

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): November 3, 2016

**LION BIOTECHNOLOGIES, INC.**

(Exact Name of Registrant as Specified in Charter)

**Nevada**

(State of Incorporation)

**000-53127**

Commission File Number

**75-3254381**

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

**999 Skyway Road, Suite 150  
San Carlos, CA**

(Address of Principal Executive Offices)

**94070**

(Zip Code)

**(650) 260-7120**

(Registrant's Telephone Number, Including Area Code)

112 W. 34th Street, 17th floor, New York, NY 10120

(Former name, former address and formal fiscal year, 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:

- 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”) intends to make presentations to current and prospective investors 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

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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.

Date: November 3, 2016

LION BIOTECHNOLOGIES, INC.

By: /s/ MARIA FARDIS

Maria Fardis, Chief Executive Officer

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Leadership & Innovation in Oncology

## Corporate Presentation

October 2016

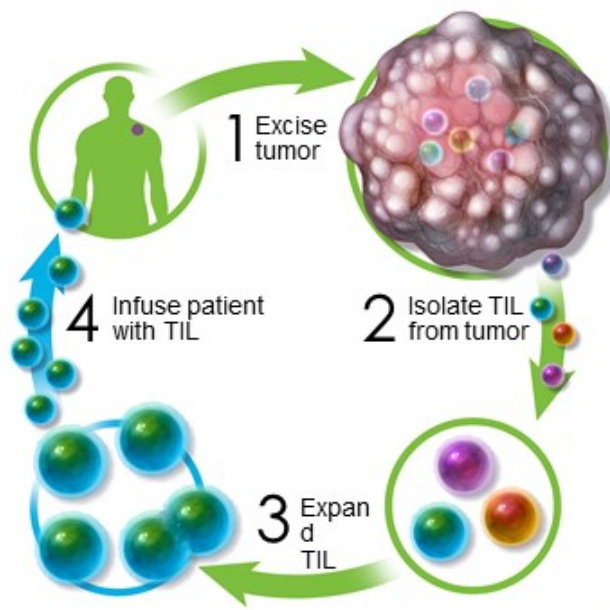
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# Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that 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. In particular, management’s expectations regarding future results could be affected by, among other things, uncertainties relating to clinical trials and product development; unexpected regulatory delays or government regulation generally; the Company’s ability to obtain or maintain patent and other proprietary intellectual property protection; and competition in general. 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.

Driven by scientific vision and grounded in collaboration, **Lion Biotechnologies** is establishing **leadership in immuno-oncology** by developing Tumor-Infiltrating Lymphocyte (TIL) technology to deliver **personalized oncology therapies** to patients with unmet medical needs

# Tumor-Infiltrating Lymphocyte (TIL) Therapy



- Autologous adoptive cell therapy
  - Resect tumor
  - Isolate and expand TIL *ex vivo*
  - Lymphodeplete patients 7 days prior to TIL infusion
  - Infuse TIL followed by IL-2

# 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 lymphocytes (TILs) to treat solid tumors
- **Broad pipeline** of programs using TILs
  - Durable responses in metastatic melanoma patients observed from the NCI study
  - Responses seen in patients who failed prior checkpoint therapy (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, and HPV-associated cancers, pancreatic and glioblastoma
- **Key collaborations and partnerships** with MedImmune, NCI/NIH, Moffitt and Karolinska Institute/PolyBioCept
- Expanded BOD and new senior management
- New corporate headquarters in San Carlos, California





# Company Snapshot

## Financial Snapshot

- **Market Cap:** \$516.8 million
- **Cash & Cash Equivalents:** \$191.6 million – strong cash position based on recent equity raise
- **Debt:** \$0
- **Enterprise Value:** \$325.3 million

Note: Market Cap and Enterprise Value as of 10/5/16; Cash & cash equivalents as of 6/30/16

## News Highlights

Date	Event
10/3/16	Lion appoints Gregory Schiffman as CFO
9/15/16	LION enters Exclusive License Agreement with PolyBioCept AB & Clinical Trial Agreements with Karolinska University Hospital
8/24/16	Lion announces 5-Year Extension of NCI CRADA for development of novel TIL immunology therapies
6/3/16	Lion appoints Maria Fardis as CEO and announced \$100 million equity raise
3/28/16	Lion names Michael Lotze as CSO
2/4/16	Lion announces hiring of Dr. Steven Fischhoff as CMO
2/1/16	Lion announces allowance of IND application to begin clinical trials in cervical, head & neck cancers
12/21/15	Lion enters clinical and preclinical research collaboration with Medimmune
10/7/15	Lion obtains license from NIH to develop and commercialize TIL in bladder, lung, breast and HPV-associated cancers

## Top 10 Shareholders

Investor Name	Position		Out standing %
	Shares (mm)	(\$ mm)	
Fidelity	5.6	\$42.6	11.6%
venBio	4.3	32.7	8.9%
Quogue Capital	3.8	29.0	7.9%
Perceptive Advisors	3.6	27.2	7.4%
Franklin Advisers	3.4	25.5	7.0%
OrbiMed	3.4	25.5	7.0%
Auris Capital	3.2	24.4	6.7%
Broadfin Capital	3.2	23.9	6.5%
BlackRock	2.9	22.2	6.1%
Victory Capital	2.2	16.7	4.8%
<b>Total of Top 10 Institutions:</b>	<b>56.8</b>	<b>\$269.8</b>	<b>78.7%</b>

## Stock Price Performance



# Lion Biotechnologies Pipeline and Partners

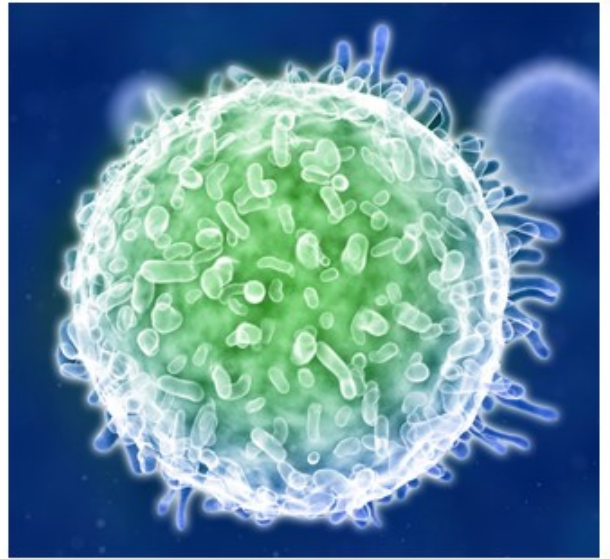
Indication	Regimen	Partner	Preclinical	Phase 1	Phase 2
Melanoma	TIL LN-144 (n=20)	—			Phase 2, enrolling
Melanoma	Combination TIL ± TBI (n=101)	NCI			Trial completed, 56% ORR, 24% CR
Melanoma	Combination TIL + Keytruda (n=170)	NCI			Enrolling
Melanoma	Combination TIL + ipi	Moffitt			Trial completed, publishing results soon
Cervical Cancer	TIL LN-145	—			Phase 2 trial to initiate in 2017
Head & Neck Cancer	TIL LN-145	—			Phase 2 trial to initiate in 2017
Glioblastoma	TIL	Karolinska University Hospital		Phase 1 trial to initiate in 2017	
Pancreatic Cancer	TIL	Karolinska University Hospital		Phase 1 trial to initiate in 2017	

A microscopic view of immune cells, likely TILs, showing various cell shapes and structures in shades of blue and white.

# Leveraging and enhancing the power of each patient's own **immune cells through TIL**

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

- Leverages 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
- Minimal unpredicted effects in other tissues
- 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 removed from suppressive tumor microenvironment (via surgical resection of lesions or biopsies)

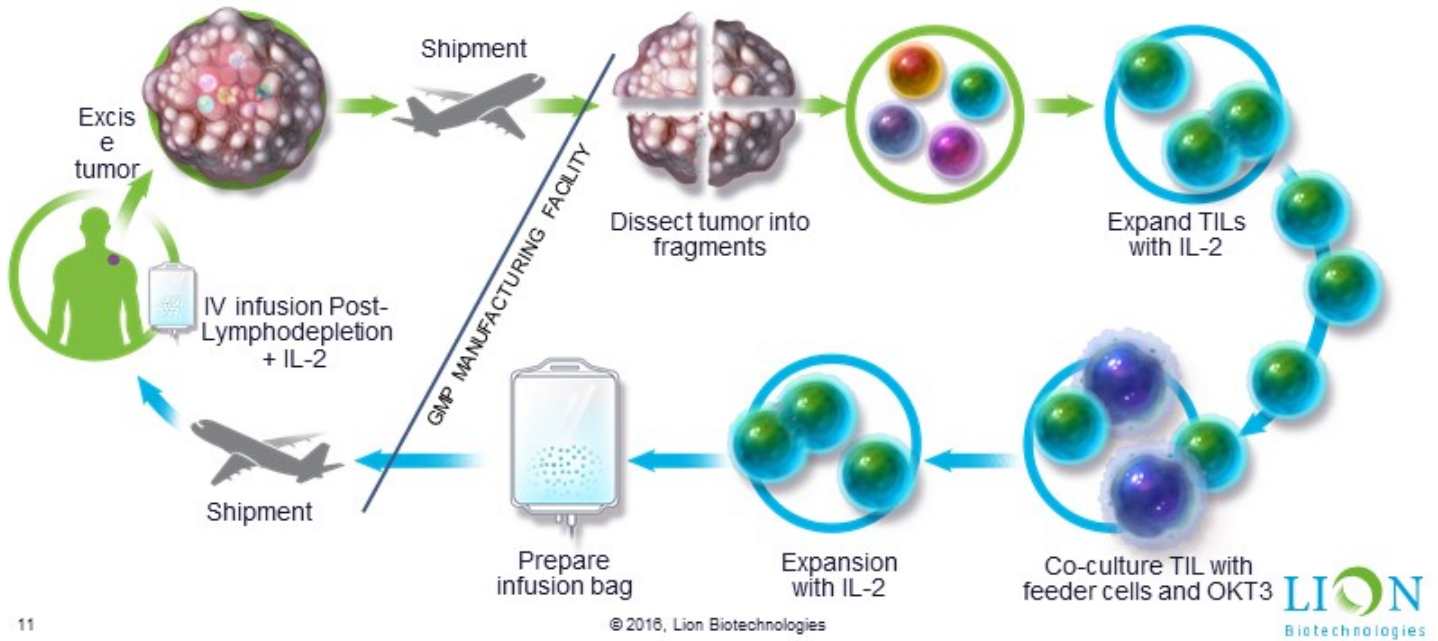
**EXPANSION:** TILs expanded from small tumor fragments using T-cell growth factor interleukin 2 (IL-2) –TILs allowed to multiply to large numbers before re-infusing them into patient

**PREPARATION:** Patients 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 (6 doses) given to help TILs multiply further, engraft and activate to attack tumor



# Manufacturing Process & Logistics



# Melanoma

# TIL Therapy in Melanoma is Very Promising

- Recent data from a randomized Phase 2 trial at NCI in 101 patients with metastatic melanoma at NCI confirmed TIL treatment was associated with high, durable objective response rates, including for patients that were refractory to checkpoint inhibitors<sup>1</sup>
  - Complete responses have been observed in 24% of patients, some of whom have been free from disease for 10 plus years
  - 23 of 24 complete responders showed durability of 30 to 47 months
  - Overall response rate was 56%
  - Overall survival was approximately 80% at 12 months; median not yet achieved
- Complete response rate of 29% reported in 34 patients that had failed either Anti-CLA4 or Anti-PD1

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>

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.

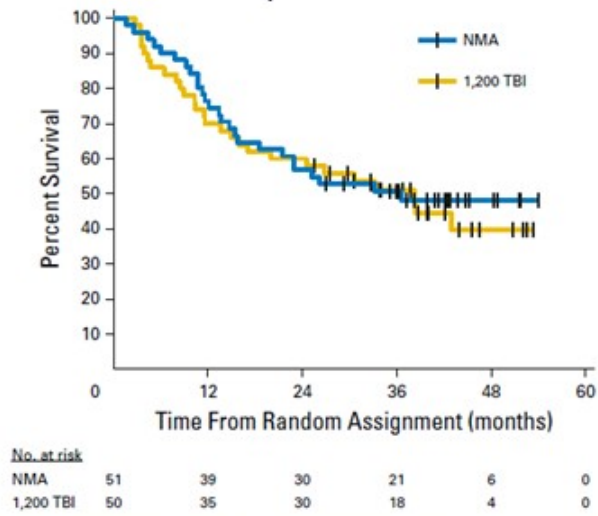
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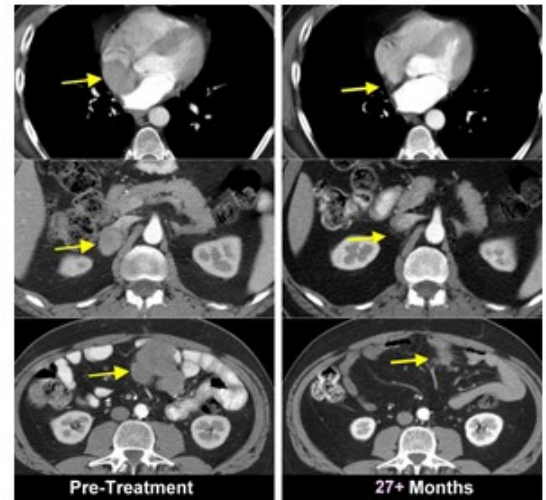
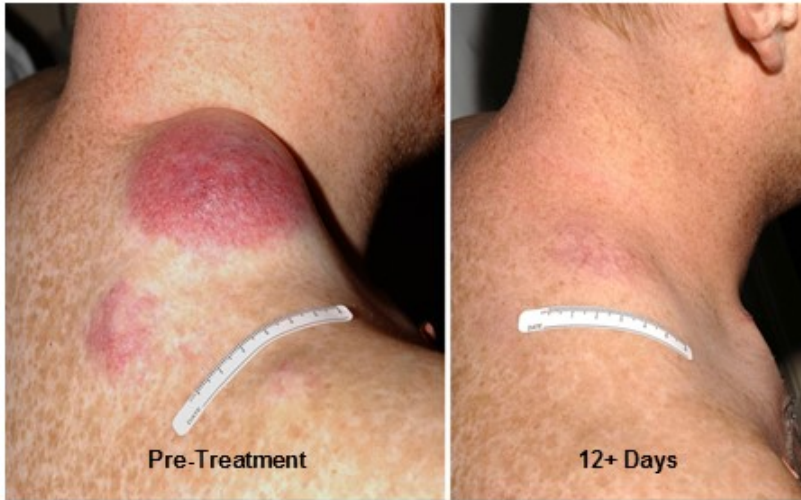
# Excellent Survival in Melanoma

Overall Survival of patients in TIL ± TBI study



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.

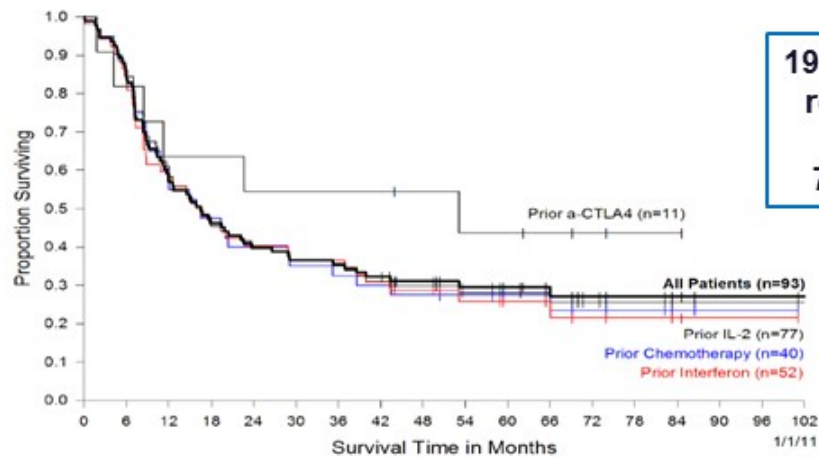
# Melanoma Patient



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



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 Refractory Metastatic Melanoma

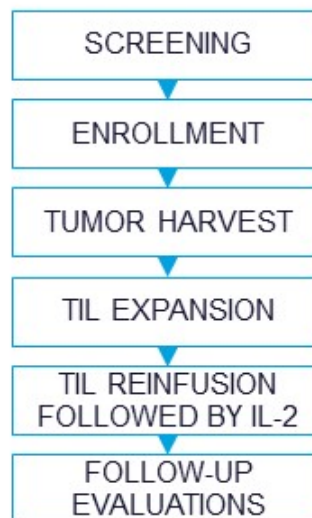
A Phase 2, Multicenter, Single-arm Study to Assess the Safety and Efficacy of Cell Transfer Therapy Using Autologous Tumor Infiltrating Lymphocytes (LN-144) Followed by IL-2 for Treatment of Patients with Metastatic Melanoma

- **Key Inclusion Criteria:**

- Measurable metastatic melanoma and  $\geq 1$  lesion resectable for TIL generation
- Age  $\geq 18$  to 80
- ECOG PS 0-1
- ANC  $> 1000/\text{mm}^3$
- Hemoglobin  $> 9.0 \text{ g/dL}$
- Platelet count  $> 100,000/\text{mm}^3$

- **Endpoints:**

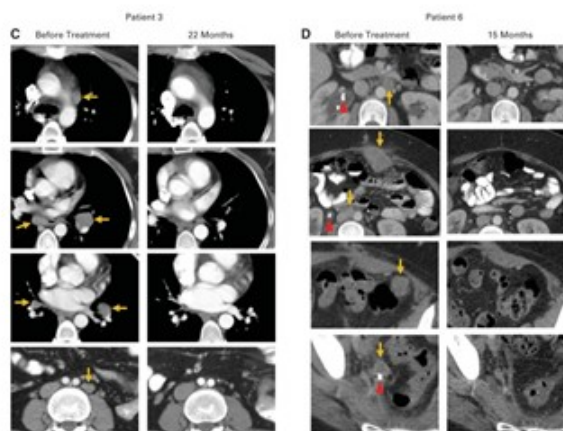
- Safety and Efficacy



# Cervical Cancer

# Cervical Cancer and TIL Treatment Data

	<b>Patients (%)</b>	<b>Duration (months)</b>
Total	9 (100)	
PR	1 (11)	3
CR	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.

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# 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

(1) 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	Utility in melanoma and HPV cancers
Long maintenance period	One-time treatment	One-time treatment	One-time treatment
No genetic modification	Genetic modification	Genetic modification	No genetic modification
Long-term irreversible toxicities	Potential on-target, off-tissue effects	Potentially immunogenic: cytokine release syndrome	Minimal chance of unpredicted on-target, off-tissue effects
Target multiple tumor antigens	Target only single tumor antigen	Target only single/surface tumor antigen	Target multiple tumor antigens
Off-the-shelf	Autologous	Autologous	Autologous
No HLA restriction	HLA restriction	No HLA restriction	No HLA restriction

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

- **Pre-sorted TILs offer many benefits**
  - Select high potency TIL (Select for PD-1, 4-1BB Expression)
  - Need lower cell numbers
  - Duration of manufacturing
  - COGS
  - IP generation
- **Genetic engineering of TIL**
  - Expression of cytokines to increase potency
  - Modulation of PD-1/CTLA-4/LAG-3 on cell surface
  - Persistence



# Key Collaborations and Partnerships

- National Cancer Institute/NIH

- Cooperative Research And Development Agreement with Dr. Steve Rosenberg (CRADA)
- Development of TIL for metastatic melanoma, bladder, lung, breast, and HPV-associated cancers and combination therapies
- TIL + PD-1 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



# Leadership and Organization Overview

# Management Team

Maria Fardis, Ph.D.,  
MBA  
President and CEO  
**AcertaPharma**  
INNOVATE DEVELOP CURE



Gregory Schiffman,  
MBA  
CFO  
**AB** applied  
biosystems™



Michael Lotze,  
M.D.



Steven Fischkoff,  
M.D.  
CMO  
**Celgene**



# Management Team (Cont'd)

## Maria Fardis, Ph.D. – President & CEO

- Most recently, Maria was COO at Acerta, served as a key component to the Company's rapid growth
  - Responsible for increasing the number of patients enrolled in studies from less than 100 to 1,300+
  - AstraZeneca acquired Acerta in early 2016, as Acerta was preparing for commercialization; deal valued at up to \$7 billion
- Extensive experience leading clinical oncology programs
- A key executive responsible for development and marketing authorization applications of ibrutinib (IMBRUVICA) at Pharmacyclics
- Prior experience with life cycle management of products (IMBRUVICA at Pharmacyclics, AMBRISANTAN at Gilead)

## Greg Schiffman – CFO

- Extensive experience in cell-based therapy
- Prior companies include Dendreon, Affymetrix and Applied Biosystems
- Was responsible for implementation of commercial infrastructure processes and systems, supply chain logistics, procurement and manufacturing in prior roles

## Michael Lotze, M.D. – CSO

- Renowned expert in immuno-oncology with 35+ years of clinical experience
- One of the original researcher responsible for development of IL-2

## Steven Fischkoff, M.D. – CMO

- 25 years of biopharma experience, most recently serving as VP of Clinical and Medical Affairs at Celgene
- Was VP, Clinical Science at Medarex, Inc., which developed CTLA-4 and PD-1 monoclonal antibodies, later sold for \$2.4 billion to BMS

# Board of Directors

## Iain Dukes, Ph.D. – Chairman

- Partner of OrbiMed; formerly SVP, Bus. Dev. and Licensing at Merck
- 20+ years in pharma research, drug discovery, scientific and technology licensing, start-up company leadership, and valuing commercial stage assets

## Wayne Rothbaum – Director

- President and Managing Member of Quogue Capital, LLC, a life sciences investment fund
- Co-founder, Executive Chairman and largest investor of Acerta, grew the company from pre-clinical stage to its up to \$7 billion sale value to AstraZeneca

## Merrill McPeak – Director

- Retired a four-star general after nearly four decades in the US Air Force and served as USAF chief of staff from 1990 to 1994
- Currently chairman of Ethicspoint and a director of several public and private companies

## Sanford Hillsberg, J.D. – Director

- Attorney at TroyGould PC since 1976 and member of the firm's management committee
- Has served as Chairman of Galena Biopharma since 2007
- Founder and former director and secretary of ImmunoCellular Therapeutics

## Jay Venkatesan, M.D. – Director

- Founder, portfolio manager and managing director of Ayer Capital Management

## Ryan Maynard – Director

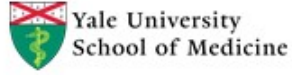
- Currently EVP and CFO of Rigel Pharmaceuticals, Inc., a clinical-stage drug development public company

## Maria Fardis, Ph.D., MBA – President & CEO



# Scientific Advisory Board

Mario Sznol, M.D.



Jeffrey Weber, M.D.



James Mulé, PhD.



Patrick Hwu,  
M.D.



Daniel Powell, PhD.



# Financial Summary

<b>As of June 30, 2016</b>	<b>(in millions)</b>
Common shares outstanding	58.4
Preferred shares	12.2
Warrants/options	6.95
Cash	\$191.6
Debt	\$0

A microscopic view of various cells, likely cancer cells, is the background of the slide. The cells are shown in shades of blue and green, with some appearing as bright, glowing structures. The overall image has a soft, ethereal quality.

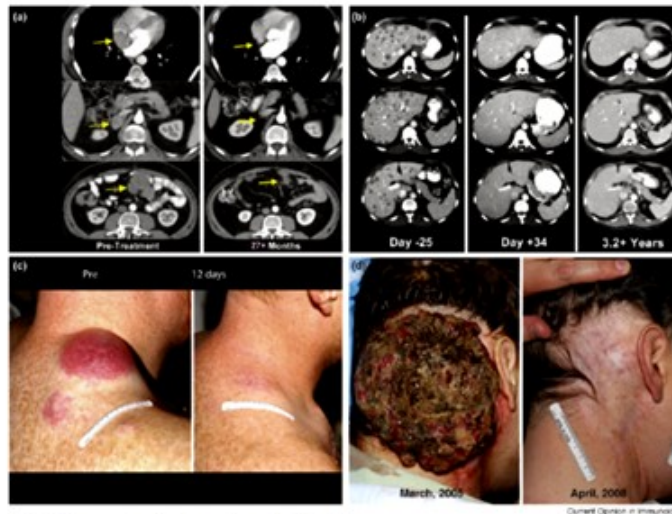
**LION**  
Biotechnologies

Leadership & Innovation in Oncology

Thank you

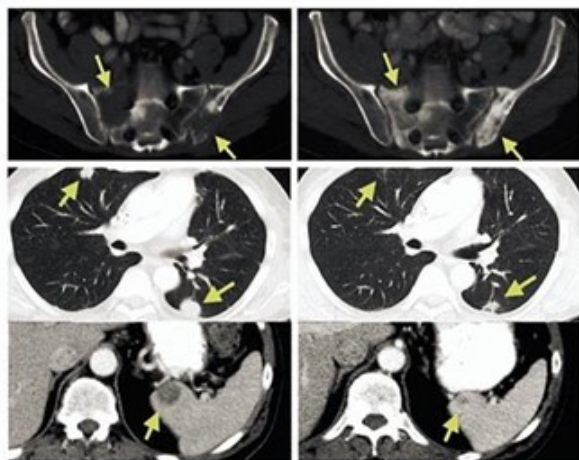
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# Clinical Regressions in Late-Stage Disease



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

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.



Day -9

Day +11

Day +76