**OTHER TRANSACTION AUTHORITY**
**FOR PROTOTYPE**
**AGREEMENT**

**BETWEEN**

**Rigel Pharmaceuticals Inc. (Awardee)**
**1180 Veterans Blvd.,**
**South San Francisco, CA 94080**
**DUNS: 967965468**
**CAGE: 60TS7**
**And**
**NATICK CONTRACTING DIVISION (Government)**
**110 Thomas Johnson Dr.**
**Frederick, MD 21702**

**Effective Date: 29 January 2021**

**Agreement No.: W911QY-21-9-0018**

**Total Amount of the Agreement: $16,500,000.00**

**Awardee**

(b) (6)

**Signature**

(b) (6)

**Printed Name**

(b) (6)

**Title**

January 28, 2021

**Date**

(b) (6)

**Printed Name**

**Agreements Officer**

**Title**

29 January 2021

**Date**

This Other Transaction Authority for Prototype Agreement is entered into between the United States of America, hereinafter called the "Government", pursuant to and under U.S. Federal law and Rigel Pharmaceuticals Inc., a non-traditional defense contractor, hereinafter called the "Awardee". The United States of America and Awardee are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, the Awardee is eligible for an Other Transaction Authority for Prototype Agreement in accordance with 10 USC § 2371b(d)(1)(A) as amended by the National Defense Authorization Act for Fiscal Year 2018 as they are non-traditional defense contractor, attesting to "An entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subcontract for the Department of Defense that is subject to the full coverage under the cost accounting standards prescribed pursuant to Section 1502 of title 41 and the regulations implementing such section.";

WHEREAS, the DoD currently has authority under 10 U.S.C. § 2371b to award "other transactions" (OTs) in certain circumstances for prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the DoD, or to improve platforms, systems, components, or materials in use by the Armed Forces;

WHEREAS, a prototype can generally be described as a physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system;

WHEREAS, Awardee currently markets TAVALISSE (fostamatinib disodium hexahydrate) tablets, which is approved in the U.S. and Europe as a treatment for adult chronic immune thrombocytopenia (ITP), a rare autoimmune disorder;

WHEREAS, this Agreement meets the criteria for a prototype project;

NOW THEREFORE, the Parties have agreed as follows:

**ARTICLE 1. Scope.**

A. This Other Transaction Authority for Prototypes Agreement (the "Agreement") is entered into between the Government and the Awardee on the Effective Date set forth above. For the avoidance of doubt, this Agreement is entered into pursuant to 10 U.S.C. § 2371b and is not a procurement contract governed by the Federal Acquisition Regulation (FAR), a grant, or cooperative agreement. The FAR and the

Defense Federal Acquisition Regulation Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not intended to be, nor will it be construed as, forming, by implication or otherwise, a partnership, a corporation, or other business organization. This Agreement is not subject to the Bayh-Dole Act, 35 U.S.C. §§ 200- 12.

B. The Parties agree that the ultimate purpose of this Agreement is the development of a countermeasure against COVID-19 by rapidly obtaining safety and efficacy data that will facilitate approval by the FDA for Emergency Use Authorization (EUA) of a repurposed FDA-approved oral SYK inhibitor (fostamatinib), (hereinafter referred to as the "Prototype Project" or "Prototype"). A Prototype may be a clinical trial, a demonstration of efficacy or safety, or other process, or a combination of the foregoing in defense of SARS-CoV-2/COVID-19. This Prototype Project is a combination of an agile development activity, design, and demonstration of the technical and operational utility of a product to move forward as an FDA-approved therapeutic against COVID-19. The Awardee shall develop the Prototype(s) as described in the Awardee's Statement of Work (SOW), which is incorporated herein and attached hereto as Appendix A.

C. The prototype will be deemed successful upon the Government's determination that the Awardee's efforts meet the key technical requirements of the SOW and are sufficient to meet an FDA compliant final report(s) that supports the completion of a human clinical trial(s). In accordance with 10 U.S.C. 2371b(f), this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction for a quantity not to exceed 10 million treatment courses.

**ARTICLE 2. Term and Termination.**

A. Term: The Term of this Agreement commences upon the Effective Date and extends through final payment. This Agreement is anticipated to end 14 months after the Effective Date, subject to completion of the project(s). A transaction for a prototype project is complete upon the written determination of the appropriate official for the matter in question that efforts conducted under a Prototype OT: (1) met the key technical goals of a project, or (2) accomplished a particularly favorable or unexpected result that justifies the completion of the prototype.

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least thirty (30) calendar days' prior written notice to the Awardee. The Government and Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination by the Government for convenience, consistent with the terms of this Agreement.

Following notice of termination, Awardee shall use commercially reasonable efforts to terminate ongoing performance costs. The parties recognize that vendor agreements may include termination clauses and that not all costs may be terminable in full. Awardee shall not be paid for any post-termination work performed or costs incurred which reasonably could have been avoided.

The Government and the Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination, consistent with the terms of this Agreement. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article 5.H (Disputes). In the event of termination, the Parties shall negotiate in good faith a reasonable wind-down plan and neither Party shall have any continuing obligations to perform under the Agreement except as otherwise specified herein.

C. Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, the Other Transaction Agreement Officer (OTAO), after issuance of a cure notice and failure of the Awardee to cure the defect within ten (10) business days or the time allowed by the OTAO after Awardee's receipt of the cure notice, whichever is longer, may take one or more of the following actions as appropriate:

    (i) temporarily withhold payments pending correction of the deficiency,
    (ii)disallow all or part of the cost of the activity or action not in compliance,
    (iii) wholly or partly suspend or terminate this Agreement,
    (iv) withhold further funding, or
    (v)take any other legally available remedies.

Notwithstanding this Article 2.C, the Government's rights and Awardee's obligations under this paragraph will cease to exist if the Government terminates this Agreement for any reason other than for Awardee's failure to materially comply with the terms of this Agreement.

D. Survival: In the event of Termination, all rights, obligations, and duties hereunder, which by their nature or by their express terms extend beyond the expiration or termination of this Agreement, including but not limited to warranties, indemnifications, intellectual property (including rights to and protection of Intellectual Property and proprietary information), and product support obligations shall survive the expiration or termination of this Agreement.

**ARTICLE 3. Project Management.**

A. Program Governance: The Awardee is responsible for the overall management of the project development program and related program decisions. The Government will have continuous involvement with the Awardee. The Awardee shall provide access to project results in accordance with the Awardee's Project Timeline located in Appendix A.

B. Project Managers: The Awardee and the Government will each designate a Project Manager responsible for facilitating the communications, reporting, and meetings between the Parties. Each Party will also designate an alternate to the Project Manager, in case the primary Project Manager is unavailable. See Project Manager/Alternate Project Manager point of contact information for each respective party below:

Awardee Project Managers

(b) (6)

(b) (6)

C. Key Personnel: Any key personnel specified in this agreement are considered to be essential to work performance. At least thirty (30) calendar days prior to the Awardee voluntarily diverting any of the specified individuals to other programs or contracts the Awardee shall notify the Agreements Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the Agreement (including, when applicable, Human Subjects Testing requirements). If the employee of the Awardee is terminated for cause or separates from the Awardee voluntarily with less than thirty (30) calendar-day notice, the Awardee shall provide the maximum notice practicable under the circumstances. The Awardee shall not divert, replace, or announce any such change to key personnel without the written consent of the Agreements Officer. The Agreement will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The key personnel are listed in Appendix C. The requirements of this Article 3.C are intended to be read in combination with the requirements of the immediately following Article 3.D, and with Appendix C.

D. Substitution of Key Personnel

The Contractor agrees to assign the Key Personnel listed in Appendix C to the Agreement as those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the Agreement. No substitutions shall

be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the Agreements officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The Agreements officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

The contractor further agrees to include the substance of this clause in any relevant subcontract, which may be awarded under this Agreement.

E. Subaward Approval: Modifications to subawards and/or new subcontracts under this Agreement that could reasonably impact the technical approach proposed and accepted by the Government require the approval of the OTAO prior to being executed.

F. The OTAO has assigned an Agreements Officer's Representative (AOR) for this agreement. The Awardee will receive a copy of the written designation outlining the roles and responsibilities of the AOR and specifying the extent of the AOR's authority to act on behalf of the OTAO. The AOR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the Agreement.

**ARTICLE 4. Agreement Administration.**

In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this Agreement between the Awardee and a person other than the OTAO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the OTAO.

**Government Representatives:**

Other Transaction Agreements Officer (OTAO)

(b) (4), (b) (6)

ACC-APG-Fort Detrick 110 Thomas Johnson
Dr. Frederick, MD 21702

(b) (4), (b) (6)

Other Transaction Agreement Specialist (OTAS)

(b) (6)

ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702

(b) (6)

**Agreements Officer Representative (AOR):**

(b) (6)

1564 Freedman Drive
Fort Detrick, MD 21702

(b) (6)

**Awardee Representatives:**

(b) (6)

1180 Veterans Blvd.
South San Francisco, CA 94080

(b) (6)

**Awardee Administrative Contact:**

(b) (6)

1180 Veterans Blvd.
South San Francisco, CA 94080

(b) (6)

**ARTICLE 5. Performance Objectives and Changes.**

A. Statement of Work (SOW): The SOW, Appendix A, describes the scope of activities that will be undertaken by the Awardee to achieve the objective.

B. Recommendations for Modifications: At any time during the term of this Agreement,

progress or results may indicate that a change in the SOW would be beneficial to the project objectives. Recommendations for modifications, including justifications to support any changes to the SOW, will be documented in a letter and submitted by Awardee to the GPM with a copy to the OTAO. This letter will detail the technical, chronological and financial impact, if any, of the proposed modification to the project. Any resultant modification is subject to the mutual agreement of the Parties. The Government is not obligated to pay for additional or revised amounts unless and until this Agreement is formally revised by the OTAO and made part of this Agreement. Any modification to this Agreement to account for recommended changes in the SOW or Payable Milestones will be considered a supplemental agreement.

C. Review of Recommendations: The OTAO will be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement, the SOW, the milestone payments, or other proposed changes to the terms and conditions of this Agreement.

D. Minor Modifications: The Government may make minor or administrative Agreement modifications unilaterally (e.g., changes in the paying office or appropriation data, changes to Awardee personnel proposed by Awardee, etc.).

E. Amending the Agreement: The Government will be responsible for effecting all modifications to this Agreement, with the concurrence of the Awardee for modifications that are not minor or administrative. Administrative and material matters under this Agreement will be referred to OTAO.

F. Modification Communications: No other communications, whether oral or in writing, that purport to change this Agreement are valid.

G. Government Property: If applicable, terms and conditions applicable to Government Property shall be incorporated through Appendix D.

H. Disputes: For any disagreement, claim, or dispute arising under this Agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the OTAO. The OTAO will review the matter and render a decision in writing within sixty (60) calendar days. Thereafter, either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree by mutual consent to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute. The Awardee shall proceed diligently with performance under

this agreement pending resolution of the dispute.

**ARTICLE 6. Inspection/Acceptance**

A. Inspection: The Government has the right to inspect and test all work called for by this Agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the premises of the Awardee or any subawardee engaged in performance, with seven (7) calendar days advance notice to the Awardee, or fourteen (14) calendar days advance notice to any such subawardee. The scope and duration of any such Government inspection will be mutually agreed between the Parties in writing in advance, such agreement not to be unreasonably withheld. The Government shall perform inspections and tests in a manner that will not unduly delay the work. If the Government performs any inspection or test on the premises of the Awardee or a subawardee, the Awardee shall furnish and shall require subawardees to furnish, at no increase in price, all reasonable facilities and assistance for the safe and convenient performance of these duties. Except as otherwise provided in the Agreement, the Government shall bear the expense of Government inspections or tests made at other than the Awardee's or subawardee's premises.

B. The Government shall inspect/accept or reject the work as promptly as practicable after completion/delivery, unless otherwise specified in the Agreement. Government failure to inspect and accept or reject the work shall not relieve the Awardee from responsibility, nor impose liability on the Government, for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. The Government has the right to reject nonconforming work. Inspection/Acceptance of the Prototype performed should not exceed 90 days after completion.

**ARTICLE 7. Financial Matters**

This Agreement is a fixed milestone Other Transaction Authority agreement. The payments provided under this Agreement are intended to compensate the Awardee upon completion of milestones of performance under this Agreement.

A. Payment. The Awardee shall be paid for each milestone executed and accomplished in accordance with the performance schedule set forth in Appendix B. The schedule is predicated upon the Government's fiscal year, which begins on October 1 of each year, and ends on September 30 of the subsequent calendar year.

The Awardee will provide AOR, OTAO and OTAS notification of milestone success and any documentation that supports successful completion of the milestone. Within

ten (10) business days of receipt, the OTAO will either, 1) confirm milestone completion and authorize the Awardee to invoice against the completed milestone or, 2) notify the Awardee of any deficiencies, additional documentation or clarifications reasonably needed by the Government to complete its review of the milestone. The Parties agree that payments will be made upon the OTAO's acceptance of completed milestones.

B. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The amount of Government funds obligated by this Agreement and available for payment is set forth in the administrative document generated from PD2, demonstrating the appropriate Contract Line Item Number, and Accounting and Appropriation information. The Government may incrementally fund this agreement.

C. The Government is not obligated to provide payment to the Awardee for amounts in excess of the amount of obligated funds allotted by the Government.

D. After accomplishment of each milestone, the Awardee will submit the corresponding invoice through a Government provided invoicing and payment system, as detailed in Section 7.G. The Government shall pay the Awardee, upon submission of proper invoices, the amounts stipulated in this Agreement for work delivered or rendered and accepted, less any deductions provided in this Agreement. Unless otherwise specified, payment shall be made upon acceptance of any portion of the work delivered or rendered for which a price is separately stated in the Agreement. Payments will be made within thirty (30) calendar days of receipt of a request for payment.

E. Subject to paragraph H of this clause, the Awardee shall maintain adequate records to account for all funding under this Agreement. Neither the Cost Accounting Standards nor any other aspect of the Federal Acquisition Regulation or its supplements apply to Awardee's accounting of costs under this Agreement. Costs shall be accounted for in accordance with Awardee's established commercial accounting practices and the requirements of this Agreement, with appropriate arrangements for receipt, distribution and accounting for Federal funds.

F. Prior written approval by the OTAO, or the AOR, is required for all travel directly and identifiably funded by the Government under this agreement. The Awardee shall present to the OTAO or AOR, an itinerary for each planned trip, showing the name of the traveler, purpose of the trip, origin/destination, dates of travel, and estimated cost broken down by line item as far in advanced of the proposed travel as possible, but no less than two weeks before travel is planned to commence. In the event that emergency travel is required (e.g., in the event of an outbreak) that would make two weeks' notice impractical, travel requests may be submitted to the Government for an expedited review. Emergency travel requests shall be labelled as such and shall

include a brief summary of the emergency situation and rationale for expedited review.

G. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

(a) Definitions. As used in this clause–

Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Awardee shall (i) have a designated electronic business point of contact in the System for Award Management at https://www.acquisition.gov; and (ii) be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this website.

(d) WAWF training. The Awardee should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb.mil/.

(e) WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Awardee must use the following information when submitting payment requests and receiving reports in WAWF for this Agreement:

(1) Document type. The Awardee shall use the following document type: 2 in 1 combo.

(2) Inspection/acceptance location. The Awardee shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

(3) Document routing. The Awardee shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table

| ***Field Name in WAWF*** | ***Data to be entered in WAWF*** |
|---|---|
| Pay Official DoDAAC | **HQ0490** |
| Issue By DoDAAC | **W911QY** |
| Admin DoDAAC | **W911QY** |
| Inspect By DoDAAC | **W56XNH** |

(4) Payment request and supporting documentation. The Awardee shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, costs, fee (if applicable), and all relevant back-up documentation in support of each payment request.

(5) WAWF email notifications. The Awardee shall enter the email address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.

(b) (6)

(g) WAWF point of contact.

(1) The Awardee may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

(End of Clause)

H. Comptroller General Access to Records: To the extent that the total Government payments under this Agreement exceed $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain to, and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such Party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement other than sub-agreements with a component of the U.S. Government. The Comptroller General may not examine records pursuant to a clause included in an agreement more than three years after the final payment is made by the United States under the agreement.

**ARTICLE 8. Report and Data Requirements**

A. Weekly Teleconferences and Communication

Awardee shall conduct weekly teleconferences with the Government throughout the performance of the Agreement to discuss tasks accomplished and direction for the upcoming tasks. The Government anticipates reducing the teleconferences once enrollment executes and again after completion of the trial. Awardee shall provide agendas and read-ahead material as required two days prior to the meetings and shall provide minutes of each meeting to the Government. Awardee shall include key subawardees as attendees at these teleconferences when applicable. The Awardee shall provide meeting minutes within three (3) business days after each formal scheduled meeting/teleconference conducted with JPEO JPM CBRN Medical.

B. Quarterly Progress Reports

The Awardee shall submit a Quarterly Progress report within twenty (20) calendar days after the end of each quarter of performance. The Quarterly Progress report shall contain the technical progress made during the previous quarter and the updated resource loaded Integrated Master Schedule (IMS) in Microsoft Project format. The schedule update shall include the explanation for any changes in the schedule, and drivers for the changes, as applicable. The report should also address any concerns that would impact the performance, schedule, or cost planned for the

effort. The Awardee shall report risk matrix format to include risk mitigation strategies. Note: Any identified changes require formal notification to the OTAO in accordance with the Agreement provisions.

In addition, the Quarterly Progress Report shall contain regular status updates of all Intellectual Property (IP) license(s) related to the effort to ensure that all license(s) are in good standing as the project progresses. In the event of any change in IP license(s) status or potentially imminent change in status, the Awardee shall immediately contact the OTA and GPM in writing.

The Government will have ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional five (5) calendar days to revise the deliverable or respond to those comments.

C. Monthly Financial Status Report

The Awardee shall submit a Monthly Financial Status Report no later than twenty (20) calendar days after the end of each month of performance. The Government will have ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional ten (10) calendar days to revise the deliverable or respond to those comments. Reports will cover milestones accomplished monthly for the duration of the Period of Performance (PoP), in addition to a monthly milestone forecast. The Awardee shall provide all submissions in Excel format, including all formulas.

D. Final report

A Final Report shall be prepared at the end of the effort by the Awardee. The Final Report shall narrate a complete summary of the project execution and associated results obtained. The narration will include outstanding problems and their potential solutions, problems solved during the course of the agreement, and the solutions to the solved problems. The Final Report shall demonstrate how the prototype was developed and advanced.

The Awardee shall submit a Draft Final Report by the forty-fifth ($45^{th}$) calendar day following the end of the project. The Government shall provide comments to the Awardee by the thirtieth ($30^{th}$) calendar day following receipt of the Awardee's Draft Final Report. The Awardee shall submit the Final Report on the thirtieth ($30^{th}$) calendar day after receipt.

E. Ad Hoc Meetings

In addition to the monthly meetings and written quarterly program updates,

additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held. The Awardee shall provide meeting minutes within three (3) business days after each ad hoc meeting/teleconference conducted with JPEO JPM CBRN Medical.

F. Patents – Reporting of Inventions

The Awardee shall report any OTA Inventions (as defined in Article 10 hereof) in accordance with the terms and conditions of this Other Transaction Agreement (OTA).

G. Miscellaneous Data Submissions

If applicable, the Awardee must submit to the Government all briefings, regulatory strategy, United States Army Medical Research and Development Command Human Research Protection Office (HRPO) Approvals, technical presentations and publications, and any formal technical reports that have been prepared for eventual submission to FDA or other regulatory agencies. Examples include the following reports related to: completed batch records, certificates of analysis, drug substance and product stability, and clinical testing. Examples include clinical performance and clinical quality documentation.

H. Work Breakdown Structure

Three-level WBS with costs and schedule (top level is program, level two (2) is phase, level three (3) are major tasks). For WBS level two (2), show breakdown for labor, material, and other indirect costs.

WBS shall be updated annually or thirty (30) calendar days after a Statement of Work modification. Government review/approval is fifteen (15) calendar days after receipt of first submittal. Provide changes to draft within ten (10) calendar days of such request. Provide final document within ten (10) calendar days after approval of changes is received.

I. Integrated Master Schedule

The Awardee shall provide within thirty (30) calendar days after project award an IMS in Microsoft Project format. Any updates to the IMS shall be included in the quarterly progress reports.

Submission shall be thirty (30) calendar days after the end of each month of performance. The Government will have ten (10) calendar days to respond to the report with any comments and the performer will have an additional five (5) calendar days to revise the deliverable or respond to those comments.

J. Incident Report.

The Awardee shall report any incident to the Government that could result in any delay in schedule from the most recent IMS critical path delivered to the Government. Telephonically contact the GPM within one day of incident. A written summary report shall be submitted within three (3) business days of an incident, to include, what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place.

K. Source Material Reports

The Awardee shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, including but not limited to: physical locations of sources material by type of material (e.g., software, testing, analytical and environmental componentry, reagents) and location and nature of clinical study sites.

L. Awardee Locations

The Awardee shall submit detailed data regarding locations where work will be performed under this Agreement, including addresses, points of contact, and work performed per location, to include sub-awardees.

Awardee will submit Work Locations Report:

- Within 5 business days of Agreement award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

**ARTICLE 9. Confidential Information**

A. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

B. The Agreements Officer and the Awardee may, by mutual consent, identify elsewhere in this Agreement specific information and/or categories of information which the Government will furnish to the Awardee or that the Awardee is expected to generate which is confidential. Similarly, the Agreements Officer and the Awardee may, by mutual

consent, identify such confidential information from time to time during the performance of the Agreement. Failure to agree will be settled pursuant to the "Disputes" clause.

C. If it is established elsewhere in this Agreement that information to be utilized under this Agreement, or a portion thereof, is subject to the Privacy Act, the Awardee will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

D. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

E. Whenever the Awardee is uncertain with regard to the proper handling of material under the Agreement, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Awardee shall obtain a written determination from the Agreements Officer prior to any release, disclosure, dissemination, or publication.

F. Agreements Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

G. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H. Awardee acknowledges that Government-provided confidential information will not be provided to sub-agreement holders unless or until Article 9 flows down to the relevant sub-agreement, and such entity agrees to be in substantial compliance with this Article 9.

**ARTICLE 10. Intellectual Property Rights**

A. Awardee represents that the rights held by or granted to Awardee, including all intellectual property licenses, are sufficient to enable Awardee to perform its obligations under this Agreement.

B. Background IP and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, data, technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement ("Background IP").

C. Awardee's Background IP. Awardee warrants that it has filed patent application(s) or is the assignee of issued patent(s) listed below which contain claims that are

related to research contemplated under this Agreement. No Government funding was used to finance, develop, or acquire the background IP. No license(s) to any patent applications or issued patents shall be granted under this Agreement, and the application(s) and any continuing applications (except for continuing applications pursuant to this agreement) are specifically excluded from the definitions of "OTA Invention" contained in this Agreement: See Appendix F.

D. Government's Background IP. The government warrants that it has no Background IP and therefore lists "None".

E. Patent Indemnity. The Awardee shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, resulting from Awardees performance of the SOW under this Agreement, provided the Awardee is reasonably notified of such claims and proceedings.

F. Patent Prosecution. Awardee agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications listed as Awardee Background IP that are relevant to the work performed under this Agreement. Awardee shall keep the Government reasonably advised on the status of Awardee Background IP by providing an annual report on the status of Awardee Background IP. Prior to acting on a decision by Awardee to abandon or not file in any country a patent or patent application covering an OTA Invention, which is defined below, Awardee shall so inform the Government in a timely manner to allow Awardee to thoughtfully consider the Government's comments regarding such a proposed decision. Nothing in this ARTICLE shall restrict the Government in its preparation, filing, prosecution and maintenance of a patent or patent application covering an OTA Invention.

G. Patent Applications. Each Party shall report any OTA Inventions to the other Party within 60 days of the time the inventor discloses it in writing to its personnel responsible for patent matters. The Parties will respectively have the option to file a patent application claiming any OTA Invention made solely by their respective employees. The Parties will consult with each other regarding the options for filing a patent application claiming a joint OTA Invention. Within forty-five (45) calendar days of being notified of the discovery of an OTA Invention or filing a patent application covering an OTA Invention, each Party will provide notice of such discovery or filing to the other Party. The Parties will reasonably cooperate with each other in the preparation, filing, and prosecution of any patent application claiming an OTA Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by

the Parties.

H. Patent Enforcement. Awardee will have the first option to enforce any patent rights covering an OTA Invention owned jointly by the Parties or solely by Awardee, at Awardee's expense. If Awardee chooses not to exercise this option, the Government may enforce patent rights covering a joint OTA Invention only with Awardee's prior written approval.

I. OTA Inventions. Ownership of any invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement ("OTA Invention") will follow inventorship in accordance with U.S. patent law. The Bayh-Dole Act, 35 U.S.C. §§ 200-212 does not apply to this Agreement and, as such, title to inventions will accrue to the inventor or inventor-organization. In the event an OTA Invention exists, the Parties represent and warrant that each inventor will assign his or her rights in any such inventions to his or her employing organization. Notwithstanding the foregoing, neither the Government nor Awardee anticipate the Government making a Sole Government OTA Invention, nor the Parties jointly making a Joint OTA Invention, as Awardee employees are solely responsible, as between the Parties, for performing the Prototype Project under this Agreement. Any OTA Invention made solely by an Awardee employee is subject to a nonexclusive, nontransferable, irrevocable, worldwide paid-up license for the Government to practice and have practiced the OTA Invention on behalf of the Government.

J. Licenses. Upon the Awardee's request, the Government agrees to enter into good faith negotiations with the Awardee regarding the Awardee's receipt of a nonexclusive commercialization license covering the Government's interest in any OTA Invention made in whole by a Government employee.

K. Executive Order No. 9424 of 18 February 1944 requires all executive Departments and agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents.

L. The Government shall flow down the requirements of this Article 10 to their respective personnel, member entities, agents, and Awardees (including employees) at all levels, under this Agreement.

**ARTICLE 11. Data Rights**

A. Background Data. "Background Data" shall mean all technical data, as defined in DFARS 252.227-7013 that exists prior to execution of this Agreement, or are

developed outside the scope of this Agreement. The Awardee's Background Data includes, but is not limited to, the following technical data, to the extent such data exists prior to execution of this Agreement or is developed outside the scope of this Agreement: See Appendix G. The Awardee retains all of its right, title and interest in and to its Background Data, and the Government receives no rights or licenses to any such Background Data hereunder. The Government may, under a separate agreement or by modification to this agreement, obtain any rights to use or disclose the Awardee's Background Data to the extent that such material or data was produced outside the scope of this Agreement.

B. Subject Data. All data generated in connection with the performance of this Agreement, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this Agreement, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the "Subject Data"), shall be owned by the Awardee.

Subject Data in any document that would disclose an enabling disclosure of an OTA Invention will be subject to Limited Rights until publication of patent application in accordance with Article 10 of this Agreement, and such Subject Data will be identified accordingly with reasonable specificity. Once publicized, the USG shall receive Government Purpose Rights to all such Subject Data.

All other Subject Data shall be delivered with Government Purpose Rights.

As used herein, "Limited Rights" means the rights to use, modify, reproduce, perform, display, or disclose data, in whole or in part, within the Government solely for research purposes in respect of the prophylaxis and treatment of COVID-19. The Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of the Awardee, release or disclose the data outside the Government, use the data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the data to be used by another party. The Parties shall maintain the confidentiality of all data subject to or designated as falling within Limited Rights.

As used herein, "Government Purpose Rights" means the rights to (i) use, modify, reproduce, release, perform, display, or disclose data solely within the Government, (ii) release or disclose data outside the Government, and (iii) authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data; in each case (i)-(iii) solely as required for Government purposes. Government purposes do not include the rights to use, modify, reproduce, release, perform, display, or disclose data for commercial or competitive

purposes or to authorize others to do so. Even where disclosure is made for Government purposes, such disclosure will be governed by a contractual terminology or a non-disclosure agreement restricting further dissemination of the information and otherwise ensuring compliance with the government's rights and obligations in the disclosed data.

C. The Awardee agrees to retain and maintain in good condition until seven (7) years after completion or termination of this Agreement, all data generated under this Agreement. In the event of exercise of the Government's rights as potentially granted under paragraph 2.C, the Awardee agrees to deliver at no additional cost to the Government, all data, in Awardee's possession and developed under this Agreement, necessary to develop the Prototype within sixty (60) calendar days from the date of the written request.

D. Marking of Data: The Awardee will mark any data delivered under this Agreement with the following legend:

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement No. W911QY-21-9-0018 between the Government and the Awardee."

Any rights that the Awardee or the Government may have in data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

E. All Subject Data which shall be delivered under this Agreement with less than unlimited rights shall be identified in reasonable specificity and particular rights granted (Government Purpose or Limited (all as defined in this Agreement) prior to delivery under the Agreement. All other Subject Data developed under funding of this agreement shall be delivered with Government Purpose Rights.

**ARTICLE 12. Regulatory Rights**

This Agreement includes research with drugs that are regulated by the FDA and require FDA clearance before commercial marketing may begin for the COVID-19 indication. The Parties anticipate that for the Prototype Project(s) contemplated under this Agreement, the Awardee or its designated subawardee will serve as the Sponsor of the Regulatory Application (an investigational new drug application (IND), or another regulatory filing submitted to FDA) that will permit commercial marketing of fostamatinib for a COVID-19 indication. The Sponsor of the Regulatory Application to FDA (as the terms “sponsor”, “sponsor-investigator”, and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), has certain standing before the FDA that entitles him to exclusive communications related

to the Regulatory Application.

Regarding any technology developed under this agreement for which Awardee or its designated subawardee serves as regulatory Sponsor, the Awardee agrees to the following, which will flow down to appropriate subawardees performing regulatory functions:

a. Government Regulatory Representatives: The Senior Director Medical Regulatory (SDMR) is the JPEO-CBRND representative for all regulatory and quality activities. The Awardee shall coordinate with the SDMR prior to communicating or meeting with the FDA, or other regulatory authorities, as appropriate. The Awardee shall invite the SDMR to all FDA meetings if applicable and related preparatory regulatory discussions.
    1. The regulatory Sponsor shall submit a letter to FDA indicating the SDMR as a co-contact and that FDA is authorized to contact SDMR for DoD regulatory/policy input, as needed for this development effort. This notice could be part of the PL 115-92 authorization letter described below. In this circumstance and to the maximum extent practicable, the Government will include the Sponsor in any and all meetings and correspondence with the FDA. If it is not practicable to include the Sponsor in any interaction with the FDA, the Government will provide a summary of the interaction to the Sponsor within ten (10) business days.
    2. Non-compliance with section (a) may result in termination of the Agreement.

b. Regulatory Submissions. The Awardee will provide to the Government all data, including top-line summaries and key conclusions from all studies supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded by this Agreement. In addition, the Awardee will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions, which include data funded by this Agreement. The Government will review any such submissions (i.e., the IND) promptly upon receipt. The Awardee will reasonably consider any comments provided by the Government, and prior to submission will provide notification to the Government of any additional edits or revisions. The Awardee will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Agreement.

c. Communications. The Awardee shall provide the Government with all material communications and summaries thereof, both formal and informal, to or from FDA, regarding the technology within 48 hours, and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA. Awardee shall (1) ensure that the Government representatives are consulted and are invited to participate in any formal or informal Sponsor meetings

with FDA related to the technology; and (2) notify the FDA that the Government has the right to discuss with FDA any development efforts regarding the technology.

d. Rights of Reference. Awardee hereby grants to the Government and its permitted sublicensees a limited "right of reference or use" (as that term is defined in 21 C.F.R. § 314.3(b), as amended from time to time) to Awardee's filings to the FDA in connection with the Regulatory Application strictly for COVID-19 purposes. The Awardee shall provide appropriate notification of the Government's access and reference rights to the applicable regulatory authorities requested by the Government for the limited purposes described above. Awardee agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. The Government will agree to any reasonable request for information connected to its reliance on the right of reference provided under this Section. This provision is in addition to any rights in technical data described earlier in this document.

e. Product Development Failure. Certain product development failures may trigger certain remedies in this section for the Government advanced developer funding the development of this Prototype.

1. This remedy is only available to the Government if and when any of the following conditions occur during the Term of this Agreement:
    i. this Agreement is terminated for nonperformance; or
    ii. the Awardee gives notice, required to be submitted to the Government no later than 30 business days, of any formal management decision to terminate the prototype project;
    iii. the Awardee gives written notice, required to be submitted to the Government no later than 30 business days, of any filing that anticipates Federal bankruptcy protection.

2. If any of the product development failures listed above occur, the Awardee, upon the request of the Government:

    i. Shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Prototype to the Government or its designee;
    ii. Shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (2)(i) above; and
    shall negotiate in good faith and upon fair and reasonable terms a non-exclusive license to any patent, copyright, Technical Data or other intellectual property owned or controlled by the Awardee, developed prior to or outside the scope of this Agreement that is necessary for the Government to pursue

commercialization of the Prototype, with a third party for sale to the Government or otherwise.

3. This clause will survive the acquisition or merger of the Awardee by or with a third party. This clause will also be included in any subcontracts/subawards relating to the development of the Prototype entered into following execution of this Agreement. This clause will survive the expiration of this Agreement.

f. Public Law 115-92 Sponsor Authorization Letter/ DoD Medical Product Priority: Public Law 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The Awardee recognizes that only the DoD can utilize Public Law 115-92. As such, the Awardee will work proactively with the SDMR to leverage this law to its maximum potential under this Agreement.

1. The Awardee shall submit to the Government, within thirty (30) days of project award, a fully executed sponsor authorization letter enabling FDA to disclose information to JPEO-CBRND and its Government support contractors related to the proposed product under Public Law 115-92. A template for the sponsor authorization letter was included in Appendix E.
2. JPEO-CBRND shall formally submit the executed letter to the FDA under the Regulatory Application, only if the proposed product becomes a DoD medical product priority under Public Law 115-92.
3. If the product becomes a DoD medical product priority, to the maximum extent practicable, JPEO-CBRND will include the Awardee in any and all meetings and correspondence conducted with the FDA under Public Law 115-92. If it is not practicable to include the Awardee in any Public Law 115-92 interaction with the FDA regarding the product (for example, discussions conducted at quarterly or semi-annual DoD-FDA meetings mandated by the Public Law), JPEO-CBRND will provide a summary of the interaction to the Awardee within ten (10) business days.

g. Regulatory Compliance:

1. **cGCP Compliance**. Awardee shall maintain clinical development and operations as required to ensure proper clinical testing, operations, data management, biostatistical evaluation, clinical supply, and other capabilities required to ensure full compliance with Good Clinical Practices (GCP).
2. **Drug Supply Chain Security Act**. The provision of doses of the Protoype Project will be compliant with applicable provisions of the Drug Supply Chain Security Act (DSCSA) Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the public health response.

h. Flow Down: The Awardee shall flow down the requirements of this Article 12 to any

subawardee funded under this agreement.

**ARTICLE 13. Foreign Access to Data.**

A. Export Compliance: The Parties will comply with any applicable U.S. export control statutes or regulations in performing this Agreement.

**ARTICLE 14. Disclosure of Information**

A. Performance under this Agreement may require the Awardee to access non-public data and information proprietary to a Government agency, another Government Awardee or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Awardee, nor Awardee personnel, shall divulge nor release data nor information obtained under performance of this Agreement, except authorized by Government personnel or upon written approval of the OTAO in accordance with OWS or other Government policies and/or guidance. The Awardee shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this Agreement, or any information at all regarding this agency.

B. The Awardee shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the Agreement, replacement of an Awardee employee, or other appropriate redress. Neither the Awardee nor the Awardee's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

C. No information related to data obtained under this Agreement shall be released or publicized without the prior written consent of the AOR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity for submission to any securities exchange on which the Awardee's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

**ARTICLE 15. Scientific Publications and Press Releases.**

A. Public Affairs and Operational Security Review: All manuscripts, press releases, presentations and other publications will be provided to the JPEO-CBRND Public

Affairs Office (PAO) allowing for review/approval in accordance with Article 16 prior to use or release. Per JPEO-CBRND regulation the PAO review will include Operational Security (OPSEC) review.

B. The Parties shall jointly agree on a publication plan for the Study Data derived from studies executed under this Agreement. This publication plan will identify key new Data to be disclosed or presented and the target date for finalizing any related scientific abstract or manuscript. As part of its Quarterly Program Reviews, the Awardee will share the publication plan with the Government.

C. Scientific publication regarding Study results in any form, including, without limitation, manuscript(s), abstracts, posters, slides, or other materials used for presentations ("Scientific Publication"): Prior to either Party submitting a Scientific Publication for publication which contains the results of the Study under this Agreement, each Party shall notify the other Party in writing of the proposed Scientific Publication, offer ample opportunity to review proposed Scientific Publication, and to file patent applications in a timely manner (if applicable), provided that the review period is at least thirty (30) days from receipt of the draft Scientific Publication and the filing period is at least an additional sixty (60) days from the end of the review period. The Parties agree that authorship related to Scientific Publications shall be determined in accordance with and governed by the criteria defined by the International Committee of Medical Journal Editors (ICMJE) "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals." The Parties also agree to give appropriate credit to the entity responsible for the Study performed. The publishing Party shall keep the proposed Scientific Publication confidential for the entire review period and, if applicable, the patent filing period, and shall delete the other Party's proprietary information (other than the results of the Study generated hereunder) from the Scientific Publication upon request.

D. The Parties may jointly develop each abstract or manuscript and agree on the authorship and the content of the final draft to be submitted; provided that authorship for each abstract and manuscript will be determined based on whether a particular individual made a significant contribution to the conceptualization, design, execution, or interpretation of a research study, as authorship is defined in the fifth edition of the Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH, available at: https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/gui delines-conduct_research.pdf.

E. Prior to submission for publication, the Parties shall provide drafts of proposed publications to the authors of such publications for review and comment, and shall provide copies to non-authors for viewing purposes. Review periods are ten

(10) business days for abstracts, or less than ten (10) business days if agreed by Project Managers and in order to meet publication submission deadlines. Review periods are twenty (20) calendar days for manuscripts. Contributing parties shall be appropriately accredited in any publication.

F. The Parties will jointly agree on whether to issue one or more press releases related to the resulting Data. If all Parties agree that one or both Parties will issue a press release, each Party will also have the right to review and agree on the content in advance of its publication. Other parties, if any, contributing to the studies, will have review rights and will be appropriately accredited in the press release. For clarity, for data generated in studies executed by Awardee outside the scope of this Agreement, the Awardee, at its sole discretion, may issue a press release related to such data.

G. Press releases: Prior to any such release containing the Study results or other information about the Study performed under this Agreement, Parties agree to provide written notification and ample opportunity (at least five business days) for review to the other Party; provided that each Party will use best efforts to complete its review of proposed press releases in a shorter period of time if the Party initiating the press release identifies the need for an urgent review. Comments and approval by each Party shall be prior to release.

**ARTICLE 16. Publications and Publicity.**

The Awardee shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this Agreement without written notice in advance to the Government.

A. Unless otherwise specified in this Agreement, the Awardee may publish the results of its work under this Agreement. The Awardee shall promptly send a copy of each submission to the AOR for security review prior to submission. The Awardee shall also inform the AOR when the abstract article or other publication is published, and furnish a copy of it as finally published.

B. Unless authorized in writing by the AO, the Awardee shall not display Government logos including Operating Division or Staff Division logos on any publications.

C. The Awardee shall not reference the products(s) or services(s) awarded under this Agreement in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided.

D. The Awardee shall include this clause, including this section (d) in all subAwards where the subAwardee may propose publishing the results of its work under the subAward. The Awardee shall acknowledge the support of the Government whenever publicizing the work under this Agreement in any media by including an acknowledgement substantially as follows:

"This project has been funded in part by the U.S. Government under Agreement W911QY-21-9-0018. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

**ARTICLE 17. Human Subjects.**

A. Definitions. As used in this clause –

(1) Assurance of compliance means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

(2) Human Research Protection Official (HRPO) means the individual designated by the head of the applicable DoD component and identified in the component's Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

(3) Human subject means a living individual about whom an investigator (whether professional or student) conducting research (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (32 CFR 219.102(e)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

(4) Institution means any public or private entity, or department or agency (including federal, state, and other agencies). (32 CFR 219.102(f)).

(5) Institutional Review Board (IRB) means a board established in accord with and for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

(6) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) Research means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(l)).

B. The Awardee shall oversee the execution of the research to ensure compliance with this clause. The Awardee shall comply fully with 32 CFR Part 219 and DoD Instruction 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.

C. The clinical trial described in the Statement of Work will comply with ICH Good Clinical Practices (GCP) regulations.:

D. All clinical sites and IRBs utilized in the clinical trial described in the Statement of Work are required to register with the Office for Human Research Protections (OHRP) and receive Federal Wide Assurance (FWA) numbers in accordance with human subject protections regulations 45 C.F.R 46.103.

E. The Awardee shall include the substance of this clause, including this paragraph (f), in related subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Instruction 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.104. This clause does not apply to subcontracts that involve only the use of cadaver materials.

**ARTICLE 20. Most Favored Customer.**

A. In the event that the Parties agree to a follow-on production agreement pursuant to 10 U.S.C. 2371b, Awardee agrees that it shall sell to the U.S. Government up to (b) (4) treatment courses of TAVALISSE at a price not greater than (b) (4) (b) (4). Any additional treatment course will be sold to the U.S. Government at a price to be negotiated and agreed by the Parties.

B. If Awardee develops a like product (commercialized version or derivative of the production model of the Prototype) with similar capability and intended application,

but at a lower unit price ("Like Product") regardless of quantity, Awardee shall make the DoD aware of that similar product and the technical and price differences between that product and the Prototype. Such notification shall be made to the OTAO in writing, of which email is an acceptable form, within thirty (30) days of such offering.

**ARTICLE 21. Immunity from Liability.**

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "PREP Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;
(ii) Awardee's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and
(iii) Awardee is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Awardee's activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this Agreement, unless such use occurs in the United States (or a U.S. territory where U.S. law applies including, but not limited to, embassies, military installations and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Awardee prior to use and, if the Parties disagree on such use, the dispute will be resolved according to Article 5(H).

**ARTICLE 22. Miscellaneous Clauses.**

A. No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this

Agreement.

B. Patent Infringement. Each Party will advise the other Party promptly and in reasonable written detail, of each claim or lawsuit of patent infringement based on the performance of this Agreement. When requested by either Party, all evidence and information in possession of the Party pertaining to such claim or lawsuit will be provided to the other at no cost to the requesting Party.

C. Limitation of Liability. Except for claims of non-payment of amounts due under Article 7, any claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of Government funding disbursed as of the time the dispute arises. In no event will either Party be liable to the other Party or any third party claiming through such Party for any indirect, incidental, consequential or punitive damages, or claims for lost profits, arising under or relating to this Agreement, whether based in contract, tort or otherwise, even if the other Party has been advised of the possibility of such damages.

D. Disclosure of Information. Subject to Article 10, the Awardee shall not release to anyone outside the Awardee's organization any unclassified non-public information, regardless of medium (e.g., film, tape, document), pertaining to the clinical trial that is subject of this Agreement, unless (i) the OTAO has given prior written approval or (ii) the information is otherwise in the public domain before the date of release or (iii) such disclosure would be made by Awardee normally as part of such a trial in the regular course of its business. For purposes of this clause, Awardee's Organization includes entities identified as subawards..

E. Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (a Force Majeure event). Examples of such circumstances are: authorized acts of the government in either its sovereign or contractual capacity, war, insurrection, freight embargos, fire, flood, pandemic, or strikes. The Party asserting Force Majeure as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events.

F. Severability. If any provision of this Agreement, or the application of any such provision to any person or set of circumstances, is determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be impaired or otherwise affected and will continue to be valid and enforceable to the

fullest extent permitted by law.

G. Choice of Law. This Agreement and the resolution of disputes hereunder will be governed, construed, and interpreted by the statutes, regulations, and/or legal precedent applicable to the Government of the United States of America. Unless explicitly stated, the Parties do not intend that this Agreement be subject to the Federal Acquisition Regulation either directly or indirectly or by operation of law. When a specific FAR requirement is incorporated by reference in this Agreement, the text of the clause alone will apply without application or incorporation of other provisions of these regulations.

H. Order of Precedence. In the event of a conflict between the terms of this Agreement and the attachments incorporated herein, the conflict shall be resolved by giving precedence in descending order as follows:

(i) the Articles of this Agreement, and
(ii) the Appendices to the Agreement.

I. Conflicts of Interest.

The Awardee does and shall comply with the requirements of 21 CFR Part 54, Financial Disclosure by Clinical Investigators

J. Organizational Conflicts of Interest.

Performance under this Agreement may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Awardee shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the Awardee and all sub-recipients. This provision shall have effect throughout the period of performance of this Agreement, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this Agreement, upon determination that an OCI has occurred.

The work performed under this Agreement may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Awardee's performance of this Agreement, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The Awardee shall notify the Agreements Officer immediately whenever it

becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Awardee shall promptly submit a plan to the Agreements Officer to either avoid or mitigate any such OCI. The Agreements Officer will have sole discretion in accepting the Awardee's mitigation plan. In the event the Agreements Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Awardee from participating in Agreement requirements related to OCI.

Whenever performance of this Agreement provides access to another Awardee's proprietary information, the Awardee shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Awardees' offers or products under this Agreement. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the OTAO within fifteen (15) calendar days of execution.

K. Telecommunications and Video Surveillance. FAR 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment incorporated by reference.

L. Data Privacy. The Parties will comply with all applicable Laws regarding Study participant confidentiality and data protection, including, without limitation, HIPAA, HITECH, and applicable state privacy Laws, in the collection, use, storage and disclosure of protected health information (as defined under HIPAA or the relevant Law) ("PHI"). Awardee shall, or shall direct its representatives to, collect, use, store, access and disclose PHI collected from Study participants only in accordance with applicable ICFs or with applicable Laws. Awardee shall also obtain in the ICF or separate authorization document, permission for USG/USG representatives involved with or evaluating the Study to access and obtain copies of the Subject Data to the same extent as Awardee and to otherwise exercise its rights under this Agreement, including, without limitation, its audit rights.

**Appendix A**
**Statement of Work**

The Awardee plans to execute the program in accordance with the statement of work provided below. The plan is to accomplish the entire project based on the schedule prescribed in this agreement. Completion dates are expressed in Appendix B. The numbering scheme below is adopted from the Awardee's Statement of Work as included in its proposal. Only the sections of the proposal included in this Appendix A are made a part of this Agreement.

## 1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

### 1.1 Introduction

Coronavirus Disease 2019 (COVID-19) is the disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). SARS-CoV-2 primarily infects the upper and lower respiratory tract and can lead to acute respiratory distress syndrome (ARDS) in a subset of patients with a known high mortality rate. Additionally, some patients develop other organ dysfunction including myocardial injury, acute kidney injury, shock along with endothelial dysfunction and subsequently micro and macrovascular thrombosis. Accordingly, there is an urgent and unmet medical need to find treatments that can effectively reduce the risk of ARDS, organ damage, thrombosis or the mortality rate in COVID-19 subjects.

Fostamatinib is unique among FDA approved products being evaluated for the treatment of COVID-19 disease because it targets both the cytokine storm associated with SAR-CoV2 infection *as well as* the thrombotic effects of COVID-19 disease. The active metabolite of fostamatinib, R406, is a potent and selective inhibitor of SYK which can decrease stimulation of Fc receptor (FcR) by the SARS-CoV2- antibody immune complexes while also decreasing C-type lectin receptor mediated coagulopathy disorders by inhibiting immune cell activation caused by COVID-19 related tissue damage or pathogen signals.

Fostamatinib is marketed in the U.S. as TAVALISSE (fostamatinib disodium hexahydrate) tablets. The product is approved in the U.S. and Europe as a treatment for adult chronic immune thrombocytopenia (ITP)-- a rare autoimmune disorder. Fostamatinib is a tablet that is administered orally.

Rigel has initiated a Phase 3 clinical trial entitled *Double-Blind, Randomized, Placebo-Controlled, Adaptive Design, Multi-Center Phase 3 Study to Evaluate the Efficacy and Safety of Fostamatinib in COVID-19 Subjects*. This trial is evaluating the safety and efficacy of Fostamatinib in hospitalized COVID-19 patients without respiratory failure that have certain high-risk prognostic factors. This multi- center, double-blind, placebo-controlled, adaptive design study is expected to enroll over 300 evaluable patients that will be randomly assigned

to either fostamatinib plus standard of care (SOC) or matched placebo plus SOC (1:1). Treatment will be administered orally twice daily for 14 days. For subjects who are discharged from the hospital before completing 14 days of study treatment, subjects will self-administer in an out-patient setting. There will be a follow-up period to day 60. The primary endpoint of this study is the proportion of subjects who progress to severe/critical disease within 29 days.

## 1.2 Scope

Rigel will complete the on-going Phase 3 trial. (b) (4)

[redacted]

## 1.3 Objective

The program is designed to provide the following end products:

- Application for an EUA supporting the use of Fostamatinib for the prevention of progression to severe/critical COVID-19 Disease in hospitalized and out-patient populations, as appropriate.
- Final Clinical Study Reports (CSR) for the Phase 3 study, conducted under Good Clinical Practice (GCP) on the benefit and safety of Fostamatinib in COVID-19 patients, delivered to the FDA and JPEO-CBRND, JPM-Medical under eCTD standards.

The Rigel development plan provides a complete solution to the US Government's requirement, with an estimated period of performance of twelve months.

This is a prototype project because Rigel will develop Fostamatinib by conducting randomized placebo- controlled clinical study(s) and filing for an EUA, in order to evaluate the technical

feasibility of using Fostamatinib for the prevention of progression to severe/critical COVID-19 Disease in hospitalized patients, and if appropriate an out-patient population, an indication(s) not currently approved by the FDA.

## 2.0 APPLICABLE DOCUMENTS

NA

## 3.0 REQUIREMENTS

### Overall Scope & Objectives of the Prototype Project

Rigel will conduct a randomized controlled clinical trial of Fostamatinib in COVID-19 patients and provide an option to support other clinical trials as well as support DoD efforts to obtain an EUA for Fostamatinib for the prevention of progression to severe/critical COVID-19 Disease in hospitalized and out-patient populations as appropriate.

### WBS 1 BASE PERIOD

Rigel will complete the on-going Phase 3 trial. (b) (4) [redacted]

### WBS 1.1 CLINICAL STUDIES
### WBS 1.1.1 INPATIENT STUDIES
### WBS 1.1.1.1 COMPLETE PHASE 3 EFFICACY STUDY – DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, ADAPTIVE DESIGN, MULTI-CENTER PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF FOSTAMATINIB IN COVID-19 SUBJECTS

This study is a double-blind, randomized, placebo-controlled, adaptive design, multi-center, Phase 3 study to evaluate the efficacy and safety of fostamatinib in COVID-19 subjects. It is estimated that approximately 300 hospitalized COVID-19 subjects without respiratory failure and with certain high-risk factors will be evaluated. Subjects will be randomized 1:1 to either SOC plus fostamatinib or SOC plus placebo. In addition to SOC, fostamatinib or placebo will be administered orally for 14 days at a dose of 150 mg twice daily. If patients are discharged,

treatment will be self-administered. The primary efficacy endpoint of the study is: Progression to severe/critical disease within 29 days of first dose of study treatment, defined as proportion of subjects with a change of clinical status score from 3, 4, or 5 to a clinical status score of 6, 7, or 8 on the 8-point ordinal scale. A number of other secondary, efficacy, and safety endpoints are included in the study.

**WBS 1.1.2 OUTPATIENT STUDIES**
**WBS 1.1.2.1 OUTPATIENT STUDY SUPPORT**

Rigel will provide technical, regulatory and clinical trial planning expertise to support the development and planning of a Phase 2 clinical trial designed to evaluate the safety and efficacy of fostamatinib in preventing the progression to severe/critical COVID-19 disease in out-patient populations.

**WBS 1.2 REGULATORY ACTIVITIES**
**WBS 1.2.1 FDA FILINGS, CORRESPONDENCE & EUA SUBMISSIONS**
**WBS 1.2.1.1 ROUTINE FDA CORRESPONDENCES**

The trial defined in SOW# 1.1.1.1 will be conducted under IND #151287 which was opened for the development of fostamatinib in COVID-19 patients. Study safety clearance letter to proceed with the phase 3 clinical study outlined in SOW #1.1.1.1 was received from the FDA on November 5th, 2020.

Rigel will complete all filings and correspondences required as part of this clinical trial. Rigel will participate in all filings and correspondences with the FDA as required to support the development and planning of the Phase 2 outpatient study.

**WBS 1.2.1.2 EMERGENCY USE AUTHORIZATION**

(b) (4)

[redacted]

**WBS 1.3 CONTRACT ADMINISTRATION & PROJECT MANAGEMENT**
**WBS 1.3.1 PROJECT MANAGEMENT**
**WBS 1.3.1.1 BASE PERIOD (CLIN 0001) PROJECT MANAGEMENT**

Rigel will provide the NHLBI Phase 2 clinical study and its Phase 3 clinical study with high-level project management support including the potential Pre-EUA and EUA applications with the US FDA.

| | BASE PERIOD (CLIN 0001) |
|---|---|
| 1.1 | **Clinical Studies** |
| 1.1.1 | Clinical Study – In Patient |
| 1.1.1.1 | Complete Phase 3 - Double-Blind, Randomized, Placebo-Controlled, Adaptive Design, Multi-Center Phase 3 Study to Evaluate the Efficacy and Safety of Fostamatinib in COVID-19 Subjects |
| 1.1.2 | Clinical Study – Outpatient |
| 1.1.2.1 | Provide Outpatient Study Support – Planning |
| 1.2 | **Regulatory Activities** |
| 1.2.1 | FDA Filings and Correspondence |
| 1.2.1.1 | Routine FDA Communications |
| 1.2.1.2 | Submit Emergency Use Authorization Package |
| 1.3 | **Contract Administration & Project Management** |
| 1.3.1 | Project Management |
| 1.3.1.1 | Base Period (CLIN 0001) Project Management |

## COVID-19: Program Timeline


[1]Timing dependent upon on-going discussions with NHLBI

**Appendix B**
**Project Schedule/Milestone Payment Schedule**

The Government shall pay the Awardee, upon the submission of proper invoices or vouchers, the prices stipulated in this Agreement for supplies delivered and accepted or services rendered and accepted, less any deductions provided in this Agreement. Invoices shall be submitted based on the awarded milestones. The below payment schedule is traceable to applicable task(s)/deliverable(s) identified within the statement of work. Payments are due upon completion and acceptance of all deliverables within each phase. An invoice will be submitted through Wide Area Work Flow (WAWF) in accordance with agreement requirements within ten (10) days of the deliverable being submitted.

| Event | Month | Year | Amount |
|---|---|---|---|
| (b) (4) | | | |
| Total | | | $16,500,000 |

The Awardee shall proceed with the performance in accordance with the terms and conditions of this Agreement and its Appendices. However, the Government may require the Awardee to cease performance at any time prior to the commencement of any milestone or task. Such notice to cease performance must be from the AO and be in writing, of which email is an acceptable form.

The Parties acknowledge that the nature of this Prototype Project requires flexibility and the ability to react to changing circumstances. Although the Statement of Work

sets the scope for activities the Government may require under this Agreement, it is not intended to, and does not, prescribe with specificity each task that Awardee will perform.

## Appendix C
## Key Personnel

**1. Awardee's Organization and Key Personnel.**

a. The Awardee's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the Agreement and its integrity shall be maintained for the duration of the effort.

b. Any key personnel specified in this agreement are considered to be essential to work performance. At least thirty (30) calendar days prior to the Awardee voluntarily diverting any of the specified individuals to other programs or contracts the Awardee shall notify the Agreements Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the Agreement (including, when applicable, Human Subjects Testing requirements). If the employee of the Awardee is terminated for cause or separates from the Awardee voluntarily with less than thirty (30) calendar-day notice, the Awardee shall provide the maximum notice practicable under the circumstances. The Awardee shall not divert, replace, or announce any such change to key personnel without the written consent of the Agreements Officer. The Agreement will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The key personnel are listed in Appendix C. The requirements of this Appendix C are intended to be read in combination with the requirements of Article 3, Sections C and D.

**Table 2: Key Personnel**
**Summary**

(b) (6)

[redacted]

## Appendix D
## Government Property

Government Property: "Government Property" means any property (i) furnished by the Government and facilitating performance of this Agreement, (ii) acquired by the Awardee under cost reimbursement terms of this Agreement, or (iii) acquired by the Awardee under fixed price terms of this Agreement (FP-GP) if specifically identified in this Government Property Appendix. Except for commercial off the shelf software and licenses thereto, Government Property does not include intellectual property and software. The Government owns and holds title to all Government Property.

The Government shall deliver to the Awardee any Government Property required to be furnished as described in this Agreement together with related data and information needed for its intended use. The delivery and/or performance dates specified in this Agreement are based upon the expectation that the Government-furnished property will be suitable for performance and will be delivered to the Awardee by the dates stated in the Agreement. If not so suitable, the Awardee shall give timely written request to the OTAO who will advise the Awardee on a course of action to remedy the problem.

FPGP includes: [Mark N/A if none]:

| |
|---|
| Reference Government provided spreadsheet maintained by the Awardee and incorporated into the agreement upon approval by the OTAO. |

The Awardee shall have, initiate and maintain a system of internal controls to manage, control, use, preserve, protect, repair, account for and maintain Government Property in its possession and shall initiate and maintain the processes, systems, procedures, records required control and maintain accountability of Government Property. The Awardee shall include this clause in all subAwards under which Government Property comes into the possession of any subawardee. Unless otherwise provided for in this Agreement or approved by the OTAO, the Awardee shall not: (i) use Government Property for any purpose other than to fulfill the requirements of this Agreement, or (ii) alter the Government Property.

The Awardee shall establish and implement property management plans, systems, and procedures regarding its acquisition of Government Property, its receipt of Government Property, in addition to, the status, dates furnished or acquired, identification, quantity, cost, marking, date placed in service, location, inventory and disposition of Government Property, to include a reporting process for all discrepancies, loss of Government Property, physical inventory results, audits and self-assessments, corrective actions, and other property related reports as directed by the OTAO.

Upon conclusion or termination of the Agreement, the Awardee shall submit a request in writing to the OTAO, for disposition/disposal instructions and shall store Government Property not to exceed 120 days pending receipt of such instructions. Storage shall be at no additional cost to the Government unless otherwise noted in the Agreement. The Government, upon written notice to

the Awardee, may abandon any Government Property in place, at which time all obligations of the Government regarding such Government Property shall cease.

**Awardee Liability for Government Property**. "Loss of Government Property" means the loss, damage or destruction to Government Property reducing the Government's expected economic benefits of the property and includes loss of accountability but does not include planned and purposeful destructive testing, obsolescence, reasonable wear and tear or manufacturing defects. THE AWARDEE SHALL BE LIABLE FOR LOSS OF GOVERNMENT PROPERTY IN AWARDEE'S POSSESSION, EXCEPT WHEN ANY ONE OF THE FOLLOWING APPLIES: (I) OTAO GRANTS RELIEF OF RESPONSIBILITY AND LIABILITY FOR LOSS OF THE PARTICULAR GOVERNMENT PROPERTY; (II) GOVERNMENT PROPERTY IS DELIVERED OR SHIPPED UNDER THE GOVERNMENT'S INSTRUCTIONS AND SHIPPERS; OR (III) GOVERNMENT PROPERTY IS DISPOSED OF IN ACCORDANCE WITH THE GOVERNMENT'S DIRECTIONS.

MODEL AUTHORIZATION FOR FDA TO SHARE NON-PUBLIC INFORMATION WITH THE DEPARTMENT OF DEFENSE

*[To be completed on applicant/sponsor/information-owner letterhead]*

*[FDA Official – e.g., Center or Office Director]*

United States Food and Drug Administration

10903 New Hampshire Avenue

Building __, Room ____

Silver Spring, MD 20993

*[Identify relevant FDA Tracking number – e.g., NDA/ANDA/BLA, EUA/Pre-EUA, master file, etc.)]*

Re: FDA Sharing of Non-Public Information Concerning [*insert name of regulated product(s)*] with Department of Defense (DoD) Partners[1]

On behalf of [*insert name of information owner*], I authorize the United States Food and Drug Administration (FDA) to share with DoD Partners, and with contractors to those Partners, all information concerning the above described product(s) that [*insert name of information owner*] has provided or will provide to FDA or to any other DoD Partner. I understand that those Partners have committed to use such information only for the purposes of the DoD and have committed or are otherwise legally required to maintain the confidentiality of such information (or both), and that contractors to DoD are bound by their contracts to maintain the confidentiality of the information. I understand that the information may contain confidential commercial or financial information or trade secrets within the meaning of 18 USC § 1905, 21 USC § 331(j), and 5 USC § 552(b)(4), that is exempt from public disclosure.

Authorization is given to FDA to share this information without deleting confidential commercial or financial or trade secret information. This authorization shall remain valid unless revoked in writing. As indicated by my signature, I am authorized to provide this consent on behalf of [*insert name of information owner*] and my full name, title, address, telephone number, and facsimile number are set out below for verification.

Sincerely,

[1] DoD Partners include the U.S. Army Medical Research and Materiel Command (USAMRMC), the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), Joint Science and Technology Office (JSTO) of the Defense Threat Reduction Agency (DTRA), the Defense Advanced Research Projects Agency (DARPA), and other DoD entities.

(Signature)

(Printed name)

(Title)

(Address)

(Telephone & Facsimile Numbers)

cc:
Office of Counterterrorism and Emerging Threats (OCET), Office of the Chief Scientist, FDA (EUA.OCET@fda.hhs.gov)
The primary MCM Center, as follows:
For CBER, (Counterterrorism and Medical Countermeasures Staff or CBEREUA@fda.hhs.gov)
For CDER, (Counter-Terrorism and Emergency Coordination Staff or CDEREUA@fda.hhs.gov)
For CDRH, for IVD medical devices, (device@fda.hhs.gov) and for non-IVD medical devices (cdrhemcm@fda.hhs.gov)

## Appendix F

Rigel Pharmaceuticals, Inc. is the sole owner of intellectual property rights, as described below, covering the drug substance fostamatinib, drug products comprising fostamatinib, and methods of making and using such drug substance and drug product. The drug product is currently marketed in the US by Rigel, and in Europe and Canada under license from Rigel, for the treatment of immune thrombocytopenia.

### Patent Properties Owned by Rigel Pharmaceuticals

**Patent Family 1:** *US Patents 7,060,827, 7,803,393, 7,906,644, 10,682,350*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | R. Singh, A. Argade, D. Payan, S. Molineaux, S. Holland, J. Clough, H. Keim, S. Bhamidipati, C. Sylvain, H. Li, A. Rossi |
| **Priority Data** | Continuations from US Patent 7,557,210, claiming priority to 60/353,267, 60/353,333, 60/399,673, 60/434,277 |
| **Earliest Priority Date** | February 1, 2002 |
| **International Application PCT No [Publication Number]** | PCT/US03/03022. [WO/2003/063794] |
| **International Application Filing Date** | January 31, 2003 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers intermediates of Fostamatinib Drug Substance and processes for making such intermediates

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted Expiry |
|---|---|---|---|
| Austria | EP1471915 | Issued | 1/31/2023 |
| Austria | EP2281563 | Issued | 1/31/2023 |
| Australia | 3208931 | Issued | 1/31/2023 |
| Belgium | EP1471915 | Issued | 1/31/2023 |
| Belgium | EP2281563 | Issued | 1/31/2023 |
| Bulgaria | EP1471915 | Issued | 1/31/2023 |
| Bulgaria | EP2281563 | Issued | 1/31/2023 |
| Brazil | PI0307355-6 | Issued | 11/13/2028 |
| Belarus | 12599 | Issued | 1/31/2023 |
| Canada | 2,474,277 | Issued | 1/31/2023 |
| China | ZL03803180.9 | Issued | 1/31/2023 |
| China | ZL201110056352.5 | Issued | 1/31/2023 |
| Cyprus | EP1471915 | Issued | 1/31/2023 |
| Cyprus | EP2281563 | Issued | 1/31/2023 |
| Croatia | P20040684 | Issued | 1/31/2023 |
| Czech Republic | EP1471915 | Issued | 1/31/2023 |
| Czech Republic | EP2281563 | Issued | 1/31/2023 |
| Denmark | EP1471915 | Issued | 1/31/2023 |
| Denmark | EP2281563 | Issued | 1/31/2023 |
| Estonia | EP1471915 | Issued | 1/31/2023 |
| Estonia | EP2281563 | Issued | 1/31/2023 |

| Country | Official No. | Status | Predicted Expiry |
|---|---|---|---|
| Europe | EP1471915 | Granted (validated in AT,BE,BG,CH,CY,CZ,DE,DK,EE,ES,FI,FR,GB,GR,HU,IE,IT,LT,LU,LV,MC,NL,PT,RO,SE,SI,SK,TR | 1/31/2023 |
| Europe | EP2281563 | Granted (validated in AT,BE,BG,CH,CY,CZ,DE,DK,EE,ES,FI,FR,GB,GR,HU,IE,IT,LT,LU,LV,MC,NL,PT,RO,SE,SI,SK,TR | 1/31/2023 |
| Finland | EP1471915 | Issued | 1/31/2023 |
| Finland | EP2281563 | Issued | 1/31/2023 |
| France | EP1471915 | Issued | 1/31/2023 |
| France | EP2281563 | Issued | 1/31/2023 |
| Germany | EP1471915 | Issued | 1/31/2023 |
| Germany | EP2281563 | Issued | 1/31/2023 |
| Greece | EP1471915 | Issued | 1/31/2023 |
| Greece | EP2281563 | Issued | 1/31/2023 |
| Hong Kong | HK 1069538 | Issued | 1/31/2023 |
| Hong Kong | HK1154216 | Issued | 1/31/2023 |
| Hungary | EP1471915 | Issued | 1/31/2023 |
| Hungary | EP2281563 | Issued | 1/31/2023 |
| India | 239514 | Issued | 1/31/2023 |

| Country | Official No. | Status | Predicted Expiry |
|---|---|---|---|
| Ireland | EP1471915 | Issued | 1/31/2023 |
| Ireland | EP2281563 | Issued | 1/31/2023 |
| Israel | 163206 | Issued | 1/31/2023 |
| Israel | 221381 | Issued | 1/31/2023 |
| Italy | EP1471915 | Issued | 1/31/2023 |
| Italy | EP2281563 | Issued | 1/31/2023 |
| Japan | 4658477 | Issued | 1/31/2023 |
| Japan | 5357116 | Issued | 1/31/2023 |
| Latvia | EP1471915 | Issued | 1/31/2023 |
| Latvia | EP2281563 | Issued | 1/31/2023 |
| Lithuania | EP1471915 | Issued | 1/31/2023 |
| Lithuania | EP2281563 | Issued | 1/31/2023 |
| Luxembourg | EP1471915 | Issued | 1/31/2023 |
| Luxembourg | EP2281563 | Issued | 1/31/2023 |
| Monaco | EP1471915 | Issued | 1/31/2023 |
| Monaco | EP2281563 | Issued | 1/31/2023 |
| Mexico | 334572 | Issued | 1/31/2023 |
| Mexico | 341239 | Issued | 1/31/2023 |
| Netherlands | EP1471915 | Issued | 1/31/2023 |
| Netherlands | EP2281563 | Issued | 1/31/2023 |
| New Zealand | 534361 | Issued | 1/31/2023 |
| Norway | 328071 | Issued | 1/31/2023 |
| Poland | 214 988 | Issued | 1/31/2023 |
| Portugal | EP1471915 | Issued | 1/31/2023 |

| Country | Official No. | Status | Predicted Expiry |
|---|---|---|---|
| Portugal | EP2281563 | Issued | 1/31/2023 |
| Romania | EP1471915 | Issued | 1/31/2023 |
| Romania | EP2281563 | Issued | 1/31/2023 |
| Russia | 2343148 | Issued | 1/31/2023 |
| Russia | 2493150 | Issued | 1/31/2023 |
| Serbia | 53367 | Issued | 1/31/2023 |
| Serbia | 54105 | Issued | 1/31/2023 |
| Singapore | 105788 | Issued | 1/31/2023 |
| Singapore | 167664 | Issued | 1/31/2023 |
| Slovenia | EP1471915 | Issued | 1/31/2023 |
| Slovenia | EP2281563 | Issued | 1/31/2023 |
| Slovak Republic | EP1471915 | Issued | 1/31/2023 |
| Slovak Republic | EP2281563 | Issued | 1/31/2023 |
| South Africa | 2004/05979 | Issued | 1/31/2023 |
| South Korea | 10-1037856 | Issued | 1/31/2023 |
| Spain | EP1471915 | Issued | 1/31/2023 |
| Spain | EP2281563 | Issued | 1/31/2023 |
| Sweden | EP1471915 | Issued | 1/31/2023 |
| Sweden | EP2281563 | Issued | 1/31/2023 |
| Switzerland | EP1471915 | Issued | 1/31/2023 |
| Switzerland | EP2281563 | Issued | 1/31/2023 |
| Turkey | EP1471915 | Issued | 1/31/2023 |
| Turkey | EP2281563 | Issued | 1/31/2023 |
| Ukraine | 81758 | Issued | 1/31/2023 |
| United Kingdom | EP1471915 | Issued | 1/31/2023 |

| Country | Official No. | Status | Predicted Expiry |
|---|---|---|---|
| United Kingdom | EP2281563 | Issued | 1/31/2023 |
| United States of America | 7,060,827 | Issued | 4/20/2023 |
| United States of America | 7,906,644 | Issued | 11/21/2024 |
| United States of America | 7,803,939 | Issued | 3/25/2023 |
| United States of America | 10,682,350 | Issued | 11/21/2024 |

**Patent Family 2:** *US Patent 7,122,542 & 7,560,466*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | R. Singh, A. Argade, H. Li, S. Bhamidipati, D. Carroll, C. Sylvain, J. Clough, H. Keim |
| **Priority Data** | 60/572,256, 60/531,598, and 60/491,641 |
| **Earliest Priority Date** | July 30, 2003 |
| **International Application PCT No [Publication Number]** | WO 2005/016893 |
| **International Application Filing Date** | July 30, 2004 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers intermediates useful for making, and the active metabolite of, Fostamatinib Drug Substance

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Australia | 2011200367 | Pending | 7/30/2024 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Austria | EP1656372 | Issued | 7/30/2024 |
| Belarus | 18495 | Issued | 7/30/2024 |
| Belgium | EP1656372 | Issued | 7/30/2024 |
| Bulgaria | EP1656372 | Issued | 7/30/2024 |
| Brazil | 0413018-9 | Issued | 7/30/2024 |
| Canada | 2533377 | Issued | 7/30/2024 |
| China | ZL200480022235.5 | Issued | 7/30/2024 |
| Croatia | EP1656372 | Issued | 7/30/2024 |
| Cyprus | EP1656372 | Issued | 7/30/2024 |
| Czech Republic | EP1656372 | Issued | 7/30/2024 |
| Denmark | EP1656372 | Issued | 7/30/2024 |
| Estonia | EP1656372 | Issued | 7/30/2024 |
| Europe | EP1656372 | Granted (validated in AT,BE,BG,CH,CY,CZ,DE,DK,EE,ES,FI,FR,GB,GR,HR,HU,IE,LU,MC,NL,PO,PT,RO,SI,SK,TR | 7/30/2024 |
| Finland | EP1656372 | Issued | 7/30/2024 |
| France | EP1656372 | Issued | 7/30/2024 |
| Germany | EP1656372 | Issued | 7/30/2024 |
| Greece | EP1656372 | Issued | 7/30/2024 |
| Hong Kong | HK1091209 | Issued | 7/30/2024 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Hungary | EP1656372 | Issued | 7/30/2024 |
| India | 259745 | Issued | 7/30/2024 |
| Ireland | EP1656372 | Issued | 7/30/2024 |
| Israel | 173299 | Issued | 7/30/2024 |
| Italy | EP1656372 | Issued | 7/30/2024 |
| Japan | 4886511 | Issued | 7/30/2024 |
| Luxembourg | EP1656372 | Issued | 7/30/2024 |
| Monaco | EP1656372 | Issued | 7/30/2024 |
| Mexico | 307152 | Issued | 7/30/2024 |
| Netherlands | EP1656372 | Issued | 7/30/2024 |
| New Zealand | 545270 | Issued | 7/30/2024 |
| Norway | 333771 | Issued | 7/30/2024 |
| Poland | EP1656372 | Issued | 7/30/2024 |
| Portugal | EP1656372 | Issued | 7/30/2024 |
| Romania | EP1656372 | Issued | 7/30/2024 |
| Russia | 2356901 | Issued | 7/30/2024 |
| Serbia | 53109 | Issued | 7/30/2024 |
| Singapore | 118995 | Issued | 7/30/2024 |
| Singapore | 145698 | Issued | 7/30/2024 |
| Slovak Republic | EP1656372 | Issued | 7/30/2024 |
| Slovenia | EP1656372 | Issued | 7/30/2024 |
| South Korea | 10-1201603 | Issued | 7/30/2024 |
| Spain | EP1656372 | Issued | 7/30/2024 |
| Sweden | EP1656372 | Issued | 7/30/2024 |
| Switzerland | EP1656372 | Issued | 7/30/2024 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Turkey | EP1656372 | Issued | 7/30/2024 |
| Ukraine | 91000 | Issued | 7/30/2024 |
| United Kingdom | EP1656372 | Issued | 7/30/2024 |
| United States of America | 7,122,542 | Issued | 2/12/2025 |
| United States of America | 7,560,466 | Issued | 7/30/2024 |
| South Africa | 2006/01460 | Issued | 7/30/2024 |

**Patent Family 3: Stemming from** *US Patent 7,449,458*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | S. Bhamidipati, R. Singh , V. Stella, T. Sun |
| **Priority Data** | 60/645,424 and 60/654,620 |
| **Earliest Priority Date** | January 19, 2005 |
| **International Application PCT No [Publication Number]** | PCT/US06/01945 [WO2006078846] |
| **International Application Filing Date** | January 19, 2006 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers Fostamatinib Drug Substance, specifically and generically, as well as methods of making and using.

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Australia | 2006206458 | Issued | 1/19/2026 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Austria | EP 1856135 | Issued | 1/19/2026 |
| Belarus | 17180 | Issued | 1/19/2026 |
| Belgium | EP 1856135 | Issued | 1/19/2026 |
| Bermuda | 448EP | Registered | 1/19/2026 |
| British Virgin Islands | EP 1856135 | Registered | 1/19/2026 |
| Bulgaria | EP 1856135 | Issued | 1/19/2026 |
| Brazil | PI0606318-7 | Published | 1/19/2026 (10 years from grant) |
| Canada | 2,591,948 | Issued | 1/19/2026 |
| Cayman Islands | EP 1856135 | Registered | 1/19/2026 |
| China | ZL200680002643.3 | Issued | 1/19/2026 |
| Cyprus | EP 1856135 | Issued | 1/19/2026 |
| Czech Republic | EP 1856135 | Issued | 1/19/2026 |
| Denmark | EP 1856135 | Issued | 1/19/2026 |
| Estonia | EP 1856135 | Issued | 1/19/2026 |
| Europe | EP 1856135 | Granted (validated in AT,BE,BG,CH,CY,CZ,DE,DK,EE,ES,FI,FR,GB,GR,HR,HU,IE,IS,LU,MC,NL,LT,LV,PO,PT,RO,SI,SK,TR | 1/19/2026 |
| Fiji | EP 1856135 | Registered | 1/19/2026 |
| Finland | EP 1856135 | Issued | 1/19/2026 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| France | EP 1856135 | Issued | 1/19/2026 |
| Germany | EP 1856135 | Issued | 1/19/2026 |
| Gibraltar | 673 | Registered | 1/19/2026 |
| Greece | EP 1856135 | Issued | 1/19/2026 |
| Grenada | EP 1856135 | Registered | 1/19/2026 |
| Hong Kong | HK1108896 | Issued | 1/19/2026 |
| Hungary | EP 1856135 | Issued | 1/19/2026 |
| Iceland | EP 1856135 | Issued | 1/19/2026 |
| India | 262177 | Issued | 1/19/2026 |
| Ireland | EP 1856135 | Issued | 1/19/2026 |
| Israel | 183890 | Issued | 1/19/2026 |
| Italy | EP 1856135 | Issued | 1/19/2026 |
| Japan | 4,801,096 | Issued | 1/19/2026 |
| Jersey | EP 1856135 | Registered | 1/19/2026 |
| Kiribati | EP 1856135 | Registered | 1/19/2026 |
| Latvia | EP 1856135 | Issued | 1/19/2026 |
| Lithuania | EP 1856135 | Issued | 1/19/2026 |
| Luxembourg | EP 1856135 | Issued | 1/19/2026 |
| Monaco | EP 1856135 | Issued | 1/19/2026 |
| Mexico | 297057 | Issued | 1/19/2026 |
| Mexico | 346822 | Issued | 1/19/2026 |
| Netherlands | EP 1856135 | Issued | 1/19/2026 |
| New Zealand | 555947 | Issued | 1/19/2026 |
| Norway | 339146 | Issued | 1/19/2026 |
| Poland | EP 1856135 | Issued | 1/19/2026 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Portugal | EP 1856135 | Issued | 1/19/2026 |
| Romania | EP 1856135 | Issued | 1/19/2026 |
| Russia | 2416616 | Issued | 1/19/2026 |
| Singapore | 133812 | Issued | 1/19/2026 |
| Singapore | 167710 | Issued | 1/19/2026 |
| Slovak Republic | EP 1856135 | Issued | 1/19/2026 |
| Slovenia | EP 1856135 | Issued | 1/19/2026 |
| South Africa | 2007/05410 | Issued | 1/19/2026 |
| South Korea | 10-1278397 | Issued | 1/19/2026 |
| Spain | EP 1856135 | Issued | 1/19/2026 |
| Sweden | EP 1856135 | Issued | 1/19/2026 |
| Switzerland | EP 1856135 | Issued | 1/19/2026 |
| Turkey | EP 1856135 | Issued | 1/19/2026 |
| Turks & Caicos | EP 1856135 | Registered | 1/19/2026 |
| Ukraine | 91210 | Issued | 1/19/2026 |
| United Kingdom | EP 1856135 | Issued | 1/19/2026 |
| United States of America | 7,449,458 | Issued | 9/4/2026 |
| United States of America | 7,538,108 | Issued | 3/28/2026 |
| United States of America | 7,563,892 | Issued | 6/17/2026 |
| United States of America | 7,989,448 | Issued | 6/12/2026 |
| United States of America | 8,211,889 | Issued | 1/19/2026 |
| United States of America | 10,577,381 | Issued | 1/19/2026 |
| United States of America | US-2020-0270271-A1 | Published | 1/19/2026 |

**Patent Family 4: Stemming from** *US Patent 8,163,902*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | S. Bhamidipati, R. Singh , T. Sun, E. Masuda |
| **Priority Data** | 60/866,722 |
| **Earliest Priority Date** | November 21,2006 |
| **International Application PCT No [Publication Number]** | PCT/US2007/085313 [WO/2008/064274] |
| **International Application Filing Date** | November 20, 2007 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers Fostamatinib Drug Substance crystal and oral dosage forms..

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Canada | 2673137 | Issued | 11/20/2027 |
| Denmark | EP2078026 | Issued | 11/20/2027 |
| Europe | EP2078026 | Granted (validated in CH,DE,DK, ES,FR,GB,I E,LU,NL | 11/20/2027 |
| France | EP2078026 | Issued | 11/20/2027 |
| Germany | EP2078026 | Issued | 11/20/2027 |
| Hong Kong | 1133257B | Issued | 11/20/2027 |
| Ireland | EP2078026 | Issued | 11/20/2027 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Italy | EP2078026 | Issued | 11/20/2027 |
| Japan | 5264759 | Issued | 11/20/2027 |
| Luxembourg | EP2078026 | Issued | 11/20/2027 |
| Netherlands | EP2078026 | Issued | 11/20/2027 |
| Spain | EP2078026 | Issued | 11/20/2027 |
| Sweden | EP2078026 | Issued | 11/20/2027 |
| Switzerland | EP2078026 | Issued | 11/20/2027 |
| United Kingdom | EP2078026 | Issued | 11/20/2027 |
| United States of America | 8,163,902 | Issued | 6/17/2026 |
| United States of America | 8,445,485 | Issued | 6/17/2026 |
| United States of America | 7,563,892 | Issued | 6/17/2026 |
| United States of America | 9,737,554 | Issued | 6/17/2026 |

**Patent Family 5: Stemming from** *US Patent 8.263.112*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | T. Sun and R. Lo |
| **Priority Data** | 60/986,237 |
| **Earliest Priority Date** | November 7, 2007 |
| **International Application PCT No [Publication Number]** | PCT/US08/082618 [WO2009/061909] |
| **International Application Filing Date** | November 6, 2008 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers Fostamatinib Drug Substance formulations and methods of formulating.

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Albania | EP2217241 | Issued | 11/6/2028 |
| Australia | 2008323938 | Issued | 11/6/2028 |
| Austria | EP2217241 | Issued | 11/6/2028 |
| Barbados | 2001/1533 | pending | 11/6/2028 |
| Belgium | EP2217241 | Issued | 11/6/2028 |
| Bermuda | 448EP | Registered | 1/19/2026 |
| Bosnia | EP2217241 | Issued | 11/6/2028 |
| Bulgaria | EP2217241 | Issued | 11/6/2028 |
| Brazil | PI0820389A2 | Published | 11/6/2028 (10 years from grant) |
| Canada | 2,704,474 | Issued | 11/6/2028 |
| Croatia | EP2217241 | Issued | 11/6/2028 |
| Cyprus | EP2217241 | Issued | 11/6/2028 |
| Czech Republic | EP2217241 | Issued | 11/6/2028 |
| Denmark | EP2217241 | Issued | 11/6/2028 |
| Estonia | EP2217241 | Issued | 11/6/2028 |
| Eurasian Patent | 020210 | Issued | 11/6/2028 |
| Europe | EP2217241 | Granted (validated in AL,AT,BA, BE,BG,CH, CY,CZ,DE, DK,EE,ES,F I,FR,GB,GR, | 11/6/2028 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| | | HR,HU,IE,IS,IT,LU,MC,MK,MT,NL,LT,LV,PO,PT,RO,SI,SK,TR | |
| Finland | EP2217241 | Issued | 11/6/2028 |
| France | EP2217241 | Issued | 11/6/2028 |
| Germany | EP2217241 | Issued | 11/6/2028 |
| Greece | EP2217241 | Issued | 11/6/2028 |
| Guatemala | A-2010-000135 | Published | 11/6/2028 |
| Hong Kong | HK10110227.2 | Issued | 11/6/2028 |
| Hungary | EP2217241 | Issued | 11/6/2028 |
| Iceland | EP2217241 | Issued | 11/6/2028 |
| India | 278101 | Issued | 11/6/2028 |
| Indonesia | IDP000048679 | Issued | 11/6/2028 |
| Ireland | EP2217241 | Issued | 11/6/2028 |
| Israel | 205204 | Issued | 11/6/2028 |
| Italy | EP2217241 | Issued | 11/6/2028 |
| Japan | 5567487 | Issued | 11/6/2028 |
| Latvia | EP2217241 | Issued | 11/6/2028 |
| Liechtenstein | EP2217241 | Issued | 11/6/2028 |
| Lithuania | EP2217241 | Issued | 11/6/2028 |
| Luxembourg | EP2217241 | Issued | 11/6/2028 |
| Malaysia | MY-169761-A | Issued | 11/6/2028 |
| Malta | EP2217241 | Issued | 11/6/2028 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Monaco | EP2217241 | Issued | 11/6/2028 |
| North Macedonia | EP2217241 | Issued | 11/6/2028 |
| Mexico | 309713 | Issued | 11/6/2028 |
| Netherlands | EP2217241 | Issued | 11/6/2028 |
| New Zealand | 585913 | Issued | 11/6/2028 |
| Norway | EP2217241 | Issued | 11/6/2028 |
| Poland | EP2217241 | Issued | 11/6/2028 |
| Portugal | EP2217241 | Issued | 11/6/2028 |
| Romania | EP2217241 | Issued | 11/6/2028 |
| Russia | 2416616 | Issued | 1/19/2026 |
| Serbia | EP2217241 | Issued | 11/6/2028 |
| Singapore | 185961 | Issued | 11/6/2028 |
| Slovak Republic | EP2217241 | Issued | 11/6/2028 |
| Slovenia | EP2217241 | Issued | 11/6/2028 |
| South Africa | 2010/02918 | Issued | 11/6/2028 |
| South Korea | 10-1663838 | Issued | 11/6/2028 |
| Spain | EP2217241 | Issued | 11/6/2028 |
| Sweden | EP2217241 | Issued | 11/6/2028 |
| Switzerland | EP2217241 | Issued | 11/6/2028 |
| Turkey | EP2217241 | Issued | 11/6/2028 |
| Trinidad & Tobago | TT/A/2010/00075 | Pending | 11/6/2028 |
| Ukraine | 102825 | Issued | 11/6/2028 |
| United Kingdom | EP2217241 | Issued | 11/6/2028 |
| United States of America | 8,263,122 | Issued | 11/24/2030 |
| United States of America | 8,372,415 | Issued | 11/6/2028 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| United States of America | 8,652,492 | Issued | 11/6/2028 |
| Vietnam | 14296 | Issued | 11/6/2028 |

**Patent Family 6: Stemming from** *US Patent 8,299,242*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | U. Felfer, K-H. Giselbrecht and M. Wolberg |
| **Priority Data** | 61/270,073 |
| **Earliest Priority Date** | July 2, 2009 |
| **International Application PCT No [Publication Number]** | PCT/US2010/040792 [WO2011/002999A1] |
| **International Application Filing Date** | July 1, 2010 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers Fostamatinib Drug Substance processes for preparing and formulations.

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Albania | EP2448950 | Issued | 7/1/2030 |
| Australia | 2010266213 | Issued | 7/1/2030 |
| Austria | EP2448950 | Issued | 7/1/2030 |
| Belgium | EP2448950 | Issued | 7/1/2030 |
| Bosnia | EP2448950 | Issued | 7/1/2030 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Bulgaria | EP2448950 | Issued | 7/1/2030 |
| Brazil | BRPI1011888A2 | Published | 7/1/2030 (10 years from grant) |
| Canada | 2,766,801 | Issued | 7/1/2030 |
| China | ZL 201080039108.1 | Issued | 7/1/2030 |
| Croatia | EP2448950 | Issued | 7/1/2030 |
| Cyprus | EP2448950 | Issued | 7/1/2030 |
| Czech Republic | EP2448950 | Issued | 7/1/2030 |
| Denmark | EP2448950 | Issued | 7/1/2030 |
| Estonia | EP2448950 | Issued | 7/1/2030 |
| Eurasian Patent | 021657 | Issued | 7/1/2030 |
| Europe | EP2448950 | Granted (validated in AL,AT,BA, BE,BG,CH, CY,CZ,DE, DK,EE,ES,F I,FR,GB,GR, HR,HU,IE,IS ,IT,LU,MC, MK,MT,NL, LT,LV,PO,P T,RO,SI,SK, TR | 7/1/2030 |
| Finland | EP2448950 | Issued | 7/1/2030 |
| France | EP2448950 | Issued | 7/1/2030 |
| Germany | EP2448950 | Issued | 7/1/2030 |
| Greece | EP2448950 | Issued | 7/1/2030 |
| Hong Kong | 1169996B | Issued | 7/1/2030 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Hungary | EP2448950 | Issued | 7/1/2030 |
| Iceland | EP2448950 | Issued | 7/1/2030 |
| India | 296496 | Issued | 7/1/2030 |
| Ireland | EP2448950 | Issued | 7/1/2030 |
| Italy | EP2448950 | Issued | 7/1/2030 |
| Japan | 5739882 | Issued | 7/1/2030 |
| Latvia | EP2448950 | Issued | 7/1/2030 |
| Lithuania | EP2448950 | Issued | 7/1/2030 |
| Luxembourg | EP2448950 | Issued | 7/1/2030 |
| Macedonia | EP2448950 | Issued | 7/1/2030 |
| Malta | EP2448950 | Issued | 7/1/2030 |
| Monaco | EP2448950 | Issued | 7/1/2030 |
| Montenegro | EP2448950 | Issued | 7/1/2030 |
| North Macedonia | EP2448950 | Issued | 7/1/2030 |
| Netherlands | EP2448950 | Issued | 7/1/2030 |
| Norway | EP2448950 | Issued | 7/1/2030 |
| Poland | EP2448950 | Issued | 7/1/2030 |
| Portugal | EP2448950 | Issued | 7/1/2030 |
| Romania | EP2448950 | Issued | 7/1/2030 |
| San Marino | EP2448950 | Issued | 7/1/2030 |
| Serbia | EP2448950 | Issued | 7/1/2030 |
| Singapore | 176799 | Issued | 7/1/2030 |
| Slovak Republic | EP2448950 | Issued | 7/1/2030 |
| Slovenia | EP2448950 | Issued | 7/1/2030 |
| Spain | EP2448950 | Issued | 7/1/2030 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Sweden | EP2448950 | Issued | 7/1/2030 |
| Switzerland | EP2448950 | Issued | 7/1/2030 |
| Turkey | EP2448950 | Issued | 7/1/2030 |
| Ukraine | 108077 | Issued | 7/1/2030 |
| United Kingdom | EP2448950 | Issued | 7/1/2030 |
| United States of America | 8,299,242 | Issued | 7/1/2030 |
| United States of America | 8,481,724 | Issued | 7/1/2030 |
| United States of America | 8,691,798 | Issued | 7/1/2030 |

**Patent Family 7: Stemming from** *US Patent 8,771,648*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | B. Gururajan, F.A.K Alhusban, I.P Gabbott, D. Bradley, B. Simpson and D. Sievwright |
| **Priority Data** | 61/512,621 |
| **Earliest Priority Date** | July 28, 2011 |
| **International Application PCT No [Publication Number]** | PCT/GB2012/051791 [WO2013/014454 A1] |
| **International Application Filing Date** | July 26, 2012 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers Fostamatinib Drug Product unit dosage formulations.

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Albania | EP2736487 | Issued | 7/26/2032 |
| Australia | 2012288632 | Issued | 7/26/2032 |
| Austria | EP2736487 | Issued | 7/26/2032 |
| Belgium | EP2736487 | Issued | 7/26/2032 |
| Bulgaria | EP2736487 | Issued | 7/26/2032 |
| Brazil | BR112014001999A2 | Published | 7/26/2032 (10 years from grant) |
| Canada | 2,843,138 | Issued | 7/26/2032 |
| China | ZL 201280046605.3 | Issued | 7/26/2032 |
| Croatia | EP2736487 | Issued | 7/26/2032 |
| Cyprus | EP2736487 | Issued | 7/26/2032 |
| Czech Republic | EP2736487 | Issued | 7/26/2032 |
| Denmark | EP2736487 | Issued | 7/26/2032 |
| Estonia | EP2736487 | Issued | 7/26/2032 |
| Eurasian Patent | 0028432 | Issued | 7/26/2032 |
| Europe | EP2736487 | Granted (validated in AL,AT,BA, BE,BG,CH, CY,CZ,DE, DK,EE,ES,F I,FR,GB,GR, HR,HU,IE,IS ,IT,LU,MC, MK,MT,NL, LT,LV,PO,P T,RO,SI,SK, TR | 7/26/2032 |
| Finland | EP2736487 | Issued | 7/26/2032 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| France | EP2736487 | Issued | 7/26/2032 |
| Germany | EP2736487 | Issued | 7/26/2032 |
| Greece | EP2736487 | Issued | 7/26/2032 |
| Hong Kong | 1198741B | Issued | 7/26/2032 |
| Hungary | EP2736487 | Issued | 7/26/2032 |
| Iceland | EP2736487 | Issued | 7/26/2032 |
| Ireland | EP2736487 | Issued | 7/26/2032 |
| Italy | EP2736487 | Issued | 7/26/2032 |
| Jamaica | 18/1/5318 | Pending | 7/26/2032 |
| Japan | 6019116 | Issued | 7/26/2032 |
| Latvia | EP2736487 | Issued | 7/26/2032 |
| Liechtenstein | EP2736487 | Issued | 7/26/2032 |
| Lithuania | EP2736487 | Issued | 7/26/2032 |
| Luxembourg | EP2736487 | Issued | 7/26/2032 |
| Malta | EP2736487 | Issued | 7/26/2032 |
| Mexico | 339685 | Issued | 7/26/2032 |
| Monaco | EP2736487 | Issued | 7/26/2032 |
| Montenegro | EP2736487 | Issued | 7/26/2032 |
| North Macedonia | EP2736487 | Issued | 7/26/2032 |
| Netherlands | EP2736487 | Issued | 7/26/2032 |
| Norway | EP2736487 | Issued | 7/26/2032 |
| Pakistan | 490/2012 | Pending | 7/26/2032 |
| Panama | 89809-01 | Issued | 7/26/2032 |
| Poland | EP2736487 | Issued | 7/26/2032 |
| Portugal | EP2736487 | Issued | 7/26/2032 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Romania | EP2736487 | Issued | 7/26/2032 |
| San Marino | EP2736487 | Issued | 7/26/2032 |
| Serbia | EP2736487 | Issued | 7/26/2032 |
| Slovak Republic | EP2736487 | Issued | 7/26/2032 |
| Slovenia | EP2736487 | Issued | 7/26/2032 |
| South Korea | 10-2024120 | Issued | 7/26/2032 |
| South Korea | 10-2090440 | Issued | 7/26/2032 |
| Spain | EP2736487 | Issued | 7/26/2032 |
| Sweden | EP2736487 | Issued | 7/26/2032 |
| Switzerland | EP2736487 | Issued | 7/26/2032 |
| Turkey | EP2736487 | Issued | 7/26/2032 |
| Ukraine | 108077 | Issued | 7/1/2030 |
| United Kingdom | EP2736487 | Issued | 7/26/2032 |
| United States of America | 8,771,648 | Issued | 7/27/2032 |
| United States of America | 8,951,504 | Issued | 7/27/2032 |
| Uruguay | UY34223A | Published | 7/26/2032 |
| Venezuela | 931-12 | Pending | 7/26/2032 |

**Patent Family 8: Stemming from** *US Patent 9,388,203*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | B. McKeever, L.J. Diorazio, M.F> Jones, L. Ferris, S.L.M. Janbon, S. Siedlecki, G.H. Churchill and P.A. Crafts |
| **Priority Data** | 61/919,671 |
| **Earliest Priority Date** | December 20, 2013 |
| **International Application PCT No [Publication Number]** | PCT/US2014/071613 [WO2015/095765] |
| **International Application Filing Date** | December 19, 2014 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers process for making Fostamatinib Drug Substance.

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Albania | EP3083648 | Issued | 12/19/2034 |
| Australia | 2012288632 | Issued | 7/26/2032 |
| Austria | EP3083648 | Issued | 12/19/2034 |
| Belgium | EP3083648 | Issued | 12/19/2034 |
| Bosnia | EP3083648 | Issued | 12/19/2034 |
| Bulgaria | EP3083648 | Issued | 12/19/2034 |
| Canada | CA2898644A1 | Published | 12/19/2034 |
| China | ZL201480069979.6 | Issued | 12/19/2034 |
| Croatia | EP3083648 | Issued | 12/19/2034 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Cyprus | EP3083648 | Issued | 12/19/2034 |
| Czech Republic | EP3083648 | Issued | 12/19/2034 |
| Denmark | EP3083648 | Issued | 12/19/2034 |
| Estonia | EP3083648 | Issued | 12/19/2034 |
| Europe | EP3083648 | Granted (validated in AL,AT,BA, BE,BG,CH, CY,CZ,DE, DK,EE,ES,F I,FR,GB,GR, HR,HU,IE,IS ,IT,LU,MC, MK,MT,NL, LT,LV,PO,P T,RO,SI,SK, TR | 12/19/2034 |
| Finland | EP3083648 | Issued | 12/19/2034 |
| France | EP3083648 | Issued | 12/19/2034 |
| Germany | EP3083648 | Issued | 12/19/2034 |
| Greece | EP3083648 | Issued | 12/19/2034 |
| Hong Kong | 1229336B | Issued | 12/19/2034 |
| Hungary | EP3083648 | Issued | 12/19/2034 |
| Iceland | EP3083648 | Issued | 12/19/2034 |
| Ireland | EP3083648 | Issued | 12/19/2034 |
| Italy | EP3083648 | Issued | 12/19/2034 |
| Japan | 6522005 | Issued | 12/19/2034 |
| Latvia | EP3083648 | Issued | 12/19/2034 |

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| Liechtenstein | EP3083648 | Issued | 12/19/2034 |
| Lithuania | EP3083648 | Issued | 12/19/2034 |
| Luxembourg | EP3083648 | Issued | 12/19/2034 |
| Malta | EP3083648 | Issued | 12/19/2034 |
| Monaco | EP3083648 | Issued | 12/19/2034 |
| Montenegro | EP3083648 | Issued | 12/19/2034 |
| North Macedonia | EP3083648 | Issued | 12/19/2034 |
| Netherlands | EP3083648 | Issued | 12/19/2034 |
| Norway | EP3083648 | Issued | 12/19/2034 |
| Poland | EP3083648 | Issued | 12/19/2034 |
| Portugal | EP3083648 | Issued | 12/19/2034 |
| Romania | EP3083648 | Issued | 12/19/2034 |
| San Marino | EP3083648 | Issued | 12/19/2034 |
| Serbia | EP3083648 | Issued | 12/19/2034 |
| Slovak Republic | EP3083648 | Issued | 12/19/2034 |
| Slovenia | EP3083648 | Issued | 12/19/2034 |
| Spain | EP3083648 | Issued | 12/19/2034 |
| Sweden | EP3083648 | Issued | 12/19/2034 |
| Switzerland | EP3083648 | Issued | 12/19/2034 |
| Turkey | EP3083648 | Issued | 12/19/2034 |
| United Kingdom | EP3083648 | Issued | 12/19/2034 |
| United States of America | 9,388,203 | Issued | 12/19/2034 |
| United States of America | 9,695,204 | Issued | 12/19/2034 |

**Patent Family 9: Stemming from** *US Patent Application US-2020-0377518-A*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | E. Masuda |
| **Priority Data** | 62/853,937 |
| **Earliest Priority Date** | May 29, 2019 |
| **International Application PCT No [Publication Number]** | PCTUS2020/035383 [not yet published] |
| **International Application Filing Date** | May 29, 2020 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers method for using Fostamatinib Drug Product to prevent thrombosis.

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| United States of America | US-2020-0377518-A1 | Published | 05/29/2040 |

**Patent Family 10: Stemming from** *PCT Patent Application PCT/US2020/046060A*

| | |
|---|---|
| **Owner** | Rigel Pharmaceuticals, Inc. |
| **Inventors** | V. Taylor, S. Issakani and C. Young |
| **Priority Data** | 62/886,806 |
| **Earliest Priority Date** | August 14, 2019 |
| **International Application PCT No [Publication Number]** | PCT/US2020/046060 [not yet published] |
| **International Application Filing Date** | August 13, 2020 |

### Ownership

This patent family is owned by Rigel Pharmaceuticals.

### Brief Summary of the Invention

Covers method for using Fostamatinib Drug Product genus to prevent or treat cytokine release syndrome.

### Status

The Table below summarizes the status of this patent family.

| Country | Official No. | Status | Predicted expiry |
|---|---|---|---|
| PCT | PCT/US2020/046060 | Pending | August 13, 2040 |

(b) (4) [redacted]


(b) (4)

## Appendix G

**Data Rights:**

| Technical Data or Computer Software to be Furnished with Restrictions | Basis for Assertion | Asserted Rights | Name of Organization Asserting Restrictions |
|---|---|---|---|
| Know-how and documentation associated with the manufacturing of Fostamatinib Drug Substance | Developed exclusively at private expense | Limited Rights | Rigel Pharmaceuticals |
| Know-how and documentation associated with the manufacturing of Fostamatinib Drug Product | Developed exclusively at private expense | Limited Rights | Rigel Pharmaceuticals |
| Documents related to communication with FDA on non-COVID-19 related indications | Developed exclusively at private expense | Limited Rights | Rigel Pharmaceuticals |
| Documents related to communication with FDA on COVID-19 generated prior to contract award. | Developed exclusively at private expense | Limited Rights | Rigel Pharmaceuticals |