

## **ACQUISITION BY ROCHE HOLDINGS, INC. OF SPARK THERAPEUTICS, INC.**

### **Initial Enforcement Order made by the Competition and Markets Authority pursuant to section 72(2) of the Enterprise Act 2002 (the Act)**

Whereas:

- (a) the Competition and Markets Authority (CMA) has reasonable grounds for suspecting that it is or may be the case that arrangements are in progress or in contemplation which, if carried into effect, will result in: (i) Roche Holdings, Inc., including its subsidiary 022019 Merger Subsidiary, Inc.; and (ii) Spark Therapeutics, Inc. (**Spark**) ceasing to be distinct;
- (b) the CMA is considering whether to make a reference under section 22 or 33 of the Act;
- (c) the CMA wishes to ensure that no action is taken pending final determination of any reference under sections 22 or 33 of the Act which might prejudice that reference or impede the taking of any action by the CMA under Part 3 of the Act which might be justified by the CMA's decisions on the reference; and
- (d) the circumstances set out in section 72(6) of the Act do not apply and the reference has not been finally determined in accordance with section 79(1) of the Act.

Now for the purposes of preventing pre-emptive action in accordance with section 72(2) of the Act the CMA makes the following order addressed to Roche Holding AG (**Roche Holding**), Roche Holdings, Inc. including its subsidiary 022019 Merger Subsidiary, Inc. (**Roche US**) and Roche Holding (UK) Limited (**Roche UK**) (Order).

#### **Commencement, application and scope**

1. This Order commences on the commencement date: being the date of completion of the transaction.
2. This Order applies to Roche Holding, Roche US and Roche UK.

3. Notwithstanding any other provision of this Order, no act or omission shall constitute a breach of this Order, and nothing in this Order shall oblige Roche Holding, Roche US or Roche UK to reverse any act or omission, in each case to the extent that it occurred or was completed prior to the commencement date.
4. This Order does not prohibit the completion of the transaction provided that Roche Holding, Roche US and Roche UK observe the restrictions set out below.

### **Management of the Roche Holding and Spark businesses until determination of proceedings**

5. Except with the prior written consent of the CMA, Roche Holding, Roche US and Roche UK shall not, during the specified period, take any action which might prejudice a reference of the transaction under section 22 or 33 of the Act or impede the taking of any action under the Act by the CMA which may be justified by the CMA's decisions on such a reference, including any action which might:
  - (a) lead to the integration of the Spark business with the Roche Holding business;
  - (b) transfer the ownership or control of the Roche Holding business or the Spark business or any of their subsidiaries; or
  - (c) otherwise impair the ability of the Spark business or the Roche Holding business to compete independently in any of the markets affected by the transaction.
6. Further and without prejudice to the generality of paragraph 5 and subject to paragraphs 3 and 4, Roche Holding, Roche US and Roche UK shall at all times during the specified period procure that, except with the prior written consent of the CMA:
  - (a) the Spark business is carried on separately from the Roche Holding business and the Spark business's separate sales or brand identity is maintained;
  - (b) the Spark business and the Roche Holding business are maintained as a going concern and sufficient resources are made available for the development of the Spark business and the Roche Holding business, on the basis of their respective pre-merger business plans;

- (c) except in the ordinary course of business, no substantive changes are made to the organisational structure of, or the management responsibilities within, the Spark business or the Roche Holding business;
- (d) the nature, description, range and quality of goods and/or services supplied in the UK by each of the two businesses are maintained and preserved;
- (e) except in the ordinary course of business for the separate operation of the two businesses:
  - (i) all of the assets of the Spark business and the Roche Holding business are maintained and preserved, including facilities and goodwill;
  - (ii) none of the assets of the Spark business or the Roche Holding business are disposed of; and
  - (iii) no interest in the assets of the Spark business or the Roche Holding business is created or disposed of;
- (f) there is no integration of the information technology of the Spark or Roche Holding businesses, and the software and hardware platforms of the Spark business shall remain essentially unchanged, except for routine changes and maintenance;
- (g) the customer and supplier lists of the two businesses shall be operated and updated separately and any negotiations with any existing or potential customers and suppliers in relation to the Spark business will be carried out by the Spark business alone and for the avoidance of doubt the Roche Holding business will not negotiate on behalf of the Spark business (and vice versa) or enter into any joint agreements with the Spark business (and vice versa);
- (h) all existing contracts of the Spark business and the Roche Holding business continue to be serviced by the business to which they were awarded;
- (i) no changes are made to key staff of the Spark business or Roche Holding business;
- (j) no key staff are transferred between the Spark business and the Roche Holding business;
- (k) all reasonable steps are taken to encourage all key staff to remain with the Spark business and the Roche Holding business; and

- (l) no business secrets, know-how, commercially-sensitive information, intellectual property or any other information of a confidential or proprietary nature relating to either of the two businesses shall pass, directly or indirectly, from the Spark business (or any of its employees, directors, agents or affiliates) to the Roche Holding business (or any of its employees, directors, agents or affiliates), or vice versa, except where strictly necessary in the ordinary course of business (including for example, where required for compliance with external regulatory and/or accounting obligations or for due diligence, integration planning or the completion of any merger control proceedings relating to the transaction) and on the basis that, should the transaction be prohibited, any records or copies (electronic or otherwise) of such information that have passed, wherever they may be held, will be returned to the business to which they relate and any copies destroyed.

## **Compliance**

7. Roche Holding, Roche US and Roche UK shall procure that each of their subsidiaries complies with this Order as if the Order had been issued to each of them.
8. Roche Holding, Roche US and Roche UK shall provide to the CMA such information or statement of compliance as it may from time to time require for the purposes of monitoring compliance by Roche Holding, Roche US and Roche UK and their subsidiaries with this Order. In particular, two weeks after the commencement date and subsequently every two weeks (or, where this does not fall on a working day, the first working day thereafter) the Chief Executive Officer of Roche Holding, Roche US and Roche UK or other persons of Roche Holding, Roche US and Roche UK as agreed with the CMA shall, on behalf of each of Roche Holding, Roche US and Roche UK, provide a statement to the CMA in the form set out in Annex A to this Order confirming compliance with this Order.
9. Roche Holding, Roche US and Roche UK shall ensure that on the commencement date and subsequently every two weeks (or, where this does not fall on a working day, the first working day thereafter) the person responsible for the management of Spark or other persons of Spark as agreed with the CMA shall, on behalf of Spark, provide a statement to the CMA in the form set out in Annex B to this Order confirming compliance with this Order.
10. At all times, Roche Holding, Roche US and Roche UK shall, or shall procure that Spark shall, actively keep the CMA informed of any material

developments relating to the Spark business or the Roche Holding business, which includes but is not limited to:

- (a) details of key staff who leave or join the Spark business or the Roche Holding business;
  - (b) any interruption of the Spark or Roche Holding business (including without limitation its procurement, production, logistics, sales and employee relations arrangements) that has prevented it from operating in the ordinary course of business for more than 24 hours;
  - (c) all substantial customer volumes won or lost or substantial changes to the customer contracts for the Spark or Roche Holding business including any substantial changes in customers' demand; and
  - (d) substantial changes in the Spark or Roche Holding business's contractual arrangements or relationships with key suppliers.
11. If Roche Holding, Roche US or Roche UK have any reason to suspect that this Order might have been breached it shall immediately notify the CMA and any monitoring trustee that Roche Holding and/or Roche US and/or Roche UK may be directed to appoint under paragraph 12.
12. The CMA may give directions to a specified person or to a holder of a specified office in any body of persons (corporate or unincorporated) to take specified steps for the purpose of carrying out, or ensuring compliance with, this Order, or do or refrain from doing any specified action in order to ensure compliance with the Order. The CMA may vary or revoke any directions so given.
13. Roche Holding, Roche US and Roche UK shall comply in so far as they are able with such directions as the CMA may from time to time give to take such steps as may be specified or described in the directions for the purpose of carrying out or securing compliance with this Order.

## **Interpretation**

14. The Interpretation Act 1978 shall apply to this Order as it does to Acts of Parliament.
15. For the purposes of this Order:

**'the Act'** means the Enterprise Act 2002;

**'an affiliate'** of a person is another person who satisfies the following condition, namely that any enterprise (which, in this context, has the meaning

given in section 129(1) of the Act) that the first person carries on from time to time and any enterprise that the second person carries on from time to time would be regarded as being under common control for the purposes of section 26 of the Act;

**'business'** has the meaning given by section 129(1) and (3) of the Act;

**'commencement date'** means the date of completion of the transaction;

**'control'** includes the ability directly or indirectly to control or materially to influence the policy of a body corporate or the policy of any person in carrying on an enterprise;

**'the decisions'** means the decisions of the CMA on the questions which it is required to answer by virtue of sections 35 or 36 of the Act;

**'key staff'** means staff in positions of executive or managerial responsibility and/or whose performance affects the viability of the business;

**'the ordinary course of business'** means matters connected to the day-to-day supply of goods and services by Spark or Roche Holding and does not include matters involving significant changes to the organisational structure or related to the post-merger integration of Spark and Roche Holding;

**'Roche Holding'** means Roche Holding AG, a public company registered in Switzerland and parent company of the Roche Group with UID number CHE-101.602.521;

**'the Roche Holding business'** means the business of Roche Holding and its subsidiaries carried on as at the commencement date;

**'Roche UK'** means Roche Holding (UK) Limited, a company registered in England and Wales with company number 03372540;

**'Roche US'** means Roche Holdings, Inc., a company incorporated in the State of Delaware with file number 2145312, and its subsidiaries including its wholly owned subsidiary 022019 Merger Subsidiary, Inc., a company incorporated in the State of Delaware with file number 7290659;

**'Spark'** means Spark Therapeutics, Inc., a company incorporated in the State of Delaware with file number 5302780;

**'the Spark business'** means the business of Spark and its subsidiaries carried on as at the commencement date;

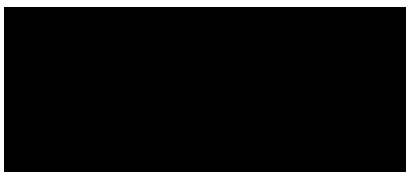
**'specified period'** means the period beginning on the commencement date and terminating in accordance with section 72(6) of the Act;

**'subsidiary'**, unless otherwise stated, has the meaning given by section 1159 of the Companies Act 2006;

**'the transaction'** means the transaction by which Roche US and Spark will cease to be distinct within the meaning of section 23 of the Act;

**'the two businesses'** means the Roche Holding business and the Spark business;

unless the context requires otherwise, the singular shall include the plural and vice versa.



**Elie Yoo, Assistant Director, Mergers**

**Compliance statement for [Roche Holding / Roche US / Roche UK]**

I [insert name] confirm on behalf of [Roche Holding Limited (Roche Holding) / Roche Holdings, Inc. (Roche US) / Roche Holding (UK) Limited (Roche UK)] that:

**Compliance in the Relevant Period**

1. In the period from the commencement date to [insert date] (the Relevant Period):
  - (a) Roche Holding / Roche US / Roche UK has complied with the Order made by the CMA in relation to the transaction on 6 June 2019 (the Order).
  - (b) Roche Holding / Roche US / Roche UK's subsidiaries have also complied with this Order.
2. Subject to paragraph 3 and 4 of the Order, and except with the prior written consent of the CMA:
  - (a) No action has been taken by Roche Holding / Roche US / Roche UK that might prejudice a reference of the transaction under section 22 or 33 of the Act or impede the taking of any action by the CMA which may be justified by its decision on such a reference, including any action which might:
    - (i) lead to the integration of the Spark business with the Roche Holding business;
    - (ii) transfer the ownership or control of the Roche Holding business or the Spark business or any of their subsidiaries; or
    - (iii) otherwise impair the ability of the Spark business or the Roche Holding business to compete independently in any of the markets affected by the transaction.
  - (b) The Spark business has been carried on separately from the Roche Holding business and the Spark business's separate sales or brand identity has been maintained.
  - (c) The Spark business and the Roche Holding business have been maintained as a going concern and sufficient resources have been made available for the development of the Spark business and the Roche



Holding business, on the basis of their respective pre-merger business plans.

- (d) No substantive changes have been made to the organisational structure of, or the management responsibilities within, the Spark business or the Roche Holding business, except in the ordinary course of business.
- (e) The nature, description, range and quality of goods and/or services supplied in the UK by the Spark business and the Roche Holding business have been maintained and preserved.
- (f) Except in the ordinary course of business for the separate operation of the two businesses:
  - (i) all of the assets of the Spark business and the Roche Holding business, including facilities and goodwill, have been maintained and preserved as at the start of the Relevant Period;
  - (ii) none of the assets of the Spark business or the Roche Holding business have been disposed of; and
  - (iii) no interest in the assets of the Spark business or the Roche Holding business has been created or disposed of.
- (g) There has been no integration of the information technology of the Spark or Roche Holding businesses, and the software and hardware platforms of the Spark business have remained essentially unchanged, except for routine changes and maintenance.
- (h) Subject to integration which had occurred prior to the commencement date, the customer and supplier lists of the two businesses have been operated and updated separately and any negotiations with any existing or potential customers and suppliers in relation to the Spark business have been carried out by the Spark business alone and, for the avoidance of doubt, the Roche Holding business has not negotiated on behalf of the Spark business (and vice versa) or entered into any joint agreements with the Spark business (and vice versa).
- (i) All existing contracts of the Spark business and the Roche Holding business have been serviced by the business to which they were awarded, except to the extent novated, assigned or subcontracted prior to the commencement date.
- (j) No changes have been made to key staff of the Spark business or the Roche Holding business.

- (k) No key staff have been transferred between the Spark business and the Roche Holding business.
- (l) All reasonable steps have been taken to encourage all key staff to remain with the Spark business and the Roche Holding business.
- (m) Except as permitted by the Order, no business secrets, know-how, commercially-sensitive information, intellectual property or any other information of a confidential or proprietary nature relating to either of the two businesses, has passed, directly or indirectly, from the Spark business (or any of its employees, directors, agents or affiliates) to the Roche Holding business (or any of its employees, directors, agents or affiliates), or vice versa.
- (n) Except as listed in paragraph (o) below, there have been no:
  - (i) key staff that have left or joined the Spark business or the Roche Holding business;
  - (ii) interruptions of the Spark business or the Roche Holding business (including without limitation procurement, production, logistics, sales and employee relations arrangements) that have prevented it from operating in the ordinary course of business for more than 24 hours;
  - (iii) substantial customer volumes won or lost or substantial changes to the customer contracts for the Spark business or the Roche Holding business; or
  - (iv) substantial changes in the Spark or Roche Holding business's contractual arrangements or relationships with key suppliers.
- (o) *[list of material developments]*

3. Roche Holding and its subsidiaries remain in full compliance with the Order and will continue actively to keep the CMA informed of any material developments relating to the Spark or the Roche Holding business in accordance with paragraph 9 of the Order.

### **Interpretation**

4. Terms defined in the Order have the same meaning in this compliance statement.

**I understand that:**

it is a criminal offence under section 117 of the Enterprise Act 2002 for a person recklessly or knowingly to supply to the CMA information which is false or misleading in any material respect. Breach of this provision can result in **finest, imprisonment for a term not exceeding two years, or both.** (Section 117 of the Enterprise Act 2002.)

Failure to comply with this order without reasonable excuse may result in the CMA imposing a **penalty of up to 5% of the total value of the turnover** (both in and outside the United Kingdom) of the enterprises owned or controlled by the person on whom the penalty is imposed. (Section 94A of the Enterprise Act 2002.)

FOR AND ON BEHALF OF ROCHE HOLDING / ROCHE US / ROCHE UK

Signature .....

Name .....

Title .....

Date .....

## Compliance statement for Spark

I [insert name] confirm on behalf of Spark Therapeutics, Inc. (Spark) that:

### Compliance in the Relevant Period

1. In the period from the commencement date to [insert date] (the Relevant Period):
  - (a) Spark has complied with the Order made by the CMA in relation to the transaction on 6 June 2019 (the Order).
  - (b) Spark's subsidiaries have also complied with this Order.
2. Subject to paragraph 3 and 4 of the Order, and except with the prior written consent of the CMA:
  - (a) No action has been taken by Spark that might prejudice a reference of the transaction under section 22 or 33 of the Act or impede the taking of any action by the CMA which may be justified by its decision on such a reference, including any action which might:
    - (i) lead to the integration of the Spark business with the Roche Holding business;
    - (ii) transfer the ownership or control of the Roche Holding business or the Spark business or any of their subsidiaries; or
    - (iii) otherwise impair the ability of the Spark business or the Roche Holding business to compete independently in any of the markets affected by the transaction.
  - (b) The Spark business has been carried on separately from the Roche Holding business and the Spark business's separate sales or brand identity has been maintained.
  - (c) The Spark business and the Roche Holding business have been maintained as a going concern and sufficient resources have been made available for the development of the Spark business and the Roche Holding business, on the basis of their respective pre-merger business plans.

- (d) No substantive changes have been made to the organisational structure of, or the management responsibilities within, the Spark business, except in the ordinary course of business.
- (e) The nature, description, range and quality of goods and/or services supplied in the UK by the Spark business have been maintained and preserved.
- (f) Except in the ordinary course of business for the separate operation of the two businesses:
  - (i) all of the assets of the Spark business, including facilities and goodwill, have been maintained and preserved as at the start of the Relevant Period;
  - (ii) none of the assets of the Spark business have been disposed of; and
  - (iii) no interest in the assets of the Spark business has been created or disposed of.
- (g) There has been no integration of the information technology of the Spark or Roche Holding businesses, and the software and hardware platforms of the Spark business have remained essentially unchanged, except for routine changes and maintenance.
- (h) Subject to integration which had occurred prior to the commencement date, the customer and supplier lists of the two businesses have been operated and updated separately and any negotiations with any existing or potential customers and suppliers in relation to the Spark business have been carried out by the Spark business alone and, for the avoidance of doubt, the Roche Holding business has not negotiated on behalf of the Spark business (and vice versa) or entered into any joint agreements with the Spark business (and vice versa).
- (i) All existing contracts of the Spark business and the Roche Holding business have been serviced by the business to which they were awarded, except to the extent novated, assigned or subcontracted prior to the commencement date.
- (j) No changes have been made to key staff of the Spark business.
- (k) No key staff have been transferred between the Spark business and the Roche Holding business.
- (l) All reasonable steps have been taken to encourage all key staff to remain with the Spark business.

(m) Except as permitted by the Order, no business secrets, know-how, commercially-sensitive information, intellectual property or any other information of a confidential or proprietary nature relating to either of the two businesses, has passed, directly or indirectly, from the Spark business (or any of its employees, directors, agents or affiliates) to the Roche Holding business (or any of its employees, directors, agents or affiliates), or vice versa.

(n) Except as listed in paragraph (o) below, there have been no:

(i) key staff that have left or joined the Spark business;

(ii) interruptions of the Spark business (including without limitation procurement, production, logistics, sales and employee relations arrangements) that have prevented it from operating in the ordinary course of business for more than 24 hours;

(iii) substantial customer volumes won or lost or substantial changes to the customer contracts for the Spark business; or

(iv) substantial changes in the Spark business's contractual arrangements or relationships with key suppliers.

(o) *[list of material developments]*

3. Spark and its subsidiaries remain in full compliance with the Order and will continue actively to keep the CMA informed of any material developments relating to the Spark or the Roche Holding business in accordance with paragraph 9 of the Order.

### **Interpretation**

4. Terms defined in the Order have the same meaning in this compliance statement.

### **I understand that:**

it is a criminal offence under section 117 of the Enterprise Act 2002 for a person recklessly or knowingly to supply to the CMA information which is false or misleading in any material respect. Breach of this provision can result in **fines, imprisonment for a term not exceeding two years, or both.** (Section 117 of the Enterprise Act 2002.)

Failure to comply with this order without reasonable excuse may result in the CMA imposing a **penalty of up to 5% of the total value of the turnover**

(both in and outside the United Kingdom) of the enterprises owned or controlled by the person on whom the penalty is imposed. (Section 94A of the Enterprise Act 2002.)

FOR AND ON BEHALF OF SPARK THERAPEUTICS, INC.

Signature .....

Name .....

Title .....

Date .....