RESPONSIBILITIES OF AN EXCLUSIVE LICENSEE OF A CIRM-FUNDED PROJECT FROM A NON-PROFIT CIRM GRANTEE

CIRM has prepared this document to outline the responsibilities of a company that exclusively licenses a CIRM-Funded project[1] from a non-profit CIRM grantee, such as a university, under California law. This summary is not intended to be an exhaustive description of a licensee's obligations. Prospective licensees should therefore review the laws themselves before entering into a license. The obligations of a licensee of a CIRM-Funded project can be found in the CIRM Intellectual Property Regulations at the following link: https://www.cirm.ca.gov/sites/default/files/files/funding_page/Reg100600_100611_27_January_2014.pdf

Summary of Obligations of Exclusive Licensee of CIRM-Funded Project from Non-Profit Awardee:

No Revenue Sharing Obligations (Section 100608). A company that exclusively licenses a CIRM-funded project from a non-profit awardee has NO revenue sharing obligations to CIRM or the State of California. Under CIRM regulations, the licensor (the non-profit awardee) must share a portion of its licensing revenue with the State of California General Fund. Please see Section 100608 beginning on page 23 of the Regulations at the following link: https://www.cirm.ca.gov/sites/default/files/files/funding_page/Reg100600_100611_27_January_2014.pdf

Patient Assistance Plan (Section 100607). A company that exclusively licenses a CIRM-funded project from a non-profit awardee and that obtains final approval from the FDA to market a drug that arises from the CIRM-Funded project must submit a plan to afford access to the drug to Californians who have no other means to purchase the drug. The access plan must be consistent with the industry standard for patient assistance programs at the time of commercialization, accounting for the size of the market for the drug and the resources of the company. CIRM's governing board is authorized to waive the requirement if it determines that, in the absence of the waiver, development and broad delivery of the drug will be unreasonably hindered or that the waiver will provide significant benefits that equal or exceed the benefits of

[1] The term "CIRM-Funded project" refers to the intellectual property arising in whole or in part from the CIRM research award. Specifically, it covers all generated data which does not fall under a publication exemption, trade secrets, and patent/patent applications, if any.

the access plan. Please see Section 100607 beginning on page 20 of the Regulations at the following link:
https://www.cirm.ca.gov/sites/default/files/files/funding_page/Reg100600_100611_27_January_2014.pdf

Drug Pricing (Section 100607). A company that exclusively licenses a CIRM-funded project from a non-profit awardee and that commercializes a drug arising from the CIRM-funded project is required to abide by any statewide prescription drug discount program in effect. Currently, there is NO statewide prescription drug discount program in effect In addition, an exclusive licensee must make a drug arising from the CIRM-funded project available at one of the benchmarks described in CalRx (e.g., Medicaid best price). Please see Section 100607 beginning on page 20 of the Regulations at the following link:
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March-In Rights (Section 100610). A company that exclusively licenses a CIRM-funded project from a non-profit awardee is subject to CIRM's march-in rights. The march-in rights parallel federal march-in rights under Bayh-Dole, which apply to discoveries arising from NIH funding and which are intended to prevent a useful drug discovery from being shelved. Like federal march-in rights, CIRM's march-in rights are designed to be used rarely (e.g., a licensee's refusal to use a discovery to address a public health emergency) and only after the exclusive licensee has had an opportunity to cure or appeal CIRM's determination to its Board. Please see Section 100610 beginning on page 27 of the Regulations at the following link:
https://www.cirm.ca.gov/sites/default/files/files/funding_page/Reg100600_100611_27_January_2014.pdf

Reporting Requirements (Section 100602). CIRM awardees have reporting obligations to CIRM, such as reporting the initiation of clinical testing, the initiation of pivotal studies, the filing of an application for marketing approval, etc. Although these reporting obligations belong to the awardee, CIRM expects that these requirements will be incorporated into a license in order to allow the awardee to fulfill its obligations to CIRM. Please see Section 100602 beginning on page 9 of the Regulations at the following link:
https://www.cirm.ca.gov/sites/default/files/files/funding_page/Reg100600_100611_27_January_2014.pdf

Licensing Requirements (Section 100606). CIRM awardees are required to include a commercial development plan, remedies for failure to develop a drug, and grounds for modification/termination in an exclusive license. As a result, CIRM expects that an exclusive licensee will have corresponding obligations to the licensor under its license agreement. Please see Section 100606 beginning on page 17 of the Regulations at the following link:

https://www.cirm.ca.gov/sites/default/files/files/funding_page/Reg100600_100611_27_January_2014.pdf

Successor in Interest (Section 100611). A successor in interest (by merger, purchase or assignment) of an exclusive licensee assumes all obligations of the exclusive licensee. Please see Section 100611 beginning on page 30 of the Regulations at the following link: https://www.cirm.ca.gov/sites/default/files/files/funding_page/Reg100600_100611_27_January_2014.pdf

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