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): January 7, 2019

IOVANCE BIOTHERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	
(State of Incorporation)	
001-36860	**75-3254381**
Commission File Number	**(I.R.S. Employer Identification No.)**
999 Skyway Road, Suite 150 **San Carlos, California**	**94070**
(Address of Principal Executive Offices)	**(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)).

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

Iovance Biotherapeutics, Inc. (the "Company") is currently in the process of finalizing its financial results for the fiscal year ended December 31, 2018. Based on information currently available, the Company estimates that as of December 31, 2018, cash, cash equivalents, and short-term investments were approximately $469 million.

These estimates are preliminary and actual results may differ from these estimates due to the completion of the Company's closing procedures with respect to the fiscal year ended December 31, 2018, final adjustments and other developments that may arise between now and the time the financial results for the 2018 fiscal year are finalized. As such, these estimates should not be viewed as a substitute for the full audited financial statements prepared in accordance with U.S. generally accepted accounting principles. These expected results could change materially and are not necessarily indicative of the results to be achieved for the 2018 fiscal year or any future period. As a result of the foregoing considerations and the other limitations described herein, investors are cautioned not to place undue reliance on this preliminary financial information. The Company does not undertake any obligation to publicly update or revise this estimate, except as required by law.

The information in this Item 2.02 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 shall not be incorporated by reference into any registration statement or other document filed by the Company with the Securities and Exchange Commission, whether made before or after the date of this Current Report on Form 8-K, regardless of any general incorporation language in such filing (or any reference to this Current Report on Form 8-K generally), except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

The Company from time to time makes presentations at healthcare conferences and to analysts, current stockholders, and others. A copy of the Company's presentation that it intends to use at such events is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Iovance Biotherapeutics, Inc., Corporate Presentation - January 2019.

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: January 7, 2019

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

IOVANCE BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY

Corporate Presentation

January 2019

Forward Looking Statements

This presentation contains "forward-looking statements" of Iovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "we," "us," or "our"). We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. The forward-looking statements include, but are not limited to, risks and uncertainties relating to the success, timing, projected enrollment, manufacturing capabilities, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates (including both Company-sponsored and collaborator-sponsored trials in both the U.S. and Europe), such as statements regarding the timing of initiation and completion of these trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; the strength of Company's product pipeline; the successful implementation of the Company's research and development programs and collaborations; the success of the Company's manufacturing, license or development agreements; the acceptance by the market of the Company's product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company's control. This presentation also contains certain preliminary financial numbers and estimates for the most recently completed financial period. These numbers are good faith estimates based on currently available information and do not present all necessary information for an understanding of our financial condition as of the most recently completed financial period. Readers are cautioned not to place undue reliance on these estimates, which are unaudited and remain subject to review and adjustment by our auditors. As we complete our quarter-end financial close process and finalize the results for our most recently completed financial period, we may be required to make significant judgments in a number of areas. The preliminary financial information presented herein has been prepared by and is the responsibility of our management. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. Actual results may differ from those set forth in this presentation due to the risks and uncertainties inherent in the Company's business, including, without limitation: the FDA may not agree with the Company's interpretation of the results of its clinical trials; later developments with the FDA that may be inconsistent with already completed FDA meetings; the preliminary clinical results, including efficacy and safety results, from ongoing Phase 2 studies described above may not be reflected in the final analyses of these trials including new cohorts within these trials; the results obtained in the Company's ongoing clinical trials, such as the studies and trials referred to in this release, may not be indicative of results obtained in future clinical trials or supportive of product approval; regulatory authorities may potentially delay the timing of FDA or other regulatory authority approval of, or other action with respect to, the Company's product candidates (specifically, the Company's description of FDA interactions are subject to FDA's interpretation, as well as FDA's authority to request new or additional information); the Company may not be able to obtain or maintain FDA or other regulatory authority approval of its product candidates; the Company's ability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical and safety requirements as well as manufacturing and control requirements; risks related to the Company's accelerated FDA review designations; the ability of the Company to obtain and maintain intellectual property rights relating to its product pipeline; and the acceptance by the market of the Company's product candidates and their potential reimbursement by payors, if approved.

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.

Leveraging Tumor Infiltrating Lymphocyte (TIL) to Address Unmet Need

Discovery | **Manufacturing Development, Clinical Program Establishment** | **Commercialization**

2011

TIL therapy conducted by Steven Rosenberg/NCI published results showing: 56% ORR[1] and 24% CR rate in melanoma patients, with durable CRs as an early line therapy[2]

2015

FDA Orphan Drug Designation for lifileucel in malignant melanoma

2016

First patient dosed for Gen 1 lifileucel in melanoma

Gen 2 manufacturing developed and transferred to CMOs

2017

Efficacy data from Gen 2 proprietary, centralized and commercial process presented

Head & Neck and Cervical studies began

FDA Fast Track Status for lifileucel in melanoma received

Partnership with MD Anderson on multiple solid tumors executed

Partnership with Ohio State University for PBL in hematological malignancies initiated

2018

European sites activated for Melanoma & Cervical

FDA RMAT designation for lifileucel in advanced melanoma received

FDA End-of-Phase 2 Meeting for lifileucel held

Lifileucel Cohort 2 clinical data showed 38% ORR in 47 patients, Median DOR: 6.4 months, DCR: 77% in with average 3.3 prior lines of therapy

2019

Begin enrollment for melanoma registrational cohort

Discuss registration path for cervical

Initiate building US manufacturing facility for commercial supply

Move TIL into earlier lines of therapy by combining with anti-PD/L-1 antibodies in CPI-naïve population

File IND for PBL in CLL

2020

Complete enrollment for registrational cohort in melanoma

BLA submission for lifileucel

[1] Rosenberg, S. A., *et al.* Clinical Cancer Research, 2011, 17, 4550
[2] Goff, S. L. et al. *Journal of Clinical Oncology*, 2016, 34(20), 2389-2397

IOVANCE

Leveraging Tumor Infiltrating Lymphocyte (TIL) to Address Unmet Need

Key Highlights

2017: Efficacy data from **Gen 2 proprietary, centralized and commercial process** generated and presented

2018: Lifileucel Cohort 2 data showed **38% ORR in 47 patients,** Median DOR: 6.4 months, DCR: 77% in patients with average 3.3 prior lines of therapy

FDA End-of-Phase 2 Meeting for lifileucel held FDA agreed with the single arm registration plan

2019: Begin enrollment for **melanoma registrational cohort** (fast to market registration plan)

IOVANCE

Investment Highlights

Leading cell therapy company focused on treatment of solid tumors

Large market opportunity starting in solid tumors

- Initial focus in post-checkpoint solid tumors
- Expansion into combinations and earlier lines of therapy
- Five company-sponsored programs in melanoma, cervical, head & neck, NSCLC

Accelerated path to approval in melanoma confirmed with FDA

- Single arm registrational cohort commencing in 2019
- BLA submission in melanoma expected in 2H 2020
- RMAT, Orphan Drug, and Fast Track Designations in melanoma

Efficient and scalable proprietary manufacturing

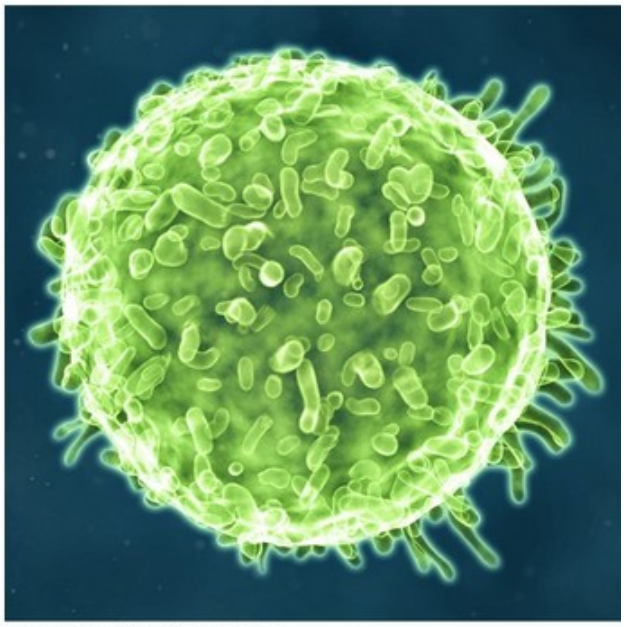
- Demonstrated U.S. and E.U. manufacturing capacity
- Rapid 22 day manufacturing with >90% success rate
- **100+ patients treated with proprietary Gen 2 process**

Broad platform: proof-of-concept applications are explored through partnerships

- Investigator-led programs to evaluate additional solid tumors or new combinations
- Touch points with institutions including NIH/NCI, Moffitt Cancer Center, MD Anderson, Roswell Park, and Ohio State University

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 single treatment
- Potential to establish immunological memory, requiring no additional maintenance therapy after infusion
  - Responses seen both in treatment naïve and refractory melanoma patients who have failed other options, including checkpoint inhibitors
  - Complete responses observed in cervical cancer patients, maintained at 53 and 67 months[1]



[1] Stevanovic, et al., Treatment of Metastatic Human Papillomavirus-Associated Epithelial Cancers with Adoptive Transfer of Tumor-Infiltrating T Cells, ASCO 2018, Abstract #3004

IOVANCE

Competitive Advantages of TIL in Solid Tumors

CHECKPOINTS	TCR	CAR-T (LIQUID TUMORS)	TIL (SOLID TUMORS)
Target multiple tumor antigens	Target only single tumor antigen	Mainly target only single/ surface tumor antigen	**Target multiple tumor antigens**
Long maintenance period	One-time treatment	One-time treatment	**One-time treatment**
Utility in several solid tumors	Few solid tumors treated so far	No examples of successful utility in solid tumors	**Available data in: melanoma, head & neck lung and cervical cancers**
Potential long-term irreversible toxicities	Potential on-target, off-tissue effects	Potentially immunogenic: cytokine release syndrome	**Minimal chance of unpredicted on-target, off-tissue effects found to date**
Off-the-shelf	Autologous	Autologous	**Autologous**

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

IOVANCE

Developed Centralized, Scalable and Efficient GMP Manufacturing

EXCISE: Patient's TIL are removed via surgical resection of a lesion

EXTRACT: Tumor is fragmented and placed in media for TIL to leave the tumor and enter media

EXPAND: TIL expanded via IL-2 + OKT3 exponentially *ex vivo* to yield $10^9 – 10^{11}$ TIL

PREPARE & INFUSE: Patient receives non-myeloablative lymphodepletion and is infused with their expanded TIL and IL-2

Process time: 22 days

Courier from clinical site

Co-culture TIL and feeder cells for expansion *ex vivo*

Harvest and cryopreserved TIL infusion product

Courier to clinical site for infusion

IOVANCE

Broad, Iovance-Owned IP Around TIL Therapy

Manufacturing

Multiple layers of patent applications filed for Gen 2 TIL products

- Iovance is pursuing claims covering cryopreserved TIL products, manufacturing processes and methods of treatment
- Includes two recently granted U.S. patents for methods of treatment in a broad range of cancers
  - U.S. Patent No. 10,166,257
  - U.S. Patent No. 10,130,659

Advanced technologies

Patent applications filed for a wide range of TIL technologies including

- Marrow infiltrating and peripheral blood lymphocyte therapies
- Use of costimulatory molecules in TIL therapy
- Stable and transient genetically-modified TIL therapies
- Patient subpopulations for TIL therapies

Significant Market Potential in Solid Tumors

90%

of all cancer cases are solid tumors

1.6M

New cases of solid tumors in the U.S.[1]

Move into earlier line of therapy →

Expand into other indications ↓

Solid Tumor Indication	Deaths[1]	New Cases[1]
Melanoma	9,320	91,270
Cervix Uteri	4,170	13,240
Oral Cavity, Pharynx & Larynx	13,740	64,690
Lung & Bronchus	154,050	234,030
Bladder	17,240	81,190
Breast	41,400	268,670
Pancreatic	44,330	55,440
Brain & Other Nervous System	16,830	23,880
	Potential to address unmet need in late lines of treatment	Potential market for early lines in combo with standard of care

[1] https://seer.cancer.gov

IOVANCE

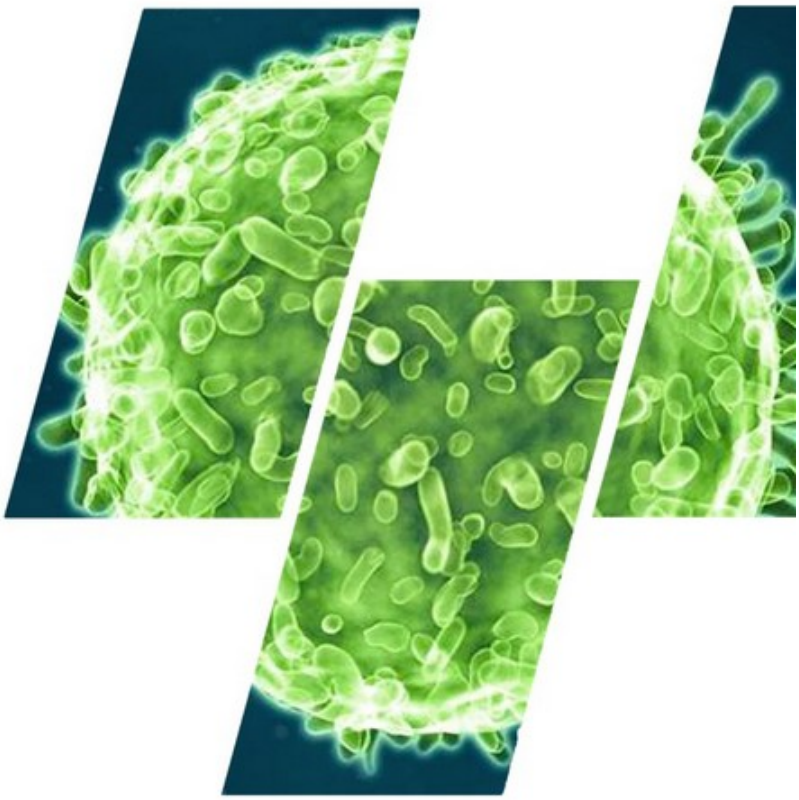
Current Clinical Pipeline and Select Collaboration Studies

	Regimen	Trial	Indication	N	Partner	Phase 1	Phase 2	Pivotal
Company sponsored studies	Lifileucel	C-144-01	Melanoma	164	—			
	LN-145	C-145-04	Cervical cancer	47	—			
	LN-145	C-145-03	Head & neck cancer	47	—			
	Lifileucel + pembrolizumab LN-145 + pembrolizumab LN-145	IOV-COM-202	Melanoma Head & neck Non-small cell lung	36	—			
	LN-145 + durvalumab	IOV-LUN-201	Non-small cell lung	12	MedImmune			
Select investigator sponsored proof-of-concept studies	MDA TIL	NCT03610490	Ovarian, sarcomas, pancreatic	~54	MD Anderson Cancer Network			
	LN-145	NCT03449108	Ovarian, sarcomas	~54	MD Anderson Cancer Network			

IOVANCE

IOVANCE
BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY



Metastatic Melanoma

Potential Market for Metastatic Melanoma

- Estimated **9,320** U.S. patients deaths due to melanoma in 2018[1]
- Limited options after progression on checkpoint and BRAF/MEK inhibitors
  - **4,950** U.S. patients are on 3rd and 4th line of therapy[2]
  - **6,282** U.S. patients are on 2nd line therapy[2]
  - **TIL is available as a 2nd line** for those who are BRAF WT (3rd line if BRAF mutant)

Metastatic Melanoma Facts

91k Diagnoses in U.S. each year[1]

9k Deaths in U.S. each year[1]

Available care: **immuno-therapy** as first line option

BRAF positive patients treated with BRAF/MEK inhibitors

ORR 4-10% Retreatment with checkpoint inhibitors or chemotherapy post progression on anti-PD1 and BRAF/MEK[3]

[1] https://seer.cancer.gov
[2] Decision Resources Group – Disease Landscape and Forecast for Malignant Melanoma- Reprinted with permission. © 2018 DR/Decision Resources, LLC
[3] Keynote-37 Trial Results

IOVANCE

Cohort 2, Phase 2 Trial in Metastatic Melanoma (C-144-01)

COHORT 2

Key inclusion criteria

- Measurable metastatic melanoma and ≥ 1 lesion resectable for TIL generation
- Progression on at least one prior line of systemic therapy including immune checkpoint inhibitor or a BRAF or BRAF/MEK
- Age ≥ 18
- ECOG PS 0-1

Endpoints

- Primary: efficacy defined as ORR by investigator per RECIST 1.1
- Secondary: safety and efficacy

Study updates

- Cohort 2 fully enrolled
- Data readout on 47 patients at SITC
- Cohort 4 (registrational) will enroll in 2019

CHARACTERISTIC	N=47 (%)
Prior therapies	
Mean # prior therapies (min, max)	3.3 (1-9)
Anti-PD-1	47 (100)
Anti-CTLA-4	37 (79)
BRAF/MEK	12 (26)
Target lesions sum of diameter (mm)	
Mean (SD)	112 (73)
Min, Max	17, 343
Baseline LDH (U/L)	
Median	246
1-2 times ULN	12 (26)
> 2 times ULN	7 (15)
Number of target & non-target lesions (at baseline)	
>3	37 (79)
Mean	6

"This is a heavily pre-treated cohort. There are usually pre-treated patients with only 1 line of therapy, but these patients in cohort 2 have on average 3.3 prior lines. Given there are no 2L/3L standard of care treatments, these patients got every treatment, and then some."

Dr. Diwakar Davar, Assistant Professor, Hillman Cancer Center

IOVANCE

Adverse Events Tend to be Early and Transient

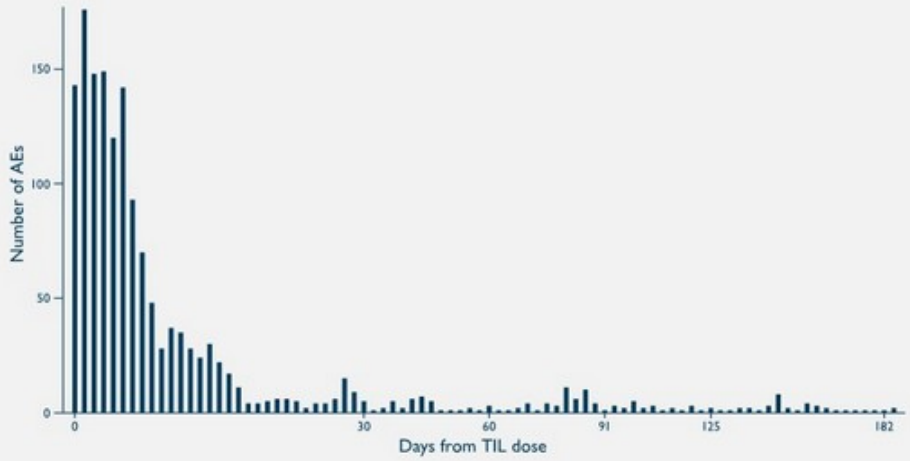
Frequency of AEs over time is reflective of potential benefit of one time treatment with TIL (lifileucel)

COHORT 2

Lifileucel Treatment-Emergent Adverse Events (≥ 30%)

PREFERRED TERM	Cohort 2 (N=47) Any Grade n (%)	Grade 3/4 n (%)	Grade 5 n (%)
Patients reporting at least one Treatment-Emergent Adverse Events[1]	47(100)	45 (95.7)	2 (4.3)
Thrombocytopenia	42 (89.4)	38 (80.9)	0
Chills	36 (76.6)	3 (6.4)	0
Neutropenia	29 (61.7)	25 (53.2)	0
Febrile neutropenia	28 (59.6)	25 (53.2)	0
Anemia	27 (57.4)	22 (46.8)	0
Pyrexia	25 (53.2)	7 (14.9)	0
Hypophosphatemia	23 (48.9)	17 (36.2)	0
Leukopenia	21 (44.7)	20 (42.6)	0
Fatigue	17 (36.2)	0	0
Hypotension	17 (36.2)	4 (8.5)	0
Lymphopenia	17 (36.2)	17 (36.2)	0
Tachycardia	15 (31.9)	1 (2.1)	0

Adverse Events Over Time



[1] Treatment-Emergent Adverse Events refer to all AEs starting on or after the first dose date of TIL up to 30 days
Patients with multiple events for a given preferred term are counted only once using the maximum grade under each preferred term. Safety terms which describe the same medical condition were combined.

IOVANCE

Lifileucel is Potentially an Efficacious Treatment for Patients with Limited Options

COHORT 2

- In heavily pretreated metastatic melanoma patients, preliminary efficacy is notable for:
  - **ORR 38%** (3.3 prior lines of therapy) vs. standard of care chemotherapy has ~10% ORR (in 2nd line)
  - **Median DOR is 6.4 months**, range 1.3+ to 14+
  - **Single treatment of TIL led to DCR of 77%** in late stage metastatic patients
  - Mean number of TIL cells infused: **26×10^9**
  - Median number of IL-2 doses administered was 6.0 as per protocol

RESPONSE	N=47 (%)
Objective Response Rate	**18 (38%)**
Complete Response	1 (2%)
Partial Response (PR + uPR[1])	17 (36%)
Stable Disease	18 (38%)
Progressive Disease	7 (15%)
Non-Evaluable	4 (9%)
Disease Control Rate	36 (77%)

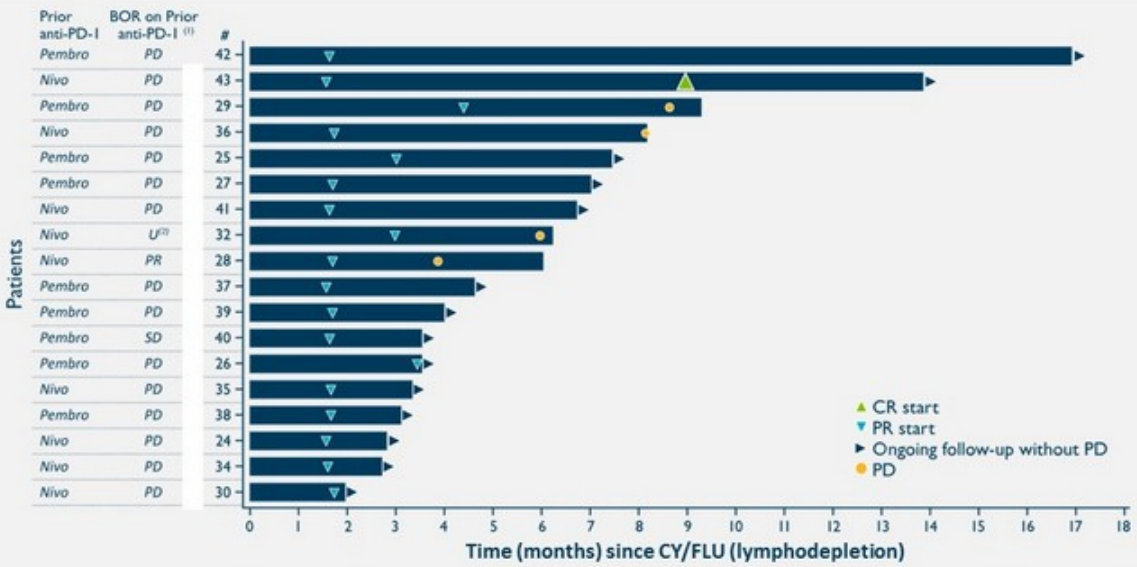
[1] Only one patient is uPR due to not having reached the follow on assessment as of end Dec 2018

IOVANCE

Responders from TIL Therapy had Progressed on Checkpoint Inhibitors

Lifileucel time to response and current duration of for evaluable patients (partial response or better)

COHORT 2



(1) BOR is best overall response on prior anti-PD-1 immunotherapy
(2) U: unknown best overall response on prior anti-PD-1 immunotherapy

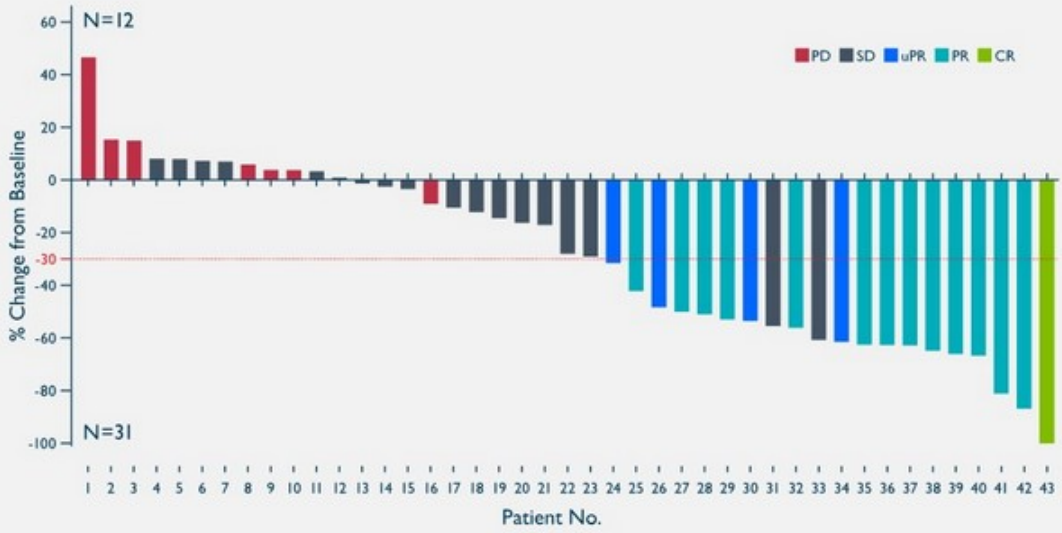
IOVANCE

TIL Therapy Provides Deep Responses

Lifileucel best overall response rate[1]

COHORT 2

- 72% of patients had a reduction in tumor burden
- Median study follow up is 6.0 months
- All assessments are by RECIST 1.1
- Responses are deep – nearly all responders are greater than 30%



[1] Per RECIST 1.1, two patients (31,33) had BOR of SD: met PR criteria at Day 42 and PD at Day 84 due to new lesions

IOVANCE

Lifileucel in Metastatic Melanoma Single-Arm Registrational Cohort 4

COHORT 4

Key inclusion criteria

- Measurable metastatic melanoma and ≥ 1 lesion resectable for TIL generation
- Progression on at least one prior line of systemic therapy including immune checkpoint inhibitor and if BRAF V600 mutation positive, BRAF or BRAF/MEK targeted therapy
- 75 patients

Endpoints

- Primary: efficacy defined as ORR by BIRC
- Secondary: safety and efficacy

Study updates

- Confirmed with FDA that a randomized Phase 3 study is not feasible in advanced melanoma post-CPI
- FDA has acknowledged acceptability of single-arm data for registration
- Enrollment to begin early 2019

Cohort 1:
Non-cryopreserved TIL product
N=30
Enrollment Closed

Cohort 2:
Cryopreserved TIL product (Gen 2)
N=60
Enrollment Closed

Cohort 4:
Cryopreserved TIL product (Gen2)
N=75

FDA

IOVANCE

Development Efforts in Late Stage (2L/3L) Melanoma Treatment

2L/3L melanoma treatment has no current standard of care

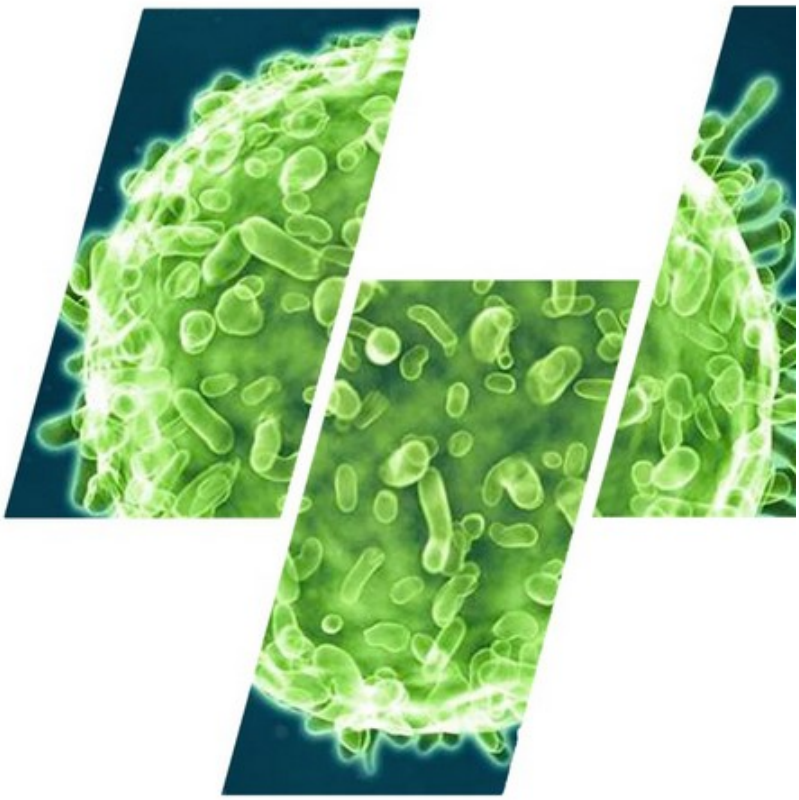
	Agent	ORR % (N)	Current Development Status	Prior Lines of Tx	Patient Characteristics
Combination with anti-PD-1	**TLR9 agonists, HDAC**				
	IMO-2125 (Idera) + ipi	29% (N=34)[1]	Phase 3, post-PD-1 melanoma (ILLUMINATE 204)	1-3	ECOG ≤1, intratumoral injection
	CMP-001 (CheckMate) + PD-1	22% (N=69)[2]	Phase 1b	1+	ECOG ≤1, intratumoral injection
	SD-101 (Dynavax) + PD-1	15% (N=13)[3]	Phase 1b	1+	ECOG ≤1
	Entinostat + pembro	18% (N=34)[6]	ENCORE 601 (phase 2, ongoing)	1+	ECOG ≤1
Single agent	**Checkpoints**				
	LAG-3	12% (N=61)[4]	Multiple 1L studies	1+	All comers, ECOG ≤2 • LAG-3 expression ≥1% (n=33) ORR=18%; • LAG-3 expression <1% (n=22) ORR=5%
	TIGIT, TIM-3	Unknown	Phase 1/2		
	Cytokines				
	HD IL-2	8% (N=9)[5]		1+	HD IL-2 post PD-1
	Other				
	TIL	**38%**	**Phase 2**	**3**	**All post-anti-PD1, 79% post anti-CTLA-4, 86% post-BRAF (if mutant)**

IOVANCE

[1] Idera Pharmaceuticals Results Dec 14, 2018
[2] Milhem M *et al.*, AACR 2018
[3] Ribas A *et al.*, Cancer Discovery 2018
[4] Ascierto P *et al.*, ESMO 2017
[5] Buchbinder EI *et al.*, JCO 2017
[6] Agarwala *et al.*, ASCO 2018

IOVANCE BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY



Cervical Cancer

Potential Market for Cervical Cancer

"TIL immunotherapy with LN-145 is literally redefining what is treatable and potentially curable in advanced metastatic chemo-refractory cervical cancer. Patients who only two years ago would be facing hospice as their only alternative now have access to this potentially life extending new treatment. This is the most exciting news in this field in decades."

Amir Jazaeri, M.D.
Director of the Gynecologic Cancer Immunotherapy Program in the Department of Gynecologic Oncology and Reproductive Medicine at MD Anderson

Cervical Cancer Facts

511k New Cases WW each year[1]

247k Deaths WW each year[1]

13k Diagnoses in U.S. each year[2]

4k Deaths in U.S. each year[2]

Available care: **Chemo-therapy** as first line option

For PD-L1 + patients, post-chemo receiving Keytruda[3] **ORR 14.3%**

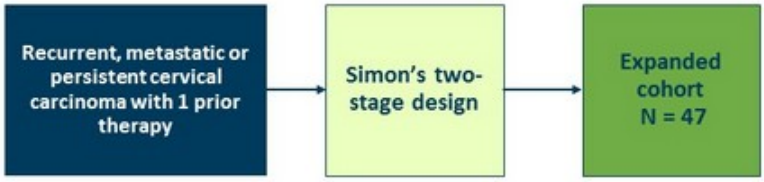
Post-chemo, **TIL ORR 28%** [4]

[1] Global Burden of Disease Cancer Collaboration, Global, Regional, and National Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-years for 29 Cancer Groups, 1990 to 2016: A Systematic Analysis for the Global Burden of Disease Study. JAMA Oncol. 2018 Nov 1;4(11):1553-1568. doi: 10.1001/jamaoncol.2018.2706
[2] https://seer.cancer.gov/
[3] https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf
[4] Stevanovic, et al., Treatment of Metastatic Human Papillomavirus-Associated Epithelial Cancers with Adoptive Transfer of Tumor-Infiltrating T Cells, ASCO 2018, Abstract #3004

IOVANCE

Phase 2 Trial in Cervical Cancer (C-145-04)

Phase 2, multicenter study to evaluate the efficacy and safety of autologous Tumor Infiltrating Lymphocytes (LN-145) in patients with recurrent, metastatic or persistent cervical carcinoma (NCT03108495)



Endpoints

- Primary: ORR
- Secondary: safety and efficacy

Key updates

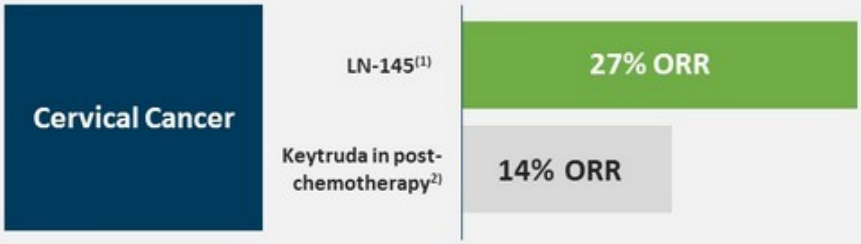
- Protocol amended to enroll patients with 1-3 prior therapies and exclude prior immunotherapy

BASELINE DEMOGRAPHICS	N=15[1] (%)
Prior therapies	
Median prior therapies (min, max)	5 (1, 8)
Anti-PD-1	8 (53)
Anti-CTLA-4	2 (13)

[1] The patients reported are a combination of Gen 1 and Gen 2 manufacturing processes

IOVANCE

TIL Offers a Favorable Treatment for Cervical Cancer Patients



- N=15
- **27% ORR**
  - 4 PRs (all confirmed)
- **DOR** (min, max): 2.4, 2.5+ months

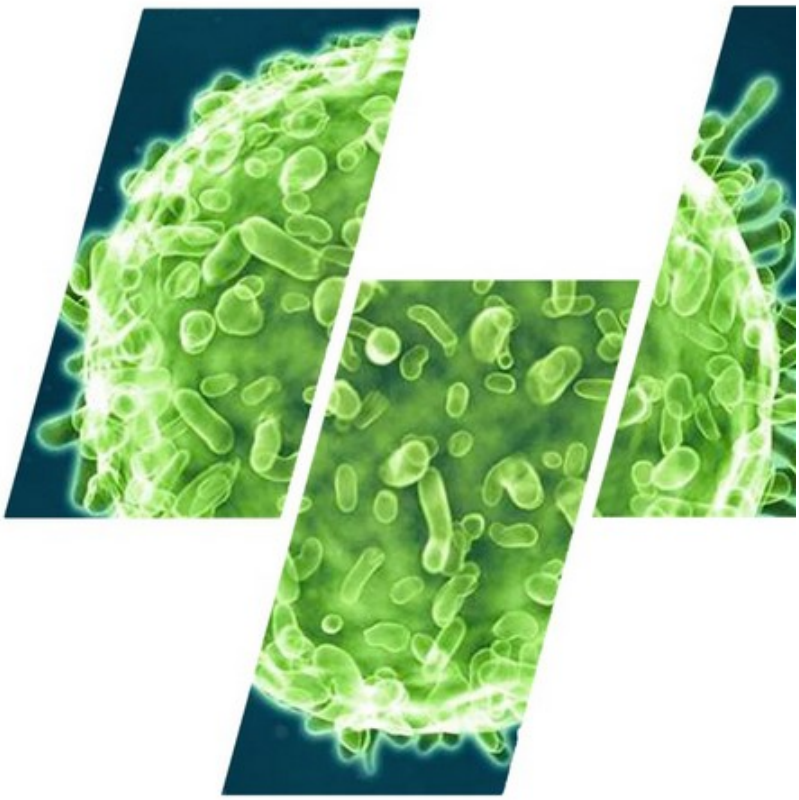
Treatment-Related Adverse Events[3]	
TEAE (≥40%), ANY GRADE	N=15 (%)
Chills	11 (73)
Pyrexia	8 (53)
Anaemia	7 (47)
Hypotension	6 (40)
Platelet count decreased	6 (40)
Vomiting	6 (40)

[1] The patients reported are a combination of Gen 1 and Gen 2 manufacturing process
[2] The composition of the relevant patient population may differ between Iovance trials and published data for CPIs (USPI used) but serves as a point of reference for assessing the overall efficacy landscape for relevant therapies
[3] Treatment-Emergent Adverse Events refer to all AEs starting on or after the first dose date of TIL up to 30 days

IOVANCE

IOVANCE
BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY



Head & Neck Cancer

Potential Market for Head & Neck Cancer

Head & Neck Cancer Facts

694k **New Cases WW** each year[1]

303k **Deaths WW** each year[1]

65k **Diagnoses in U.S.** each year[2]

14k **Deaths in U.S.** each year[2]

Available care in first line:

Chemotherapy and **Immunotherapy**

Anti-PD-1 immunotherapy as second line (Opdivo and Keytruda)

ORR 13-16% [3]

[1] Global Burden of Disease Cancer Collaboration, Global, Regional, and National Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-years for 29 Cancer Groups, 1990 to 2016: A Systematic Analysis for the Global Burden of Disease Study. JAMA Oncol. 2018 Nov 1;4(11):1553-1568. doi: 10.1001/jamaoncol.2018.2706

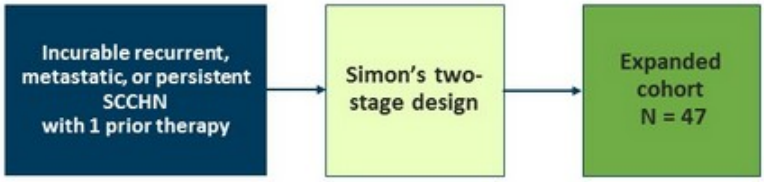
[2] https://seer.cancer.gov/

[3] The composition of the relevant patient population may differ between Iovance trials and published data for CPIs (USPI used) but serves as a point of reference for assessing the overall efficacy landscape for relevant therapies

IOVANCE

Phase 2 Trial in Head & Neck Cancer (C-145-03)

Phase 2 study to evaluate the efficacy and safety of autologous Tumor Infiltrating Lymphocytes (LN-145) for the treatment of patients with recurrent metastatic squamous cell carcinoma of the head and neck (NCT03083873)



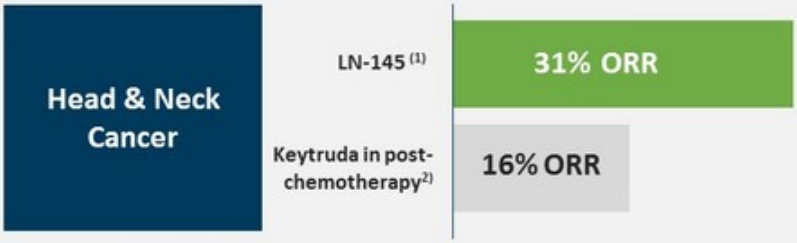
Endpoints

- Primary: ORR
- Secondary: safety and efficacy

BASELINE DEMOGRAPHICS	N=13 (%)
Prior therapies	
Median prior therapies (min, max)	3 (1, 5)
Anti-PD-1	11 (85)
Anti-CTLA-4	3 (23)
Number of target & non-target lesions (at baseline)	
>3	10 (77)

IOVANCE

TIL Offers a Favorable Treatment Option for Head & Neck Cancer in post-CPI Patients



- N=13
- **31% ORR**
- **4 PRs**
- DOR (min, max): 2.8, 7.6 months

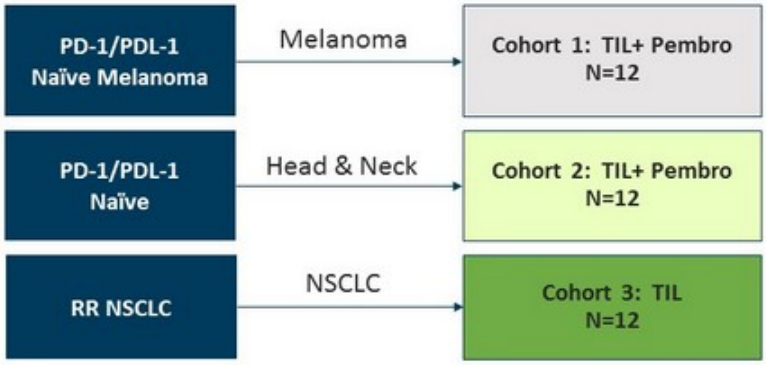
Treatment-Related Adverse Events[3]	
TEAE (≥40%), any grade	N=13 (%)
Chills	10 (77)
Hypotension	8 (62)
Hyponatremia	7 (54)
Pyrexia	7 (54)

[1] The patients reported are a combination of Gen 1 and Gen 2 manufacturing process
[2] The composition of the relevant patient population may differ between Iovance trials and published data for CPIs (USPI used) but serves as a point of reference for assessing the overall efficacy landscape for relevant therapies
[3] Treatment-Emergent Adverse Events refer to all AEs starting on or after the first dose date of TIL up to 30 days

IOVANCE

Investigation of TIL in Earlier Lines of Therapy in Combination with SOC

A Phase 2, Multicenter Study of Autologous Tumor Infiltrating Lymphocytes (LN-144 or LN-145) in Patients with Solid Tumors (NCT03645928)



Endpoints

- Primary: ORR and safety
- Secondary: CR rate

Key updates

- Six U.S. sites are activate
- First ex-U.S. Health Authority has approved the CTA (UK)

IOVANCE

Research Focus into Next Generation TIL

Expand the TIL platform into new indications

- Heme indication (OSU collaboration)
- Bladder cancer (Roswell Park Cancer Institute)

Prepare or select more potent TIL

- Use anti-4-1BB, anti-OX40, or other co-stimulants in cocktails in *ex vivo* growth of TIL
  - License to uses of 4-1BB agonists obtained from Moffitt Cancer Center
- Select more potent TIL

Genetically modify to make a more tumor-reactive TIL

- Cellectis TALEN® collaboration
- Phio RNAi collaboration

Identify biomarkers to find a better TIL product or better patient population

IOVANCE

Value Drivers for 2019

- **Single arm registrational trial** beginning in early 2019 aiming towards BLA in 2020
- **Manufacturing optimization** has demonstrated scalability and is moving towards commercialization
- **Strong balance sheet** providing three years of cash runway
- Multiple **shots on goal for proof-of-concept** studies through collaborations on additional indications, combination and earlier lines of therapy

Achieved and Upcoming Milestones

2018

- [x] Demonstrate consistent, scalable, rapid proprietary manufacturing method
- [x] Secure new IP around TIL technology and manufacturing
- [x] Secure adequate financing providing 3 years of runway
- [x] Demonstrate activity in melanoma post-checkpoint inhibitor (difficult to treat patients)
- [x] Align on registration pathway with FDA
- [x] Demonstrate activity in post-CPI cervical, head & neck tumors

2019

- [ ] Enrollment into Cohort 4 for C-144-01 in support of registration
- [ ] Continue the dialog with FDA for both LN-144 and LN-145 in support of registration
- [ ] Initiate building Iovance manufacturing facility
- [ ] Present updated data in cohort 2 for melanoma
- [ ] Present data from Gen 2 of cervical study
- [ ] Explore therapeutic potential of TIL in other indications
- [ ] File new IND for new manufacturing process and/or new indications

IOVANCE

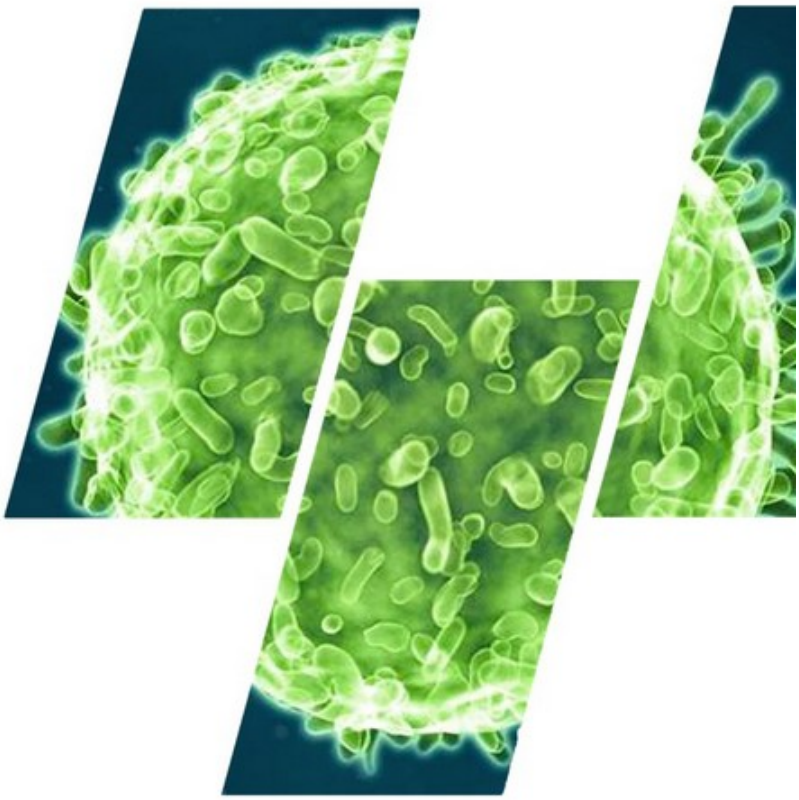
Well Capitalized in Pursuit of TIL Commercialization

	In millions - unaudited[2]
Common shares outstanding	123
Preferred shares	6[1]
Warrants/options/RSU's	7
Cash, cash equivalents, short-term investments	$469[3]
Debt	0

[1] Preferred shares are shown on an as-converted basis
[2] As of December 31, 2018. Financial numbers presented herein are unaudited preliminary estimates based upon currently available information and remain subject to review and adjustment by the Company's auditors.
[3] Based upon currently available information, there has been no material change to the liabilities of the Company since the last filed periodic report.

IOVANCE
BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY



Thank you