INFRASTRUCTURE

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CALIFORNIA'S STEM CELL AGENCY

Accelerating Therapies: Public-Private Partnership (ATP^3)

INFR 3

REQUEST FOR APPLICATIONS

07.01.16

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INFR3

Objective

The mission of the California Institute for Regenerative Medicine (CIRM) is to accelerate the development of stem cell treatments to patients with unmet medical needs.

The objective of the ATP3 program is to create a sustainable enterprise (the "Company") by aggregating CIRM's most promising technologies to successfully advance CIRM-funded stem cell technologies toward commercialization. In this case, CIRM is the public partner, and the Company is the private partner.

CIRM will provide up to $75 million to enable the creation of the Company. The award structure offers financial risk-sharing at favorable terms to the awardee while ensuring that the citizens of California have an opportunity to benefit from the success of the Company. All of the in-licensed CIRM-funded technologies will have been previously approved for funding by CIRM. Because many of these technologies have current CIRM funding for research and development costs, the Company will be able to leverage this investment to decrease overall cost and risk and establish sustainable growth and value.

CIRM will devote significant internal resources to the ATP3 program to form a true partnership with the awardee that both accelerates projects and gives the Company the greatest opportunity for success. The awardee will have access to the following CIRM resources: (1) administrative and peer review infrastructure, (2) industry-leading world-class subject matter experts, (3) stem cell knowledge base, (4) a growing portfolio of development stage programs, and (5) coordinated infrastructure programs. CIRM's Infrastructure programs include the Translating Center and its process development and IND-enabling resources; the Accelerating Center and its regulatory, clinical development and operations expertise; and the Alpha Clinics Network and its clinical trial sites and resources. The ATP3 awardee will be well positioned to bring best-in-class stem cell products and technologies to patients through commercialization.

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Award Information

What is the CIRM funding allocation and project term?

A single applicant organization will be awarded up to $75 million in funding within a five-year period. Under the terms of this Request for Applications (RFA), the applicant will be required to demonstrate an upfront financial commitment of $75 million and a business plan to in-license and advance to commercial development CIRM-funded technologies from the current IP holders at universities, non-profit research institutions, and for-profit companies. The Company is expected to be sustainable and exhibit growth beyond the five-year award period.

What activities must be performed under the CIRM award?

CIRM resources will be used to support the continued development and commercialization of existing CIRM-funded programs. CIRM will support the following activities under this opportunity:

- ✓ Translational, preclinical, and clinical development activities
- ✓ Manufacturing of product or device to supply or conduct clinical trials
- ✓ Patent filing and execution costs
- ✓ Personnel costs associated with carrying out the above activities

What activities will CIRM not fund?

CIRM funds cannot be used to support the following activities under this opportunity:

- ✘ Construction or renovation of physical infrastructure
- ✘ Costs associated with in-licensing of CIRM-funded technology (i.e. legal and licensing fees)
- ✘ Product marketing and sales

Projects in-licensed by the ATP3 awardee and approved by CIRM's Application Review Subcommittee will be funded under the $150 million ATP3 program and therefore will not be eligible to receive additional CIRM funding under the CIRM Clinical, Translational, or Discovery programs until all CIRM funds under this RFA have been disbursed.

What are "Allowable Project Costs"?

Allowable Project Costs are those that: (1) are permitted under CIRM policies and regulations, and (2) are allowable project activities (see above). Allowable Project Costs include both direct costs and facility operating costs.

What are the expected outcomes of the ATP3 Program?

Establish a Public-Private Partnership. This RFA provides funding for the establishment of a stem cell-focused enterprise (the Company) and for the development of CIRM-funded stem cell products and technologies.

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Accelerate the Development and Increase the Likelihood of Commercialization of Stem Cell Projects. The Company will in-license and, as described in its business plan, accelerate the development of these products to the market and to patients.

Value Creation. The ATP3 program will realize financial returns for its stakeholders (including researchers and the citizens of California) by reaching critical value inflection points for CIRM-funded projects and driving them toward commercialization.

How will funds be awarded?

The award will be issued in the form of a convertible loan. The terms of the award are outlined in the Term Sheet (see Appendix) and the Research Funding and Financing Agreement (which will be available on the CIRM website on approximately July 22, 2016).

The awardee's business plan will have thoughtfully accounted for foreseeable project risks and developed contingency plans that **do not** involve additional funding from CIRM.

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Eligibility

What are the eligibility requirements for partnering with CIRM?

To be eligible, the applicant and proposed project must satisfy the following requirements:

(1) Must be incorporated

Applicants must be incorporated by the date the application is submitted.

(2) Must be ready to initiate work on the funded project within 45 days of approval

Given the urgency of CIRM's mission, the approved awardee must initiate work on the funded project within 45 days of approval and authorization for funding by the Application Review Subcommittee of CIRM's governing board, the Independent Citizens' Oversight Committee (ICOC).

(3) Must have a California operating location

Applicants must conduct, or plan to conduct, a majority of the Company's operations from a facility or facilities located within California. The management team and a majority (greater than 50%) of the Company's dedicated staff must work out of the California facility (i.e., be located and paid in the State of California). Any effort for which salary is claimed must be expended in California.

(4) Applicants must demonstrate upfront financial commitment

CIRM requires applicants to provide documentation that shows an upfront $75 million financial commitment. The financial commitment may come from any funding source arranged by the applicant, but may not include "in-kind" or similar types of support. Only funds that will be spent concurrently with CIRM funds (i.e., no sooner than ICOC approval, and no later than the award end date) will qualify toward the financial commitment.

(5) Application must be accurate and complete

All required components of the application must be completed and may not contain false or inaccurate information.

Who can serve as the Principal Investigator?

The PI must be the CEO of the Company. To be eligible, the CEO must be a full time employee of the Company.

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Schedule and Deadlines

Applications Due	2:00 PM PT, October 31, 2016
Grants Working Group (GWG) Review	1Q 2017
ICOC Review	1Q 2017
Award Start	Must start within 45 days of award approval

Application Review Information

What is the process for evaluating an application?

Pre-submission Consultation

In accordance with CIRM's mission, the Agency is committed to helping ensure the submission of high quality applications. Therefore, prospective applicants are encouraged to contact CIRM before applying with questions or to discuss their eligibility. Please see contact information provided at the end of the RFA.

Eligibility Review

CIRM will assess whether the applicant organization and application meets eligibility requirements defined in this RFA. If CIRM determines, in its sole discretion, that an application does not meet the eligibility requirements, or that the submitted application is incomplete or contains false or inaccurate information, CIRM will notify the applicant of its decision, allow an opportunity to remedy, and if not remedied in a timely manner satisfactory to CIRM, terminate all further action on the application.

Application Review

The merit of each application will be assessed by the GWG, which is composed of up to fifteen subject matter experts from outside California, up to seven patient advocate members of the ICOC, and the Chair of the ICOC. The list of scientific members who may participate in the GWG review can be found at http://www.cirm.ca.gov/WorkingGroup_GrantsReview. The composition of the ICOC can be viewed at http://www.cirm.ca.gov/GoverningBoard.

The subject matter experts on the GWG will evaluate the applications and score them according to the review criteria described below. The GWG will score each applications, and its recommendations will be presented to the ICOC's Application Review Subcommittee for a funding decision.

The ICOC's Application Review Subcommittee will make final funding decisions giving consideration to the GWG recommendation and any CIRM team recommendation.

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Confidentiality

CIRM's confidentiality and conflict screening rules apply to everyone who will have access to applications or who will attend any review meeting in which confidential information is discussed, including but not limited to CIRM team members, reviewers and members of the ICOC. (Per Gov. Code §6254.5(e), non-public records may be disclosed to government agencies under confidentiality agreements.)

How will the merit of an application be evaluated?

Members of the GWG will evaluate applications and score the applications based on the following key questions:

1. Does the project hold the necessary significance and potential for impact?

Is the Company's mission and focus likely to accelerate CIRM-funded technologies toward commercialization?

2. Is the project well planned and designed?

Is there a viable business plan to achieve the objectives of the RFA? Does the strategy for in-licensing CIRM-funded technology create a compelling value proposition? Is the business plan likely to create value for both patients and shareholders? Will it support growth of the business beyond the five-year award period?

3. Is the proposal feasible?

Does the management team have the experience and qualifications to execute on the business plan? Is the organizational structure appropriate to carry out the business plan and achieve the objectives of the RFA? Is the team likely to successfully in-license CIRM-funded technologies? Will the team be able to raise capital from sources other than CIRM? Is the Company likely to in-license the technologies within the proposed timelines? Is the Company likely to be successful in accelerating the development of CIRM-funded technologies toward commercialization? Does the business plan appropriately account for project risks and mitigation strategies? Is the proposed budget appropriate to achieve the RFA objective?

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Application Components and Submission

How does one apply?

Applications must be completed and submitted online using the CIRM Grants Management Portal at https://grants.cirm.ca.gov. Any prospective PI (the CEO of the Company) must create a login in the system to access application materials and apply. Applications are available in the system only to the PI or their delegate. A PI may submit only a single application.

What components does an application include?

The Grants Management Portal provides instructions for completing all the necessary components and submitting a final application. The application is designed to collect information necessary to appropriately evaluate the proposal and for CIRM to rapidly initiate an award if approved for funding. Applicants are required to indicate key personnel involved in the project, complete the application components described below, and provide reference materials that confirms the status of the project.

The main body of the proposal contains the following sections:

1. **Executive Summary:** A brief description of the overall strategy and business plan.
2. **Statement of Significance and Impact**: Describe the mission and focus of the Company and how it will accelerate CIRM-funded technologies toward commercialization.
3. **Business Plan**: Describe the business plan and how it meets the requirements set forth in this RFA, creates value, and supports growth of the business beyond the five-year award period.
4. **Budget**. Provide a high level description of how the $150 million budget will be utilized to achieve the objectives of the RFA, and how the applicant intends to maximize the use of CIRM funds for research purposes.
5. **Management Team**: Describe the expertise and qualifications of each management team member and how these will be leveraged to drive success.
6. **Organizational Plan**: Describe the leadership, team structure (including subcontractors), and communications plan. Discuss how the team will coordinate with any external third parties (such as external CROs or CMOs), and how the Company will utilize CIRM Infrastructure programs (Accelerating Center, Translating Center, and Alpha Clinics Network) to achieve commercialization of CIRM-funded technologies.
7. **In-licensing**: Describe the strategy to negotiate licensing agreements.
8. **Raising Capital:** Describe the strategy to raise additional capital as necessary.
9. **Timeline**
    a. Provide a timeline for hiring employees and establishing a California location (if applicable).
    b. Provide an activities-based timeline for the in-licensing and development of CIRM-funded projects in Gantt chart-like format.
10. **References:** List all references used in the body of the proposal.

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Who are Key Personnel?

In the application, we ask you to identify by name pertinent Key Personnel and their specific roles in the company. Key Personnel are defined as (1) any member of the management team; or (2) any other person, including members of a scientific advisory board, board of directors, or an independent consultant or an employee of a Subcontractor or Partner, who is expected to contribute to the scientific development or execution of the project in a substantive, measurable way *and* who is expected to: (a) receive or has been promised income, or anything else of value, of $10,000 or more per year for his or her contribution to the project or (b) contribute one percent (1%) or more effort to the proposed project. "Key Personnel" does not include a person who is expected to be involved in the proposed project but who does not satisfy conditions (1) or (2).

Individuals who do not meet the definition of Key Personnel may be supported with CIRM funds, but should not be identified by name in the application. Such unnamed personnel may be referenced indirectly by their role on the project (e.g., technician).

What should one know before preparing the budget?

A well-justified budget must be provided that clearly outlines the total costs of the proposal, including those costs not proposed to be funded by CIRM. Allowable and unallowable Project Costs are detailed in the CIRM Grants Administration Policy for Clinical Stage Programs. Generally, project costs for personnel, supplies, travel, equipment, and subcontracts may be claimed. Limits for specific cost categories must be observed. The budget should also account for the costs associated with the applicant's mitigation strategies to address project risks.

What are the rules for spending CIRM funds outside of California?

Awardees may use CIRM funds for Allowable Project Activities conducted both in California and outside of California. "Allowable Project Activities" means those activities that are conducted in California and those activities conducted outside of California, provided that: (a) the Awardee exercises direction, supervision and control over the activities and (b) a separate out-of-state organization that performs project activities does not retain intellectual property or publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM funded project.

What are Facilities Operating Costs?

Facilities operating costs are limited to no more than 25% of the direct project costs and can be budgeted to cover the general operating costs of the applicant's facility attributable to housing all elements of the CIRM-Funded Project. Facilities rates are applied to direct project costs exclusive of the costs of equipment, tuition and fees, research patient care costs, as well as the costs of each individual subcontract, consultant, and service agreement in excess of $25,000. The facilities rates approved and in place at the time of the application are to be applied to the entire award project period. Applicants will be evaluated on the extent to which they maximize the use of CIRM funds for research purposes rather than overhead, including facilities costs.

How much can an applicant claim for indirect costs?

Organizations cannot claim indirect costs under this RFA.

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Award Administration

Issuance of Award and Payment

The CIRM award will be issued via a Research Funding and Financing Agreement, which is the formal contract that defines the terms and conditions of an award and documents the commitment of funds from CIRM. This document will be available for reference on the CIRM website on approximately July 22, 2016. CIRM funds under the award will be disbursed based on written requests for disbursement on a reimbursement basis. CIRM expects that the applicant's business plan and proposed budget will identify project timeline and budget risks and will provide details for covering such costs, including the source of funding.

Advancement Milestones

The CIRM award will include advancement milestones (subject to negotiation) to ensure that the awardee implements its business plan in a timely manner consistent with the urgency of CIRM's mission. CIRM reserves the right to reduce the award amount or terminate the award if the awardee fails to achieve an advancement milestone, after notice and a reasonable opportunity to cure.

Reporting

The Awardee will be required to provide periodic written progress and financial reports to CIRM. These reporting requirements are included in the Research Funding and Financing Agreement.

CIRM Regulations

The award made pursuant to this RFA will be subject to all applicable CIRM regulations. These regulations can be found on CIRM's website at http://www.cirm.ca.gov/reg/default.asp. Unless the Research Funding and Financing Agreement provides otherwise, the CIRM Grants Administration Policy for Clinical Stage Programs will govern this award.

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Contacts

For information about this RFA or the review process:

Send email correspondence to Infrastructure@cirm.ca.gov

or

Call our main line at 510-340-9101 and select “Funding Opportunities” then “Infrastructure”

TERM SHEET

Convertible Promissory Note Financing
By
The California Institute of Regenerative Medicine

April 8, 2016

This Term Sheet sets forth the principal terms and conditions of a proposed convertible promissory note financing by the California Institute of Regenerative Medicine ("CIRM"). The financing will be offered to one successful applicant for CIRM funding (the "Company"). The successful applicant will have the opportunity (but will not be required) to obtain technology licenses from licensors of CIRM-funded projects.

Under the subject financing program, the approved applicant is expected to own 100% of the equity of the Company. CIRM's interest in the Company will be in the form of convertible promissory notes based on the amount of its advances. These notes will include Company-favorable discounts on repayment or conversion, as more specifically described herein. Because CIRM may not hold securities, CIRM will be permitted to sell the notes to third parties prior to conversion. The Company will be responsible for performing its own analysis of the tax impacts of the transactions.

Although the terms herein are subject to the execution of a definitive financing agreement ("Financing Agreement") between CIRM and the Company, they have been approved by a subcommittee of CIRM's Board, the Independent Citizens' Oversight Committee, and may not be materially modified. The Financing Agreement will govern the overall relationship between CIRM and the Company and include the form of the convertible notes. The Financing Agreement will include representations and warranties, conditions to effectiveness and conditions to draws, covenants, and other terms and conditions customary for a transaction of this type.

Certain capitalized terms used in this Term Sheet are defined on Appendix A.

Convertible Notes

Type of Security	Convertible Promissory Notes of the Company (the "Notes").
Ranking and Seniority	Unsecured debt of the Company. CIRM may from time to time subordinate this debt to other debts of the Company.
Amount of Financing	Three Notes with aggregate principal of $75 million, each individual Note having aggregate principal of $25 million. All advances under the Financing Agreement will be made under the First Note (until an aggregate of $25 million has been advanced), then under the Second Note (until an additional $25 million has been advanced), and finally under the Third Note (until the final $25 million has been advanced).
Interest Rate	Compound interest will accrue on an annual basis at the rate of 4.5% per annum based on a 365 day year. Interest will be payable on the Maturity Date of the Notes.
Term	As more specifically provided herein, outstanding principal and interest under all Notes will be due and payable five (5) years after the initial advance under the First Note (the "Maturity Date").

Appendix

Enforcement	The Notes will include standard provisions for acceleration and enforcement in the event of (a) payment default or other material default, (b) criminal, scientific, or financial misconduct by the Company, (c) bankruptcy and (d) the occurrence of Liquidity Event (each, an "Acceleration Event").
Repayment	Upon an Acceleration Event other than a Liquidity Event, the entire amount of principal and interest then outstanding under the Notes will immediately become due and payable. Upon the Maturity Date, CIRM or its transferee (the "Note holder" may either (a) require repayment of 50% of the sum of principal plus all interest then outstanding under the Notes (the "Discounted Amount") or (b) convert the Notes in accordance with the terms set forth in ***Conversion*** and ***Equity Kicker***.
Timing of Repayment	If the Note holder requires repayment of the Notes in whole or in part, the Company will pay one-half of the Discounted Amount on the Maturity Date and one-half six (6) months after the Maturity Date.
Prepayment	The Company may not prepay any Note in whole or in part except upon the prior written consent of the Note holder, which may be withheld in its sole discretion.
Conversion	The Note holder may convert a Note at any time after a Note has been fully funded. The Note holder may also convert one or more Notes, whether or not fully funded, upon the Maturity Date or the date of a Qualified Financing or Liquidity Event. Any conversion shall be in the sole discretion of the note holder. All conversion calculations will be on a fully diluted basis. Upon conversion after full funding of a Note or on the Maturity Date, the Discounted Amount will convert into shares of common stock of the Company, at the price per share determined in the most recent valuation of the Company in an arms' length transaction (or a new valuation by an independent appraiser if the Note holder so elects), subject to a per share discount of 20%. Upon conversion upon a Qualified Financing, the Discounted Amount will convert into shares of Equity Securities of the Company, at a price per share determined by the Qualified Financing, subject to a per share discount of 20%. Upon conversion upon a Liquidity Event, the Discounted Amount will convert into shares of common stock of the Company, at the price per share determined in the Liquidity Event, subject to a per share discount of 20%.
Equity Kicker	In addition to the above conversion rights, the Note holder will be entitled to receive additional common stock (or Equity Securities in the case of conversion in connection with a Qualified Financing), determined on a pro rata basis, as follows:

- First Note: A number of shares equal to 0.20% of the Company's fully-diluted capitalization per million dollars of principal advanced under this Note;

- Second Note: A number of shares equal to 0.13% of the Company's fully-diluted capitalization per million dollars of principal advanced under this Note; and

- Third Note: A number of shares equal to 0.07% of the Company's fully-diluted capitalization per million dollars of principal advanced under this Note.

Alternatives Upon Liquidity Event Upon the occurrence of a Liquidity Event, with respect to both fully funded and partially funded Notes, the Note holder shall have the option to either (a) accelerate the Discounted Amount under the Notes on the terms set forth in ***Enforcement*** or (b) convert the Discounted Amount under the Notes into common stock of the Company on the terms set forth in ***Conversion*** and ***Equity Kicker***.

Disbursements and Co-Funding Requirements

Request for Draws The Company will provide a written request for disbursements under the Notes on a quarterly basis in accordance with CIRM requirements.

Each draw request will include (1) a summary report on the current status of the stem cell project, (2) documentation evidencing the specific expenditures for which the Company is seeking reimbursement from CIRM, (3) evidence of sufficient available funds for the Company to operate as a going concern for at least the next six months following the date of the draw, (4) certifications with respect to compliance with laws, CIRM regulations and requirements and all other terms of Financing Agreement and Notes; (5) substantiation, in reasonable detail, that the Company has previously expended its own funds (the "Co-Funding") in an aggregate amount exceeding all prior draws under the Notes plus the amount of the requested draw. CIRM will make payment within ten (10) business days of the receipt of each quarterly draw request..

Use of Funds Advances under the Notes will be used solely for stem cell research approved by CIRM in accordance with applicable regulations and requirements.

Co-Funding The Company will be required to contribute to its stem cell enterprise amounts equal to or greater than the amounts funded by CIRM under the Notes. The co-funded amounts may be utilized for a broad range of costs (including actual overhead costs) in furtherance of the Company's approved enterprise.

Cessation of Funding CIRM will have no obligation to make further advances under the Notes during the pendency of an event of default, from or after a Liquidity Event, upon or after the Maturity Date, or upon or after conversion of the Notes.

Appendix

Other Financing Agreement Terms

Transferability	CIRM has the right to transfer any Note or Notes that have been fully funded to a third party, without the Company's consent, subject only to the ***Right of First Offer***. Certain competitors of the Company may be identified in the Financing Agreement as prohibited transferees of CIRM's rights. The Company may not transfer or assign its rights or obligations under the Financing Agreement or the Notes without CIRM's prior written consent, which may be withheld in its sole discretion.
Right of First Offer	In the event that CIRM wishes to transfer one or more Notes to any third party, it shall provide notice to the Company setting forth the terms and conditions of the proposed sale ("ROFO Notice"). The Company may elect in writing to purchase the subject Notes on the terms set forth in the ROFO Notice within fifteen (15) days from the date of the ROFO Notice. If the Company does not elect to purchase the Notes within the Company's fifteen (15) day acceptance period, CIRM will be free to transfer the Notes to any third party (other than a prohibited transferee) on terms no less favorable than those set forth in the ROFO Notice.
Covenants	The Company will operate pursuant to an approved stem cell business plan and budget and will not change the scope of its stem cell business, without CIRM prior approval, which will not be unreasonably withheld. Greater than 50% of the Company's employees must be based in California at all times while any Note is outstanding. The Company will submit to CIRM (1) annual budget forecasts and quarterly progress reports, (2) annual and quarterly financial statements, and (3) copies of all tax returns. The Company will also provide CIRM and its representatives reasonable access to the management and books and records of the Company. The Company will comply with all applicable laws, including all CIRM regulations, including Scientific and Medical Accountability Regulations (Cal. Code Regs., tit. 17, § 100010 et seq.) and CIRM's Intellectual Property Regulations (Cal. Code Regs., tit. 17, § 100600 et seq.) in connection with its activities, including the Company's licensing of CIRM funded technologies or inventions.
Conditions	Prior to initial and subsequent advances under the Notes, CIRM's Grants Working Group must review and approve projects to be funded by said advances. The Financing Agreement will also require the satisfaction of conditions to draws similar to those utilized in commercial revolving credit facilities.

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Consent Rights	The Company will not make dividends or distributions, voluntarily enter bankruptcy or liquidate or dissolve without the Note holder's prior written consent, which will not be unreasonably withheld. In addition to these consent rights, after transfer of the Note to a third party, the Note holder will have preemptive rights to participate in future Company financings on a pro rata basis.
Technology Licensing	Technology licensing matters will be addressed through CIRM licensing documentation that will be independent from the Financing Agreement. The Company will provide claw-back rights to licensors of CIRM-funded projects if the Company does not take reasonable steps to develop said projects.
Expenses	CIRM and the Company will each bear its own fees and expenses incurred in the transactions contemplated by this Term Sheet.
Governing Law	The foregoing provisions shall be governed by the laws of the State of California (without regard to its conflict of laws principals).
Jurisdiction and Venue	Jurisdiction and venue for all disputes will be in the state or federal courts located in San Francisco, California.

Appendix

APPENDIX A

Certain Definitions

"Equity Securities" means the preferred stock or other form of security to be issued by the Company in a Qualified Financing.

"IPO" means any offering of the Company's common stock pursuant to a registration statement filed in accordance with the Securities Act of 1933, as amended, in an aggregate amount of $25,000,000 or more.

"Liquidity Event" means any of the following: (i) the sale of all or substantially all the assets of the Company, (ii) any merger, consolidation or acquisition of the Company with, by or into another corporation, entity or person; or any change in the ownership of more than fifty percent (50%) of the voting capital stock of the Company in one or more related transactions, (iii) the winding up, dissolution or liquidation of the Company, or (iv) an IPO.

"Qualified Financing" shall mean a preferred stock financing resulting in aggregate proceeds to the Company of at least $5,000,000 (excluding conversion of any existing debt) in a single transaction or series of related transactions.