Master Collaboration and License Agreement
by and between

MODERNA THERAPEUTICS, INC.

and

MERCK SHARP & DOHME CORP.

January 12, 2015

Master Collaboration and License Agreement

This Master Collaboration and License Agreement (this “Agreement”), dated as of January 12, 2015 (the “Effective Date”), is made by and between Moderna Therapeutics, Inc., a corporation organized and existing under the laws of Delaware (“Moderna”), and Merck Sharp & Dohme Corp., a corporation organized and existing under the laws of New Jersey (“Merck”). Each of Moderna and Merck may be referred to herein as a “Party” or together as the “Parties”.

WHEREAS, Moderna has developed expertise and technology useful for the discovery, development, Manufacture, characterization, or use of pharmaceutical products that function using mRNA;

WHEREAS, Merck is a pharmaceutical company focused on identifying, Developing and Commercializing innovative therapeutic products;

WHEREAS, Moderna and Merck wish to collaborate together to discover and Develop therapeutic and vaccine products using mRNA Constructs, with the goal of identifying or creating Collaboration mRNA Constructs that are suitable for Development and Commercialization by Merck; and

WHEREAS, Moderna is, as of the Effective Date, granting Merck a license under Moderna Technology to Develop, Commercialize and otherwise Exploit certain Product Candidates, Elected Candidates and Products (including [***]), in each case as further described herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Definitions.

The following terms and their correlatives will have the following meanings:

1.1. “AAA” has the meaning set forth in Section 16.1(c).

1.2. “Act” means, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., as such may be amended from time to time.

1.3. “Activity” means [***].

1.4. [***]

1.5. “Affiliate” of a Person means any other Person which (directly or indirectly) is controlled by, controls or is under common control with such Person. A Person will be deemed to “control” another Person if it: (a) with respect to such other Person that is a corporation, owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person, or, with respect to such other Person that is not a corporation, has other comparable ownership interest; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and
policies of such other Person. For the avoidance of doubt, as of the Effective Date, Moderna LLC and Valera LLC are Affiliates of Moderna.

1.6. “Agreement” has the meaning set forth in Recitals.

1.7. “Applicable Field” means, with respect to (a) an R&D Program, the applicable Collaboration Field for such R&D Program, (b) the period prior to the first Regulatory Approval of a Product Candidate, Elected Candidate and Product, the applicable Collaboration Field of the Target Product Profile of such Product Candidate, Elected Candidate and Product, and (c) the period following the first Regulatory Approval of a Product. [***]; provided that, for purposes of this clause (c), [***].

1.8. “Back-Up Elected Candidate” has the meaning set forth in Section 2.10(d)(i).

1.9. “Bankruptcy Code” has the meaning set forth in Section 9.5.

1.10. [***]

1.11. “BLA” means a Biologics License Application filed with the FDA or an equivalent application to any Regulatory Authority (including an NDA or its foreign equivalent) requesting Regulatory Approval for a new product.

1.12. “Business Combination” means with respect to a Party (or its Affiliate), any of the following events: (a) any Third Party (or group of Third Parties acting in concert) acquires (including by way of a tender or exchange offer or issuance by such Party (or its Affiliate)), directly or indirectly, beneficial ownership or a right to acquire beneficial ownership of shares of such Party (or its Affiliate) representing fifty percent (50%) or more of the voting shares (where voting refers to being entitled to vote for the election of directors) then outstanding of such Party (or its Affiliate); (b) such Party (or its Affiliate) consolidates with or merges into another corporation or entity which is a Third Party, or any corporation or entity which is a Third Party consolidates with or merges into such Party (or its Affiliate), in either event pursuant to a transaction in which more than fifty percent (50%) of the voting shares of the acquiring or resulting entity outstanding immediately after such consolidation or merger is not held by the holders of the outstanding voting shares of such Party (or its Affiliate) immediately preceding such consolidation or merger; or (c) such Party (or its Affiliate) sells, transfers, leases or otherwise disposes of all or substantially all of the assets to which this Agreement relates to a Third Party.

1.13. “Business Day” means any day other than a Saturday or Sunday on which banking institutions in New York, NY are open for business.

1.14. “Calendar Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (i) the first Calendar Quarter of this Agreement shall commence on the Effective Date and end at the end of the Calendar Quarter in which the Effective Date occurs and (ii) the last Calendar Quarter of this Agreement shall commence at the commencement of such Calendar Quarter and end on the date of expiration or termination of this Agreement.

1.15. “Calendar Year” means each twelve (12)-month period beginning on January 1, 2015 and each subsequent anniversary thereof; provided, however, that (i) the first Calendar Year of this Agreement shall commence on the Effective Date and end on December 31 of the same year and (ii) the last Calendar Year of this Agreement shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of expiration or termination of this Agreement.

1.16. “cGMP” means the then current good manufacturing practices, standards, guidelines and regulations promulgated and published by FDA, European Medicines Agency and/or any other applicable Regulatory Authorities having jurisdiction over the Manufacture of Moderna mRNA API (or Drug Product) or the Development or sale of any Product containing such Moderna mRNA API (or Drug Product), as applicable, relating to the testing, manufacturing, processing, packaging, holding or distribution of drug substances and finished drugs including any standards, guidelines and regulations as promulgated by, as applicable: (i) the FDA under and in accordance with the U.S. Federal Food, Drug and Cosmetic Act and Title 21, Parts 210 and 211 of the U.S. Code of Federal Regulations; (ii) the EMA and the EU Commission under European Directive 2003/94/EC; and/or (iii) the ICH Harmonised Tripartite Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients (ICH Q7), as such standards, guidelines and regulations may be amended from time to time.

1.17. “Clinical Data” means all information with respect to a Collaboration mRNA Construct, Product Candidate, Elected Candidate or Product made, collected or otherwise generated under or in connection with
clinical studies for such Collaboration mRNA Construct, Product Candidate, Elected Candidate or Product, including any data, reports and results with respect thereto.

1.18. “Clinical Supply Agreement” has the meaning set forth in Section 4.2.

1.19. “Code” has the meaning set forth in Section 2.16(d).

1.20. “Collaboration Activities” means the collaborative program of activities for the Development of Collaboration mRNA Constructs and Product Candidates that is engaged in by or on behalf of the Parties under this Agreement during the Collaboration Term, including [***].

1.21. “Collaboration Fields” means the [***], the RSV Field, the [***] and the [***].

1.22. “Collaboration Know-How” means all Know-How conceived, discovered, developed or otherwise made by or on behalf of a particular Party or any of its Affiliates or permitted subcontractors of any of the foregoing (solely or jointly by or on behalf of a particular Party or any of its Affiliates or permitted subcontractors of any of the foregoing) in the course of [***].

1.23. “Collaboration mRNA Constructs” means [***].

1.24. “Collaboration Pathogens” means [***] and RSV.

1.25. “Collaboration Patents” means any and all Patents that claim or cover any of the Collaboration Know-How.

1.26. “Collaboration Technology” means [***].

1.27. “Collaboration Term” means, collectively, the R&D Term and the Post-R&D Period.

1.28. “Combination Product” means a Product which includes one or more active ingredients other than an Elected Candidate. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be “active ingredients”, except in the case where such delivery vehicle, adjuvant, or excipient is recognized as an active ingredient in accordance with 21 C.F.R. 210.3(b)(7). All references to Product in this Agreement shall be deemed to include Combination Product, provided that the licenses granted to Merck herein apply only with respect to those mRNA Constructs which are Collaboration mRNA Constructs, as incorporated in Products Candidates or Elected Candidates, and not to any other mRNA Constructs.

1.29. “Commencement” means, with respect to a clinical study for a product, [***] in such clinical study.

1.30. “Commercialization” means any and all activities related to the import, export, marketing, detailing, promotion, distribution and/or sale of a pharmaceutical or vaccine product in a country or region in the Territory. When used as a verb, “to Commercialize” and “Commercializing” means to engage in Commercialization, and “Commercialized” has a corresponding meaning. [***]

1.31. “Commercially Reasonable Efforts” means with respect to the efforts to be expended by a Party with respect to any objective, [***].

1.32. “Competitive Infringement” means [***].

1.33. “Competitive TPP” means a TPP proposed by Merck in accordance with Section 2.9 that is [***].

1.34. “Confidentiality Agreement” means the Mutual Confidential Disclosure Agreement between the Parties made effective as of February 27, 2013 (as amended on February 5, 2014).

1.35. “Confidential Information” has the meaning set forth in Section 12.1(a).

1.36. [***]

1.37. [***]

1.38. [***]

1.39. [***]

1.40. “Control” or “Controlled” means, with respect to any Know-How or Patent, the possession (whether by ownership, license or sublicense, other than by a license, sublicense or other right granted (but not assignment) pursuant to this Agreement) by a Party (or its Affiliate) of
the ability to assign or grant to the other Party the licenses, sublicenses or rights to access and use such Know-How or Patent as provided for in this Agreement, without violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party would be required hereunder to grant such license, sublicense, or rights of access and use, provided that Know-How and Patents that are licensed to Moderna pursuant to a Moderna In-License are not “Controlled” for purposes of this Agreement unless and only after such Moderna In-License is deemed to be a Moderna Collaboration In-License pursuant to Section 7.

1.41. [***]
1.42. [***]

1.43. “Development” means any and all research, preclinical and clinical drug development activities, including all activities relating to the identification of mRNA Constructs, the testing of mRNA Constructs, test method development and stability testing, toxicology, formulation, process development, qualification and validation, Manufacture scale-up, development-stage Manufacturing, quality assurance/quality control, holding/keeping (whether for disposal or otherwise), clinical studies, statistical analysis and report writing, the preparation and submission of Regulatory Filings, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise required or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval, and “Develop”, “Developed” and “Developing” will have corresponding meanings. For clarity, (a) “Development” excludes [***] and (b) with respect to a Product, Development shall include modifying, enhancing and/or improving such Product (e.g., changing dosage, formulation, etc.) provided that such modification, enhancement and/or improvement does not change the Collaboration mRNA Construct(s) in such Product.

1.44. “Development Milestone Product” has the meaning set forth in Section 8.4(a).
1.45. “Disclosing Party” has the meaning set forth in Section 12.1(a).
1.46. “Discontinued mRNA Construct” means any Collaboration mRNA Construct that has by any of the terms of this Agreement become a “Discontinued mRNA Construct”.
1.47. “Discontinued Program” means any R&D Program that has by any of the terms of this Agreement become a “Discontinued Program”.
1.48. “Discontinued Target” means any Target that has by any of the terms of this Agreement become a “Discontinued Target”.
1.49. “Disputes” has the meaning set forth in Section 16.1(a).

1.50. “Distributor” means any Person, other than a Sublicensee or an Affiliate of Merck, in one or more countries in the Territory that (a) purchases Product from Merck, its Affiliates or Sublicensees for such country(ies), (b) assumes responsibility from Merck for all or a portion of the Commercialization of such Product in such country(ies), and (c) sells Product in such country(ies).

1.51. “DMF” means any drug master file filed with the FDA, and any equivalent filing in other countries or regulatory jurisdictions.
1.52. “Drug Product” means [***].
1.53. [***]
1.54. “Effective Date” has the meaning set forth in the Preamble.
1.55. “Elected Candidate” means a Product Candidate for which Merck has issued an “Elected Candidate Notice” pursuant to Section 2.10(a) or “Replacement Notice” pursuant to Section 2.10(d), including [***].
1.56. “Elected Candidate Cap” has the meaning set forth in Section 2.10(a).
1.57. “Elected Candidate Notice” has the meaning set forth in Section 2.10(a).
1.58. “EMA” means the Regulatory Authority known as the European Medicines Agency and any successor agency thereto.
1.59. “Environmental, Health and Safety (EHS) Laws” means all applicable environmental and similar Laws, directives, rules, ordinances, codes, guidelines, regulations, governmental, administrative or judicial orders or decrees or other legal requirements of any kind, whether currently in existence or hereafter promulgated, enacted, adopted or amended, relating to (a) safety (including occupational health and safety); conservation, preservation or protection of human health, drinking water, natural resources, biota and the environment; (b) the introduction of any chemical substances, products or finished articles into the stream of commerce; (c) the imposition of any discharge levy or other economic instrument to prevent or reduce discharge of pollutants; (d) the conduct of environmental impact assessment in connection with the design, development and operation of any facility or project; (e) the notification, classifications, registrations and labeling of new chemical substances; or (f) the generation, use, storage, handling, treatment, transportation or disposal of waste, including any matters related to releases and threatened releases of hazardous materials.

1.60. [***]

1.61. “Executive Officer” means, for Moderna, [***], and for Merck, [***]. Either Party may change its Executive Officer upon written notice to the other Party, provided that such replacement individual has decision-making authority on behalf of such Party in respect of this Agreement.

1.62. “Existing Partner” means each of the [***] Development and Commercialization partners of Moderna as of the Effective Date with which Moderna has entered into an Existing Partner Agreement that is in effect as of the Effective Date.

1.63. “Existing Partner Agreements” mean, [***].

1.64. “Existing Partner Fields” means the fields listed on Exhibit D.

1.65. “Exploit” means to make, have made, import, use, sell, or offer for sale, including to Develop, Commercialize, register, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), formulate, have used, export, transport, distribute, promote, market, or have sold or otherwise dispose of, and “Exploiting” and “Exploitation” will have corresponding meanings. [***]

1.66. “FDA” means the United States Food and Drug Administration and any successor agency thereto.

1.67. “FFDCA” means the United States Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.68. “First Commercial Sale” means, with respect to a Product and a country, the first sale for monetary value for use or consumption by the general public of such Product in such country after all required Regulatory Approvals for commercial sale of such Product have been obtained in such country. Sales prior to receipt of Regulatory Approval for such Licensed Product, such as so-called “treatment IND sales,” “named patient sales,” and “compassionate use sales,” shall not be construed as a First Commercial Sale.

1.69. “FTE” means the equivalent of a full-time scientific or technical person’s work time over a twelve (12) month period (including normal vacation, sick days and holidays) devoted to, and directly related to, conducting Collaboration Activities [***] under an R&D Program, [***], in accordance with this Agreement, based on [***] person-hours or greater per year. In the event that an individual devotes less than such full time to conducting Collaboration Activities [***] under an R&D Program, [***] in accordance with this Agreement during such twelve (12) month period, then for purposes of this Agreement, such individual shall only count as a portion of an FTE which shall be determined by dividing the number of full days during the applicable twelve (12) month period devoted to, and directly related to, conducting Collaboration Activities [***] in accordance with this Agreement by the total number of working days during such twelve (12) month period. No individual may be charged at greater than one (1) FTE in a given Calendar Year.

1.70. “FTE Costs” means, (a) with respect to Moderna, the actual FTEs employed by Moderna or its Affiliates in the conduct of any Collaboration Activities [***] pursuant to the [***] and (b) with respect to Merck, the actual FTEs employed by Merck and its Affiliates in the conduct of Collaboration Activities pursuant to [***], in each case ((a) and (b)), multiplied by the FTE Rate, which represents [***].

1.71. “FTE Rate” means [***] per one (1) full FTE per full twelve (12) month Calendar Year; provided, that, starting [***], [***] such rate shall adjust [***] of each Calendar Year by an amount equal to the change, if
any, in [***]. Notwithstanding the foregoing for any Calendar Year during the Term that is less than a full year, the above referenced rate shall be proportionately reduced to reflect such portion of such full Calendar Year.

1.72. “GAAP” means U.S. generally accepted accounting principles or International Financial Reporting Standards, consistently applied, as designated and used by the applicable Party.

1.73. [***]

1.74. “GLP Toxicology Study” means a GLP study of the toxicological effects of a product.

1.75. “Good Laboratory Practice” or “GLP” means the applicable then-current standards for laboratory activities for pharmaceuticals (including biologicals) or vaccines, as applicable, as set forth in the Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with any similar standards of good laboratory practice as are required by any Regulatory Authority having jurisdiction over the applicable activity.

1.76. [***]

1.77. [***]

1.78. “Human Materials” shall have the meaning set forth in Section 2.16(b).

1.79. “[***] Target” means [***].

1.80. “IND” means with respect to a Product Candidate, an Investigational New Drug Application filed with the FDA with respect to such Product Candidate pursuant to 21 C.F.R. § 312 before the commencement of human clinical trials involving such Product Candidate, including all amendments and supplements to such application, or any equivalent filing with any Regulatory Authority outside the United States.

1.81. “Indemnification Claim Notice” has the meaning set forth in Section 14.5(c).

1.82. “Indemnified Party” has the meaning set forth in Section 14.5(c).

1.83. [***]

1.84. [***]

1.85. “Initial R&D Term” has the meaning set forth in Section 2.2(a).

1.86. “In-License Payments” means any amounts payable under any Moderna Collaboration In-License that are incurred by Moderna or its Affiliates as a result of (a) the grant of [***] or (b) the grant of any [***], in each ((a) and (b)) under this Agreement. Any such payments may include [***]. Notwithstanding the foregoing, In-License Payments shall not include any [***].

1.87. “Issuing Party” has the meaning set forth in Section 12.3(c).

1.88. “Joint Know-How” means all Collaboration Know-How that is jointly owned by the Parties in accordance with Section 10.5.

1.89. “Joint Patents” means all Collaboration Patents that are jointly owned by the Parties in accordance with Section 10.5.

1.90. “Joint Technology” means all Collaboration Technology that is jointly owned by the Parties in accordance with Section 10.5.

1.91. “JSC” has the meaning set forth in Section 3.2(a).

1.92. “Know-How” means all non-public technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and Materials, including: biological, chemical, vaccine-related, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality
control data and information, including study designs and protocols, assays, and biological methodology, in all cases, whether or not copyrightable or patentable, in written, electronic or any other form now known or hereafter developed.

1.93. “Knowledge” means with respect to the matter in question, the knowledge of [***].

1.94. “Law” or “Laws” means all laws, statutes, enactments, acts of legislature, rules, regulations, orders, judgments, guidelines, policies, directions, directives, or ordinances having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision of any jurisdiction which are applicable to any of the Parties or their respective Affiliates in carrying out activities hereunder or to which any of the Parties or their respective Affiliates in carrying out the activities hereunder is subject, including the Act and GLPs and cGMPs.

1.95. [***]

1.96. [***]

1.97. “Losses” has the meaning set forth in Section 14.5(a).

1.98. “Manufacturing” means the production, manufacture, synthesis, processing, filling, finishing, packaging, labeling, shipping and holding of product or any intermediate thereof, including process development, process qualification and validation, scale-up, commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control. “Manufacturing” refers to both pre-clinical and clinical Manufacturing for Development, and Manufacturing for Commercialization. “Manufacture” and “Manufactured” will have corresponding meanings. [***]

1.99. “Materials” means any tangible chemical or biological material, including any compounds, DNA and RNA (modified and unmodified), mRNA Constructs, Polypeptides, clones, cells, constructs, vectors, receptors and other nucleic acids, proteins, peptides and any expression product, progeny, derivative or improvement thereto, along with any tangible chemical or biological material embodying any Know-How.

1.100. “Merck” has the meaning set forth in Recitals.

1.101. “Merck Background Know-How” means any and all Know-How Controlled by Merck or its Affiliates as of the Effective Date or as to which Merck or its Affiliates obtains Control during the Collaboration Term that [***], including [***], but in each case [***] excluding any Merck Collaboration Know-How.

1.102. “Merck Collaboration Know-How” means any and all Collaboration Know-How owned by Merck or any of its Affiliates [***], including Merck’s right and interest in any Joint Know-How.

1.103. “Merck Collaboration Patents” means any and all Patents that claim or cover any of the Merck Collaboration Know-How, including Merck’s right and interest in any Joint Patents.


1.105. “Merck Background Know-How” means any and all Know-How Controlled by Merck or its Affiliates as of the Effective Date or as to which Merck or its Affiliates obtains Control during the Collaboration Term that [***], including [***], but in each case [***] excluding any Merck Collaboration Know-How.

1.106. “Merck Business Program” means any and all Business Program Collaborations between Merck and its Affiliates [***], including Merck’s right and interest in any Joint Know-How.

1.107. “Merck Collaboration Patents” means any and all Patents that claim or cover any of the Merck Collaboration Know-How, including Merck’s right and interest in any Joint Patents.

1.108. “Merck Collaboration Technology” means the Merck Collaboration Know-How and the Merck Collaboration Patents. For clarity, all Merck Collaboration Technology will be “Controlled” by Merck for purposes of this Agreement.

1.109. “Merck Election Period” has the meaning set forth in Section 2.11(d).

1.110. “Merck Exclusive Targets” means the Targets identified on Exhibit C.

1.111. [***]

1.112. [***]
1.113. “Merck Indemnitees” has the meaning set forth in Section 14.5(b).

1.114. “Merck In-License” has the meaning set forth in Section 7.8.

1.115. “Merck Program Director” has the meaning set forth in Section 3.1.

1.116. [***]

1.117. “Merck Technology” means collectively, Merck Background Technology and Merck Collaboration Technology.

1.118. “Milestone Event” has the meaning set forth in Section 8.4.

1.119. “Milestone Payment” has the meaning set forth in Section 8.4.

1.120. “Moderna” has the meaning set forth in Recitals.

1.121. “Moderna Acquisition” has the meaning set forth in Section 11.8(a).

1.122. “Moderna Background Know-How” means any and all Know-How Controlled by Moderna or any of its Affiliates as of the Effective Date or as to which Moderna or any of its Affiliates obtains Control during the Term that [***], excluding any Moderna Collaboration Know-How. For the avoidance of doubt, Moderna Background Know-How shall not include any Know-How licensed to Moderna pursuant to a Moderna In-License unless and until such Moderna In-License becomes a Moderna Collaboration In-License pursuant to Section 7.

1.123. “Moderna Background Patents” means those Patents that are Controlled by Moderna or any of its Affiliates as of the Effective Date or as to which Moderna or any of its Affiliates obtains Control during the Term that [***], including those set forth on Schedule 1.123, but excluding [***]. For the avoidance of doubt, Moderna Background Patents shall not include any Patents licensed to Moderna pursuant to a Moderna In-License unless and until such Moderna In-License becomes a Moderna Collaboration In-License pursuant to Section 7.

1.124. “Moderna Background Technology” means Moderna Background Know-How and Moderna Background Patents.

1.125. “Moderna Business Program” has the meaning set forth in Section 11.8(a).

1.126. “Moderna Collaboration In-License” has the meaning set forth in Section 7.4.

1.127. “Moderna Collaboration Know-How” means any and all Collaboration Know-How owned by Moderna or any of its Affiliates [***], including Moderna’s right and interest in any Joint Know-How.

1.128. “Moderna Collaboration Patents” means any and all Patents that claim or cover any of the Moderna Collaboration Know-How, including Moderna’s right and interest in any Joint Patents.

1.129. [***]

1.130. “Moderna Collaboration Technology” means the Moderna Collaboration Know-How and Moderna Collaboration Patents. For clarity, all Moderna Collaboration Technology will be “Controlled” by Moderna for the purpose of this Agreement.

1.131. “Moderna Collaboration Technology In-License” has the meaning set forth in Section 7.2.

1.132. [***].

1.133. [***]

1.134. [***].

1.135. [***]

1.136. [***]
1.137. “Moderna [***] In-License” means an agreement between Moderna (or its Affiliate) and a Third Party [***] pursuant to which a Third Party grants rights or licenses under Patents or Know-How that [***]. Each such agreement is set forth on Schedule 1.137. For clarity, no Moderna [***] In-License will be a Moderna Collaboration In-License until included as such pursuant to Section 7.

1.138. “Moderna [***] In-License” means an agreement between Moderna (or its Affiliate) and a Third Party in effect as of the Effective Date pursuant to which a Third Party grants rights or licenses under any [***]. Each such agreement is set forth on Schedule 1.138.

1.139. [***]

1.140. “Moderna [***] In-License” has the meaning set forth in Section 7.1(b).

1.141. [***]

1.142. “Moderna Indemnitees” has the meaning set forth in Section 14.5(a).

1.143. “Moderna In-License” means a Moderna [***] In-License, a Moderna [***] In-License or a Moderna [***] In-License.

1.144. “Moderna Internal Virology Program” means a program for the Development of mRNA Constructs and associated mRNA Products [***] in the [***]. All Moderna Internal Virology Programs in existence as of the Effective Date are set forth on Schedule 1.144.


1.146. “Moderna mRNA API” means [***].

1.147. “Moderna Patents” means the Moderna Background Patents and Moderna Collaboration Patents.

1.155. “Moderna Program Director” has the meaning set forth in Section 3.1.

1.156. [***]


1.158. “mRNA Construct” means [***].

1.159. [***]

1.160. “mRNA Product” means [***].

1.161. “mRNA Technology” means any Know-How and Patents directed or otherwise pertaining to [***].

1.162. “Net Sales” means the gross invoice price (not including [***]) of Product sold by a Selling Party to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received:

1.164. “New Program” has the meaning set forth in Section 11.8(b).

1.165. “Non-cGMP Construct Cap” has the meaning set forth in Section 4.1(b)(i).

1.166. “non-cGMP Order Form” has the meaning set forth in Section 4.1(a).

1.175. “Out-of-Pocket Costs” means costs and expenses paid [***] to Third Parties by [***], all in accordance with the budget set forth in the applicable R&D Plan, Post R&D Plan, [***].

1.176. “Parties” has the meaning set forth in Recitals.

1.177. “Party” has the meaning set forth in Recitals.

1.178. “Patent” means (a) a patent or a patent application, (b) any additions, priority applications, divisions, continuations, and continuations-in-part of any of the foregoing and (c) all patents issuing on any of the foregoing patent applications, together with all invention certificates, substitutions, reissues, reexaminations, registrations, supplementary protection certificates, confirmations, renewals and extensions of any of (a), (b) or (c), and foreign counterparts of any of the foregoing, but not including any rights that give rise to Regulatory
Exclusivity Periods (other than supplementary protection certificates, which will be treated as "Patents" hereunder).

1.179. “Patent Costs” means the reasonable, documented, out-of-pocket costs and expenses paid to outside legal counsel, and filing and maintenance expenses, [***] in Prosecuting and Maintaining Patents.

1.180. “Payment” has the meaning set forth in Section 2.16(e).

1.181. “Person” means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

1.182. “Phase I Clinical Study” means a human clinical study of a product, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, as described in 21 C.F.R. 312.21(a).

1.183. “Phase II Clinical Study” means a human clinical study of a product initiated to determine the safety and efficacy in the target patient population, as described 21 C.F.R. 312.21(b).

1.184. “Phase III Clinical Study” means a human clinical study of a product on a sufficient number of subjects that is designed to establish that such product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such product, as described in 21 C.F.R. 312.21(c).

1.185. [***]

1.186. [***]

1.187. “Polypeptide” means [***].

1.188. “Post-R&D Period” means the period beginning on the expiration of the R&D Term and ending on the earlier to occur of (a) the date on which Merck has properly designated its fifth (5th) Elected Candidate hereunder, (b) if Merck elects to add the R&D Extension Term pursuant to Section 2.2(b), the seventh anniversary of the Effective Date, and (c) if Merck does not elect to add the R&D Extension Term pursuant to Section 2.2(b), the sixth anniversary of the Effective Date, as such period may be extended pursuant to Section 2.8(c).

1.189. “Post R&D Plan” has the meaning set forth in Section 2.14(b).

1.190. “Product” means a pharmaceutical or vaccine product comprised of [***], in all forms, presentations, formulations and dosage forms. For clarity, different forms, presentations, formulations and dosage forms of a given Product (regardless of whether for human beings and/or animals) shall be considered the same Product for the purposes of this Agreement.

1.191. “Product Candidate” means, with respect to Product Candidate Pool, [***].

1.192. “Product Candidate Notice” has the meaning set forth in Section 2.9(d).

1.193. “Product Candidate Pool” means, with respect to a Target Product Profile, all Collaboration mRNA Constructs that are [***].

1.194. “Program Directors” has the meaning set forth in Section 3.1.

1.195. [***].

1.196. “Prosecution and Maintenance” means, with regard to a particular Patent, the preparation, filing, prosecution and maintenance of such Patent, as well as re-examinations, reissues and the like with respect to that Patent, together with the conduct of interferences, the defense of oppositions and other similar proceedings with respect to that Patent.

1.202. “R&D Plan” has the meaning set forth in Section 2.4(a)(i).

1.203. “R&D Polypeptide” means, with respect to an R&D Program, [***].

1.204. “R&D Program” means each collaborative program of Development activities established in accordance with Sections 2.3(a) or 2.7, as applicable, and conducted by or on behalf of the Parties during the
R&D Term in accordance with the terms and conditions of this Agreement, and that is not a Discontinued R&D Program.

1.205. “R&D Program Costs” means all Out-of-Pocket Costs and FTE Costs incurred by Moderna or Merck and their respective Affiliates after the Effective Date directly in connection with the performance of [***].

1.206. “R&D Program Pathogen” means a Collaboration Pathogen or that is the subject of an R&D Program.

1.207. “R&D Program Proposal” has the meaning set forth in Section 2.3(a).

1.208. “R&D Target” means a Merck Exclusive Target that is selected and included in an R&D Program in accordance with Section 2.3(b), and that is not a Discontinued Target.

1.209. “R&D Term” has the meaning set forth in Section 2.2(b).


1.211. “Registrational Study” means, with respect to a given product, any clinical study that is intended to be the basis for initial Regulatory Approval of such product.

1.212. “Regulatory Approval” means, with respect to a country or extra-national territory, any and all approvals (including BLAs), licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market a Product in such country or some or all of such extra-national territory, including any pricing or reimbursement approvals.

1.213. “Regulatory Authority” means any national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, in any jurisdiction in the world, involved in the granting of Regulatory Approval or otherwise involved in regulating the Exploitation of a Product.

1.214. “Regulatory Exclusivity Period” means with respect to a Product in a country, the period of time during which Merck or any of its Sublicensees has been granted the exclusive legal right, other than Patent protection, by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of Law) in such country to market and sell the Product (e.g., pediatric exclusivity, or any applicable data exclusivity).

1.215. “Regulatory Filing” means any submission to a Regulatory Authority, including all applications, registrations, licenses, authorizations and approvals (including Regulatory Approvals), together with any related correspondence and documentation submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to a product and all data contained in any of the foregoing, including all INDs, Drug Approval Applications, regulatory drug lists, advertising and promotion documents, Clinical Data, adverse event files and complaint files, and include any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment thereto.

1.216. “Release” has the meaning set forth in Section 12.3(c).

1.217. “Replacement Notice” has the meaning set forth in Section 2.10(d)(i).

1.218. “Response Notice” has the meaning set forth in Section 2.3(d).

1.219. “Reviewing Party” has the meaning set forth in Section 12.3(c).

1.220. [***]

1.221. [***]

1.222. [***]

1.223. “Royalty Term” has the meaning set forth in Section 8.5(b).

1.224. “RSV” means human respiratory syncytial virus, [***].

1.225. “RSV Field” means the prevention, treatment, control, palliation or elimination of RSV infection.

1.226. “SEC” has the meaning set forth in Section 12.3(b).
1.227. “Selling Party” means Merck and its Sublicensees (including its Affiliates that have been granted sublicenses pursuant to Section 9.4), but not Distributors.

1.230. “Sublicensee” means any person or entity that is granted a sublicense as permitted by Section 9.4, either directly by Merck or indirectly by any other Sublicensee (including any Affiliate that is granted a sublicense hereunder but excluding, for clarity, any Distributors).

1.231. “Supply Agreement” means any supply agreement entered into by the Parties pursuant to Section 4.

1.232. “Supply Failure” has the meaning set forth in Exhibit A.

1.233. [***]

1.234. “Target” means [***].

1.235. [***]

1.236. “Target Product Profile” or “TPP” means, with respect to a given R&D Program, collectively, [***].

1.237. “Tax” and “Taxation” means any form of tax or taxation, levy, duty, charge or withholding (including any related fine, penalty, addition to tax, surcharge or interest) imposed by, or payable to, a governmental authority.

1.238. “Term” has the meaning set forth in Section 15.1.

1.239. “Terminated Rights” has the meaning set forth in Section 15.4.

1.240. “Termination Costs” has the meaning set forth in Section 2.15(d)(i).

1.241. “Territory” means all the countries and territories of the world.

1.242. “Therapeutic Product” means, [***].


1.244. “Third Party Acquiror” has the meaning set forth in Section 11.8(b).

1.245. “Third Party Claims” has the meaning set forth in Section 14.5(a).

1.246. “Third Party Exclusive Target” means a Target regarding which Moderna or its Affiliates has, as of the Effective Date (***), granted to a Third Party [***] for such Target, which license would preclude Moderna from granting licenses or other rights to Merck to Develop or Commercialize [***] for such Target hereunder.

1.247. “TPP Notice” has the meaning set forth in Section 2.9(b).

1.248. “United States” or “U.S.” means the United States of America, including its territories and possessions, the District of Columbia and Puerto Rico.

1.249. “Upfront Payment” has the meaning set forth in Section 8.1.

1.250. “Vaccine Product” means [***].

1.251. “Valid Claim” means, [***].

1.252. [***]

1.253. “Violation” means that Moderna or any of its officers or directors or any other Moderna personnel (or other permitted agents of Moderna performing activities hereunder) has been: (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (http://oig.hhs.gov/exclusions/authorities.asp); (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (http://exclusions.oig.hhs.gov/) or listed as having an active exclusion in the System for Award Management (http://www.sam.gov); or (3) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) (each of (1), (2) and (3) collectively the “Exclusions Lists”).
2. R&D Collaboration

2.1. General. Subject to and in accordance with the terms of this Agreement, during the R&D Term the Parties will undertake Development activities as set forth in R&D Plans with the goal of identifying and Developing Collaboration mRNA Constructs and Product Candidates directed to R&D Program Pathogens, (*** the “R&D Programs”) and (c) [***]. Following the expiration of the R&D Term there will be a Post-R&D Period during which Merck may define up to five (5) Target Product Profiles for which Merck may Develop [***] Product Candidates incorporating Collaboration mRNA Constructs from the Product Candidate Pool for such Target Product Profiles. Prior to the expiration of the Collaboration Term, Merck may designate up to five (5) Elected Candidates for which Merck will continue Development, [***] and Commercialization activities. All of the foregoing shall be subject to and in accordance with the terms of this Agreement.

2.2. R&D Term.

(a) Duration. Unless (i) terminated pursuant to Section 15 hereof, (ii) extended by Merck as set forth in Section 2.2(b), or (iii) extended on an R&D Program-by-R&D Program basis pursuant to Section 2.8(c), the term of the R&D Collaboration will commence on the Effective Date and continue for a period of three (3) years (the “Initial R&D Term”).

(b) Extension Right. If, upon expiration of the Initial R&D Term, Merck (a) has not designated its fifth (5th) Elected Candidate in accordance with Section 2.10 and [***], Merck may, at its written election, extend the R&D Collaboration for [***] that will begin upon the expiration of the Initial R&D Term and end on the earlier to occur of (i) the fourth anniversary of the Effective Date and (ii) the date on which Merck designates its fifth (5th) Elected Candidate hereunder (the “R&D Extension Term”, and together with the Initial R&D Term, the “R&D Term”). Merck may exercise such right by providing written notice to Moderna at [***] prior to the expiration of the Initial R&D Term and, subject to [***], the R&D Extension Term will automatically go into effect. Absent further agreement of the Parties but subject to Section 2.8(c) for an applicable R&D Program, the maximum duration of the R&D Term is four (4) years, and all R&D Programs will terminate upon expiration of the R&D Term.

(c) Discontinuance of a given R&D Program by Merck. Merck shall have the right, in its discretion, to discontinue a given R&D Program upon [***] prior written notice to Moderna. Upon the effective date of any such discontinuance, such R&D Program will become a Discontinued Program. For clarity, any such notice shall not be applicable to any other R&D Programs or otherwise affect the R&D Term.

2.3. R&D Program Initiation.

(a) R&D Program Proposals. Subject to the remainder of this Section 2.3, at any time during the R&D Term, Merck may propose new R&D Programs by providing Moderna with written notice identifying for each such proposed new R&D Program, (i) the proposed R&D Program Pathogen, the proposed R&D Targets (and, if applicable, [***]), and (ii) if Merck is nominating a new R&D Program to replace an existing R&D Program, the R&D Program that is being replaced (each such notice, an “R&D Program Proposal”), provided that the number of concurrent R&D Programs in effect during the R&D Term may not exceed [***]. If an R&D Program Proposal submitted by Merck satisfies the requirements of this Section 2.3(a), Section 2.3(b) and Section 2.3(c), the proposed R&D Program will become an R&D Program hereunder. Any R&D Program that is being replaced by a new R&D Program will be a Discontinued Program hereunder.

(b) Inclusion of R&D Targets. Merck may nominate and include any Merck Exclusive Target as an R&D Target in any R&D Program Proposal. Furthermore, during the R&D Term, Merck at its sole discretion may add or remove any Merck Exclusive Target as an R&D Target of an established R&D Program by providing written notice to Moderna.

(c) Inclusion of R&D [***] Targets.

(i) Subject to the remainder of this Section 2.3(c), Merck may nominate and include any [***] Target as an R&D [***] Target in any R&D Program Proposal, provided that [***].

(ii) [***]

(iii) Notwithstanding any other provision of this Agreement to the contrary:

D. [***]
Subject to the terms and conditions of this Agreement, during the R&D Term, Merck may add or remove any [***] Target as an R&D [***] Target of an established R&D Program by providing written notice to Moderna; provided that if Merck desires to add a [***] Target, the foregoing provisions of this Section 2.3(c) shall apply.

At least [***] during the R&D Term, the JSC will review Merck’s Development efforts with respect to R&D [***] Targets against available data and anticipated experimental plans of such R&D Programs and [***]. Merck agrees that it will make available to Moderna, in advance of each such review by the JSC, a copy of the relevant data and results generated from the applicable R&D Program that would be useful for the JSC’s review (which will be Confidential Information of Merck).

(d) R&D Program Proposal Review and Addition of R&D [***] Target. Within [***] of Moderna’s receipt of an R&D Program Proposal issued in accordance with Section 2.3(a), or a proposal to add a new R&D Target or R&D [***] Target to an R&D Program in accordance with Section 2.3(b) or 2.3(c), as applicable, Moderna will provide a “Response Notice” indicating whether or not the R&D Program Proposal and the proposed R&D Program satisfy the requirements of Sections 2.3(a), 2.3(b) and 2.3(c). If Moderna notifies Merck in a Response Notice that the R&D Program Proposal and the proposed R&D Program described therein (or the addition of new Targets, as applicable) satisfy the requirements of Sections 2.3(a), 2.3(b) and 2.3(c), as applicable, or Moderna fails to provide a Response Notice to Merck within such [***] period, such proposed R&D Program or proposed additional Targets, as applicable, will be included as an R&D Program.

(e) Non-Conforming Proposals. If Moderna issues a Response Notice stating that the R&D Program Proposal or the proposed R&D Program (or additional Targets, as applicable) described therein does not satisfy the requirements of Sections 2.3(a), 2.3(b) or 2.3(c), then Moderna will include in such Response Notice the specific provision of 2.3(a), 2.3(b) or 2.3(c) that such R&D Program Proposal, proposed R&D Program or proposed additional Target, as applicable, failed to satisfy. If Merck in good faith disputes any assertion by Moderna in a Response Notice, Merck may deliver written notice of such dispute to Moderna within [***] of Merck’s receipt of the applicable Response Notice, in which case the dispute will be resolved in accordance with the dispute resolution procedure set forth in [***].

(f) Confirmation. Once a R&D Program Proposal and the proposed R&D Program (or additional Targets, as applicable) are confirmed to comply with the requirements of this Agreement pursuant to Sections 2.3(d) or 2.3(e) or pursuant to the dispute resolution procedure set forth in [***], as applicable, (i) such proposed R&D Program will become an R&D Program, (ii) the proposed R&D Program Pathogens will become the R&D Program Pathogens for such R&D Program, and (iii) the proposed R&D Targets and proposed R&D [***] Targets will become the R&D Targets and R&D [***] Targets for such R&D Program, as applicable.

(g) JSC List. The JSC will maintain a current list of all R&D Program Pathogens, R&D Targets and R&D [***] Targets included in each R&D Program.

2.4. R&D Plans.

(a) R&D Plan Preparation.

(i) Collaboration Activities of the Parties with respect to each R&D Program, but excluding [***] will be described in separate written Development plans (each, an “R&D Plan”). Within [***] of the establishment of a new R&D Program in accordance with Section 2.3, Merck shall prepare an R&D Plan for such R&D Program, which R&D Plan shall set forth: [***], provided that the Parties acknowledge and agree that, [***].

(ii) Merck shall provide the proposed R&D Plan to Moderna for review and comment by Moderna, which comments shall be provided within [***] of receipt. To the extent Merck agrees with such comments, Merck shall update the proposed R&D Plan accordingly. Notwithstanding the foregoing, if Moderna, in good faith provides comments to Merck within such [***]-period reflecting Moderna’s reasonable belief that [***].

(b) Contents. The purpose of each R&D Plan is to set forth [***].

(c) Responsibilities. The Parties acknowledge and agree that (i) it is their expectation that each R&D Plan will provide that Merck will be primarily responsible for preclinical Development activities (excepting those preclinical Development activities that are specified in an R&D Plan as being Moderna’s responsibility), (ii)
Moderna, subject to Section 2.5 and Section 4 and Exhibit A, will be responsible for designing Collaboration mRNA Constructs and Manufacturing all Moderna mRNA API for use under any R&D Program during the R&D Term, [***], and (iii) unless otherwise agreed to by the Parties pursuant to Section 4, Merck shall be responsible for Manufacturing Drug Product utilizing Moderna mRNA API supplied by or on behalf of Moderna for use under any R&D Program during the R&D Term.

(d) Updates. Each of Merck and Moderna will have the right to propose modifications or amendments to a given R&D Plan, provided that, subject to Section 2.7, any modifications or amendments to any R&D Plan that are proposed by either Party will be subject to review and approval by the JSC pursuant to and in accordance with the terms of Section 3.2(c).

2.5. Moderna Design Activities. For each R&D Program, Moderna shall design [***] Collaboration mRNA Constructs [***], and such Collaboration mRNA Constructs will be Manufactured and supplied by or on behalf of Moderna in accordance with Section 4.1 for use in the applicable R&D Program. For purposes of this Agreement, the design activities included in the Customary Design/Manufacturing Activities, shall be deemed to be performed under the R&D Plan (and R&D Program) and shall be subject to the same terms and conditions hereunder (other than cost reimbursement) as are applicable to the performance of activities under an R&D Plan (and R&D Program), mutatis mutandis. [***]

2.8. Program Performance.

(a) Generally. Each Party will use Commercially Reasonable Efforts to perform (itself or through its Affiliates or by permitted subcontracting hereunder) its respective obligations under each R&D Program, and will cooperate with and provide reasonable support to the other Party in such other Party’s performance of its responsibilities under such Program. Each Party will keep the other Party reasonably informed of such Party’s Development activities under each R&D Program and will reasonably consult with such other Party and reasonably consider such other Party’s comments and advice with respect to all material decisions relating to such activities. The Parties acknowledge and agree that no outcome or success is or can be assured and that failure to achieve desired results will not in and of itself constitute a breach or default of any obligation in this Agreement (notwithstanding the focus of the R&D Programs described above).

(b) FTEs. Moderna will support the Development and other activities to be undertaken by Moderna hereunder as set forth in each R&D Plan, with FTEs selected by Moderna to perform such activities, provided such FTEs will [***]. Moderna’s obligation to provide FTEs across all R&D Programs (excluding the [***]) at any one time shall not exceed [***] without Moderna’s prior written consent. For clarity, Moderna shall also be required to provide, at its own cost, sufficient FTEs to perform the [***].

(c) [***]

2.9. Target Product Profile; Product Candidate Designation.

(a) Target Product Profile. During the Post R&D Period, Collaboration Activities will be directed to the Development of Collaboration mRNA Constructs against specified Target Product Profiles, in each case as determined [***].

(b) [***]

(c) Product Candidate Pool Determination. Prior to issuing any TPP Notice, Merck will review the most current data and results generated from performance of the applicable R&D Program and will make a good faith determination, based on such data and results, as to which Collaboration mRNA Constructs from such R&D Program should be included in the Product Candidate Pool [***].

(d) [***]

(e) [***]

(f) Discontinuance of a given TPP by Merck. Merck shall have the right, in its discretion, to discontinue a given TPP upon [***] prior written notice to Moderna. Upon the effective date of any such discontinuance, such TPP shall no longer exist and all [***] under such discontinued TPP [***] will become Discontinued Targets and all Collaboration mRNA Constructs in the Product Candidate Pool for such TPP will become Discontinued mRNA Constructs (to the extent such mRNA Constructs are not within another Product Candidate Pool). For clarity, any such notice shall not be applicable to any other TPP.
2.10. **Elected Candidate Designation.**

(a) **Elected Candidate Notice.** Prior to the expiration of the Collaboration Term, Merck may designate a Product Candidate as an “Elected Candidate” hereunder by providing Moderna with written notice of the same (an “Elected Candidate Notice”); provided that Merck may make no more than five (5) such designations, in the aggregate, hereunder (the “Elected Candidate Cap”). Upon Moderna’s receipt of the Elected Candidate Notice, such designated Product Candidate will be an Elected Candidate. For the avoidance of doubt, a separate Elected Candidate Notice is required for each of the five (5) possible designations of Elected Candidates, and following the designation of the fifth (5th) Elected Candidate, Merck shall no longer have the right to designate any additional Elected Candidates hereunder.

(b) **Target Product Profile Update.** Within [***] of the designation of an Elected Candidate, Merck shall update, if required, the Target Product Profile from which such Elected Candidate was selected by providing written notice to Moderna of [***].

(c) **Designation of Patents.** At the time an Elected Candidate is selected, the Parties shall mutually agree upon which [***] claim or cover such Elected Candidate; provided that if the Parties are not able to agree upon which category of Patents a particular patent falls into, such disagreement shall be resolved in accordance with the dispute resolution procedure set forth in [***].

(d) **Replacement of Elected Candidates.**

(i) **Elected Candidate Replacement Notice.** Subject to Section 2.10(d)(ii), on an Elected Candidate-by-Elected Candidate basis, Merck may elect at any time prior to the earlier to occur of [***], to replace such Elected Candidate with a back-up Elected Candidate (a “Back-Up Elected Candidate”) by providing Moderna with written notice of same (a “Replacement Notice”).

(ii) **Back-Up Elected Candidate.** Each Back-Up Elected Candidate identified in a Replacement Notice (i) may be comprised of [***], and (ii) must have [***]. For the avoidance of doubt, [***].

(iii) **Moderna Support.** Following Merck’s issuance of a Replacement Notice, Merck may request Moderna’s reasonable support to initiate the Manufacturing of the Backup Elected Candidate, such support from Moderna not to be unreasonably conditioned or withheld. Any such support will be conducted consistent with the terms of this Agreement and any applicable Supply Agreement, and Merck will pay for any reasonable expenses incurred by Moderna in providing such support.

(iv) **Results of Elected Candidate Replacement.** Upon any replacement of an Elected Candidate pursuant to this Section 2.10(d), (A) the Back-Up Elected Candidate that replaced such Elected Candidate shall be deemed to be the same Elected Candidate as the Elected Candidate that is being replaced for the purposes of (1) Merck’s Milestone Payment obligations hereunder, and (2) the Elected Candidate Cap and (B) such Elected Candidate that was replaced shall no longer be the Elected Candidate from such TPP and the Collaboration mRNA Constructs in such replaced Elected Candidate remain part of the Product Candidate Pool.

(v) **Target Product Profile Update.** Within [***] of the designation of a Back-Up Elected Candidate, Merck shall update, if required, the Target Product Profile from which such Back-Up Elected Candidate was selected by providing written notice to Moderna of [***].

(vi) **Designation of Patents.** At the time a Back-Up Elected Candidate is selected, the Parties shall mutually agree upon which [***] claim or cover such Back-Up Elected Candidate; provided that if the Parties are not able to agree upon which category of Patents a particular patent falls into, such disagreement shall be resolved in accordance with the dispute resolution procedure set forth in [***].

2.11. [***].

(a) [***]

(b) [***]

(c) [***]

(d) Merck [***].
2.12. **Subcontracting.** Each Party may subcontract any of its activities to be performed under this Agreement to an Affiliate or Third Party, provided that any such Third Party will have entered into a written agreement with such Party that includes terms and conditions protecting and limiting use and disclosure of Confidential Information and Know-How at least to the same extent as under this Agreement, and such Party shall require such Affiliate or Third Party and its personnel to assign to such Party all right, title and interest in and to any Patents or Know-How created, conceived or discovered in connection with the performance of subcontracted activities. Each Party shall oversee the performance by any of its Affiliate or Third Party subcontractors, and shall remain responsible and primarily liable for the performance of such activities in accordance with this Agreement. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against any subcontractor for any obligation or performance hereunder, prior to proceeding directly against the Party engaging the subcontractor.

2.13. **Collaboration Records, Reports and Materials.**

(a) **Records.** Each Party will maintain, or cause to be maintained, records of its activities under the R&D Programs in sufficient detail and in good scientific manner appropriate for scientific, Patent and regulatory purposes, that will properly reflect all work performed therein, for a period consistent with each Party’s record retention policies, but in no event less than required by applicable Laws. Each Party will have the right to reasonably request a copy of any such records upon providing reasonable rationale for needing such records.

(b) **Collaboration Reports.** Each Party will furnish to the JSC a summary written report within after each [***] and [***] occurring during the R&D Term, describing its progress under the R&D Plans and [***] as part of the Collaboration Activities during the previous [***] period. Each Party agrees that it will promptly respond to the other Party’s reasonable questions regarding any of such Party’s reports.

(c) **Materials.** Each Party will use any Materials provided by the other Party only in accordance with the R&D Plans and otherwise in accordance with the terms and conditions of this Agreement (including [***]) and any reasonable instructions provided by the Party furnishing the Materials. Except with the prior written consent of the supplying Party, [***], the Party receiving any Materials will not distribute or otherwise allow the release of such Materials to any Third Party, except for [***]. All Materials delivered to the receiving Party, other than [***], will remain the sole property of the supplying Party and will be used in compliance with all applicable Law. The Materials supplied under this Agreement will be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known.

2.14. **Post-R&D Period.**

(a) **Generally.** The purpose of the Post-R&D Period is to provide Merck with an opportunity to, at its election, further Develop Product Candidates. Subject to Section 2.14(b) and any obligation of Moderna to supply Merck with Moderna mRNA API, Merck will be solely responsible for all Development activities during the Post-R&D Period.

(b) **Moderna Activities.** If during the Post-R&D Period, Merck reasonably requests that Moderna perform additional activities (excluding [***]) in support of Merck’s Development of Product Candidates, Elected Candidates or Products during the Post-R&D Period, the Parties will negotiate in good faith the terms and conditions of such performance; provided, however, that the Parties acknowledge and agree that, unless otherwise agreed to by the Parties, the terms and conditions of this Agreement shall apply to any such activities, [***] (each, a “Post R&D Plan”), and in connection therewith, the provisions of Sections 2.4(a)(ii) and 2.4(b) shall apply, mutatis mutandis. Upon finalization of such Post R&D Plan, Moderna will use Commercially Reasonable Efforts to perform (itself or through its Affiliates or by permitted subcontracting pursuant to Section 2.12) such activities in accordance with the terms and conditions of this Agreement as if such Post R&D Plan were an R&D Plan hereunder, mutatis mutandis.

(c) **Non-cGMP mRNA Construct Supply.** In addition to Section 4, Exhibit A and any Supply Agreement, during the Post-R&D Period Merck may request, and Moderna will supply, reasonable quantities of Collaboration mRNA Constructs for Merck to conduct such assays and Development as necessary to identify and nominate new Product Candidates, provided that the Parties acknowledge and agree that Merck may only request Collaboration mRNA Constructs that were included in a Product Candidate Pool established pursuant to Section 2.9.
2.15. Termination of Collaboration Activities.

(a) **Collaboration Activity Termination.** Each Party will perform its respective activities for a given R&D Program as set forth in the R&D Plan for such R&D Program until the earlier to occur of [***]. Subject to Moderna’s obligation to supply Merck with Moderna mRNA API and/or Drug Product as set forth in Section 4, all Development work performed hereunder by Moderna will terminate upon the expiration of the R&D Term, unless Moderna will perform Development activities to support Merck’s Development of Product Candidates during the Post-R&D Period pursuant to Section 2.14(b).

(b) **R&D Program Termination.** At the expiration of the R&D Term, (i) all R&D Programs will become “Discontinued Programs” (ii) all R&D Targets and R&D [***] Targets that are not Locked Targets will become Discontinued Targets and (iii) all Collaboration mRNA Constructs that are not in a Product Candidate Pool will become Discontinued mRNA Constructs. For the avoidance of doubt, upon the expiration of the R&D Term, [***].

(c) [***] of Effective Date. Upon the [***] of the Effective Date[***] For the avoidance of doubt, upon the [***] of the Effective Date, [***]. [***]

(d) **Discontinued Items.**

(i) In the event an R&D Program is discontinued or replaced by Merck pursuant to Section 2.2(c) or 2.3(a), as applicable and becomes a Discontinued Program, the rights and obligations of the Parties under the applicable R&D Work Plan shall terminate, and the Out-of-Pocket Costs incurred by Moderna and its Affiliates with respect to such R&D Program will be deemed to include amounts payable for non-cancellable commitments made to Third Parties in order to [***] (the “Termination Costs”).

(ii) The licenses and other rights granted to Merck hereunder will not apply with respect to any Discontinued Program, Discontinued Target or Discontinued mRNA Construct.

(iii) Subject to Section 11, Merck hereby grants to Moderna a non-exclusive, royalty free and fully paid-up, [***], sublicensable (through multiple tiers), worldwide license under the Merck Collaboration Technology owned by Merck or its Affiliate relating to any Discontinued mRNA Construct to Exploit such Discontinued mRNA Constructs and mRNA Products incorporating such Discontinued mRNA Constructs in any field (other than within the TPP of any Elected Candidate or Product), provided that [***].

2.16. Compliance.

(a) **General.** Moderna shall conduct the R&D Programs and other activities hereunder in compliance with all applicable Laws. Moderna shall notify Merck in writing of any deviations from applicable Laws. In addition, Moderna hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any person debarred under United States law, including Section 21 USC 335a, or any foreign equivalent thereof, in performing any portion of an R&D Program and other activities hereunder. Moderna shall notify Merck in writing if any such debarment occurs or comes to its attention, and shall, with respect to any person or entity so debarred promptly remove such person or entity from performing any R&D Program activities and other activities hereunder, function or capacity related thereto. Without limiting the foregoing, if animals are used in Development hereunder, Moderna will comply with the Animal Welfare Act and any other applicable Laws relating to the care and use of laboratory animals. Merck encourages Moderna to use the highest standards, such as those set forth in the Guide for the Care and Use of Laboratory Animals (NRC, 1996), for the humane handling, care and treatment of such research animals. Any animals which are used in the course of an R&D Program or other activities hereunder, or products derived from
those animals, such as eggs or milk, will not be used for food purposes, nor will these animals be used for commercial breeding purposes.

(b) Use of Human Materials. Without limiting the provisions of Section 2.16(a), if any human cell lines, tissue, human clinical isolates or similar human-derived materials (“Human Materials”) are to be collected and/or used in an R&D Program or other activity hereunder, Moderna represents and warrants (i) that it shall comply, with all applicable Laws relating to the collection and/or use of the Human Materials and (ii) that it has obtained or shall obtain, all necessary approvals and appropriate informed consents, in writing, for the collection and/or use of such Human Materials. Moderna shall provide documentation of such approvals and consents upon Merck’s request. Moderna further represents and warrants that such Human Materials may be used as contemplated in this Agreement without any obligations to the individuals or entities (“Providers”) who contributed the Human Materials, including any obligations of compensation to such Providers or any other Third Party for the intellectual property associated with, or commercial use of, the Human Materials for any purpose.

c) Compliance with Corporate Policy. Moderna acknowledges that Merck’s corporate policies require that business must be conducted within the letter and spirit of the law. By signing this Agreement, Moderna agrees to conduct the activities contemplated herein in a manner which is consistent with both law and good business ethics.

(d) Business Partner Code of Conduct. Merck endeavors to hold itself and its business partners to the highest performance, ethical and compliance standards, including basic human rights, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. In performing its duties under this Agreement, Moderna acknowledges the value and importance of performance and ethical behavior in its performance under this Agreement. Without limiting any of Moderna’s other obligations hereunder, Merck expects that Moderna will abide by the letter and spirit of Merck’s Supplier Performance Expectations and Business Partner Code of Conduct (the “Code”), a copy of which is available at http://www.merck.com/about/how-we-operate/code-of-conduct/values.html, in its performance of this Agreement. Moderna is also expected to follow the Pharmaceutical Supply Chain Initiative (PSCI) principles, a copy of which is available at http://www.pharmaceuticalsupplychain.org/.

e) Governments and International Public Organizations. Without limitation of the foregoing, Moderna warrants that none of its employees, agents, officers or other members of its management are officials, officers, agents, representatives of any government or international public organization. Moderna agrees that it shall not make any payment, either directly or indirectly, of money or other assets, including to the compensation derived from this Agreement (hereinafter collectively referred as a “Payment”), to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as “Officials”) where such Payment would constitute a violation of any Law. In addition, regardless of legality, Moderna shall make no Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of Merck’s businesses.

(f) No Authority. Moderna acknowledges that no employee of Merck or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by Moderna or its agents to any Third Party in violation of terms of this or any other provisions of this Agreement.

g) Exclusions Lists. Moderna certifies to Merck that as of the Effective Date Moderna has screened itself, and its officers and directors, against the Exclusions Lists and that it has informed Merck whether Moderna, or any of its officers or directors has been in Violation. After the execution of this Agreement, Moderna shall notify Merck in writing immediately if any Violation occurs or comes to its attention, and shall, with respect to any person or entity in Violation, promptly remove such person or entity from performing any R&D Program activities or and other activities hereunder, function or capacity related thereto.

3. Governance

3.1. Collaboration Management. Promptly after the Effective Date, each Party will appoint a person who will oversee day-to-day contact between the Parties for all matters related to the management of the
Collaboration Activities in between meetings of the JSC and will have such other responsibilities as the Parties may agree in writing after the Effective Date. One person will be designated by Merck (the “Merck Program Director”) and one person will be designated by Moderna (the “Moderna Program Director”) together will be the “Program Directors”. Each Party may replace its Program Director at any time by notice in writing to the other Party. Any Program Director may designate a substitute to temporarily perform the functions of that Program Director by written notice to the other Party. The initial Program Directors will be:

For Moderna: [***]
For Merck: [***]

3.2. Joint Steering Committee.

(a) Formation and Membership. As soon as practicable (but not later than sixty (60) days) following the Effective Date, the Parties will establish a joint steering committee (the “JSC”), comprised of [***] representatives of Moderna (or its Affiliate) and [***] representatives of Merck (or its Affiliate). Each JSC member will be a senior development leader or have similar experience and expertise as a senior development leader. Each Party may replace its representatives on the JSC at any time upon written notice to the other Party. With the consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), each Party may invite non-voting employees and consultants to attend meetings of the JSC, subject to their agreement to be bound to the same extent as a permitted subcontractor under Section 2.12.

(b) Meetings. While in existence, the JSC will meet [***] (or more frequently as may be determined by the JSC) and may hold meetings in person or by audio or video conference as determined by the JSC, but at a minimum, [***] of such meetings each Calendar Year starting in 2015 will be in person (which in-person meeting will be held at one of Moderna’s U.S. facilities, and the other held at Merck’s U.S. facilities). Meetings of the JSC will be effective only if at least [***] representative of each Party is present or participating. Each Party will be responsible for all of its own expenses of participating in the meetings. The Parties will endeavor to schedule meetings of the JSC at least [***] in advance. The JSC will determine the JSC operating procedures, which shall in all cases be consistent with the terms of this Agreement, and will codify these operating procedures in the written minutes of the first meeting (or subsequent meetings as such procedures are updated). The JSC will prepare and circulate a meeting agenda prior to each such meeting. The Parties will alternate in preparing written minutes of such meeting, and the preparing Party will circulate such minutes within [***] after such meeting. The Parties will agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JSC. Each Party will designate one of its [***] representatives who is empowered by such Party to make decisions regarding issues within the purview of the JSC as set forth below in Section 3.2(c) to act as the co-chair of each JSC. The co-chairs will be responsible for overseeing the activities of its JSC members consistent with the responsibilities set forth in Section 3.2(c).

(c) Responsibilities. The JSC will oversee the Collaboration Activities and the performance of the R&D Plans. The JSC may form project teams to deal with the day-to-day work to execute the R&D Plans. Without limiting the generality of the foregoing, within such scope, the JSC will have the following responsibilities:

(i) Review each Party’s performance of Collaboration Activities;

(ii) Review and approve (other than the [***]) any proposed modifications or amendments to any R&D Plan;

(iii) Prioritize and oversee execution of specific activities to be performed under the R&D Plans [***];

(iv) Review data, reports or other information submitted by either Party with respect to Development activities performed under R&D Plans [***];

(v) Form such other committees or project teams as the JSC may deem appropriate (including any project teams to deal with the day-to-day work to execute any R&D Plan [***]) and oversee the work of any committees or project teams formed by the JSC, including by receiving and reviewing reports and other information submitted by those joint committees and project teams (if applicable); provided, that any such committee or project team may make recommendations to the JSC but may not be delegated JSC decision-making authority;
(vi) Review proposed publications regarding the results of the R&D Programs proposed to be published in accordance with Section 12.2;

(vii) Review Third Party technology identified by Moderna that could have reasonable utility for the Collaboration Activities; and

(viii) Attempt to resolve any disputes relating to this Agreement on an informal basis.

(d) Decision-making. The [***] JSC representatives of each Party will collectively have one (1) vote. The JSC members will use diligent efforts to reach agreement on all matters. If, despite such efforts, agreement on a particular matter cannot be reached by the JSC within [***] days after the JSC first considers such matter (or such shorter time as may be reasonable in the circumstances), then [***].

(e) Resolution of Certain Matters. Notwithstanding the provisions of Section 3.2(d) in the event of a dispute or disagreement arising in, or referred to, the JSC relating to [***] that cannot be resolved by the members of the JSC, upon the written request of a Party, such matter will be referred to the Executive Officers (or their designees, which designee is required to have decision-making authority on behalf of such Party), who will attempt in good faith to resolve such dispute by negotiation and consultation for a [***] period following receipt of such written notice. If, despite such efforts, agreement on a particular matter cannot be reached by the Executive Officers within such [***] period, then [***].

(f) Limits on JSC Authority. Each Party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers, or discretion will be delegated to or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The JSC will not have the power [***]. Any dispute between the Parties regarding the issues set forth in this Section 3.2(f) will be resolved pursuant to the procedures set forth in [***].

(g) JSC Term. The JSC will cease to exist [***] after the end of the R&D Term, provided that during the Post R&D Period, the JSC shall be maintained to oversee any ongoing activities but it shall meet on ad hoc basis to govern activities as specified in Section 2.14.


4.1. Non-cGMP Supply. The following provisions of this Section 4.1 shall apply with respect to Manufacture of non-cGMP Moderna API:

(a) Manufacture by Moderna. Moderna will Manufacture (or have Manufactured) and supply to Merck, and Merck will purchase exclusively from Moderna, [***], quantities of non-cGMP Moderna mRNA API as Merck may reasonably require in connection with the performance of its Collaboration Activities. Such supply shall be in accordance with the terms of this Section 4.1 and the terms with respect to non-cGMP Moderna API or supply hereunder set forth in Exhibit A, including the pricing terms set forth therein. Merck shall issue purchase orders in substantially the form set forth on Schedule 1 to Exhibit A to Moderna for the purchase of non-cGMP Moderna mRNA API (the “non-cGMP Order Form”). [***]

(b) mRNA Construct Cap. During the R&D Term or Post R&D Period, as applicable, the aggregate number of different non-cGMP mRNA Constructs being Manufactured [***] by Moderna under this Agreement may not exceed the Non-cGMP Construct Cap without Moderna’s prior written consent. [***] For the purposes of the foregoing:

(i) During the R&D Term, the non-cGMP Construct Cap shall be [***] (“the “Non-cGMP Construct Cap”) [***];

(ii) During the Post-R&D Period [***], the non-cGMP Construct Cap shall be [***];

(iii) During the Post-R&D Period [***], the Non-cGMP Construct Cap shall be [***].

4.2. cGMP Moderna mRNA API Supply for Early Clinical Studies. The Parties shall negotiate and execute a clinical supply agreement and quality agreement containing the provisions set forth in Exhibit A, and
such other terms and conditions that are customary for agreements of this type as the Parties mutually agree (the “Clinical Supply Agreement”). Such Clinical Supply Agreement and quality agreement shall be entered into no later than [***] after the Effective Date (or such longer period of time as the Parties may agree), but in any event prior to the commencement of any activities relating to such supply, and the Parties will enter into specific statements of work for each Product Candidate and Elected Candidate, as additional Product Candidates and Elected Candidates are identified under this Agreement. Without limiting the Clinical Supply Agreement, the following provisions of this Section 4.2 shall apply with respect to Manufacture of cGMP Moderna mRNA API on a Product Candidate-by-Product Candidate or Elected Candidate-by-Elected Candidate basis to be supplied by Moderna under the Clinical Supply Agreement for the period commencing [***]:

(a) Manufacture by Moderna.

(i) Moderna will Manufacture (or have Manufactured) and supply to Merck, and Merck will purchase exclusively from Moderna, quantities of cGMP Moderna mRNA API (on a Product Candidate-by-Product Candidate or Elected Candidate-by-Elected Candidate basis) as Merck may reasonably require; provided that, [***]. Notwithstanding the foregoing described exclusivity, from and after the initiation of a Registrational Study with respect to a given Product Candidate or Elected Candidate, Merck and/or its Third Party Manufacturer can Manufacture, and Merck may purchase, cGMP Moderna mRNA API for each such Product Candidate or Elected Candidate, in accordance with Section 4.3; provided, that, [***].

(ii) In connection with [***], at the reasonable request of Moderna, Merck may, at Merck’s discretion and to the extent determined by Merck, consult with Moderna regarding [***]. Further, Moderna’s [***].

(iii) In the event that Moderna [***], then such supply activities shall be in accordance with the Clinical Supply Agreement. Within [***] after Merck notifies Moderna of Merck’s reasonably anticipated needs for supplies of cGMP Moderna mRNA API [***]. Moderna will [***]

(iv) If Merck identifies any audit observations in connection with any audit under this Section 4, Exhibit A or the Clinical Supply Agreement, the Parties will discuss in good faith suitable approaches for correcting such observations, and Moderna shall have a reasonable time following such consultation with Merck to make appropriate corrections.

(b) Clinical Supply cGMP Supply Cap. Unless otherwise agreed by the Parties, during the Collaboration Term, Merck may request cGMP mRNA Constructs pursuant to Section 4.2(a) for up to [***] Product Candidates concurrently, and Moderna will supply such cGMP mRNA Constructs in accordance with the terms of this Agreement. For the avoidance of doubt, [***], provided that [***]. For the purposes of the foregoing, “concurrently” means with respect to Product Candidates, [***].

(c) [***] If Moderna (a) complies with the relevant terms and conditions of Section 4 and Exhibit A (including the audit provisions), and (b) Moderna complies with the following criteria, then Moderna [***]:

(i) Moderna shall ensure that Merck has the right within [***] after the Effective Date, or such longer period of time as agreed to by Merck, to [***]. Within [***] of receipt of an audit report from Merck, Moderna shall [***]. Upon [***], Moderna shall address and correct [***] audit observations provided by Merck [***] prior to Manufacturing of cGMP Moderna mRNA API for Merck.

(ii) [***]

(iii) [***]

(iv) As part of Merck’s audit of Moderna’s proposed manufacturing location, Merck’s audit may include [***].
4.3. cGMP Supply For Registrational Study and Commercial Supply. The following provisions of this Section 4.3 shall apply with respect to Manufacture of cGMP Moderna mRNA API for Registrational Studies and commercial supply on a Product Candidate-by-Product Candidate or Elected Candidate-by-Elected Candidate basis from and after the earlier of [***]:

(a) [***]
(b) [***]
(c) [***]

4.4. Drug Product. At the request of Merck, and if agreed to by the Parties, such agreement not to be unreasonably withheld, conditioned or delayed, the Parties shall discuss and agree on the terms pursuant to which Moderna would Manufacture and supply of Drug Product to Merck. If the Parties agree to enter into an agreement with respect to the Manufacture and supply of Drug Product, such agreement will include similar terms and conditions, including similar quality standards and audit rights, as set forth in this Section 4 and Exhibit A, provided, that the Parties acknowledge and agree that different pricing will need to be negotiated with respect to the Manufacture and supply of Drug Product.

5. Regulatory Responsibilities.

5.1. In General. As set forth in greater detail below in this Section 5, but subject to Sections 5.4, 5.5 and 15.5, [***] will lead and have sole control of, and bear all costs of, all regulatory efforts for Collaboration mRNA Constructs, Product Candidates, Elected Candidates and Products worldwide, including with respect to preparing and filing the relevant Regulatory Filings and all communications (formal and informal) with Regulatory Authorities.

5.2. Regulatory Filings. Other than with respect to the performance of the [***], (a) [***] will be responsible for preparing and submitting all Regulatory Filings related to Collaboration mRNA Constructs, Product Candidates, Elected Candidates and Products, including all applications for Regulatory Approval, and (b) all applications for Regulatory Approval, the Regulatory Approvals, and other Regulatory Filings (including all ANDAs) relating to Collaboration mRNA Constructs, Product Candidates, Elected Candidates and Products will be the property of [***] and held in the name of [***] or its designees.

5.3. Interactions with Regulatory Authorities. Other than with respect to the performance of the [***] or as otherwise set forth in Section 4 or Exhibit A, [***] will have the sole right to conduct all communications with the Regulatory Authorities, including all meetings, conferences and discussions (including advisory committee meetings and formal agency/sponsor meetings), including all requests and materials submitted for such, with regard to Collaboration mRNA Constructs, Product Candidates, Elected Candidates and Products in the Territory.

5.4. [***]

5.5. Moderna Support for Regulatory Filings. If not previously prepared and filed, Moderna will, at Merck’s request, prepare and file with all applicable Regulatory Authorities a DMF for the Moderna mRNA API and Moderna shall also provide such other information and assistance as Merck may reasonably request in connection with the completion of and submission of applications for Regulatory Approvals for Products and the maintenance thereof. Merck and its Affiliates and Sublicensees may refer to such DMF in any filing made in connection with obtaining or maintaining a Regulatory Approval for a Product. Moderna will be responsible for assuring that during the Term, such DMF will be in the form appropriate for filing with all applicable Regulatory Authorities, including those in the United States, the European Union, Japan and such other countries as requested by Merck, and such DMF shall be maintained in full force and effect by Moderna during the Term and will not be amended without the consent of Merck. Moderna will, on written request by Merck or its Affiliate or Sublicensee, provide to the requesting party and to any specified Regulatory Authority a letter, in the form reasonably required by the requesting party, acknowledging that the requesting party has a right of reference to any such DMF. If [***] has not filed [***] will provide such [***]. In the case where information [***] will provide such other information and assistance [***] in connection with responding to Regulatory Authorities. This includes [***].
6. Development Meetings & Reports; Diligence.

6.1. Annual Update Meetings. At least [***] during each consecutive [***] period from the date of the Elected Candidate Notice until the first Regulatory Approval for Product, within [***] of Moderna’s written request, the Parties will meet in person at a U.S. site of Merck for Merck to provide Moderna with an update on the Development of a Product by Merck and its Affiliates and Sublicensees.

6.2. Reports by Merck. Merck will prepare and maintain, and will cause its Affiliates and Sublicensees to prepare and maintain, reasonably complete and accurate records regarding the Development of Product Candidates, Elected Candidates and Products. At least [***] every [***] period from the Effective Date, Merck shall provide to Moderna a written progress report which shall [***]. For clarity, all such reports shall be considered the Confidential Information of Merck.

6.3. Diligence. Merck, directly or through one or more of its Affiliates or Sublicensees, will use Commercially Reasonable Efforts: (a) to Develop [***] Product Candidate from each TPP; (b) seek to obtain Regulatory Approval for a Product for each Elected Candidate; and (c) Commercialize Products after obtaining such Regulatory Approval.

7. Third Party In-Licenses.

7.1. Moderna [***] In-Licenses.

(a) [***] In-Licenses. All Moderna [***] In-Licenses shall be deemed to be Moderna Collaboration In-Licenses for purposes of this Agreement and the Patents and Know-How in-licensed under such Moderna [***] In-Licenses will be deemed Moderna Technology, provided that notwithstanding anything to the contrary contained herein (including Section 7.7), Moderna shall be solely responsible for [***].

(b) Moderna [***] In-Licenses. In the event that after the Effective Date, Moderna identifies any Patents or Know-How of a Third Party related to the Moderna [***] Technology to which Moderna (and its Affiliates) does not have rights and that [***] Moderna may independently negotiate and enter into an agreement to obtain a license to such Patents or Know-How (each such agreement, a “Moderna [***] In-License”). Notwithstanding the foregoing, if any Patents or Know-How licensed to Moderna under a given Moderna [***] In-License are [***] in order for Moderna to perform its obligations under the Collaboration Activities, then such Moderna [***] In-License shall automatically be deemed to be a Moderna [***] In-License for purposes of this Agreement, and shall be treated in accordance with the provisions of Section 7.1(a). With respect to the Moderna [***] In-Licenses, Moderna (i) will [***] and (ii) will use [***].

7.2. Moderna Collaboration Technology In-Licenses. In the event that Moderna identifies any Patents or Know-How of a Third Party related to the Development or Commercialization of any Collaboration mRNA Construct, and associated Products, including [***], to which Moderna (and its Affiliates) does not have rights and that [***] pursuant to the terms of this Agreement, in either case other than those related to [***] (each such agreement, a “Moderna Collaboration Technology In-License”), Moderna may independently negotiate and enter into such Moderna Collaboration Technology In-License to obtain a license to such Patents or Know-How provided that (i) [***], (ii) Moderna will [***] and (iii) will use [***].

7.3. Moderna [***] In-Licenses. Moderna shall not use any [***] in connection with Collaboration Activities that is [***] licensed to Moderna pursuant to a Moderna [***] In-License without the prior written approval of Merck. In the event that Merck desires to use any such [***] in connection with Collaboration Activities, Merck may provide written notice to Moderna of same, and, [***], such notice will constitute Merck’s approval to use such [***] in connection with Collaboration Activities. (a) such Moderna [***] In-License shall become a Moderna Collaboration In-License in accordance with Section 7.4, and (b) the applicable milestone, royalty and other payments due under the applicable Moderna Collaboration In-License will be passed through to Merck [***] pursuant to Section 7.7.

7.4. Moderna Collaboration In-Licenses. Moderna shall notify Merck in writing of the terms of any Moderna In-License promptly after entering into such Moderna In-License (subject to confidentiality
obligations and reasonable redactions), including any restrictions or obligations with respect to the Prosecution and Maintenance and/or enforcement any Patents licensed thereunder. To the extent that the rights granted to Moderna under a Moderna In-License are limited (e.g., [***]), Moderna, [***], will equitably apportion such limited rights amongst Moderna and its Affiliates, Merck and Moderna’s and its Affiliates’ Third Party Development and Commercialization partners. If Merck notifies Moderna in writing that a Moderna In-License should be made available for use by either Party for the performance of Collaboration Activities, or [***], in each case pursuant to the terms of this Agreement and to the extent permissible under such Moderna In-License (each such Moderna In-License, a “Moderna In-License”), then (a) the Patents and Know-How in-licensed under such Moderna In-License will be deemed Moderna Technology (but subject to any limitations set forth in such Moderna In-License [***]), and (b) Merck will be required to make the payments set forth in Section 7.7; provided, that [***]. If Merck concludes that a Moderna In-License should not be made available for use by either Party for the performance of Collaboration Activities, or made available for use by Merck to Exploit or Optimize Elected Candidates and Products, in each case pursuant to the terms of this Agreement, then [***].

7.5. Conversion of Moderna In-Licenses. If Merck [***], then subject to [***], Merck may [***] elect to convert such Moderna In-License to a Moderna Collaboration In-License by (a) providing written notice to Moderna of the same and (b) being required to make the payments set forth in Section 7.7; provided, that such amounts have been disclosed to Merck pursuant to Section 7.4. Upon Moderna’s receipt of such notice, Moderna will promptly notify [***] and, to the extent [***], then such Moderna In-License will thereafter be deemed to a Moderna Collaboration In-License hereunder, and the provisions of this Agreement applicable to Moderna Collaboration In-Licenses will apply with respect to such Moderna In-License. Notwithstanding the foregoing, prior to converting any Moderna In-License to a Moderna Collaboration In-License, the Parties will agree on [***].

7.6. Moderna Collaboration In-License Requirements. Merck will abide, and will cause all its Affiliates and applicable Sublicensees to abide, by all requirements of each Moderna Collaboration In-License in all material respects (and in any case in all respects in the case that [***]), to the extent applicable to sublicensees thereunder and to the extent disclosed by Moderna to Merck pursuant to Section 7.4 prior to Merck’s conclusion to have the Moderna In-License made available and converted to a Moderna Collaboration In-License hereunder, with the understanding that disclosure by Moderna of the terms of any Moderna Collaboration In-License to Merck will be deemed disclosure of such requirements of such Moderna Collaboration In-License so disclosed to Merck.

7.7. Moderna Collaboration In-License Payments. If any In-License Payments previously disclosed to Merck pursuant to Section 7.3 or 7.4, as applicable, become due during the Term under any Moderna Collaboration In-License, Moderna will be responsible for such payments, provided, that Merck will reimburse Moderna for [***] such In-License Payment within [***] days of Merck’s receipt of Moderna’s invoice therefor (a) that [***].

7.8. Merck In-Licenses. In the event that Merck identifies any Patents or Know-How of a Third Party that may be [***] pursuant to this Agreement, Merck may independently negotiate and enter into an agreement to obtain a license or other rights to such Patents or Know-How for use in connection with such Development or Commercialization (each such agreement, an “Merck In-License”). Merck will notify Moderna of such Merck In-License. In the event that such notice is given and Moderna concludes that such Merck In-License should be made available for use by Moderna to perform Collaboration Activities or other Manufacturing activities, then the Parties will discuss in good faith whether and on what terms Merck would grant Moderna rights under any such Merck In-License.

7.9. Moderna Collaboration In-Licenses. Moderna represents, warrants and covenants to Merck that it has [***] as of the Effective Date [***]. Moderna further covenants and agrees that during the Term, (a) it shall satisfy all of its material obligations under (including making all payments), and maintain in full force and effect, each of the Moderna Collaboration In-Licenses; (b) it will not assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 16.13), [***] without the prior written consent of Merck, not to be unreasonably withheld, to the extent any of the foregoing actions would reasonably be expected to have an adverse effect on Merck’s rights hereunder or thereunder or Moderna’s obligations
hereunder; (c) it will provide Merck with prompt notice of any claim of [***] and (d) to the extent permitted under the applicable Moderna Collaboration In-License, it shall promptly [***].

8. **Payments**

8.1. **Up-Front Payment.** Within ten (10) Business Days after the Effective Date and receipt of an invoice from Moderna, Merck will pay to Moderna a one-time payment of US $50,000,000 as consideration for access to Moderna’s research capabilities and the licenses granted herein (the “**Upfront Payment**”), which payment will be non-refundable, non-creditable, not subject to set-off, and not be reduced by any withholding or similar taxes.

8.2. **R&D Program Costs.** Except as set forth in Section 8.3, commencing on the Effective Date and continuing during the Collaboration Term, Merck will reimburse Moderna for all R&D Program Costs incurred by Moderna and its Affiliates on a Calendar Quarter-by-Calendar Quarter basis. Moderna will send a reasonably detailed invoice to Merck for each Calendar Quarter, which invoice will include a summary of all [***]. All of the foregoing shall be auditable by Merck pursuant to Section 8.6(c). For clarity, unless otherwise mutually agreed in writing by the Parties, in no event shall Moderna be entitled to receive payment for (and Moderna shall be solely responsible for) any FTEs or other R&D Program Costs in a given Calendar Quarter in connection with the performance of activities that are not included in the applicable R&D Plan or that are not specifically included in the budget set forth therein. Merck agrees to pay undisputed amounts in each such invoice within [***] days of Merck’s receipt thereof.

8.3. **Sharing of Certain R&D Program Costs.**

(a) [***]

(b) [***]

8.4. **Milestone Payments.** Subject to the remainder of this Section 8.4, Merck will make the following milestone payments set forth in Section 8.4(d) (each, a “**Milestone Payment**”) to Moderna upon the first achievement by Merck (or its Affiliate or Sublicensee) of each of the milestone events set forth in the tables below in Section 8.4(d) (each, a “**Milestone Event**”), and such payments when owed or paid will be non-refundable and non-creditable and not subject to set-off.

(a) **Development Milestones.** The Milestone Payments for Development events are set forth in Table 1 below. Such Milestone Payments will be payable to Moderna by Merck within [***] of the first achievement [***] by Merck (or its Affiliate or Sublicensee) of the applicable Milestone Event with respect to a Development Milestone Product (as defined below). For the purposes of this Section 8.4, “**Development Milestone Product**” shall mean:

(i) With respect to [***]; *provided that if [***]

(ii) With respect to [***]; *provided that if [***];

(b) **Commercialization Milestones.** The Milestone Payments for Commercialization Milestone Events are set forth in Table 2 below. Such Milestone Payments will be payable to Moderna by Merck within [***] days of the end of the Calendar Quarter in which first achievement [***] by Merck of the applicable Milestone Event with respect to a given Product occurs.

(c) **Exceptions; Additional Conditions.** Notwithstanding the foregoing, the following shall apply:

(i) With respect to a Development Milestone Product from the [***] or [***] for which Merck has issued an Elected Candidate Notice pursuant to Section 2.11(d), the Milestone Payment [***]. Furthermore, if a Milestone Event is achieved that triggers a Milestone Payment set forth in Table 1 below for a given Development Milestone Product, and the preceding Milestone Events set forth in Table 1 for such Development Milestone Product have not occurred such that the previous Milestone Payments set forth in Table 1 have not been previously paid for such Development Milestone Product (to the extent such Milestone Payment would otherwise be payable with respect to such Development Milestone Product), then all such previous Milestone Payments shall become due and payable upon achievement of such Milestone Event for such Development Milestone Product.
(ii) In the event that more than one Milestone Event set forth in Table 2 are achieved in the same Calendar Year with respect to a Product, Milestone Payments will be payable with respect to each such Milestone Event.

(iii) In all cases, the maximum number of times a Milestone Payment shall be payable for a given Milestone Event is [***].

(d) Milestones and Payments.

### Table 1: Development Milestone Payments

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
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</tbody>
</table>

### Table 2: Commercialization Milestone Payments

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
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<tr>
<td>[***]</td>
<td>[***]</td>
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<tr>
<td>[***]</td>
<td>[***]</td>
</tr>
</tbody>
</table>

8.5. Royalties.

(a) Rates. Subject to the terms and conditions of this Agreement, Merck will pay to Moderna running royalties, as set forth in this Section 8.5, which royalties shall be determined on a Product-by-Product basis and shall only be payable with respect to Net Sales occurring during the Royalty Term, based on the total global aggregate annual Net Sales by Selling Parties of such Product in a given Calendar Year at the following royalty rates (provided that the Royalty Term for such Product in the applicable country has not expired):

<table>
<thead>
<tr>
<th>Annual Net Sales of each Product in a Calendar Year</th>
<th>Royalty Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>[***]</td>
<td>[***]</td>
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<td>[***]</td>
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<td>[***]</td>
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<td>[***]</td>
<td>[***]</td>
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</tbody>
</table>

(b) Royalty Term. Royalties under Section 8.5(a) will be payable commencing with the First Commercial Sale of a Product, on a Product-by-Product and country-by-country basis, on the Net Sales of such Product if during any period at least one of the following conditions apply (the "Royalty Term"): (i) if one or more Valid Claims within [***] in such Product in such country (even if such Patent is a Joint Patent); (ii) if such Product in such country is covered by a Regulatory Exclusivity Period; or (iii) for [***] from the First Commercial Sale of such Product in such country.

(c) [***] Notwithstanding Section 8.5(b), if the Royalty Term for a particular Product in a given country is scheduled to expire pursuant to Section 8.5(b) in a given Calendar Quarter, and during the next Calendar Quarter, [***], then the Royalty Term for such Product in such Country shall [***].
(d) **Royalty Reduction**. If a Product is royalty-bearing only on account of Section 8.5(b)(iii), then the royalty rates set forth in Section 8.5(a) with respect to Net Sales attributable to such Product will be reduced by [***].

(e) **Third Party Royalty Payments**. If a Selling Party, [***] a license from any Third Party under any intellectual property right [***], and if such Selling Party is required after the Effective Date to pay to such Third Party under such license [***], provided however, that the royalties payable under Section 8.5(a) will not be reduced in any such event pursuant to this Section 8.5(e) below [***] of the amounts set forth in Section 8.5(a) [***]; provided further, however, [***]. Any royalties or other payments payable under any Moderna Collaboration In-License may not be deducted under this Section 8.5(e) from royalties owed to Moderna.

(f) **Compulsory Licenses**. If a court or a governmental agency of competent jurisdiction requires Merck or its Sublicensee to grant a compulsory license to a Third Party with respect to Product in any country in the Territory with a royalty rate lower than the royalty rate provided by Section 8.5(a), then the royalty rate to be paid by Merck on Net Sales in that country under Section 8.5(a) shall be reduced [***].

(g) **Additional Royalty Provisions**. The royalties payable under Section 8.5(a) will be subject to the following:

(i) only one royalty will be payable hereunder with respect to each Product unit;

(ii) royalties when owed or paid hereunder will, except as provided in Section 8.5(e), be non-refundable and non-creditable and not subject to set-off;

(iii) no royalties shall be due upon the sale or other transfer among Merck or its Selling Parties, but in such cases the royalty shall be due and calculated upon Merck’s or its Selling Party’s Net Sales to the first independent Third Party;

(iv) no royalties shall accrue on the sale or other disposition of Product by Merck or its Selling Parties for use in any clinical trial;

(v) for purposes of this Section 8.5, all sales of a Product by any Selling Party for use in the [***] field (to the extent permitted pursuant to Section 9.2) shall be counted as “Net Sales” of such Product for the purposes of calculating Net Sales, applicable royalty tiers and otherwise under this Section 8.5;

(vi) except as expressly set forth in Sections 8.5(d), 8.5(e) and 8.5(f), no other royalty deductions are permitted hereunder; and

(vii) no royalties shall accrue on the disposition or sale of Product (A) in reasonable quantities by Merck, its Affiliates or Sublicensees as part of an expanded access program or (B) as donations (for example, to non-profit institutions or government agencies for non-commercial purposes) or as test marketing or samples (promotion or otherwise) or (C) at no margin (including taking into account the royalties that would be payable to Moderna).

8.6. **Payment Terms**.

(a) **Manner of Payment**. All payments to be made by Merck hereunder will be made in U.S. dollars by wire transfer to such bank account as Moderna may designate.

(b) **Reports and Royalty Payments**. For as long as royalties or other payments are due under this Section 8, Merck will furnish to Moderna a written report, after the end of each Calendar Quarter, showing the amount of Net Sales and royalty due under Section 8.5(a), and any other payments accrued during such Calendar Quarter, which report will be furnished within [***] of the end of the quarter for Net Sales generated by Merck and its Affiliates and Sublicensees. Royalty and other payments for each Calendar Quarter will be due at the same time as such written reports for the Calendar Quarter. The reports will include, at a minimum, the following information for the applicable Calendar Quarter, each listed by country of sale and use: [***].

(c) **Records; Audits**. Merck will keep, and will cause each of the other Selling Parties, as applicable, to keep, and Moderna will keep, adequate books and records of accounting for the purpose of calculating all royalties and other amounts payable by either Party to the other Party hereunder and ensuring each Party’s
compliance hereunder. For the [***] following the end of the Calendar Year to which each will pertain, such books and records of accounting (including those of its Affiliates, as applicable) will be kept at each of their principal place of business. At the request of either Party, the other Party will permit (and procure its Affiliates, to permit) an independent certified public accounting firm of internationally recognized standing selected by the auditing Party and reasonably acceptable to the other Party to have access during normal business hours to such of the records as may be reasonably necessary to verify the accuracy of the payments due hereunder for any Calendar Year ending not more than [***] following the end of any Calendar Year. Such examinations may not be conducted more than once in any Calendar Year or be repeated for any Calendar Year. The accounting firm shall disclose to the auditing Party only whether the reports are correct or incorrect and the amount of any discrepancy. No other Confidential Information shall be provided. If such accounting firm correctly identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy within [***] of the date of delivery of such accounting firm’s written report so correctly concluding, or as otherwise agreed upon by the Parties. The fees charged by such accounting firm shall be paid by the auditing Party, provided that if the underpayment or overcharge exceeds [***], the audited Party shall pay the fees. Upon the expiration of [***] following the end of any Calendar Year, absent willful misconduct or fraud by a Party (its Affiliates, as applicable) the calculation of amounts payable with respect to such Calendar Year shall be binding and conclusive upon the Parties, and the Parties shall be released from any liability or accountability with respect to amounts payable for such Calendar Year. The auditing Party shall treat all financial information subject to review under this Section 8.6(c) in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party obligating it to retain all such Confidential Information in confidence pursuant to such confidentiality agreement.

(d) Taxes. Subject to Section 8.1, Merck may deduct or withhold from any payments due to Moderna amounts for payment of any withholding Tax that is required by Law to be paid to any Tax Authority with respect to such payments. To the extent that any such amounts are so deducted or withheld, such amounts will be treated for all purposes of this Agreement as having been paid to Moderna. Merck will give written notice of its intent to withhold any amounts under this Section 8.6(d) at least [***] days in advance of any payment being made. Merck will give proper evidence from time to time as to the payment of any such Tax. Moderna will provide Merck all necessary documents and correspondence, and will also use commercially reasonable efforts to provide to Merck any other cooperation or assistance on a reasonable basis as may be necessary to enable Merck to claim exemption from such deduction or withholding Taxes. The Parties will reasonably cooperate with each other in seeking relief or reduction in the deduction or withholding of any Tax under any double Taxation or other similar treaty or agreement from time to time in force and in seeking to receive a refund of any withholding Tax or to claim a foreign Tax credit.

(e) Currency Exchange. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due to Moderna hereunder will be expressed in U.S. dollars. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States Dollars due Moderna shall be made at the monthly rate of exchange utilized by Merck in its worldwide accounting system. For purposes of calculating the Net Sales thresholds set forth in Sections 8.4(d) and 8.5(a), the aggregate Net Sales with respect to each Calendar Quarter within a Calendar Year will be calculated based on the currency exchange rates for the Calendar Quarter in which such Net Sales occurred, in a manner consistent with the exchange rate procedures set forth in the immediately preceding sentence.

(f) Blocked Payments. In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for Merck (or any other Selling Party) to transfer, or have transferred on its behalf, payments owed Moderna hereunder, Merck will promptly notify Moderna of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Moderna in a recognized banking institution designated by Moderna or, if none is designated by Moderna within a period of [***] days, in a recognized banking institution selected by Merck or another Selling Party, as the case may be, and identified in a written notice given to Moderna.
(g) Interest Due. If any payment due to either Party under this Agreement is overdue (and is not subject to a good faith dispute), then such paying Party will pay interest thereon [***] at an annual rate [***] after payment of such sum became due until payment thereof in full together with such interest.

(h) Mutual Convenience of the Parties. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Moderna.

(i) Other Expenses. Except as expressly set forth herein or in any Supply Agreement, each Party will be solely responsible for costs and expenses incurred by such Party in connection with the activities contemplated by this Agreement.


(a) Development & Commercialization Licenses. Subject to the terms of this Agreement, including Section 9.1(b), Moderna, on behalf of itself and its Affiliates, hereby grants to Merck a royalty-bearing, worldwide, exclusive license in the Applicable Field, with the right to grant sublicenses in compliance with Section 9.4, under the Moderna Technology:

(i) On an R&D Program-by-R&D Program basis, to Develop Collaboration mRNA Constructs, under and in accordance with the applicable R&D Plan during the R&D Term;

(ii) To Develop [***] Collaboration mRNA Constructs in a Product Candidate Pool or in an Elected Candidate or Product;

(iii) To Develop Product Candidates, Elected Candidates and Products (including the Collaboration mRNA Constructs as they are included therein);

(iv) To Commercialize and otherwise Exploit Elected Candidates and Products (including the Collaboration mRNA Constructs as they are included therein); and

(v) Subject to Article 4 (including Exhibit A), to Manufacture Collaboration mRNA Constructs, Product Candidates, Elected Candidates and Products.

(b) [***]

(c) Retained Rights; Limitations. Notwithstanding the exclusive licenses set forth in Section 9.1(a), Moderna retains rights under the Moderna Technology to perform and to have performed its obligations under this Agreement and any Supply Agreement.

9.2. [***]

9.3. Development License by Merck. Subject to the terms and conditions of this Agreement, Merck hereby grants to Moderna a non-exclusive, worldwide license, with the right to grant sublicenses to permitted subcontractors pursuant to Section 2.12 only, under the Merck Background Technology and Merck Collaboration Technology, solely to perform the Collaboration Activities in accordance with the terms of this Agreement and the applicable R&D Plan provided that the grant of any such sublicense shall not relieve Moderna of its obligations under this Agreement, and Moderna will be responsible for ensuring the performance and compliance by such sublicensee with the terms this Agreement as if such sublicensee were “Moderna”, in each case, to the extent applicable to such sublicensee.

9.4. Sublicensing.

(a) Merck Sublicensing. Merck may grant sublicenses under any of the licenses granted to Merck by Moderna under Section 9.1, without Moderna’s consent, to (x) one or more Affiliates (with the right to sublicense through multiple tiers), (y) to one or more Third Party subcontractors (in accordance with Section 2.12) of Merck (or its Affiliate) and/or (z) with respect to an Elected Candidate or Product to one or more Third Parties (with the right to sublicense through multiple tiers), provided that the grant of any such sublicense to an Affiliate or Third Party shall not relieve Merck of its obligations under this Agreement, and
9.5. Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement, are, and will be deemed to be for all purposes of Section 365(n) of Title 11 of the United States Code and of any similar provisions of applicable Laws under any other jurisdiction (the “Bankruptcy Code”), rights and licenses to “intellectual property” (as defined in Section 101(35A) of the Bankruptcy Code). Each Party agrees that the other Party, as a licensee of rights and licenses under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the Bankruptcy Code or analogous provisions of applicable Law outside the U.S., the other Party will be entitled to a complete duplicate of, or complete access to (as appropriate), any intellectual property licensed to such other Party held by such first Party and its successors and assigns (including all embodiments thereof), which, if not already in such other Party’s possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon such other Party’s written request therefor, unless such first Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a), following the rejection of this Agreement by such first Party in the bankruptcy proceeding upon written request therefor by such other Party.

9.6. No Grant of Inconsistent Rights by Moderna. Moderna (and its Affiliates) shall not assign, transfer, convey or otherwise grant to any Person or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise, but excluding liens in connection with financings) (a) any rights to any Moderna Technology (or any rights to any intellectual property that would otherwise be included in the Moderna Technology), in any manner that is inconsistent with or would interfere with the grant of the rights or licenses to Merck hereunder, or (b) any rights to any Collaboration mRNA Constructs, Product Candidates, Elected Candidates or Products (provided that Moderna shall grant to Merck the rights to the Collaboration mRNA Constructs, Product Candidates, Elected Candidates or Products as set forth herein), other than with respect to the right to receive royalty payments on the Net Sales of Products.


10.1. Disclosure. Each Party will promptly disclose to the other Party in writing, and will cause its Affiliates and subcontractors to so disclose, the conception, creation or discovery of any inventions within the Collaboration Know-How.

10.2. Ownership of Certain Moderna Technology. Subject to the license grants to Merck under this Agreement, as between the Parties, Moderna will own and retain all right, title and interest in and to all [***], conceived, created or discovered during the performance of Collaboration Activities. Accordingly, Merck will promptly disclose to Moderna in writing, the conception, creation, or the discovery, of any [***] by or on behalf of Merck or its Affiliates. Merck, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to Moderna all its right, title and interest in and to any [***] conceived, created or discovered during the performance of Collaboration Activities. Merck will cooperate, and will cause the foregoing persons and entities to cooperate, with Moderna to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership.
10.3. **License.** To the extent that Merck solely conceives, creates or discovers any Moderna Collaboration Platform Technology or Moderna Formulation Technology that is assigned to Moderna pursuant to Section 10.2, Moderna hereby grants to Merck [***], worldwide license under [***] to research, develop, manufacture, use, commercialize, offer for sale, sell, distribute, import or export [***].

10.4. **Ownership of [***].** Subject to the license grants to Moderna under this Agreement, as between the Parties, Merck will own and retain all right, title and interest in and to all [***]. Accordingly, Moderna will promptly disclose to Merck in writing, the conception, creation or discovery of any [***] by or on behalf of Moderna or its Affiliates. Moderna, for itself and on behalf of its Affiliates, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to Merck all its right, title and interest in and to any [***] conceived, created or discovered during the course of performing Collaboration Activities. Moderna will cooperate, and will cause the foregoing persons and entities to cooperate, with Merck to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership. To the extent that Moderna conceives, creates or discovers any [***] (solely or jointly with Merck) that is assigned to Merck pursuant to this Section 10.4, Merck hereby grants to Moderna a non-exclusive, royalty free and fully paid-up, sublicensable, worldwide license under such assigned [***], subject to Section 11, to research, develop, manufacture, use, commercialize, offer for sale, sell, distribute, import or export any product (or component thereof).

10.5. **Ownership of Other Technology.** Except as set forth in Section 10.2 and Section 10.4, and subject to the license grants by one Party to the other under this Agreement, all Know-How and Patents conceived, created or discovered, by or on behalf of either Party or its Affiliates either alone or jointly with Third Party(ies), or by the Parties or their Affiliates jointly under or in connection with the this Agreement, whether or not conceived, created or discovered at a facility owned or controlled by such Party and whether or not patented or patentable, and any and all Patent and other intellectual property rights with respect thereto will be owned in accordance with inventorship and in accordance with applicable Law in the United States.

10.6. **United States Law.** The determination of whether Know-How and Patents are conceived, created or discovered by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, will, for purposes of this Agreement, be made in accordance with applicable Law in the United States. In the event that United States Law does not apply to the conception, creation or discovery of any Know-How or Patents hereunder, each Party will, and does hereby, assign, and will cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Know-How and Patents as well as any intellectual property rights with respect thereto, as is necessary to fully effect ownership as would have been determined under U.S. Law.

10.7. **Exploitation of Joint Technology.** Subject to Section 10.2 and Section 10.4 and to the license grants in this Agreement, the Parties will each own an equal, undivided interest in and to all Joint Technology. Each Party will exercise its ownership rights in and to such Joint Technology, including the right to license and sublicense or otherwise to Exploit, transfer or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party, but subject to Section 11 and the license grants under this Agreement. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint Technology. Each Party will, and does hereby, assign, and will cause its Affiliates and subcontractors to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Joint Technology as well as any intellectual property rights with respect thereto, as is necessary to fully effect the joint ownership provided for in the first sentence of this Section 10.7.

10.8. **No Implied Rights.** No license, sublicense or other right is or will be created or granted hereunder by implication, estoppel or otherwise. Any licenses, sublicenses or rights will be granted only as expressly provided in this Agreement. Neither Party nor any of its Affiliates will use or practice any Know-How or Patents licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.
11. Exclusivity

11.1. Target Exclusivity.

(a) R&D Term. During the R&D Term, Moderna will not, [***].

(b) After R&D Term. From and after the end of the R&D Term, Moderna will not, [***].

11.2. Collaboration mRNA Construct, Product Candidate, Elected Candidate and Product Exclusivity. Moderna will not, [***].

11.3. Collaboration Field Exclusivity.

(a) R&D Term. Subject to [***], during the R&D Term, Moderna will not, and will cause each of its Affiliates not to, either itself, or together with any Third Party, [***].

(b) Non-Restricted Activities. Notwithstanding anything in Section 11.3(a) to the contrary, the provisions of Section 11.3(a) do not restrict Moderna or its Affiliates or licensees from:

(i) performing Moderna’s obligations pursuant to this Agreement or any Supply Agreement;

(ii) [***];

(iii) conducting such assays or other research as reasonably necessary to maintain compliance with Section 11.3(a);

(iv) granting the rights and licenses set forth in, and performing obligations under, any Existing Partner Agreement regarding [***] but in all cases subject to the other provisions of this Section 11; [***];

(v) granting any Third Party [***]

(vi) [***]

11.4. [***]

11.8. Exception for Business Combination.

(a) Notwithstanding Sections [***], if (a) a Business Combination occurs with respect to Moderna or its Affiliate with a Third Party or (b) Moderna or its Affiliate acquires a Third Party (by merger, consolidation or otherwise) so that such Third Party becomes an Affiliate over which Moderna or its Affiliate has control (as defined in Section 1.4), or (c) Moderna or its Affiliate acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof) (each of (a), (b) and (c), a “Moderna Acquisition”), and, in each case, the Third Party (or any of such Third Party’s Affiliates or any successors or assigns of such Third Party or such Third Party’s Affiliates, other than Moderna and its Affiliates as of the Moderna Acquisition) already has, or the acquired assets contain, as applicable, a program that existed prior to, or was substantially in the process of being implemented prior to such Moderna Acquisition and is in fact implemented shortly after such Moderna Acquisition, the Moderna Acquisition that would otherwise violate any of Sections [***] (a “Moderna Business Program”), then [***]; provided that [***].

(b) In addition, in the event a Business Combination occurs with respect Moderna or an Affiliate that does work hereunder or is in possession of Merck’s Confidential Information (including [***]), with a Third Party, then with respect to such acquiring Third Party (or any Affiliates of such acquiring Third Party prior to the consummation of Business Combination (collectively with such acquiring Third Party, a “Third Party Acquiror”), but excluding, for clarity, Moderna and the Moderna Affiliates prior to the consummation of such Business Combination) and after such Business Combination such Third Party Acquiror initiates a program that was not substantially in the process of being implemented prior to such Business Combination (each, a “New Program”):

(i) the provisions of [***] shall not apply to such Third Party Acquiror with respect to such New Program provided that [***]
(ii) the provisions of [***] shall not apply to such Third Party Acquiror with respect to such New Program provided that [***].

(c) In addition to the other provisions of this Section 11.8, Merck shall have the right to [***].

11.9. Merck Exclusivity.

(a) R&D Term. During the R&D Term, Merck will not, and will cause each of its Affiliates not to, either itself, or together with any Third Party, [***].

(b) Post R&D Period. [***], during the Post-R&D Period, Merck will not, [***].

(c) Notwithstanding Section 11.9(a) and Section 11.9(b), if (a) a Business Combination occurs with respect to Merck or its Affiliate with a Third Party or (b) Merck or its Affiliate acquires a Third Party (by merger, consolidation or otherwise) so that such Third Party becomes an Affiliate over which Merck or its Affiliate has control (as defined in Section 1.4), or (c) Merck or its Affiliate acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof) (each of (a), (b) and (c), a “Merck Acquisition”), and, in each case, the Third Party (or any of such Third Party’s Affiliates or any successors or assigns of such Third Party or such Third Party’s Affiliates, other than Merck and its Affiliates as of the Merck Acquisition) already has, or the acquired assets contain, as applicable, a program that existed prior to, or was planned prior to and is demonstrably to be implemented shortly after, the Merck Acquisition that would otherwise violate Section 11.9(a) or Section 11.9(b) (a “Merck Business Program”), then [***]; provided that [***].

12. Confidentiality.

12.1. Confidential Information.

(a) Confidential Information. Each Party (“Disclosing Party”) may have disclosed or will disclose to the other Party (“Receiving Party”), and Receiving Party may acquire during the course and conduct of activities under this Agreement, certain proprietary or confidential information of Disclosing Party. The term “Confidential Information” means (i) all proprietary tangible samples of, and confidential information about, Materials and (ii) all confidential ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available to Receiving Party by Disclosing Party or at the request of Receiving Party. Without limiting the foregoing, all confidential information about (1) [***], (2) [***], and (3) Joint Technology will be treated as Confidential Information of both Parties.

(b) Restrictions. During the Term and for [***] thereafter, Receiving Party will, and will cause its Affiliates and their respective officers, directors, employees and agents to, keep all Disclosing Party’s Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information (though no less than reasonable care). Receiving Party will not use, and will cause its Affiliates and their respective officers, directors, employees and agents not to use, Disclosing Party’s Confidential Information except in connection with the performance of its obligations and exercise of its rights under this Agreement. Receiving Party has the right to disclose Disclosing Party’s Confidential Information without Disclosing Party’s prior written consent (such consent not to be unreasonably withheld, delayed or conditioned), to the extent and only to the extent reasonably necessary or useful, to Receiving Party’s Affiliates and their employees, subcontractors, Sublicensees, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this Agreement and who are required to comply with restrictions on use and disclosure similarly restrictive as those in this Section 12.1(b). Receiving Party will use [***] to cause those entities and persons to comply with such restrictions on use and disclosure. Notwithstanding the foregoing sentence, Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party’s Confidential Information in confidence and using same only for the purposes described herein.

(c) Exceptions. Receiving Party’s obligation of nondisclosure and the limitations upon the right to use the Disclosing Party’s Confidential Information set forth in Section 12.1(b) will not apply to the extent that
Receiving Party can demonstrate that the Disclosing Party’s Confidential Information: (i) was known to Receiving Party or any of its Affiliates prior to the time of disclosure; (ii) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (iii) is obtained by Receiving Party or any of its Affiliates from a Third Party under no obligation of confidentiality to Disclosing Party; or (iv) has been independently developed by employees, subcontractors, consultants or agents of Receiving Party or any of its Affiliates without the aid, application or use of Disclosing Party’s Confidential Information, as evidenced by contemporaneous written records. Notwithstanding the foregoing, (A) any Confidential Information will not be deemed to be within the foregoing exceptions merely because such information is embraced by more general information in the public domain or in the possession of the Receiving Party or any of its Affiliates, and (B) any combination of features will not be deemed to be within the foregoing exceptions merely because individual features are in the public domain or in the possession of the Receiving Party or any of its Affiliates, but only if the combination itself and its principle of operation are in the public domain or in the possession of the Receiving Party or any of its Affiliates.

(d) Permitted Disclosures. Receiving Party may disclose Disclosing Party’s Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(i) in order to comply with applicable Law or with a legal or administrative proceeding;

(ii) in connection with (a) prosecuting or defending litigation or for Prosecuting or (b) the Prosecution and Maintenance of Patents in accordance with this Agreement;

(iii) in connection with exercising any rights or other licenses under this Agreement, including with respect to any Joint Technology;

(iv) in the case of Merck to [***]; and

(v) in the case of Moderna, to [***].

In the case of a disclosure pursuant to (A) Sections [***], where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party’s intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as [***], and (B) with respect to Sections [***], each of those named people and entities are required to comply with restrictions on use and disclosure [***].

12.2. Publications. The Parties may desire to publish in scientific journals and present at scientific conferences the results of the Collaboration Activities, subject to the following process. Notwithstanding anything to the contrary herein, either Party may propose publication of the results of the Collaboration Activities following scientific review by the JSC (if in force); provided, that no such publication will be made without written approval by Moderna and Merck. After receipt of the proposed publication by both Merck and Moderna, such written approval or disapproval will be provided within [***] days. Both Parties understand that a reasonable commercial strategy may require delay of publication of information or filing of Patent applications, therefore the Parties agree to review and consider delay of publication and filing of patent applications under certain circumstances for a reasonably limited period of. Once publications have been reviewed by each Party and have been approved for publication, the same publications do not have to be provided again to the other Party for review for a later submission for publication. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreeable to the Parties. Each Party will acknowledge the other Party’s technical, non-financial contributions in any such publication. Notwithstanding the foregoing, Merck shall have the sole right to publish with respect to Elected Candidates and Products, provided any such publication does not include any Confidential Information of Moderna.

12.3. Terms of this Agreement; Publicity.

(a) Restrictions. The Parties agree that the terms of this Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 12.1(d). Each Party will also be permitted to disclose the terms of this Agreement and any Supply Agreement (including the exhibits hereto and thereto), in each case under appropriate confidentiality provisions, on a need to know basis, to a Party’s (and its Affiliates’) existing investors and unit holders and to any /[***], provided that (1) the disclosing Party agrees to redact information that it reasonably believes is not relevant to the proposed transaction, and (2) [***]. Except as required by Law, each Party agrees not to issue any press release or public statement
disclosing information relating to this Agreement, the transactions contemplated hereby or any of the terms hereof without the prior written consent of the other Party (such consent not to be unreasonably withheld, delayed or conditioned), or as such consent may be obtained in accordance with Section 12.3(c), or as permitted by Section 12.3(d).

(b) **Securities Filings; Law.** Each Party acknowledges and agrees that the other Party may submit this Agreement (including for clarity, the Exhibits and Schedules hereto) to the United States Securities and Exchange Commission (the “SEC”) or any other securities exchange and if a Party does submit this Agreement to the SEC or any other securities exchange, such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement. If a Party is required by Law to make a disclosure of the terms of this Agreement in a filing with or other submission to the SEC or any other securities exchange or otherwise to comply with Law, and (i) such Party has provided copies of the disclosure to the other Party as far in advance of such filing or other disclosure as is reasonably practicable under the circumstances, (ii) such Party has promptly notified the other Party in writing of such requirement and any respective timing constraints, and (iii) such Party has given the other Party a reasonable time under the circumstances from the date of notice by such Party of the required disclosure to comment upon, request confidential treatment or approve such disclosure, then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by Law. [***]

c) **Press Releases.** Neither Party may issue any press release or make any other public announcement or statement concerning this Agreement, the transactions contemplated hereby or the terms hereof, without the prior written approval of the other Party, except as may be required by applicable Law. In the event either Party (the “Issuing Party”) desires to issue a press release or other public statement disclosing information relating to this Agreement, the transactions contemplated hereby or the terms hereof, the Issuing Party will provide the other Party (the “Reviewing Party”) with a copy of the proposed press release or public statement (the “Release”) and seek the Reviewing Party’s prior written consent. The Issuing Party will specify with each such Release, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Receiving Party may provide any comments on such Release and if the Receiving Party fails to provide any comments during the response period called for by the Issuing Party, the Reviewing Party will be deemed to have not consented to the issuance of such Release. If the Receiving Party provides any comments, the Parties will consult on such Release and work in good faith to prepare a mutually acceptable Release. Either Party may subsequently publicly disclose any information previously contained in any Release so consented to.

d) **Joint Press Release.** The Parties agree to issue the joint press release in Exhibit H promptly following the Effective Date.

12.4. **Relationship to the Confidentiality Agreement.** This Agreement supersedes the Confidentiality Agreement; provided, that all “Confidential Information” disclosed or received by the Parties thereunder will be deemed “Confidential Information” hereunder and will be subject to the terms and conditions of this Agreement.

13. **Patent Prosecution, Maintenance and Enforcement.**

13.1. **Prosecution and Maintenance.**

(a) **Moderna [***] Patents.**

(i) Subject to [***], Moderna will have the sole right, but not the obligation, using counsel of its choosing, to Prosecute and Maintain all Moderna [***] Patents throughout the Territory.

(ii) Moderna will be solely responsible for the Patent Costs incurred by Moderna in connection with this Section 13.1(a).

(b) **Moderna [***] Patents and Moderna [***] Patents.**

(i) [***]

(ii) [***]
13.2. Patent Extensions. With respect to any election for patent term restoration or extension, supplemental protection certificate or any of their equivalents, (a) Merck will have the sole right to make any such decision relating to the [***]; and (b) Moderna will have the right to make any such decision relating to the Moderna [***] Patents and Moderna [***] Patents. Upon the request by a Party, such other Party through will reasonably cooperate in the implementation of such requesting Party’s decisions under this Section 13.2.

13.3. Patent Listings. With respect to any filings made to Regulatory Authorities with respect to the Moderna Patents for any Elected Candidate or Product, including as required or allowed in connection with in the United States, the FDA’s Orange Book, if applicable, or outside the United States, other international equivalents, Merck will have the sole right to make all decisions regarding such filings as Merck deems appropriate. Upon the request by Merck, Moderna will reasonably cooperate in the implementation of Merck’s decisions regarding the filing and listing pursuant to this Section 13.3.

13.4. Joint Patents. With respect to any Joint Patents included in the [***] or Moderna [***] Patents, the provisions of Sections [***] shall apply to the Prosecution and Maintenance of such Joint Patents to the extent such Joint Patent is included as either a Moderna [***] Patent or Moderna [***] Patents, as applicable. With respect to all other Joint Patents, the Parties shall mutually agree upon the responsibility for the Prosecution and Maintenance of such Joint Patents and the Patent Costs therefor.

13.5. Third Party Rights. Notwithstanding the foregoing provisions of this Section 13, each Party’s rights and obligations under this Section 13 with respect to any Moderna [***] Patent or Moderna [***] Patent licensed to Moderna or its Affiliate pursuant to a Moderna Collaboration In-License will be subject to the Third Party rights and obligations under such Moderna Collaboration In-License[***]; provided, however, that, to the extent that Moderna has [***].

13.6. [***]


(a) Notice. Each Party will promptly notify the other Party, in writing, upon learning of any actual or suspected Competitive Infringement of [***] by a Third Party, [***], and will, along with such notice, provide any evidence in its possession pertaining thereto.

(b) [***] and Competitive Infringement.

(i) As between the Parties, [***].

(ii) [***]

(c) Defense. As between the Parties, [***].

(d) Withdrawal, Cooperation and Participation. With respect to any infringement or defensive action identified above in this Section 13.7.
(i) If the controlling Party ceases to pursue or withdraws from such action, it will promptly notify
the other Party (in sufficient time to enable the other Party to meet any deadlines by which any action must be
taken to preserve any rights in such infringement or defensive action) and such other Party may substitute itself
for the withdrawing Party and proceed under the terms and conditions of this Section 13.7.

(ii) The non-controlling Party will cooperate with the Party controlling any such action (as may be
reasonably requested by the controlling Party), including [***]. The Party controlling any such action will keep
the non-controlling Party updated with respect to any such action, including providing copies of all documents
received or filed in connection with any such action.

(iii) Each Party will have the right to participate or otherwise be involved in any such action
controlled by the other Party, in each case at the non-controlling Party’s sole cost and expense. If a Party elects
to so participate or be involved, the controlling Party will provide the non-controlling Party and its counsel with
an opportunity to consult with the controlling Party and its counsel regarding the prosecution of such action
(including reviewing the contents of any correspondence, legal papers or other documents related thereto), and
the controlling Party will take into account reasonable requests of the non-controlling Party regarding such
enforcement or defense.

(iv) Damages. Unless otherwise agreed by the Parties, all monies recovered upon the final judgment
or settlement of any action described in [***] will be [***].

(v) Third Party Rights. To the extent that a Third Party licensor under a Moderna Collaboration In-
License has retained any right to [***], Moderna will use Commercially Reasonable Efforts to cause such Third
Party licensor to take the actions specified by this Section 13.7 in a manner consistent with the Moderna
Collaboration In-License applicable thereto, but Moderna will not be deemed to be in breach of its obligations
under this Section 13.7 if, after using such Commercially Reasonable Efforts, it is unable to comply with such
obligations because of actions taken or not taken by such Third Party licensor.

14. Representations and Warranties; Limitations of Liability; Indemnification; Covenants

14.1. Representations and Warranties of Each Party. Each Party represents and warrants to the other as of
the Effective Date that:

(a) Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction in
which it is organized.

(b) Such Party (i) has the legal right and power to enter into this Agreement, to extend the rights granted
or to be granted to the other in this Agreement, and to fully perform its obligations hereunder, including to grant
the licenses set forth herein, and (ii) has taken all requisite action on its part to authorize the execution and
delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly
executed and delivered on behalf of such Party, and constitutes a legal, valid and binding obligation, enforceable
against such Party in accordance with its terms, except as may be limited by bankruptcy, insolvency,
reorganization or other laws affecting creditors’ rights generally and by general equitable principles.

(c) Neither such Party nor its Affiliates has been debarred or is subject to debarment. Neither it nor its
Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any
person who has been debarred pursuant to Section 306 of the FFDCA, or who is the subject of a conviction
described in such section. In addition, neither it nor its Affiliates has used in any capacity, in connection with
any Development activities with respect to

the mRNA Technology, mRNA Construct or any Polypeptide included hereunder carried out prior to the
Effective Date, any person who has been debarred or was the subject of a conviction described in Section 306.
Such Party agrees to inform the other Party in writing immediately if it or any person who is performing
services under this Agreement is debarred or is the subject of a conviction described in Section 306, or if any
action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of such Party’s
or its Affiliates’ Knowledge, is threatened, relating to the debarment or conviction of such Party or any person
performing services under this Agreement, or if such Party becomes aware that it or any person performing Development activities with respect to an mRNA Construct, Polypeptide, Product Candidate, Elected Candidate or Product included hereunder carried out prior to the Effective Date was debarred or was the subject of a conviction described in Section 306.

(d) All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party to enter into, or perform its obligations under, this Agreement have been obtained.

(e) The execution and delivery of this Agreement and the performance of such Party’s obligations hereunder (i) will not conflict with or violate any requirement of applicable Law or orders of governmental bodies, (ii) do not conflict with, or constitute a default under, any contractual obligation of such Party and (iii) do not conflict with or violate any provision of the corporate charter, by-laws or other organizational documents of such Party.

14.2. Additional Representations of Moderna. Moderna represents and warrants to Merck that as of the Effective Date:

(a) there are no [***] and to Moderna’s Knowledge, no [***] relating to the Moderna Patents and/or Moderna Know-How;

(b) Schedule 1.123 sets forth a true, correct and complete list of Moderna Patents and such schedule contains all application numbers and filing dates, registration numbers and dates, jurisdictions and owners. [***]

(c) to Moderna’s Knowledge (i) all Patents within the Moderna Patents have been procured or are being procured from the respective patent offices in accordance with applicable Law, and (ii) the issued Patents within the Moderna Patents are [***];

(d) it (and its Affiliates) has not prior to the Effective Date (i) assigned, transferred or conveyed its right, title and/or interest in Moderna Patents or Moderna Know-How, or (ii) otherwise granted any rights to any Third Parties that would, in the case of clauses (i) and/or (ii), conflict with the rights granted to Merck hereunder, and, to Moderna’s Knowledge, there is no unauthorized use, infringement or misappropriation of any Moderna Patent or Moderna Know-How;

(e) it or its Affiliate is the sole and exclusive owner of the [***] which are as at the Effective Date free and clear of any liens, charges and encumbrances (excluding those entered into the ordinary course of financing its business), and no other Person has as at the Effective Date any claim of ownership whatsoever with respect to the [***];

(f) [***]

(g) [***]

(h) [***]

(i) neither Moderna nor any of its Affiliates has obtained, or filed for, any INDs, NDAs or Regulatory Approval for any mRNA Constructs or mRNA Products in [***];

(j) all Development related to the [***] prior to the Effective Date has been conducted in accordance with all applicable Laws;

(k) [***]

(l) [***]

(m) [***]

14.3. Disclaimers. Without limiting the respective rights and obligations of the Parties expressly set forth herein, each Party specifically disclaims any guarantee that the Collaboration Activities or any Product Candidate will be successful, in whole or in part. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED (AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES NOT EXPRESSLY PROVIDED IN THIS AGREEMENT), INCLUDING WITH RESPECT TO ANY PATENTS OR KNOW-HOW, MRNA
CONSTRUCTS, PRODUCT CANDIDATES, MATERIALS, OR MRNA PRODUCTS, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY OF ANY PATENTS, TITLE, QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE, AND NONINFRINGEMENT OF ANY THIRD PARTY PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS.

14.4. No Consequential Damages. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT, EXCEPT FOR DAMAGES DUE TO THE FRAUD OR WILLFUL MISCONDUCT OR GROSS NEGLIGENCE OF THE LIABLE PARTY, NEITHER PARTY WILL BE LIABLE TO THE OTHER OR ANY THIRD PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT FOR ANY INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF SUCH PARTY HAS BEEN INFORMED OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED, THAT THIS SECTION 14.4 WILL NOT APPLY TO THE PARTIES’ INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER SECTION 14.5.

14.5. Indemnification.

(a) Indemnification by Merck. Merck will indemnify Moderna, its Affiliates and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, “Moderna Indemnitees”), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys’ fees and expenses) (collectively, “Losses”) in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, “Third Party Claims”) arising from or occurring as a result of: [***], except in each case for those Losses and Third Party Claims for which Moderna has an obligation to indemnify Merck pursuant to Section 14.5(b) (or would have had such Third Party Claim been made against Merck under this Agreement), as to which Losses each Party will indemnify the other to the extent of their respective liability; provided, that Merck will not be obligated to indemnify Moderna Indemnitees for any Losses or Third Party Claims to the extent that such Losses or Third Party Claims arise as a result of gross negligence or willful misconduct on the part of a Moderna Indemnitee or breach of this Agreement by Moderna.

(b) Indemnification by Moderna. Moderna will indemnify Merck, its Affiliates and their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, “Merck Indemnitees”), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: [***], and except in each case for those Losses and Third Party Claims for which Merck has an obligation to indemnify Moderna pursuant to Section 14.5(a)(i) or 14.5(a)(ii) (or would have had such Third Party Claim been made against Moderna under this Agreement), as to which Losses each Party will indemnify the other to the extent of their respective liability for the Losses; provided, that Moderna will not be obligated to indemnify Merck Indemnitees for any Losses or Third Party Claims to the extent that such Losses or Third Party Claims arise as a result of gross negligence or willful misconduct on the part of an Merck Indemnitee or breach of this Agreement by Merck.

(c) Notice of Claim. All indemnification claims provided for in Section 14.5(a) and 14.5(b) will be made solely by such Party to this Agreement (the “Indemnified Party”). The Indemnified Party will promptly notify the indemnifying Party (an “Indemnification Claim Notice”) of any Losses or the discovery of any fact upon which the Indemnified Party intends to base a request for indemnification under Section 14.5(a) or 14.5(b), but in no event will the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and estimated amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party will furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims. Notwithstanding the foregoing, any delay or failure to provide any notices or copies pursuant to this Section 14.5(c) shall not constitute a waiver or release of, or otherwise limit, the Indemnified Party’s rights to indemnification under this Section 14.5, except to the extent that such delay or failure materially prejudices the indemnifying Party’s ability to defend against the relevant claims.

(d) Defense, Settlement, Cooperation and Expenses.

(i) Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [***] days after the indemnifying Party’s receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party will not be construed as an acknowledgment that the indemnifying Party is liable to
indemnify the Indemnified Party in respect of the Third Party Claim, nor will it constitute a waiver by the
indemnifying Party of any defenses it may assert against the Indemnified Party’s claim for indemnification.
Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the
defense of the Third Party Claim any legal counsel selected by the indemnifying Party (the indemnifying Party
will consult with the Indemnified Party with respect to a possible conflict of interest of such counsel retained by
the indemnifying Party). In the event the indemnifying Party assumes the defense of a Third Party Claim, the
Indemnified Party will immediately deliver to the indemnifying Party all original notices and documents
(including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the
indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 14.5(d)(ii), the
indemnifying Party will not be liable to the Indemnified Party for any legal costs or expenses subsequently
incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party
Claim. [***]

(ii) **Right to Participate in Defense.** Without limiting Section 14.5(d)(i), any Indemnified Party will
be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its
choice for such purpose; provided, that such employment will be at the Indemnified Party’s own cost and
expense unless [***].

(iii) **Settlement.** With respect to any Third Party Claims that relate solely to the payment of money
damages in connection with a Third Party Claim and that will not result in the Indemnified Party’s becoming
subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any
manner, and as to which the indemnifying Party will have acknowledged in writing the obligation to indemnify
the Indemnified Party hereunder, the indemnifying Party will have the sole right to agree to the entry of any
judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party,
in its sole discretion, will deem appropriate. With respect to all other Losses in connection with Third Party
Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with
Section 14.5(d)(i), the indemnifying Party will have authority to agree to the entry of any judgment, enter into
any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified
Party (such consent not to be unreasonably withheld, delayed or conditioned). The indemnifying Party will not
be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the
prior written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to
defend or prosecute any Third Party Claim, no Indemnified Party will admit any liability with respect to or
settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying
Party, such consent not to be unreasonably withheld, delayed or conditioned.

(iv) **Cooperation.** If the indemnifying Party chooses to defend or prosecute any Third Party Claim,
the Indemnified Party will, and will cause each other Indemnified Party to, cooperate in the defense or
prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend
such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in
connection therewith. Such cooperation will include access during normal business hours afforded to
indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are
reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents
available on a mutually convenient basis to provide additional information and explanation of any material
provided hereunder, and the indemnifying Party will reimburse the Indemnified Party for all its reasonable out-
of-pocket costs and expenses in connection therewith.

(v) **Costs and Expenses.** Except as provided above in this Section 14.5(d), the reasonable and
verifiable costs and expenses, including attorneys’ fees and expenses, incurred by the Indemnified Party in
connection with any claim will be reimbursed on a Calendar Quarter basis by the indemnifying Party, without
prejudice to the indemnifying Party’s right to contest the Indemnified Party’s right to indemnification and
subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the
Indemnified Party.

14.6. **Insurance.** Each Party will maintain at its sole cost and expense, an adequate liability insurance or
self-insurance program (including product liability insurance) to protect against potential liabilities and risk
arising out of activities to be performed under this Agreement, and any agreement related hereto and upon such
terms (including coverages, deductible limits and self-insured retentions) as are customary in the U.S.
pharmaceutical industry, or, if such activities are conducted outside the U.S., as are customary in such country,
for the activities to be conducted by such Party under this Agreement. The coverage limits set forth herein will not create any limitation on a Party’s liability to the other under this Agreement. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [***] days prior to the cancellation, non renewal or material change in such insurance or self insurance which materially adversely affects the rights of the other Party hereunder.

14.7. Covenants of Moderna. Moderna hereby covenants that:

(a) [***]
(b) [***]

14.8. Additional Covenants. [***]

15. Term and Termination.

15.1. Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated in accordance with the terms hereof or by mutual written consent, shall continue on a Product-by-Product and country-by-country basis until the end of the Royalty Term with respect to such Product in such country (the “Term”). On a country-by-country and Product-by-Product basis, upon the expiration of the Royalty Term for such Product in such country the licenses granted to Merck shall become fully-paid, perpetual and irrevocable for such Product in such country.

15.2. Termination by Moderna for Breach. Moderna will have the right to terminate this Agreement in full in the event of a material breach by Merck of this Agreement; provided, that to the extent that any such material breach is limited to a particular R&D Program, Product Candidate, Elected Candidate, Product or country, Moderna will have the right to terminate this Agreement only with respect to such R&D Program, Product Candidate, Elected Candidate, Product or country to which such material breach primarily relates. Notwithstanding the foregoing, any such termination under this Section 15.2 will not be effective if such material breach has been cured within [***] days after written notice thereof is given by Moderna to Merck specifying the nature of the alleged material breach (or, if such default cannot be cured within such [***]-day period, such longer period as reasonably required to cure such material breach; provided, that Merck commences actions to cure such default within such [***]-day period and thereafter diligently continues such actions); provided, that to the extent such material breach involves the failure to make an undisputed payment when due, such material breach must be cured within [***] days after written notice thereof is given by Moderna to Merck. [***]

15.3. Termination by Merck.

(a) Breach. Merck will have the right to terminate this Agreement in full in the event of a material breach by Moderna of this Agreement; provided, that to the extent that any such material breach is limited to a particular R&D Program, Product Candidate, Elected Candidate, Product or country, Merck will have the right to terminate this Agreement only with respect to such R&D Program, Product Candidate, Elected Candidate, Product or country to which such material breach primarily relates. Notwithstanding the foregoing, any such termination under this Section 15.3(a) will not be effective if such material breach has been cured within [***] days after written notice thereof is given by Merck to Moderna specifying the nature of the alleged material breach (or, if such default cannot be cured within such [***]-day period, such longer period as reasonably required to cure such material breach; provided, that Moderna commences actions to cure such default within such [***]-day period and thereafter diligently continues such actions). [***]

(b) Discretionary Termination.

(i) Merck will have the right to terminate this Agreement in its entirety or with respect to an Product Candidate, Elected Candidate, or Product upon [***] days after delivery of written notice to Moderna if Merck concludes due to scientific, technical, regulatory or commercial reasons, including [***].

(ii) Merck will have the right to terminate this Agreement for any reason in its entirety or with respect to a Product Candidate, Elected Candidate and associated Product upon [***] days after delivery of written notice to Moderna.
15.4. Terminated Rights. In the event this Agreement is terminated with respect only to particular R&D Programs, Product Candidates, Elected Candidates or Products (and is not terminated in full), such terminated R&D Programs, Product Candidates, Elected Candidates and associated Products are referred to herein as the “Terminated Rights”, and the rights and obligations of the Parties as to the remaining R&D Programs, Product Candidates, Elected Candidates and associated Products in which termination has not yet occurred shall be unaffected by such termination.

15.5. Effects of Termination by Moderna for Merck Material Breach. Upon termination of this Agreement in full or with respect to any Terminated Rights by Moderna pursuant to Section 15.2:

(a) all rights and licenses granted by Moderna to Merck in Section 9.1 with respect to the Terminated Rights will terminate, and Merck and its Affiliates will cease all use of Moderna Technology hereunder and all Development of and Commercialization of such Terminated Rights. Subject to the remainder of this Section 15.5, all rights and licenses granted by Merck to Moderna in Section 9.2 with respect to the Terminated Rights will terminate and Moderna and its Affiliates will cease all use of the applicable Merck Technology.

(b) any R&D Targets and R&D [***] Targets and R&D Polypeptides therefor, Product Candidates, Elected Candidates, Collaboration mRNA Constructs and Products with respect to the Terminated Rights will become, respectively, Discontinued Targets, and Discontinued mRNA Constructs.

c) Merck will responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, any on-going clinical studies with respect to the Terminated Rights in which patient dosing has commenced or, if requested by Moderna, Merck will transfer responsibility for such clinical study to Moderna. Merck will be responsible for any costs associated with such wind-down. [***]

d) to the extent permitted by applicable Law, [***] owned (in whole or in part) by Merck or its Affiliates or Sublicensees relating exclusively to the Terminated Rights (but excluding any Combination Product), as such items exist as of the effective date of such termination (including [***]) will be assigned to Moderna, and Merck will provide to Moderna one (1) copy of the foregoing and all [***] in any such items. In the event of failure to obtain assignment, Merck hereby consents and grants to Moderna the [***].

e) Merck hereby grants to Moderna, and Moderna shall automatically have, a worldwide, [***], royalty-free and fully paid-up, exclusive license, with the right to grant sublicenses through multiple tiers, under the [***] owned by Merck or any of its Affiliates as of the date of such termination and [***] the Terminated Rights, effective only as of and after the effective date of such termination, for Developing and Commercializing such Terminated Rights (but excluding [***]) but solely as such Terminated Rights were being Developed or Commercialized by Merck as of the effective date of such termination.

15.6. Effects of Termination by Merck for Discretionary Reasons or for Moderna Breach. Upon termination of this Agreement by Merck pursuant to Section 15.3(a) in full or with respect to any Terminated Rights:

(a) all rights and licenses granted by Moderna to Merck in Section 9.1 with respect to the Terminated Rights will terminate, and Merck and its Affiliates will cease all use of Moderna Technology hereunder and all Development of and Commercialization of such Terminated Rights. All rights and licenses granted by Merck to Moderna in Section 9.2 with respect to the Terminated Rights will terminate and Moderna and its Affiliates will cease all use of the applicable Merck Technology.

(b) any R&D Programs, R&D Targets and R&D [***] Targets (and [***]), Product Candidates, Elected Candidates, Collaboration mRNA Constructs and Products with respect to the Terminated Rights will become, respectively, Discontinued Programs, Discontinued Targets and Discontinued mRNA Constructs.

c) Merck will responsibly wind-down, [***], any on-going clinical studies with respect to the Terminated Rights in which patient dosing has commenced or, if requested by Moderna, Merck will transfer responsibility for such clinical study to Moderna; provided that Moderna shall not have the right to request a transfer of such clinical study if the termination is pursuant to Section 15.3(b)(i)(A). Merck will be responsible for any costs associated with such wind-down; provided that if the termination is pursuant to Section 15.3(a), Moderna shall be responsible for such costs. [***]
(d) Merck will covenant not to, alone or in cooperation with any Third Party, sue or to bring any cause of action against Moderna, its Affiliates, or any sublicensees of the foregoing for any type of infringement or misappropriation under the Merck Technology owned by Merck or its Affiliates for the development, manufacture, use, commercialization, offer for sale, sale, distribution, import or export of any of the Terminated Rights (but excluding any Combination Product).

(e) The Parties hereby acknowledge and agree that in the event that Merck delivers notice of termination to Moderna pursuant to Section 15.3(a), but prior to the effective date of such termination, a Milestone Payment under Table 1 in Section 8.4 becomes payable in accordance with Section 8.4, then, notwithstanding the provisions of Section 8.4 or anything to the contrary contained herein, Merck shall not be required to pay any such Milestone Payment to Moderna.

15.7. Alternative to Termination. Notwithstanding the foregoing, in the event this Agreement (or any particular Terminated Right) may otherwise be validly terminated by Merck pursuant to Section 15.3(a), then in lieu of such termination, Merck may elect, at its option, to [***] but otherwise to continue this Agreement in force with respect to such Terminated Right.

15.8. Return of Confidential Information. Except as otherwise necessary to continue exercising any ongoing licenses under this Agreement, upon expiration or termination of this Agreement, the Parties will return (or destroy or erase, as directed by the other Party) all data, files, records and other materials containing or comprising the other Party’s Confidential Information with respect to the Terminated Rights. Notwithstanding the foregoing, (i) in respect of physical embodiments of information, the Parties will be permitted to retain one copy of such data, files, records, and other materials for non-commercial archival purposes, and (ii) in respect of any information stored electronically or in other non-physical media, it will be sufficient for such Party to procure that access to such information is restricted to non-commercial archiving purposes only.

15.9. Survival. In addition to the consequences of expiration or termination set forth in Section 15.4, the following provisions will survive termination or expiration of this Agreement: [***]. Termination or expiration of this Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement. All other rights and obligations will terminate upon expiration of this Agreement.


16.1. Dispute Resolution.

(a) Disputes. Disputes of any nature arising under, relating to, or in connection with this Agreement (“Disputes”) will be resolved pursuant to this Section 16.1.

(b) Dispute Escalation. In the event of a Dispute between the Parties, the Parties will first attempt to resolve such dispute by negotiation and consultation between themselves or the JSC. In the event that such dispute is not resolved on an informal basis within [***] days from receipt of the written notice of a Dispute, any Party may, by written notice to the other, have such dispute referred to the Executive Officers (or their designees, which designee is required to have decision-making authority on behalf of such Party), who will attempt to resolve such Dispute by negotiation and consultation for a [***]-day period following receipt of such written notice.

(c) Full Arbitration. In the event the Parties have not resolved such Dispute within [***] days of receipt of the written notice referring such Dispute to the Executive Officers, either Party may at any time after such [***]-day period submit such Dispute to be finally settled by arbitration administered in accordance with the procedural rules of the American Arbitration Association (“AAA”) in effect at the time of submission, as modified by this Section 16.1(c). The arbitration will be governed by the Laws of the state of New York. The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least [***] of relevant experience in the pharmaceutical and biotechnology industry, each of whom will be impartial and independent. Each Party will appoint one arbitrator and the third arbitrator will be selected by the two Party-appointed arbitrators, or, failing agreement within [***] days following appointment of the second arbitrator, by AAA. Such arbitration will take place in [***]. The arbitration award so given will be a final and binding determination of the dispute, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 14.4. Fees, costs and expenses of arbitration are to be
divided by the Parties in the following manner: Merck will pay for the arbitrator it chooses, Moderna will pay for the arbitrator it chooses, and the Parties will share payment for the third arbitrator. Except in a proceeding to enforce the results of the arbitration or as otherwise required by law, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties (each such consent not to be unreasonably withheld, delayed or conditioned).

(d) Injunctive Relief. Notwithstanding the dispute resolution procedures set forth in this Section 16.1, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief), without first submitting to any dispute resolution procedures hereunder.

(e) Tolling. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) will be tolled while the dispute resolution procedures set forth in this Section 16.1 are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such a result. [***]

16.2. Cumulative Remedies and Irreparable Harm. All rights and remedies of the Parties hereunder will be cumulative and in addition to all other rights and remedies provided hereunder or available by agreement, at law or otherwise. Each Party acknowledges and agrees that breach of any of the terms or conditions of this Agreement may cause irreparable harm and damage to the other and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party would be entitled to seek on an interim basis from a court and on a permanent basis from an arbitral tribunal equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages or posting bond. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of law or equity, including money damages.

16.3. Business Combination. Notwithstanding anything to the contrary herein, in the event of an acquisition of a Party by a Significant Third Party as part of a Business Combination, then for purposes of this Agreement, [***]. “Significant Third Party” means a Third Party [***].

16.4. Relationship of Parties. Nothing in this Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein. There are no express or implied third party beneficiaries hereunder.

16.5. Compliance with Law. Each Party will perform or cause to be performed any and all of its obligations or the exercise of any and all of its rights hereunder in good scientific manner and in compliance with all applicable Law.

16.6. Force Majeure. Neither Party will be liable to the other for failure of or delay in performing obligations set forth in this Agreement, and neither will be deemed in breach of such obligations, if such failure or delay is due to natural disasters or any causes reasonably beyond the control of such Party; provided, that the Party affected will promptly notify the other of the force majeure condition and will exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.

16.7. Governing Law. This Agreement will be governed by and construed in accordance with the Laws of the state of New York, without respect to its conflict of laws rules or principles that might otherwise refer construction or interpretation of this Agreement to the substantive Law of another jurisdiction; provided, that any dispute relating to the scope, validity, enforceability or infringement of any Patents will be governed by, and construed and enforced in accordance with, the substantive Laws of the jurisdiction in which such Patents apply. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

16.8. Counterparts; Facsimiles. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Facsimile or PDF execution and delivery of this Agreement by either Party will constitute a legal, valid and binding execution and delivery of this Agreement by such Party.

16.9. Headings. All headings in this Agreement are for convenience only and will not affect the meaning of any provision hereof.
16.10. Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting party will not apply.

16.11. Interpretation. Whenever any provision of this Agreement uses the term “including” (or “includes”), such term will be deemed to mean “including without limitation” (or “includes without limitations”). “Herein,” “hereby,” “hereunder,” “hereof” and other equivalent words refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used. Except where the context otherwise requires, whenever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Unless otherwise provided, all references to Sections, Schedules and Exhibits in this Agreement are to Sections, Schedules and Exhibits of this Agreement. References to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered “Section 2.1” would be part of “Section 2”, and references to “Section 2.1” would also refer to material contained in the subsection described as “Section 2.1(a”)).

Citations to a statute or regulation will be deemed to mean such statute or regulation and any amendment or supplement thereto or any replacement thereof.

16.12. Binding Effect. This Agreement will inure to the benefit of and be binding upon the Parties, their Affiliates, and their respective lawful successors and assigns.


(a) This Agreement may not be assigned by either Party, nor may either Party delegate its obligations or otherwise transfer any licenses granted herein or other rights created by this Agreement, except as expressly permitted hereunder, without the prior written consent of the other Party, which consent will not be unreasonably withheld, delayed or conditioned; provided, that either Party may assign this Agreement to an Affiliate (provided that the Party assigning to an Affiliate will remain fully liable for any acts or omissions, including financial liabilities, of such Affiliate) or to such Party’s successor in connection with the merger, consolidation, sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, or any Business Combination of such Party. The rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party’s successors and permitted assigns to the extent necessary to carry out the intent of this Section 16.13.

(b) In the event Moderna or any Affiliate of Moderna that does work hereunder or is in possession of Confidential Information of Merck (including Moderna LLC) undergoes as a Business Combination, Moderna shall [***].

16.14. Extension to Affiliates. Each Party shall have the right to extend the rights, licenses, immunities and obligations granted or imposed in this Agreement to one or more of its Affiliates, and in the case of Moderna, Moderna acknowledges that it will use its wholly-owned Affiliate Valera LLC to perform certain Collaboration Activities hereunder. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to such Party. Each Party shall remain fully liable for any acts or omissions, including financial liabilities, of such Affiliates. To the extent that this Agreement imposes obligations on any Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations.

16.15. Notices. All notices, requests, demands and other communications required or permitted to be given pursuant to this Agreement will be in writing and will be deemed to have been duly given upon the date of receipt if delivered by hand, recognized international overnight courier, confirmed facsimile transmission, or registered or certified mail, return receipt requested, postage prepaid to the following addresses or facsimile numbers:

If to Moderna:

Modernia Therapeutics, Inc.
200 Technology Square
Cambridge, MA 02139
Attention: Chief Executive Officer

With a copy to:

Modernia Therapeutics, Inc.
200 Technology Square
Cambridge, MA 02139
Attention: General Counsel
Either Party may change its designated address and facsimile number by notice to the other Party in the manner provided in this Section 16.14.

16.16 Amendment and Waiver. This Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both Parties; provided, that any unilateral undertaking or waiver made by one Party in favor of the other will be enforceable if undertaken in a writing signed by the Party to be charged with the undertaking or waiver. Any waiver of any rights or failure to act in a specific instance will relate only to such instance and will not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.

16.17 Severability. In the event that any provision of this Agreement will, for any reason, be held to be invalid or unenforceable in any respect, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provisions will be given no effect by the Parties and will not form part of this Agreement, (b) all other provisions of this Agreement will remain in full force and effect, and (c) the Parties will negotiate in good faith to modify this Agreement to preserve (to the extent possible) their original intent.

16.18 Entire Agreement. This Agreement is the sole agreements with respect to the subject matter and supersedes all other agreements and understandings between the Parties with respect to same (including the Confidentiality Agreement).

IN WITNESS WHEREOF, the Parties have caused this Master Collaboration and License Agreement to be executed by their respective duly authorized officers as of the Effective Date.

MODERNA THERAPEUTICS, INC.

By: /s/ Stéphane Bancel
    (Signature)
Name: Stéphane Bancel
Title: President and CEO

MERCK SHARP & DOHME CORP.

By: /s/ Iain D. Dukes
    (Signature)
Name: Iain D. Dukes
Title: SVP, Business Development and Licensing