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

FORM 8-K

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

Date of Report (Date of earliest event reported): February 4, 2025 (January 12, 2025)

Ensysce Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38306**	**82-2755287**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

7946 Ivanhoe Avenue, Suite 201	
La Jolla, California	**92037**
(Address of principal executive offices)	**(Zip Code)**

(858) 263-4196
Registrant's telephone number, including area code

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**ENSC**	**The Nasdaq Stock Market LLC**

Emerging growth company ☐

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

Item 1.01 Entry Into a Material Definitive Agreement

On January 15, 2025, Ensysce Biosciences, Inc. (the "***Company***" or "***we***") entered into a Product Development and Commercial Manufacturing Supply Master Services Agreement (the "***Agreement***"), dated as of January 12, 2025, with Galephar Pharmaceutical Research, Inc., a Puerto Rico corporation ("***Galephar***").

The Agreement provides for Galephar to expend up to $10 million (the "***Cap***") to support research and development, manufacture, packaging and testing of the Company's PF614 drug product and PF614-MPAR project in return for the consideration specified below. First, the Company will issue one percent (1%) of the Company's outstanding shares pursuant to a restricted stock grant. The grant will provide for vesting against defined milestones over the term of the project, such shares being subject to a three-year lock-up, except in the event of a change of control of the Company. The Company is also required to compensate Galephar's development costs against defined milestones in the form of fifty percent (50%) restricted stock or fifty percent (50%) freely tradeable shares at up to 1.2 times Galephar's actual costs, subject to the Cap. The number of shares to be issued by the Company will be determined with reference to the trailing five-day closing price divided by the payment. The Agreement does not permit future variable pricing to determine share price. Payments to Galephar may require a gross-up of thirty percent (30%) in certain cases if the Company raises more than $10 million from a third party for development of the Company's products and payment, which may not exceed fifty percent (50%) in cash, is made in cash.

The Company is required to provide Galephar with a limited license of Intellectual Property to perform under the Agreement and supply sufficient quantities of certain active pharmaceutical ingredients, and Galephar is required to supply the Company with other material and store certain products, material, supplies, batches and other items. All intellectual property that is created under the Agreement which relates to Ensysce's products shall be the exclusive property of Ensysce. The parties will enter into other agreements in furtherance of the project, such as a Quality Agreement and Commercial Supply Agreement. The Agreement has a term of at least fifteen (15) years but is subject to termination following a material breach by, or insolvency of, the other party. The Agreement includes representations, warranties covenants, indemnification, and other provisions that are typical for contracts of this type. The Agreement is filed as an exhibit to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
10.1	Product Development and Commercial Manufacturing Supply Master Services Agreement
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Dated: February 4, 2025

Ensysce Biosciences, Inc.

By: */s/ Lynn Kirkpatrick*
Name: Dr. Lynn Kirkpatrick
Title: President and Chief Executive Officer

Exhibit 10.1

PRODUCT DEVELOPMENT AND COMMERCIAL MANUFACTURING SUPPLY MASTER SERVICES AGREEMENT

This Product Development and Commercial Manufacturing Supply Master Services Agreement (this "Agreement") is made as of January 12, 2025 (the "Effective Date"), by and between Galephar Pharmaceutical Research, Inc., a Puerto Rico corporation located at Carr. 925 M 6.1 Bo, Junquito, Humacao, PR 00791("Galephar") and Ensysce Biosciences, Inc., a Delaware corporation located at 7946 Ivanhoe Ave., Suite 201, La Jolla, CA 92037 (the "Ensysce"). Galephar and Ensysce may be individually referred to herein as a "Party" or may be collectively referred to herein as the "Parties."

RECITALS

WHEREAS, Galephar is in the business of providing certain pharmaceutical development and commercial manufacture services ("Services"), as more specifically described in the Statement of Work attached as Annex I-B ("Statement of Work").

WHEREAS, Ensysce desires to obtain from Galephar, and Galephar desires to provide to Customer, the Services pursuant to the terms and subject to the conditions of this Agreement and in accordance with cGMP.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below, the Parties, intending to be legally bound, hereby agree as follows.

1. DEFINITIONS: The following terms shall have the meanings set forth below:

1.1. "Affiliate" means any person, firm, trust, partnership, corporation, company or other entity or combination thereof which, directly or indirectly, (i) controls a Party, (ii) is controlled by a Party, or (iii) is under common control with a Party. For the purposes of this definition, the terms " control" and "controlled" means ownership of fifty percent (50%) or more, of the voting and equity rights of such person or the power to direct the management of such person, firm, trust, partnership, corporation, company or other entity or combination thereof.

1.2. "Agreement" shall have the meaning set forth in the preamble.

1.3. "API" means the active pharmaceutical ingredient of the Product.

1.4. "Applicable Law" means all laws, treaties and regulations applicable to the provision of the Services.

1.5. "Arising Ensysce Intellectual Property" shall have the meaning set forth in Section 6.2.

1.6. "Arising Intellectual Property" means any and all Intellectual Property generated or derived by either Party or jointly by the Parties in the course of performance or pursuant to the Services.

1.7. "Arising Galephar Intellectual Property" shall have the meaning set forth in Section 6.3.

1.8. "Change Order" means a written document executed by authorized officers of both Parties which alters or modifies a Statement of Work.

1.9. "Current Good Manufacturing Practices" or "cGMPs" mean all Applicable Laws relating to manufacturing practices for medicinal products for human use promulgated by any relevant Governmental Authority, including the FDA, as may be updated, supplemented or amended from time to time.

1.10. "Deficiencies" shall have the meaning set forth in Section 10.3.

1.11. "Ensysce" shall have the meaning set forth in the preamble.

1.12. "Ensysce Indemnitees" shall have the meaning set forth in Section 7.1.

1.13. "Effective Date" shall have the meaning set forth in the preamble.

1.14. "Facility" means Galephar's manufacturing facilities located at Juncos and the analytical laboratory facilities located in Humacao and/or such other facility of Galephar as may be mutually agreed by the Parties.

1.15. "FDA" means the United States Food and Drug Administration.

1.16. "Galephar" shall have the meaning set forth in the preamble.

1.17. "Galephar Indemnitees" shall have the meaning set forth in Section 7.1.

1.18. "Governmental Authority" means any federal, state or other governmental department, governmental authority, or judicial, regulatory or administrative body.

1.19. "Intellectual Property" shall include, without limitation, rights in patents, patent applications, formulae, trade-marks, trade-mark applications, trade-names, trade secrets, inventions, copyright, industrial designs, data and know-how.

1.20. "Losses" means any and all losses, actions, causes of action, costs (including reasonable legal fees), claims, damages, settlements, payments, obligations, penalties, liabilities and expenses.

1.21. "Materials" shall include all common materials and supplies required to perform the Services, including certain analytical columns, reagents, common excipients, packaging components, third party raw material shipping, handling and brokerage fees, and storage fees.

1.22. "Milestone" shall mean the individual deliverables as set forth in the Statement of Work.

1.23. "Person" means a corporation, association, joint venture, partnership, trust, business, individual, government or political subdivision thereof, or any

Governmental Authority.

1.24. "Product(s)" means the drug products to be manufactured by Galephar for Ensysce, specifically PF614 (TAAP oxycodone prodrug immediate release PF614 capsules) and PF614-MPAR (a combination product of immediate release PF614 and both immediate as well as extended release nafamostat, formulated as a tamper-resistant solid oral dosage form to be developed).

1.25. "Project Plan" shall mean the processes agreed to by the Parties to achieve the Milestones set forth in the Statement of Work.

1.26. "Services" shall have the meaning set forth in the Preamble.

1.27. "Statement of Work" has the meaning set forth in the Preamble.

1.28. "Supplied Items" shall have the meaning set forth in Section 9.1.

1.29. "Term" shall have the meaning set forth in Section 5.1.

1.30. "Third Parties" means any Person except a Party or an Affiliate of a Party.

2. SCOPE OF SERVICES

2.1. Scope of Work.

2.1.1. Galephar shall support the pharmaceutical and clinical R&D, manufacture, packaging, release testing, and stability testing of the Products in accordance with the specifications provided by Ensysce from time to time, which may be amended pursuant to the terms of this Agreement due to feedback from any Governmental Authority, including without limitation, the FDA, or as required by Applicable Law, in each case, adhering to all applicable regulatory requirements and quality standards. Galephar's specific objectives with respect to the Services are set forth in Annex I-A.

2.1.2. Galephar shall fund the Services with total expenses capped at $10 million ("Cap"), unless the Parties determine to mutually increase the Cap due to unforeseen circumstances or to further expand the scope of the relationship.

2.2. Statement of Work. Galephar shall achieve the Milestones set forth on the Statement of Work. The Statement of Work shall include the following information: (i) the deliverables, (ii) the budget and payment schedule for the deliverables, (iii) the timing or schedule for the deliverables, and (iv) any other relevant information. The Statement of Work shall be incorporated by reference into this Agreement and shall be construed under the terms of this Agreement. In the event of any inconsistency between the terms of the Statement of Work and this Agreement, the terms of this Agreement shall govern.

2.3. Changes or Modifications. Any material alteration, modification or other change to a Statement of Work shall be effected by a Change Order executed by each Party's applicable representative to the JDC. There shall be no additional charges for Change Orders unless the Change Order materially changes the scope of the Services. Both Parties agree to act in good faith to promptly identify, review and execute Change Orders.

2.4. Facility. Galephar shall perform all manufacturing activities and all storage activities at the Facility. Galephar may use other facilities for the manufacture and storage of Product, provided that such facilities have been approved for such manufacture and storage by all applicable Governmental Authorities.

2.5. Representations and Warranties. Galephar represents and warrants that (a) it is in good standing with all applicable Governmental Authorities and has not been the subject of any inspection or audit which has found Galephar to be out of compliance with regulatory requirements, including cGMP and (b) all Services will be provided (i) in compliance with all Applicable Laws, including any requirements of the Federal Food, Drug, and Cosmetic Act relating to the performance of the Services; (ii) in compliance with all applicable Current Good Manufacturing Practices and in accordance with industry standards; (iii) in a professional and workmanlike manner and in a timely fashion.

3. COMPENSATION AND PAYMENT

3.1. Payments.

(a) Generally. Except as otherwise provided in this Section 3.1, Ensysce shall pay Galephar as compensation in accordance with the payment schedule set forth in Annex I B for PF614 and Statement of work to be defined for PF614-MPAR. All payments shall be inclusive of all applicable taxes.

(b) Issuance of Common Stock.

(i) Upon the signing of this Agreement, Ensysce shall make an equity grant to Galephar equal to one percent (1%) of its outstanding shares at such time pursuant to a restricted stock grant (the "Restricted Shares"). One-third (1/3) of the Restricted Shares will vest upon signing this Agreement, one-third (1/3) of the Restricted Shares will vest when fifty percent (50%) of the project is completed, and the remaining one-third (1/3) of the Restricted Shares will vest upon the satisfaction when 100% of the project is completed, in each case as determined by the JDC (collectively, the "Repayment Period"). Any Restricted Shares issued shall be subject to a three-year lock-up, except in the event of a change of control event of Ensysce, in which case such Restricted Shares shall immediately vest.

(ii) Ensysce will (i) compensate Galephar's development costs in restricted stock (50%) or freely tradeable shares (50%) equivalent to 1.2 times Galephar's actual investment subject to the Cap.

(iii) During the Repayment Period, Ensysce shall issue shares for payment as set forth on the Statement of Work schedule. Ensysce shall not be required to effect more than two (2) registration statements to issue freely tradeable shares each year, the first of which shall be filed no earlier than April 15, 2025.

(iv) Notwithstanding the preceding, if Ensysce raises more than $10m for development of the Products from one or more institutional investors which require that some percentage of the payment to Galephar must be made in cash, then, based upon such requirement, at Ensysce's option, up to fifty percent (50%) of the payment may be in cash distributed evenly between restricted stock and freely tradeable stock. In such a case, Ensysce will provide a tax gross-up of thirty percent (30%) on the cash payment to offset the resulting tax liability for Galephar.

(v) The number of Shares to be issued shall be determined by applying the trailing five day closing price divided by the payment. By way of example, if the payment amount is $200,000 and the trailing five day closing price is $5/Share, 40,000 Shares will be delivered, 20,000 of which shall be registered and 20,000 of which shall be restricted. There will be no future variable pricing in the determination of the share price, i.e., each issuance shall be a fixed number of shares at a fixed

determination price.

(vi) Good Faith Dispute. In the event of any good faith dispute with regard to completion of a Milestone, Ensysce shall notify Galephar of such dispute within fifteen (15) days of receipt of the invoice, and any undisputed portion of the invoice shall be paid as provided herein. The Parties, which may be pursuant to the JDC, will work together in good faith to resolve any dispute with respect to an invoice.

4. SUPPLY OF API AND MATERIALS

4.1. API Supply. Ensysce will, at its sole cost and expense, supply Galephar with sufficient quantities of the API for Galephar to perform the Services. Ensysce will be responsible for providing Galephar with a Material Safety Data Sheet at the time of the API transfer showing information relating to handling risks.

4.2. Material Supply.

(a) Acquisition of Materials. Unless otherwise agreed to by the Parties, Galephar shall procure all Materials related to perform the Services.

(b) Storage of Supplied Items. All manufactured products, clinical trial materials, placebo, development, feasibility, scale-up, registration, validation or any other batches, components, raw materials or supplies (collectively, "Supplied Items") shall be stored at the Facility under appropriate industry standard storage conditions.

(c) Disposal of Materials. For any Materials procured by Galephar which have expired or which no longer have any forecasted requirements, Galephar shall dispose such Materials at its expense.

4.3. Qualification of Materials and Vendors. Galephar is responsible for any vendor qualification of Galephar furnished Materials and for providing any required certificates of compliance for such Galephar furnished Materials. Ensysce is responsible for any vendor qualification of Ensysce furnished materials and for providing any required certificates of compliance for such Ensysce furnished materials.

4.4. Quality Agreement. Within ninety (90) days after the Effective Date, the Parties shall enter into a mutually agreed quality agreement specifying their respective responsibilities for manufacture, storage, release, quality control and quality assurance for Products (the "Quality Agreement"). Upon signature, the Quality Agreement will be deemed incorporated into and made a part of this Agreement. Unless otherwise specified in the Quality Agreement, if there is a conflict between this Agreement and the Quality Agreement with respect to a commercial matter, such as allocation of risk, liability or financial responsibility, the provisions of this Agreement shall govern. Unless otherwise specified in the Quality Agreement, if there is a conflict between this Agreement and the Quality Agreement with respect to quality-related activities, the provisions of the Quality Agreement shall govern.

4.5. Commercial Supply. During the Term, the Parties will negotiate the terms of an agreement for commercial supply of Products by Galephar to Ensysce (the "Commercial Supply Agreement"). The Parties will negotiate the terms of the Commercial Supply Agreement in good faith and use commercially reasonable efforts to complete and sign the Commercial Supply Agreement within one hundred eighty (180) days of the initiation of any Phase 3 Clinical Trial for a Product.

5. DELIVERY AND SHIPPING

5.1. Delivery. Shipments of Products and other deliverables will be made at Ensysce's expense to Ensysce's designated facility. Risk of loss or damage to the products and deliverables will transfer to Ensysce when such products and other deliverables are leaving Galephar's facility (EX WORKS). Such products and other deliverables will be packaged for transport in accordance with Ensysce's instructions.

5.2. Deadlines. If Galephar fails to deliver to Ensysce the milestone deliverable specified in the Statement of Work by the delivery date specified therein (or during a 30 day grace period following), for any reason whatsoever other than a breach of this Agreement by Ensysce, then Galephar shall deliver the such milestone deliverable at actual cost, without the 1.2x mark-up specified in Section 3.1(b)(ii).

6. INTELLECTUAL PROPERTY

6.1. License to Ensysce IP. For the term of this Agreement, Ensysce hereby grants to Galephar, a limited, non-exclusive, royalty-free, non-transferable, non-sublicensable license of Ensysce's Intellectual Property that is necessary to perform the Services.

6.2. Arising Ensysce IP. All Intellectual Property generated or derived by Galephar while performing the Services, to the extent it is related to, specific to, or dependent upon, Ensysce's Products or Materials or Intellectual Property of Ensysce that are the subject of the Services, will be the exclusive property of Ensysce ("Arising Ensysce Intellectual Property")..

6.3. Arising Galephar IP. All Intellectual Property generated or derived by Galephar while performing the Services which is not related to, specific to, or dependent upon, Ensysce's Products or Arising Ensysce Intellectual Property and which has general application to manufacturing processes or formulation development of drug products or drug delivery systems or which is an improvement to Galephar's Intellectual Property as applied to perform the Services, will be the exclusive property of Galephar ("Arising Galephar Intellectual Property").

7. JOINT DEVELOPMENT COMMITTEE.

7.1.1. The Parties will establish a Joint Development Committee ("JDC"), comprising two (2) representatives from each of the Parties, to oversee the Product transfer to the Facility, and its subsequent development and manufacture, and at least one of each Party's JDC representatives will be a member of such Party's senior management with authority to make binding decisions on behalf of such Party.

7.1.2. The JDC will meet no less than monthly. The JDC will be responsible for preparing, reviewing, and approving each Project Plan, including any amendments, updates, and modifications. The JDC will establish a budget for each set of activities needed to meet the development objectives and review actual costs against budget on a quarterly basis to monitor and track overall spending on the programs.

7.1.3. Any non-consensus on issues assessed by the JDC will be decided by Ensysce for clinical trial related items and by Galephar for manufacturing/CMC related items. The JDC shall not have the power to amend or modify this Agreement, and no decision of the JDC shall be in contravention of this Agreement.

8. INDEMNIFICATION; LIMITATIONS OF LIABILITY

8.1. Indemnification by Ensysce. Subject to Sections 8.2 and 8.4, Ensysce will defend and indemnify Galephar, its Affiliates and their respective directors, officers,

employees and agents (collectively, the "Galephar Indemnitees") from all Losses relating to or arising from: (i) the distribution of Ensysce's products or the use of Ensysce's products by patients either as part of or outside of the scope of any clinical trials; (ii) any misrepresentation, gross negligence or willful misconduct by Ensysce or any of its Affiliates and their respective directors, officers, employees and agents (collectively, the "Ensysce Indemnitees"); (iii) any breach by Ensysce of its obligations or warranties under this Agreement; or (iv) any claim of infringement of any third party's intellectual property rights in or by Ensysce's products or that is related to Galephar's use of Ensysce's Intellectual Property (including any Arising Ensysce Intellectual Property) to perform the Services. This indemnity will not apply to the extent that these Losses are those for which Galephar is obligated to indemnify the Ensysce Indemnitees under Section 7.2.

8.2. Indemnification by Galephar. Subject to Sections 8.1 and 8.4, Galephar will defend and indemnify the Ensysce Indemnitees from all Losses relating to or arising from: (i) any misrepresentation, gross negligence or willful misconduct by the Galephar Indemnitees; (ii) any failure to manufacture products in accordance with cGMP, where applicable; (iii) the breach by Galephar of any of its obligations or warranties under this Agreement; or (iv) any claim of infringement of any third party's intellectual property rights in or by Galephar's Intellectual Property that is used to perform the Services. This indemnity will not apply to the extent that these Losses are those for which Ensysce is obligated to indemnify the Galephar Indemnitees under Section 7.1.

8.3. Notice of Claims. If a third-party claim occurs under Section 8.1 or 8.2, the indemnified party will: (a) promptly notify the indemnifying party of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with the indemnifying party in the defense of the claim; and (d) permit the indemnifying party to control the defense and settlement of the claim, all at the indemnifying party's cost and expense.

8.4. Limitation of Liability; Exclusions; Warranty.

(a) Subject to Section 5.2, if Galephar fails to perform any part of the Services in accordance with the terms of this Agreement or any applicable Statement of Work, then Ensysce may request Galephar, in mitigation of damages, to: (i) repeat that part of the Services at Galephar's cost; or (ii) reimburse Ensysce for the price for that part of the Services already paid by Ensysce. Notwithstanding the foregoing, to the extent that any loss of API resulted from the gross negligence or malfeasance of Galephar, the costs relating to the replacement of that API will be borne by Galephar rather than Ensysce.

(b) UNDER NO CIRCUMSTANCES WHATSOEVER WILL EITHER PARTY BE LIABLE TO THE OTHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR (I) ANY (DIRECT OR INDIRECT) DELAY, PENALTY, LOSS OF PROFITS, OF PRODUCTION, OF ANTICIPATED SAVINGS, OF BUSINESS, OF GOODWILL OR OF USE OF ENSYSCE'S PRODUCT, OR COSTS OF ANY SUBSTITUTE SERVICES OR (II) ANY OTHER LIABILITY, DAMAGE, COST OR EXPENSE OF ANY KIND INCURRED BY THE OTHER PARTY OF AN INDIRECT OR CONSEQUENTIAL NATURE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF THESE DAMAGES.

(c) Limited Warranty. EACH PARTY HEREBY EXCLUDES ALL REPRESENTATIONS, WARRANTIES AND CONDITIONS OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING EXCEPT AS SET FORTH HEREIN OR IN A STATEMENT OF WORK, GALEPHAR MAKES NO EXPRESS OR IMPLIED WARRANTY OR CONDITION: (I) OF FITNESS FOR A PARTICULAR PURPOSE, OR (II) OF MERCHANTABILITY FOR ENSYSCE'S PRODUCT, AND THESE WARRANTIES AND CONDITIONS ARE EXPRESSLY EXCLUDED.

9. OTHER COVENANTS OF THE PARTIES.

9.1.1. Debarment. Galephar is not and has not been debarred and it does not and shall not employ, contract with or retain any person or organization directly or indirectly to perform Services under this Agreement or any Statement of Work or provide any services in any capacity if such person is or has been debarred under 21 U.S.C. 335a (a) or (b) or other equivalent laws, rules, regulations or standards of any other relevant jurisdiction. Upon written request of Ensysce, Galephar shall, within ten (10) business days, provide written confirmation that it has complied with the foregoing obligation. Galephar shall immediately disclose in writing to Ensysce if it or any employee or agent is debarred, or if any action or investigation is pending or, to the best of Galephar's knowledge, is threatened in relation to the debarment of Galephar or any person performing Services or providing services in any capacity in connection with this Agreement.

9.2. Regulatory Inspections. Galephar shall make its facilities and all records relating to the Services available to the FDA or other regulatory authorities, and shall notify Ensysce within one business day if the FDA or any other Regulatory Authority begins or schedules an inspection of Galephar's records, facilities, or manufacturing processes related to the Services, including the Facility used for production of Products. Galephar shall provide Ensysce access to any documentation related to or resulting from each such inspection within one business day after receipt. Galephar will provide copy of the response to any findings by a Regulatory Authority (such as a Form 483 or an equivalent foreign Regulatory Authority form) to Ensysce

9.2.1. Information and Assistance. Each Party shall provide to the other all information which is requested by the other to facilitate the performance of the Services, including any information which either Party needs to comply with any disclosure requirements of Applicable Laws.

9.2.2. Adverse Events. Both Galephar and Ensysce shall promptly notify and forward to the other party any information concerning any potentially serious or unexpected side effect, injury, toxicity, or sensitivity reaction, or any unexpected incidence or other adverse experience related to the Product.

10. REGULATORY FILINGS

10.1. Use of Reports. Ensysce shall be permitted to reference all reports and data provided by Galephar in its regulatory and legal filings, and Galephar will cooperate with Ensysce with respect to such filings

10.2. Filings with Regulatory Bodies. Prior to filing with any relevant Governmental Authorities any clinical trial or new drug application that is to be prepared by Galephar, Galephar will work with Ensysce to ensure the accuracy of such application, providing Ensysce with at least seven (7) days to perform its evaluation and review prior to the finalization of such filing (or such longer period as may be required). Ensysce shall notify Galephar of any deficiencies. Acting in good faith, Galephar shall resolve any such deficiencies before making such filing.

11. TERM AND TERMINATION

11.1. Term. This Agreement shall commence as of the Effective Date set forth above and shall continue in full force and effect for a period of fifteen (15) years, or ten (10) years from the first Product commercial launch date, whichever is longer (the "Term").

11.2. Termination for Either Party. Either Party may terminate this Agreement, and any Statement of Work, if a Party is in material breach of any part of this Agreement and that party fails to remedy the breach within sixty (60) days after receiving written notice of the breach from the other Party, or if the other Party becomes

insolvent or goes into bankruptcy, liquidation or receivership, or is admitted to the benefits of any procedure for the settlement of debts or becomes a party to dissolution proceedings.

11.3. Effects of Termination. Upon termination or expiration of this Agreement,

(a) Each Party shall (beginning upon receipt of notice of termination) seek to mitigate damages under this Agreement.

(b) Ensysce shall pay Galephar in accordance with the applicable Statement(s) of Work for any completed Milestones and all Milestones following shall be cancelled with no amount owed thereunder. Galephar shall refund any amounts paid for and for which the relevant Milestone was not achieved. For the avoidance of doubt, any Restricted Shares not earned pursuant to Article 3 shall be forfeited.

(c) Ensysce will arrange for the pickup from the relevant Galephar site of all Materials owned by Ensysce within thirty (30) days after the earlier of the completion, termination or expiration of this Agreement or any applicable Statement of Work.

12. MISCELLANEOUS

12.1. Right to Visit, Audit and Inspect. Ensysce, or representatives thereof (subject to such representatives entering into confidentiality agreements reasonable acceptable to Galephar), have the right to audit Galephar's facilities and systems and review documents as they relate to the manufacture, packaging, testing, shipping and storage of Ensysce's products or deliverables at a time, date and duration mutually agreed upon by the parties. Galephar will permit one standard cGMP compliance audit to be conducted annually for at least two (2) business days , but such period may be extended if reasonably agreed and warranted. In addition, Ensysce may conduct "for cause" audits if either party received a warning letter or notice of other regulatory actions from any Governmental Authority related to the products or deliverables subject to this Agreement. All visits, inspections and audits shall be conducted in a manner that does not interrupt or impair in any significant manner the manufacturing operations of the Facility. Ensysce agrees to follow all internal Galephar Standard Operating Procedures and safety policies when visiting any Galephar facility.

12.2. Independent Contractor Status. Ensysce is an independent contractor under this Agreement, and nothing herein shall be construed to create a partnership, joint venture or agency relationship between the Parties. Neither Party shall have the authority to enter into agreements of any kind on behalf of the other Party and shall have no power or authority to bind or obligate the other Party in any manner to any third party.

12.3. Assignment. Neither Party may assign this Agreement and the rights and duties hereunder shall without the prior written consent of the other Party (not to be unreasonably withheld); provided that each Party may assign this Agreement to an Affiliate or to a successor to its business by virtue of merger, consolidation reorganization, stock sale or sale of all or substantially all of such Party's assets or the line of business to which the Services relate. This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their successors and permitted assigns, if any. This Agreement does not create any third-party beneficiaries.

12.4. Notice. Whenever a Party hereto is required to give any legal notice, demand or request with respect to this Agreement, such communication shall be effective only if it is in writing and delivered by personal service, facsimile transmission (with satisfactory evidence of receipt), courier service (with satisfactory evidence of delivery) or mailed, certified mail, postage prepaid, addressed as follows:

If to Ensysce, to the address set forth on Page 1

Attn: Dr. Lynn Kirkpatrick

Email: lkirkpatrick@Ensysce.com

With a courtesy copy via email to eric.kline@troutman.com

If to Galephar, to the address set forth on Page 1

Attn: Arthur Deboeck

Email: adeboeck@galephar.com

With a courtesy copy via email to hafid@tradepassrx.com

Such communications shall be effective when they are received by the addressee thereof, but if sent by certified mail in the manner set forth above, they shall be effective two (2) business days after being deposited in the mail or if sent by courier or facsimile transmission they shall be effective on the day after delivery. Correspondence sent by email shall be received upon confirmation of receipt by the other Party. A Party may change its address for such communications by giving notice thereof to the other Party in conformity with this Section 12.4.

12.5. Confidentiality.

12.5.1. Non-disclosure and Non-use. The Parties reconfirm the provisions of the Confidentiality Agreement between them dated September 24, 2024.

12.5.2. Information Required by Law. If the receiving Party is requested to disclose the Confidential Information of the disclosing Party or the substance of this Agreement in connection with a legal or administrative proceeding or otherwise to comply with a requirement under applicable Law, the receiving Party will, to the extent legally permissible, give the disclosing Party prompt written notice of such request so that the disclosing Party may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. If the disclosing Party seeks a protective order or other remedy, the receiving Party, at the disclosing Party's expense, will cooperate with and assist the disclosing Party in such efforts. If the disclosing Party fails to obtain a protective order or waives compliance with the relevant provisions of this Agreement, the receiving Party will disclose only that portion of the Confidential Information which its legal counsel determines it is required by applicable Law to disclose.

12.6. Insurance. Each Party will maintain during the term of this Agreement and for five (5) years after termination or expiration of this Agreement general liability (including liabilities for fire, flood, and casualty) and product liability insurance which is sufficient to cover their respective liability under this Agreement. Either Party will provide evidence of this insurance upon the request of the other Party.

12.7. Force Majeure. Except as otherwise set forth herein, neither Party will be responsible for delay or failure in performance resulting from acts beyond the reasonable control and without the fault or negligence of the party, including, but not limited to, strikes or other labor disturbances, lockouts, quarantines, communicable disease outbreaks, riots, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power or components, or

compliance with any order or regulation of any government entity. Notwithstanding the foregoing, if a Force Majeure results in more than a sixty (60) day delay in performance of Services, Ensysce may terminate this agreement without penalty.

12.8. Entire Agreement and Priority. This Agreement and all of its attachments, including any Statements of Work incorporated herein at a later date, constitute the entire agreement between the Parties with respect to the Services. In the event there is any conflict between this Agreement and any Statement of Work, the Statement of Work shall govern.

12.9. Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware, without giving effect to the provisions thereof relating to conflicts of laws. Subject to Section 12.10 and 12.11, the Parties hereby agree to submit to the jurisdiction of the state or federal courts in the State of Delaware solely for purposes of any claim, action, suit or other proceeding enforcing, interpreting or otherwise related to this Agreement.

12.10. Disputes. Upon the written request of either Party to the other Party, any claim, dispute, or controversy as to the breach, interpretation, enforcement, termination or validity of this Agreement ("Dispute") will first be referred to the JDC (which must include the CEO of Galephar and the CEO of Ensysce if they are not otherwise on the JDC) for attempted resolution. In the event the parties are unable to resolve such Dispute within thirty (30) days after such Dispute is referred to them, then, upon the written demand of either Party, the Dispute shall be subject to arbitration in accordance with Section 12.11 below.

12.11. Arbitration. Any Dispute that is not resolved pursuant to Section 12.10 shall be resolved by final and binding arbitration by the International Chamber of Commerce ("ICC") in New York, NY, USA, in accordance with the ICC Rules of Arbitration, as modified by this Section 12.1 (the "Rules"), by a single arbitrator appointed in accordance with such Rules (i) the arbitrator shall have experience and familiarity with product development and supply practices in the pharmaceutical and biotechnology industries. The arbitral tribunal shall permit discovery (including both the production of documents and deposition testimony) as reasonably necessary for an understanding of any legitimate issue raised in the arbitration, while also taking into account the desirability of making discovery efficient and cost-effective. The arbitral tribunal shall, in rendering an award, apply the substantive law of the State of Delaware, without giving effect to its principles of conflicts of law that would result in a different governing law, and without giving effect to any of its rules or laws relating to arbitration. The award shall include a written statement describing the essential findings and conclusions upon which the award is based, including the calculation of any damages awarded. The arbitral tribunal's authority to award special, incidental, consequential or punitive damages shall be subject to the limitation set forth in this Agreement. The award rendered by the arbitral tribunal shall be final, binding and non-appealable, and judgment upon the award may be entered in any court of competent jurisdiction. The costs of such arbitration shall be shared equally by the Parties, and each Party shall bear its own expenses in connection with the arbitration.

12.12. Non-Solicitation. During the term of this Agreement, and for one year after its termination, a Party nor its Affiliates will not, directly or indirectly, solicit, induce, recruit, encourage or otherwise endeavor to cause or attempt to cause any officer, employee, director or consultant of the other party or any of its Affiliates.

12.13. Headings. The headings of this Agreement are for purposes of reference only and shall not limit or otherwise affect the meaning hereof.

12.14. No Waiver; Modifications. No provision of this Agreement may be waived, amended or otherwise modified, except by a written agreement signed by each Party hereto. The waiver by a Party of the breach of any provision hereof shall not be construed as a waiver of subsequent breaches or as a continuing waiver of such breach.

12.15. Publicity. Neither Party shall use or reference in any advertising, sales promotion, press release or other communication, the endorsement, direct or indirect quote, code, drawing, logo, trademark, specification, or picture of the other Party or the other Party's Affiliates without the prior written consent of the other Party. The Parties agree to coordinate any external communications (e.g., a joint press release) regarding their collaboration or this Agreement. Notwithstanding the preceding, the Parties agree that Ensysce will be required to make filings with the Securities and Exchange Commission related to this arrangement, and shall make disclosure thereof pursuant to a required regulatory filings and a press release.

12.16. Severability. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity and enforceability of the other provisions hereof. If any provision of this Agreement, or the application thereof to any person or entity or any circumstance, is invalid or unenforceable, (a) a suitable and equitable provision shall be substituted therefore in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid and unenforceable provision and (b) the remainder of this Agreement and the application of such provision to other persons, entities or circumstances shall not be affected by such invalidity or enforceability.

12.17. Survival. The following provisions shall survive expiration or termination of this Agreement: Articles 3, 6, 8, and 12.

12.18. Counterparts. This Agreement and any Statement of Work may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For the purposes hereof, an electronic, .pdf or facsimile copy of this Agreement or any Statement of Work, including signed signature pages hereto, shall be deemed an original.

[*Signature page follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the Effective Date by their duly authorized representatives.

Galephar Pharmaceutical Research, Inc.		**Ensysce Biosciences, Inc.**	
By	*/s/ Arthur M. Deboeck*	By	*/s/ Lynn Kirkpatrick*
Name	Arthur M. Deboeck	Name	Lynn Kirkpatrick
Title	V.P. & General Manager	Title	CEO
Date:	January 15, 2025	Date:	January 12, 2025