Laurus Labs

July 23-27, 2018
IAS Conference, Amsterdam

Overview – Laurus Labs

FOUNDING PRINCIPLES

VISION

To become a leading player in offering integrated solutions to global pharmaceutical needs in creating a healthier world.

MISSION

We constantly strive for innovation to enhance quality and to provide affordable integrated pharmaceutical solutions to facilitate wellness and wellbeing across the globe.

OUR VALUES

KNOWLEDGE

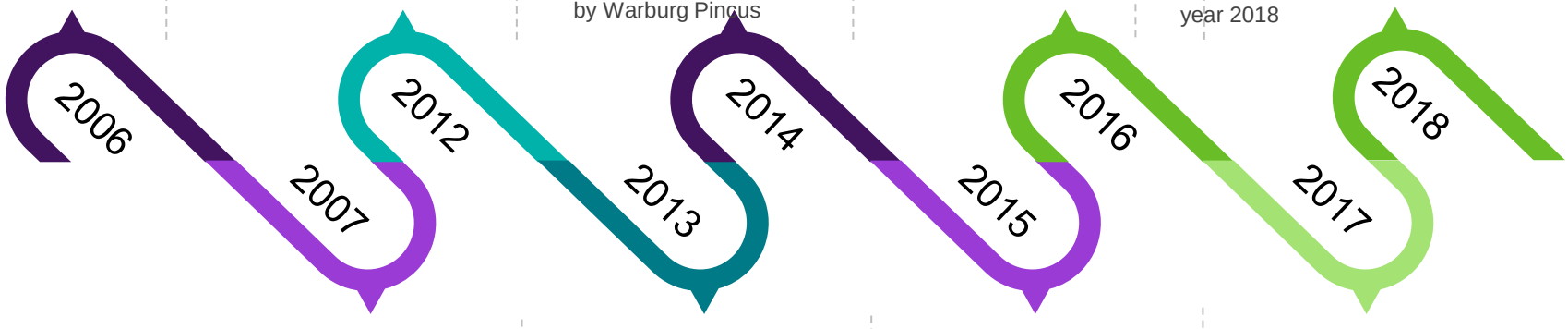
INNOVATION

EXCELLENCE

CARE

INTEGRITY

Key Milestones in Laurus Journey…



2006
- Set up the R&D Centre at IKP, Knowledge Park, Hyderabad

2007
- Investment of Rs. 600 mn in the Company by FIL Capital Management and Promoters.

2012
- Commenced commercial operations at Unit 1

2013
- Incorporated Laurus Inc. at Delaware as a wholly owned subsidiary of our company.
- Investment of Rs 3000 mn by Warburg Pincus

2014
- Crossed INR.10 billion of revenues
- Commenced construction of Unit 2 (FDF site)

2015
- Successfully listed on BSE & NSE (Indian Stock Exchanges)
- Filed first ANDA for US market

2016
- Commenced commercial operations at Unit 3
- Commenced operations at Unit 2
- Got EU approval for Unit 2

2017
- Crossed INR 20 billion of revenue
- Commenced commercial operations from Unit 4
- Incorporated a subsidiary in Germany
- Unit 2-Formulations, inspected by USFDA with Zero 483 observations
- Launched maiden FDF product Tenofovir in USA, Canada and emerging markets.
- Certified as Great Place to Work for the year 2018

2018
- Commenced commercial operations at Unit 2
- Successfully completed more than 7 regulatory inspections across manufacturing locations

Key Indices' highlighting the progress of Laurus

55+
R&D Labs
(India, USA)

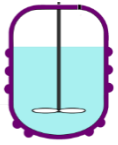
8
Manufacturing Facilities
(8 API (incl. Pilot); 1 FDF)

90+
APIs manufactured

290+
Million USD in
revenue in FY17

66
Million USD EBIDTA
in FY17

800+
Scientific personnel
(of 3,000+ total)



3+
Million litres of
reactor capacity

5Bn
Tabs/Caps
Installed Capacity

227
Patents filed

63
granted
till FY17

56
Countries served

One of the key differentiators for Laurus is its strong R&D investments and capabilities

- **"Research-first"** approach – Set up dedicated R&D center in Hyderabad in 2006 prior to commissioning API manufacturing facility in 2007
- R&D team comprising 800+ plus scientists (25.0% of total employee strength) including over 45 PhDs
- Kilo Lab at R&D center accredited by international regulators
- Completed expansion of R&D at Hyderabad
- Currently setting up new R&D center in Visakhapatnam

Key Accreditations

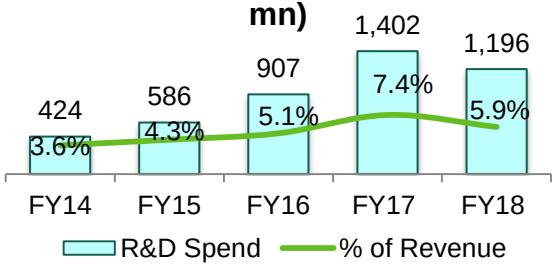
USFDA

FDA S Korea

PMDA Japan

WHO

Increasing R&D Spend (INR mn)



59	46	227	63	10
Products commercialized since inception	Filed DMFs	Patents filed	Patents granted	ANDAs & NDA /Dossiers filed

LAURUS Labs
Knowledge . Innovation . Excellence

Manufacturing Facilities at Parawada, Vizag

- Located at Jawaharlal Nehru Pharma City, Vishakhapatnam, India.
- API manufacturing facility and includes capacity for ingredients, synthesis and contract manufacturing.
- Commenced operations in 2007.
- 315 reactors with 1,141 Kilo Liters capacity.
- Received approvals from US FDA, WHO-Geneva, NIP Hungary, KFDA & PMDA.

- Located at Jawaharlal Nehru Pharma City, Vishakhapatnam, India.
- API manufacturing facility and includes capacity for ingredients, synthesis and contract manufacturing.
- Commenced operations in 2015.
- 126 reactors with 775 Kilo Litres capacity, on going capacity expansion of 600 Kilo Liters
- Received approvals from USFDA, WHO – Geneva, & NIP – Hungary .

- Located at Jawaharlal Nehru Pharma City, Vishakhapatnam, India. (SEZ)
- A dedicated Hormone and Steroid facility for Aspen
- Commenced operations in 2017.
- 46 reactors with 125 Kilo Litres capacity .

Manufacturing Facilities at Achutapuram, Vizag

Unit-II

- Located at APIIC, Achutapuram, Visakhapatnam, India. (SEZ)
- FDF and API manufacturing facility
- Commenced operations in 2017.
- FDF - capacity of 5 bn tablets per year.
- API block with 12 reactors with 83 Kilo Liters capacity.
- Received approvals from BVG Hamburg Germany, USFDA, WHO – Geneva

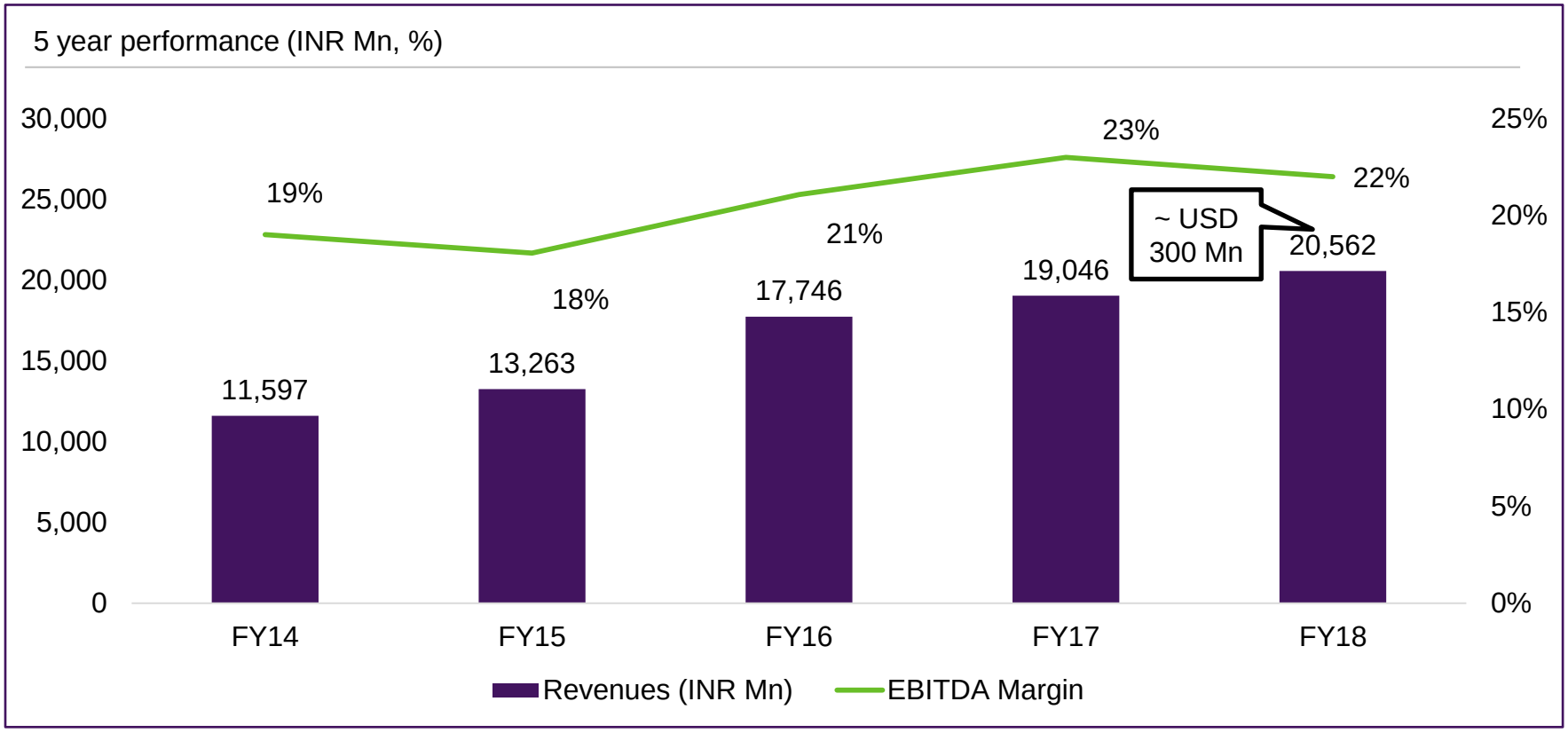
Unit-IV

- Located at APIIC, Achutapuram, Visakhapatnam, India. (SEZ)
- API manufacturing facility and includes capacity for ingredients, synthesis and contract manufacturing.
- Commercial operations in 2018
- 16 reactors with 51 Kilo Liters capacity, ongoing capacity expansion

Unit-VI

- Located at APIIC, Achutapuram, Visakhapatnam, India.
- API manufacturing facility.
- Commercial operations in 2018
- 41 reactors with 244 Kilo Liters capacity.
- Unit acquired through slump sale from Sriam Labs (100% Subsidiary)

Laurus revenues in FY18 stood at ~USD 300Mn

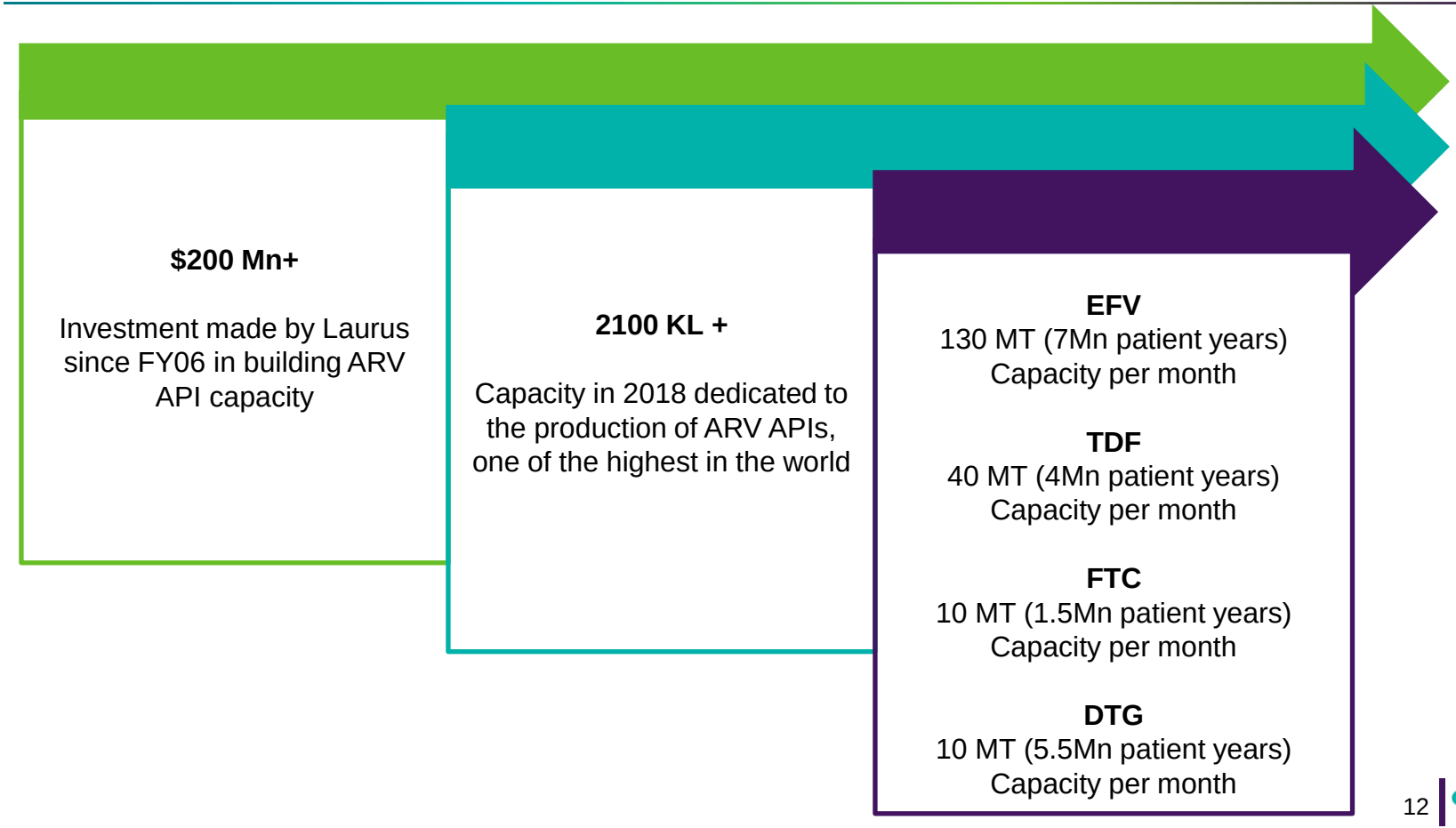


Laurus is internally organized as four business units, based on customer segmentation

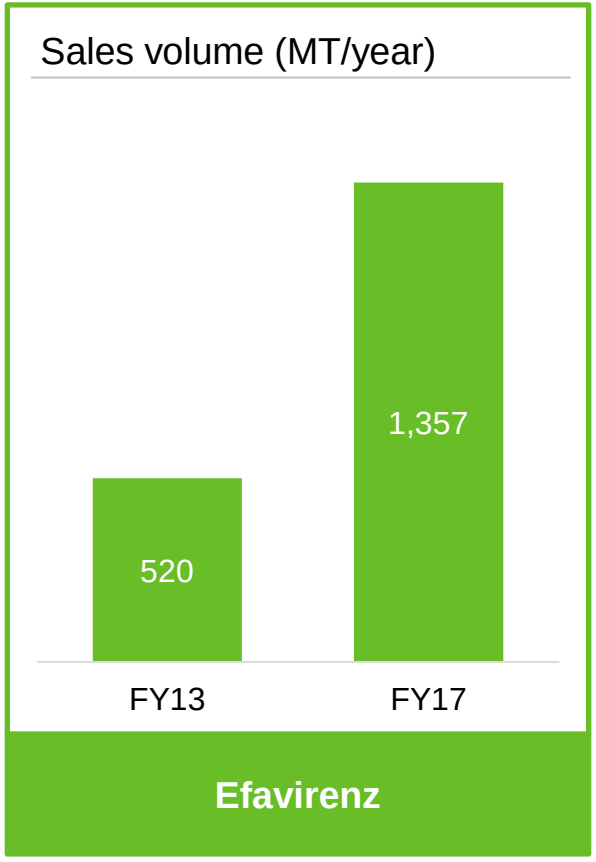
	LAURUS Generics Active Pharmaceutical Ingredients & Intermediates	LAURUS Generics Finished Dosage Forms	LAURUS Synthesis Contract Development & Manufacturing Services	LAURUS Ingredients Specialty Ingredients for Nutraceutical & Allied Industry
Overview	• Development, manufacture and sale of Active Pharmaceutical Ingredients (APIs) and advanced intermediates	• Developing and manufacturing oral solid formulations	• Contract development and manufacturing services for global pharmaceutical companies	• Sale and manufacture of specialty ingredients for use in nutraceuticals, dietary supplements and cosmeceutical products
Product and Service Offerings	• Anti-retroviral (ARV) • Hepatitis C • Oncology • Large volume APIs for cardio-vascular, antidiabetic, anti-asthmatic, gastroenterology therapeutic areas • Small volume APIs for the ophthalmic therapeutic area	• ARVs • Anti-diabetic • Cardio Vascular • Proton Pump Inhibitors.	• Commercial scale contract manufacturing • Clinical phase supplies • Analytical and research services • Set up a dedicated block in Unit 4 for global partner , C2 Pharma • 24 projects executed	• Nutraceuticals, dietary supplements and cosmeceutical products

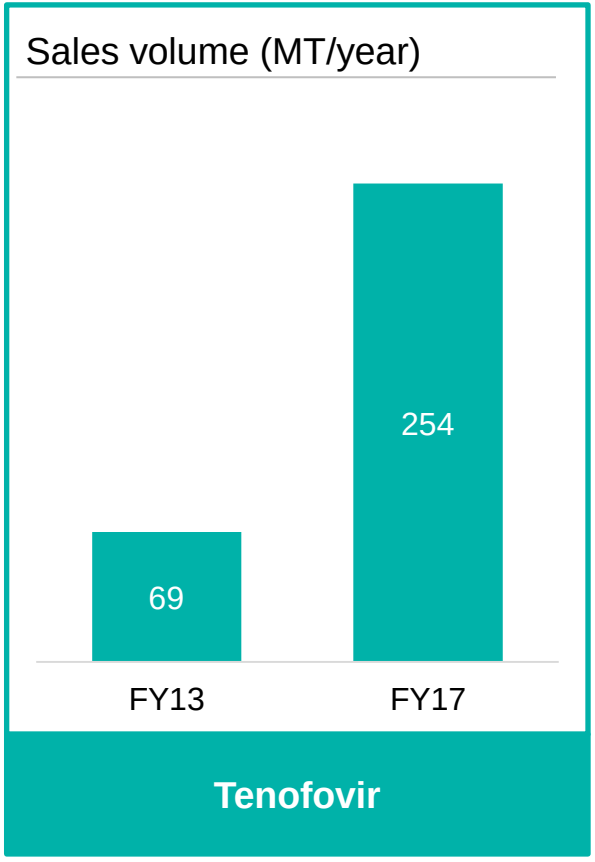
Laurus’ contribution to ARV

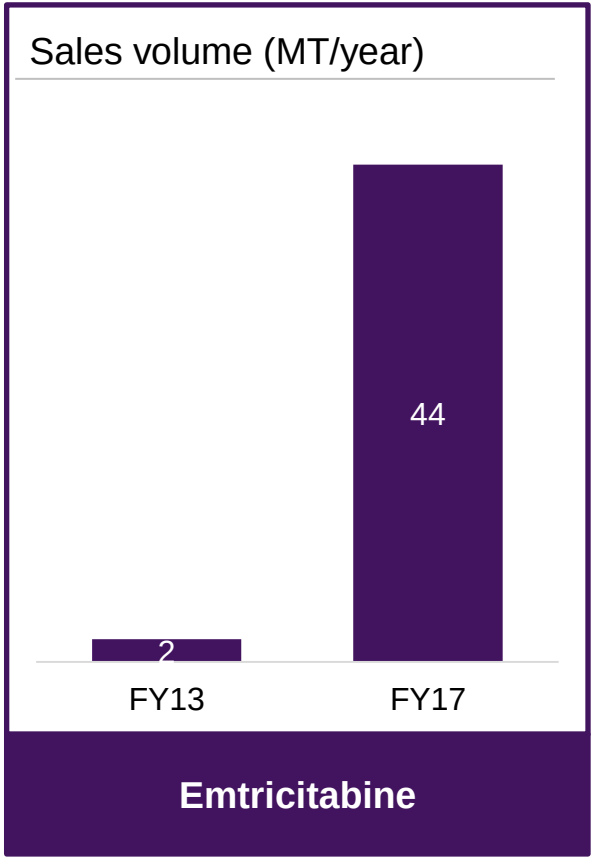
Laurus Ensures Sustainable Supply of APIs



Rapid scale-up of Key ARV APIs (sold per year)

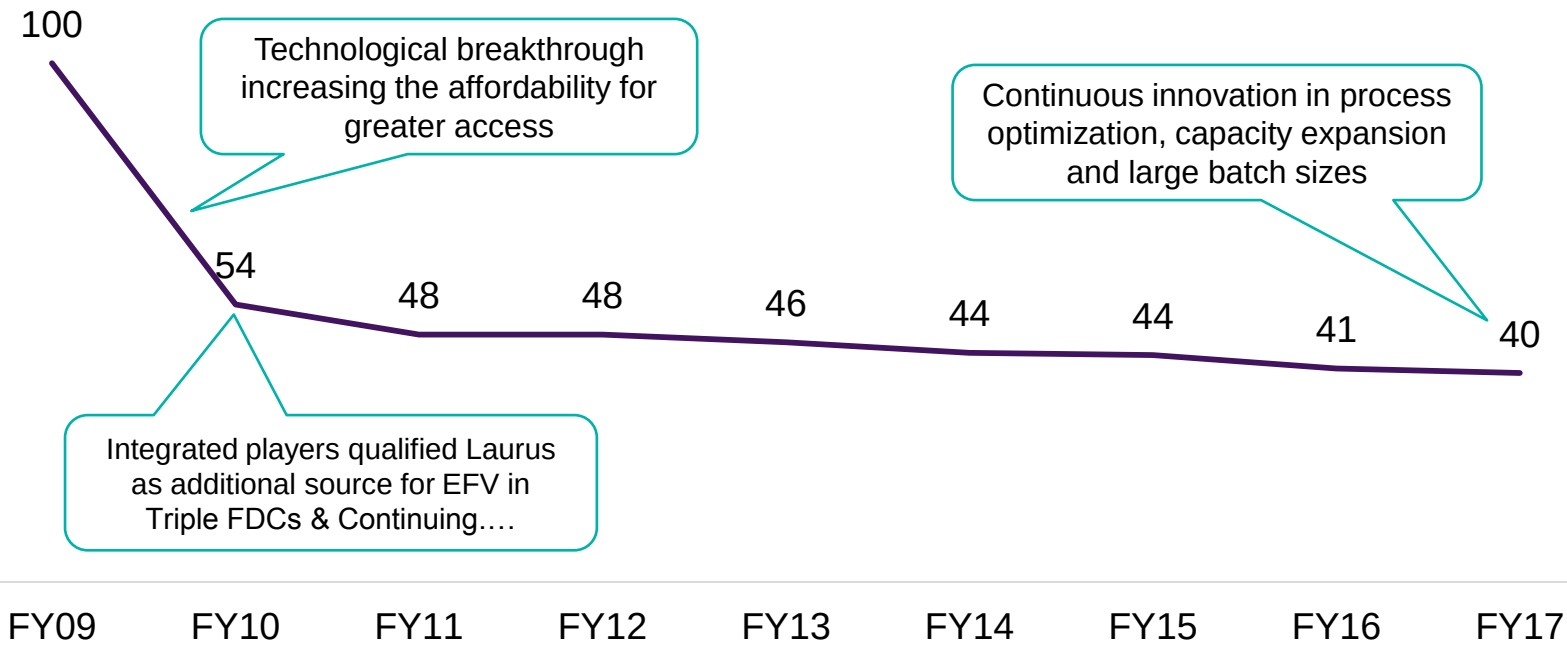






Increasing Affordability with continuous Innovation

Laurus Selling price of Efavirenz with 2009 as base year (Consider 100 as Base Price..)



Large API's Portfolio Encompassing Major Regimens

First Line	Second Line	New API's
1. Tenofovir	1. Lopinavir	1. Tenofovir Alafenamide
2. Efavirenz	2. Ritonavir	2. Bictegravir
3. Emtricitabine	3. Darunavir	
4. Lamivudine	4. Atazanavir	
5. Dolutegravir	5. Abacavir	

Portfolio of 12 ARV APIs

Quality at Laurus

In addition, APIs are also validated at multiple sites in the Laurus manufacturing network as a risk mitigation strategy

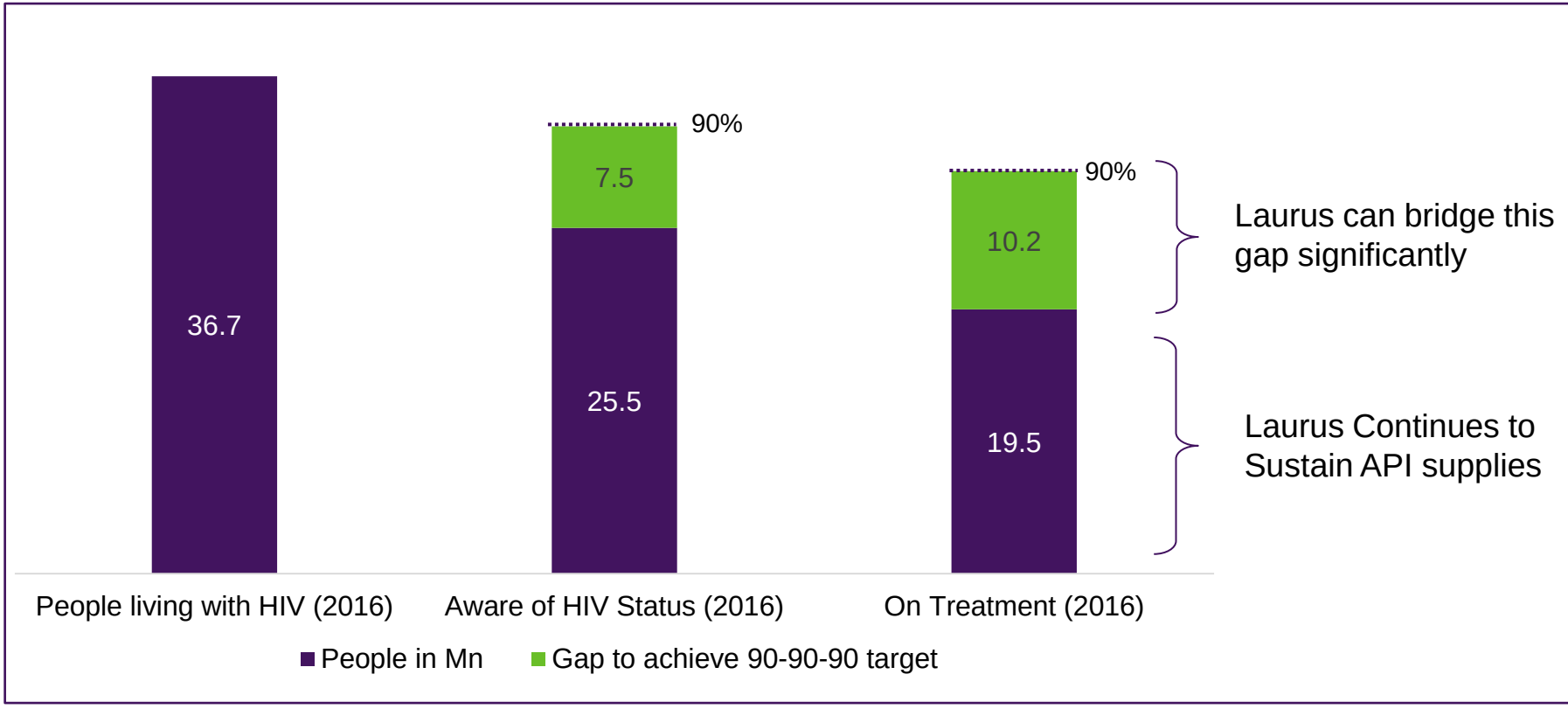
API	Primary Mfg site	Risk Mitigation site	Additional site if required
Tenofovir	Unit 1	Unit 3	Unit 2, Unit 4
Efavirenz	Unit 1	Unit 2*	Unit 4
Emtricitabine	Unit 3	Unit 1	NA
Lamivudine	Unit 3	Unit 1	NA
Dolutegravir	Unit 1	Unit 4*	NA

Currently, for all the APIs Primary Manufacturing site and Risk mitigation sites are also used for regular production

* Planned

ARV formulations at Laurus

Laurus entry into ARV FDF to help achieve 90-90-90 target



Source: UNAIDS/WHO estimates

Laurus ARV business strategy is based on the need for a new credible player in the ARV space

Maintain leadership in first line ARV APIs

- Continuous investment in capacity augmentation
- Focus on Internal Cost Improvements for offering better price
- Backward integration to ensure supply security in KSM & Intermediates
- Therapy life cycle management through investments in R&D

Entry into FDF to bridge 90-90-90 gap

- Large portfolio to cater to 1st line, 2nd line and pediatric formulations
- Manufacturing capacity to serve 4-5Mn patients/month
- Registration footprint in LMICs to increase ARV FDF access

Build leadership in 2nd line & pediatric therapies

- Strengthen supply security to 2nd line and pediatric patients with affordable and consistent supply
- Broad portfolio in API and FDF to cater to all patient segments
- Focus on low volume products to ensure wider treatment coverage

Developing Broader Portfolio of Formulations (20 products)

	Launched	Ready to file/Filed	Under Development
First Line adult	1. Tenofovir	1. TLD 2. DTG 50mg 3. TEE 4. ET 5. TLE 600 6. TLE 400	1. TAF/E/D 2. TAF/L/D 3. TAF/FTC
Second line adult		1. DRV 2. ATV 3. LPV/r	1. ATV/r 2. DRV/r 3. ABC/3TC
Paediatric			1. LPVr 2. ATVr 3. ABC/3TC 4. DTG
Total	**1**	**7**	**12**

Key KSM/ Intermediates

S.No	KSM For API	In House	In House KSM Facility Sources	Additional KSM Source In India	Additional Outsource Facilities (other than India)	Total No Of Sources
1	Tenofovir Disoproxil Fumarate	Y	Unit 1	3	17	21
2	Lamivudine	Y	Unit 3 & Unit 6	3	5	10
3	Darunavir	Y	Unit 1		3	4
4	Efavirenz	Y	Unit 1 & Unit 6	2	9	13
5	Tenofovir Alafenamide	Y	Unit 1	--	--	1
7	Abacavir Sulfate			2	2	4
8	Dolutegravir	Y	Unit 1 & Unit 6	1	4	7
9	Atazanavir Sulfate	Y	Unit 3		4	5
10	Ritonavir	--	--	1	1	2
11	Raltegravir	--	--	2	1	3
12	Rilpivirine	--	--	1	2	3

Laurus intends to foray into the FDF while ensuring or increasing supply of the intermediates and APIs to our customer base

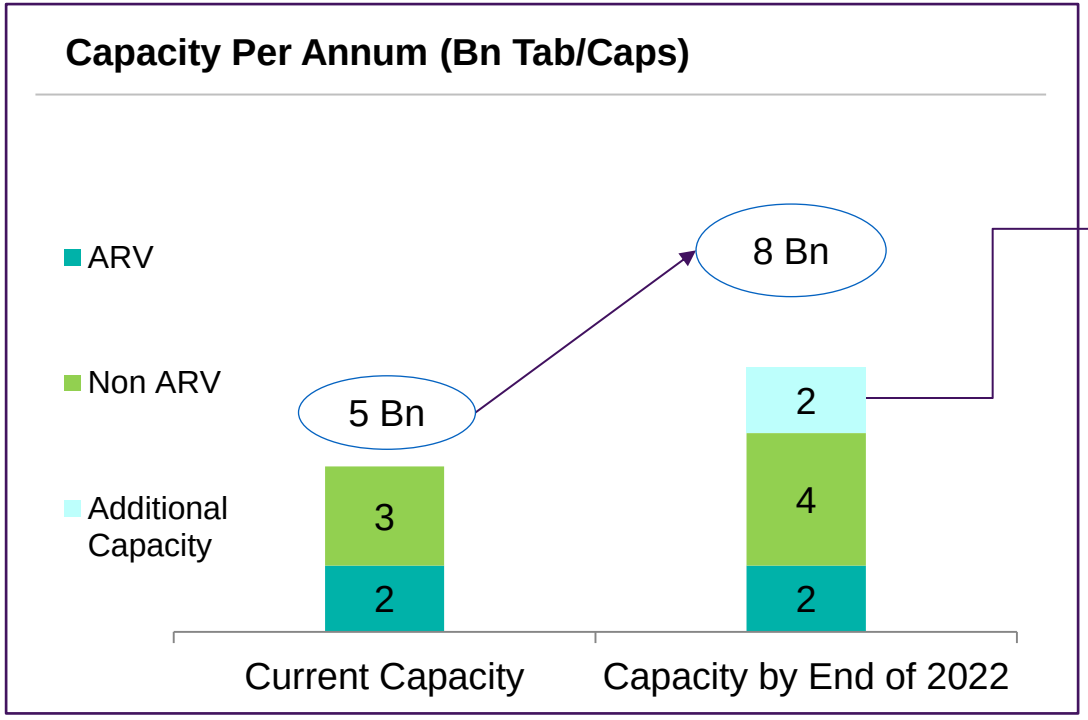
API	Existing Capacity (MT) per month	Expansion (MT) per month	Total Capacity (MT) per month	Total Allocable Capacity for FDF (MT)	% Available to FDF
Tenofovir	40 Unit 1, Unit 3	17 Unit 2, Unit 4	57	25	44%
Efavirenz	130 Unit 1	30 Unit 2, Unit 4	160	60	38%
Emtricitabine	10 Unit 3	5 Unit 3	15	5	33%
Lamivudine	10 Unit 3	60 Unit 3	70	60	86%
Dolutegravir	5 Unit 1	5 Unit 4	10	8	80%

Capacity is Risk Mitigated with diversified expansion across In House facilities itself

We believe in strategy that our Own Facility is our Back Up facility as all API's are Manufactured across 2 plants a minimum

- **Sustain and grow 3rd party API market supplies and meet internal FDF business requirement**
- Continuous Investment planned for Capacity expansion in both API & FDF
- Focus on Internal Cost Improvements for offering better price of ARV APIs and Finished Products
- Grow ARV division to provide medication for the treatment of 4-5Mn patients years while ensuring business sustainability

Capacity Expansion (FDF) Contd…

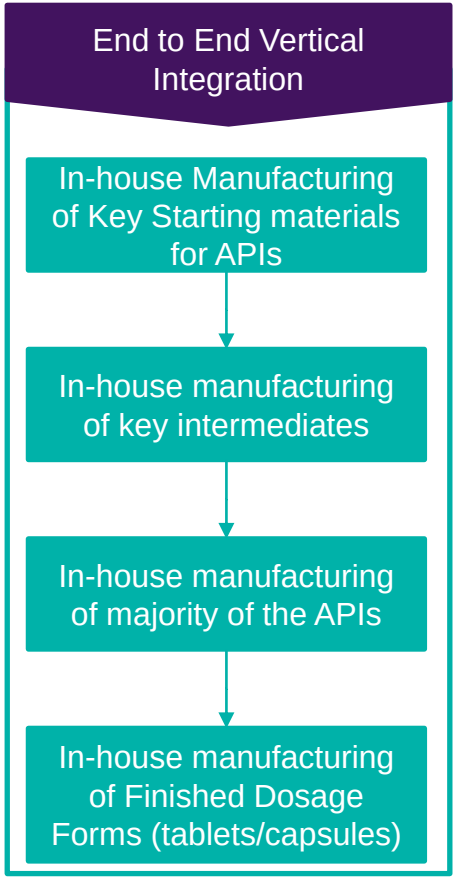


2Bn Capacity is Fungible & available for ARV

Laurus can treat up to 6 Mn patients with Existing Installed Capacity

Capacity is Risk Mitigated with diversified expansion

Reliable and consistent supply



- Large Manufacturing Infrastructure for TDF, EFV, FTC, 3TC, ABC, DTG, TAF, LPV, ATV, Ritonavir APIs
- Current formulation capacity of 5 billion tablet/capsule per year
- Expansion for formulation plant planned, would increase the capacity to 8 billion tablet/capsule by 2022
- Capacity would accommodate requirement for 6 million packs of triple FDCs per month apart from absorbing demand for other products
- Formulation plant already approved by USFDA, WHO, EU GMP
- API and Formulation plants are co-located in same city
- Distance between API and Formulation plant 25Kms
- Supply risks reduced substantially given visibility and control over KSM/Intermediates/APIs/Formulations

Quality Management System at Laurus

- Committed to maintain best quality standards in Research & Development, Contract services and Manufacturing of Pharmaceutical Products through Periodic Reviews and continual Improvement of QMS, and strive to enhance customer satisfaction
- Policies are in conformance with the requirements of:
  - Current Good Manufacturing Practices (cGMP) as per US FDA , EU-GMP, Schedule M & WHO
  - ICH Guidelines
  - ISO 9001:2008 Quality Management System
- Upgrading QMS system to Electronic Documentation for more security & quick access during Audits
- Laurus has dedicated Pharmacovigilance team to monitor adverse affects raised by thorough analysis & evaluation
- Change Management, Deviation Management and OOS handling System
- Periodic internal audits assure adherence to the Quality System
- Preventive and Corrective measures taken to address any non-conformities identified
- Quality Risk Assessment System and Training
- Validation Master Plan and Management review

Product Portfolio Phase I

S No.	Product Name	Description	Strength
01	Tenofovir	Tablets	300mg
02	Emtricitabine/Tenofovir	Tablets	200 mg / 300 mg
03	Efavirenz / Emtricitabine / Tenofovir	Tablets	600 mg / 200 mg / 300 mg
04	Dolutegravir Sodium / Lamivudine / Tenofovir Disoproxil Fumarate	Tablets	50 mg / 300 mg / 300 mg
05	Efavirenz/ Lamivudine / Tenofovir Disoproxil Fumarate	Tablets	600 mg /300 mg /300 mg
06	Efavirenz / Lamivudine / Tenofovir Disoproxil Fumarate	Tablets	400 mg / 300 mg / 300mg
07	Lopinavir / Ritonavir	Tablets	200 mg / 50mg
08	Dolutegravir sodium	Tablets	50mg
09	Darunavir	Tablets	400 mg / 600 mg / 800 mg

Product Portfolio Phase II

S No.	Product Name	Description	Strength
01	Atazanavir/Ritonavir	Tablets	300 mg / 100mg
02	Lamivudine / Tenofovir	Tablets	300 mg / 300 mg
03	Abacavir / Lamivudine	Tablets	600mg 300mg
04	Darunavir / Ritonavir	Tablets	400 mg / 50 mg, 600/100mg & 800/100mg
05	Lopinavir / Ritonavir	Tablets	100 mg / 25 mg
06	Abacavir / Lamivudine	Dispersible Tablets	120mg / 60mg
07	Abacavir / Lamivudine / Lopinavir / Ritonavir	Sachets (Sprinkle)	30 mg / 15 mg / 40 mg / 10 mg
08	Dolutegravir	Tablets	25 mg & 10 mg
09	Dolutegravir Sodium / Emtricitabine / Tenofovir Alafenamide	Tablets	50 mg / 200 mg / 25 mg

Product Portfolio (long term)

S No.	Product Name	Description	Strength
01	Bictegravir / Emtricitabine / Tenofovir Alafenamide	Tablets	75 mg / 200 mg / 25 mg
02	Dolutegravir Sodium / Lamivudine / Tenofovir Alafenamide	Tablets	50 mg / 300 mg / 25 mg
03	Emtricitabine / Tenofovir Alafenamide	Tablets	200 mg / 25 mg
04	Abacavir Sulfate / Efavirenz / Lamivudine	Dispersible Tablets	120 mg / 100 mg / 60 mg, 60 mg / 50 mg / 30 mg
05	Abacavir Sulfate / Dolutegravir / Lamivudine	Dispersible Tablets	30mg / 5mg / 60mg
06	Abacavir Sulfate / Dolutegravir Sodium / Lamivudine	Tablets	600 mg / 50 mg / 300 mg
07	Darunavir / Dolutegravir Sodium / Ritonavir	Tablets	400 mg / 25 mg / 50 mg
08	Darunavir / Ritonavir	Dispersible Tablets	120 mg / 20 mg
09	Efavirenz / Lamivudine / Tenofovir Disoproxil Fumarate	Dispersible Tablets	150 mg / 75 mg / 75 mg
10	Lamivudine / Tenofovir Disoproxil Fumarate	Dispersible Tablets	75 mg / 75 mg
11	Raltegravir Potassium	Tablets	400 mg

Continuous Innovation Process

- Introduce Innovative packaging models – 90 Tabs, 180 Tabs, Carton Less Packing
- Customizes labelling depending on country requirements
- Serialisation Under Implementation (with “TraceLink”) for all Products Manufactured by end of 2018
- Focus for Extending Shelf life of products for Key ARV Products (TLD, TLE, TEE, ET)
- Expand the Portfolio into Hep C Drugs Formulations with existing API background
- Affordable & Continuous supplies towards 2nd line ARV drugs
- Fast track development of Paediatric Drugs in both 1st & 2nd Line (4 in 1, ATV/r Peads, DTG 10mg Disp)
- Extend Non ARV portfolio drugs into Access Markets in Anti Diabetic, Anti Inflammatory, Oncology Divisions


LAURUS Labs
Knowledge . Innovation . Excellence