

Your reliable partner in
Patient Care



Renata UK Overview

March 2022





COMPANY OVERVIEW

Renata UK's parent company, Renata Limited, is the 4th largest pharma in terms of sales and 2nd largest publicly traded co. in Bangladesh with a commitment to **strong science and manufacturing quality.**

Renata's uniqueness lies in its devotion to alleviation of poverty, access to quality healthcare and increasing financial inclusion through its majority shareholder **Sajida foundation.**



Publicly listed on the Dhaka stock exchange with a market capitalisation in excess of US \$1.5 billion

- Erstwhile Chairman of Renata was Chairman and Founder of Transparency International's Bangladesh chapter
- Erstwhile Independent Board member Manzoor Hasan was the Executive Director of Transparency International Bangladesh and was awarded the Officer of the Order of the British Empire (OBE) by Her Majesty Queen Elizabeth II for his service
- Recently included in the 1st Frontier Market ETF, listed as \$CUBS on the New York Stock Exchange
- Recognized by Forbes as one of the top 200 publicly listed companies with sales under \$1 Billion in Asia.

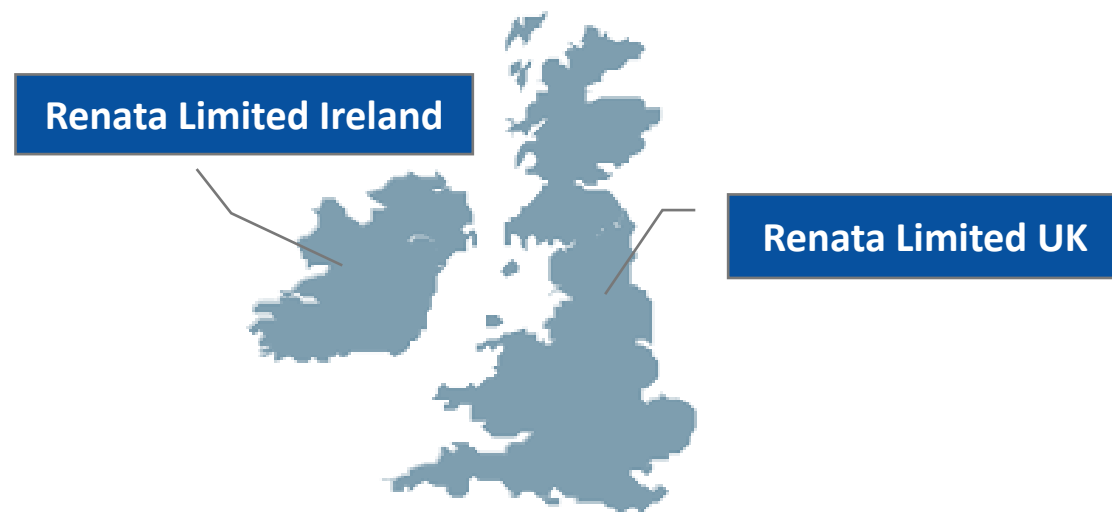


Ranking 4th in sales in Bangladesh Pharmaceuticals Market

GLOBAL PRESENCE

- Renata limited has its presence **over 30 countries** in the world with active operation and business under development.
- **Subsidiaries in UK and Ireland.** Renata UK is the wholly owned subsidiary of Renata Limited that develops novel products as well as complex generics solely for the regulated markets.
- **Strong partnership with global NGOs and organizations** (UNICEF, DKT International, Marie Stopes International, Population Service International, Family Planning Association etc.).

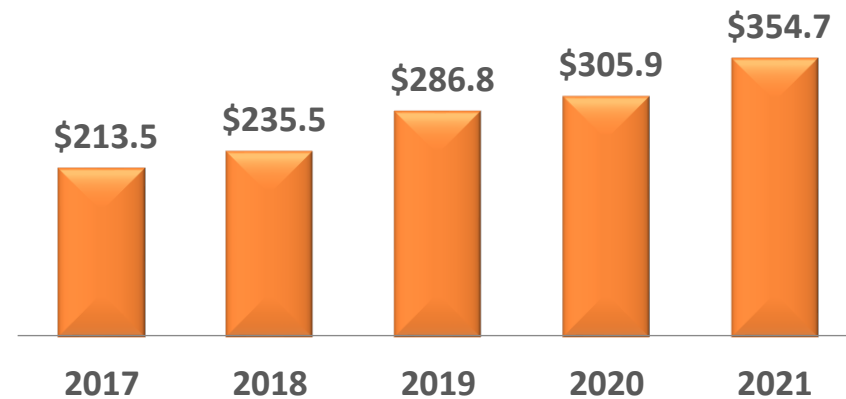
Global presence strengthened by Renata's two international subsidiaries catering to the UK and EU markets



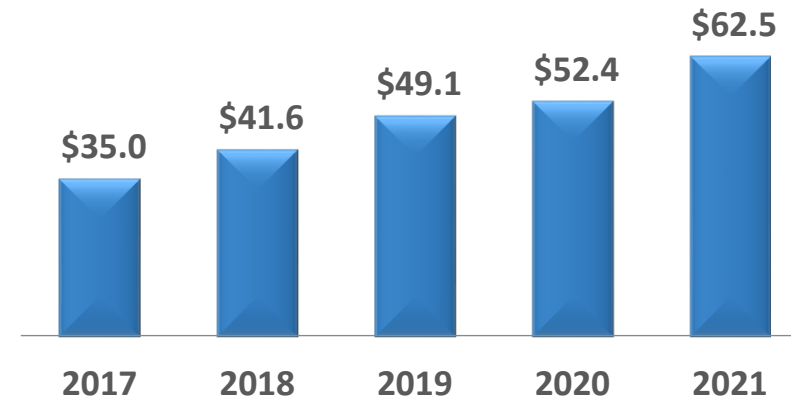


FINANCIAL PERFORMANCE

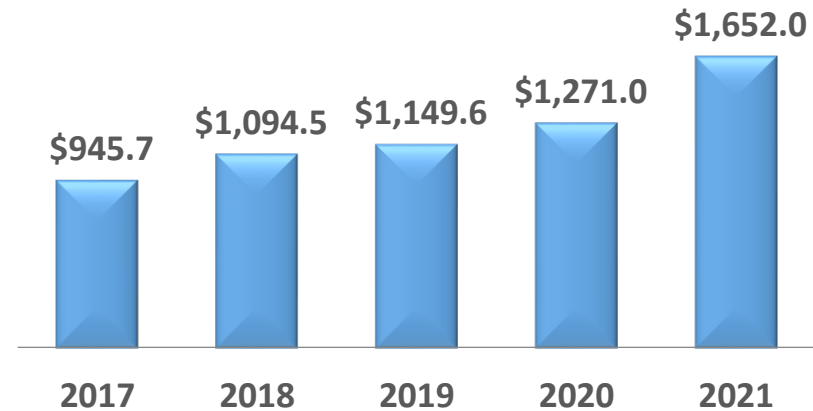
Net Sales (US \$m)



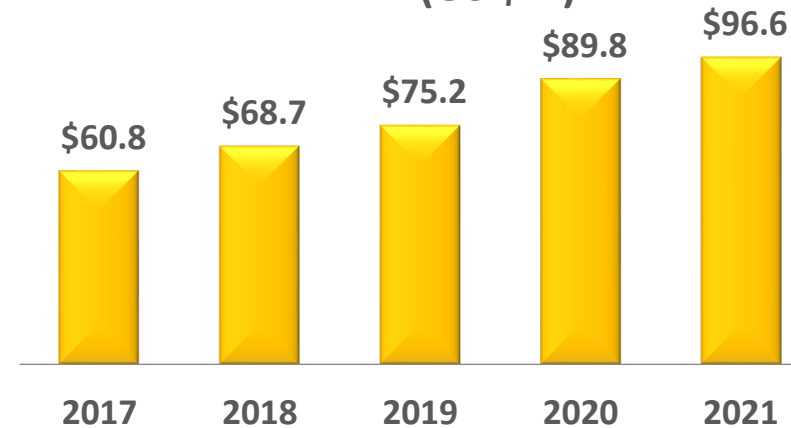
Net Profit (US \$m)



Market Capitalisation (US \$m)



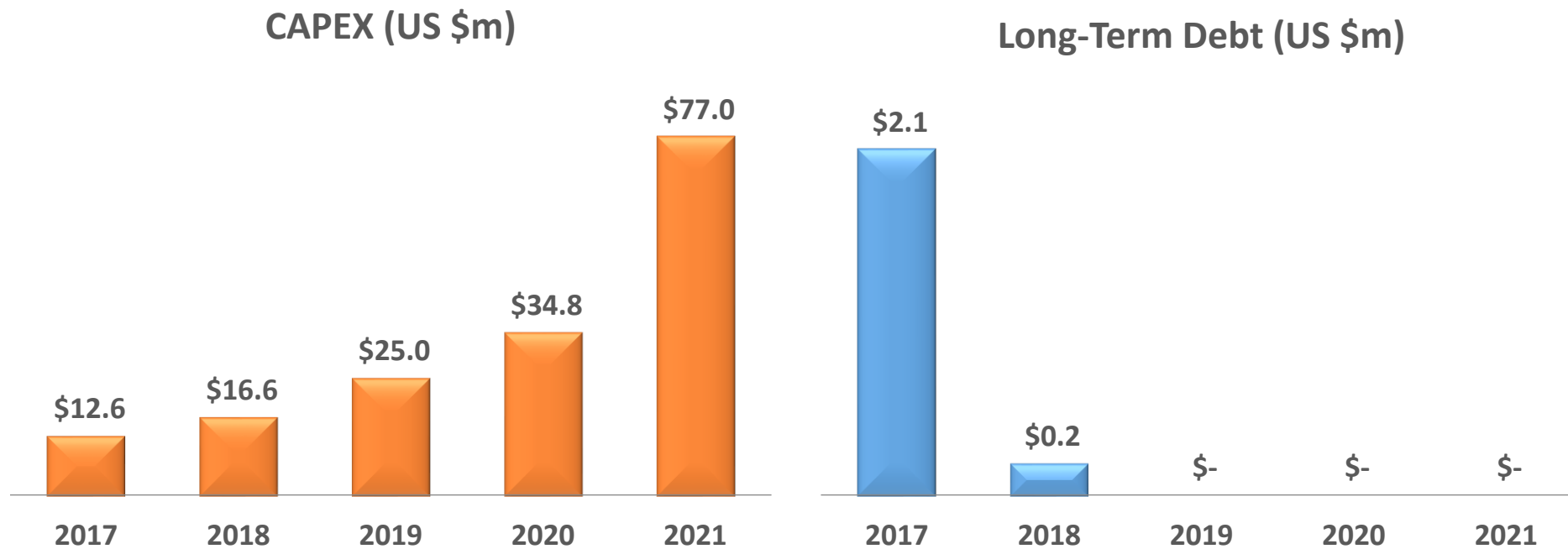
EBITDA (US \$m)





CAPITAL INVESTMENT AND LONG-TERM DEBT

Renata continually reinvests capital specially in the areas of R&D and infrastructure (modalities) development. This allows Renata to be flexible in investing in new assets and exploring meaningful partnerships.



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CAPABILITIES IN MANUFACTURING, FORMULATION AND R&D

Manufacturing strengths

Pelletization

BCS Class IV Compounds

Soft gel (Oncology, Potent and General Products)

State-of-the art cephalosporin facility

Vertically integrated tyrosine kinase and Janus kinase inhibitor API synthesis and manufacturing facility

Specialise in developing high potency low dosage formulations

Hormone and Oncology sterile

Novel dosage form

We have highly capable formulation scientists with combined 50+ years of experience and 3 dedicated formulation labs



Future vision is to repurpose this entire facility for R&D and formulation

Formulation capabilities

Immediate Release (IR)

Sustained Release (SR)

Prolonged release (PR)

Modified Release pellets

Enteric coated tablets, pellets

Soft gel across all therapeutic classes

OROS (osmotic-controlled release oral delivery system)

Granules R&D – for paediatric patient compliance

Sublingual

Hot Melt Extrusion

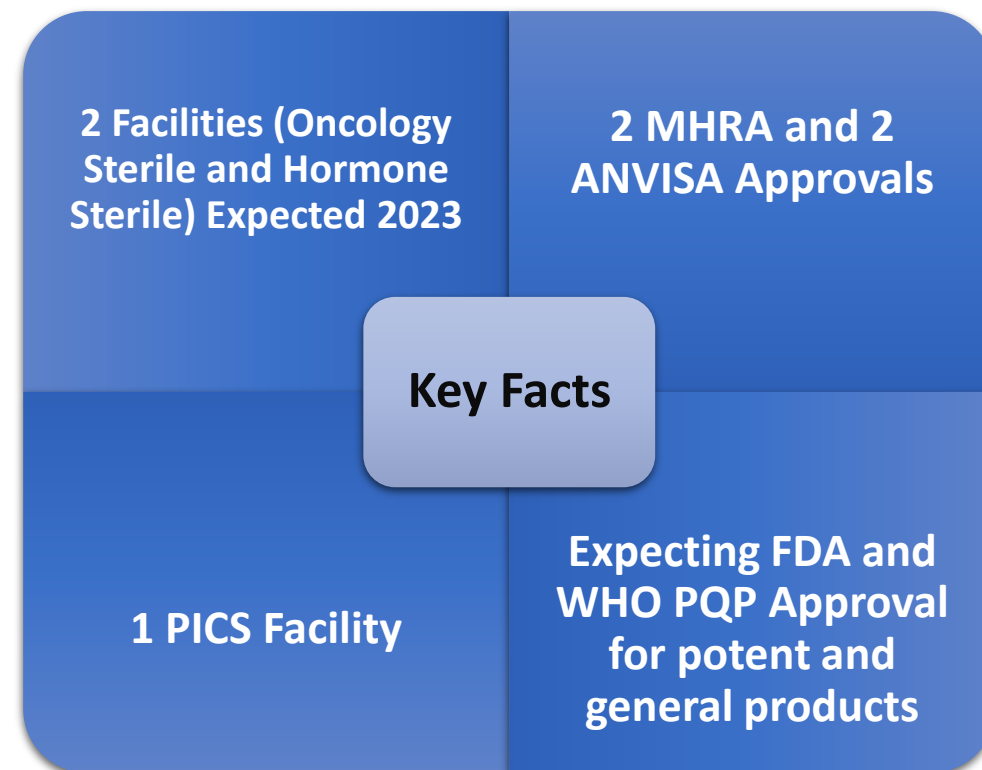
Self-emulsifying Drug Delivery systems (SEDDs)



MANUFACTURING – AN OVERVIEW OF OUR PLANTS

Fifteen state-of-the-art manufacturing facilities
on three separate sites

	No. of Factories	Type of Factories
Mirpur	3	General (GP-1 Sterile and Orals), Potent, and Sachet filling
Rajendrapur	8	General facility (all oral dosage forms ¹), Cephalosporin, Penicillin, Potent (oral and sterile), Oncology API, Oncology FDF (orals ² & steriles), Hormone sterile
Kashor	3	KGF, Inhaler & Suppositories, Herbal
TOTAL	14	



1. Includes Soft-Gel, Orally Disintegrating Tablets (ODTs), Osmotic-controlled Release Oral Delivery System (OROS), and Multi-Unit Pellet Systems.
2. Both Oncology and Potent Products include Soft-Gel Oral capabilities.



RENATA'S UK/EU GENERICS PIPELINE

PRODUCTS AVAILABLE/SUBMITTED

Molecule	Dosage Form	Dosage Strengths	Expected Filing	Current registrations (Approved or Targeted)
Hydrocortisone Tablets	Tablets	20 mg	Available (DCP)	UK+EU
		10mg		
		5 mg		
Carbimazole	Tablets	5 mg	EU : D120 assessment report received from the HPRA (RMS) with no outstanding query. Submitted to UK(national) on Aug-2021	UK + EU
		20 mg		
Rivaroxaban	FC tablets	10 mg	Submitted on July 2022 for both DCP and UK	UK + EU
		15 mg		
		20 mg		
Naratriptan Hydrochloride*	FC tablets	2.5 mg (as Naratriptan)	Submitted to UK on Feb 22; Submitted to Europe on Mar 2022	UK + EU
Cabergoline	Tablets	1 mg	Submitted for DCP on June 2022 and UK on July 2022	UK + EU
		2 mg		
Apixaban	FC tablets	2.5 mg	Submitted for DCP on June 2022 and UK on July 2022	UK +EU
		5 mg		
Nefopam Hydrochloride	FC tablets	30mcg	September 2022	UK + EU
Levothyroxine Sodium	Tablets	25mcg	January 2023	UK + EU
		50mcg		
		100mcg		



RENATA'S UK/EU GENERICS PIPELINE

PRODUCTS AVAILABLE/SUBMITTED

Molecule	Dosage Form	Strengths	Remarks
Escitalopram	FC tablets	5 mg	Submitted on April 22
		10 mg	Submitted on April 22
		20 mg	Submitted on April 22
Terbinafine	Tablets	250 mg	Approved on Jan-22
Topiramate	FC tablets	25 mg	Drug product: Submitted on April 22; Drug Substance: Submitted on May 22
	FC tablets	50 mg	Drug product: Submitted on April 22; Drug Substance: Submitted on May 22
	FC tablets	100 mg	Drug product: Submitted on April 22; Drug Substance: Submitted on May 22
	FC tablets	200mg	Drug product: Submitted on April 22; Drug Substance: Submitted on May 22



RENATA'S UK/EU GENERICS PIPELINE

PRODUCTS IN ADVANCED DEVELOPMENT

Molecule	Dosage Form	Strengths	Remarks
Acamprosate Ca	Gastro resistant tablets	333 mg	Pilot BE Ongoing
Pazopanib	Tablets	200mg and 400mg	Pilot BE passed successfully. Exhibit-batch manufacturing for Pivotal BE ongoing.
Rifampicin (Capsules)	Hard Capsules	300 mg	Pilot BE passed successfully, awaiting pivotal. Will only require replicate of Pilot Study.
		150mg	
Doxepin Hydrochloride (Hard Capsules)	Hard Capsules	50mg	Pilot BE successfully completed.
Esomeprazole Magnesium trihydrate (MUPS)	Tablet	20 mg	Machine under commissioning
Esomeprazole Magnesium trihydrate (MUPS)		40 mg	
Tadalafil	FC tablets	5 mg	Pivotal Fed passed successfully. Pivotal fasting to be done.
		10 mg	
		20 mg	
Febuxostat	FC tablets	120 mg	Pilot BE passed successfully, Awaiting pivotal
Dicycloverine Hydrochloride	Tablets	20 mg	Pilot BE passed successfully, Awaiting pivotal
Imatinib	FC tablets	400mg	Pivotal BE passed using Australian RLD. Looking for a CMO to manufacture exhibit batches in order to conduct Pivotal BE with EU RLD.
Sertaline Hydrochloride	Tablets	100mg	Variation submitted on Dec-21; Variation Approved for Drug Substance and Drug product. Variation ongoing for Artwork/mock up.
		50mg	Sep-22



RENATA'S UK/EU GENERICS PIPELINE

PRODUCTS UNDER DEVELOPMENT

Molecule	Dosage Form	Dosage Strengths	Registration	Remarks
Dimethyl fumarate	Capsules	120 mg, 240mg	EU+ UK	In-vitro dissolution successfully matched, awaiting Pilot-BE.
Dapagliflozin Propanediol Monohydrate	FC Tablets	5 mg, 10mg	EU+ UK	In-vitro dissolution successfully matched, awaiting Pilot-BE.
Primidone	Tablets	50mg, 250mg	EU+ UK	In-vitro dissolution successfully matched, awaiting Pilot-BE.
Eltrombopag	FC tablets	75, 50, 25mg	EU+ UK	Pilot BE batch manufacturing completed.
Melatonin	PR tablets	1,2,5, mg	EU+ UK	Awaiting Pilot Study
Mefenamic acid	FC tablets	500mg	EU+ UK	TBD
Mirabegron	ER tablets	25mg, 50mg	EU+ UK	Awaiting Pilot Study
Tafamidis	Capsules	61mg	EU + UK	Under Development
Tafamidis Meglumine	Capsules	20mg	EU+ UK	Under Development
Tofacitinib	Tablet	5mg, 10mg	EU+ UK	Under Development
Lymecycline	Capsules	150mg, 300mg	EU+ UK	Under Development
Bempedoic acid	FC tablets	180mg	EU+ UK	Awaiting Pilot BE Results
Bempedoic acid + Ezetimibe	Tablets	180mg + 10mg	EU+ UK	Under Development



RENATA'S UK/EU GENERICS PIPELINE

PRODUCTS UNDER DEVELOPMENT

Molecule	Dosage Form	Dosage Strengths	Remarks
Sorafenib Tosylate	FC tablets	200 mg	Awaiting Pivotal
Progesterone	Soft-Gel Capsules	100mg, 200mg	Conducting Second Pilot BE
Dicycloverine Hydrochloride	Tablets	10 mg	Under Development
Procyclidine Hydrochloride	Tablets	5 mg	Under Development
Linagliptin	FC tablets	5mg	Awaiting Pilot BE – F2 Completed, Batch-Manufacturing Completed.
Ticagrelor	Tablets	30 mg, 60mg, 90mg	Awaiting Pilot BE – F2 Completed, Batch-Manufacturing Completed.
Nitrofurantoin Macrocrystal	Capsules	50 mg, 100mg	Pilot Successful
Macitentan	FC tablets	10mg	Awaiting Pilot BE – F2 Completed, Batch-Manufacturing Completed.
Nitrofurantoin Macrocrystal & Nitrofurantoin Monohydrate	PR Capsules	100 mg	Under Development
Liothyronine Sodium	Tablets	20 mcg	Awaiting Pilot BE – F2 Completed, Batch-Manufacturing Completed.



RENATA'S EXPERIENCE IN CLINICAL DEVELOPMENT

Generics / 505(b)(2)

Type of Clinical Study	Number of studies
Pivotal Study (completed)	21
Pilot Study (completed)	11
Pivotal Study (ongoing)	7
Pilot Study (ongoing)	4

Renata has already completed 32 trials, (pivotal and pilot studies combined) and currently recruiting for 4 pilot and 7 pivotal studies

NCE

Ph 2a POC: TK – 90 for 5-FU induced mucositis in Colorectal cancer patients

Pilot evaluation of safety and non-interference with 5-FU efficacy

3 cancer centers in India

Patients: adults receiving 5-FU/Leucovorin for Colon Cancer

6 Patients /Center

Once a week dosing for 4 weeks

Dosing : 500 mg/m² 5-FU/Leucovorin + Oral nutritional supplement and TK-90 (45mg/kg) or placebo 1 hour before and after 5-FU/LV

Efficacy endpoints measured in NCI, WHO, PROMS Scales

Adverse Events graded in accordance with the CTCAE V5.0

Follow – up one month post dosing

Ph 2a POC: TK – 90 for Radiation induced mucositis in SCCHN

Pilot evaluation of safety and non-interference with radiation efficacy

3 cancer centers in India

Patients: adults with histologically or cytologically confirmed diagnosis of locally residual, recurrent or metastatic SCCHN

8 Patients /Center | 12 patients in placebo/treatment group each

2 Gy radiation for 35 days

Dosing: Daily 2 Gy radiation + Oral nutritional supplement and TK-90 (45mg/kg) or placebo 1 hour before and after radiation

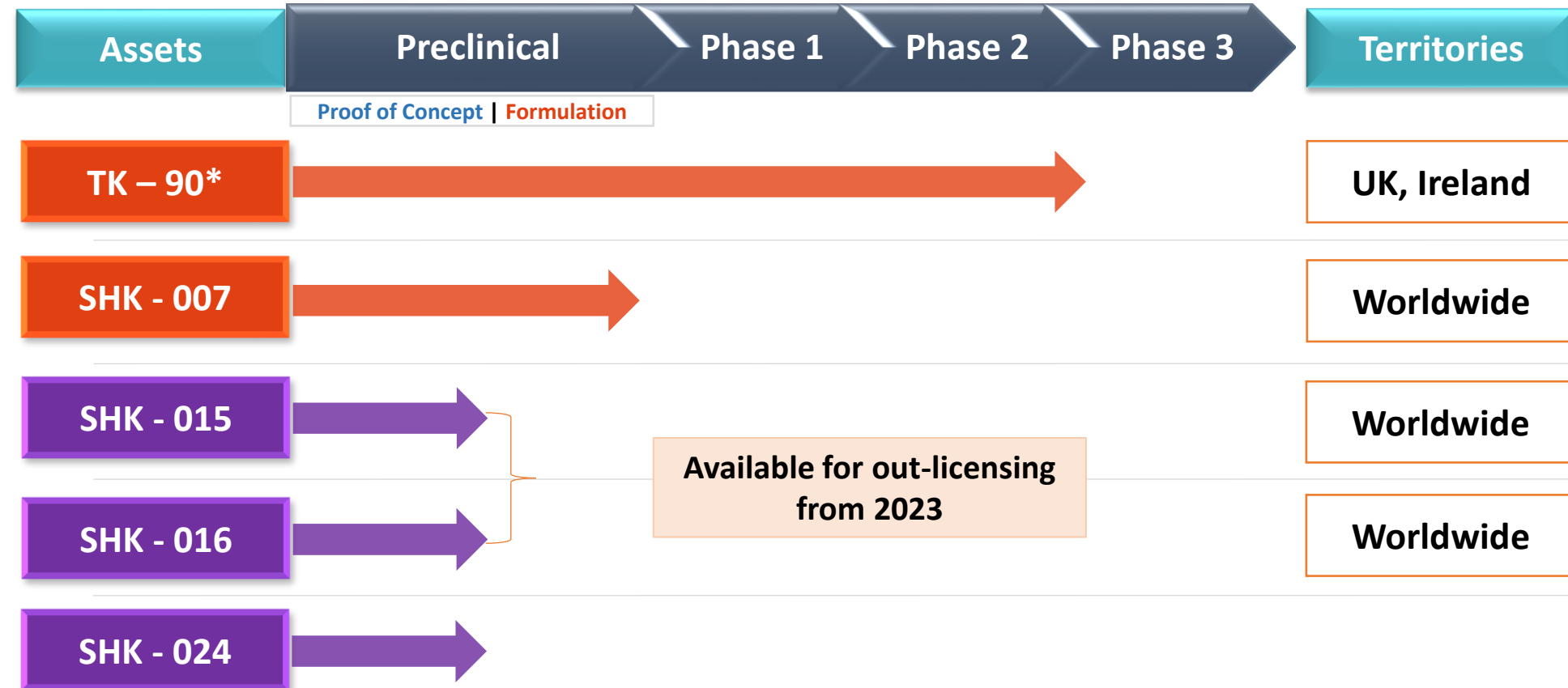
Efficacy endpoints measured in NCI, WHO, PROMS and RTOG Scales

Adverse Events graded in accordance with the CTCAE V5.0

Follow – up one month post dosing



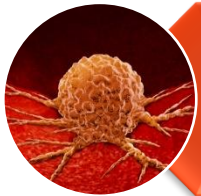
RENATA UK'S BRANDED PIPELINE



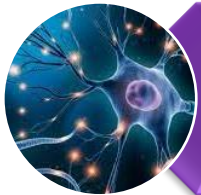
* Asset in global co-development with founders Tosk Inc.

Aside from this, Renata has an extensive generics portfolio of 19 DCP approved SKUs and 30 other generics under different stages of development/filing

Our interests



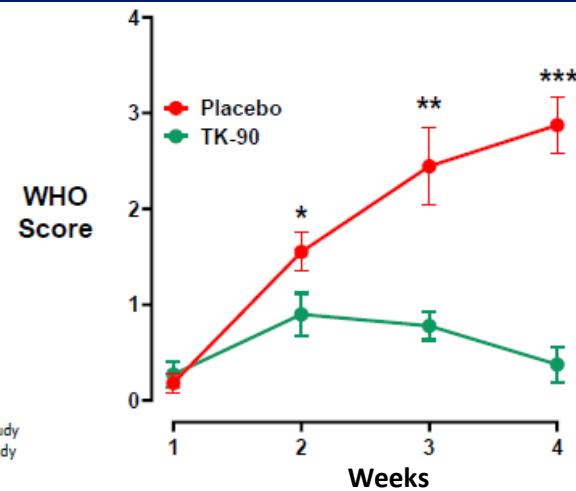
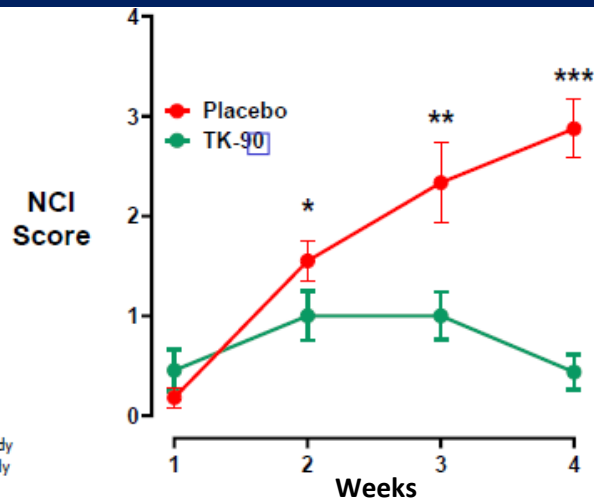
Oncology &
Supportive
Care Oncology



Neurology and
Psychiatry



TK 90 – PRESENT AND FUTURE



- **Phase 2a : Placebo controlled double blinded study in 22 patients with advanced SCCHN**
- TK-90 co-administered with methotrexate (MTX) (45 mg/kg) in 11 patients while the other arm received placebo.
- Mucositis score measured in WHO and NCI scale

Future directions with TK-90

Preclinical / Phase 1 / Phase 2 / Phase 3

TK – 90 for MTX induced mucositis in SCCHN patients

Phase 2b/3

TK – 90 for 5-FU induced mucositis in Colorectal cancer patients

Phase 2a Proof of Concept

TK – 90 for Radiation induced mucositis in SCCHN

Phase 2a Proof of Concept

Renata in conjunction with its co-development partner Tosk has created a **steering committee** to **execute and oversee all future trials involving TK-90**



General facility – 1
To be fully made into R&D formulation



MHRA approved dedicated endocrinology facility:
Blister pack and pot-fill



Penicillin facility : Orals, Sterile



Kashor General Facility (KGF)



Cephalosporin facility:
Oral, Sterile, DPS



MHRA and ANVISA approved General facility (GP-2)



Vertically integrated API facility for immunological therapeutics



Dedicated endocrinology facility - 2



Immunological therapeutics (orals) facility

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CONTACT US

<http://www.renata-ltd.com/>

Email: businessdev@renata-ltd.com

Syed Omar Kabir

R&D, Business Development and Sales Lead

Email: omar.kabir@renata-ltd.com

LinkedIn: <https://www.linkedin.com/in/syed-omar-kabir>

Labiba Mustabina Oishee

Business and Clinical Development Associate

Email: labiba.oishee@renata-ltd.com