expand Regulatory Approval of the Product, including pricing approval, and outside regulatory services related thereto; (iii) fill/finish work associated with the supply of Product for Regulatory Approval and commercial supplies, and related quality assurance technical support activities; (iv) stability studies; (v) clinical trials, (vi) post-Regulatory Approval product support for the Product (including manufacturing and quality assurance technical support, efforts directed toward the further understanding of the safety and efficacy of Product and clinical trials); and (vii) Product-related medical affairs (including regulatory support necessary for product maintenance).

1.27. "Regulatory Approvals" means any approval of any applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product in any country or regulatory jurisdiction in the Territory, including any separate pricing or reimbursement approvals that may be required in any country or regulatory jurisdiction in the Territory.

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1.28. “Regulatory Authority” means any federal, national, multi-national, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing or sale of pharmaceutical products.

1.29. “Regulatory Materials” means regulatory applications, submissions, notifications, registrations, Regulatory Approvals and/or other filings made to or with a Regulatory Authority that are necessary or reasonably desirable in order to Pursue Approval, manufacture, or Market and Distribute the Product in a particular country or regulatory jurisdiction.

1.30. “RFN Eligible Countries” shall mean the countries in South and Central America other than Columbia. For the avoidance of doubt, Mexico and the Caribbean are not RFN Eligible Countries.

1.31. “RFN Notice” has the meaning set forth in Section 2.3.

1.32. “RFN Term” has the meaning set forth in Section 2.3.

1.33. “Sales Price” shall initially be \$[\*\*\*\*] USD per Formulated Dose, subject to change pursuant to Sections 2.1 and 9.1.

1.34. “Specifications” means the applicable release specifications for Compound agreed to by the Parties and set out in Exhibit B attached hereto and incorporated herein, as may be amended from time to time by mutual agreement of the Parties.

1.35. “Term” has the meaning set forth in Section 18.

1.36. “Territory” means Columbia and such RFN Eligible Countries, if any, to which Galectin Therapeutics grants Procaps exclusive distribution rights to the Product pursuant to Section 2.3.

1.37. “Third Party” means any Person not a Party to this Agreement, excluding any Affiliate of either Party.

1.38. “Transfer Price” means the total price at which Galectin Therapeutics will sell the Compound to Procaps, which shall be [\*\*\*\*] percent ([\*\*\*\*]%) of the Sales Price. The Sales Price shall be \$[\*\*\*\*] for Colombia and can only be changed by mutual agreement. The Transfer Price may be different for each RFN Eligible Country, if any, for which Galectin Therapeutics grants Procaps exclusive distributions rights to the Product pursuant to Section 2.3, as determined by mutual agreement of the Parties. Under no circumstances will the Transfer Price be less than \$[\*\*\*\*] in any country. If it is determined that a country(ies) to which Procaps has exclusive distribution rights to the Product will not support a final sales price of \$[\*\*\*\*], the Parties may mutually decide not to pursue approval in such country(ies). The transfer price for all RFN Eligible Countries will be a maximum of \$[\*\*\*\*].

## **2. APPOINTMENT OF PROCAPS**

2.1. Scope of Arrangement. Subject to the terms and conditions of this Agreement, Galectin Therapeutics hereby grants Procaps exclusive rights during the term of this Agreement, and Procaps

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accepts such appointment, to Market and Distribute Product solely in the Territory in the Field to Purchasers. However, Galectin Therapeutics may render this arrangement non-exclusive upon written notice to Procaps in accordance with the provisions of Sections 19.1. Procaps shall purchase Compound exclusively from Galectin Therapeutics and Market and Distribute the Product for its own account and this Agreement does not make Procaps an agent of Galectin Therapeutics for any purpose. Procaps shall not purchase or make Product other than through the purchase of Compound from Galectin Therapeutics pursuant to the terms of this Agreement. Procaps shall not sell Product as a Combination Product without the prior written consent of Galectin Therapeutics. If Galectin Therapeutics consents to the sale by Procaps of a Combination Product, the parties shall mutually agree upon changes, if any, to the definitions of Formulated Dose, Transfer Price and Sales Price for purposes of the Combination Product only to reflect any difference in the quantity of Compound in a dose of the Combination Product. In addition, and subject to the terms and conditions of this Agreement, Procaps shall perform the additional responsibilities set forth in this Agreement. Procaps shall not outsource or otherwise delegate any of its rights or obligations under this Agreement to any Third Party unless pre-approved in writing by Galectin Therapeutics.

2.2. Reservation of Rights. All rights not expressly granted to Procaps are reserved to Galectin Therapeutics, including, without limitation the right to Market and Distribute the Compound or Product outside the Territory itself or through one or more other Persons.

2.3 Right of First Negotiation. Following the Regulatory Approval and for a period ending [\*\*\*\*] months after the First Commercial Sale of the Product in Columbia (the “RFN Term”) and provided that Procaps is not in breach of this Agreement, Procaps may provide Galectin Therapeutics written notice (the “RFN Notice”) that it wishes to exercise its right of first negotiation to procure distribution rights to the Product in the Field for those RFN Eligible Countries specified in the RFN Notice; provided however, with respect to Argentina and Brazil only, the RFN Term shall end [\*\*\*\*] months after Regulatory Approval of the Product in Colombia, unless the RFN Term and Procaps’ right of first negotiation is terminated earlier pursuant to this Agreement. Thereafter, Procaps shall not have a right of first negotiation for any other country or jurisdiction not specified in the RFN Notice. Galectin Therapeutics and Procaps shall negotiate in good faith an amendment to this Agreement or a separate commercial agreement (such amendment or new agreement, the “RFN Agreement”) which will include an upfront license payment, Transfer Price for the Compound, royalties on Net Sales and other business terms and conditions typically found in similar commercial agreements, under which Procaps shall be granted the exclusive distribution rights to the Product in the Field in the RFN Eligible Countries specified in the RFN Notice. The rights granted to Procaps to the Compound and the Product in the RFN Agreement shall be non-exclusive and Galectin Therapeutics have the right to terminate the RFN Agreement upon ten (10) days prior notice until Galectin Therapeutics receives all upfront license payments provided for in the RFN Agreement, at which point the exclusivity and termination rights shall revert to those set forth in the RFN Agreement.

The upfront license payment for each RFN Eligible Country in the RFN Notice shall be determined using the following model:

Based on the assumption that the license fee for Colombia [\*\*\*\*] USD ([\*\*\*\*]), then the maximum upfront license fee for each RFN Eligible Country in the RFN Notice will be a ratio of the population of that country to the population of Colombia. Population estimates will be from a source agreed to by both parties. The license fee may be adjusted for the specific economic situation of each RFN Eligible Country in the RFN Notice. For example, if the population of Colombia is estimated to be 49,000,000 (August

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2011), and the population of Venezuela is estimated to be 29,000,000 (August 2011 - Source True Knowledge), then the upfront license fee due for Venezuela would be \$[\*\*\*\*]. The upfront license fee for each country added pursuant to the RFN Agreement will be paid according to the following schedule; [\*\*\*\*]% is due within ten (10) days of signing of the RFN Agreement for that country, and [\*\*\*\*]% is due within ten (10) days of Regulatory Approval of the Product in such country. If Regulatory Approval is not received in a country, the [\*\*\*\*]% of the upfront license fee for such country will not be due; provided, however, that the [\*\*\*\*]% of the upfront license fee paid to Galectin Therapeutics for each country added pursuant to the RFN Agreement is non-refundable and non-creditable. The parties understand and agree that agreement on the upfront license fee to be paid for one or more RFN Eligible Country(ies) shall not obligate either party to enter an RFN Agreement for such country and that additional terms including, without limitation, the Transfer Price for the Compound, the Sales Price, royalties and/or milestones on Net Sales and other business terms and conditions must be negotiated and agreed upon.

Procaps shall provide Galectin Therapeutics within thirty (30) days of Procaps' issuance of the RFN Notice an approval plan for the Product in the RFN Eligible Countries in the RFN Notice describing the proposed overall program of Approval Pursuit, including stability studies, fill and finish production, process development, regulatory plans and other elements of obtaining Regulatory Approval(s), as well as timelines for key regulatory authority meetings, drug approval applications and Regulatory Approvals. If the Parties are unable to reach an agreement with respect to one or more of the countries within ninety (90) days of Galectin Therapeutics' receipt of the RFN Notice, Procaps shall have no further contractual rights to negotiation with respect to such countries. If, during the RFN Term, and after Procaps has sent the RFN notice, Galectin Therapeutics' desires to distribute or commercialize the Compound or Product in one or more RFN Eligible Countries for which Procaps has not sent a RFN Notice, Galectin Therapeutics shall provide written notice to Procaps identifying such countries and Procaps shall have ten (10) Business Days in which to send an RFN Notice with respect to such countries. If Procaps does not send an RFN Notice with respect to such RFN Eligible Countries identified by Galectin Therapeutics within ten (10) Business Days, its right of first negotiation and the RFN Term for such RFN Eligible Countries shall immediately expire.

### **3. GOVERNANCE**

3.1. Joint Steering Committee. Within thirty (30) days after the Effective Date, Galectin Therapeutics and Procaps shall form a joint steering committee ("JSC") consisting of three (3) representatives from Galectin Therapeutics or one of its Affiliates and three (3) representatives from Procaps. Each Party may replace its JSC representatives at any time upon prior written notice to the other Party. JSC membership shall evolve over time as the Agreement progresses so that each Party's combined membership represents the key functions (such as Approval Pursuit, manufacturing or Marketing and Distribution) that are the current focus of work on the Product.

3.2. Meetings of the JSC. The JSC shall meet at least four (4) times every calendar year unless a particular meeting is waived by mutual consent, on such dates and at such times as agreed to by the Parties, alternating between Galectin Therapeutics' and Procaps' places of business, or such other mutually agreeable locations. Each Party may permit visitors to attend meetings of the JSC; provided that (i) such Party provides the other Party at least twenty (20) days notice of its intent to bring such visitor(s) to the JSC meeting, providing a reasonable description of such visitor(s) and the purpose of their attendance; (ii) the other Party does not object in writing to such visitor(s) attendance within five (5) days of receipt of such notice, and (iii) each such visitor has executed prior to attendance a confidentiality

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agreement with each Party containing restrictions on disclosure and use substantially similar to Section 15 of this Agreement. Each Party shall be responsible for its own expenses for participating in the JSC. Meetings of the JSC shall be effective only if at least one representative of each Party is present and participating.

3.3. Responsibilities of the JSC. The JSC shall have the responsibility and authority to:

- (a) Oversee the Approval Pursuit, Regulatory Approval, and Marketing and Distribution of the Product in the Field in the Territory in support of such activities;
- (b) Review and approve the overall strategy for Approval Pursuit in the Field in the Territory;
- (c) Review and approve any proposed amendments or updates to the Approval Plan;
- (d) Monitor the Approval Pursuit of the Product in the Field in the Territory against the Approval Plan;
- (e) Discuss the requirements for Regulatory Approval in applicable countries in the Territory and oversee regulatory matters with respect to the Product in the Territory;
- (f) Review the Marketing and Distribution Plan and any proposed amendments or updates thereto;
- (g) Monitor the Marketing and Distribution of the Product in the Territory against the Marketing and Distribution Plan;
- (h) Monitor, review and oversee safety issues that may arise from use of the Product in Colombia including, but not limited to, potential recalls, market withdrawals and regulatory issues and responses;
- (i) Establish subcommittees pursuant to Section 3.6 on an as-needed basis, oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees; and
- (j) Perform such other functions as the Parties may agree in writing.

3.4. Areas Outside the JSC's Authority. Neither the JSC nor the Chief Executive Officer of Galectin Therapeutics acting through the authority provided in Section 3.5(b) herein shall have any authority other than that expressly set forth in Section 3.3 and, specifically, shall have no authority (a) to amend or interpret this Agreement, (b) to determine whether or not a Party has met its diligence or other obligations under the Agreement, or (c) to determine whether or not a breach of this Agreement has occurred.

3.5. JSC Decisions.

- (a) Consensus; Good Faith; Action Without Meeting. The JSC shall decide all matters by consensus, with the Chairperson acting as the facilitator, except in the case of safety issues, such as the disposition of adverse events or recalls, which shall be decided by the Joint Safety

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Management Committee pursuant to Section 3.6. Consistent with Section 3.7, the members of the JSC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the JSC. Action that may be taken at a meeting of the JSC also may be taken without a meeting if a written consent setting forth the action so taken is signed by all members of the JSC.

(b) Failure to Reach Consensus. Except as set forth in Section 3.6, in the event that the members of the JSC cannot come to consensus within fifteen (15) days with respect to any matter over which the JSC has authority and responsibility, the JSC shall submit the respective positions of the Parties with respect to such matter for discussion in good faith by the Parties' respective Chief Executive Officers or their respective designees. If such individuals are not able to mutually agree upon the resolution to such matter within fifteen (15) days after the JSC's submission to them, then the Chief Executive Officer of Galectin Therapeutics shall have the right to decide such matter, taking into account and seeking reasonably to accommodate (i) Procaps' legitimate interest under the Agreement and (ii) the operating principals in Section 3.7; provided, that in no event can the Chief Executive Officer of Galectin Therapeutics unilaterally decide such matter in a manner that would violate the limitations set forth in Section 3.4 or increase Procaps' costs to Pursue Approval or Market and Distribute the Product greater than ten percent (10%) of the amount set forth in the then current Approval Plan or Marketing and Distribution Plan, as applicable, unless such increase is necessitated by the requirement, order or request of a Regulatory Authority. Notwithstanding the foregoing, consensus of the JSC or mutual agreement of the Chief Executive Officers shall be necessary with respect to any decision that materially impairs or is reasonably likely to impair any rights or assets of either Party or any of their respective Affiliates, and unless and until the JSC reaches consensus or the Chief Executive Officers reach mutual agreement on any such matter, the Parties shall continue to operate under the status quo with respect to such matter and neither Party shall have the right, without the prior written consent of the other Party, to take any action that departs from the status quo with respect to such matter.

### 3.6. Subcommittees.

(a) The JSC shall establish the Joint Safety Management Committee ("JSMC") as a subcommittee to the JSC, the primary purpose of which shall be to monitor, review, oversee and authorize such actions as necessary to address safety issues that may arise from use of the Product in the Territory including, but not limited to, potential recalls, market withdrawals and regulatory issues and responses. The JSMC shall take into account the requirements, regulations and guidance of Regulatory Authorities in the Territory as well as the United States, Europe and Japan in fulfilling its duties. The JSMC shall consist of the Chief Medical Officer of each Party and up to one additional member designated by each Party. Each Party shall have one vote on the JSMC. In the event the representatives of the Parties on the JSMC are unable to reach agreement on a matter, the Chief Medical Officer of Galectin Therapeutics shall have responsibility for the final decision.

(b) The JSC shall have the right to establish subcommittees and to delegate certain of its powers and responsibilities thereto. Except as mutually agreed by the Parties, such subcommittees shall decide all matters by consensus, with each Party having one collective vote, and any disputes that cannot be resolved by a subcommittee in a reasonable time period shall be submitted to the JSC for resolution in accordance with Section 3.5.

3.7. Operating Principles. The Parties hereby acknowledge and agree that the deliberations and decision-making of the JSC and any subcommittee established by the JSC shall be in accordance with the following operating principle:

(a) The Parties' mutual objective is to maximize the commercial success of the Product in the Field in the Territory, consistent with sound and ethical business and scientific practices.

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3.8. Termination of JSC. The JSC shall continue to exist until the first to occur of: (a) the Parties mutually agreeing to disband the committee; or (b) Galectin Therapeutics providing to Procaps written notice of its intention to disband and no longer participate in the JSC. Thereafter, the JSC shall have no further obligations under this Agreement, and Procaps shall continue to provide to Galectin Therapeutics the reports, summaries, correspondences, notices, minutes, etc. and take such actions and provide such rights to Galectin Therapeutics as required by this Agreement.

#### **4. APPROVAL PURSUIT**

4.1. Overview. Subject to the oversight of the JSC, Procaps shall be responsible for Approval Pursuit of the Product in the Field in the Territory. Procaps shall perform all Approval Pursuit activities in accordance with the Approval Plan. The costs of Approval Pursuit shall be borne by Procaps.

##### **4.2. Approval Project Plan.**

(a) Scope. The Approval Pursuit of the Product under this Agreement shall be governed by an Approval Pursuit Project plan for the Field in the Territory (the "Approval Plan"). The Approval Plan shall be developed in good faith with the overall objective of optimizing the commercial potential of the Product in the Field in the Territory. The Approval Plan shall describe the proposed overall program of Approval Pursuit for the Product in the field in Colombia, including stability studies, fill and finish production, process development, regulatory plans, clinical trials required for Regulatory Approval and other elements of obtaining Regulatory Approval(s) in Colombia as well as timelines for key regulatory authority meetings, drug approval applications and Regulatory Approvals. In the event of any inconsistency between the Approval Plan and this Agreement, the terms of this Agreement shall prevail.

(b) Initial Approval Plan. Within ten (10) days after the Effective Date, Procaps shall provide Galectin Therapeutics with a draft Approval Plan for Galectin Therapeutics' review. The Parties shall use commercially reasonable efforts to reach agreement on the initial Approval Plan within thirty (30) days after the Effective Date (the "Initial Approval Plan"). The Parties may agree to extend the period in which to reach mutual agreement on the Initial Approval Plan, but no later than forty-five (45) days after the Effective Date.

4.3. Updates to the Approval Plans. As early as necessary in each calendar year, Procaps shall update and prepare the Approval Plan for the following calendar year to take into account completion, commencement or cessation of Approval Pursuit activities not contemplated by the then-current Approval Plan, and submit such proposed Approval Plan to the JSC no later than February 15<sup>th</sup> of such year for review and approval. Procaps may, at its election, update the Approval Plan between annual updates subject to review and approval by the JSC. If additional countries are added to the Territory, Procaps shall present a revised Approval Plan to the JSC with thirty (30) days of the addition of such countries to the Territory for review and approval. Notwithstanding the above, the JSC will review the Approval Plan, progress to the Approval Plan and updates at each JSC meeting.

4.4. Diligent Approval Pursuit. Procaps shall use Diligent Efforts to Pursue Approval of the Product in the Field in the Territory. Without limiting the generality of the foregoing, Procaps shall,

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among other things, receive Regulatory Approval of the Product in Colombia by June 15, 2012. Any failure by Procaps to comply with the obligations set forth in this Section 4.4 shall be deemed to be a material breach of this Agreement, for which Galectin Therapeutics may exercise its rights under Section 19 to terminate this Agreement.

4.5. Approval Reports. Procaps shall maintain complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it under the Approval Plan and all information and data resulting from such work. Such records, including any electronic files, shall fully and properly reflect all work done and results achieved in the performance of the Approval Plan in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Galectin Therapeutics shall have the right to review such records maintained by Procaps at reasonable times upon reasonable notice. Procaps shall provide Galectin Therapeutics:

(a) with regular reports detailing its Approval Pursuit activities under the Approval Plan and the results of such activities;

(b) on or before January 31 and July 31 of each calendar year during the term of this Agreement, with a written report that summarizes, in reasonable detail, all Approval Pursuit activities performed by Procaps, its Affiliates, and approved contractors during the preceding six (6) month period, and compares such performance with the goals and timelines set forth in the Approval Plan; and

(c) with any additional information regarding its Approval Pursuit of the Product reasonably requested thereby.

4.6. Standards of Conduct. Procaps shall perform, and shall ensure that its Affiliates, and approved contractors perform, the Approval Pursuit activities for which it is responsible under the Approval Plan in good scientific and regulatory manner and in material compliance with applicable laws, rules and regulations.

## **5. REGULATORY**

### **5.1. Regulatory Filings**

(a) Procaps shall be responsible for preparing and filing all Regulatory Materials, including without limitation furnishing timely notice of all side effects, drug interactions and other adverse effects identified or suspected with respect to the Product, and seeking all Regulatory Approvals in the Territory. All Regulatory Materials for the Product in the Territory shall be filed in the name of Galectin Therapeutics, and Procaps alone shall be responsible for all communications and other dealings with the Regulatory Authorities relating to the Product in the Territory, except as required by a Regulatory Authority; provided that such communications and dealings have been agreed upon by the JSC or its applicable subcommittees and/or Galectin Therapeutics. To the maximum extent permitted by law, Galectin Therapeutics shall be the legal and beneficial owner of all Regulatory Approvals and Regulatory Materials in the Territory or in the event such Regulatory Approvals and/or Regulatory Materials may not be owned by Galectin Therapeutics, they shall be held for the benefit of Galectin Therapeutics and shall be transferable as directed by Galectin Therapeutics. In the event that any such Regulatory Approvals and/or Regulatory Materials are not transferable to Galectin Therapeutics, then upon expiration or termination of this Agreement or earlier upon request of Galectin Therapeutics,

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Procaps shall use its best efforts to assist Galectin Therapeutics in obtaining Regulatory Approvals and/or Regulatory Materials substantially similar to the non-transferable Regulatory Approvals and/or Regulatory Materials.

(b) The JSC shall develop and implement procedures for drafting and review of Regulatory Materials for the Product in the Territory, which shall provide sufficient time for Galectin Therapeutics to provide substantive comments. Procaps shall consider Galectin Therapeutics comments on such Regulatory Materials in good faith.

(c) Procaps shall promptly notify Galectin Therapeutics of all Regulatory Materials that it submits, and, at Galectin Therapeutics' request, shall promptly provide Galectin Therapeutics with a copy (which may be wholly or partly in electronic form) of such Regulatory Materials. Procaps will provide Galectin Therapeutics with reasonable advance notice of any scheduled meeting with any regulatory agency relating to Approval Pursuit and/or any Regulatory Approval in Colombia, and Galectin Therapeutics shall have the right to participate in any such meeting, to the extent permitted by law. Procaps also shall promptly furnish Galectin Therapeutics with summaries of all material correspondence or material meetings with any Regulatory Authority relating to Approval Pursuit, Regulatory Materials and/or a Regulatory Approval in the Territory, and Procaps shall, at Galectin Therapeutics' request, promptly furnish Galectin Therapeutics with copies of such correspondence or copies of minutes of such meetings in both Spanish and English, if requested.

5.2. Product Withdrawals and Recalls. In the event that any Regulatory Authority (a) threatens or initiates any action to remove the Product from the market in any country in the Territory or (b) requires Procaps or its Affiliates to distribute a "Dear Doctor" letter or its equivalent regarding use of the Product in the Field, Procaps shall notify Galectin Therapeutics and the JSMC of such event within one (1) business day after Procaps becomes aware of the action, threat, or requirement (as applicable). The JSMC shall immediately evaluate the request of such Regulatory Authority prior to initiating a recall or withdrawal of the Product in Colombia; provided, however, the JSMC shall review the recall information and medical data within five (5) business days. If the JSMC does not reach an agreement within five (5) business days the final decision as to whether to recall or withdraw the Product or take other remedial action in Colombia pursuant to Section 3.6, will be the responsibility of the CMO of Galectin Therapeutics. Galectin Therapeutics will be responsible, at its sole expense, for conducting any recalls or taking such other necessary remedial action if the recall is related to the Compound. If the recall or remedial action is the result of Procaps process, quality, fill and finish or marketing or violation of any laws, regulations, rules or guidelines or the breach of this Agreement, Procaps shall be responsible for the expense of such recall or remedial action. Procaps shall maintain complete distribution records by Purchaser, and by unique patient code and batch number for all Product Marketed and Distributed within the Territory in accordance with Galectin Therapeutics' procedures and instructions. If either Party becomes aware of information about the Product indicating that it may not conform to the specifications for the Product, or that there are potential adulteration, misbranding and/or other issues regarding safety or effectiveness, it shall promptly so notify the other Party. The Parties shall discuss such circumstances and consider appropriate courses of action. Galectin Therapeutics shall control all recalls of Product. Each Party will maintain complete and accurate recall records relating to the Product for any periods that are required by applicable laws, rules or regulations.

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## 6. MARKETING AND DISTRIBUTION

6.1. General. Procaps shall have sole responsibility and decision-making authority for Marketing and Distribution activities, all of which shall be carried out in accordance with the Marketing and Distribution Plan. Procaps shall be responsible for all costs and expenses associated with the Marketing and Distribution activities.

### 6.2. Marketing and Distribution Plan.

(a) Procaps shall deliver to the JSC upon the formation of the JSC for its review and comment the draft Marketing and Distribution Plan which shall at such time be set forth in Exhibit C. Procaps shall implement all such reasonable comments received from the JSC and shall submit such revised document to the JSC for review. The JSC shall approve the final initial Marketing and Distribution Plan within forty-five (45) days after the Regulatory Approval for the Product in Colombia.

(b) Procaps shall thereafter update the Marketing and Distribution Plan on a semi-annual basis as follows: Procaps shall provide the JSC with a draft update to the Marketing and Distribution Plan within forty-five (45) days of the anniversary of the Effective Date and within forty-five (45) days of the sixth (6<sup>th</sup>) month after such anniversary. Procaps shall implement all such comments received from the JSC and shall submit such revised document to the JSC for review. Procaps may, at its election, update the Marketing and Distribution Plan between annual updates by following this same procedure. If additional countries are added to the Territory, Procaps shall present a revised Marketing and Distribution Plan to the JSC with thirty (30) days of the addition of such countries to the Territory for review and approval.

(c) The Marketing and Distribution Plan shall include, without limitation: (i) a description of Procaps' anticipated marketing activities (both pre- and post-launch), including the plans to use key opinion leaders and focus groups; (ii) four (4) year sales projections, broken down by calendar quarter; (iii) any requirements for additional marketing studies, including without limitation clinical trials appropriate to meet the objectives set forth in Section 3.7; (iv) competitive analysis including specific actions to mitigate competitive threats; (v) planned promotional material and sales/detailing protocols and (vi) a forecast of the amount of Compound to be purchased from Galectin Therapeutics in each of the next four (4) calendar quarters. Each annual Marketing and Distribution Plan shall have the minimum annual sales targets set forth in Exhibit D. The minimum annual sales targets after the first year of this Agreement may be updated, but not reduced for the first four (4) years of this Agreement, upon the mutual agreement of the Parties. The failure of Procaps to meet a minimum annual sales target shall be deemed a material breach of this Agreement.

(d) In the event of any inconsistency between the Marketing and Distribution Plan and this Agreement, the terms of this Agreement shall prevail.

6.3. Diligent Commercialization. Procaps shall use Diligent Efforts to Market and Distribute the Product in the Field in the Territory in each country for which a Regulatory Approval has been received. Without limiting the generality of the foregoing, Procaps shall satisfy each of the following requirements:

(a) commence commercial sales of the Product to end users in a country, in commercially significant quantities, promptly after, and in any case not later than three (3) months after, the date upon which Regulatory Approval and any necessary pricing approval for the Product is granted with respect to such country.

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(b) undertake a sales effort commensurate with optimizing the gross sales of the Product in the Territory taking full advantage of the resources of Procaps and its Affiliates, which shall include a competent marketing and sales organization.

(c) assist Galectin Therapeutics, at and to the extent of its request, in designing and constructing a Spanish language website for the Product.

(d) develop a market for the Product, and enhance Galectin Therapeutics' image in the marketplace as a provider of quality pharmaceuticals.

Any failure by Procaps to comply with the obligations set forth in this Section 6.3 shall be deemed to be a material breach of this Agreement for which Galectin Therapeutics may exercise its rights under Section 19 to terminate this Agreement or any other available remedies at law or in equity.

**6.4. Marketing and Distribution Reports.** Procaps shall:

(a) Keep the JSC fully informed regarding the progress and results of its Marketing and Distribution activities and those of its Affiliates and approved contractors, agents, etc.

(b) Within thirty (30) days after the end of each calendar quarter, provide the JSC with a written report that (i) summarizes, in reasonable detail, all Marketing and Distribution activities performed during such quarter, (ii) compares such performance with the goals and timelines set forth in the Marketing and Distribution Plan, (iii) describes the sales, market share, business trends and key marketing issues of or related to the Product, (iv) contains (A) a list of all Product Distributed per Purchaser and patient code, (B) an action plan to resolve and issues and sales discrepancies, and (C) any other information as Galectin Therapeutics may reasonably request.

(c) Also promptly provide the JSC or Galectin Therapeutics with any additional information or data regarding the Marketing and Distribution of the Product reasonably requested thereby.

**6.5. Safety and Product Reports.** Within ten (10) Business Days following the end of every calendar quarter, Procaps shall provide Galectin Therapeutics with a report related to pharmacovigilence during the calendar quarter, which shall contain: (a) all Product safety information reported to Procaps during such calendar quarter, (b) any other comments or information reported to Procaps regarding the Product, and (c) any other information as Galectin Therapeutics may reasonably request. In addition, Procaps will maintain safety information, including information contained in the safety reports, in an organized and up to date manner at all times so that it can be provided to Galectin Therapeutics upon request. Procaps shall notify Galectin Therapeutics in writing of any serious adverse events potentially relating to the Product within twenty four (24) hours of such event, including, but not limited to, an unexpected event, injury, toxicity or sensitivity reaction or any unexpected incidents of which Procaps becomes aware, in accordance with all applicable laws and regulations including without limitation the International Committee of Harmonization guidelines (hereinafter the "ICH Guidelines") to the extent that such ICH Guidelines comport with U.S. FDA guidelines.

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6.6. Marketing and Distribution Standards of Conduct. Procaps shall in all respects comply with all applicable laws, regulations and guidelines in Marketing and Distributing the Product in the Territory under this Agreement, including without limitation, all United States Food and Drug Administration and ICH pharmacovigilance requirements and guidelines, the pharmacovigilance guidelines of each country in the Territory for which the Product has received Regulatory Approval, and the Foreign Corrupt Practices Act of 1977, as amended ("FCPA"). Distributor shall not make any false or misleading representations to Purchasers or others regarding Galectin Therapeutics or the Compound or Product. Distributor shall not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Compound or Product that are not consistent with Galectin Therapeutics documentation accompanying the Compound or Galectin Therapeutics' literature describing the Compound or Product, including the limited warranty and disclaimers. Distributor shall not make any commitments on behalf of Galectin Therapeutics except as specifically defined in this Agreement or as agreed to in writing by Galectin Therapeutics.

## **7. ADDITIONAL DUTIES, RESPONSIBILITIES, AND WARRANTIES OF PROCAPS**

7.1. General Compliance. Procaps and its employees and agents shall: (i) comply with all applicable laws and regulations of each country in the Territory and the U.S. FDA rules and regulations. Procaps shall collect, monitor, research and evaluate information from healthcare providers and patients in the Territory on the adverse effects of the cancer treatments which include the Product. This information shall be provided to the JSMC as required in Sections 3.5 and 3.6. Procaps shall also follow Galectin Therapeutics' standards, policies, instructions and procedures relating to the Product and its activities under this Agreement, and (ii) not engage in any false, misleading or deceptive practices with respect to Galectin Therapeutics or the Product.

7.2. Procaps Licenses and Permits. Procaps represents, warrants and covenants to Galectin Therapeutics that Procaps shall possess during the term of this Agreement all licenses, permits and other authorizations required by any Regulatory Authority or other each governmental body within the Territory to import and Market and Distribute the Product, and fulfill its other obligations in accordance with the terms of this Agreement.

7.3. Product Importation. Procaps shall apply to necessary Regulatory Authority to import Product into the Territory and will be responsible for completing all necessary paperwork to enable importation of Product into the Territory at its expense.

(a) Product Licenses and Documentation. Procaps shall be responsible for the satisfaction of all relevant licenses and requirements for Product in the Territory that apply to this Agreement, including without limitation, import and pharmaceutical licenses and providing guidance on all documents necessary for the importation of Product into the Territory. Each Party shall cooperate with the other in executing any other documents or licenses necessary for each Party to comply with any export or import or other similar applicable laws of the Territory.

(b) Batch Certifications and Customs Clearance. Procaps shall provide for Product batch certification to be performed by customs inspectors or others, as applicable. In addition, Procaps shall ensure the integrity of the Product is maintained at all times prior to successful delivery to the Purchaser, including following all procedures and instructions of Galectin Therapeutics.

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7.4. Notice Upon Change of Control. Procaps shall promptly provide Galectin Therapeutics with written notice in the event that Procaps undergoes a change in its principal place of business or name, identity, or corporate structure, or any merger, consolidation, sale or transfer of all or substantially all of the assets, or other similar transaction to which Procaps is a party.

7.5. U.S. Foreign Corrupt Practices Act Compliance.

(a) Procaps acknowledges that it understands that Galectin Therapeutics is an issuer of securities in the United States and is subject to the provisions of the FCPA. This law prohibits making, promising or offering to make corrupt payments to foreign officials, political parties or candidates, or making payments to other persons who will offer or make payments to any of the aforementioned parties in order to obtain business, retain business or gain an improper advantage. Procaps represents and warrants to Galectin Therapeutics that it is familiar with and understands the FCPA.

(b) Procaps represents, warrants, and covenants to Galectin Therapeutics that throughout the term of this Agreement, neither Procaps, nor any Person performing activities on behalf of Procaps will engage in any activity that could cause a violation of any provision of the FCPA. Procaps represents and warrants that it has not made, promised to make, or arranged for any Third Party to make any payments or gifts to foreign officials in connection with its engagement by Galectin Therapeutics. Further, Procaps represents and warrants to Galectin Therapeutics that it has not violated any anti-corruption law, including any law applicable within the Territory, and further that Procaps is not involved in, or the subject of, any investigation involving bribery, corruption or improper payments to foreign government officials, as defined in the FCPA. Procaps agrees to update these representations and warranties on a periodic basis as required by Galectin Therapeutics in a format prescribed by Galectin Therapeutics.

(c) Procaps agrees to notify Galectin Therapeutics immediately in writing if Procaps or any Person who is performing activities hereunder on behalf of Procaps is suspected of violating any anti-corruption law or becomes involved in, or a subject of, an investigation or law enforcement inquiry into possible improper payments to foreign officials or possible violations of anti-corruption laws. Procaps further agrees to provide such notification if Procaps or any Person performing activities on behalf of Procaps becomes involved in any action, suit, claim, investigation or proceeding that is pending, or to the knowledge of Procaps threatened, relating to a potential violation of any anti-corruption laws, including the FCPA.

(d) Procaps shall maintain all records related to the import and Marketing and Distribution of the Product as required by any applicable laws, rules, regulations and guidelines. Procaps agrees to grant Galectin Therapeutics the right to audit Procaps' books and records regarding the receipt and disposition of any payments made to or by Procaps relating to the Product. Procaps further agrees to cooperate with Galectin Therapeutics in connection with such audits.

(e) It is agreed between Procaps and Galectin Therapeutics that this Section 7.5 is deemed by the Parties to be a material provision of this Agreement.

**8. ADDITIONAL RIGHTS, DUTIES, RESPONSIBILITIES, AND WARRANTIES OF GALECTIN THERAPEUTICS**

8.1. Compound Manufacture. Galectin Therapeutics itself or through its Third-Party manufacturer will be responsible for manufacturing and supplying the Compound, in bulk form, to

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Procaps in such amounts consistent with the then current Marketing and Distribution Plan; provided that if Procaps requests more than the Maximum Amount, Galectin Therapeutics shall have six (6) months in which to supply any amount of the Compound requested by Procaps over the Maximum Amount ("Excess Amount"). On any Product Order for, in whole or part, an Excess Amount, Procaps shall provide Galectin Therapeutics a deposit equal to fifty percent (50%) of the product of the Excess Amount times the Transfer Price. The second payment of 50% shall be due in 60 days from shipment. Galectin Therapeutics shall have no obligation to initiate the manufacture of any Excess Amount prior to receipt of the full deposit for such Excess Amount. Galectin Therapeutics or its Third Party manufacturer shall comply with all regulatory requirements and obtain any necessary regulatory approvals to manufacture the Compound.

8.2. Delayed Shipments. Except as provided in Section 8.1, Galectin Therapeutics shall ship all Compound within ninety (90) days of receipt of a Product Order compliant with this Agreement. If the Compound is not shipped within ninety (90) days of receipt of the applicable Product Order, Galectin Therapeutics will have thirty (30) days to initiate shipment of the Compound for such Product Order. If the Compound is not shipped by the end of such additional thirty (30) day period, Procaps will receive a xx discount to the invoice price of such Product Order. If the Compound shipment is (i) delayed beyond one-hundred and twenty (120) days and (ii) Procaps inventory of Product and Compound is fully depleted due to the delayed shipment, Procaps will receive a [\*\*\*\*]% discount to the invoice price of such Product Order. Galectin Therapeutics' shipment obligations end upon transfer of the shipment to the Carrier. Such delayed shipment discounts shall be Procaps' sole remedy in the event of Galectin Therapeutics' failure to ship Compound within the time required under this Agreement. The above delayed shipment discounts shall not apply if due to an Act of God or a Force Majeure. Galectin Therapeutics and Procaps agree to maintain levels of inventory as provided in Sections 10.3 and 10.6, respectively.

8.3. Technology Transfer and Compound Supply. Galectin Therapeutics shall cooperate with Procaps to transfer to Procaps for use solely with the fulfillment of Procaps' obligations under this Agreement, such formulation and fill and finish technology and processes as reasonably requested by Procaps. Procaps shall have no right to use such transferred technology and processes other than to fulfill its obligations under this Agreement or after the termination or expiration of this Agreement. Galectin Therapeutics shall be free to use, license or transfer such transferred technology and processes in any manner it sees fit.

8.4. Supply of Compound for Approval Pursuit Purposes. Galectin Therapeutics has supplied Procaps [\*\*\*\*] mg of Compound for use by Procaps to define the vial filling process and stability testing for the Product as required by Regulatory Authorities. Such Compound shall not be sold commercially by Procaps and shall be used only for such vial filling and stability testing.

8.5. Compound for Increasing Capacity of Production Process. If Regulatory Approval of the Product is received in Colombia by December 31, 2011, Galectin Therapeutics will provide Procaps within ninety (90) days of notice of such Regulatory Approval, [\*\*\*\*] of Compound free of charge to be used for the qualification and approval of the increased capacity production process for the Product in Colombia. Compound provided pursuant to this Section 8.5, or any Product produced from such Compound, shall not be sold commercially by Procaps and shall be used only for the qualification and approval of the increased capacity production process for the Product in Colombia.

8.6. Training for Procaps' Personnel. Galectin Therapeutics or its Third Party designee(s) shall provide training to Procaps' personnel at periodic intervals mutually agreed upon, as Galectin Therapeutics and Procaps deem necessary. The cost for such training shall be shared equally.

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8.7. U.S. Export Controls. Galectin Therapeutics or its Third Party designee(s) shall be responsible for satisfaction of United States export and import licenses and requirements that apply to this Agreement. Each Party shall cooperate with the other in executing any other documents or licenses necessary for each Party to comply with any export or import or other similar laws of the United States applicable in this connection.

## 9. PRICING AND PAYMENT PROCESSES

9.1. Product Pricing. Unless otherwise agreed between the Parties and reflected in the applicable Product Order, Procaps shall purchase, and Galectin Therapeutics shall sell to Procaps, the Compound at the Transfer Price. The Transfer Price shall be subject to annual increases based upon the increase Producer Price Index, Pharmaceutical Preparation Mfg- pcu325412325412 PCU, as reported by the Bureau of Labor Statistics, U.S. Department of Labor. The Transfer Price is inclusive of packaging but exclusive of any applicable value added or any other sales tax and customs duties for which Procaps shall be responsible. Distributor shall be responsible for costs for insurance during shipment. Unless otherwise agreed between the Parties, Procaps shall sell Formulated Doses at the Sales Price. The difference between the Transfer Price and the Sales Price shall be Procaps' sole remuneration for the Approval Pursuit and Marketing and Distribution of the Product and for all other obligations of Procaps under this Agreement. In the event that the Procaps sells Product at a price above the Sales Price, Procaps shall provide Galectin Therapeutics a written statement within thirty (30) days of the end of each calendar quarter detailing the number of Formulated Doses sold above the Sales Price, if any, during such quarter and pay Galectin Therapeutics at such time pursuant to Section 9.3 an amount equal to fifty percent (50%) of product of (i) the number of Formulated Doses sold above the Sales Price and (ii) the difference between the price such Formulated Doses were sold at and the Sales Price. Procaps shall have the right to decide appropriate credit terms for Purchasers, including requiring pre-payment.

9.2. Payments to Galectin Therapeutics. Galectin Therapeutics shall invoice Procaps for each Product Order by Procaps under this Agreement. Invoices may be sent by Galectin Therapeutics via email to (or such other email address as provided by Procaps) or in hard copy. Invoices for the Transfer Price shall be sent to Procaps after Galectin Therapeutics' receipt of the Product Order for such Compound. Unless otherwise elected by Galectin Therapeutics, Procaps shall make all payments required under this Agreement in U.S. Dollars by wire transfer to an account specified by Galectin Therapeutics. Procaps shall be responsible for the banking charges associated with any wire transfers under this Section 9.3. Galectin Therapeutics reserves the right to withhold delivery of Compound during any period in which Procaps has any amounts outstanding and past due. Such withholding of delivery will not constitute a breach of Galectin Therapeutics' obligations under this Agreement.

9.3. Payment Terms. Except as provided in Sections 8.1 and 19.3, Procaps shall pay the first [\*\*\*\*] in advance of shipment and thereafter, unless otherwise agreed, Procaps shall pay [\*\*\*\*]% of the amount of each invoice within thirty (30) days of the date of Galectin Therapeutics' invoice and the remaining [\*\*\*\*]% within 60 days of the date of invoice.

## 10. PRODUCT ORDERING

10.1. Product Orders. Procaps may order Compound from Galectin Therapeutics in accordance with this Agreement and the following procedures. Compound may be ordered by use of the

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order form in a form and substance satisfactory to Galectin Therapeutics (the “Product Order”). Each Product Order shall be for at least one (1) kilogram of Compound and shall be sent by Procaps to Galectin Therapeutics at the address sent forth in Section 21.13 to the attention of Maureen Foley with copies to Theodore Zucconi and Lillian DePasquale. Notwithstanding Section 9.3, Galectin Therapeutics shall have no obligation to ship any Compound to Procaps for a Product Order compliant with this Agreement while unpaid amounts are outstanding for prior Product Orders or if any royalty, upfront, license or milestone payments due to Galectin Therapeutics are overdue.

10.2. Commitment to Purchase. Procaps shall purchase all Compound that Galectin Therapeutics produces based on Product Orders submitted by Procaps under this Agreement.

10.3. Compound Inventory. Galectin Therapeutics will use its reasonable commercial efforts to maintain an inventory of Compound sufficient to supply Procaps needs as set forth in the then current Marketing and Distribution Plan such that Compound will be shipped to Procaps within ninety (90) days of receipt by Galectin Therapeutics of a Product Order.

10.4. Shipment. Galectin Therapeutics agrees to deliver the Compound using a carrier selected by Procaps for shipment to Procaps (the “Carrier”). Title to and risk for loss or damage shall pass to Procaps upon delivery to the Carrier. Procaps shall be responsible for selecting and making all arrangements for a Carrier to ship the Compound from Galectin Therapeutics’ manufacturing facility. Procaps shall not make any modifications to the Compound or its packaging or labeling other than as required in connection with the production of Formulated Doses. Unless otherwise agreed, delivery of the Compound to the Carrier shall take place at Galectin Therapeutics’ manufacturer’s premises ex works (ICC Incoterms 2000). Risk of loss and damage shall pass to Procaps upon shipment in accordance with this Section 10.4.

10.5. Testing and Acceptance. Procaps shall have thirty (30) days after the delivery to Procaps of an order of Compound supplied hereunder to determine whether Compound conforms to the Specifications (using the same validated test methods as Galectin Therapeutics) and order quantity. Procaps will be deemed to have acknowledged that an order of Compound conforms to the Specifications and order quantity and is accepted, unless Procaps rejects such Compound order by giving written notice of non-conformity to Galectin Therapeutics within such thirty (30) day period. If Procaps determines that a Compound order fails to meet the Specifications, or that there is a shortage in the quantity delivered, it shall promptly so notify Galectin Therapeutics in writing within such thirty (30) day period. Any such notice shall specify the reason, with supporting documentation, for the non-conformity or the details of any quantity shortage, as the case may be. In the event that Galectin Therapeutics agrees that an order of Compound is non-conforming with the Specifications or that there was a shortage in quantity delivered, Galectin Therapeutics shall, at its own cost (including shipping) use commercially reasonable efforts to replace the non-conforming quantities of Compound or make up the shortage, as soon as reasonably possible. If Galectin Therapeutics does not agree that the particular order of Compound fails to meet the Specifications or that it delivered a shortage of Compound, it shall notify Procaps and the Parties (through the JSC) shall try to negotiate a mutually satisfactory resolution of their differences. Should a dispute over the conformity of a Compound order persist beyond thirty (30) days after Galectin Therapeutics’ notice to Procaps of disagreement, a representative sample of the Compound at issue shall be submitted to an independent testing laboratory designated by Galectin Therapeutics and reasonably agreeable to Procaps for testing against the Specifications using the same validated test methods in use by Galectin Therapeutics. Both Parties shall cooperate in method transfer and supply of reference materials to enable qualification of the independent test laboratory. The test results obtained from such laboratory shall be

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final and binding on the Parties. The cost of such test shall be borne by the Party whose results disagree with those of the independent laboratory. Where the test results demonstrate that the Compound order fails to meet any of the Specifications, Galectin Therapeutics shall replace the non-conforming quantities of Compound at no additional cost to Procaps as soon as reasonably possible after receipt of such results. The provisions of this Section shall not apply to any Compound damaged or lost in transit after delivery by Galectin Therapeutics to the Carrier, which shall be the responsibility of Procaps.

10.6. Product Inventory. During the term of this Agreement, (i) Procaps shall maintain reasonable inventory levels of the Product at a level equal to at least the amount of Product forecasted to be needed for the following two calendar quarters as set forth in the then current Marketing and Distribution Plan and (ii) Galectin Therapeutics shall maintain reasonable inventory levels of the Compound at a level equal to at least the amount of Compound forecasted to be needed for the following calendar quarter as set forth in the then current Marketing and Distribution Plan.

## 11. ROYALTIES

11.1 Royalties. For the term specified in Section 11.2, Procaps shall pay to Galectin Therapeutics royalties on Net Sales in Columbia, at an incremental royalty rate determined by annual Net Sales of all Product in aggregate in each calendar year as follows:

<u>Annual Net Sales of Product</u>	<u>Royalty Rate</u>
Portion less than or equal to USD \$[****] million	[****]%
Portion greater than USD \$[****] million and less than or equal to USD \$[****] million	[****]%
Portion greater than USD \$[****] million and less than or equal to USD \$[****] million	[****]%
Portion greater than USD \$[****] million	[****]%

For example, if the calendar year Net Sales to which the royalty obligations in this Section 11.1 apply, were \$[\*\*\*\*], there would be [\*\*\*\*] royalty on the first \$[\*\*\*\*] million of such Net Sales, the [\*\*\*\*]% royalty rate would apply to the next \$[\*\*\*\*] of such Net Sales, the [\*\*\*\*]% royalty rate would apply to the next \$[\*\*\*\*] of such Net Sales and the [\*\*\*\*]% royalty rate would apply to the final \$[\*\*\*\*] of such Net Sales. For the avoidance of doubt, royalty rates for countries other than Columbia in the Territory will be separately negotiated at the time the Parties agree, if at all, to add additional RFN Eligible Countries pursuant to Section 2.3; provided, that the maximum royalty rate in such countries shall be [\*\*\*\*]% of Net Sales. Minimum annual sales requirements for each RFN Eligible Country included in the RFN Agreement will be proportional to the minimum annual sales requirements for Columbia set forth in Exhibit D taking into account for each such country the factors set forth in Section 2.3 to determine upfront license fees. Royalties in each RFN Eligible Country included in the RFN Agreement will commence upon the First Commercial Sale in such country (i.e., royalties shall be due upon the first dollar of Net Sales in such country), except for Colombia which royalty schedule is set forth above.

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11.2 Royalty Term. Royalties due under Section 11.1 with respect to the Product will commence upon the first commercial sale of the Product to a Third Party after Regulatory Approval ("First Commercial Sale") in any RFN country or jurisdiction and will be payable until the later of (i) the Term and (ii) any post-termination sales pursuant to Section 19.3.

11.3 Royalty Payments and Net Sales Reports. All amounts payable to Galectin Therapeutics pursuant to Section 11.1 shall be paid in United States dollars within thirty (30) days after the end of each calendar quarter with respect to Net Sales in such calendar quarter. Within thirty (30) days after the end of each calendar quarter, following Regulatory Approval of the Product in Colombia, Procaps shall provide Galectin Therapeutics a report setting forth (i) the amount of gross sales of Product during the applicable calendar quarter, (ii) an itemized calculation of Net Sales showing deductions provided for in the definition of Net Sales during such calendar quarter, (iii) the Net Sales Price for such calendar quarter, and (iv) a calculation of the amount of royalty payment due on such Net Sales for such calendar quarter.

11.4 Foreign Exchange. The rate of exchange to be used in computing the amount of currency equivalent in United States dollars of Net Sales invoiced in other currencies shall be made at the period-end rate of exchange quoted on the last business day of the applicable calendar quarter by Citibank in New York City or, to the extent mutually agreed by the Parties, any other widely accepted source of published exchange rates.

11.5 Late Payments. If Galectin Therapeutics does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to Galectin Therapeutics from the due date until the date of payment at the prime rate (as stated in the Wall Street Journal on the date such payment was due) plus four percent (4%) or the maximum rate allowable by applicable law, whichever is less.

11.6 Financial Records; Audits. Procaps shall maintain complete and accurate records in sufficient detail to permit Galectin Therapeutics to confirm the accuracy of the Net Sales generated by Procaps and the calculation of royalty payments and the Net Sales Price. Upon reasonable prior notice of at least five (5) Business Days, such records shall be open during regular business hours for a period of three (3) years from the creation of individual records for examination at Galectin Therapeutics' expense, and not more often than twice each calendar year, by an independent certified public accountant selected by Galectin Therapeutics for the sole purpose of verifying for Galectin Therapeutics the accuracy of the financial reports, royalty payment or Net Sales and Net Sales Price calculations or of any payments made by Procaps to Galectin Therapeutics pursuant to this Agreement. Any such auditor shall not disclose Procaps' Confidential Information to Galectin Therapeutics, except to the extent such disclosure is necessary to verify the accuracy of the financial reports, royalty payment or Net Sales and Net Sales Price calculation furnished by Procaps or the amount of payments due by Procaps under this Agreement. Any amounts shown to be owed but unpaid or overpaid and in need of reimbursement shall be paid or refunded (as the case may be) within thirty (30) days after the accountant's report, plus interest (as set forth in Section 11.5) from the original due date. Galectin Therapeutics shall bear the full cost of such audit unless such audit discloses that Procaps paid too little because of a discrepancy in a report that Procaps provided to the JSC or Galectin Therapeutics during the applicable audit period, which underpayment was equal to more than five percent (5%) of the amount set forth in such report, in which case Procaps shall bear the full cost of such audit.

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## 12. REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:

(a) Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

(b) Authority and Binding Agreement. It has the corporate or organizational power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary corporate or organizational action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on its behalf, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms and this Agreement will not violate (a) such Party's certificate of incorporation or bylaws, (b) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (c) any requirement of any applicable laws or regulation, or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party.

(c) No Conflict. It is not a party to and will not enter into any agreement that would materially prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement.

(d) No Debarment. To the best of such Party's knowledge, such Party has not used prior to the Effective Date and shall not use, during the term of the Agreement, any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or is the subject of debarment proceedings by a Regulatory Authority.

12.2. Disclaimer. Procaps understands that the Compound and Product are the subject of ongoing clinical research and development and that the safety or efficacy profile of the Compound and Product are not fully defined.

## 13. PRODUCT WARRANTY AND CONDITIONS

13.1. Warranty. Galectin Therapeutics warrants to Procaps that the Product delivered by Galectin Therapeutics to Procaps pursuant to this Agreement: (a) shall be free from defects in material or workmanship or design, and (b) shall conform to the Product specifications, any technical conditions or standards provided by the certificate of analysis, and all applicable laws. The warranties in this Section 13.1 are exclusive and in lieu of all other warranties, whether oral or in writing, express or implied or statutory. In the event that Galectin Therapeutics delivers Product in non-conformance with these warranties, Procaps shall have the right to return the Product, at the cost and expense of Galectin Therapeutics, and Galectin Therapeutics shall reimburse Procaps any Transfer Price paid for such non-conforming Product. The above warranties shall only apply to the extent the Product is handled, stored, transported and used by or on behalf of Procaps, and Purchasers in accordance with this Agreement, Galectin Therapeutics' instructions, and applicable laws, rules and regulations. Any disputes between the Parties regarding whether Product delivered to Procaps meets the warranty provided in this Section shall be resolved pursuant to Section 20.

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13.2. No Modification of Product Warranty. Procaps shall provide in each product order with a Purchaser, a written notice containing the Product warranty provisions of Section 13.1. Procaps shall not modify or supplement such warranty or disclaimer without the express prior written consent of an authorized representative of Galectin Therapeutics, or provide any additional warranty. Procaps shall indemnify and hold Galectin Therapeutics harmless from all liabilities, claims, damages and expenses, including attorneys' fees that may be incurred by Galectin Therapeutics during or after the term of this Agreement that result from or arise out of the failure of Procaps to comply with the terms of this Section 13.

13.3. WARRANTY DISCLAIMER. THE EXPRESS REPRESENTATIONS AND WARRANTIES OF GALECTIN THERAPEUTICS STATED IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, OR STATUTORY, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. NO REPRESENTATION OR WARRANTY MADE BY EMPLOYEES OF GALECTIN THERAPEUTICS, PROCAPS OR ANY OTHER PARTY SHALL BE CONSIDERED A WARRANTY BY GALECTIN THERAPEUTICS FOR ANY PURPOSE OR CREATE ANY LIABILITY OF GALECTIN THERAPEUTICS.

#### **14. INTELLECTUAL PROPERTY**

14.1. Intellectual Property. Procaps acknowledges that all current and future patents, patent applications, trade marks, trade names, service marks, internet domain names, copyrights, design rights, trade secrets, and other intellectual property rights in or related to the Compound and/or Product or any materials used in connection with the manufacture, Approval Pursuit, use or Marketing and Distribution of the Compound and/or Product (the "Product Related IP Rights") are and shall remain the exclusive property of Galectin Therapeutics. Galectin Therapeutics shall be solely responsible for prosecution, maintenance and enforcement of the Galectin Therapeutics Patents, Product Related IP Rights and Licensed Marks. Except as explicitly provided under this Agreement, Procaps has no right to, and shall not, make, use, modify, reproduce, disassemble, reverse engineer, translate, reconstruct, or improve the Compound and/or Product, the Confidential Information, or any other materials used in connection with the manufacture, Approval Pursuit, use or Marketing and Distribution of the Compound and/or Product, or practice any of Galectin Therapeutics' current or future intellectual property rights, except upon the prior written consent of Galectin Therapeutics. Procaps hereby assigns, or in jurisdictions that do not allow present assignment of future rights, agrees to assign, to Galectin Therapeutics, without additional consideration, all of Procaps' rights in any Product Related IP Rights that now exists or hereafter arises including the right to claim priority from the relevant patent application(s). Procaps shall execute such documents and take such actions as Galectin Therapeutics may reasonably request in connection with the documentation of any Product Related IP Right or the assignment of such right to Galectin Therapeutics. All copyrightable works included within the Product Related IP Rights that are created (solely or jointly) by Procaps shall be assigned to Galectin Therapeutics to the maximum extent possible under applicable law. Procaps shall promptly notify Galectin Therapeutics of any action by any Person that comes to Procaps' attention that constitutes or may constitute an infringement of Galectin Therapeutics' intellectual property.

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14.2. Cooperation of Procaps. Procaps shall provide Galectin Therapeutics all reasonable assistance and cooperation in Galectin Therapeutics' patent prosecution efforts with respect to Product Related IP Rights, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution. In addition, Procaps shall provide to Galectin Therapeutics reasonable assistance in enforcement of patents or patent applications claiming Product Related IP Rights, at Galectin Therapeutics' request and expense, including joining such action as a party plaintiff if required by applicable law to pursue such action.

14.3. Licensed Marks. The Licensed Marks, and any reputation and goodwill in them, are, and will remain, the exclusive property of Galectin Therapeutics, and Procaps does not have and shall not have any right to use any such Licensed Mark other than in connection with the Marketing and Distribution of the Product under the terms and conditions of this Agreement. All use of the Licensed Marks shall inure solely to the benefit of Galectin Therapeutics. Procaps shall not: (a) use any Licensed Mark, or any word, symbol, or design confusingly similar to any Licensed Mark or other Galectin Therapeutics mark, as part of its corporate or legal name or in connection with any product sold by Procaps; (b) do or suffer to be done any act or thing which would in any way impair the rights of Galectin Therapeutics in and to any Licensed Mark; (c) apply for any registration of any trademark or other designation which includes in whole or in part any Licensed Mark or which otherwise would affect the ownership of any Licensed Mark, no file any document with any governmental authority to take any action that would affect the ownership of any Licensed Mark or assist any other Person or entity to undertake any such action; or (d) acquire or claim any title to any Licensed Mark adverse to Galectin Therapeutics by virtue of the rights granted to Procaps under this Agreement or through Procaps' use of such Licensed Mark. If any Licensed Marks are to be used in conjunction with another trademark on or in relation to the Product, then the Licensed Mark(s) shall be presented equally legibly, equally prominently, and of greater size than the other, but nevertheless separated from the other, so that each appears to be a mark in its own right, distinct from the other mark.

14.4. Patent Marking. Procaps shall, and shall require its Affiliates, to mark the Product sold by it hereunder with appropriate patent numbers or indicia to the extent permitted by applicable law and regulations, in those countries in which such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringements of patents.

14.5. Employee Obligations. Prior to the Effective Date, each employee, agent or independent contractor of Procaps or its Affiliates that may be involved at any time during the Term in the Approval Pursuit or Distribution of the Product or other obligations under this Agreement shall sign, to the extent it has not already signed, a non-disclosure and invention assignment agreement pursuant to which such person agrees to comply with all of the obligations of Procaps, as appropriate, in this Section 14, including without limitation: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) assigning to Procaps all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property right; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any patent and patent application; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) abiding by the obligations of confidentiality and non-use set forth in Section 15. It is understood and agreed that such non-disclosure and invention assignment agreement need not reference or be specific to this Agreement. New employees shall sign such an agreement before receiving or being exposed to Galectin Confidential information.

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## 15. CONFIDENTIALITY

15.1. Definition. “Confidential Information” shall mean any technical, scientific, clinical, financial, commercial or business information furnished by one Party to the other Party in connection with this Agreement or developed by Procaps in the course of fulfilling its obligations under this Agreement, regardless of whether such Confidential Information is in oral, electronic or written form. Such Confidential Information includes, without limitation, all trade secrets, know-how, inventions, developments, technical data or specifications, formulations, formulae, testing methods, research and development activities, product and marketing plans, customer and supplier information, materials, compositions of matter, manuals, processes, procedures, reports, instructions, databases, information, marketing reports, expertise, technology, test data including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, stability data, studies and procedures relating to Galectin Therapeutics, Procaps, the Compound or the Product. All Confidential Information is and shall remain the exclusive property of the disclosing Party; provided that Confidential Information developed by Procaps in the course of fulfilling its obligations under this Agreement shall be Confidential Information of Galectin Therapeutics.

15.2. Obligations. The receiving Party shall:

- (a) maintain all Confidential Information of disclosing Party in strict confidence;
- (b) use all Confidential Information of disclosing Party solely for the purpose of fulfilling its obligations under this Agreement; and
- (c) reproduce the Confidential Information of disclosing Party only to the extent necessary for fulfilling its obligations under this Agreement, with all such reproductions being considered Confidential Information.

15.3. Exceptions. Information shall not be deemed Confidential Information if the receiving Party can demonstrate that such information:

- (a) was in the public domain prior to the disclosure of such information by the disclosing Party;
- (b) entered the public domain after receipt from the disclosing Party through means other than an unauthorized disclosure resulting from an act or omission by the receiving Party in violation of this Agreement; or
- (c) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party.

15.4. Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:

- (a) regulatory filings and other filings with Governmental Authorities, including filings with the SEC, with respect to the Compound or Product;

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(b) complying with applicable laws and regulations, including regulations promulgated by securities exchanges;

(c) disclosure to its Affiliates, employees, agents, and approved independent contractors, only on a need-to-know basis and solely as necessary in connection with the performance of this Agreement, provided that each disclosee must be bound by similar obligations of confidentiality and non-use at least as equivalent in scope as those set forth in this Section 15 prior to any such disclosure; and

(d) solely with respect to the material terms of this Agreement, disclosure to any bona fide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner; provided that in connection with such disclosure, the disclosing Party shall use all reasonable efforts to inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to this Section 15.4, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use reasonable efforts to limit the scope of such disclosure, as well as any subsequent use or disclosure of the information so disclosed, by seeking confidential treatment, a protective order, or the like and reasonably assist the other Party in its efforts to seek such confidential treatment, protective order or the like. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

15.5. Return of Confidential Information. Upon the expiration or termination of this Agreement, the receiving Party shall return to the disclosing Party or destroy all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information in the possession or control of the receiving Party; except that one copy may be retained by the other Party's legal counsel to ascertain compliance with this Agreement.

15.6. Survival of Obligations. The obligations set forth in this Section 15 shall remain in effect for a period of ten (10) years after expiration or termination of this Agreement, except that the obligations of the receiving Party to return Confidential Information shall survive until fulfilled.

## **16. INDEMNIFICATION; INSURANCE; LIMITATION OF LIABILITY**

16.1. Scope of Indemnification. Each Party (the "Indemnitor") hereby agrees to indemnify and hold the other Party and its Affiliates and their respective shareholders, officers, directors, employees, consultants and agents (the "Indemnitees") harmless for any loss, claim, damage, cost, expense (including reasonable attorney's fees), or liability by or to a Third Party (a "Claim") arising out of: (a) the negligence or willful misconduct of the Indemnitor, its Affiliates or any of their respective officers, directors, employees, consultants or agents; (b) a breach by the Indemnitor of any of its representations, warranties or obligations under this Agreement or any breach of applicable law; or (c) the Indemnitor's Approval Pursuit and Marketing and Distribution of the Product.

16.2. Process. If any claim is asserted against an Indemnitee by any Third Party, which claim is subject to indemnity under this Section 16, the Indemnitee shall notify the Indemnitor thereof promptly after its receipt of such claim, but any delay in giving such notice shall not affect the Indemnitee's rights under this Section 16 except to the extent the Indemnitor is actually prejudiced thereby. The Indemnitor

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shall have the right to take charge of the defense of such claim by giving notice to the Indemnitee within ten (10) days after Indemnitee's notice. If the Indemnitor so assumes the defense, (i) the defending counsel shall be selected by the Indemnitor and shall be free of material conflicts with the Indemnitee's interests and otherwise reasonably satisfactory to the Indemnitee, (ii) all costs and expenses of defense, including without limitation all attorney, witness, investigation, and court fees and expenses, (collectively, "Defense Costs") shall be borne and promptly paid by the Indemnitor, and (iii) any engagement of separate counsel by Indemnitee shall be solely at the Indemnitee's expense. If the Indemnitor does not so assume the defense, or if the Indemnitor fails to diligently pursue such defense or timely pay any Defense Costs, then the Indemnitee may take charge of the defense of such claim, including the designation of defense counsel, and all Defense Costs, including without limitation the reasonable fees and expenses of counsel designated by the Indemnitee, shall be borne and promptly paid by the Indemnitor. No settlement of a claim for which indemnification will be sought under this Section 16 shall be made without the consent of the Indemnitor, which shall not unreasonably be withheld. No settlement of a claim shall be entered into without the consent of the Indemnitee unless it fully and finally releases the Indemnitee from all obligations and liability relating to or arising out of the subject matter of the claim and imposes no restrictions or burdens on the Indemnitee.

16.3. Insurance. Each Party shall secure and maintain in full force and effect throughout the term of this Agreement policies of insurance, including general commercial liability and product liability, with limits, deductibles and other terms appropriate to the conduct of their business. Each Party shall furnish certificates evidencing such insurance upon the other Party's request.

16.4. LIMITATION OF LIABILITY. EXCEPT TO THE EXTENT GALECTIN THERAPEUTICS MAY BE REQUIRED TO INDEMNIFY PROCAPS UNDER SECTION 16, NEITHER GALECTIN THERAPEUTICS NOR ITS AFFILIATES OR AGENTS SHALL BE LIABLE FOR SPECIAL, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE. ANY LIABILITY OF GALECTIN THERAPEUTICS FOR DAMAGES RELATING TO THE PRODUCT SHALL NOT EXCEED THE PRICE PAID BY PROCAPS FOR THE PRODUCT.

16.5. No Goodwill. Procaps shall not be entitled to compensation for any goodwill which may have accrued due to the Approval Pursuit and Marketing and Distribution of the Product by Procaps. Procaps shall have no claim against Galectin Therapeutics based on, arising out of, or in connection with, the alleged value of any particular customer account or group of accounts located within the Territory. Upon termination or expiration of this Agreement, Galectin Therapeutics shall be free, at its sole discretion, to make whatever other arrangements for Pursuing Approval and Marketing and Distributing the Product in the Territory as Galectin Therapeutics may deem appropriate, with whatever party and under whatever terms and pricing as Galectin Therapeutics shall determine.

## 17. NON-COMPETE

Procaps hereby covenants and agrees that during the term of this Agreement and for a period of five (5) years thereafter it will not, and will cause its Affiliates, not to, directly or indirectly, other than as provided in this Agreement, import, develop, manufacture, market, sell or distribute any products that can be substituted for the Compound or Product or enter into a collaboration or license agreement with any Third Party to do the same. A product that can be substituted for the Product shall be any oncology

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therapeutic that can be used instead of a regime containing 5-FU (whether alone or in combination with other therapeutics) for an oncology indication in which a 5-FU containing regime is used or any oncology therapeutics that can be used to replace 5-FU in a regime otherwise containing 5-FU. Notwithstanding the prior sentence, Procaps may import, develop, manufacture, market, sell or distribute products used solely to diagnose cancer or treat side effects associated with cancer treatments or those products which it currently imports, develops, manufactures, markets, sells or distributes or for which it has the right to do so that are identified on Exhibit E. Procaps agrees that any breach or threatened breach by it of this Section 17 shall entitle Galectin Therapeutics, in addition to all other legal remedies available to them, to a temporary or permanent injunction to enjoin such breach or threatened breach without having to post bond, together with an award of its attorneys' fees incurred in connection with same.

## **18. TERM**

This Agreement shall begin on the Effective Date and shall continue until the seventh (7th) anniversary of the Effective Date unless terminated earlier in accordance with the terms of Section 19 or another provision of this Agreement, or unless extended by written agreement of both Parties for one or more countries in the Territory upon mutually agreeable terms within sixty (60) days of the then current termination date (the "Term").

## **19. TERMINATION**

19.1. Termination by Either Party. Except as otherwise provided in this Agreement, either Party may terminate this Agreement or, in the case of Galectin Therapeutics, render Procaps' rights under this Agreement non-exclusive: (a) for cause upon the material breach of any obligation or responsibility by the other Party which breach remains uncured for thirty (30) days after written notice thereof; (b) for cause upon the non-material breach of any obligation or responsibility by the other Party which breach remains uncured for sixty (60) days after written notice thereof; (c) upon thirty (30) days written notice upon the revocation, termination of a Regulatory Approval or the suspension of sales of the Product for a period of greater than one hundred and eighty days (180) days by a Regulatory Authority in the Territory. For the avoidance of doubt, subject to Section 21.6, this Agreement shall survive a merger, consolidation or sale of all or substantially all of a Party's assets.

19.2. Post-Termination Obligations. In the event of Termination of this Agreement, (i) Galectin Therapeutics shall, in its sole discretion, process in the ordinary course of business all Product Orders confirmed by Galectin Therapeutics prior to the written notice of termination, or prior to the expiration date of this Agreement; provided, however, that Procaps shall pay the invoice for all such Product Orders in advance of shipment, (ii) Procaps may sell any existing Product in its inventory during the period ending one hundred eighty (180) days following receipt of notice of termination, provided Regulatory Approval has not been revoked, terminated or suspended, (iii) Galectin Therapeutics shall have the option to purchase all or part of Compound in Procaps' inventory as of the date notice of termination is received at the price paid by Procaps for such Compound, and (iv) at the end of the period ending one hundred eighty (180) days following receipt of notice of termination, Procaps shall destroy any remaining Compound not purchased by Galectin Therapeutics and any remaining Product and provide Galectin Therapeutics with written certification thereof. Termination or expiration of this Agreement shall not prevent or excuse Procaps from settling accounts, collecting funds, or engaging in any activity necessary to bring successfully to completion any transaction outstanding at the time of the termination or expiration of this Agreement. In the event of termination for breach by Procaps or a termination pursuant to Section 19.1(d), (A) all outstanding Product Orders shall be immediately terminated, (B) Procaps shall immediately cease all Marketing and Distribution of the Product, (C) Galectin Therapeutics shall have the option to purchase all or part of Compound in Procaps inventory as of the date notice of termination is

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received at the price paid by Procaps for such Compound, and (D) Procaps shall destroy any remaining Compound not purchased by Galectin Therapeutics and any remaining Product and provide Galectin Therapeutics with written certification thereof. Immediately after termination or expiration, Procaps shall provide all cooperation and assistance reasonably requested by Galectin Therapeutics to enable Galectin Therapeutics to assume and/or continue, with as little disruption as reasonably possible, the continued Approval Pursuit and Marketing and Distribution of the Product in the Territory, including, without limitation, (a) as directed by Galectin Therapeutics, terminate all agreements between Procaps and any Third Parties relating to the Approval Pursuit or Marketing and Distribution of the Product, or assign them to Galectin Therapeutics or a Third Party designated by Galectin Therapeutics, (b) at Galectin Therapeutics' request, transfer to Galectin Therapeutics or its designee all inventory of the Compound and the Product (c) at the direction of Galectin Therapeutics, remove from any literature or other media of Procaps any and all references to Galectin Therapeutics and the Product, (d) cease to use any trademarks or trade names of Galectin Therapeutics, the Compound or the Product and assign to Galectin Therapeutics all right, title and interest in any such trademarks or trade names to the extent necessary, (e) transfer or assign to Galectin Therapeutics all Regulatory Materials, Regulatory Approvals, Product Related IP Rights, licenses, permits, authorizations or similar documents for the Product that Procaps holds as of the time of any such termination, (f) return to Galectin Therapeutics all Confidential Information of Galectin Therapeutics, (g) pay Galectin Therapeutics any outstanding invoices and royalty amounts, and (h) provide Galectin Therapeutics with a final Marketing and Distribution report containing data through the effective date of the termination or expiration of the Agreement, including without limitation, customer account information and market data and intelligence. The provisions of Sections 5.1, 5.2, 6.5, 7.5, 13.2, 13.3, 14, 15, 16, 17, 20 and this Section 19.3 shall survive expiration or termination of this Agreement. In addition, the following provisions shall survive expiration or termination of this Agreement with respect to sales made prior to such expiration or termination, or in accordance with this Section 19.3: 4.4, 4.6, 5.2, 6.3, 6.5, 6.6, 7.5, 9.1, 9.2, 9.3, 11 and 13.

## **20. DISPUTE RESOLUTION**

20.1. Disputes. Any contractual dispute arising under this Agreement (the "Dispute") shall be discussed first by the respective chief executive officers of each Party or his/her designee for attempted resolution by good faith discussions within sixty (60) days. In the event that the chief executive officers or his/her designee are not able to resolve such Dispute within such sixty (60) day period, and do not agree to extend the time period for resolving the Dispute, unless the Parties otherwise agree to extend the time period for resolving the Dispute, then such Dispute shall be resolved pursuant to the provisions of Section 20.2.

20.2. Arbitration. If the Dispute is not resolved pursuant to Section 20.1, such Dispute must be referred to and finally resolved by arbitration, to which the Parties hereto expressly agree and submit. The arbitration will be submitted to the International Centre for Dispute Resolution of the American Arbitration Association ("AAA") and conducted in accordance with the Commercial Arbitration Rules of the AAA ("Rules"). Pre-hearing information exchange shall be limited to the reasonable production of relevant, nonprivileged documents and carried out expeditiously. There will be one arbitrator selected by mutual agreement of the Parties. It is the intent of the Parties that, barring extraordinary circumstances, arbitration proceedings will be concluded within ninety (90) days from the date the arbitrator is appointed. The arbitral tribunal may extend this time limit in the interests of justice. Failure to adhere to this time limit shall not constitute a basis for challenging the award. The arbitration will be conducted in English and the place of arbitration will be in New York City, New York, USA. Either Party may, without waiving any remedy under this Agreement, apply to the arbitral tribunal and/or any court having

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jurisdiction any interim, provisional, injunctive or conservatory relief that is necessary to protect the rights or property of that Party until the arbitration award is rendered or the Dispute is otherwise resolved. Any decision rendered by the arbitral tribunal will be final and binding on the Parties, and judgment thereon may be entered by any court of competent jurisdiction, including, but not limited to, any court that has jurisdiction over either of the Parties or any of their assets. The Parties expressly agree that the arbitral tribunal will be empowered to award and order equitable or injunctive relief with respect to matters brought before it, provided however, that such remedy or relief is consistent with the remedies and limitations set forth in this Agreement. The Parties agree that all arbitral proceedings conducted pursuant to this Section, including the existence of any arbitral proceedings, information disclosed in the course of such arbitral proceedings, and any settlements, negotiations, discussions, proposals, and awards related thereto shall be considered Confidential Information. The Parties may, however, disclose such information to an appropriate court, as is necessary to seek enforcement of any award rendered by the arbitral tribunal.

**20.3. Governing law; Venue.** This Agreement shall be governed by and construed under the substantive laws of the United States of America and the Commonwealth of Massachusetts, without regard to conflicts of law rules. Each Party (a) hereby irrevocably submits itself to and consents to the exclusive jurisdiction of the Commonwealth of Massachusetts for the purposes of any action, claim, suit or proceeding in connection with any controversy, claim or dispute arising out of or relating to this Agreement for which Section 20.2 permits access to the courts, and (b) hereby waives, and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, claim, suit or proceeding, any claim that it is not personally subject to the jurisdiction of such court(s), that the action, claim, suit or proceeding is brought in an inconvenient forum or that the venue of the action, claim, suit or proceeding is improper. The Parties agree that the 1980 United Nations Convention on Contracts for the International Sale of Goods shall not apply to or affect any term of this Agreement.

## **21. GENERAL PROVISIONS**

**21.1. Relationship of the Parties.** The Parties are and shall remain independent contractors. Procaps shall conduct all of its business in its own name and shall pay all expenses of its office and activities and be solely responsible for the acts and expenses of its employees. Procaps shall purchase and resell the Product for its own account and at its own risk. This Agreement does not constitute a partnership or joint venture and does not establish either Party as the agent, franchisee, or legal representative of the other for any purpose, and neither Party has the authority to act for, bind, or make commitments on behalf of the other, except as specifically provided for in this Agreement.

**21.2. Force Majeure.** Neither Procaps nor Galectin Therapeutics shall be liable for any delay or failure to perform its obligations under this Agreement because of events beyond its reasonable control and which were not reasonably foreseeable at the time of signing this Agreement, including but not limited to strikes, riots, war, fire, acts of God, acts of government, supplier delays, and breakdown or general unavailability of materials or transportation facilities. In the event that a Party's non-performance extends for a period greater than one hundred eighty (180) days as permitted by this Section 21.2, the other Party may terminate the Agreement upon written notice to the non-performing Party.

### **21.3. Publicity.**

(a) If Galectin Therapeutics desires to make public announcements related to this Agreement concerning (i) completion of clinical studies in the Territory and top line results thereof, (ii)

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filings for Regulatory Approvals in the Territory; iii ) Regulatory Approvals in the Territory; and (iv) milestone achievements and/or payments, Galectin Therapeutics shall give reasonable prior advance notice of the proposed text of such announcement to Procaps for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld. Procaps shall provide its comments, if any, within three (3) business days after receiving the announcement for review. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that have already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 21.3.

(b) Procaps acknowledges that Galectin Therapeutics may be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission. Galectin Therapeutics shall be entitled to make such a required filing, provided that it requests confidential treatment of at least the commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available to Galectin Therapeutics. In the event of any such filing, Galectin Therapeutics will provide Procaps with a copy of the Agreement a reasonable time in advance of filing marked to show provisions for which Galectin Therapeutics intends to seek confidential treatment and shall reasonably consider and incorporate Procaps' comments thereon (which shall be provided to Galectin Therapeutics a reasonable time in advance of filing) to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed.

21.4. Entire Agreement and Amendment. This Agreement, including its exhibits, schedules and attachments constitutes the entire agreement between the Parties with respect to its subject matter and cancels and supersedes all prior agreements, understandings, and arrangements, whether written or oral, between the Parties with respect to such subject matter. No amendment, modification, or waiver of the terms of this Agreement, or any of its exhibits, schedules, or attachments will be binding on either Party unless reduced to writing and signed by an authorized representative of the Party to be bound.

21.5. Performance by Galectin Therapeutics. Any of Galectin Therapeutics' obligations to be performed under this Agreement may be performed by any subsidiary or Affiliate or Third party designee of Galectin Therapeutics.

21.6. Assignment. Procaps may not assign, delegate, or subcontract its rights or obligations under this Agreement or otherwise engage agents to perform or assist in performing its duties and obligations under this Agreement without the prior written consent of Galectin Therapeutics. For purposes of this Agreement, a merger, consolidation or sale of all or substantially all of a Party's assets shall not be deemed an assignment; *provided* that such Party's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction and shall not be transferred separate from all or substantially all of its other business assets, including those business assets that are the subject of this Agreement. Any successor in interest to a Party may terminate this Agreement only pursuant to the terms hereof or pursuant to mutual written agreement with the other Party.

21.7. Language of the Agreement. This Agreement is written in the English language and the English language shall govern its interpretation.

21.8. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable or inoperative, either in whole or in part, the remaining provisions shall

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be severable and continue in full force and effect, and the Parties shall negotiate in good faith enforceable, operative replacement provisions for the unenforceable or inoperative ones that meets the original intention of the Parties as much as possible.

21.9. No Waiver. The failure of either Party to this Agreement to insist upon the performance of any of its terms and conditions, or the waiver of any breach of any of the terms and conditions of this Agreement, shall not be construed as later waiving any terms and conditions, but they shall continue and remain in full force and effect as if no forbearance or waiver had occurred.

21.10. Headings. The headings of this Agreement have been included solely for reference and are to have no force or effect in interpreting its provisions.

21.11. Gender and Number. Words used in this Agreement, regardless of the number and gender specifically used, will be deemed and construed to include such other number, singular or plural, and such other gender, masculine, feminine, or neuter, as the context requires and the term "including" or "includes" means including, without limiting the generality of any description preceding such term.

21.12. Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

21.13. Notices. Any notice or other communication required or permitted by this Agreement shall be in writing in the English language and sent to the following addresses (or such other addresses as provided in writing by the applicable Party):

If to Galectin Therapeutics:

Galectin Therapeutics Inc.  
7 Wells Avenue  
Newton, MA 02459  
Attn: CEO  
Fax No.: 617-928-3450  
Telephone No.: 617-559-0033

If to Procaps:

[PROCAPS TO COMPLETE]

Any such notice or other communication shall be deemed given (a) when delivered personally, (b) three (3) Business Days after having been sent by registered or certified mail, return receipt requested, postage prepaid; (c) one (1) day after deposit with a commercial express courier specifying next day delivery, with written verification or receipt, or (d) when acknowledged or confirmed after being faxed.

Notwithstanding the foregoing, notices to be sent pursuant to Section 9.2 shall be sent via email to \_\_\_\_\_ (or such other email address as provided by Procaps) followed by a hard copy sent by fax.

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*(Remainder of page intentionally left blank.)*

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IN WITNESS WHEREOF, the Parties by their duly authorized representatives have executed this Agreement as of the Effective Date.

GALECTIN THERAPEUTICS, INC.

By: \_\_\_\_\_

Name: Dr. Peter G. Traber

Title: CEO and President

PROCAPS S.A.

By: \_\_\_\_\_

Name: Ruben Minski

Title: President

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**Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rules 24b-2 of the Securities Exchange Act of 1934, as amended.**

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Exhibit A  
LICENSED MARKS

Trademarks, trade names, names, brands, logos and symbols for GM-CT-01 (DAVANAT®) in Latin America to be agreed upon by Procaps and by Galectin Therapeutics.

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Exhibit B  
SPECIFICATIONS

The specifications shall be those specifications for the Compound set forth in the Technical Dossier to be submitted to INVIMA.

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Exhibit C  
MARKETING AND DISTRIBUTION PLAN

To be provided by Procaps pursuant to Section 6.2

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**Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rules 24b-2 of the Securities Exchange Act of 1934, as amended.**



Exhibit D  
MINIMUM ANNUAL SALES TARGETS  
(In U.S. Dollars)

YEAR	SALES		PATIENTS	DOSES
One	\$	**** million	****	****
Two	\$	**** million	****	****
Three	\$	**** million	****	****
Four	\$	**** million	****	****
****		****	****	****
Metric for Contract				
Minimums			example	example

Portions of this Exhibit were omitted, as indicated by [\*\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rules 24b-2 of the Securities Exchange Act of 1934, as amended.

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Exhibit E  
CURRENT AND FUTURE PROCAPS ONCOLOGY PRODUCTS

To be provided by Procaps before Regulatory Approval

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**Portions of this Exhibit were omitted, as indicated by [\*\*\*], and have been provided separately to the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rules 24b-2 of the Securities Exchange Act of 1934, as amended.**