SCO ID: 4140-2223025

STATE OF CALIFORNIA - DEPARTMENT OF GENERAL SERVICES
STANDARD AGREEMENT
STD 213 (Rev. 04/2020)

AGREEMENT NUMBER	PURCHASING AUTHORITY NUMBER (If Applicable)
22-23025	

1. This Agreement is entered into between the Contracting Agency and the Contractor named below:

CONTRACTING AGENCY NAME
Department of Health Care Access and Information

CONTRACTOR NAME
Civica Foundation

2. The term of this Agreement is:

START DATE
February 23, 2023 (or the date the Agreement is executed, whichever is latest)

THROUGH END DATE
Ten (10) years after the First Commercial Sale

3. The maximum amount of this Agreement is:
$50,000,000.00

4. The parties agree to comply with the terms and conditions of the following exhibits, which are by this reference made a part of the Agreement.

Exhibits	Title	Pages
Exhibit A	Scope of Work	12
Exhibit B	Budget Detail and Payment Provisions	2
Exhibit C	General Terms and Conditions	6
Exhibit D	Special Terms and Conditions	2
Exhibit E	Insurance Requirements	1
Exhibit F	Contractor Certification Clauses	5
Exhibit G	Definitions	3

Items shown with an asterisk (*), are hereby incorporated by reference and made part of this agreement as if attached hereto.
These documents can be viewed at https://www.dgs.ca.gov/OLS/Resources

IN WITNESS WHEREOF, THIS AGREEMENT HAS BEEN EXECUTED BY THE PARTIES HERETO.

CONTRACTOR

CONTRACTOR NAME (if other than an individual, state whether a corporation, partnership, etc.)
CIVICA Foundation

CONTRACTOR BUSINESS ADDRESS	CITY	STATE	ZIP
2912 W. Executive Pkwy, suite 325	Lehi	UT	84043

PRINTED NAME OF PERSON SIGNING	TITLE
Allan Coukell Ned McCoy	President of Civica Foundation CEO and President of Civica, Inc.

CONTRACTOR AUTHORIZED SIGNATURE	DATE SIGNED
Ned Mccoy Allan Coukell	2.23.2023

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STATE OF CALIFORNIA

CONTRACTING AGENCY NAME
Department of Health Care Access and Information

CONTRACTING AGENCY ADDRESS	CITY	STATE	ZIP
2020 West El Camino Ave	Sacramento	CA	95833

PRINTED NAME OF PERSON SIGNING	TITLE
Elizabeth Landsberg	Director

CONTRACTING AGENCY AUTHORIZED SIGNATURE	DATE SIGNED
Elizabeth A Landsberg	2/24/2023

CALIFORNIA DEPARTMENT OF GENERAL SERVICES APPROVAL	EXEMPTION (If Applicable)
	Health and Safety Code section 127692(b)

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EXHIBIT A
SCOPE OF WORK

1. Background and Purpose of Agreement

   The California Department of Health Care Access and Information ("HCAI") is committed to expanding equitable access to quality, affordable health care for all Californians—ensuring every community has the health workforce they need, safe and reliable health care facilities, and health information that can help make care more effective and affordable.

   The California Affordable Drug Manufacturing Act of 2020 (Cal. Health & Safety Code sections 127690 to 127696) calls for the California Health and Human Services Agency ("CalHHS"), or its departments, such as HCAI, to enter into partnerships to accomplish, among other things, increased patient access to affordable drugs, and specifies that these agreements shall result "in the production or distribution of generic prescription drugs…" including at least one form of insulin. (Health and Safety Code section 127693 (2023).) CalHHS has delegated the responsibility of implementing the Act to HCAI, including entering into a partnership for the production of insulin. This program is called the "CalRx Biosimilar Insulin Initiative."

   Assembly Bill (AB) No. 178 (2022), California's Amended Budget Act of 2022, appropriated $50 million for the Initiative "to support the development of three low-cost interchangeable biosimilar insulin products." (AB 178 (2022), Section 130, Provision 8.)

   This Agreement is to govern a collaboration (the "Collaboration") between the Parties to provide for the supply of insulin by Civica Foundation and Civica, Inc. (collectively, "Contractor") to consumers in the State of California (the "Territory") whereby Contractor will Develop the Products and submit the BLA to the FDA for approval and will engage in the Manufacture of the Products and Commercialization of the Products for the Territory in accordance with the terms set forth in this Agreement.

   The purpose of the Collaboration is for Contractor to provide a lower cost, affordable and reliable ongoing supply of the Products to Californians as identified by HCAI within the Territory.

   This agreement would lay the groundwork for future collaborations on other high-priority drugs, including building supply chain resiliency and increasing access to low-cost generics.

   Additionally, Contractor and HCAI will also mutually agree on and implement the initial process to identify suitable locations within the Territory to establish and operate a manufacturing facility dedicated to the manufacture and supply of the Products.

2. State Contracting Exemption

   This Agreement is executed pursuant to Cal. Health and Safety Code Section 127692(b) (2022), which exempts the Agreement from certain parts of the California Government Code and the California Public Contracting Code. Health and Safety Code section 127692(b) states:

   > "Until December 31, 2027, for purposes of implementing [the Act], CHHSA and its departments, including the Department of Health Care Access and Information, may enter into exclusive or nonexclusive contracts on a bid or negotiated basis. Contracts entered into or amended pursuant to this section are exempt from Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code and Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code and are exempt from the review or approval of any division of the Department of General Services."

3. Period of Performance

   a. The term of this Agreement shall commence on February 23, 2023, or the date the Agreement is executed, whichever is later (the "Effective Date") and continue until the date that is ten (10) years after the First Commercial Sale (the "Term").

   b. This Agreement may be renewed only upon mutual agreement of the Parties.

4. Contract Representatives

   The contract representatives (the "Representatives") during the term of this Agreement shall be:

State Agency: HCAI	**Contractor**: Civica
Name: Vishaal Pegany, Deputy Director	**Name**: Allan Coukell, SVP Public Policy and Civica Foundation
Phone: [redacted]	**Phone**: [redacted]
Email: [redacted]	**Email**: [redacted]

The Representatives will serve as the primary contact points between the Parties regarding the activities contemplated by this Agreement. The Representatives will facilitate the flow of information and otherwise promote communication, coordination, and collaboration between the Parties, providing single point communication for seeking consensus both internally within each Party's respective organization, including facilitating review of external corporate communications, and raising cross-Party or cross-functional disputes in a timely manner. Each Party may replace its Representative by written notice to the other Party.

Direct all inquiries concerning the terms and conditions of this Agreement to:

State Agency: HCAI	**Contractor**: Civica
Section: Office of Legal Services	
Attention: James Yi	**Attention**: Jennifer Spalding
Address: 2020 W El Camino Avenue, Suite 800 Sacramento, CA 95833	**Address**: 2912 W. Executive Pkwy, suite 325 Lehi, Utah 84043
Phone: [redacted]	**Phone**: [redacted]
Email: [redacted]	**Email**: [redacted]

5. Board Representation

   a. During the Term and for as long as any CalRx-branded Products are sold in the Territory, Contractor will ensure that HCAI is entitled to designate directors (the "HCAI Directors") on the Civica Foundation board of directors (the "Foundation Board") as follows:

      i. For so long as the Foundation Board is composed of no more than 10 directors, Contractor will ensure the number of HCAI Directors is at least two.

      ii. If the size of the Foundation Board grows beyond 10 directors, Contractor will ensure that the number of HCAI Directors increases in a proportionate manner such that the HCAI

Directors constitute approximately 20% of the number of directors on the Foundation Board, provided that in no event shall the number of HCAI Directors decrease below two.

b. Additionally, HCAI may designate one representative from the JSC (the "HCAI Representative") to attend the meetings of the Civica, Inc. board of directors via electronic means only during presentations and discussion related to the Products. The HCAI Representative will be an observer with no right to vote.

c. Additionally, Contractor will notify HCAI of material issues happening with Civica, Inc., Civica Foundation and Civica Script that may impact the viability of the Products or the Collaboration. This shall include, but is not limited to, providing quarterly, unaudited financial reports from Civica, Inc. and Civica Foundation, annual audited reports of Civica, Inc. or Civica Foundation. Contractor will also provide prompt notification of any lawsuits, or regulatory investigations or notifications, product safety or recall issues impacting the insulin project or Civica ("Critical Matters"). All Critical Matters will be shared at the JSC or with a Subcommittee upon which both Parties agree and Civica Foundation Board Meetings.

6. Joint Steering Committee

a. As soon as reasonably practicable, the Parties will establish a joint steering committee (the "JSC") to coordinate and oversee the Development, Manufacture and Commercialization of the Products for the Territory. The JSC will be composed of an equal number of representatives from each Party and who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Any such representative who serves on the JSC or any committee under this Agreement may also serve on one or more other committees under this Agreement. Each Party's representatives on the JSC will inform and coordinate within their respective organization to enable each Party to fulfill its obligations as agreed upon between the Parties under this Agreement, including within the time frames set forth thereunder. The JSC shall have the right throughout the term of the Definitive Agreement to form additional subcommittees as appropriate to coordinate the Development, Manufacture and Commercialization of the Products in the Territory. HCAI has the right to use Third-Party consultants to serve on the JSC on their behalf, with notification to Civica and with assurances that any Third-Party consultant meets all HCAI conflict of interest requirements. Each Party will appoint one of its JSC representatives to act as a co-chairperson of the JSC. All information shared with the JSC will be subject to the Information Sharing requirements below.

b. The scope of the JSC's responsibilities, decision-making and final approval authority includes:

i. Monitoring the Regulatory Approval process for the Products;
ii. Administration of the HCAI Funding in accordance with the terms of this Agreement;
iii. Reviewing the Manufacture and Commercialization of the Products in relation to the Territory;
iv. Overseeing and establishing the communications strategy concerning the Collaboration to the public and outside entities (such as through websites, news releases);
v. Overseeing the reinvestment of any profits from the Commercialization of CalRx-branded Products in Development, Manufacturing and Commercialization; and
vi. Establish joint subcommittees (each, a "Subcommittee," and, together with the JSC, each a "Committee") as necessary or advisable to further the purpose of this Agreement;
vii. Settle any disputes that arise within any Subcommittees;

viii. Discuss and evaluate potential future high-priority generic drugs for partnership between HCAI and Civica based on evaluating the legal and technical feasibility, sufficient funding, and other market factors; and

ix. Perform such other functions as expressly set forth in this Agreement or assigned to it by the Parties' written agreement.

c. The JSC and each Subcommittee will hold meetings at such times as it elects to do so, but in no event will such meetings be held less frequently than once every Calendar Quarter until the first receipt of Regulatory Approval for a Product in the Territory. Thereafter, the JSC and each Subcommittee will come to the mutual agreement on the frequency of meetings required. Each Party may call additional Committee meetings with reasonable advance notice to the other Party. Meetings of each Committee may be held in person, by audio or video teleconference as determined by the mutual agreement of the Parties. In-person Committee meetings will be held at locations selected in an alternating manner by the Parties. The co-chairpersons of each Committee will jointly prepare the agenda and minutes for each Committee meeting. Each Party will be responsible for all of its own expenses of participating in each Committee meetings. No action taken at any Committee meeting will be effective unless at least one representative from each Party is participating in such Committee meeting.

d. With respect to a Committee meeting, each Party may from time to time invite a reasonable number of participants, in addition to such Party's Committee representatives, to attend such Committee's meetings in a nonvoting capacity; provided that if either Party intends to have any Third Party attend such a meeting, such Party will provide prior written notice to the other Party and will ensure that such Third Party is bound by written confidentiality and non-use obligations consistent with the terms of this Agreement.

e. The JSC and any Subcommittees established hereunder will only have the powers expressly assigned to such Committees in this Exhibit A, Section 6 or otherwise expressly provided in this Agreement and will not have the authority to: (a) modify or amend the terms of this Agreement; or (b) waive either Party's compliance with or rights under the terms of this Agreement. All decisions by the JSC and any Subcommittee will be made by unanimous vote, with each Party's representatives having one vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before a Subcommittee, such Subcommittee cannot reach a decision as to such matter within 15 days after such matter was brought to such Subcommittee for resolution, such matter will be referred to the JSC. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the JSC cannot reach a decision as to such matter within 30 days after such matter was brought to the JSC for resolution, such matter will be referred to the HCAI Director and the CEO of Civica for resolution.

f. Pursuant to Exhibit A, Section 6(b)(vi), the JSC will have the authority to establish Subcommittees. Each Subcommittee will be composed of at least one representative from each Party. Each Party may replace its Subcommittee representatives upon written notice to the other Party. All recommendations coming from a Subcommittee will be presented to the JSC for final decision-making authority. For the avoidance of doubt, nothing will prohibit a Party from appointing any suitably qualified Person to serve as that Party's representative on multiple Committees.

g. Each Subcommittee will be promptly disbanded 30 days after the mutual written agreement of the Parties. Once a Subcommittee is disbanded, such Subcommittee will have no further

obligations under this Agreement. In the event that a Subcommittee is disbanded, any recommendations that are designated under this Agreement as being subject to the review or approval of such Subcommittee will be made by the JSC subject to the other terms and conditions of this Agreement.

7. Product Development

   a. Contractor will conduct all Development of the Products pursuant to a development plan (the "Development Plan") detailing Contractor's Development for the Products, including timelines for all stages of completion to file a Biologics License Application for Product, and the Development Plan will be periodically reviewed by the JSC. Contractor will provide regular status updates to the JSC on the Development Plan and the Development, Manufacture, and Commercialization of the Products. Contractor will use its Commercially Reasonable Efforts for Development of Products.

   b. Contractor shall prepare the initial Development Plan, to be provided to and reviewed by HCAI through due diligence, and the Development Plan may be amended from time to time in accordance with this Agreement. The Development Plan will contain in reasonable detail the Development activities to be undertaken by Contractor with respect to the Products in the Territory and the timelines for achieving such activities. From time-to-time Contractor, through its Representative or its other members of the JSC, may propose updates or amendments to the Development Plan in consultation with HCAI and submit such proposed updated or amended plan to the JSC for review and discussion. In accordance with Exhibit A, Section 6, the JSC will review and may, but is not required to, approve any updates or amendments to the Development Plan. During the Term, Contractor shall conduct Development of each Product in the Territory in accordance with the Development Plan.

   c. Except for the HCAI Funding payable at such times and in such amounts as set forth in Exhibit B, Contractor is solely responsible for all costs and expenses incurred in connection with Development of the Products.

   d. The status, progress, and results of Contractor's Development activities under this Agreement will be discussed at meetings of the JSC. At least three Business Days before the applicable regularly scheduled JSC meeting, Contractor will provide the JSC with a written report detailing its Development activities and the results thereof, covering subject matter at a level of detail reasonably required by HCAI and reasonably sufficient to enable HCAI to monitor Contractor's compliance with this Agreement. In addition, Contractor will make available to HCAI such additional information about its Development activities as may be reasonably requested by HCAI from time to time.

8. Regulatory Matters

   a. Contractor will be responsible for conducting all regulatory and clinical development activities required to obtain Regulatory Approval of the Products in the United States by FDA at its sole cost and expense. Contractor will use its Commercially Reasonable Efforts to seek Regulatory Approval of Products.

   b. Contractor will share with HCAI, through the JSC, summaries for material information sent to regulatory authorities related to the Products, including, but not be limited to, FDA regulatory submissions, communications with regulatory authorities, minutes of meetings with the FDA and other regulatory agencies, results, and data from clinical studies (collectively, "Regulatory Submission Summaries"). All Regulatory Submission Summaries will be unredacted, unless otherwise prohibited under Applicable Laws. In turn, HCAI will keep confidential and not share

publicly any Regulatory Summaries, Civica FDA communications or submissions provided by Contractor without Contractor prior approval.

c. The Parties will discuss the ongoing process to obtain regulatory approval of the Products through the JSC which will make recommendations concerning the ongoing Development Plan and regulatory process. Contractor will consider and, in good faith incorporate or address with the JSC all such reasonable recommendations. Contractor or its designee will own and hold all Regulatory Approvals for a Product in the Territory. Contractor will notify HCAI of any Regulatory Submissions for a Product submitted to or received from any Regulatory Authority in the Territory and will provide HCAI with summaries thereof within five days after submission or receipt, or as otherwise mutually agreed.

d. Each Party will immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection, or communication by any Regulatory Authority, which may affect the safety or efficacy claims of any Product or the continued marketing of any Product. Upon receipt of such information, the Parties will consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action. Ultimate decision rights and responsibilities remain with Civica.

e. Each Party will notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any Product may be subject to any recall, corrective action or other regulatory action by any Governmental Authority or Regulatory Authority (a “Remedial Action”). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. The cost and expenses of any Remedial Action in the Territory will be borne solely, as between the Parties, by Contractor.

f. Contractor will address all reports of product quality complaints and adverse events. HCAI will forward all reports of product quality complaints and adverse events received directly by HCAI to Contractor’s established notification mechanism and will allow for incorporation of Contractor’s public contact information into HCAI specific labeling for direct receipt of product quality complaints and reports of adverse events.

9. <u>Commercialization</u>

a. Except for the HCAI Funding, Contractor is solely responsible for all costs and expenses incurred in connection with Commercialization of the Products. Contractor will take responsibility for all matters related to Commercialization and will ensure the wide availability of CalRx branded insulin throughout the Territory.

b. All Commercialization of the Products in the Territory will be conducted pursuant to a commercialization plan (the “Commercialization Plan”). No later than 12 months prior to the anticipated date of the first filing of the first Regulatory Approval for a Product in the Territory, Contractor will deliver to the JSC an initial written plan regarding Commercialization of the Products in the Territory. The Commercialization Plan will contain in reasonable detail the Commercialization activities to be undertaken by or on behalf of Contractor and Subcontractors and the timelines for achieving such activities. The Commercialization Plan will cover matters such as Contractor’s distribution strategy of Products in the Territory. In light of Civica’s low-cost strategy and non-profit mission, Civica does not anticipate engaging a sales force or costly marketing and advertising efforts, and any additional marketing and advertising efforts will be mutually agreed by the Parties. The Parties will consult with each other regarding, Commercialization activities for the Products in the Territory, and HCAI will have the right to review and provide comments, and Contractor will consider all such comments in good faith.

c. From time to time during the Term, as reasonably requested by Contractor, HCAI may facilitate conversations between Contractor and certain State agencies (e.g., Department of Health Care Services, California Public Employee Retirement System (CalPERS), Covered California, and Department of General Services), which agencies may elect to purchase and/or cover the purchase of Products from Contractor. HCAI however, provides no assurance that any such agencies will elect to purchase/cover Products from Contractor.

d. Contractor will update the JSC at each regularly scheduled JSC meeting, but in no event less frequently than once every three months, regarding Contractor's Commercialization activities with respect to the Products in the Territory. Each such update will be in a form to be agreed by the JSC and will summarize Contractor's and Subcontractors' Commercialization activities with respect to the Products in the Territory, covering subject matter at a level of detail reasonably required by HCAI and sufficient to enable HCAI to determine Contractor's compliance with its obligations under this Agreement. In addition, Contractor will make available to HCAI such additional information about its Commercialization activities as may be reasonably requested by HCAI from time to time.

e. Contractor acknowledges and agrees that Contractor will have the responsibility to Commercialize the Products and for all purchase order and inventory management.

10. Price of Products

a. Contractor shall Commercialize all CalRx-branded Products with the same manufacturer suggested retail price as the Civica-branded Products for as long as CalRx-branded Products are sold within the Territory. Contractor announced the pricing for the Products will be available at no more than $30 per 10mL vial or $55 per five pack of 3mL pens at launch, including the cost of distribution. Contractor will support Health and Safety Code Section 127693(b)(4) in that each drug shall be made available to providers, patients, and purchasers at a transparent price and without rebates, other than rebates required by Governmental Authorities.

b. For so long as any CalRx-branded Products are sold in the Territory, Contractor will use its Commercially Reasonable Efforts to lower its costs to Manufacture the CalRx-branded Products and to improve efficiencies. Any profits made from the CalRx-branded Products will be reinvested in Development, Manufacturing and Commercialization of Products or to lower the price for the Products or as the JSC may otherwise designate. Contractor will present to the JSC and the Civica Foundation Board any proposed price increases for the Products.

c. To the extent that Civica-branded Product is sold in the Territory to meet any inventory shortfalls pursuant to Exhibit A, Section 12, such Product shall be sold at the same prices as the CalRx–branded Products.

11. Manufacture of Products

a. Contractor acknowledges and agrees that upon BLA approval, it will have the obligation to Manufacture and supply all quantities of CalRx-branded Products (as quantities of such Products may increase or change during the term of the Definitive Agreement) as are necessary for Commercialization in the Territory. After BLA approval and at all times during the Term, Contractor will ensure that it will provide and ensure that all Third-Party suppliers of drug substance and other raw materials will provide sufficient manufacturing capacity to meet the CalRx-branded Product supply requirements in the Territory and that the Territory will not suffer shortfalls due to Contractor's other manufacturing commitments of Products to other third parties.

b. Contractor (with input provided by HCAI through the JSC) will be responsible for quarterly forecasting of CalRx-branded Products. Contractor will be responsible for managing CalRx-branded Product Manufacturing schedules and all other matters necessary to ensure a continuous supply of such Products to the Territory and in such quantities as are necessary to meet ongoing and increasing demand during the Term. For the avoidance of doubt:

   i. Nothing in this Agreement or the Collaboration will require HCAI or the State of California to purchase any quantities of Products from Contractor; and

   ii. Contractor will produce CalRx-branded Products that substantially meets market demand in the State of California based on quarterly demand planning conducted jointly by Contractor (with input provided by HCAI through the JSC).

c. Through the JSC, HCAI will share information with Contractor concerning potential groups of consumers of the Products and such reasonably related data and information that may facilitate the expansion of the consumer base for the Products in the Territory and which Contractor may use in developing Product forecasts.

12. Branding and Labeling

a. Products sold within the Territory will be branded with "CalRx" brand-related labeling to build public awareness and demonstrate the State of California's commitment to insulin affordability. Pursuant to the terms of this Agreement, HCAI hereby grants to Contractor a limited, non-exclusive, terminable, royalty-free, fully paid-up, non-sublicensable (except pursuant to this Agreement), non-transferable, license to the CalRx branding for use in the Development, Manufacture and Commercialization of the Products in the Territory.

b. In the event that the JSC determines, in its reasonable discretion, that the inventory of the CalRx-branded Products do not or will not meet reasonably anticipated demand (an "Inventory Shortfall") then Contractor shall be permitted to sell Civica-branded Products within the Territory for as long as such Inventory Shortfall continues, as determined by the JSC. De minimis sales of Civica-branded Products within the Territory will not be considered a breach of this Agreement.

c. Notwithstanding these branding and labeling requirements, neither HCAI nor any State of California agency or entity will be subject to any liability associated with Development, Manufacture or Commercialization of the Products. Contractor will indemnify HCAI (and all other agencies, employees, agent, contractors, and representatives of the State of California) for any losses or liabilities relating to the Development, Manufacture or Commercialization of the Products to the extent attributable to Contractor.

13. Subcontractors

a. The Parties agree that the performance by the following entities support the Development, Manufacture and Commercialization of the Products: Contractor's supplier(s) of drug substance; Contractor's supplier(s) of insulin pens; and Contractor's provider(s) of clinical trials; and CivicaScript, LLC, Contractor's provider of Commercialization services (collectively, the "Subcontractors"). Contractor hereby represents and warrants that it has made available to HCAI true, correct, and complete copies of all contracts with all Subcontractors related to Development, Manufacture and Commercialization of Products, except where redacted or Contractor has notified HCAI it is prohibited by Subcontractor from disclosing. Contractor further covenants and agrees that it will promptly make available updated copies of any updates, revisions, or new agreements with the Subcontractors related to the Development, Manufacture and Commercialization of Products throughout the Term. HCAI reviewed Contractor's contracts

with Subcontractors, and proposed amendments to date, and the terms of the agreements as disclosed would not impair Milestone Payments.

b. During the Term, Contractor will promptly notify HCAI in advance and as soon as reasonably practicable of Contractor's decision to add or change any Subcontractor, or any supplier of component(s) used in Manufacturing the Products which would require a regulatory notification or approval.

c. All Subcontractors must comply with all Applicable Laws.

d. Notwithstanding anything to the contrary contained in this Agreement, Contractor shall be, and shall remain, fully and primarily responsible for the compliance and performance of each Subcontractor.

14. Information Sharing

a. Contractor shall establish the Contractor VDR for purposes of sharing information with HCAI pursuant to the terms of this Agreement.

b. Subject to confidentiality restrictions set forth in this Agreement, by means of the Contractor VDR, HCAI will receive from Contractor all documents the Parties agree to share in diligence as concerning Contractor or its Subcontractors and all documents shared through the JSC.

15. Failure to Supply or Develop

a. Effective upon HCAI's termination of this Agreement due to a Failure to Supply or Develop, Contractor hereby grants to HCAI, or any Third Party designated by HCAI, a non-exclusive, irrevocable perpetual, fully paid up, royalty-free license to (with a right to sublicense) all Intellectual Property Rights owned or controlled by Contractor and its Affiliates including rights of access to all development data and information on the Product, clinical data and other information on the Products, in each case covering or as may be necessary or useful for the Development, Manufacture and Commercialization of Products.

b. Additionally, in the event a of a termination for Failure to Supply or Develop, Contractor shall promptly conduct a nonexclusive transfer of all Intellectual Property Rights granted in Section 15a above to enable HCAI or any Third Party designated by HCAI to engage in the Development, Manufacture and Commercialization of Products.

16. Representation, Warranties and Covenants of Both Parties

Each Party represents and warrants, and, as applicable, covenants to the other Party as of the Effective Date that:

a. (i) it has the authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any Applicable Law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it;

b. all consents, approvals, and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained;

c. it is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement;

d. neither it nor its Affiliates or Subcontractors have not been debarred, disqualified or excluded by any Governmental Authority, and no proceeding that could result in such Party or an Affiliate or to such Party's knowledge Subcontractor being debarred, disqualified or excluded by any Governmental Authority is pending, and neither it nor its Affiliates or to such Party's knowledge Subcontractors have used, in any capacity, any employee, subcontractor, consultant, agent, representative, or other Person who has been debarred, disqualified or excluded by any Governmental Authority; and

e. in the course of performing its obligations or exercising its rights under this Agreement, it will comply with all Applicable Laws, in including as applicable, cGMP, GCP and GLP standards, and will not employ or engage any party who has been debarred, disqualified or excluded by any Governmental Authority, or, to such Party's Knowledge, is the subject of debarment, disqualification or exclusion proceedings by a Governmental Authority.

17. Representations, Warranties and Covenants of Contractor

Contractor represents, warrants, and, as applicable, covenants to HCAI that as of the Effective Date:

a. it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement;

b. (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; and (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder;

c. there are no legal claims, actions by any Governmental Authority, judgments, or settlements against or owed by Contractor, or pending or, to Contractor's knowledge, threatened, legal claims or litigation, in each case, relating to violations of Applicable Law, including Anti-Corruption Laws, or that would materially adversely affect Contractor's ability to Develop, Manufacture and Commercialize and otherwise Exploit the Products in the Territory as contemplated by this Agreement;

d. Once the HCAI Funding is received, Contractor will have sufficient financial wherewithal to (i) perform all of its obligations pursuant to this Agreement, including all obligations relating the Development, Commercialization and Manufacture of the Products, and (ii) meet all of its obligations that come due in the ordinary course of business. HCAI understands Contractor will continue to raise additional funds relating to the Products;

e. The HCAI Funding will solely be used by Contractor to perform its obligations pursuant to this Agreement, including all obligations relating the Development, Commercialization and Manufacture of the Products;

f. All documentation provided by Contractor to HCAI in connection with entry into this Agreement is true, accurate and complete in all material respects, except where redacted or Contractor has notified HCAI it is not permitted to disclose, and there has been no material adverse change in Contractor's financial outlook or status since the period reflected in any such financial statements; and

g. Contractor has, or will obtain, sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development, Manufacturing, Commercialization, and obtaining Regulatory Approvals of the Products as contemplated by this Agreement.

EXHIBIT B
BUDGET DETAIL & PAYMENT PROVISIONS

1. HCAI Funding

   a. Under the parameters established by the legislature of the State of California, HCAI will fund up to US $50 million (the "HCAI Funding") for the sole and exclusive use by Contractor towards the Development, Manufacture and Commercialization of the Products, which HCAI Funding will be paid to Civica at such times and in such amounts as set forth herein.

   b. Payments made pursuant to this Agreement shall be made in accordance with the State of California's Prompt Payment Act (Government Code sections 927 *et seq*.).

2. Cost and Payment Schedule

   a. The total cost to HCAI of this Agreement shall not exceed $50,000,000.

   b. Within 45 Business Days after the first achievement of each milestone as set forth the filename, "CalRx Biosimilar Insulin Project Milestone Payment Schedule.pdf", located in the Contractor VDR or as otherwise agreed in writing by the Parties (each, a "Milestone"), HCAI shall pay to Contractor the Milestone payments (each, a "Milestone Payment) upon completion or satisfaction by Contractor of the Milestones and no payment shall become due and owing for any future work not yet achieved or work performed by Contractor that is not for the benefit of HCAI and the State of California.

3. Payment

   a. All payments to be made under this Agreement will be made within net 45 days from the date HCAI receives an invoice for each such payment. All payments will be made in U.S. Dollars and will be paid by electronic transfer in immediately available funds to such bank account in the United States as is designated in writing by a Party. All payments will be free and clear of any transfer fees or charges.

   b. If by reason of Applicable Law in any country or region, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed the other Party hereunder, then such Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country or region (or to such other country or region to which deposit of such payment could be made and remitted to the other Party) to the credit of the other Party in a recognized banking institution designated by the other Party, or, if none is designated by the other Party within a period of 45 days, in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party.

   c. HCAI is not obligated to pay any Milestone Payments in the event that Contractor becomes insolvent or is otherwise in breach of the Agreement. Upon a termination of the Agreement for material breach or an insolvency of Contractor, HCAI shall have the right to require the return of any unused funds paid to Contractor.

EXHIBIT C
GENERAL TERMS AND CONDITIONS

1. Approval

   This Agreement is of no force or effect until signed by both Parties.

2. Amendment

   No amendment or variation of the terms of this Agreement shall be valid unless made in writing, signed by the parties, and approved as required. No oral understanding or Agreement not incorporated in the Agreement is binding on any of the Parties.

3. Assignment

   This Agreement is not assignable by Contractor, either in whole or in part, without the prior written consent of HCAI.

4. Audit

   a. Contractor will maintain and will cause its Subcontractors to maintain, reasonably complete, current and accurate records in either tangible or electronic form of (a) all Development, Manufacturing, and Commercialization events and activities such Party generates related to a Product in the Territory; and (b) all Information generated by it or on its behalf in connection with Development, Manufacture, and Commercialization of a Product, in each case in accordance with Contractor's usual documentation and GCP, cGMP record retention practices ("Records").

   b. Contractor agrees to seek amendments that permit HCAI or their designated representative and consultants to review Records to ensure performance of its obligations under this Agreement or in the case of a Subcontractor to ensure its obligations under the applicable agreement with Contractor related to a Product. Contractor agrees to maintain Records for possible audit for a minimum of three years after final payment unless a longer period of records retention is stipulated. Contractor shall allow the auditor(s) access to Records in accordance with this Agreement stored on the Contractor VDR, during normal business hours and to allow interviews of any employees who have information related to such Records. All audits by HCAI or their designated representative and consultants must be conducted in compliance with the laws of the jurisdiction(s) applicable to the records of a Subcontractor's operations, including the laws of the jurisdiction in which such audit is conducted.

   c. Upon reasonable prior notice, Records of the Examined Party (as defined below) will be available on the Contractor VDR and shall be open during regular business hours for examination by the State of California, HCAI or its designated representative and consultants (the "Examining Party") for the sole purpose of verifying compliance by Contractor and Subcontractor (the "Examined Party") with this Agreement, or for Subcontractor compliance with the Agreement between Subcontractor and Contractor. Such audit will not be (a) performed more frequently than once per Calendar Year during the Term or once during the three-year period after final payment under this Agreement, (b) conducted for any Calendar Year more than three years after the end of such year, or (c) repeated for any Calendar Year or with respect to the same set of records unless a material discrepancy with respect to such records is discovered during a prior audit. The State of California, HCAI or its designated auditor will also have rights to audit Contractor at any time in situations to address emergency situations involving health and safety, including follow-up audits, to address prior identified deficiencies.

5. Indemnification

   a. Contractor agrees to indemnify, defend, and save harmless HCAI, the State of California, its officers, agents, and employees (each, an "Indemnified Party") from any and all Losses accruing or resulting from (a) the Exploitation of the Products, by or on behalf of Contractor its Affiliates any of their respective subcontractors, including product liability and intellectual property claims arising from such Exploitation, (b) the negligence or willful misconduct of Contractor, it Affiliates or any of their respective subcontractors, (c) Contractor's breach of any of its representations, warranties, covenants, or obligations set forth in or entered into pursuant to this Agreement, (d) the failure of Contractor, it Affiliates or any of their respective subcontractors to comply with any Applicable Law in performing the obligations pursuant to this Agreement, and (e) product liability claims arising from use of the Products by consumers.

   b. If any Indemnified Party is seeking indemnification under this Agreement, then it will inform Contractor of the Loss giving rise to such indemnification obligations within 30 days after receiving written notice of the Loss (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a Loss will not affect Contractor's indemnification obligations hereunder except to the extent the Indemnifying Party will have been actually and materially prejudiced as a result of such failure or delay to give notice). Contractor will have the right to assume the defense of any such Loss for which it is obligated to indemnify the Indemnified Party. The Indemnified Party will cooperate with Contractor and Contractor's insurer as the Indemnifying Party may reasonably request, and at Contractor's cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any Loss that has been assumed by Contractor. Contractor will have no obligation to indemnify any Indemnified Party in connection with any settlement made without Contractor's written consent, which consent will not be unreasonably withheld, conditioned, or delayed. Contractor will not admit liability of the Indemnified Party without the Indemnified Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed.

6. LIMITATION OF LIABILITY

   SUBJECT TO AND WITHOUT LIMITING THE INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT AND THE BREACH OF A PARTY'S CONFIDENTIALITY OBLIGATIONS UNDER EXHIBIT G, NO PARTY OR ANY OF ITS AFFILIATES WILL BE LIABLE TO THE OTHER PARTY UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, MULTIPLIED OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS (EVEN IF DEEMED DIRECT DAMAGES) ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT.

7. Termination

   a. In the event that Contractor has not achieved all Milestones by June 30, 2026, then HCAI may terminate this Agreement by providing written notice to Contractor.

   b. At any time after December 31, 2027, HCAI may terminate this Agreement, in its entirety, or on a Product-by-Product basis, by providing 30 days' prior written notice to Contractor.

   c. This Agreement may be terminated in its entirety at any time during the Term upon written notice by either Party if the other Party materially breaches this Agreement and, if such breach is curable, such breach has not been cured within 60 days after receipt of such termination notice, or such longer period as is reasonably agreed to by the Parties.

d. HCAI will have the right to terminate this Agreement upon delivery of written notice to Contractor in the event that (a) Contractor files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) Contractor is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within 90 days of its filing, (c) Contractor makes an assignment of substantially all of its assets for the benefit of its creditors (collectively, "Insolvency") (d) Failure to Supply or Develop (e) termination by HCAI as a result of material or chronic non-material issues with Product quality or safety or late deliveries, (f) termination by HCAI if the price of the Products exceeds contracted amount in the Agreement, and (g) termination by HCAI for convenience after December 31, 2027 upon agreed upon notice terms and payment terms.

8. Effect of Termination or Expiration

a. Upon the termination of this Agreement for any reason, Contractor will be permitted to continue to Commercialize CalRx-branded Product for a period of one year after termination (the "Sell Off Period"). In the event that this Agreement is Terminated pursuant to Failure to Supply or Develop, then the terms Exhibit A, Section 15 will apply.

b. Termination of this Agreement for any reason will not release either Party of any obligation or liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination. Notwithstanding anything herein to the contrary, termination of this Agreement by a Party will be without prejudice to other remedies such Party may have at law or equity.

c. At the Disclosing Party's election, the Receiving Party will return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to any Product that are in the possession or control of the Receiving Party, its Affiliates', or Subcontractor's possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); *provided* that the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding any provision to the contrary set forth in this Agreement, the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

d. All rights and licenses granted under or pursuant to this Agreement by Contractor and HCAI are and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a party to such proceeding will be entitled to a duplicate of (or access to, as appropriate) any such intellectual property licensed hereunder and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-

subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under subsection (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

e. The following provisions will survive the termination or expiration of this Agreement for any reason: Exhibit A, Section 5(a), Exhibit C, Sections 4, 5, 6, 8, 12-20, Exhibit G, Exhibit H.

9. Independent Contractor

Contractor, and the agents and employees of Contractor, in the performance of this Agreement, shall act in an independent capacity and not as officers or employees or agents of the State.

10. Applicable Law.
The Parties, each Party's Affiliates, and Subcontractors will comply with all Applicable Law.

11. Timeliness

Time is of the essence in this Agreement.

12. Governing Law

This Agreement shall be governed by and shall be interpreted in accordance with the laws of the State of California; venue of any action brought with regard to this Contract shall be in Sacramento County, Sacramento, California.

13. Unenforceable Provision

In the event that any provision of this Agreement is unenforceable or held to be unenforceable, then the parties agree that all other provisions of this Agreement have force and effect and shall not be affected thereby.

14. Severability

If any one or more of the provisions contained in this Agreement is held invalid, illegal, or unenforceable in any respect, the validity, legality, and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal, and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

15. Entire Agreement; Amendments

The Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with regard to the subject matter hereof (including the licenses granted hereunder) are superseded by the terms of this Agreement. Neither Party is relying on any representation, promise, nor warranty not expressly set forth in this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

16. Headings

The captions to the several Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the Sections of this Agreement.

17. Waiver

The waiver by either Party of any right hereunder, or the failure of the other Party to perform, or a breach by the other Party, will not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

18. Waiver 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.

19. Construction

Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation”, (c) the word “shall” will be construed to have the same meaning and effect as the word “will”, (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person will be construed to include the Person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Schedules, or Exhibits will be construed to refer to Sections, Schedules or Exhibits of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any Committee hereunder “agree”, “consent” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or,” (l) references to a number of days will be construed to refer to calendar days unless Business Days are specified.

20. Counterparts

This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

21. Publicity.

Neither Party shall issue any press release concerning this Agreement or the subject matter hereof, nor will either Party use the other Party’s name, trademarks, or logos in any advertising, press release, websites or promotional materials, except with the prior written consent of the other Party. Furthermore, HCAI shall not make any public references concerning the functionality, performance or regulatory status of the Product(s) without Civica’s prior written approval. HCAI will allow Civica to review any written communications prior to publication that reference Civica or the

Products. References to prior approved communications shall be permissible unless such approval is withdrawn in writing. Any consent or approval required under this Section 21 shall not to be unreasonably withheld, conditioned or delayed.

EXHIBIT D
SPECIAL TERMS AND CONDITIONS

1. Excise Tax

   The State of California is exempt from federal excise taxes, and no payment will be made for any taxes levied on employees' wages. The State will pay for any applicable State of California or local sales or use taxes on the services rendered or equipment or parts supplied pursuant to this Agreement. California may pay any applicable sales and use tax imposed by another state.

2. Settlement of Disputes

   In the event of a dispute, Contractor shall file a "Notice of Dispute" with the HCAI Director within ten (10) days of discovery of the problem. Within ten (10) days, the HCAI Director shall meet with Contractor's CEO for purposes of resolving the dispute, in good faith, within thirty (30) days.

   In the event that the Parties' representatives are not able to resolve the dispute, then either Party may seek any other available recourse.

3. Potential Subcontractors

   Nothing contained in this Agreement or otherwise, shall create any contractual relation between the State and any Subcontractors, and no Subcontractor shall relieve Contractor of its responsibilities and obligations hereunder. Contractor's obligation to pay its Subcontractors is an independent obligation from the State's obligation to make payments to Contractor. As a result, the State shall have no obligation to pay or to enforce the payment of any moneys to any Subcontractor.

4. Force Majeure

   Neither party shall be responsible for delays or failures in performance resulting from acts beyond the control of the offending party. Such acts shall include but shall not be limited to acts of God, fire, flood, earthquake, other natural disaster, nuclear accident, strike, lockout, riot, freight embargo, public regulated utility, or governmental statutes or regulations superimposed after the fact. If a delay or failure in performance by Contractor arises out of a default of its subcontractor, and if such default of its subcontractor, arises out of causes beyond the control of both Contractor and subcontractor, and without the fault or negligence of either of them, Contractor shall not be liable for damages of such delay or failure, unless the supplies or services to be furnished by the subcontractor were obtainable from other sources in sufficient time to permit Contractor to meet the required performance schedule.

5. Health and Safety Protocol

   Contractor personnel will be required to follow all applicable state and public health requirements, and related HCAI policies when in a HCAI building.

6. Executive Order N-6-22 – Russia Sanctions

   On March 4, 2022, Governor Gavin Newsom issued Executive Order N-6-22 (the "EO") regarding Economic Sanctions against Russia and Russian entities and individuals. "Economic Sanctions" refers to sanctions imposed by the U.S. government in response to Russia's actions in Ukraine, as well as any sanctions imposed under state law.

   a. The EO directs state agencies to terminate contracts with, and to refrain from entering any new contracts with, individuals or entities that are determined to be a target of Economic Sanctions. Accordingly, should the State determine Contractor is a target of Economic Sanctions or is conducting prohibited transactions with sanctioned individuals or entities, that shall be grounds for termination of this agreement. The State shall provide Contractor advance written notice of

such termination, allowing Contractor at least 30 calendar days to provide a written response. Termination shall be at the sole discretion of the State.

b. The EO also directs all state agencies that are subject to the Governor's authority to direct all state contractors and grantees with agreements valued at $5 million or more to report to the agency regarding their compliance with economic sanctions imposed by the U.S. government in response to Russia's actions in Ukraine, as well as sanctions imposed under state law, if any.

c. The EO also directs all agencies that are subject to the Governor's authority to direct their grantees and contractors with agreements valued at $5 million or more to report on the steps they have taken in response to Russia's actions in Ukraine.

EXHIBIT E
INSURANCE REQUIREMENTS

Contractor is required to maintain insurance for the term of the Agreement as outlined below.

1. Contractor shall without expense to HCAI maintain at all times during the term of the Agreement, a valid certificate of Commercial General Liability Insurance with the following requirements:
   A. Evidence of insurance shall be of a form and content acceptable to HCAI.
   B. The certificate of insurance shall be issued by an insurance company, or be provided through partial or total self-insurance, acceptable to HCAI.
   C. The certificate of insurance shall state an amount of Commercial General Liability of no less than $5,000,000.00 per occurrence for bodily injury and property damage liability combined.
   D. The certificate of insurance shall state an amount of Product Liability of no less than $10,000,000.00 per incidence.
   E. The certificate of insurance shall provide that the insurer shall not cancel the insured's coverage without thirty (30) days prior written notice to the state.
   F. The certificate of insurance shall provide that HCAI and its employees are included as additional insured.
   G. The certificate of insurance shall meet such additional standards as may be determined by HCAI.
2. Contractor shall without expense to HCAI maintain at all times during the term of the Agreement, Automobile Liability insurance with limits not less than $500,000.00.
3. Contractor shall without expense to HCAI maintain at all times during the term of the Agreement, Professional Liability Insurance covering any damages caused by a negligent error, act or omission with limits not less than $1,000,000.00 per occurrence and $1,000,000.00 policy aggregate.
4. Contractor shall without expense to HCAI maintain at all times during the term of the Agreement Workers Compensation and Employers' Liability Insurance.
5. In the event the required insurance coverage lapses, expires, or is canceled at any time or times during the term of the Agreement, Contractor shall provide at least thirty (30) days prior to said date a new certificate of insurance evidencing insurance coverage as provided for herein for not less than the remainder of the term of the Agreement, or for a period of not less than one (1) year. New certificates of insurance are subject to the approval of ORIM. Contractor agrees that no work or services shall be performed prior to such approval. In the event Contractor fails to keep current and in effect at all times, insurance coverage as herein provided, the state may, in addition to any other remedies, terminate the Agreement.

   All certificates of insurance shall clearly indicate **HCAI [#22-23025]** and be submitted to:

The Department of Health Care Access and Information
Administrative Services Division
Attn: Monica Erickson
2020 West El Camino Avenue, Ste. 1000
Sacramento, CA 95833

EXHIBIT F
CONTRACTOR CERTIFICATION CLAUSES (CCC 04/2017)

Certifications

I, the official named below, CERTIFY UNDER PENALTY OF PERJURY that I am duly authorized to legally bind the prospective Contractor to the clause(s) listed below. This certification is made under the laws of the State of California.

1. STATEMENT OF COMPLIANCE: Contractor has, unless exempted, complied with the nondiscrimination program requirements. (Cal. Government Code section 12990 (a-f) and 2 Code Cal. Regs, title 2, sections 11102 and 11109).

2. DRUG-FREE WORKPLACE REQUIREMENTS: Contractor will comply with the requirements of the Drug-Free Workplace Act of 1990 and will provide a drug-free workplace by taking the following actions:

   A. Publish a statement notifying employees that unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance is prohibited and specifying actions to be taken against employees for violations.

   B. Establish a Drug-Free Awareness Program to inform employees about the dangers of drug abuse in the workplace;

      i. the Person's policy of maintaining a drug-free workplace;
      ii. any available counseling, rehabilitation, and employee assistance programs; and,
      iii. penalties that may be imposed upon employees for drug abuse violations.

   C. Every employee who works on the proposed Agreement will:
      i. receive a copy of the company's drug-free workplace policy statement; and,
      ii. agree to abide by the terms of the company's statement as a condition of employment on the Agreement.

   Failure to comply with these requirements may result in suspension of payments under the Agreement or termination of the Agreement or both and Contractor may be ineligible for award of any future State agreements if the department determines that any of the following has occurred: Contractor has made false certification or violated the certification by failing to carry out the requirements as noted above. (Cal. Government Code sections 8350 *et seq*.)

3. SWEAT-FREE CODE OF CONDUCT:

   A. All contractors contracting for the procurement or laundering of apparel, garments or corresponding accessories, or the procurement of equipment, materials, or supplies, other than procurement related to a public works contract, declare under penalty of perjury that no apparel, garments or corresponding accessories, equipment, materials, or supplies furnished to the state pursuant to the contract have been laundered or produced in whole or in part by sweatshop labor, forced labor, convict labor, indentured labor under penal sanction, abusive forms of child labor or exploitation of children in sweatshop labor, or with the benefit of sweatshop labor, forced labor, convict labor, indentured labor under penal sanction, abusive forms of child labor

or exploitation of children in sweatshop labor. Contractor further declares under penalty of perjury that they adhere to the Sweat-free Code of Conduct as set forth on the California Department of Industrial Relations website located at https://www.dir.ca.gov/, and Public Contract Code Section 6108.

B. Contractor agrees to cooperate fully in providing reasonable access to Contractor's records, documents, agents or employees, or premises if reasonably required by authorized officials of the contracting agency, the Department of Industrial Relations, or the Department of Justice to determine Contractor's compliance with the requirements under paragraph (a).

"Doing Business with the State of California" section in CCC

The following laws apply to Persons doing business with the State of California.

1. CONFLICT OF INTEREST: Contractor needs to be aware of the following provisions regarding current or former state employees. If Contractor has any questions on the status of any Person rendering services or involved with the Agreement, the awarding agency must be contacted immediately for clarification.

   A. Current State Employees (Cal. Public Contract Code section 10410):

      i. No officer or employee shall engage in any employment, activity, or enterprise from which the officer or employee receives compensation or has a financial interest, and which is sponsored or funded by any state agency, unless the employment, activity or enterprise is required as a condition of regular state employment.

      ii. No officer or employee shall contract on his or her own behalf as an independent contractor with any state agency to provide goods or services.

   B. Former State Employees (Cal. Public Contract Code section 10411):

      i. For the two-year period from the date he/she/they left state employment, no former state officer or employee may enter into a contract in which he/she/they engaged in any of the negotiations, transactions, planning, arrangements or any part of the decision-making process relevant to the contract while employed in any capacity by any state agency.

      ii. For the twelve-month period from the date he/she/they left state employment, no former state officer or employee may enter into a contract with any state agency if he/she/they was employed by that state agency in a policy-making position in the same general subject area as the proposed contract within the 12-month period prior to his or her leaving state service.

2. AMERICANS WITH DISABILITIES ACT: Contractor assures the State that it complies with the Americans with Disabilities Act (ADA) of 1990, which prohibits discrimination on the basis of disability, as well as all applicable regulations and guidelines issued pursuant to the ADA. (42 U.S.C. sections 12101 *et seq*.)

3. PAYEE DATA RECORD FORM STD. 204: This form must be completed by the Contractor.

4. CONTRACTOR NAME CHANGE: An amendment is required to change Contractor's name as listed on this Agreement. Upon receipt of legal documentation of the name change the State will process the amendment. Payment of invoices presented with a new name cannot be paid prior to approval of said amendment.

5. CORPORATE QUALIFICATIONS TO DO BUSINESS IN CALIFORNIA:

   A. When agreements are to be performed in the state by corporations, the contracting agencies will be verifying that Contractor is currently qualified to do business in California in order to ensure that all obligations due to the state are fulfilled.

   B. "Doing business" is defined in R&TC Section 23101 as actively engaging in any transaction for the purpose of financial or pecuniary gain or profit. Although there are some statutory exceptions to taxation, rarely will a corporate contractor performing within the state not be subject to the franchise tax.

   C. Both domestic and foreign corporations (those incorporated outside of California) must be in good standing in order to be qualified to do business in California. Agencies will determine whether a corporation is in good standing by calling the Office of the Secretary of State.

6. AIR OR WATER POLLUTION VIOLATION (Cal. Government Code section 4477): Under State law, Contractor shall not be: (1) in violation of any order or resolution not subject to review promulgated by the State Air Resources Board or an air pollution control district; (2) subject to cease and desist order not subject to review issued pursuant to Section 13301 of the Water Code for violation of waste discharge requirements or discharge prohibitions; or (3) finally determined to be in violation of provisions of federal law relating to air or water pollution.

Signature: Allan Coukell

Printed name: Allan Coukell

EXHIBIT G
MUTUAL NONDISCLOSURE TERMS

1. **DEFINITIONS.**

1.1 "Discloser" and "Recipient" apply to both Parties depending on their role, whether as the discloser or the recipient of Confidential Information.

1.2 "Confidential Information" means all non-public information or data relating to the Project in any form that Discloser discloses to Recipient during the Term. It includes a Party's proprietary information, intellectual property, trade secrets, know-how, software, technology, specifications, and other non-public business or financial information. Confidential Information also means any third party's non-public information provided to a Party under a confidentiality obligation ("Third-Party Information").

1.3 "Affiliate" means any entity managing, managed by, under common management with, controlling, controlled by or under common control with the applicable Party.

2. **OWNERSHIP**. All Confidential Information remains the property of Discloser or its licensor, or both. This Agreement does not grant a license to the Confidential Information, except as expressly stated in this Agreement. Nothing in this Agreement waives any right a Party has in its Confidential Information.

3. **CALIFORNIA PUBLIC RECORDS ACT**.

3.1 The Parties acknowledge that any documents or information provided to the California Department of Health Care Access and Information for the Project may be subject to the California Public Records Act (CPRA), which requires the disclosure of the Department's records to the public unless there is an express exemption. (Cal. Gov. Code section 6253 (2022).) Exemptions include, but are not limited to, the following:

3.1.A **CalRx Exemption.** The California Affordable Drug Manufacturing Act of 2020's express exemption under Cal. Health and Safety Code section 127696 (2022):

"In order to protect proprietary, confidential information regarding manufacturer or distribution costs and drug pricing, utilization, and rebates, it is necessary that [the California Affordable Drug Manufacturing Act of 2020] limit the public's right of access to that information. Notwithstanding any other provision of law, all nonpublic information and documents obtained or prepared under [the California Affordable Drug Manufacturing Act of 2020] shall not be required to be disclosed pursuant to the California Public Records Act…."

3.1.B **Trade Secrets**. Trade secret information pursuant to Cal. Evidence Code section 1060 which is incorporated into the CPRA through Cal. Gov. Code section 6254(k).

3.1.C **Public Interest Exemption**. Pursuant to Cal. Gov. Code section 6255, to establish this exemption, the Department must demonstrate that the public's interest in nondisclosure of a record clearly outweighs the public's interest in disclosure.

3.2 If the Department receives a CPRA request for confidential information, the Department will withhold confidential information pursuant to one or more CPRA exemptions (such as the ones stated above) if Discloser properly marked the confidential information as "confidential" and provided notice as discussed in Section 4 below.

3.3 It is Civica's responsibility to determine whether the information disclosed meets a CPRA exemption prior to disclosure.

4. CONFIDENTIALITY OBLIGATIONS.

4.1 Recipient may use Discloser's Confidential Information solely for evaluating potential business opportunities with Discloser that relate to the Project. Recipient will keep Discloser's Confidential Information confidential, maintain it in a safe and secure place, and use a reasonable degree of care to safeguard it. Recipient may disclose Discloser's Confidential Information to those employees, credentialed physicians, advanced practice clinicians, Affiliates, accountants, attorneys, third party service providers, and consultants of Recipient who have a need to know and is required to keep it confidential. If Recipient copies Discloser's Confidential Information, Recipient will mark each copy as confidential. Recipient will not use, disclose, or maintain Confidential Information outside the United States without Discloser's prior written consent in each instance.

4.2 Prior to sending confidential information to Recipient, Discloser will notify Recipient that Discloser is sending confidential information and will prominently mark the confidential information as "confidential" and separate such confidential information from other information.

5. EXCEPTIONS.

5.1 **Exempt Information**. The confidentiality obligations under this Agreement do not apply to information that Recipient proves (a) is or has become publicly available without breach of this Agreement, but only from the date that it becomes publicly available; (b) was rightfully in Recipient's possession without confidentiality obligations to Discloser before Recipient received it from Discloser; (c) was disclosed to Recipient by a third party without obligation of confidentiality owed to Discloser; or (d) is independently developed by Recipient without using any Confidential Information.

5.2 **Mandated Disclosure**. If a judicial or governmental request or order seeks Confidential Information, Recipient may disclose that Confidential Information as requested or ordered. But, if permitted by applicable law, Recipient must promptly notify Discloser before disclosing the Confidential Information, and reasonably cooperate with Discloser in seeking a protective order or limiting the effect of that disclosure.

6. RETURN, DESTRUCTION, AND ONGOING RETENTION OF CONFIDENTIAL INFORMATION.

6.1 When this Agreement terminates, or earlier if Discloser requests, Recipient will: (a) promptly return or destroy all documents and tangible items in its possession or control that contain Discloser's Confidential Information; and (b) according to Recipient's standard purge processes for electronic data, delete or erase Discloser's Confidential Information that Recipient stored electronically. Recipient's obligations regarding Confidential Information survive this Agreement's termination and continue in perpetuity.

6.2 The Parties acknowledge that the Department is required to keep documentation regarding the formation of a partnership for state auditing purposes (such as pursuant to Cal. Gov. Code section 8546.7). For this reason, notwithstanding Section 6.1, the Department, at its discretion, may keep confidential information for either (a) a period of 3 years after final payment under a partnership agreement, if one is executed; or (b) a period of 3 years after discussions for a partnership agreement end, if one is not executed. The Department will provide notice to Civica regarding the confidential information it will keep under this section.

At the end of the time periods stated in this section, the Department will dispose of the confidential information as stated in Section 6.1.

7. **DISCLAIMER. All Confidential Information is provided "AS IS," WITHOUT ANY EXPRESSED OR IMPLIED WARRANTY. Discloser does not represent or warrant the Confidential Information's accuracy or completeness.**

8. **LIMITATION OF LIABILITY. DISCLOSER IS NOT LIABLE FOR ANY DAMAGE (INCLUDING, WITHOUT LIMITATION, ANY PECUNIARY LOSS, DAMAGE FOR LOSS OF BUSINESS PROFITS, OR DAMAGE FOR BUSINESS INTERRUPTION) ARISING OUT OF RECIPIENT'S USE OF OR INABILITY TO USE ANY CONFIDENTIAL INFORMATION.**

9. **MISCELLANEOUS**.

9.1 **Injunctive Relief**. Recipient acknowledges that its breach of this Exhibit G would cause Discloser irreparable harm and that money damages would be an insufficient remedy for that breach. Accordingly, if Recipient breaches this Exhibit G, Discloser is entitled to seek immediate injunctive relief without the necessity of posting bond or other security. This injunctive relief is in addition to, and not in lieu of, any other remedies at law or in equity that are available to Discloser.

9.2 **Third-Party Beneficiary**. Each third party owning Third-Party Information is a third-party beneficiary of this Agreement, having the right to take action directly against Recipient for any breach of Recipient's confidentiality obligations or other restrictions relating to that third party's Third-Party Information.

9.3 **Miscellaneous**. No failure by either Party to enforce or exercise any right under this Exhibit G shall constitute a waiver. All remedies provided in this Exhibit G, at law or in equity, are cumulative and do not limit a Party's other available rights or remedies.

EXHIBIT H
DEFINITIONS

Unless specifically set forth to the contrary in this Agreement, the following terms, whether used in the singular or plural, have the respective meanings set forth below:

“Affiliate” means, with respect to a Person, any entity that directly or indirectly controls, is controlled by or is under common control with such Person. As used in this definition, “control” (and, with correlative meanings, the terms “controlled by” and “under common control with”) means an interest that results in the ability to direct or cause the direction of the management and policies of such Person or the power to appoint more than 50% of the members of the governing body of such Person or, where ownership of more than 50% of such interest is prohibited by law, ownership of the maximum amount legally permitted.

“Agreement” means this agreement, by and between HCAI and CIVICA, and all Exhibits, which are incorporated by reference herein.

“Applicable Laws” means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority, including the FFDCA, Prescription Drug Marketing Act of 1987 (21 U.S.C. §§331, 333, 353, 381), the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335(a) et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal False Claims Act (31 U.S.C. §3729 et seq.), the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), the U.S. Foreign Corrupt Practices Act of 1977 (15 U.S.C. §§ 78dd-1, et seq.), California Affordable Drug Manufacturing Act of 2020 (Cal. Health & Safety Code sections 127690 to 127696), GMP GLP, and GCP, all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder.

“Aspart” means a rapid-acting human insulin analog, usually given 5-10 minutes before a meal, used to improve glycemic control in adults and children with diabetes mellitus. Aspart can also be administered by continuous subcutaneous infusion via insulin pump. A common brand name of this form of insulin is Novolog, produced by Novo Nordisk.

“BLA" or “Biologics License Application” means a licensure pathway in section 351(k) of the Public Health Service Act for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product, including any supplements or amendments thereto.

“Biosimilar Product” means any product that has an approved Biologics License Application.

“Business Day” means a day other than Saturday, Sunday or any day on which banks located in Sacramento, California are authorized or obligated to close.

“Calendar Quarter” means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31, except that the first Calendar Quarter of the Term will commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1, or October 1 after the Effective Date, and the last Calendar Quarter will end on the last day of the Term.

“Commercially Reasonable Efforts” means with respect to the Development, Manufacture or Commercialization of a Product, the level of effort and resources normally used by a party for a product or compound owned or controlled by it, which is of similar market potential and at a similar stage in its development or product life, taking into account, without limitation, with respect to a product issues of safety and efficacy, product profile, the proprietary position of the product, the then current competitive environment for the product and the likely timing of the product’s entry into the market, the regulatory environment of the product, and other relevant scientific, technical and commercial factors.

“Commercialization” or “Commercialize” means with respect to any Product for the Territory, any and all activities directed to the distribution, pricing, reimbursement, offering for sale, and sale of such Product and interacting with regulatory authorities following receipt of Regulatory Approval for such Product regarding the foregoing, including seeking and maintaining any required reimbursement approval, but excluding any activities directed to Manufacturing or Development.

“Contractor VDR” means (a) A secure online repository hosted by Contractor for non-public, confidential document storage as outlined by the Non-disclosure Agreement; (b) Perpetual, read-only access to HCAI and approved auditors and contractors outlined under Section B – Audit Rights, which HCAI agrees no printing or screen shots may be taken; and (c) all documents will remain in the Contractor VDR until the expiration or termination of this Agreement and for three (3) years thereafter following unless HCAI otherwise approves an earlier dissolution of the Contractor VDR

“Develop” or “Development” or “Developing” means, with respect to each Product, any and all internal and external research, development and regulatory activities regarding such Product, including (a) research, process development, non-clinical testing, toxicology, non-clinical activities, GLP toxicology and other preclinical studies, and clinical trials, and (b) preparation, submission, review, and development of data or information to obtain, support, or maintain Regulatory Approval of such Product, but excluding any activities directed to Manufacturing or Commercialization.

“Exploit” or “Exploitation” or “Exploiting” means to research, Develop, make, have made, use, have used, register, sell, have sold, offer for sale, import, export, Commercialize, Manufacture, have Manufactured, or otherwise exploit a Product.

“Failure to Supply or Develop” means: (a) Contractor fails to supply the forecasted quantities of the Products in the Territory for any period of six or more consecutive months after the First Commercial Sale; (b) Contractor is unable to perform Manufacturing services or provide the forecasted quantities of Products in the Territory for more than 12 months because of a Force Majeure Event with no remedy or cure available; (c) Contractor discontinues its insulin program before or after launch due to a severe lack of funding with no remedy available within six months, or immediately for other reasons; (d) Contractor fails to conduct Development of at least one Product for any period of six or more consecutive months after the Effective Date; or (e) Contractor suffers an insolvency.

“FDA” means the U.S. Food and Drug Administration.

“FFDCA” means the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.), as amended.

“First Commercial Sale” means with respect to a Product, the first sale of such Product to a Third Party for distribution, use, or consumption after receipt of Regulatory Approval for such Product. First Commercial Sale excludes any sale or other distribution of a Product for use in a clinical trial or other Development activity or for compassionate or named-patient use.

“GCP” or “cGCP” means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Laws in the applicable jurisdiction, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the Clinical

Data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

“Glargine” means a long-acting human insulin analog, usually given once a day, used to improve glycemic control in adult and pediatric patients with diabetes mellitus. A common brand name of this form of insulin is Lantus, produced by Sanofi-Aventis.

“GLP” or “cGLP” means all applicable Good Laboratory Practice standards, including, as applicable, as set forth in the then current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration as defined in 21 C.F.R. Part 58, or the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time.

“GMP” or “cGMP” means all applicable Good Manufacturing Practices and regulations applicable to the Manufacture of any Product that are promulgated by any applicable Regulatory Authority having jurisdiction over the Manufacture of such Product, including, as applicable, as promulgated under and in accordance with (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, and (b) the equivalent Applicable Laws the Territory, each as may be amended and applicable from time to time.

“Governmental Authority” means any federal, state, national, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body), including any regulatory authority involved in granting approval to initiate or conduct clinical testing in humans, for Regulatory Approval to market a pharmaceutical/biologic product or, to the extent required in such country or jurisdiction, for pricing or reimbursement approval for a pharmaceutical product in such country or jurisdiction, including the FDA.

“Intellectual Property Rights” means any and all intellectual property rights existing on the date hereof or created during the Term of this Agreement including (but not limited to) all of the following, and all rights in, arising out of, or associated therewith (in each case, whether registered or not): (i) Patents; (ii) know-how, trade secrets, ideas, concepts, inventions, discoveries, developments, devices, methods and processes (in each case, whether or not patentable); (iii) rights in any designs, formulas, databases and database rights.

“Lispro” means a rapid-acting human insulin analog, usually given within 15 minutes before a meal or immediately after a meal, indicated to improve glycemic control in adults and children with diabetes mellitus. Insulin lispro can also be administered by continuous subcutaneous infusion via insulin pump. A common brand name of this form of insulin is Humalog, produced by Eli Lilly.

“Losses” means damages, debts, obligations, and other liabilities, losses, claims, taxes, interest obligations, deficiencies, judgments, assessments, fines, fees, penalties, or expenses (including amounts paid in settlement, interest, court costs, costs of investigators, reasonable fees and expenses of attorneys, accountants, financial advisors, consultants, and other experts, and other expenses of litigation).

“Manufacture” or “Manufacturing” means with respect to any Product, any and all activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, supply, or storage of such product (or any components or process steps involving such product), as the case may be, including qualification, validation, and scale-up, preclinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding any activities directed to Development or Commercialization.

"Party" or "Parties" mean HCAI or Contractor, either individually or collectively.

"Patent" means (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisional, continuations, continuations-in-part, provisional, converted provisional, and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the patent applications described in clauses (a) and (b), including utility models, petty patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates) of the patents or patent applications described in clauses (a), (b) and (c); and (e) any similar rights or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such patent applications and patents described in this definition.

"Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a Governmental Authority.

"Product" means Biosimilar Products of the following insulin products: (i) Glargine; (ii) Aspart and (iii) Lispro.

"Regulatory Approval" means any approvals, registrations, or authorizations by a Regulatory Authority, necessary for the Manufacture and Commercialization of a Product.

"Regulatory Authority" means any national, supranational (e.g., the European Commission, the Council of the European Union, the European Medicines Agency), regional, state, or local regulatory agency, department, bureau, commission, council, or other governmental entity, including the FDA, in the Territory involved in the granting of Regulatory Approval for the Product.

"Third Party" means an entity other than (a) HCAI and its Affiliates or (b) Contractor and its Affiliates or Subcontractors.

"U.S. Dollars" or "$" means United States dollars, the lawful currency of the United States.

Signature:

Email: [redacted]