

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 20, 2017

**LION BIOTECHNOLOGIES, INC.**

(Exact Name of Registrant as Specified in Charter)

Nevada

(State of Incorporation)

001-36860

Commission File Number

75-3254381

(I.R.S. Employer Identification No.)

999 Skyway Road, Suite 150  
San Carlos, California

(Address of Principal Executive Offices)

94070

(Zip Code)

(650) 260-7120

(Registrant's Telephone Number, Including Area Code)

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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).
  - 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.**

Lion Biotechnologies, Inc. (the “Company”) from time to time makes presentations to analysts, current stockholders and others. A copy of the Company’s presentation is furnished as Exhibit 99.1 to this current report on Form 8-K and incorporated under this Item 7.01 by reference.

The information contained in this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for any purpose, and shall not be deemed incorporated by reference to any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing.

**Item 9.01 Financial Statements And Exhibits**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	Lion Biotechnologies, Inc., Corporate Presentation.

---

**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.

Date: April 20, 2017

LION BIOTECHNOLOGIES, INC.

By: /s/ MARIA FARDIS  
Maria Fardis, Chief Executive Officer

---



LEADERSHIP & INNOVATION IN ONCOLOGY

# Corporate Presentation

April 2017

© 2017, Lion Biotechnologies

# Forward-Looking Statements

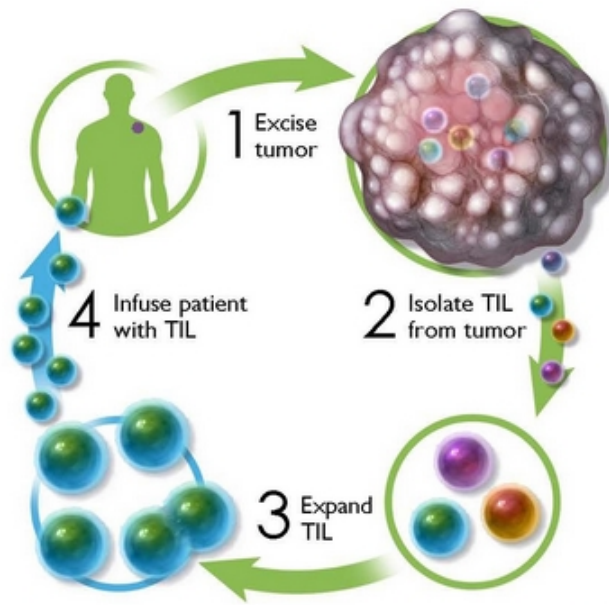
This presentation contains forward-looking statements reflecting management's current beliefs and expectations. These forward looking statements can be identified with words such as "expects", "plans", "projects", "potential", "suggests", "may", or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Forward-looking statements in this presentation include statements regarding (i) the success and timing of our product development activities and clinical trials, (ii) our ability, and the ability of our commercial partners, to manufacture, process and deliver our product candidates and to further improve on the manufacturing process, (iii) the size of the potential markets for our product candidates, (iv) our ability to develop next generation TIL and other more effective and efficient therapeutics, (v) our ability to maintain our collaborations and other relationships with third parties, including in particular with the National Cancer Institute/NIH, (vi) our ability to attract and retain key management and scientific personnel, (vii) our ability to obtain and maintain intellectual property protection for our product candidates, (viii) our ability to compete with other therapeutics that target the same indications as our product candidates, and (ix) our ability to achieve our manufacturing, clinical, regulatory, and other key milestones.

For more detailed information about the risks and uncertainties that could cause actual results to differ materially from those implied by, or anticipated in, these forward-looking statements, please refer to the Risk Factors section of the Company's Annual Report on Form 10-K and subsequent updates that may be contained in the Company's Quarterly Reports on Form 10-Q and current reports on Form 8-K on file with the SEC. Forward-looking statements speak only as to the date they are made. Except as required by law, the Company does not undertake to update forward-looking statements to reflect circumstances or events that occur after the date the forward looking statements are made. This presentation does not constitute an offer to sell or buy securities, and no offer or sale will be made in any state or jurisdiction in which such offer or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

# Corporate Highlights

- **Clinical-stage biotechnology company** focused on the development and commercialization of novel cancer immunotherapy products
- Leveraging and enhancing the power of tumor-infiltrating lymphocyte (TIL) technology to treat solid tumors
- **Broad pipeline** of programs using TIL technology:
  - Durable responses in metastatic melanoma patients observed (NCI study)
  - Responses seen in patients who failed multiple prior therapies (NCI study)
  - Phase 2 trial, LN-144 ongoing to treat metastatic melanoma (Orphan designation)
- Pipeline of potential therapies for other solid tumors including metastatic melanoma, cervical, head and neck, bladder, lung, breast, pancreatic, glioblastoma and HPV-associated cancers
- **Key collaborations and partnerships** with MedImmune, NCI/NIH, Moffitt, Karolinska Institute/PolyBioCept, and MD Anderson
- Expanded collaborations with manufacturing CMOs including Wuxi AppTec, Lonza and H. Lee Moffitt Cancer Center
- Management team has extensive drug development and cell therapy experience

# Tumor-Infiltrating Lymphocyte (TIL) Therapy


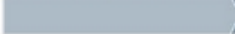

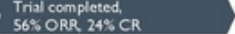

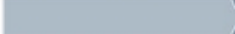

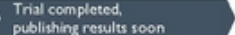

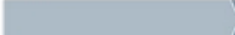
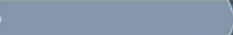






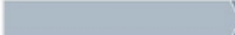
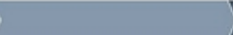
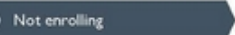






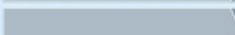
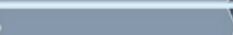




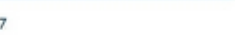

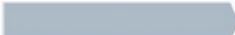








- Autologous adoptive cell therapy:
  - Resect tumor
  - Isolate and expand TIL *ex vivo*
  - Lymphodeplete patients seven days prior to TIL infusion
  - Infuse TIL followed by one to six doses of IL-2

© 2017, Lion Biotechnologies

**LION**  
BIOTECHNOLOGIES

# Lion Biotechnologies' Broad Pipeline

INDICATION	REGIMEN	N	PARTNER	PRECLINICAL	PHASE I	PHASE 2
Melanoma	Combination TIL ± TBI	101	 NIH NATIONAL CANCER INSTITUTE			
Melanoma	Combination TIL + ipi		 MOFFITT CANCER CENTER			
Melanoma	Combination TIL + Keytruda	170	 NIH NATIONAL CANCER INSTITUTE			
Melanoma	Combination TIL + Opdivo	12	 MOFFITT CANCER CENTER			
Ocular (Uveal) Melanoma	TIL	23	 NIH NATIONAL CANCER INSTITUTE			
Melanoma	TIL LN-144	40	—			
Cervical Cancer	TIL LN-145	47	—			
Head & Neck Cancer	TIL LN-145	47	—			
Glioblastoma	TIL		 Karolinska Institutet			
Pancreatic Cancer	TIL		 Karolinska Institutet			
Ovarian, Sarcomas, Pancreatic	TIL		 MD Anderson Cancer Network			



# Key Collaborations and Partnerships

## National Cancer Institute/NIH

- Cooperative Research And Development Agreement (CRADA) with Dr. Steve Rosenberg Development of TIL for metastatic melanoma, bladder, lung, breast, and HPV-associated cancers and combination therapies
- TIL + PD-I combination clinical trial to treat melanoma



## MedImmune/AstraZeneca

- TIL + PD-L1 combination clinical trial to treat head & neck cancer



## Moffitt Cancer Center

- TIL + Checkpoint inhibitor combination clinical trial to treat melanoma



## Karolinska Institute/ PolyBioCept

- TIL clinical trials to treat glioblastoma and pancreatic cancer



## MD Anderson

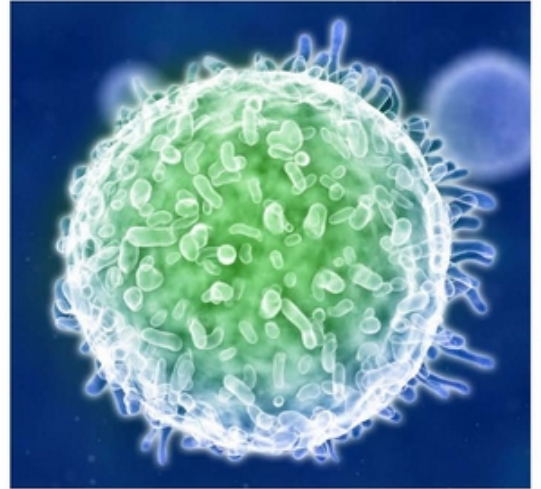
- TIL clinical trials to treat Ovarian, Sarcomas, and pancreatic cancers



# TIL Therapy

# TIL Therapy: Elicits a Highly Individualized, Specific, and Potent Attack Against Solid Tumors

- Leverages and enhances the body's natural defense against cancer using a patient's own TIL
- Polyclonal and can recognize multiple neoantigens:
  - Solid tumors are heterogeneous
- Durable response with one-time treatment:
  - Potential to establish immunological memory, requiring no additional maintenance therapy after infusion
- Consistent response rates in treatment naïve and refractory melanoma patients who have failed other options, including checkpoint inhibitors



# Adoptive Cell Transfer: Maximizes Potency of TILs to Overcome Suppressive Tumor Microenvironment

**EXTRACTION:** Patient's TILs are removed from suppressive tumor microenvironment (via surgical resection of lesions)

**EXPANSION:** TILs expanded from small tumor fragments using T-cell growth factor interleukin 2 (IL-2) – TILs are allowed to multiply to large numbers before re-infusing them into patient

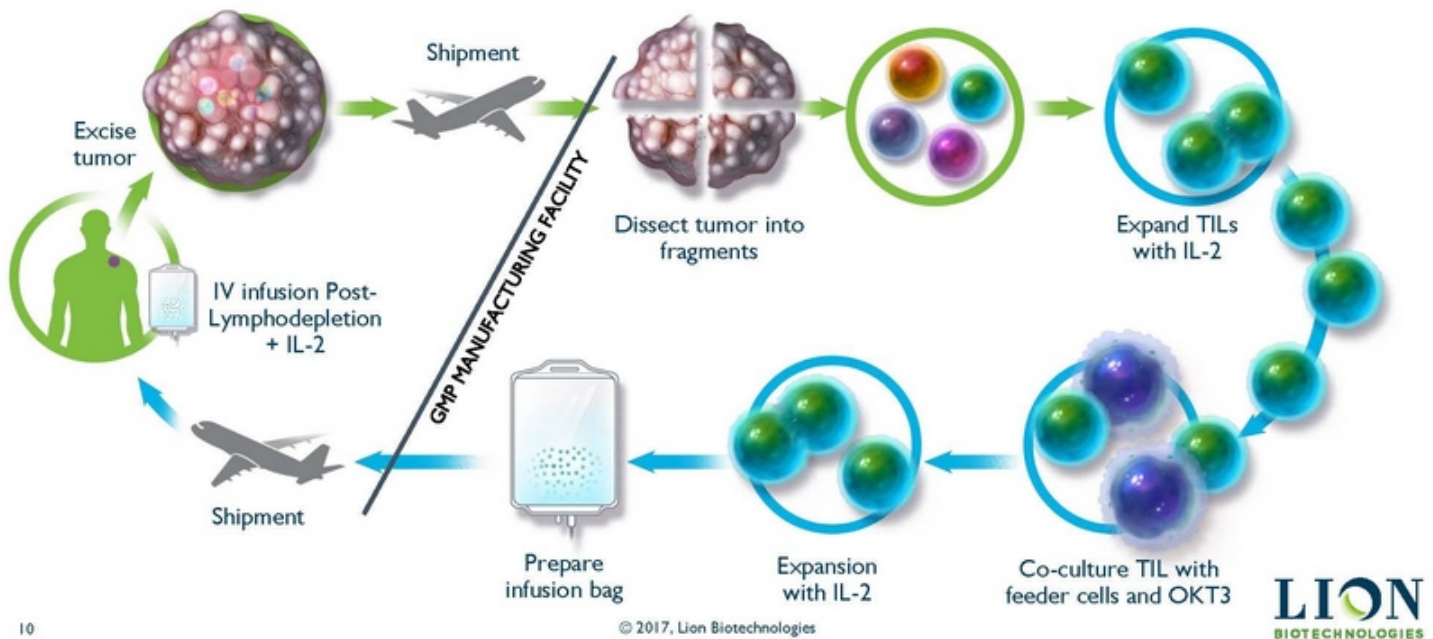
**PREPARATION:** Patients are lymphodepleted to eliminate potentially suppressive influences and maximize potency of TIL therapy

**REINFUSION:** Patients are reinfused with their expanded TILs and high-dose of IL-2 (up to 6 doses) to help TILs multiply further, engraft and activate, to attack tumor



# Manufacturing Process & Logistics

Gen 1 Duration: ~5-6 weeks; Gen 2 Duration: ~3.5 weeks



# Melanoma

# TIL Therapy in Melanoma is Very Promising

- Data from randomized Phase 2 trial in 101 patients with metastatic melanoma at the NCI confirmed TIL treatment was associated with high, durable objective response rates, including patients that were refractory to checkpoint inhibitors:<sup>(1)</sup>
  - CRs have been observed in 24% of patients, 23/24 complete responders showed durability of 30-47 months
  - Overall response rate was 56%
  - Overall survival was ~80% at 12 months; median not yet achieved
- Complete response rate of 29% reported in 34 patients that had failed either Anti-CTLA-4 or Anti-PD I
- Patient population enrolled, was broad

<sup>(1)</sup> Goff, S.L. et al. Randomized, Prospective Evaluation Comparing Intensity of Lymphodepletion Before Adoptive Transfer of Tumor-Infiltrating Lymphocytes for Patients With Metastatic Melanoma. *Journal of Clinical Oncology*, 34(20), 2389-2397.

# Treatment-Related Toxicities

ADVERSE EVENT	NMA (N=51)	TBI (N=50)
Grade 3 and 4 toxicities		
Febrile neutropenia	25	36
Bacteremia	13	5
Urinary tract infection	0	2
Atrial fibrillation	2	3
Thrombotic microangiopathy	0	13
ICU transfer on index admission		
Planned observation	0	2
Cytokine-related symptoms	0	6
Sepsis	2	1
Cardiac arrhythmia	2	3
Treatment related death	0	1

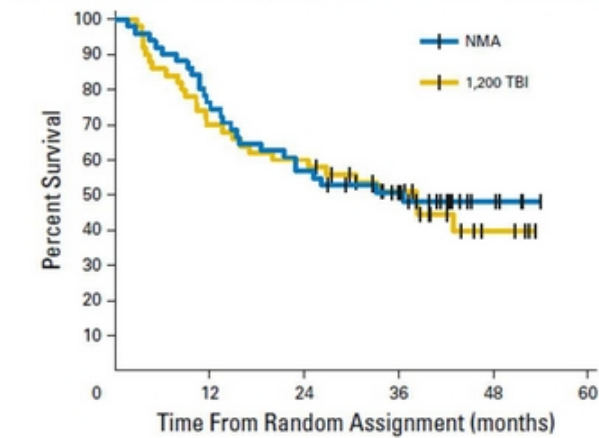
The toxicities of treatment were largely associated with the known side effects of nonmyeloablative chemotherapy (NMA) or total body irradiation (TBI) and administration of high dose IL-2<sup>(1)</sup>

<sup>(1)</sup> Goff, S.L. et al. Randomized, Prospective Evaluation Comparing Intensity of Lymphodepletion Before Adoptive Transfer of Tumor-Infiltrating Lymphocytes for Patients With Metastatic Melanoma. *Journal of Clinical Oncology*. 34(20), 2389-2397.



# Survival in Melanoma

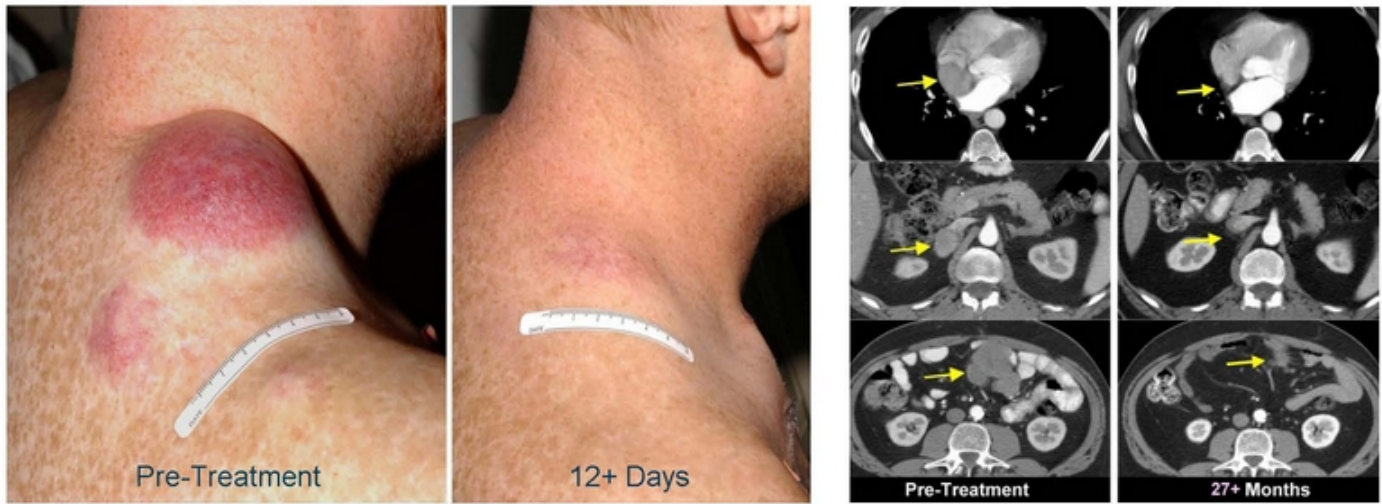
Overall Survival of patients in TIL ± TBI study



No. at risk	
NMA	51      39      30      21      6      0
1,200 TBI	50      35      30      18      4      0

Goff, S.L. et al. Randomized, Prospective Evaluation Comparing Intensity of Lymphodepletion Before Adoptive Transfer of Tumor-Infiltrating Lymphocytes for Patients With Metastatic Melanoma. *Journal of Clinical Oncology*, 34(20), 2389-2397.

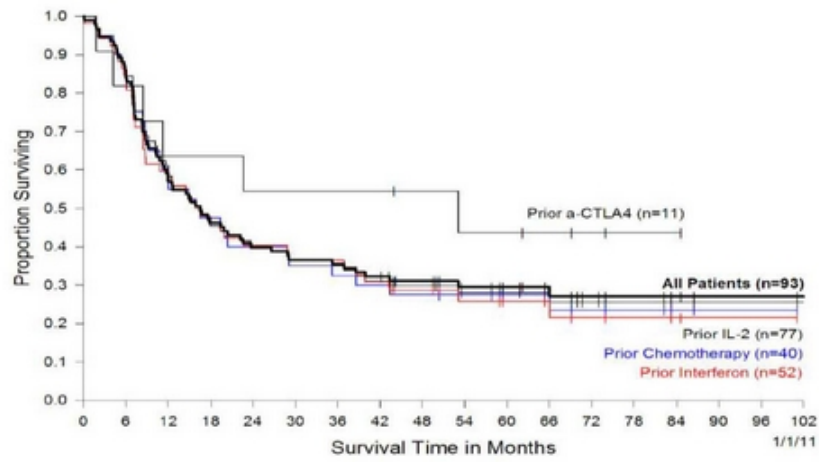
# Melanoma Patient



Rosenberg et al. Adoptive cell therapy for the treatment of patients with metastatic melanoma *Curr Opin Immunol* 21(2), 233-240.

# Survival Benefit in Second and Third Line Patients

## Durable remissions in melanoma regardless of prior therapies



19/20 complete responders are ongoing at 7 to >10 years

Rosenberg S.A., et al. Durable Complete Responses in Heavily Pretreated Patients with Metastatic Melanoma Using T-Cell Transfer Immunotherapy. *Clinical Cancer Research*, 17(13), 4550-4557.

# LN-144 Phase 2 Trial in Metastatic Melanoma

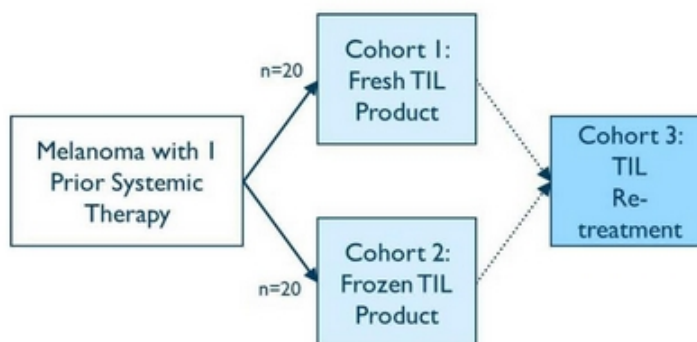
Phase 2, Multicenter, 3-Cohort Study to Assess the Safety and Efficacy of Autologous Tumor Infiltrating Lymphocytes (LN-144) for Treatment of Patients with Metastatic Melanoma

## Key Inclusion Criteria:

- Measurable metastatic melanoma and  $\geq 1$  lesion resectable for TIL generation
- At least one prior systemic therapy
- Age  $\geq 18$
- ECOG PS 0-1

## Endpoints:

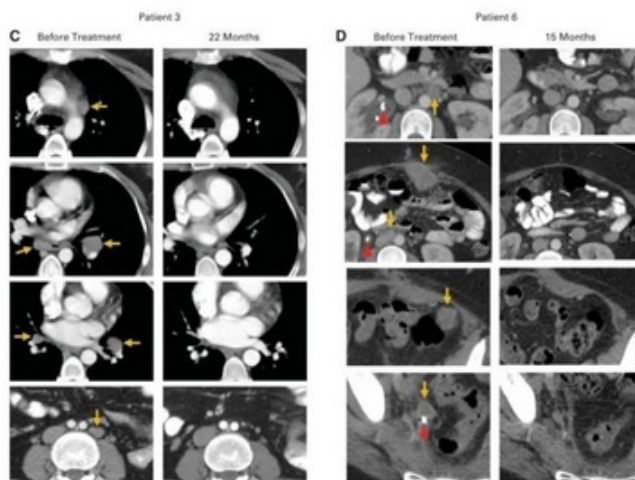
- Safety and Efficacy



# Cervical Cancer

# Cervical Cancer and TIL Treatment Data

	PATIENTS (%)	DURATION (MONTHS)
<b>Total</b>	9 (100)	
<b>PR</b>	1 (11)	3
<b>CR</b>	2 (22)	22+, 15+



Stevanovic, et al. Complete Regression of Metastatic Cervical Cancer After Treatment with Human Papillomavirus-Targeted Tumor-Infiltrating T Cells. *J Clin Oncol* 2015, 33 (15).  
 Hinrichs, et al. HPV-targeted Tumor-Infiltrating Lymphocytes for Cervical Cancer. *J Clin Oncol*, 2014, 23, 5s.

# LN-145 Phase 2 Trial in Recurrent and/or Metastatic Cervical Carcinoma

A Phase 2, Multicenter Study to Evaluate the Efficacy and Safety of Adoptive Cell Therapy Using Autologous Tumor Infiltrating Lymphocytes (LN-145) in Patients with Recurrent, Metastatic or Persistent Cervical Carcinoma

N=47; Simon's two-stage design

## Key Inclusion Criteria:

- Measurable metastatic disease and  $\geq 1$  lesion resectable for TIL generation
- At least one prior systemic therapy
- Age  $\geq 18$
- ECOG PS 0-1

## Endpoints:

- Efficacy and Safety

# Head and Neck Cancer



# LN-145 Phase 2 Trial in Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck

A Phase 2 Study to Evaluate the Safety, Tolerability and Efficacy of Cell Transfer Therapy Using Autologous Tumor Infiltrating Lymphocytes (LN-145) followed by IL-2 in Patients with Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck

N=47; Simon's two-stage design

## Key Inclusion Criteria:

- Measurable metastatic disease and  $\geq 1$  lesion resectable for TIL generation
- At least one prior systemic therapy
- Age  $\geq 18$
- ECOG PS 0-1

## Endpoints:

- Safety and Efficacy

# TIL Market Opportunity

# Market Opportunity for TIL Therapy

- 64% percent of new cases per year for patients 20-70 years old
- Metastatic (regional and distant) melanoma patients compose 13% of all new cases at ~10,000 cases
- Prevalence of melanoma in US (2013): >1 million

Market Potential for TIL Therapy

INDICATION	NEW CASES <sup>(1)</sup>	DEATHS <sup>(1)</sup>
Melanoma	76,380	10,130
Cervical	12,990	4,120
Head & neck	48,330	9,570
Lung	224,390	158,080
Bladder	76,960	16,390
Breast	246,660	40,450
Pancreatic	53,070	41,780
Glioblastoma	23,770	16,050

<sup>(1)</sup> Source: <http://seer.cancer.gov/statfacts/> | Estimates for 2016

# Competitive Advantages of TILs in Solid Tumors

TILs target a diverse array of cancer antigens; this approach represents a highly differentiated, customized and targeted immunotherapy

CHECKPOINTS	TCR	CAR	TIL
Utility in several solid tumors	Few solid tumors treated so far	No examples of utility in solid tumors	<b>Utility in melanoma and HPV cancers</b>
Long maintenance period	One-time treatment	One-time treatment	<b>One-time treatment</b>
No genetic modification	Genetic modification	Genetic modification	<b>No genetic modification</b>
Long-term irreversible toxicities	Potential on-target, off-tissue effects	Potentially immunogenic: cytokine release syndrome	<b>Minimal chance of unpredicted on-target, off-tissue effects</b>
Target multiple tumor antigens	Target only single tumor antigen	Target only single/surface tumor antigen	<b>Target multiple tumor antigens</b>
Off-the-shelf	Autologous	Autologous	<b>Autologous</b>
No HLA restriction	HLA restriction	No HLA restriction	<b>No HLA restriction</b>

# Future Directions: Next Generation TILs Enable More Efficient and Effective Therapeutics

- Selected TILs offer many benefits
  - Selection of more specific TIL (Select for PD-1, 4-1BB Expression)
  - Shorter duration of manufacturing
    - COGs
    - New IP
- Genetic engineering of TIL
  - Modulate exhaustion/inhibitory markers (PD-1, CTLA-4, LAG-3)



# Leadership and Organization Overview

# Management Team

Maria Fardis, Ph.D., MBA  
President and CEO

**AcertaPharma**  
INNOVATE DEVELOP CURE

**pharmacyclics**  
An AbbVie Company

**GILEAD**

Gregory Schiffman, MBA  
CFO

**AB** applied  
biosystems™

**affymetrix**

**Dendreon**  
Targeting Cancer, Transforming Lives®

Michael Lotze, M.D.  
CSO



**NATIONAL  
CANCER  
INSTITUTE**

**gsk** GlaxoSmithKline

# Financial Summary

AS OF DECEMBER 31, 2016	(IN MILLIONS)
Common shares outstanding	62.2
Preferred shares	8.8
Warrants/options/RSU's	13.4
Cash	\$166.5
Debt	\$0



# Anticipated 2017 Key Milestones

## MANUFACTURING

- ✓ Reduce manufacturing cycle from 5-6 weeks to ~3.5 weeks
- ✓ Complete tech transfer and ramp volumes at WuXi AppTec and H. Lee Moffitt Cancer Center and Research Institute
- ✓ Continue working with Lonza
- Expand capacity into additional CMOs continue efforts to reduce manufacturing cycle time and manufacturing costs

## CLINICAL

- Complete enrollment in ongoing Phase 2 melanoma clinical trial
- ✓ Release interim clinical data at an upcoming scientific forums
- ✓ Initiate Phase 2 clinical trials in head & neck and cervical cancers
- Support Karolinska University Hospital in initiating two Phase I clinical trials in pancreatic and glioblastoma cancers

## REGULATORY

- Define the regulatory pathway for LN-144 melanoma drug candidate in U.S.
- Initiate regulatory interactions with ex-U.S. health authorities

## PARTNERSHIPS

- Evaluate potential opportunistic partnerships in alignment with our core competencies
  - ✓ MDA



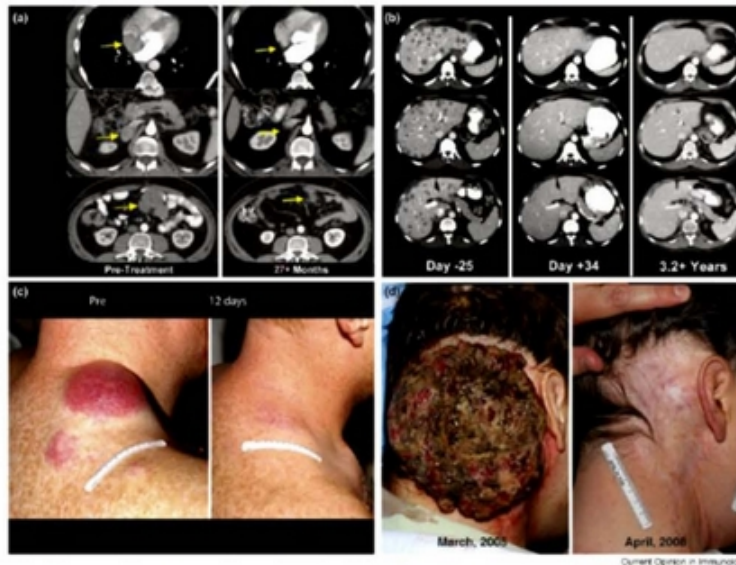
**LION**  
**BIOTECHNOLOGIES**

LEADERSHIP & INNOVATION IN ONCOLOGY

Thank you

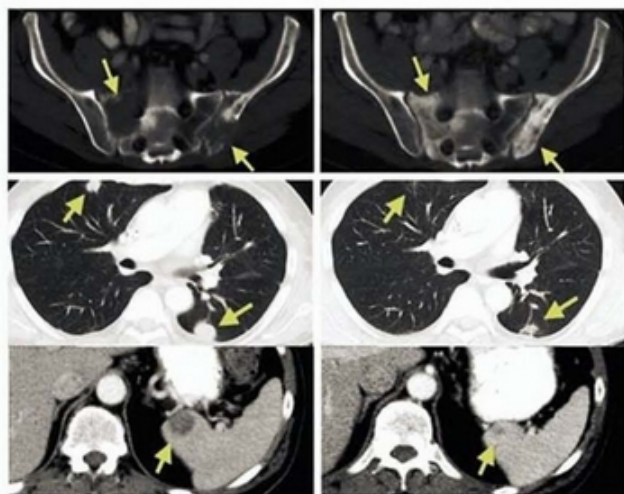
© 2017, Lion Biotechnologies

# Clinical Regressions in Late-Stage Disease



Rosenberg S.A. et al. (2009, April). Adoptive Cell Therapy for the Treatment of Patients with Metastatic Melanoma. *Current Opinion in Immunology*, 21(2), 233-240.

# Compelling Results in Late-Stage Disease



Pretreatment

2 months posttreatment



Day -9

Day +11

Day +76

Dudley, M. E., et al. (2010, December). CD8 Enriched "Young" Tumor Infiltrating Lymphocytes Can Mediate Regression of Metastatic Melanoma. *Clinical Cancer Research*, 16(24), 6122-6131.