



Life Sciences Accelerator Loan Program

Solicitation No. 2011-ACC-2

Solicitation Issued: November 14, 2011
Applications Due: December 30, 2011 (noon EST)
Submit Questions: accelerator@masslifesciences.com

1. Summary

In order to expand life sciences-related employment opportunities, promote health-related innovations and stimulate research and development, manufacturing and commercialization in the life sciences, the Massachusetts Life Sciences Center (the Center) is pleased to announce the Life Sciences Accelerator Loan Program (the Program).

To date, the Center has awarded more than \$8 million in generally unsecured loans to fourteen early-stage life sciences companies under the Program. The Center anticipates strong participation in the Program. This round of the Accelerator Loan Program will provide up to \$750,000 for each company in an unsecured loan and include a warrant which will give the Center the right to purchase equity in the company at a specific price within a certain time frame.

Eligible applicants are early-stage life sciences companies with a high potential for technology commercialization, rapid growth, and private equity financing that have raised no more than \$7.5 million in total private financing. MLSC recognizes that many companies struggle to address the significant financial investment associated with the long life sciences R&D cycle and the high cost of translating research into a commercially viable product. This solicitation is designed to help sustain these companies through a critical stage of development and funding, to leverage existing sources of capital, and to de-risk future investments in order to bring cutting edge innovation to the marketplace.

Accordingly, as part of the review process, the Program seeks to understand the degree to which companies have raised financing from a variety of: (1) private sources such as angels, friends and family, and venture capitalists; and (2) public sources such as grants or awards from federal, state and local governments, foundations and other non-profit agencies. Loan amounts, however, will be determined based on the parameters set forth in section 3.2 below.

Applications will be available online on November 14, 2011. Interested applicants will be required to submit an application that is due no later than December 30, 2011 by noon EST. Please note that if you are the recipient of an award from the Center's Accelerator Loan Program or Small Business Matching Grant Program, you are **not** eligible to apply to this Program.

The following key terms are used in this solicitation:

- **Agreement** means the loan agreement, promissory note, and warrant to be executed between the Center and Awardees under the Program, a copy of which is posted on the Center's website.
- **Applicant** means the organization submitting an Application.
- **Application** means the Program application available online at www.masslifesciences.com.
- **Awardee** means an eligible applicant that receives a notice from the Center that it has been awarded a loan pursuant to this Solicitation.
- **Life Sciences** means advanced and applied sciences that expand the understanding of human physiology and have the potential to lead to medical advances or therapeutic applications including, but not limited to, agricultural biotechnology, biogenerics, bioinformatics, biomedical engineering, biopharmaceuticals, biotechnology, chemical synthesis, chemistry technology, diagnostics, genomics, image analysis, marine biology, marine technology, medical devices, nanotechnology, natural product pharmaceuticals, proteomics, regenerative medicine, RNA interference, stem cell research and veterinary science, as defined in the Massachusetts General Laws (MGL), chapter 23I, section 2.
- **Life Sciences Company** means a business corporation, partnership, firm, unincorporated association or other entity engaged in life sciences research, development, manufacturing or commercialization in the Commonwealth of Massachusetts, and any affiliate thereof, which is, or the members of which are, subject to taxation under MGL chapters 62, 63, 64H or 64I, as defined in MGL, chapter 23I, section 2.
- **Life Sciences Statute** means Chapter 23I of the MGL.
- **Program** means the Life Sciences Accelerator Loan Program as described more fully in this Solicitation.

2. Who We Are

The Massachusetts Life Sciences Center (Center) is a quasi-public agency of the Commonwealth of Massachusetts tasked with implementing the Massachusetts Life Sciences Initiative, a ten-year, \$1 billion initiative that was signed into law in June of 2008. The Center's mission is to create jobs in the life sciences and support vital scientific research that will improve the human condition. This work includes making financial investments in public and private institutions that are advancing life sciences research, development and commercialization as well as building ties between sectors of the Massachusetts life sciences community. For more information, visit www.masslifesciences.com.

3. Life Sciences Accelerator Loan Program

3.1 General

On June 22, 2011 the Board of Directors of the Center approved the launch of the FY2012 Accelerator Loan Program. This Program reflects the Center's ongoing commitment to provide financing to small life sciences companies that will grow employment opportunities, promote manufacturing and commercialization, and stimulate innovation across the Commonwealth.

The Accelerator Loan Program is a funding program intended for early-stage life sciences companies in Massachusetts. Accelerator loans bridge the gap in a company's capital-raising lifecycle, providing the company with time and resources to advance to a point at which it would become a good candidate for private investment.

The objective of the Accelerator Loan Program is to support the growth and commercialization of life sciences technologies in Massachusetts by:

- Providing direct and flexible capital to early-stage companies for life sciences research and development; and
- Leveraging additional sources of capital to reduce investor risk and facilitate companies in gaining access to private capital.

3.2 Funding

The Center's Board of Directors has allocated six million dollars (\$6,000,000) in funding for the FY2012 Accelerator Loan Program which includes two rounds of the program. This is the second round of the Accelerator Loan program in FY2012. The Center envisions that recipients under the Program will receive a loan in an amount up to \$750,000. The total amount requested by applicants must be matched by: (1) either at-risk capital or (2) a combination of at-risk capital and grants previously awarded in accordance with the parameters set forth below. The number and amount of loans will be determined by the quality of the proposals.

- No loans will exceed \$750,000 per company.
- 100% of the at-risk capital raised by applicant will count toward the level of funding for which applicant is eligible.
- If the at-risk capital raised by applicant is less than \$750,000 and applicant has been awarded grants, applicant may count such grant amounts (i.e. public and non-profit sources of funding) towards the requested level of funding. However, the grant matching amount may not exceed 1/3 of the TOTAL AMOUNT of funding requested.

Examples are provided below:

Example 1: Applicant that has raised \$750,000 in at-risk financing is eligible for a \$750,000 loan.

Example 2: Applicant that has raised no at-risk financing and been awarded \$750,000 in grants is not eligible for any loan.

Example 3: Applicant that has raised \$300,000 in at-risk financing and been awarded \$200,000 in grants is eligible for a \$450,000 loan (i.e., \$300,000 at-risk + \$150,000 = \$450,000).

Example 4: Applicant that has raised \$300,000 in at-risk financing and been awarded \$100,000 in grants is eligible for a \$400,000 loan.

3.3 Administration

The Center is responsible for administering the Program and certifying a company as a “Certified Life Sciences Company” in accordance with the Life Sciences Statute. Funding under the Program is available only to a Certified Life Sciences Company and is valid for 5 years starting with the tax year in which certification is granted. Life Sciences Certification is granted with the award of an Accelerator Loan; therefore, companies do not have to be certified prior to submitting an Accelerator Loan Application.

3.4 Annual Reports

Pursuant to Section 5(e)(1) of MGL chapter 21, each Awardee shall, in connection with its status as a Certified Life Sciences Company, file with the Center an annual report in a form to be determined by the Center detailing whether applicant has met the specific targets established in the Application. If the applicant fails to meet the specified targets, the applicant’s status as a Certified Life Sciences Company may be subject to revocation, as more fully described below.

3.5 Revocation

The Life Sciences Statute also contains procedures for revocation of certification, and provisions regarding denial and recapture of benefits, if the Center determines that representations made by a Certified Life Sciences Company in its certification proposal are materially at variance with the conduct of the life sciences company after receiving certification. In such a case, revocation of certification is effective on the first day of the year in which the Center determines that a material variance commenced. Revocation of benefits is mandatory in the event of a material variance for two consecutive years.

3.6 Competitive Program

THE PROGRAM IS COMPETITIVE AND THE CENTER’S BOARD OF DIRECTORS HAS FULL DISCRETION AND AUTHORITY TO DETERMINE (1) WHICH LIFE SCIENCES COMPANIES, IF ANY, ARE ENTITLED TO RECEIVE LOANS UNDER THE PROGRAM AND (2) THE AMOUNTS OF ANY SUCH LOANS. SUBMISSION OF AN APPLICATION DOES NOT GUARANTEE THE AWARD OR RECEIPT OF ANY LOAN UNDER THE PROGRAM.

4. Eligibility Criteria and Requirements

4.1. Eligibility

Each Application received will be evaluated and assessed for eligibility using the following criteria:

4.1.1 Eligible Entity

The Applicant must be a legally organized, “for-profit” entity engaged in life sciences research, development, manufacturing or commercialization in the Commonwealth of Massachusetts.

As defined in the Life Sciences Statute, life sciences means “advanced and applied sciences that expand the understanding of human physiology and have the potential to lead to medical advances or therapeutic applications including, but not limited to, agricultural biotechnology, biogenerics, bioinformatics,

biomedical engineering, biopharmaceuticals, biotechnology, chemical synthesis, chemistry technology, diagnostics, genomics, image analysis, marine biology, marine technology, medical devices, nanotechnology, natural product pharmaceuticals, proteomics, regenerative medicine, RNA interference, stem cell research and veterinary science.”

If Applicant has previously applied for an Accelerator Program Loan and did NOT receive an award, Applicant may re-apply to the Program.

4.1.2 Ineligible if Recipient of Award under the Center’s Accelerator Loan Program

The companies that received awards under the Center’s Accelerator Loan Program are not eligible to apply to the Life Sciences Accelerator Loan Program.

4.1.3 Ineligible if Recipient of Award under the Center’s Small Business Matching Grant Program

Any company that received an award under the Center’s Small Business Matching Grant Program is not eligible to apply to the Life Sciences Accelerator Loan Program.

4.1.4 Raised \$7.5 Million or More in Private Financing

If you meet any of the following criteria, you are not eligible to apply to the Life Sciences Accelerator Loan Program:

- You have raised \$7.5 million or more in total equity financing.
NOTE: If you reach the \$7.5 million threshold prior to the closing and funding of the loan, you will become ineligible for an award under the program.
- You are majority owned (greater than 50%) by a parent company that is an operating or holding company and
 1. Have raised \$7.5 million or more in total equity financing, or
 2. Have received \$7.5 million or more in debt/equity financing from your parent, or
 3. Have raised/received \$7.5 million or more as a combination of 1. and 2. above.
- You are majority owned (greater than 50%) by a parent that is an investment company, investment partnership, or investment fund and have received \$7.5 million or more in financing from your parent.

4.2. Requirements of Award

The following criteria must be met by Applicant in order for the Center to consider and evaluate an Application:

4.2.1 Acceptance of Terms.

Applicants are required to indicate that they have read, understood, and are willing to accept the terms of this Solicitation, of the loan for which they are applying and the warrant rights that they are granting to the Center. Submission of the Authorized Representative’s Signature in the online application will satisfy this requirement.

Acceptance of the terms of the loan will not confer any rights to Applicant’s intellectual property to the Center.

4.2.2 Business Location.

Consistent with the purpose of the Program and the requirements of the Life Sciences Statute that its provisions for financial assistance be tied to the development of maximum benefits for citizens of the

Commonwealth, Awardees are required to perform life sciences research, development, manufacturing or commercialization in Massachusetts. Applicants are encouraged to form or make use of any partnerships and supplier relationships within Massachusetts. Applicants will be asked in the Application to represent how the proposed business benefits Massachusetts and its citizens.

4.2.3 Use of Proceeds and Proposed Business Plan.

The Life Sciences Accelerator Loan Program award is to serve as flexible working capital or for the purchase of capital assets to help Awardees achieve product development milestones and obtain private investment. The Business Plan is a key component of the Application. **A BUSINESS PLAN OUTLINE IS PROVIDED IN ATTACHMENT A TO THIS SOLICITATION AND APPLICANTS ARE STRONGLY ENCOURAGED TO ADHERE TO THIS FORMAT AND ADDRESS THE APPLICABLE QUESTIONS CONTAINED WITHIN THE OUTLINE. THE BUSINESS PLAN SHOULD BE IN NARRATIVE FORMAT AND NO LONGER THAN 15 PAGES (11 pt font) AND SUBMITTED IN A .PDF FILE FORMAT.**

4.2.4 Information Requirements.

During the course of the Center's evaluation of applications, Center staff, Board members, advisors or the Center's qualified contractors may contact the Applicant to request supplemental information, or to request an interview with, or presentation by, Applicant. Applicant may also be required to host site visits by Center staff and contractors for purposes of evaluation. Should an award be made, the Awardee will be required to provide the Center with certain information to help the Center monitor information pertaining to: employment figures, revenue generation, taxable income, employee salaries, amount of private capital leveraged, and information as to the recipient's operations and business affairs including financial statements.

4.2.5 Requirements for Submission of Confidential Information.

In accordance with the Commonwealth's Public Records Law, Awardees will be required to agree that the Center shall have the unlimited right to make use of and disseminate all periodic reports, case studies and any other deliverables and work products. **SEE SECTIONS 5.1 AND 8.1 FOR A DISCUSSION OF PUBLIC DISCLOSURE REQUIREMENTS AND PROCEDURES FOR HANDLING DOCUMENTS SUBMITTED TO THE CENTER AND IDENTIFIED BY THE APPLICANT AS "CONFIDENTIAL INFORMATION."**

5. Application Process

5.1. General Requirements

Applicants are cautioned to read carefully and conform to the requirements of this specific Solicitation. Failure to comply with the provisions of this Solicitation may serve as grounds for rejection of a proposal.

Any and all data, materials and documentation submitted to the Center in response to this Solicitation shall become the Center's property and shall be subject to public disclosure under the Massachusetts Public Records Act, with the exception of information that may be eligible as trade secrets or commercial or financial information regarding the operation of any business. **PLEASE NOTE: BY EXECUTING THE AUTHORIZED APPLICANT'S SIGNATURE AND ACCEPTANCE FORM CONTAINED AS PART OF THE APPLICATION AND SUBMITTING A RESPONSE TO THIS SOLICITATION, APPLICANTS CERTIFY THAT THEY (1) ACKNOWLEDGE AND UNDERSTAND THAT ALL MATERIALS SUBMITTED AS PART OF THIS APPLICATION ARE SUBJECT TO DISCLOSURE UNDER THE MASSACHUSETTS PUBLIC RECORDS LAW; (2) ACKNOWLEDGE AND UNDERSTAND THE PROCEDURES FOR HANDLING MATERIALS SUBMITTED TO THE CENTER AS SET FORTH HEREIN INCLUDING THE SUBMISSION OF ANY MATERIALS BELIEVED TO BE PROPRIETARY IN NATURE; (3) AGREE TO BE BOUND BY THOSE PROCEDURES; AND (4) AGREE THAT THE CENTER SHALL NOT BE LIABLE UNDER ANY CIRCUMSTANCES FOR THE DISCLOSURE OF ANY MATERIALS SUBMITTED TO THE CENTER PURSUANT TO THIS SOLICITATION OR UPON THE APPLICANT'S SELECTION AS AN AWARDEE.**

Furthermore, Applicants are cautioned to review the procedures regarding the submission of confidential information contained in Section 8.1 prior to submitting an electronic copy of any documents in response to this Solicitation.

5.2. Application Process

- (a) All Applications must be submitted online at www.masslifesciences.com and companies are limited to one application per company. Again, Applicants are cautioned to review the procedures regarding the submission of confidential information contained in Section 8.1 prior to submitting the electronic copy of their Application.
- (b) As provided in the on-line application, Applicant will be required to certify that it acknowledges, understands, and agrees to comply with all terms, conditions and specifications contained in this Solicitation. Applicants may use the Authorized Applicant's Signature and Acceptance Form attached to the Application to satisfy this requirement.

5.3 Schedule

The solicitation process will proceed according to the following anticipated schedule:

Deadline for Submission of Application	December 30, 2011 at noon EST
Projected Awards Notification	April 24, 2012
Agreement Execution	Within forty-five 45 days of receipt of award notification

6. Application Requirements

Applications **must** be completed and submitted online at www.masslifesciences.com. Applications not completed on-line will not be accepted.

Applications must include the following:

1. Completed Life Sciences Accelerator Loan Program Application
2. Completed Authorized Applicant's Signature and Acceptance Form (attached to Application)
3. Certificate of Good Standing from the Secretary of State (in PDF format)
4. Certificate of Good Standing/Letter of Compliance from the Department of Revenue (in PDF format). Please make every effort to obtain this Certificate of Good Standing from DOR by the time of application. However, we recognize that in certain circumstances this may not be possible. If this is the case, please submit this Certificate of Good Standing to the Center at the earliest date possible following the close of the application period through the accelerator e-mail address: accelerator@masslifesciences.com
5. Business Plan
6. Executive Summary

7. Application Assessment

7.1. General

Applications will be evaluated according to the criteria outlined below. The process for reviewing applications will be transparent, competitive, and based on sound science and commercial viability. Center staff will conduct the initial administrative review of all applications to ensure that Applicants are eligible for the Program.

This administrative review will be followed by a comprehensive peer review process comprised of Peer Reviewers that broadly represent the Commonwealth's life sciences scientific and business experts. Members of the Center's Scientific Advisory Board (SAB) will then review the most competitive proposals with respect to the scientific and/or technological merits of each proposal. The Center's staff will conduct corporate due diligence on the finalists that pass these reviews, and such finalists will make in-person presentations to a combined group of SAB and Board of Directors Investment Committee members. The SAB and Board of Directors Investment Committee will then make recommendations to the Center's Board of Directors for approval.

The Center reserves the right to modify this assessment process, as necessary, and to make an award only to the Applicant that, in its sole judgment, meets the following criteria. The Center reserves the right to consider other criteria in making an award among comparably qualified Applicants. The order of the criteria listed does not denote relative importance.

7.2 Threshold Criteria

The Center will conduct an administrative review of applications to screen out Applicants who have not met eligibility requirements and/or threshold criteria. Applicants must meet all of the following threshold criteria:

1. The Applicant is a life sciences company registered to do business in Massachusetts and with operations in Massachusetts (or a life sciences company registered to do business in Massachusetts that will use any award proceeds received under the Program to establish and grow operations in the Commonwealth) eligible for support under the Solicitation;
2. The Applicant has not exceeded the required financing levels;
3. The Applicant is in good standing with the Commonwealth of Massachusetts;
4. The Applicant has developed credible employment, salary, revenue, and taxable income targets for the next five years and a reasonable plan for achieving such targets; and
5. The Applicant has completed the Application.

Once an Applicant has been reviewed for compliance with threshold criteria, the Application will be evaluated using the following technical and programmatic criteria.

7.3 Technical Review Criteria

1. Scientific and Technical Merit:
 - a. Innovativeness of the technology, product or service
 - b. Potential for further technological advancements in the life sciences
 - c. Potential to offer a breakthrough medical treatment for a particular disease or medical condition
 - d. Improvement over the state-of-the-art solution, if any
 - e. Strength of intellectual property
2. Market Opportunity:
 - a. Size of potential market and market growth potential
 - b. Clear definition of target customer and a clear articulation of the significant need, niche, or "pain point" that the new product addresses
 - c. Evidence that the target market will accept the technology, product or service
 - d. Description of competitors as well as substitute products and methodologies
 - e. Ability to achieve unique, sustainable, competitive advantage
 - f. Barriers/risks to product commercialization and strategy for addressing them (e.g., competitive, reimbursement, regulatory)

4. Team Qualifications:
 - a. Qualifications and track record of management team
 - b. Qualifications and track record of scientific/technical team
 - c. Management's demonstrated ability to understand and address the identified risks and barriers to successful product commercialization
5. Commercialization Plan
 - a. Plan for achieving regulatory approval, acquiring customers, establishing pricing strategy and defining distribution and marketing approaches
 - b. Clear and identifiable path to commercialization and potential risks along this pathway
6. Work Plan
 - a. Detailed plan for using MLSC funds
 - b. Clearly stated tasks and related objectives
 - c. Milestones to be achieved with MLSC funds
 - d. Feasibility of achieving objectives and milestones with MLSC funds
7. Investment Quality:
 - a. Projected financial performance
 - b. Demonstrated ability or potential to secure additional financing for Applicant's operations or the proposed project, as applicable
 - c. A well thought-out capital structure and fundraising plan
 - d. Quality and completeness of financial analysis
 - e. Ability to repay loan

7.4 Programmatic Review Criteria

Programmatic criteria will be assessed differently for each Applicant depending on their stage of development.

1. Portfolio Objectives: MLSC may place emphasis on and consider Applications that contribute to a balanced and strong portfolio of Awardees, including but not limited to factors such as:
 - a. Wide geographic distribution of life sciences operations in Massachusetts;
 - b. Wide distribution of life sciences technologies and industries supported by the Center; and
 - c. Diversity among businesses at different stages of product development and commercialization; and
 - d. Number of jobs expected to be created or maintained in Massachusetts over next five years.
2. Other Considerations: The Center may, in its sole judgment, also take other factors into consideration in making a final award recommendation including but not limited to:
 - a. Minimal geographic overlap of project areas; and
 - b. Applicant's plans or policies with respect to environmental sustainability, corporate governance, labor standards and achieving a diverse workforce;
 - c. Contribution to Massachusetts Economic Target Areas, if applicable;
 - d. Potential to attract additional resources to Massachusetts or leverage other existing resources within Massachusetts; and
 - e. Potential to build manufacturing capacity in Massachusetts.

7.5 Corporate Due Diligence Criteria

The Center will conduct corporate due diligence on the Applicants that are finalists. Information requested may include, but is not limited to, the following:

- A. Corporate and Shareholder Information
 - 1. Detailed list of financings (date, type, amount, price).
 - a. If founders equity, documented support for contributions including stock issuance and capital provided
 - 2. Current capitalization table (including outstanding options issued and outstanding, warrants, and convertible debenture/preferred with details of same)
 - 3. Corporate chart (details of subsidiaries / affiliates with associated ownership information)
 - 4. Corporate bylaws
 - 5. Listing of Board of Directors
 - 6. Major company milestones going forward and timeline for next 5 years
- B. Financial Information
 - 1. Audited /Regulatory
 - Historical audited financial statements 2010 and 2009 **or**
 - Copies of 2010 and 2009 Federal tax returns
 - 2. Unaudited financial statements Balance Sheet, Cash Flow, and Income Statement, broken out by quarter, for calendar year 2009/2010 and YTD 2011 (electronic copy in excel)
 - 3. Detailed forecast (income statement, balance sheet, and cash flow) with supporting assumptions and detail (by quarter or month for next two fiscal years including Q4 2011, 2012 and 2013) **assuming loan from MLSC** (electronic copy in excel)
 - 4. Details of all debt or other financing arrangements, if applicable. Schedule should include:
 - Debt holder name
 - Principal amount
 - Date of issuance
 - Interest rate
 - Maturity date
 - Payment amount
 - If secured or unsecured
 - Any unique terms (convert to equity, mandatory redemption)
 - 5. Detailed listing of any grants
 - 6. Current cash balance as of due diligence response date
 - 7. Monthly/Quarterly cash burn – historical and forecast
 - 8. Fundraising plans and timeline
 - 9. List of banking relationships
 - 10. List of all off-balance sheet items / related party transactions/commitments, including amounts, if any
- C. Intellectual Property / Regulatory
 - a. List of any patents, trademark, trade names, brands, copyrights, or service marks
 - b. List licensing or other arrangements regarding any intellectual property used by the Company that is owned or controlled outside the Company
 - c. Schedule listing all agreements, options or other commitments, if any, giving anyone rights to acquire any right, title or interest in any of the Company's products or related technology, together with copies of the agreements
 - d. Freedom to operate analysis, if applicable
 - e. Regulatory steps taken to date, risks and pathway (if applicable)
- D. Sales / Marketing / Competition
 - a. List of top 10 customers by revenue (2009, 2010 and 2011 YTD), by product line, as applicable
 - b. List of competitors and write up of competitive landscape and how company differentiates itself from competitors

E. Human Resources

- a. Organizational chart with employee listing showing number of employees broken down by department and location
- b. Management profiles and CV's of the management team
- c. Planned hires over next 8 quarters beginning October 1, 2011, if any. Describe:
 - a. Total hires by quarter
 - b. Mass. hires by quarter
 - c. Identify key hires in (a) and (b) above

F. Legal

- a. Contact information for the Company's professional advisors including legal counsel
 - b. List of any threatened, pending or prior litigation, claims, proceedings, investigations, injunctions, settlements, regulatory or government action
- Employment contracts for senior management, if any

8. General Conditions

8.1 Notice of Public Disclosure.

8.1.1. General Statement.

Funds awarded are public funds and any information submitted to the Center by the Applicant in response to this loan Solicitation or generated in relation thereto is subject to public disclosure requirements as set forth in the Massachusetts Public Records Act, M.G.L. c. 66 (the "Public Records Act"), which governs the retention, disposition and archiving of public records. For purposes of the Public Records Act, "public records" include all books, papers, maps, photographs, recorded tapes, financial statements, statistical tabulations, or other documentary materials or data, regardless of physical form or characteristics, made or received by the Center.

The foregoing notwithstanding, "public records" do not include certain materials or data which fall within one of the specifically enumerated exemptions set forth in the Public Records Act or in other statutes, including the Center's enabling act, M.G.L. Chapter 23I. One such exemption that may be applicable to documents submitted by the Applicant in response to the Solicitation is for any documentary materials or data made or received by the Center that consists of trade secrets or commercial or financial information regarding the operation of any business conducted by the Applicant, or regarding the competitive position of such Applicant in a particular field of endeavor (the "MLSC Trade Secrets Exemption").

It is the Center's expectation and belief that the overwhelming percentage of documents it receives from Applicants does not contain any information that would warrant an assertion by the Center of an exemption from the Public Records Act. Applicants should therefore take care in determining which documents they submit to the Center in response to this Solicitation, and should assume that all documents submitted to the Center in response to the Solicitation are subject to public disclosure without any prior notice to the Applicant and without resort to any formal public records request.

8.1.2. Procedures for Handling Documents Identified as "Confidential Information"

In the event that Applicant's response to the Solicitation includes the submission to the Center of documents that Applicant believes may be proprietary in nature and may fall within the parameters of the MLSC Trade Secrets Exemption and/or some other applicable exemption, the following procedures shall apply:

- A) At the time of the Applicant's initial submission of documents to the Center, the Applicant must provide a cover letter, addressed to the Center's Counsel, indicating that it is submitting documents which it believes are exempt from public disclosure, including a description of the specific exemption(s) that Applicant contends is/are applicable to the submitted materials, a precise description of the type and magnitude of harm that would result in the event of the documents' disclosure, and a specific start date and end date within which the claimed exemption applies. If different exemptions, harms and/or dates apply to different documents, it is Applicant's responsibility to provide detailed explanations for each such document.
- B) At the time of the Applicant's initial submission of documents to the Center, the applicant must also clearly and unambiguously identify each and every such document that it contends is subject to an exemption from public disclosure as "Confidential Information." It is the Applicant's responsibility to ensure that all such documents are sufficiently identified as "Confidential Information," and Applicant's designation must be placed in a prominent location on the face of each and every document that it contends is exempt from disclosure under the Public Records Act.
- C) Documents that are not accompanied by the written notification to the Center's Counsel or are not properly identified by the Applicant as "Confidential Information" at the time of their initial submission to the Center are presumptively subject to disclosure under the Public Records Act,

and the procedures for providing the Applicant with notice of any formal public records request for documents, as set forth below, shall be inapplicable.

- D) At the time the Center receives documents from Applicant in response to the solicitation, any such documents designated by Applicant as "Confidential Information" shall be segregated and stored in a secure filing area when not being utilized by appropriate Center staff for purposes of evaluating the application for funds. By submitting a signed application to the Center, Applicant certifies, acknowledges and agrees that (a) the Center's receipt, segregation and storage of documents designated by Applicant as "Confidential Information" does not represent a finding by the Center that such documents fall within the MLSC Trade Secrets Exemption or any other exemption to the Public Records Act, or that the documents are otherwise exempt from disclosure under the Public Records Act, and (b) the Center is not liable for the subsequent disclosure of any documents submitted to the Center by the Applicant, whether or not such documents are designated as "Confidential Information" or the Center was negligent in disclosing such documents.
- E) In the event that the Center receives an inquiry or request for documents submitted by Applicant in response to the solicitation, the Center shall produce all responsive documents without notice to Applicant. In the event that the inquiry or request entails documents that the Applicant has previously designated as "Confidential Information", the inquiring party shall be notified in writing that one or more of the documents it has requested has been designated by the Applicant as "Confidential Information", and that a formal, written public records request must be submitted by the requesting party to the Center's Counsel for a determination of whether the subject documents are exempt from disclosure.
- F) Upon the Counsel's receipt of a formal, written public records request for documents that encompass materials previously designated by Applicant as "Confidential Information", the Applicant shall be notified in writing of the Center's receipt of the public records request, and the Center may, but shall not be required to provide Applicant an opportunity to present the MLSC with information and/or legal arguments concerning the applicability of the MLSC Trade Secrets Exemption or some other exemption to the subject documents.
- G) The Center's Counsel shall review the subject documents, the Public Records Act and the exemption(s) claimed by the Applicant in making a determination concerning their potential disclosure.

THE CENTER'S COUNSEL IS THE SOLE AUTHORITY WITHIN MLSC FOR MAKING DETERMINATIONS ON THE APPLICABILITY AND/OR ASSERTION OF AN EXEMPTION TO THE PUBLIC RECORDS ACT. NO EMPLOYEE OF THE CENTER OTHER THAN THE COUNSEL HAS ANY AUTHORITY TO ADDRESS ISSUES CONCERNING THE STATUS OF "CONFIDENTIAL INFORMATION" OR TO BIND THE CENTER IN ANY MANNER CONCERNING THE CENTER'S TREATMENT AND DISCLOSURE OF SUCH DOCUMENTS.

FURTHERMORE, THE POTENTIAL APPLICABILITY OF AN EXEMPTION TO THE DISCLOSURE OF DOCUMENTS DESIGNATED BY THE APPLICANT AS "CONFIDENTIAL INFORMATION" SHALL NOT REQUIRE THE CENTER TO ASSERT SUCH AN EXEMPTION. THE CENTER'S COUNSEL RETAINS THE SOLE DISCRETION AND AUTHORITY TO ASSERT AN EXEMPTION, AND HE MAY DECLINE TO ASSERT SUCH AN EXEMPTION IF, WITHIN HIS DISCRETION, THE PUBLIC INTEREST IS SERVED BY THE DISCLOSURE OF ANY DOCUMENTS SUBMITTED BY THE APPLICANT.

- H) The Center shall provide the requesting party and Applicant with written notice of its determination that the subject documents are either exempt or not exempt from disclosure.
- I) In the event that the Center determines that the subject documents are exempt from disclosure, the requesting party may seek review of the Center's determination before the Supervisor of Public Records, and the Center shall notify the Applicant in writing in the event that the requesting party pursues a review of the Center's determination.

- J) In the event the requesting party pursues a review of the Center's determination that the documents are exempt from disclosure and the Supervisor of Public Records concludes that the subject documents are not exempt from disclosure and orders the Center to disclose such documents to the requester, the Center shall notify the Applicant in writing prior to the disclosure of any such documents, and Applicant may pursue injunctive relief or any other course of action in its discretion.
- K) In the event that the Center determines that the subject documents are not exempt from disclosure or the Center's Counsel determines that, under the circumstances and in his discretion, the Center shall not assert an exemption, the Center shall notify the Applicant in writing prior to the disclosure of any such documents, and Applicant may pursue injunctive relief or any other course of action in its discretion.

APPLICANT'S SUBMISSION OF AN APPLICATION, WITH OR WITHOUT SUPPORTING DOCUMENTATION, SHALL REQUIRE A SIGNED CERTIFICATION THAT APPLICANT ACKNOWLEDGES, UNDERSTANDS AND AGREES WITH THE APPLICABILITY OF THE FOREGOING PROCEDURES TO ANY DOCUMENTS SUBMITTED BY APPLICANT IN RESPONSE TO THE SOLICITATION, INCLUDING BUT NOT LIMITED TO THE ACKNOWLEDGEMENTS SET FORTH IN SECTION 8.1.2(D), AND THAT APPLICANT SHALL BE BOUND BY THE PROCEDURES SET FORTH IN THIS SECTION 8.1.

All documents submitted by Applicant, whether designated as "Confidential Information" or not, are not returnable to Applicant.

8.2 Contractual Requirements

The Center intends to enter into an Agreement with the Awardees containing certain standard provisions. A copy of the standard Agreement (which includes the loan agreement, promissory note, and warrant) is available on the Center's website. The Center reserves the right to amend the Agreement without further issuance of another solicitation. The Center anticipates that Awardee will enter into an Agreement in substantially the form to be posted.

8.3 Waiver Authority

The Center reserves the right, at its sole discretion, to waive minor irregularities in submittal requirements, to request modifications of the application, to accept or reject any or all applications received, and/or to cancel all or part of this solicitation at any time prior to awards.

8.4 Disclaimer

This solicitation does not commit the Center to award any funds, pay any costs incurred in preparing an application, or procure or contract for services or supplies. The Center reserves the right to accept or reject any or all applications received, negotiate with all qualified Applicants, cancel or modify the solicitation in part or in its entirety, or change the application guidelines, when it is in its best interests.

8.5 Changes/Amendments to Solicitation

This Solicitation has been distributed electronically using the Center's website. It is the responsibility of Applicants to check the Center's website for any addenda or modifications to the Solicitation to which they intend to respond. The Center, the Commonwealth of Massachusetts, and its subdivisions accept no liability and will provide no accommodation to Applicants who submit an application based on an out-of-date solicitation document.

**ATTACHMENT A: SUBMITTED BUSINESS PLAN OUTLINE
(Narrative form in PDF, not POWERPOINT)**

**THE BUSINESS PLAN SHOULD BE IN NARRATIVE FORMAT
AND NO LONGER THAN 15 pages (11 pt font) AT THE END OF YOUR BUSINESS PLAN, ADD A
CV (1-2 pages) FOR EACH OF THE TOP 2-3 EXECUTIVE TEAM MEMBERS.**

- Executive Summary **(1-2 pages)**
 - Highlights of what the applicant is proposing and, evidence for potential success and why it merits funding from the MLSC. Answer the following questions in the summary:
- Science/Technology/ Product/Service/Industry **(1-2 pages)**
 - Provide a brief summary of the potential for the applicant's scientific and technological advancements to lead to new medical applications such as medical devices, drugs and drug delivery systems, and new therapies and diagnostics. This summary should include a description of the underlying science and/or technology; how it builds upon existing science and technologies; data and publications, if available, that may assist reviewers in assessing the likelihood of success of the science and/or technology; technical challenges that may be encountered in commercialization of the science and/or technology, and any intellectual property owned by the company. You may include a hyperlink in this summary to data, publications, and/or awarded or pending patents.
- Opportunity (1-2 pages)
 - What problem will your company's product, technology, science or service solve?
 - What is the value proposition (benefit of solving the problem?)
 - What are the differences between what currently is on the market and what you will offer?
 - Why will your product/service/technology be successful?
 - What will be required to capture the opportunity?
- Market Analysis
 - Who are your customers:
 - Current?
 - Potential?
 - Describe the size of your target market and key trends
 - What evidence can you provide of customer demand?
 - What evidence is there that customers will adopt/switch to your product, service or technology?
 - Describe your reimbursement strategy
 - Who will be the payers for your product, service or technology?
 - Why would payers cover (reimburse for) your product?
 - Discuss your plan to sell and market your product, service or technology
 - Discuss current and future barriers to entry and describe how you will address them
- Competition
 - Discuss current and potential direct and indirect competition
 - What are key substitutes and/or alternative products?
 - What is your company's competitive advantage? (Describe the characteristics that make your product, service, technology novel and set it apart from the competition)
 - Describe your company's IP/patent protection
 - Highlight any aspects of your product that are protected by your current or future IP
- Clinical/Regulatory Pathway
 - What regulatory approval(s) are required for your product, service, technology?
 - What are the critical steps in the process of receiving the approvals needed by your company?
 - What are your projected milestones for receiving these approvals?

- Outlook/Benchmarks/Development Plans
 - What are your expected milestones for:
 - Complete management team
 - Product development stages (prototype, etc.)
 - Customer acquisition
 - Reaching Breakeven
 - Becoming Cash flow positive
 - Obtaining Future Funding
- Management Team (no more than 1 page)
 - Roles and individuals
 - Qualifications and experience of current key personnel (include consultants)
 - Qualifications and experience of future personnel and timing (include consultants)
- Financials
 - A summary table of Historical Revenues, Expenses and Pre-tax profits (losses) by quarter for the prior eight quarters
 - A summary table of Projected Revenues, Expenses and Pre-tax profits (losses) by quarter for the next eight quarters
 - What is your anticipated path to profitability or exit strategy?
 - What is your current level of capitalization?
 - Brief description of your company's potential to leverage additional funding
 - How much capital will your company need to raise in order to exit?
 - Who are the current investors in your company?
 - Names
 - Type of investment(s)
 - Describe your company's cash position
 - Current cash balance as of date of application
 - Current quarterly cash burn rate
 - Projected quarterly cash burn by quarter for the next four quarters
 - Projected cash position over the next four quarters
 - Significant capital expenditures in the next 12 months
- Work Plan for use of MLSC Funds **(1-3 pages)**
 - Amount of funding requested
 - Purpose: What are the specific activities for which you plan to use Accelerator fund?
 - Specific tasks, milestones, personnel involved
 - Final product/outcome to be achieved and contribution to advancement of your company