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): October 26, 2017

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 7.01. Regulation FD Disclosure.

Iovance Biotherapeutics, Inc. (the "Company") from time to time makes presentations to analysts, current stockholders and others. A copy of the Company's October 2017 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, unless the Company expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01 Financial Statements And Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Iovance Biotherapeutics, Inc., Corporate Presentation-October 2017.

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: October 26, 2017

IOVANCE BIOTHERAPEUTICS, INC.

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

Exhibit 99.1


IOVANCE
BIOTHERAPEUTICS
ADVANCING IMMUNO-ONCOLOGY
Manufacturing Tour at Wuxi AppTec
October 26, 2017
© 2017, Iovance Biotherapeutics

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.

Manufacturing Capacity in US and EU

- Clinical and commercial manufacturing capabilities are in place in the US and EU
  - WuXi established at multiple suites in US
  - LonzaNL (formerly PharmaCell) tech transfer in process in EU
- All currently planned clinical studies can be supported with available capacity
- We chose WuXi because additional capacity exists and our commercial capacity is fully scalable at this site
  - 55,000 ft² ISO accredited facility operating under strict cGMP compliance
  - Designed to meet US and EU requirements
  - Continuous monitoring of equipment and environment
  - Back up redundancy
  - Produce multiple products and tumor type in suite at same time
  - Expand to additional suites and/or utilize existing personnel to meet demand
  - Separation of in-flow and out-flow of all materials

IOVANCE BIOTHERAPEUTICS

Manufacturing Capacity

Adequate Manufacturing Capacity and IP Rights

- Iovance's manufacturing process is centralized at the following CMO sites:
  - Lonza, Walkersville
  - Wuxi AppTec
  - Moffitt as CMO
  - LonzaNL (EU)
- Iovance developed the Gen 1 process through modification of the NCI's TIL manufacturing method. **Gen 2 and all manufacturing SOPs were developed by Iovance.**
- Iovance has certain IP rights relating to the method of manufacturing used by Polybiocept (PBC) and MDA

		IOVANCE BIOTHERAPEUTICS GENERATION		polybiocept	MD Anderson Cancer Center
#	INDICATIONS	1	2	IL-2, 15, 21	41BB
1	Melanoma	Lonza	Moffitt/Wuxi		
2	Cervical	Wuxi			
3	Head and Neck	Wuxi			
4	Pt Resistant Ovarian	Wuxi			MDA
5	Chondrosarcoma	Wuxi			MDA
6	Soft tissue sarcoma	Wuxi			MDA
7	Pancreatic ductal carcinoma				MDA
8	GBM			PBC	
9	Pancreatic			PBC	

Manufacturing IP rights

Accomplishments and Upcoming Objectives

COMPLETED

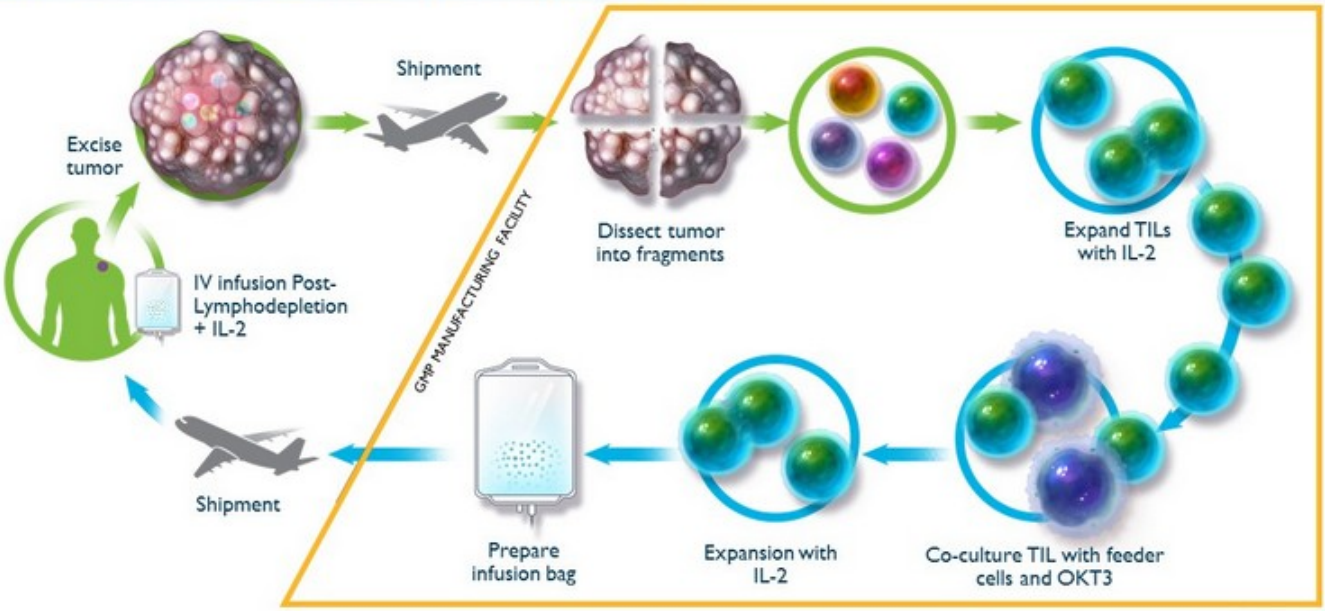
- ✓ Development of a new manufacturing cycle from 5-6 weeks to under 3.5 weeks
- ✓ Complete tech transfer and ramp volumes at WuXi AppTec and H. Lee Moffitt Cancer Center and Research Institute
- ✓ Continue working with Lonza
- ✓ Expand capacity into additional CMOs
  - ✓ *LonzaNL (EU)*
- ✓ Continue efforts to reduce manufacturing cycle time and costs

ANTICIPATED

- Continuous improvement in process development:
  - Component Optimization
  - Staffing optimization
- Select Generation 1 or 2 process
- Additional data on alternative processes
- Establishment of TrakCel Integrated Scheduling Solution
- First clinical product manufactured in Europe in early 2018

Iovance Manufacturing Process & Logistics

Gen 1 Duration: ~5-6 Weeks
Gen 2 Duration: ~3.5 Weeks Cryopreserved Product



WuXi US Clinical & Commercial Manufacturing Facility

Commercial Cell Therapy Center of Excellence

Commerce Center 3

- 55,000ft² manufacturing site
- Warehouse space
- In-process QC testing
- Compliant with US & EU regulations
- Up to 8-10 large GMP manufacturing suites

Clinical Cell Therapy Center of Excellence

League Island Blvd 1

- 16,000ft² manufacturing area in 75,000 SF facility
- Warehouse space
- In-process and release QC testing
- CBER & CDER registered
- 15 small/medium GMP Manufacturing suites + 6 cell banking suites

IOVANCE BIOTHERAPEUTICS

WuXi US Clinical & Commercial Manufacturing Facility

- Separation of in-flow and out-flow of all materials

Tumor Harvest & Shipment to Manufacturing

- Once resected tumor is placed in a bottle with media and packaged in accordance with validated shipping procedures
- Courier is notified days before scheduled pickup and arrives at site to receive package
- In conjunction with couriers we employ next flight out strategies with commercial airlines and delivers tumor to CMO for processing
- Built in redundancy with flights to ensure on-time delivery to manufacturing
- Process will be automated with the TrakCel implementation capturing chain of custody to courier, uploading forms and alerting all parties on ETA at CMO

CC3: Inbound Tumor Receipt and Gowning

- In-bound:
- In-bound receipt area where tumor is received
- Delivered by courier and verified by a unique site and patient number
- Product is matched with WuXi lot number
- Temperature data downloaded and product is delivered to manufacturing

- Gowning:
- Process necessary to enter manufacturing facility
- Ensure standard of cleanliness of a room depending on room classification
- To protect the product being manufactured

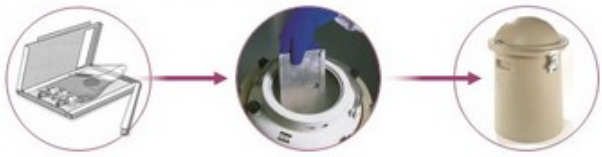
IOVANCE BIOTHERAPEUTICS

CC3: Manufacturing and Final Packaging/Cryopreservation (Gen 2)

- Manufacturing receives tumor
- Tumor is fragmented into approximately 3x3x3mm
- Placed into cell culture device with media
- Various media exchanges, transferred to larger cell culture devices, volume reduced and filled into final product bags

- Controlled rate freezing and LN2 storage area
- Courier notified to provide Cryoshipper in conjunction with manufacturing completion
- Prepare shipment utilizing validated procedures for cryofreezing product and loading into cassette racks and into Cryoshipper
- Real-time temperature monitor and GPS features

1. Inbound Tumor Receipt
2. Gowning
3. Manufacturing
4. Cryopreservation



TIL bag placed in cassette

Cassette placed in Cryoshipper

Cryoshipper ready for pickup by courier

IOVANCE BIOTHERAPEUTICS

Gen 2 Manufacturing Process

- 3.5 week cell expansion process with a cryopreserved product delivered to clinical sites for patient infusion
- Robust, efficient and scalable process
- Provides flexibility to manufacturing and clinical sites
- Provides flexibility to sites for infusion schedules due to cryopreserved final product
- Reduced COGS
- Additional data on attributes of Gen 2 manufacturing to be presented at SITC

TrakCel: Integrated Scheduling Solution

- In September 2017, announced new partnership with TrakCel
  - An automated process integrating scheduling, capacity and logistics throughout the supply chain

- **Compliance** – 21 CFR Chapter 21 compliant with electronic audit record. Maintains traceability through effective chain of identity and custody process
- **Resource Optimization** – Efficient management of internal and external resources which will streamline the scheduling process and enable scalability
- **Improved Visibility** – Provide real time visibility to selected stakeholders across the supply chain
- **Improved Communications** – Provide a tool to improve communication with collection centers/clinical sites and CMOs to improve service and confidence
- **Customer-Friendly Experience** – Simplifies and streamlines the experience for physicians and other third parties

U.S. Manufacturing and Testing | 药明康德 WuXi AppTec

Biologics • Advanced Therapies • Medical Devices

Cell & Gene Therapy Manufacturing

Our Journey

2017 Global Platform

U.S. Manufacturing and Testing | WuXi AppTec
Biologics • Advanced Therapies • Medical Devices

2017

16,000+ employees worldwide

>5 million ft^2 existing & upcoming R&D space leading capability and technology platform

Our Platform

Comprehensive R&D Enabling Capabilities

U.S. Manufacturing and Testing | WuXi AppTec
Biologics • Advanced Therapies • Medical Devices

Small Molecules

Biologics

Cell & Gene Therapies

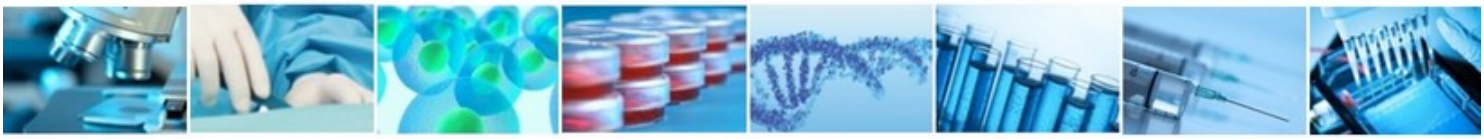
Medical Devices

Molecular Testing and Genomics

U.S. Manufacturing and Testing | 药明康德 WuXi AppTec

Biologics • Advanced Therapies • Medical Devices

Manufacturing Experience / Capabilities



Philadelphia Facilities

U.S. Manufacturing and Testing | WuXi AppTec
Biologics • Advanced Therapies • Medical Devices

Cell & Gene Therapy Manufacturing and Testing

75,000 SF - *QC Testing, PD, Cell Therapy Manufacturing*

THE NAVY YARD
PHILADELPHIA

55,000 SF - *Manufacturing for Autologous / Allogeneic Cell Therapies*

150,000 SF - *CAR-T Cell Therapies and Gene Therapy Manufacturing*

Manufacturing Team

U.S. Manufacturing and Testing | WuXi AppTec
Biologics • Advanced Therapies • Medical Devices

Cell Culture, PD and Tech Transfer Teams (~200 staff Q1 2017)

- Cross trained for Cell Banking and Cellular Therapeutics processing
- 7 days a week coverage
- Currently 2 shifts - Sun-Wed and Wed-Sat; with Manufacturing Supervisors

Quality Assurance Team

- QA Raw Materials
- QA Manufacturing
- QA Validation

Environmental Monitoring Team

- Facility, equipment, personnel monitoring

Metrology Team

- Calibration, maintenance

Facilities Team

- Facility Maintenance

Chain of Identity (COI)

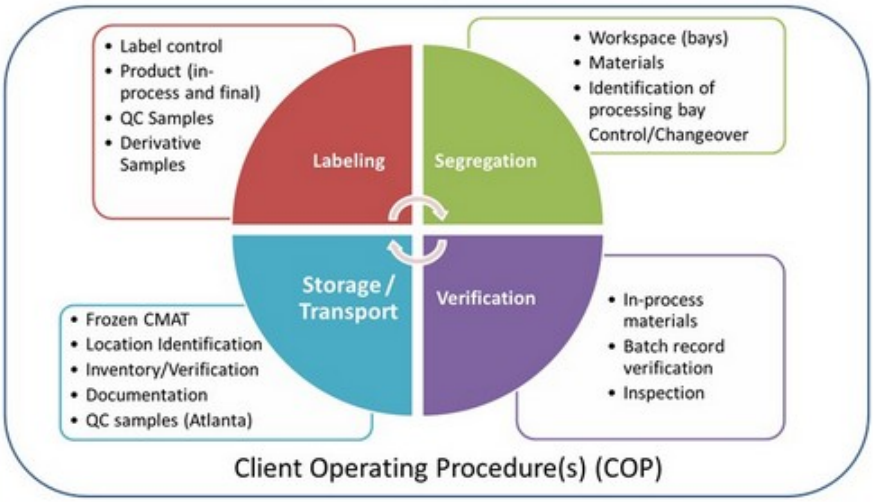
Meeting FDA Expectations

U.S. Manufacturing and Testing | WuXi AppTec
Biologics • Advanced Therapies • Medical Devices

- Tracking of all products from the donor to the consignee or final disposition, and from consignee or final disposition to donor (21 CFR 1271.290(b))
- Appropriate patient identifiers and procedures to prevent product mix-ups
- Procedures in place to ensure product segregation

Keith Wonnacott, PhD, The Office of Cellular, Tissue, and Gene Therapies Web Seminar Series, Cellular Therapy Products

WuXi AppTec Program for COI



Facilities for CT Manufacturing

FDA and EMA Expectations

U.S. Manufacturing and Testing | WuXi AppTec
Biologics • Advanced Therapies • Medical Devices

- Establish adequate facility and equipment performance standards and monitoring plans
- Ensure aseptic environment for cell processing through design and monitoring*
- Use closed systems where possible
- Use disposable equipment and process aids
- Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing -- Current Good Manufacturing Practice - 9/29/2004

Keith Wonnacott, PhD, The Office of Cellular, Tissue, and Gene Therapies, U.S. FDA, Web Seminar Series, Cellular Therapy Products

*Current European Union (EU) requirements for aseptic processing environments are more stringent than US FDA requirements – All New WuXi AppTec CFT/GT Manufacturing Facilities are designed to meet both US and EU requirements.

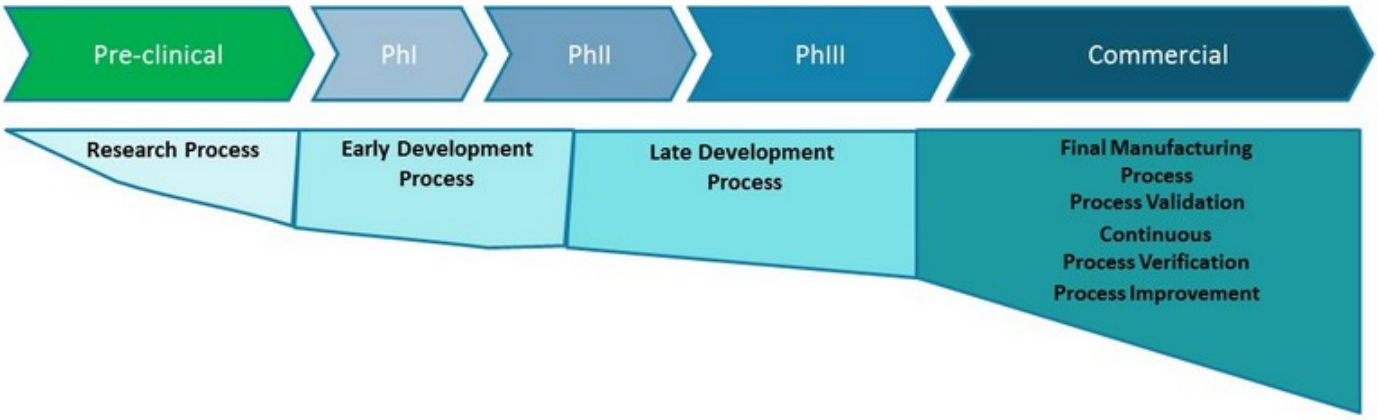
WuXi AppTec 3 Commerce Center

Process Development for Commercialization

U.S. Manufacturing and Testing | WuXi AppTec
Biologics • Advanced Therapies • Medical Devices

Early and Late Phase Development Program

- The development of a sustainable manufacturing process is a key aspect of preparing a product for marketing approval and commercialization, and consideration should be given at the earliest phases of development.
- However, to provide rapid entry to the clinic, WuXi applies a two-tier development paradigm (EDP/LDP) to most advanced therapies. A single development cycle may be possible in some cases where program timelines allow.



Capabilities – Cell Therapies

Established QC & Analytical Testing

U.S. Manufacturing and Testing | WuXi AppTec
Biologics • Advanced Therapies • Medical Devices

- GMP Cell Banking & Characterization
- Viral Bank Safety & Characterization
- Raw Material Testing
- Extractables / Leachables Testing
- Lot Release / Stability Testing
  - Mycoplasma(PCR, Points To Consider, EP)
  - Sterility(USP, BacT Alert) • Endotoxin
  - Purity (Residuals – multiple methods)
  - Potency (cell-based and/or other functional assays)
  - Virus / Retrovirus testing (endogenous & adventitious agents)
  - Identity *(Karyology, Flow Cytometry, qPCR for Expression)*

IOVANCE BIOTHERAPEUTICS

ADVANCING IMMUNO-ONCOLOGY

Manufacturing Tour at WuXi AppTec

October 26, 2017