

TaiMed Biologics, Inc.

September 2018

Corporate Structure

- TaiMed Biologics, Inc. in Taipei, Taiwan
 - Corporate Headquarter/Administration
 - Finance/Accounting
 - Research & Development (GMP Analytical Lab)
- TaiMed Biologics, HsinChu Branch, Taiwan
 - Manufacturing Operations
 - QA/QC
 - Supply Chain Management
- TaiMed Biologics USA in Irvine, CA, USA
 - Clinical
 - Regulatory
 - Business Development

Financial Status

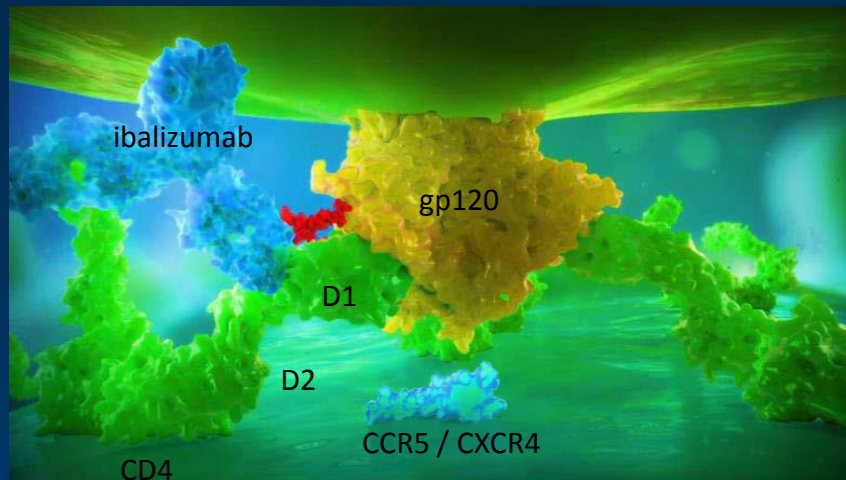
- TaiMed has been a publicly traded company on the Taipei Exchange Emerging Stock Market (stock code: 4147) since 2010.
- IPO on Nov 23, 2015 and traded on the Taipei Exchange Market (OTC)
- Current market cap is approximately USD\$2 Billion
MSCI standard index from May, 2016
- Ruentex hold ~17% of TaiMed
National Development Fund hold ~16% of TaiMed
- Shareholders exceed 24,000 (April, 2018).

Fundraising History

- Raised a total of USD\$208M through four fundraising rounds :
 - First round (2007-2008) — USD\$30M
 - Second round (2010) — USD\$22M
 - Third round (2014) — USD\$46M
 - Forth round for IPO (2015) — USD\$110M
- Cash in hand as of 6/30/2018 : USD\$85M
- Total shares outstanding : 250M

TROGARZO (ibalizumab) – Now Available (in US)!

- Humanized monoclonal antibody being developed for the treatment of multidrug resistant (MDR) HIV-1 infection
- Binds primarily to the second extracellular domain of CD4+ T cell receptor, away from MHC II molecule binding sites



- Prevents HIV from infecting CD4+ T cells while preserving normal immunological function

Milestones

Ibalizumab (TMB-355)

- US Market Launch – 4/30/2018
- The FDA granted approval of Trogarzo (trade name for ibalizumab) to TaiMed Biologics - 3/6/2018 (US time)
 - First HIV treatment approved with a new mechanism of action in more than 10 years
 - First monoclonal antibody for MDR HIV-1
 - Only ARV that does not require daily dosing (infused q2w)
- Completed Phase III trial – 11/2016 (US, TW)
- Granted US FDA breakthrough designation therapy for MDR patients in IV dosage form – 2/2015
- Granted US FDA orphan drug designation for MDR patients – 10/2014



The phase III clinical trial used to obtain FDA approval for Trogarzo™ (ibalizumab-uiyk) injection in the United States were published in the most recent edition of The New England Journal of Medicine

[NEJM Group](#) [Follow Us](#) [Sign in](#) [Create Account](#) [SUBSCRIBE](#)

 The NEW ENGLAND
JOURNAL of MEDICINE [SUBSCRIBE OR RENEW](#)   

This article is available to subscribers. [Sign in](#) or [Subscribe](#).

ORIGINAL ARTICLE [FREE PREVIEW](#)

Phase 3 Study of Ibalizumab for Multidrug-Resistant HIV-1

Brinda Emu, M.D., Jeffrey Fessel, M.D., Shannon Schrader, M.D., Princy Kumar, M.D., Gary Richmond, M.D., Sandra Win, M.D., Steven Weinheimer, Ph.D., Christian Marsolais, Ph.D., and Stanley Lewis, M.D.

Abstract

BACKGROUND Ibalizumab, a humanized IgG4 monoclonal antibody, blocks the entry of human immunodeficiency virus type 1 (HIV-1) by noncompetitive binding to CD4.

METHODS In this single-group, open-label, phase 3 study, we enrolled 40 adults with multidrug-resistant (MDR) HIV-1 infection in whom multiple antiretroviral therapies had failed. All the patients had a viral load of more than 1000 copies of HIV-1 RNA per milliliter. After a 7-day control period in which patients continued to receive their current therapy, a loading dose of 2000 mg of ibalizumab was infused; the viral load was quantified 7 days later. Through week 25 of the study, patients received 800 mg of ibalizumab every 14 days, combined with an individually optimized background regimen including at least one fully active agent. The primary end point was the proportion of patients with a decrease in viral load of at least 0.5 log₁₀ copies per milliliter from baseline (day 7) to day 14.

RESULTS A total of 31 patients completed the study. The mean baseline viral load was 4.5 log₁₀ copies per milliliter, and the mean CD4 count was 150 per microliter. Of the 40 patients in the intention-to-treat population, 33 (83%) had a decrease in viral load of at least 0.5 log₁₀ copies per milliliter from baseline ($P < 0.001$ for the comparison with the control period). The mean viral-load decrease was 1.1 log₁₀ copies per milliliter. During the control period, 1 patient, who received the optimized background regimen prematurely, had a decrease in viral load of 0.5 log₁₀ copies per milliliter. At week 25, patients

August 16, 2018
N Engl J Med 2018; 379:645-654
DOI: 10.1056/NEJMoa1711460

[Purchase this article](#)
[Print Subscriber? Activate your online access.](#)

Related Articles

PERSPECTIVE AUG 16, 2018
Ibalizumab in Multidrug-Resistant HIV — Accepting Uncertainty
V. Sheikh and Others

TaiMed Is Committed to HIV Drug Development with a Solid Pipeline

TMB-607

- Protease inhibitor
- Phase I clinical trial underway (IND sponsored by Temple University)

TMB-365

- Ibalizumab-based, IgG1-scaffold, also blocks domain 2
- FcRn, LM52 glycan modifications
- Broader, wider viral coverage range and higher, greater anti-infectivity against HIV
- PK/GLP Tox study underway

TMB – Bispecific

- Bispecific neutralizing antibody targets two different antigens
- One targets CD4 like ibalizumab while the other targets gp120
- Currently in preclinical development

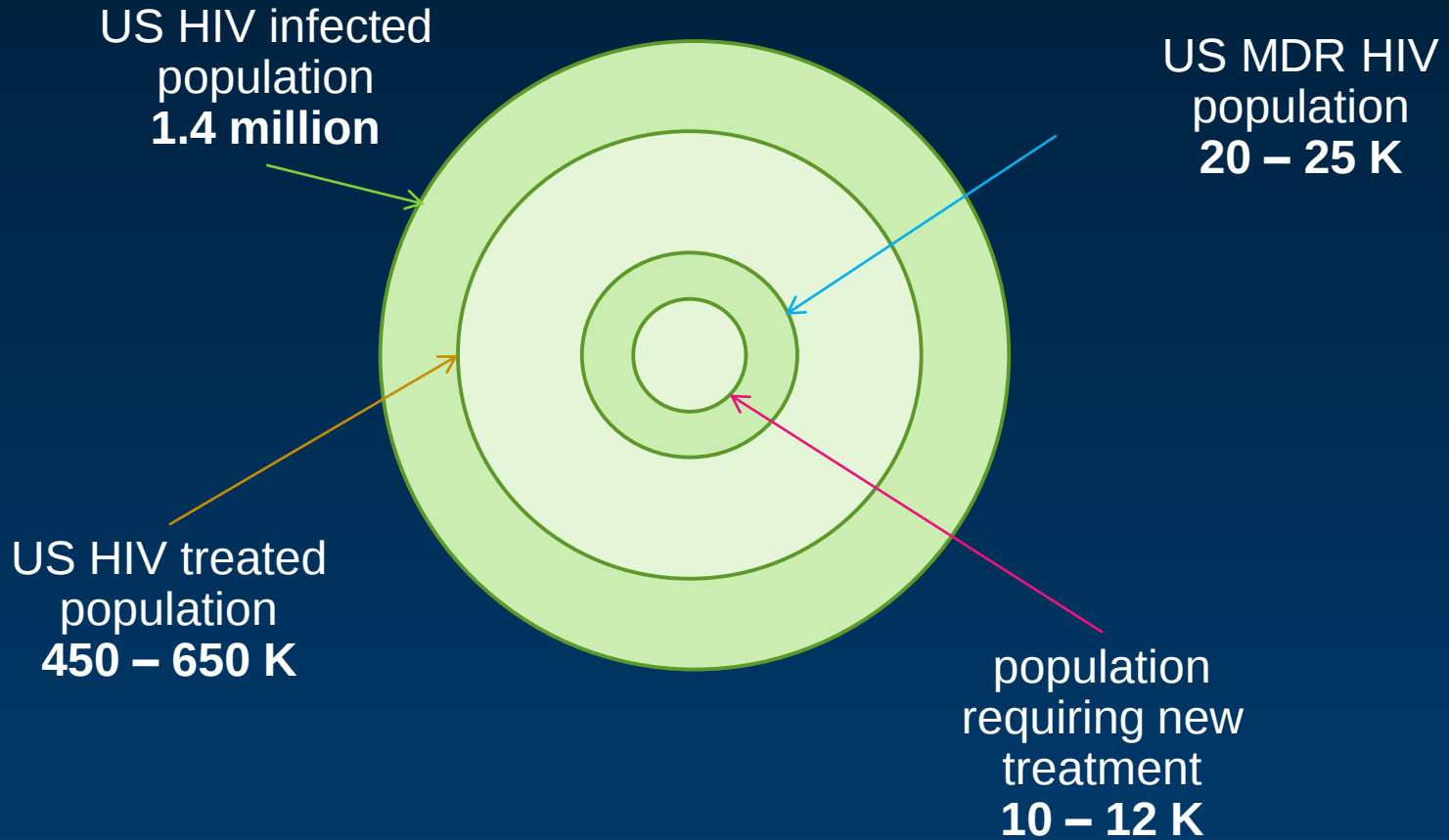
TMB – ADC

- Antibody-drug conjugate
- Tripartite drugs comprising a target-specific mAb conjugated to a potent HDAC inhibitor via a stable linker
- Currently in discovery

2018 2H Target for Operations

- Prepare the Trogarzo submission for EMA regulatory approval in Europe
 - Review will be under the accelerated assessment procedure
 - Initiation of paediatric investigation plan deferred
- Phase III start of Trogarzo IV push proposal in US
- Pre IND meeting with FDA for TMB-365 in US
- Phase I start of Bi-specific in US at the end of Q4
- Continuing phase 1 of TMB-607 in US

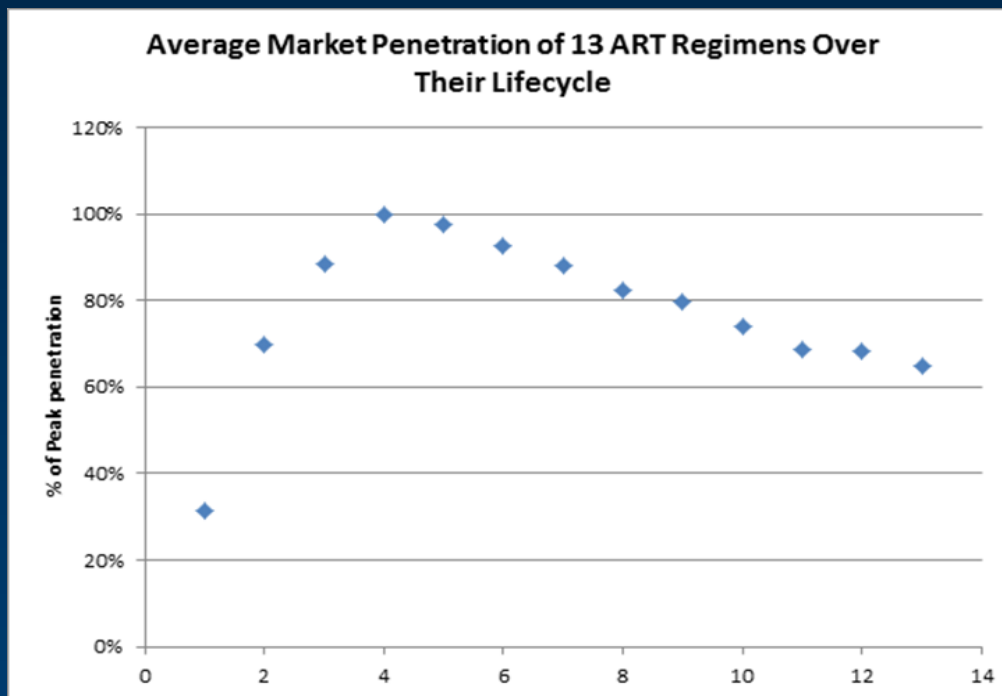
Trogarzo US Addressable Market*



*EU patient population is of similar size

Research for Market Trend

- Our sales and marketing partner - Theratechnologies
- Thera expects to complete the private and public insurance coverage in 2018
- In-line with expectations for the product launch
- Trogarzo should mimic the uptake of other successful HIV product launches



Theratechnologies Partnership

	North American Agreement	European Agreement
Date of agreement	March 18, 2016	March 6, 2017
Term	12 years from FDA approval	12 years from approval (country-by-country basis)
Transfer Price	52% of Net Sales	52% (57% of annual sales exceeding US\$50M in European Territory)
Payment at signature	US\$1M (cash)	US\$3M (common shares)
Upfront and launch milestone	US\$4M (common shares) US\$5.5M (cash – payable through an increase in transfer price)	US\$5M (cash – payable one year after launch) US\$5M (cash – payable once EU sales reach US\$50M)
Development milestones	US\$3M (Intramuscular administration approval)	50% of European clinical trial costs (if any)
Commercial milestones	Up to US\$207M upon reaching various sales levels (up to US\$1B) and label expansion objectives	Up to US\$80M upon reaching various sales levels (up to US\$1B)

Accounting Treatment for Theratechnologies contract

	IFRS 15“Revenue from Contracts with Customers”	IAS 18 “Revenue”
Effective Date	From January 1, 2018	Before December 31, 2107
Transfer Price	52% of Net Sales at the completion time of sales	52% of Net Sales at the completion time of sales
Valuation on shares received	Thera shares are measured at fair market value. The changes in the carrying amount of shares are recognized in non-operating income	Thera shares are measured at fair market value. The changes in the carrying amount of shares are recognized in other comprehensive income
Cash and shares upfront and launch milestone (including US\$5.5M milestone)	Recording as liability-“performance obligation” at the time of upfront received or milestone achieved . Recognizing revenue based on expected sales volume-based method at the drug launch time or development milestone achieved.	The upfront payments and development milestone payments are recognized according to the degree of performance over the estimated performance period stipulated in the agreement on a straight-line basis;
Development milestones		
Commercial milestones	Evaluate, on an on-going basis, each milestone in the contract to determine whether including an estimate of variable consideration in the transaction price at the drug launch time, using the most likely amount method.	the commercial milestone payments are recognized as revenue when the commercial milestones are achieved and the revenue is not expected to be reversed.
Adjustment for amortization	Estimate adjustment if significant change in expected sales volume.	straight-line based amortization except for amendment of contract periods.

Note: the above accounting treatment is only suitable for TaiMed.

Taimed Biologics Zhubei

(Manufacturing Operations)

Taimed Biologics Zhubei

- cGMP Biologics Manufacturing Facility
 - Process Development and Manufacturing
 - QC Release and Quality Assurance
 - Global Supply Chain Management
 - 3rd Party Contract Manufacturer Management



Facility Location



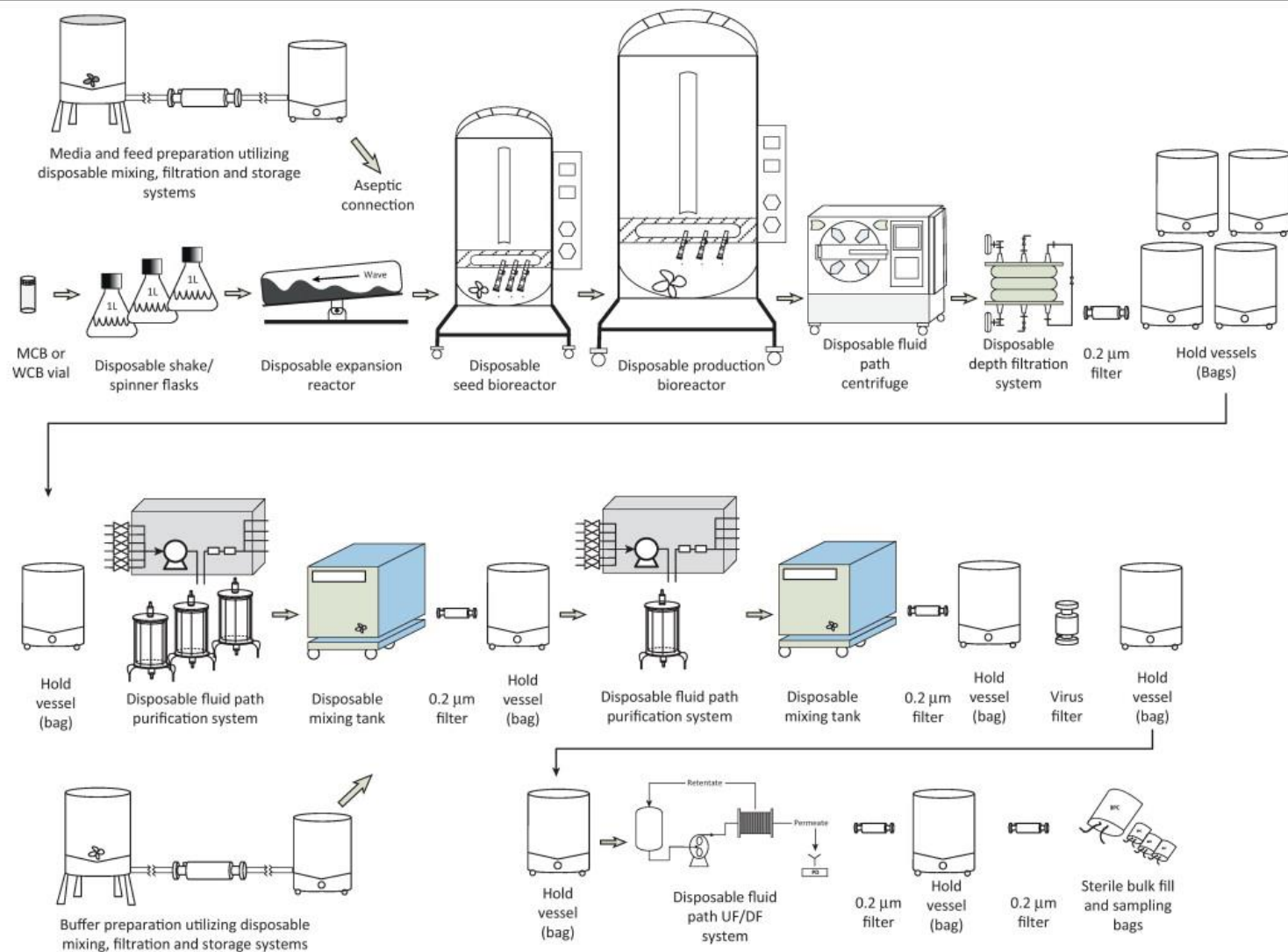
Facility Overview

- State-of-the-Art Five Story Building with $\sim 5500 \text{ m}^2$ (Production Area is 1142 m^2)
- 1F: Warehouse
- 2F:
 - QC and Microbiology Labs – Routine release and stability testing, environmental monitoring
 - Process development Lab – Process development & characterization, scale-up and optimization
- 3F: Biologics production area
- 4F: Cold chain storage of intermediates, drug substance and finished goods

Facility Design Principles

- Maintain equipment “sameness” between Zhubei facility and Wuxi Biologics to ensure high level of product comparability
- Use of single-use technology to maximize manufacturing efficiency and minimize product contamination risks
- One 500L and four 2000L single-use bioreactors (SUB) to maintain manufacturing flexibility to produce both commercial and clinical batches
- Full production capacity is 48 batches @ 4000L scale

Biologics Manufacturing Process



TRENDS in Biotechnology

Firms and Vendors

- cGMP Facility Design:
 - Facility design with Nova Pharma Solutions (Malaysia) and BPTC (USA)
- Facility Construction:
 - Ruentex Engineering & Const.Co (潤弘精密公司) – Building design and construction
 - China Ecotek (中宇環保) – Facility & utility engineering, cleanroom
- Production Equipment:
 - Alfa Laval, Merck, Sartorius, ThermoFisher, etc.

Timeline

- Ground-breaking ceremony – June 2017
- Topping-out ceremony – Nov 2017
- Obtained building use license – Feb 2018
- Initiated facility utility engineering and interior construction project – Mar 2018
- Target facility completion – Sept 2018

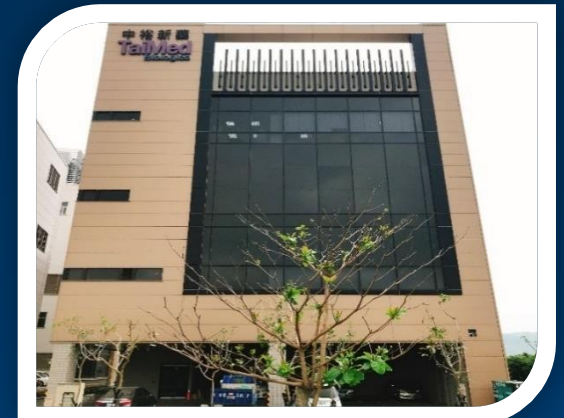
Total Investment NT\$1B



9/2017



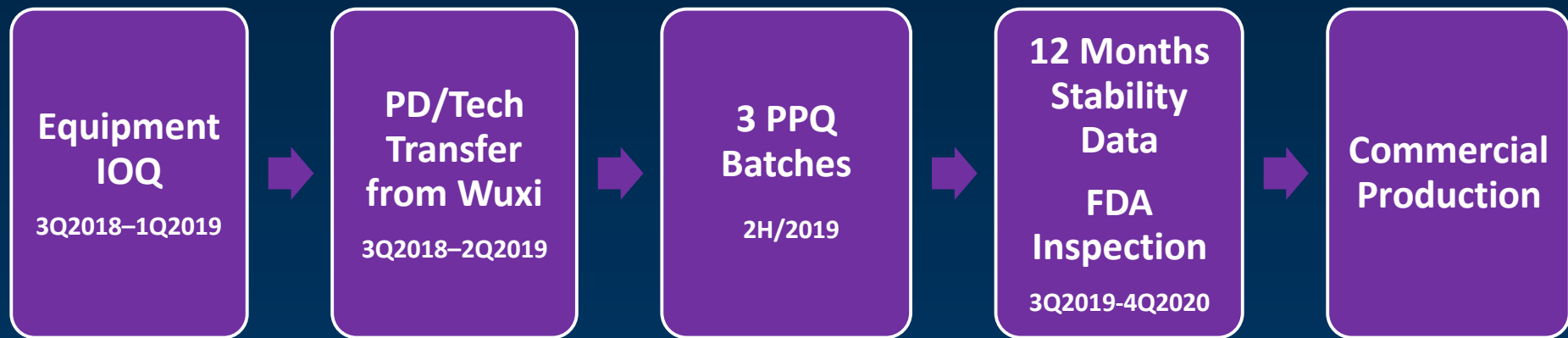
10/2017



4/2018
中裕新藥

TaiMed
Biologics

Timeline



Organization Chart



Trogarzo Supply Chain (US Market)



Thank You
Q & A