### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### FORM 8-K

CURRENT REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of Earliest Event Reported): April 17, 2013

### **Aastrom Biosciences, Inc.**

(Exact name of registrant as specified in its charter)

Michigan (State or other jurisdiction of incorporation) **000-22025** (Commission File Number) 94-3096597 (I.R.S. Employer Identification No.)

24 Frank Lloyd Wright Drive, P.O. Box 376, Ann Arbor, Michigan (Address of principal executive offices)

**48106** (Zip Code)

Registrant's telephone number, including area code: (734) 418-4400

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 7.01 Regulation FD Disclosure.

On April 17, 2013, Aastrom Biosciences, Inc. (the "Company") presented at the 1<sup>st</sup> Annual Regen Med Investor Day in New York, NY. A copy of the presentation, which includes preclinical and clinical data of ixmyelocel-T in patients with dilated cardiomyopathy, is furnished herewith as Exhibit 99.1.

#### Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description		
99.1	Slide presentation dated April 17, 2013.		
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#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aastrom Biosciences, Inc.

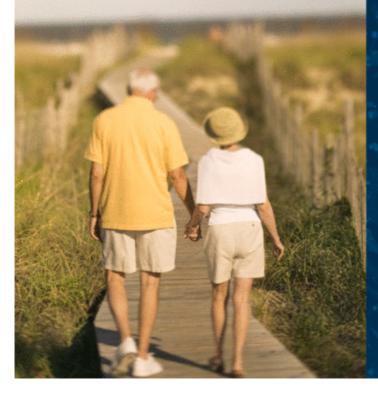
Date: April 23, 2013

By: /s/ Dominick C. Colangelo

Name: Dominick C. Colangelo Title: President and Chief Executive Officer

Exhibit 99.1





### Aastrom Biosciences The Future of Cell Therapy

April 2013

### Safe Harbor

This presentation contains forward-looking statements, including, without limitation, statements concerning product-development objectives, clinical trial strategies, clinical trial timing and expected results, market data, potential market opportunities, market development plans, anticipated milestones and potential advantages of ixmyelocel-T, all of which involve certain risks and uncertainties which could cause actual results to differ materially from the expectations contained in the forward-looking statements. Any forward-looking statement speaks only as of the date of this presentation, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after such date or to reflect the occurrence of unanticipated events.

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Among the risks and uncertainties that may result in differences are: the results obtained from, and our ability to complete, clinical trials and development activities; our ability to obtain and maintain required regulatory approvals, including required FDA approvals; changes in regulatory requirements; competitive conditions; technological and market changes and the possibility that our products may become obsolete; commercial acceptance of our products such as our cell products for tissue repair treatments; our relationships with third parties and our reliance on third parties to conduct some of our clinical trials; the availability of resources, including those resources used in our cell manufacturing process; and our ability to develop or license intellectual property rights to protect our proprietary products and technologies.

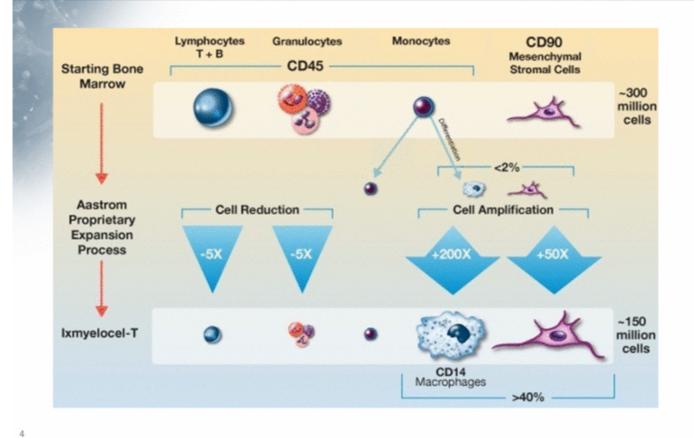
These and other significant factors are discussed in greater detail in Aastrom's Annual Report on Form 10-K and other filings with the Securities and Exchange Commission.

Aastrom Bios	ciences Highlights AASTROM
Leading Autologous Cell Therapy Platform	<ul> <li>Developing patient-specific multicellular therapies</li> <li>Automated cGMP manufacturing system</li> <li>Expandable and highly scalable</li> </ul>
Highly Differentiated Product	<ul> <li>Ixmyelocel-T is a unique multicellular therapy</li> <li>Key effector cells are M2-like macrophages and mesenchymal stromal cells</li> <li>Multiple biological activities that promote tissue repair &amp; regeneration</li> </ul>
Positive Clinical Data in Areas of Large Unmet Need	<ul> <li>Focus on severe ischemic cardiovascular diseases</li> <li>Experience in over 400 patients to date</li> <li>Well-tolerated with consistent positive efficacy data</li> </ul>
Substantial Commercial Opportunities	<ul> <li>Lead indication in advanced heart failure due to dilated cardiomyopathy</li> <li>U.S. Orphan Drug designation</li> <li>Large market opportunity</li> </ul>

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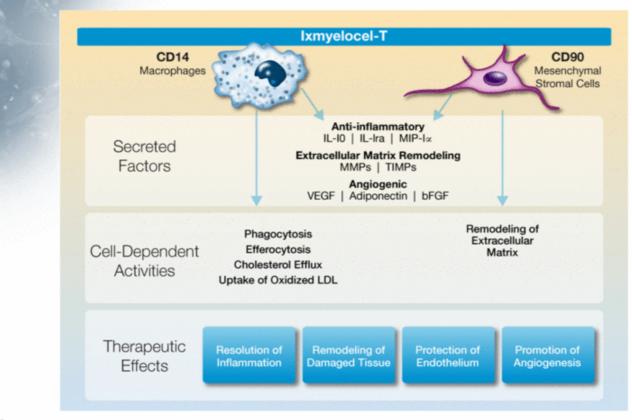
Ixmyelocel-T is a unique multicellular therapy; key effector cells are M2-like macrophages and MSCs



## Ixmyelocel-T has multiple biological activities that promote repair & regeneration of ischemic tissue

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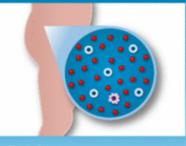
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## Aastrom's therapeutic platform provides for efficient cell collection, production and delivery

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#### EXTRACT BONE MARROW



#### Day 1

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- Bone marrow (approx. 50ml) is taken from patient's hip
- 15 minute outpatient procedure

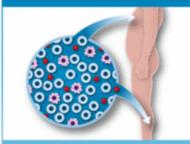
#### EXPAND CELL POPULATION



#### Days 2-13

 Aastrom's proprietary automated system expands key beneficial cell types

#### **ADMINISTER TO PATIENT**



#### Day 14

- Expanded multicellular therapy is administered to the same patient
- Intramyocardial injections via catheter for DCM patients

## Ixmyelocel-T GMP manufacturing platform is highly automated and expandable, with low COGS

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### Automated, Fully-Closed GMP Manufacturing System

- Single-use disposable bioreactor cassette
- Application key
- Incubator
- Processor
- System manager





### Highly Scalable Modular Expansion

Enables COGS < 10% at commercial scale</li>



# Ixmyelocel-T final product is convenient and easy to AASTROM

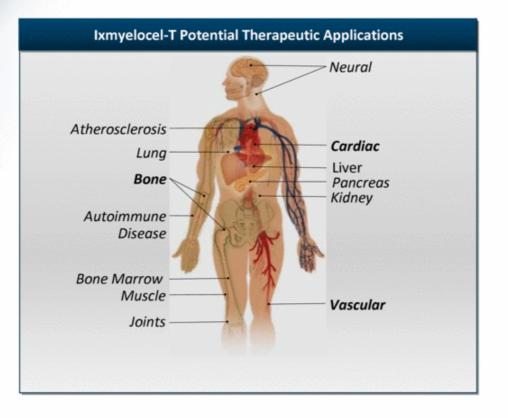
- Manufactured to finished product specifications
- Streamlined logistics
  - Shipped via Fedex overnight in a qualified container
- Ready to use when received
  - No freezing or thawing
  - No refrigeration
  - No reconstitution
- 72-hour shelf life
- Easy to administer



NOGA® Myostar™ Injection Catheter

### Aastrom's unique multicellular platform offers potential for multiple therapeutic applications

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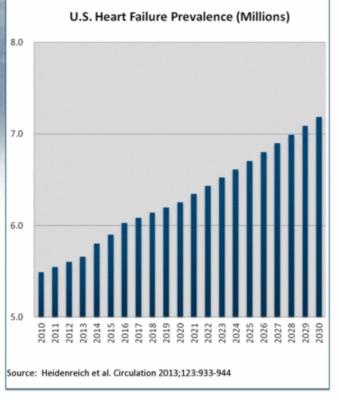


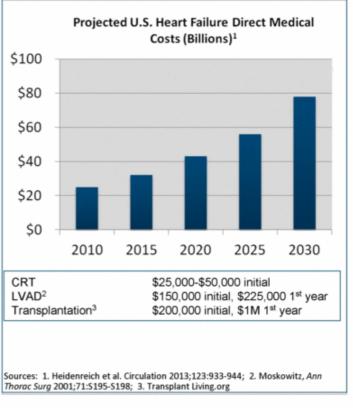
### Current focus is on developing ixmyelocel-T to treat advanced heart failure due to ischemic DCM

Ixmyelocel-T PRECLINICAL PHASE 1 PHASE 3 INDICATIONS PHASE 2 **Heart Failure** Dilated cardiomyopathy (DCM) IXCELL DCM FDA ORPHAN DESIGNATION Catheter Surgical **Peripheral Arterial Disease** Critical Limb Ischemia\* SPECIAL PROTOCOL ASSESSMENT & FAST-TRACK **Other Indications** Craniofacial Augmentation\*\* Atherosclerosis Fibrosis \*Not an active program

\*\*Investigator-sponsored trial (University of Michigan)

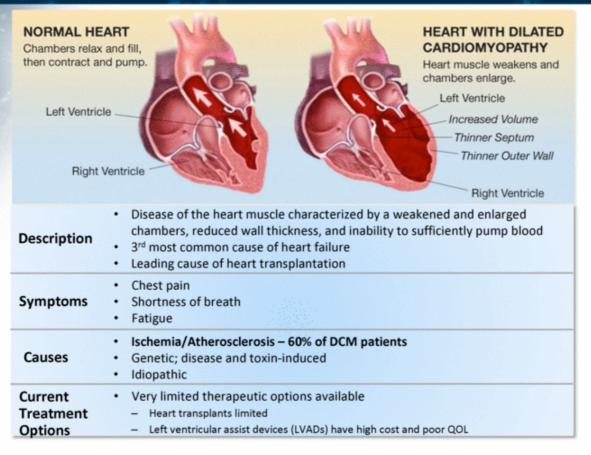
### Heart failure represents a significant unmet medical need and growing public health problem





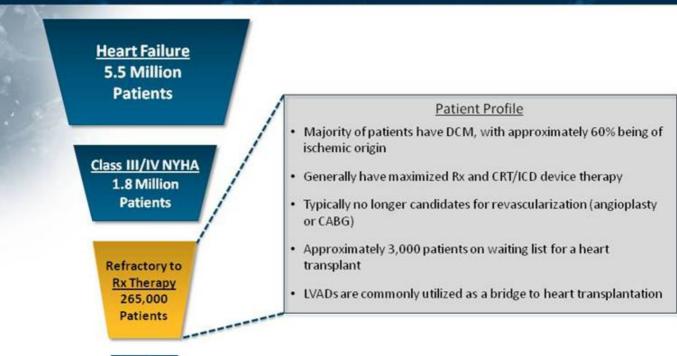
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## Ischemic DCM is a leading cause of heart failure and AASTROM heart transplantation



### A majority of advanced heart failure patients that are refractory to medical therapy have DCM

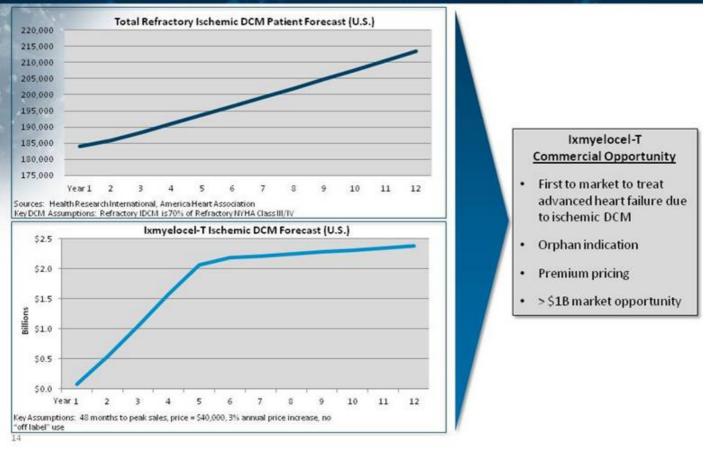
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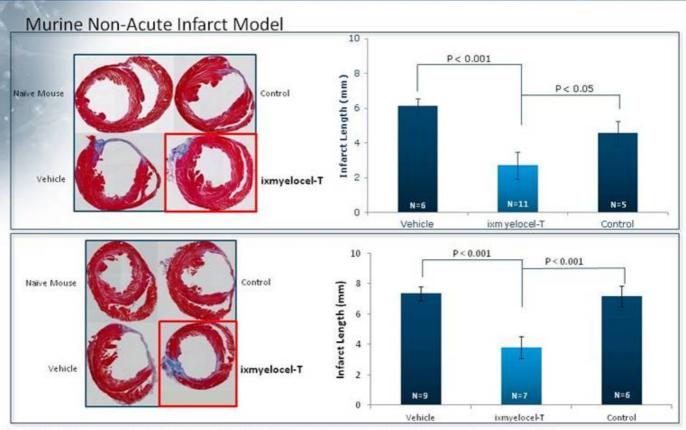
Sources: Heidenreich et al. Circulation 2013;123:933-944; Health Research International; America Heart Association Key DCM Assumptions: Prevalence Rate - 36/100,000 adults, Incidence Rates - 5.5/100,000 adults, Annual Death Rate - 20%, IDCM - 60% of DCM. NYHA ~25% (III) and ~4% (IV)

Transplants 2,000/yr

# The refractory ischemic DCM market represents a significant commercial opportunity for ixmyelocel-T



## Ixmyelocel-T significantly and reproducibly reduced tissue damage in a murine model of heart failure

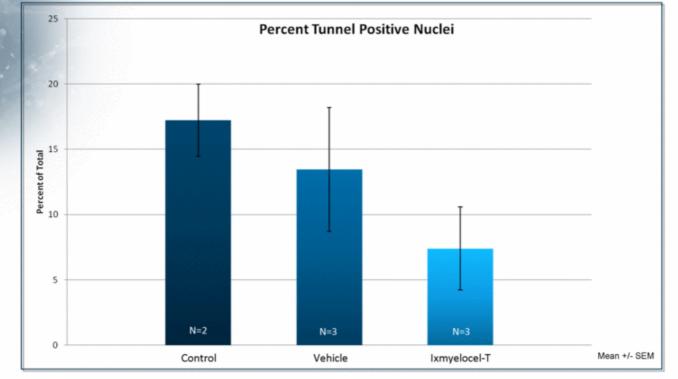


15 Study conducted at Medigenix, LLC; data presented at the 18th Annual International Society for Cellular Therapy Meeting. June 2012.

# Ixmyelocel-T demonstrated a trend towards reducing apoptosis in the infarct border zone



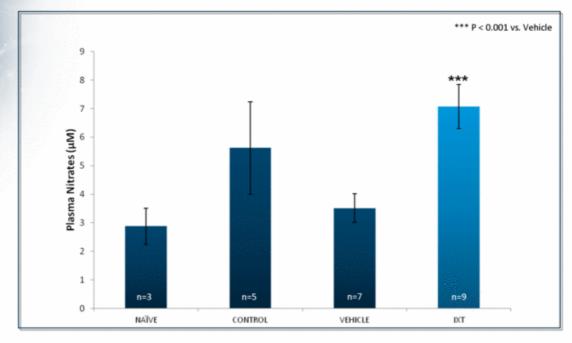
### Murine Non-Acute Infarct Model



16 Study conducted at Medigenix, LLC; data presented at the 18th Annual International Society for Cellular Therapy Meeting, June 2012.

### Ixmyelocel-T treatment increased plasma nitrates, which may contribute to observed protective effects

### Murine Non-Acute Infarct Model



17 Study conducted at Medigenix, LLC; data presented at the 18th Annual International Society for Cellular Therapy Meeting, June 2012.

## Phase 2a DCM clinical objectives focused on safety, optimizing delivery and patient selection

### Phase 2a Clinical Objectives

- 1. Demonstrate ixmyelocel-T safety in DCM patients
- 2. Evaluate delivery approaches
- 3. Gain clinical insight into patient selection

### Phase 2a Study Parameters: Two 12-month randomized open-label DCM studies

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- Delivery: Surgical (IMPACT-DCM study) vs. Catheter (CATHETER-DCM Study)
- Patient Population: Ischemic vs. non-ischemic DCM

	IMPACT-DC	M (n=39)	CATHETER-D	DCM (n=21)
Delivery	Intramyocardial delivery to the myocardium via thoracotomy		Endocardial injections delivered via NOGASTAR <sup>®</sup> endomyocardial catheter	
	Ixmyelocel-T	Control	Ixmyelocel-T	Control
Total n=60	24	15	15	6
IDCM	12	7	9	3
NIDCM	12	8	6	3

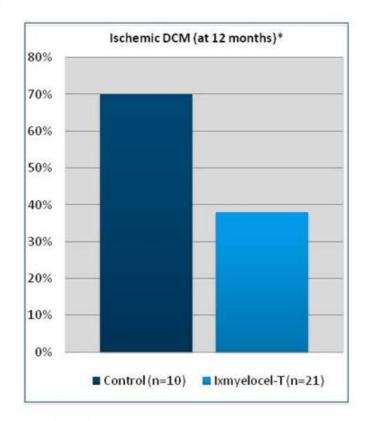
	Adv	erse Events Per Pa	atient	
	Days 0-5		Days	6+
	Ixmyelocel-T	Control	Ixmyelocel-T	Control
IMPACT-DCM	6.71*	N/A#	8.21	7.87
CATHETER-DCM	0.93*	N/A#	5.93	7.83

### Summary Conclusions

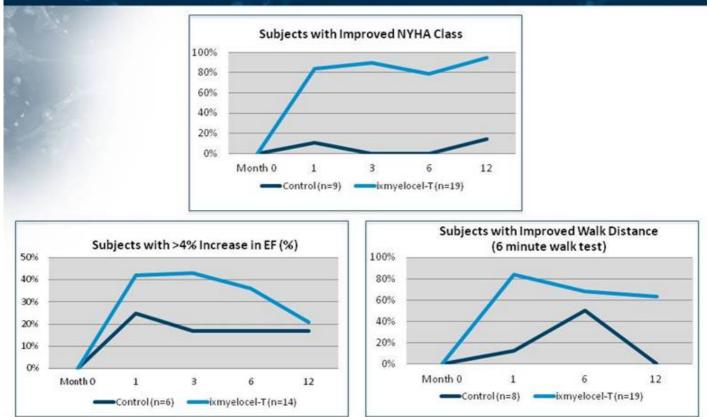
- Overall, ixmyelocel-T was well-tolerated in patients with DCM
  - IMPACT-DCM: Post-surgery, there was no difference in the incidence of AEs between ixmyelocel-T and control groups
  - CATHETER-DCM: AE incidence was comparable between the ixmyelocel-T group and the control standard of care group
- Improved patient tolerance demonstrated with catheter administration

\*Only ixmyeloceI-T subjects underwent mini-thoracotomy, thoroscopy, or catheter procedure.
\*Adverse events were not routinely collected for control patients prior to first visit (Day 6).

# Subjects treated with ixmyelocel-T in the ischemic DCM groups had a lower percentage of MACE events



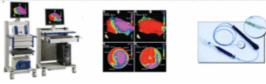
## Consistent positive trends were observed in several efficacy parameters in the ischemic DCM groups\*



21 \*Combined IMPACT-DCM and CATHETER-DCM data in the ischemic DCM groups

The phase 2b ixCELL-DCM study is a robust clinical study of ixmyelocel-T in ischemic DCM patients

	Phase 2b ixCELL-DCM Study Design
Objectives	<ul> <li>To evaluate the efficacy, safety and tolerability of ixmyelocel-T compared to placebo in patients with heart failure due to ischemic DCM</li> </ul>
Patients	<ul> <li>Males and females, age 30-85</li> <li>Diagnosis of ischemic DCM according to WHO criteria</li> <li>Not a candidate for reasonable revascularization procedures</li> <li>LVEF ≤ 30%</li> <li>NYHA class III or IV heart failure</li> </ul>
Design	<ul> <li>Multicenter, randomized (1:1), double-blind, placebo-controlled phase 2b study</li> <li>108 patients at approximately 30 sites in the US and Canada</li> <li>Administration via catheter injection into the left ventricular endocardium using the NOGA<sup>®</sup> Myostar™ injection catheter</li> </ul>
Key endpoints	<ul> <li>Primary: Number of all-cause deaths, all-cause hospitalizations, and emergency department visits for IV treatment of acute worsening heart failure over 12 months</li> <li>Secondary: Additional clinical, functional, structural, symptomatic/QOL, and biomarker measures at 3, 6 and 12 months</li> </ul>
Status	First patients enrolled and treated in April 2013







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### ixCELL-DCM Phase 2b study execution is highly achievable

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ixCELL-DCM Study Execution Attributes	
<ul> <li>Well-defined patient population at a well-defined point in disease progression         <ul> <li>Advanced heart failure patients refractory to medical therapy</li> </ul> </li> </ul>	
<ul> <li>Target physicians are motivated to perform catheter-based procedures         <ul> <li>Standard practice for interventional cardiologists</li> </ul> </li> </ul>	☑
<ul> <li>Strong coordination between heart failure specialists and interventional cardiologists         <ul> <li>Existing relationships in management of patient care</li> </ul> </li> </ul>	☑
<ul> <li>Study sites are experienced in using NOGA Myostar catheter for cell therapy studies         <ul> <li>Myostar catheter is specifically designed for cell therapy delivery</li> </ul> </li> </ul>	☑
<ul> <li>Manageable number of patients at a significant number of sites</li> <li>— 108 patients at 30 sites in U.S. and Canada</li> </ul>	
<ul> <li>Study sites are concentrated in areas of high disease prevalence         <ul> <li>Target physicians located in these areas</li> </ul> </li> </ul>	
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## The ischemic DCM indication provides a compelling path to commercialization for ixmyelocel-T

IXCELL DCM



#### Next Steps:

- Complete patient enrollment
- Hold FDA end of Phase 2 meeting
- Complete Phase 3 study design
  - Key assumptions:
    - Treatment effect from Phase 2b supports a single Phase 3 trial of "300 patients
    - 300 patient Phase 3 study will support FDA required safety database
    - One year to recruit and one year of patient observation
- Complete Phase 3 study
- BLA Orphan submission

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Substantial Commercial Opportunities	<ul> <li>Lead indication in advanced heart failure due to dilated cardiomyopathy</li> <li>U.S. Orphan Drug designation</li> <li>\$1+ billion peak revenue opportunity</li> </ul>