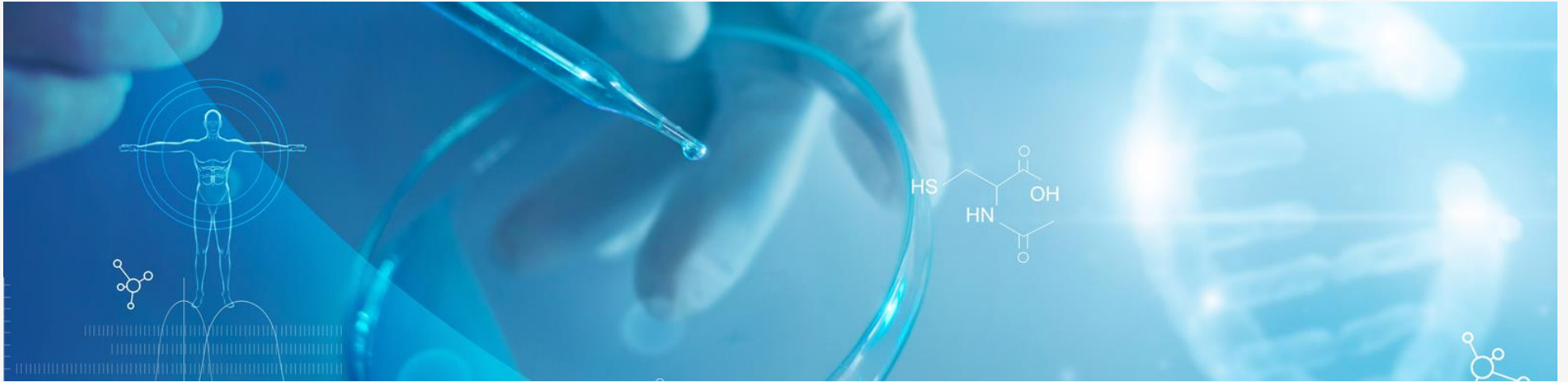


Special Report

Emerging Therapy Areas

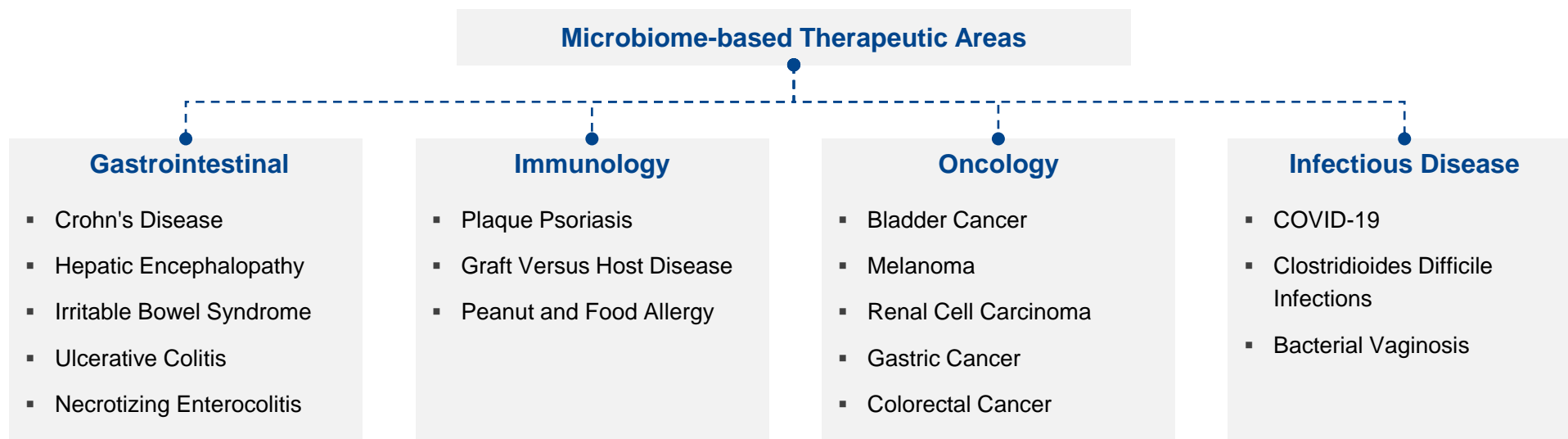


Microbiome-based Therapeutics

Microbiome-based therapeutics, an emerging field with applications in various therapeutic areas; oncology and immunology are the upcoming segments in microbiome space

Microbiome-based therapeutics

- The microbiome involves the natural bacterial colonization of the body, including the skin, gut, and stomach. Research over the past few years has shown there is an interaction between the microbiota and organ systems. Examples include the gut-brain axis and other such interactions that impact the metabolism, neurology, infection, gut health, and other chronic health conditions.
- Microbiome therapeutics received a big boost in August 2020 when Seres Therapeutics' gut microbiota capsule SER-109 met its primary end point in a Phase III clinical trial. In 2020, over 640 microbiome-related patents were granted and around 575 clinical trials were launched in the microbiome segment.
- The global microbiome therapeutics market is expected to reach approximately USD 150 Mn by 2025, recording a CAGR of 21.9% from 2023. Gastrointestinal (GI) indications, such as ulcerative colitis and irritable bowel syndrome, would be the key segments, accounting for about 36.28% of the market. Upcoming indications being explored in the microbiome space include oncology, metabolic, infectious, and inflammatory diseases.



Other therapy areas include drug candidates for metabolic disorders, dermatology, genitourinary disorders and sex hormones, and neurological disorders.

Source: Industry Reports, News Articles, Company websites, Aranca Analysis

Innovation in sequencing, increasing potential role of microbiome in immunology and oncology segments prompt companies to invest in development of microbiome-based drugs

Key market drivers and trends

Entry of Major Pharmaceutical Players



- A number of big pharmaceutical players such as MSD, Takeda, and AstraZeneca have started investing in the microbiome space.
- Since 2018, pharmaceutical-biotech partnerships and collaborations have been on the rise in the microbiome arena. For example, Takeda has partnered with several companies such as Finch, Enterome, Debiopharm, and Nubiyota in the past six years.
- Clinical trials are ongoing for a wide range of indications such as oncology, immunology (autoimmune diseases and allergies), and infectious diseases.

Novel Product Development and Impact of COVID-19



- Increased funding and investments for research and therapeutic innovation, along with significant focus on human microbiome therapeutics development, are the major factors driving the market.
- Novel products are currently in the late stage of development, with significant Phase III trial results announced in 2020 for Seres Therapeutics, Ferring, and Rebiotix.
- The COVID-19 pandemic has fueled the need to understand and investigate how the microbiome can be utilized for promoting a healthy immune system.

Government Initiatives



- Several government initiatives have supported the microbiome market. The White House Office of Science and Technology Policy, in collaboration with federal agencies and private sector stakeholders, announced the National Microbiome Initiative.
- Large-scale sequence-based microbiome projects, such as the Metagenomics of the Human Intestinal Tract consortium funded by the European Commission, have catalyzed microbiome research.

Rapid Scientific Innovations and Newer Technologies



- Research in microbiome in human health has recently gained more traction with the availability of genome sequencing and omics tools (metabolomics, metagenomics, and metatranscriptomics).
- Metagenomic sequencing would further aid the identification of the desired microbial species that can be assayed for pharmacokinetic properties and metabolites using techniques such as mass spectrometry and high-performance liquid chromatography.

Source: Industry Reports, News Articles, Company websites, Aranca Analysis

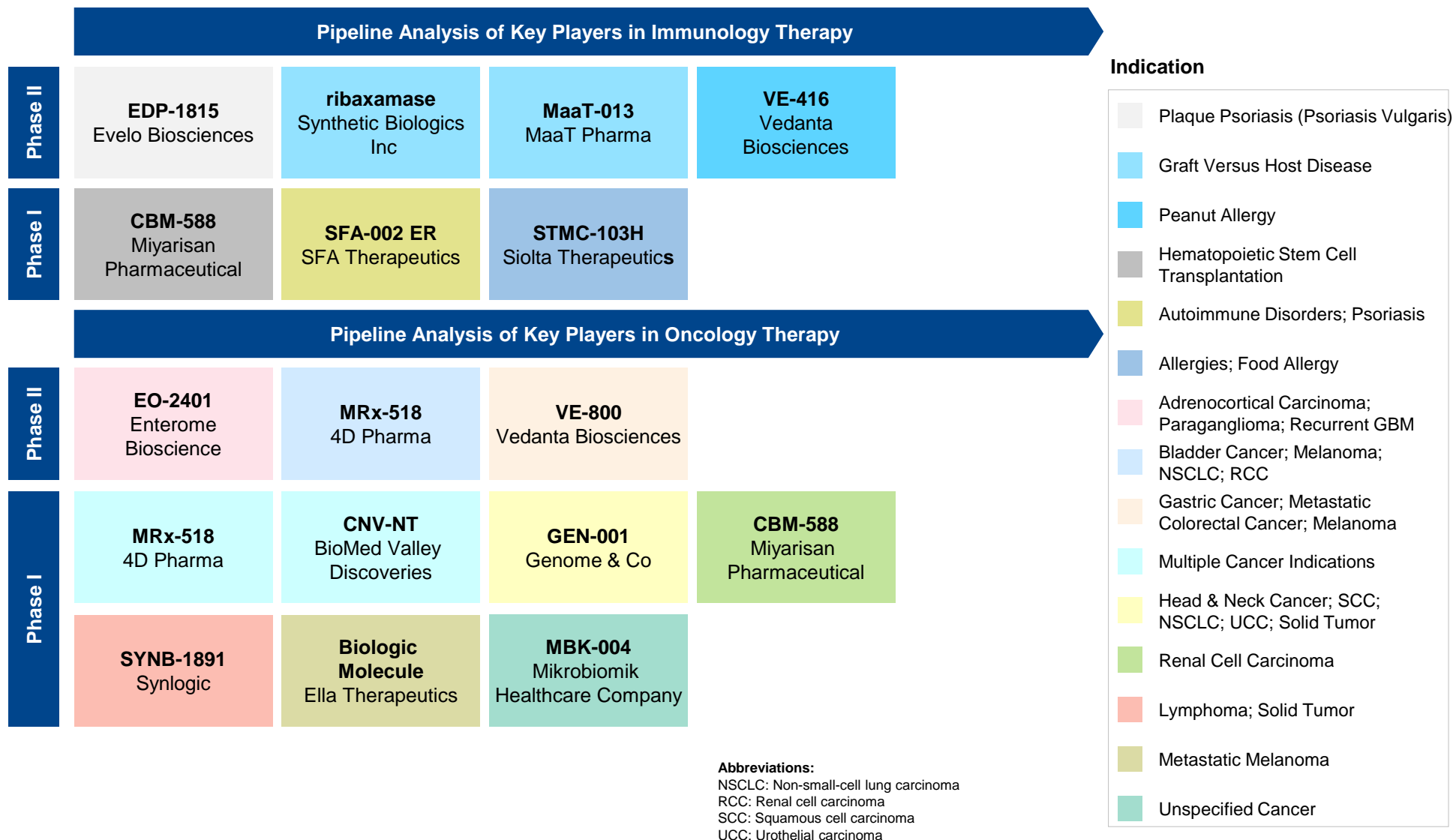
Two pipeline candidates in GI therapy are already in Phase III with encouraging results; most research molecules primarily target ulcerative colitis and Crohn's disease

Pipeline Analysis of Key Players in GI Therapy						Indication
Phase III	IBP-9414 Infant Bacterial Therapeutics AB		RBX-2660 Rebiotix Inc			
	RBX-2660 Rebiotix Inc	ribaxamase Synthetic Biologics Inc	STP-206 Leadiant Biosciences Inc	ISOT-101 ISOThrive Inc		
Phase II	MBK-002 Mikrobiomik Healthcare Company	MRx-1234 4D Pharma	SER-287 Seres Therapeutics Inc	sibofimloc Enterome Bioscience		
	RBX-2660 Rebiotix Inc	RBX-7455 Rebiotix Inc	BX-002 BiomX Inc	BX-003 BiomX Inc	TAK-039 Takeda Pharmaceutical	
Phase I	KB-295 Kaleido Biosciences Inc	KBL-697 KoBioLabs Inc	MET-2 Nubiyota LLC	ISOT-101 ISOThrive Inc	VE-202A Vedanta Biosciences	VE-303 Vedanta Biosciences
	JNJ-72537634 Johnson & Johnson	KB-174 Kaleido Biosciences Inc	MRx-1233 4D Pharma	SER-301 Seres Therapeutics Inc	SK-08 Zhiyi Pharmaceuticals	CR-1301 Conaris Research Institute

- Necrotizing Enterocolitis
- Diarrhea
- Hepatic Encephalopathy
- Reflux Esophagitis (Gastroesophageal Reflux Disease)
- Non-Alcoholic Steatohepatitis
- Irritable Bowel Syndrome
- Ulcerative Colitis
- Crohn's Disease (Regional Enteritis)
- Inflammatory Bowel Disease
- Colitis
- Intestinal Infection

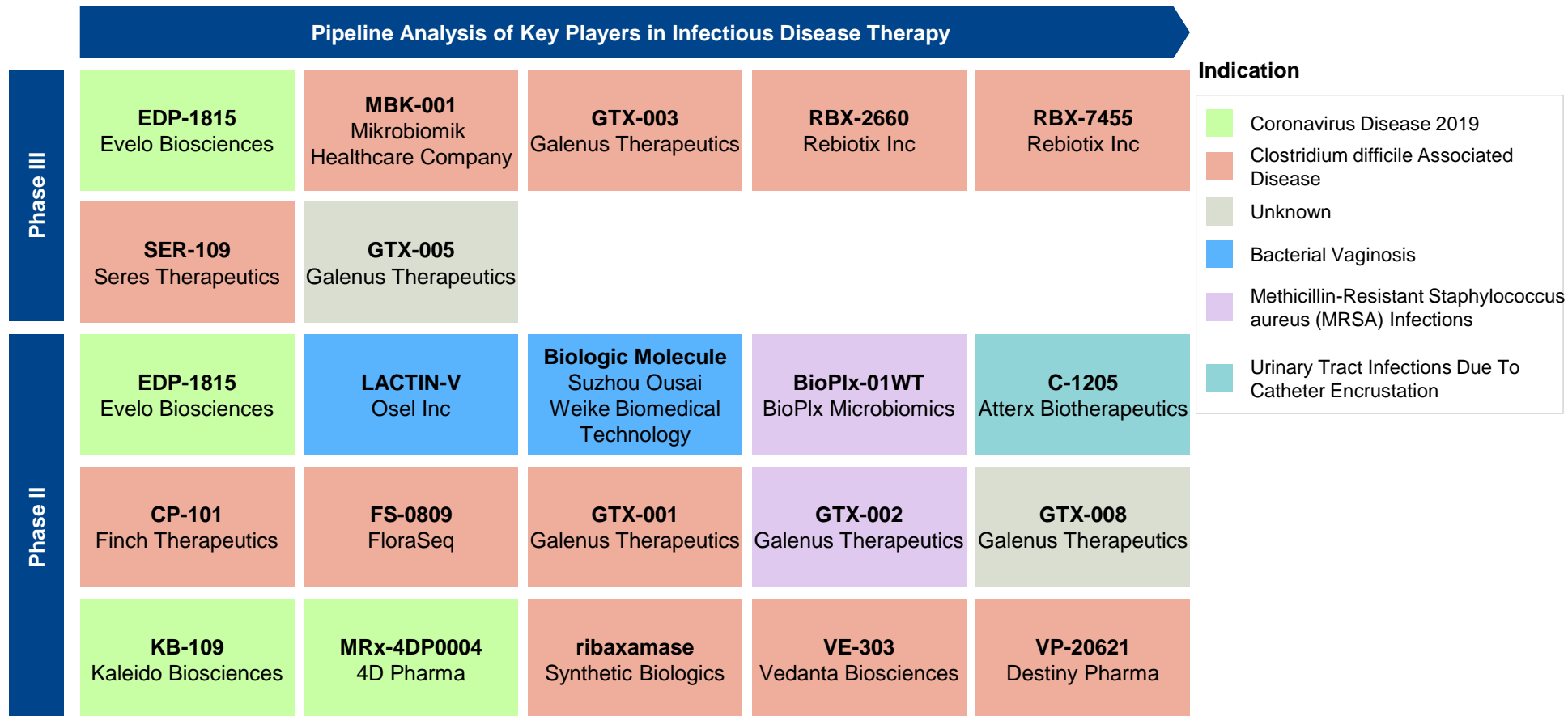
Source: Aranca Analysis

More advanced research carried out in immunology, oncology therapy, with several drugs in early stage of development for different indications



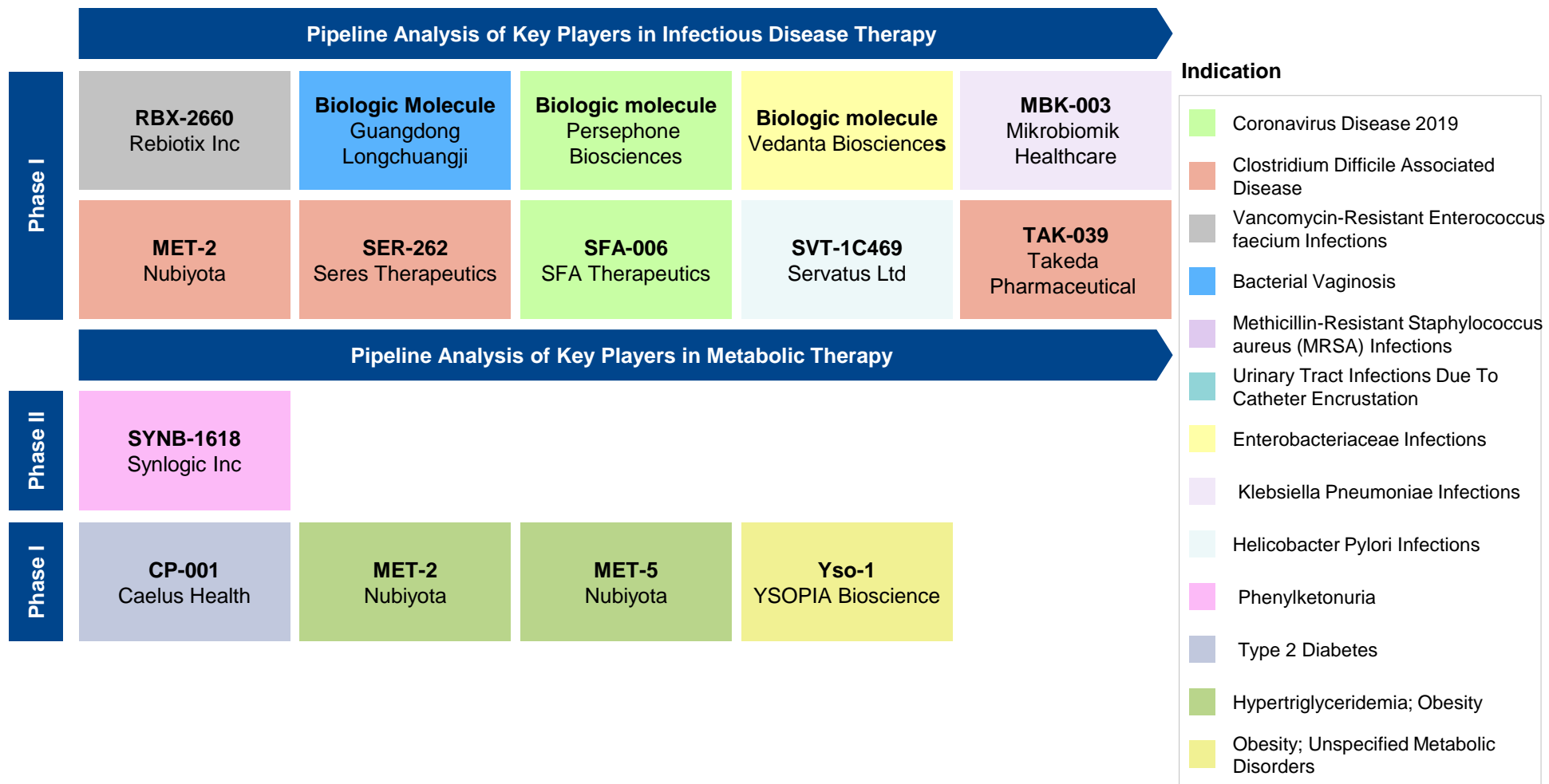
Source: Aranca Analysis

Within infectious disease space, over 50% of pipeline molecules involved in treatment of Clostridium difficile associated disease...



Source: Aranca Analysis

...several molecules also targeting COVID-19 infection; recent activity seen in metabolic therapy, with many molecules in early stage of development



Source: Aranca Analysis

Rise in collaborations in microbiome space witnessed over past five years; Takeda partners with several developers for a strong foothold in microbiome domain

Partnerships/collaborations of major pharmaceutical companies with key emerging players in microbiome domain

Developer	Partnering Company	Deal Value	Date	Key Takeaways
Debiopharm	Takeda	-	June 2020	<ul style="list-style-type: none"> Development of microbiome therapeutics for treatment of IBD and other GI disorders
Second Genome	Gilead	USD 38 Mn upfront	April 2020	<ul style="list-style-type: none"> Identification of biomarkers for five of Gilead's clinical candidates and drug targets of IBD
Holobiome	Johnson & Johnson	-	December 2019	<ul style="list-style-type: none"> Development of proprietary bacterial consortia for treatment of digestive diseases
Finch Therapeutics	Takeda	-	November 2019	<ul style="list-style-type: none"> Development of microbiome-based therapeutics using Finch's Human-First Discovery platform Evaluation of preclinical candidate FIN-524 for treatment of ulcerative colitis
4D Pharma	Merck & Co. Inc (MSD)	Up to USD 347.5 Mn in milestone payment	October 2019	<ul style="list-style-type: none"> Development of live biotherapeutics for vaccines Clinical trial conducted for evaluating combination of Keytruda (pembrolizumab) by MSD and 4D's live biotherapeutic candidate MRx0518 in patients with solid tumors
Seres Therapeutics	AstraZeneca	USD 20 Mn in three equal installments over 2 years	March 2019	<ul style="list-style-type: none"> Evaluation of microbiome-based therapies on their capacity to augment cancer immunotherapy SER-401 may be studied in combination with checkpoint inhibitors from AstraZeneca's cancer pipeline such as Imfinzi (durvalumab)
Vedanta Biosciences	BMS	-	December 2018	<ul style="list-style-type: none"> Evaluation of BMS's Opdivo (nivolumab) in combination with Vedanta Biosciences' VE800 in patients with metastatic or advanced cancers

Source: Industry Reports, News Articles, Company websites, Aranca Analysis

Market landscape for microbiome-based therapeutics to emerge with increased focus in applications for oncology, adoption of new technological platforms, and collaborations with big pharma

Opportunities in microbiome domain

Potential in cancer treatment in improving anti-PD1 efficacy

- The role of the microbiome in cancer treatment is gaining prominence and evidence suggests it plays an important part in the way patients respond to cancer therapies. The gut microbiome influences the response to checkpoint inhibitor immunotherapies. For example, improved efficacy of anti-PD1 treatment, along with increased antitumor T cell responses, is seen in mice transplanted with fecal microbiota from responding patients.
- Several companies are working on enhancing cancer immunity and therapy efficiency. For instance, AstraZeneca collaborated with Seres Therapeutics to explore the use of microbiome therapy (Ser-401) in boosting the efficacy of cancer immunotherapy.

Newer platform technologies for development of microbiome therapies

- Companies are exploring different platform technologies to target a wide range of indications.
- For example, Seres Therapeutics follows rigorous purification processes for isolating the desired subset of species and removing pathogens and contaminants.
- Other companies such as Finch, Vedanta, and Microbiotica are focusing more on live therapeutics assembled from experimentally defined consortia of the cultured microorganisms.
- 4D Pharma is using a monoclonal preparation of bacteria to achieve immunomodulation.

Adoption of inorganic growth strategies in the market

- Big pharmaceutical players are slowly gaining a strong foothold in the microbiome field through collaborations, agreements, and partnerships with biotechnology companies.
- Synergistic activities in this space have consistently increased and grew two-fold between 2017 and 2019. Most of the deals revolve around upfront payments and milestones, positively impacting the developer's revenues. For example, 4D Pharma is set to receive up to USD 347.5 Mn in milestone payments from MSD.
- The presence of big pharmaceutical companies, coupled with a drastic increase in clinical activities in the microbiome space, would be instrumental in the development of microbiome therapeutics.

Source: Industry Reports, News Articles, Company websites, Aranca Analysis

For more information on this space or any other research needs, Aranca can prove to be a suitable partner

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<ul style="list-style-type: none">▪ Market Opportunity Assessment▪ Indication Prioritization▪ Product Value Proposition Development▪ Competitor Analysis▪ Clinical Trial Analysis▪ Pricing and Market Access	<ul style="list-style-type: none">▪ Long-term Demand Capacity Planning▪ Product Portfolio Optimization▪ Inventory Planning▪ Value Chain Analysis▪ Supplier Identification & Deep Dives▪ Best Cost Sourcing Analysis	<ul style="list-style-type: none">▪ Product Launch Support▪ Brand Strategy & Communication▪ New Indication/New Market Assessments▪ Loss of Exclusivity Planning▪ In-/Out-Licensing a Product	<ul style="list-style-type: none">▪ Licensing & Acquisition Support▪ Partner Identification▪ Asset/Partner Screening▪ Due Diligence▪ Evaluation of Collaboration Options▪ Revenue Forecast Models



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Supporting clients on queries regarding running their business operations efficiently



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Identifying collaboration opportunities that enable clients to enter new therapy areas or markets through successful partnerships

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