



SUVEN PHARMACEUTICALS LIMITED SECOND ANNUAL REPORT 20**19-20** 





We could have continued to foresee our tomorrow the way we have done before. Or we could have widened our horizon to wade through untested waters.

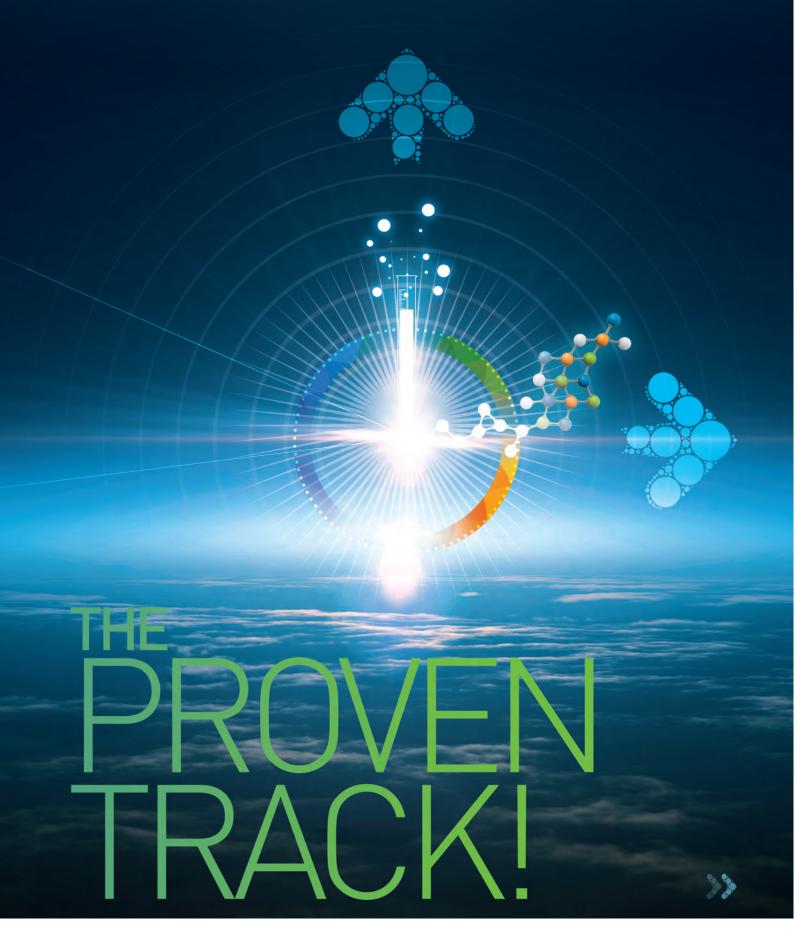
We chose the latter. Crucial alliances were forged. Important investments were made. Strong associations sustained. We chose to widen our canvass. Heighten our vision.



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We could have gone by the proven track. Or we could have envisioned something far beyond.





**TILL** some years back, we were immensely satisfied that our painstaking efforts had positioned us among the most profitable pharmaceutical CDMO players. An achievement, indeed.

We could have rested on our laurels and moved along the proven track. But we questioned our future. We asked ourselves: Do we want our success to be shaped by others? Or, do we want to build an edifice that makes success sustainable?

This questioning was critical for our business. After all, our operations were dovetailed to the risk appetite of global innovators and their financiers. Fragilities that hold the potential to impact product innovation

could drive us into the corner. Hence, despite our proven capabilities, our progress was not in our hands entirely.

### We were determined to change.

We decided to make the best use of our priceless intangibles to build the foundation of the new Suven – one that willingly takes on challenges to secure and create a more sustainable entity that's capable of shaping its destiny.

We dived into untested waters - the formulations space. We unearthed opportunity nuggets, largely uncluttered by competition owing to their miniscule market size, chemistry complexity, and other challenges.

Over the last few years, we have carefully built a robust pipeline of niche products. We filed 11 ANDAs as on March 31, 2020 and three of those secured the green light from the regulator.

We had one formulation as on March 31, 2020 for which we were supplying commercial volumes. We have started commercial supplies for two more products, and we hope to supply commercial quantities for a third by the end of FY21, taking our commercial formulations tally to four by the end of 2020-21.

We invested ₹ 90 crore in a sophisticated formulations facility which will commence operations in FY21. So, when our products gain traction, our facilities will begin to deliver.

We have profit-sharing agreements with our marketing partners which are marginally revenue-growing but significantly return-accreting.

We have taken a step forward. We have articulated our progress for one prospective marketplace. The narrative for the world at large is yet to unfold... We call it 'Growth-in-Progress'.



EXPANDING... FURTHER -FORMULATIONS... Enriching our product pipeline with 6 additions.

> Growing our regulatory pipeline with 2-3 ANDAs for FY21.

Aiming to commercialise 2-3 products in FY22.

# **GROWTH**-IN-PROGRESS



## "WE REMAIN FOCUSED ON EXPANDING OUR PERSPECTIVE, VERTICALLY AND LATERALLY, WITH THE OBJECTIVE OF MAKING SUVEN A FULL-FLEDGED PHARMACEUTICAL SOLUTIONS PROVIDER."



### Dear shareholders, **UESTIONS.** That's what

makes an entity more responsible and more accountable. The ability to ask questions and the courage to field questions are seeded deep into the genes of Suven Pharma. And, this genetic structure makes it resoundingly independent and robust right from the birth.

Representing an organisation which has shown that baby steps can be giant strides with strong determination and flawless strategy is indeed a matter of great pride.

Suven Pharma, as you all know, is it has been a healthy beginning. born out of Suven Lifesciences.

You must be wondering what drove us to create an independent entity. The answer lies in the questions you had been posing before us: Why are you restricting yourself to a small part of the entire value chain? Why aren't you expanding your activity? What stops you from leveraging your deep chemistry skills in synergic verticals? And, so on.

In response to all your queries, here I present your very own company, which is focused on expanding its horizon, vertically and laterally, with the objective of emerging as a full-fledged

pharmaceutical solutions provider.

We are steadily building the infrastructure and capabilities to reach that level. Suven Pharma will not just be about CDMO. It will be a lot more. Even in CRAMS, which was until now restricted to intermediates, will now straddle the pharmaceutical value chain. We will also expand our customer profile from innovators to virtual companies and local markets for multinationals.

Our first step in this direction was entering the formulations space. And, I must mention that We cherry-picked our niche opportunities and worked deftly in translating them into reality. And it worked with three out of eleven products we filed received approvals from the regulator. Even as I write to you, our team has shipped the first few batches of two products, while the fourth is awaiting approval. In a few-years from now, Suven should have a healthy basket of products in its pipeline, at various stages of development

Rising Pharma Holdings, Inc., our associate, may also assist us in enlarging our formulation venture. Rising is a development and distribution company in the formulations space. It has many ANDAs in development every year with its partners. Some of those may fit into our capability matrix. For those products, we will have the first right of refusal. I look forward to projects now, CDMO will not be the coming out of Rising. The additional advantage with Rising only intermediates today, and is its strong forte in distribution.

I would like to mention that we – Suven and Rising – have interesting synergies which will help us explore ways of combining our capabilities for strengthening our individual businesses and our business relations.

To cater to these opportunities, we drew up a ₹320-crore capex plan which includes creating a multi-vertical capacity. Out of this, ₹210 crore was pumped into the business up to 2019-20, while the rest will be invested this year. Our OEL facility – a highly sophisticated and automated unit which operates in a closed atmosphere – began operations during the year under review, while our other facilities such as speciality chemicals and formulations will go on stream this year.

### So, the question you would want to ask me now is: Do we have the products and customers in place? No, we don't. But we have to prepare. Because, if you do not have the capacity, you do not get the business. Conversely,

when the capacity is ready, it will not start generating revenue from day one.

At Suven, we have to take tough strategic calls. This capacity creation is one such call which is based on interactions with customers and the future requirements. The intrinsic value from our investment will come when we are able to secure projects appropriate for our capacities. Till then, we have the flexibility to utilise it for other products.

Expansion at Suven will not only transpire in terms of adding new revenue verticals, it will also expand our existing operations. Take CDMO for instance. In a few years from same. We are manufacturing we would be doing much more tomorrow.

Our customer requirements are also increasing. They want us to move up the value chain so that we are able to engage with them for managing the entire product lifecycle. We have responded to that – our first step being creating relevant capacities. We are working out the contours of moving into this higher orbit with our customers as well as within the organisation. It would take time but I am definite that this change will happen inevitably. We will prudently utilise our operational cash flow to acquire new technologies with an eye on the prospective customer category it can cater to, undertake technology-based development which will then help sourcing and securing relevant projects.

With these strategies in place, we have drawn up a comprehensive blueprint for the current year. I am cautiously optimistic about our growth. This is primarily owing to the pandemic which has ravaged the world, pushing nations, economies, businesses and people on the edge. It's a shock the world was ill-prepared for and will take long to recover from.



In 2020-21, we will bring in the power of disciplined creativity to find newer ways to grow. And then approach these opportunities with a determination to seize the future one day at a time.

From a medium-term perspective, by when we will hopefully see our strategy in motion, our business profitability should be evenly balanced between our three verticals – CDMO-Pharma, CDMO-Non-Pharma and formulations - making Suven a full-fledged pharmaceutical solutions provider.

In closing, I would like to thank the Board for guiding me to execute my responsibilities in the best possible manner. I would like to extend my gratitude to each and every member of our team for their relentless efforts in making Suven a respected and responsible partner to innovator companies globally.

My deep appreciation to all our loyal and valuable shareholders for their confidence and support. I also place on record my gratitude to all our other stakeholders – vendors, customers, bankers and government authorities – for their consistent support and assistance. I solicit your continued co-operation in helping Suven move into a brighter future.

### Regards Venkateswarlu Jasti Chairman & Managing Director

# SUVEN PHARMA IS A FULL-FLEDGED **BIOPHARMACEUTICAL SOLUTIONS PROVIDER FOR GLOBAL PHARMACOS.**

Suven Pharma is into NCE-based Contract Development and Manufacturing Operations (CDMO) for over two decades, supporting the needs of the global life science industry and fine chemical majors.

With Mr Venkat Jasti at the helm, the Company's experienced and energetic team manage day-to-day business operations.



Suven Pharmaceuticals Limited, USA (Branch operations of Suven Pharmaceuticals Limited, India)



Suven Pharma, Inc. New Jersey, USA (Wholly owned subsidiary of Suven Pharmaceuticals Limited, India)

**Rising Pharma Holdings, Inc.** New Jersey, USA (Associate company of Suven Pharma, Inc.)





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USFDA-CERTIFIED FACILITIES ALLOW THE COMPANY TO **SEAMLESSLY DELIVER VALUE TO GLOBAL CLIENTS.** 





Where we stand today

403

EBITDA

(₹ crore)

852 Revenue (₹ crore)



EXPANDING HORIZONS

Pashamylaram, Telangana API and Formulation facility



Suryapet, Telangana Intermediate facility



JNPC, Visakhapatnam, Andhra Pradesh API and Intermediate facility



Jeedimetla, Telangana Process Research and Pilot plant

New Jersey, USA Development, Project Management & IP Management









# "FISCAL 2019-20 WAS A WATERSHED IN THE JOURNEY OF SUVEN -A GREAT PERFORMANCE AND A PROMISE FOR EVEN BETTER PROSPECTS."

### How do you see the Company's performance in 2019-20?

It was a good year for the Company as business growth and profitability scaled appreciably. We delivered on our commitments made at the beginning of the year despite the economic slowdown.

### What have been the growth drivers?

If you delve deeper into the growth drivers, then you'd see that the growth has been contributed in equal measures by all the business verticals. While the CDMO vertical (Base CDMO and Commercial CDMO) jumped 24% over the previous year, specialty chemicals improved more than 40%. Growth in these knowledgedriven, return-accretive verticals has resulted in a healthy increase chemicals segment. But this in profits and a decent uptick in profitability. Our Net Profit soared 36% to ₹270 crore in 2019-20 from ₹198 crore post demerger adjusted profit a year ago and EBITDA margin at 47%.

### Which factors triggered the growth in CDMO?

In base CDMO, we secured new projects and gave supplies for one late-stage development project. We saw good growth in commercial supplies and volumes. We delivered ahead of schedule because our customer's campaign had ended. But there is a caution here. Revenue from commercial supplies will remain uneven. This is because once a customer buys is being demanded by our one batch of material, the next order comes usually after 12-18 months, depending on how the customer's product moves in the outsourcing. Hence we have market.

### Your specialty segment was a big surprise this year. Indeed. It was a stellar

performance by the specialty was not entirely unexpected. We are supplying intermediates to two commercial molecules. one of which was launched by our customer towards the close of 2018-19. Hence, we expected additional volumes for the intermediates of this new product. And it happened.

The first molecule was a bit of a surprise, though. A year back, the supply of the intermediate for this molecule dipped because the molecule came out of the patent umbrella in certain geographies. Our customer was agile and regained the patent applying the combination technique. This brought in additional intermediate supplies for Suven in 2019-20.

### What have been other highlights of the year?

The standout highlight for the year is that we took definitive steps in our expansion strategy. The moment I say this, you would feel that I am referring to the capex plan being implemented by the Company. That is a part of our expansion strategy. Our strategy is about expanding the horizon of the Company. A direction which customers and which, over a period of time, will become the new norm in pharmaceutical decided to change before we are forced to.

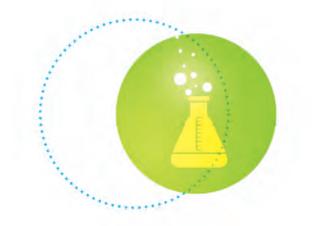
### Can you throw some light on this strategy?

**Expanding** our horizon is about doing different things as it is about doing things differently. It's about widening the opportunity canvas, it is about moving up the value chain with a single objective of being more relevant to our customers.

### What are you doing about moving up the value chain? We are entering the

formulations space in a definitive way. We have been working on this for some time now. We have filed around 11 ANDAs, out of which three are ours, six is with customers, two ANDAs in New Animal Drug Applications with customers. We have received USFDA approvals for three products. We have initiated supplies for two products and





# **OUR HORIZON**

a third formulation is being prepared for launch this year.

### Doesn't it create a conflict of interest with your innovator clients?

We have carefully chosen to be in products that have recently gone off-patent. Hence, there will be no conflict of interest with our existing CDMO clients.

### You are a research house. Manufacturing and marketing are completely different aenres.

We are ready to face challenges head on to walk the road less travelled. We have carefully chosen low-volume, complex products which are bereft of competition. We have profitshare marketing agreements for the formulations which are so structured that they are able to push our profitability.

### How does Rising Pharma fit into your formulations strategy?

**Rising** Pharma is a development and distribution company in which we have a financial stake. There are interesting synergies between Suven and Rising. For one, we can and hopefully will, help them develop their ANDA pipeline. Out of the 11 ANDAs filed, two are those of Rising's. We will also utilise their expertise in distribution of our formulations. One commercialised product is being distributed by them. We would continue to explore and work on other mutually beneficial opportunities.

### When do you start deriving returns from your investment in Rising Pharma?

Rising Pharma has reported a profit in CY2019. We will get a share of profits only when the Company declares a dividend. Rising Pharma is a growing company which has just turned around. It will need funds to build stability in the marketplace. In keeping with this reality, we can expect a dividend only after a year or two. Again judging them quarter on quarter is not fair.

### How will you grow the specialty business?

We are developing two molecules which we expect to commercialise in 2020-21. These molecules have the potential to generate an annual revenue of about \$7 million (₹50 crore) each at optimum volumes. But the scale-up to this level will take time. It will depend on the traction which our clients' products attract globally. Further, we are working on some interesting molecules which are at an early stage in

their respective developmental cycles. We expect that it will take about a couple of years to understand whether we are in the right direction or we need a course correction.

### How are your widening the CDMO business?

We have always been developing and delivering intermediates to global intermediate companies. But now things are changing. The pharmaceutical landscape has become increasingly complex. Hence, contracts have evolved from being simply transactional to being strategic. Our customers want more. In keeping with that, we are deliberating on moving up the ladder. This transition will depend on the trust we are able to build with our clients in terms of credibility and capability. We are talking with the clients on possibilities and prospects of making the climb.

### All the business verticals appear to have reasonable promise in terms of growth. How well equipped are you with your capacities?

Our capex is on-going. We invested ₹108 crore in 2019-20 and will invest about ₹120 crore this year. We have started operations at our OEL unit. Our formulations unit and our specialty chemicals facility should commence operations in the current year. Most of these capacities are created in anticipation of demand. Some capacity creation is also to address specific requirements of customers.

### How do we see Suven Pharma, say about a couple of years from now?

Suven Pharma of tomorrow will be a company with three strong and progressive verticals. While the specialty chemicals segment continues to grow as we widen our product offering, the CDMO and formulations businesses will be the key value drivers, creating opportunities for the other vertical. Within two years, we expect the formulations vertical to emerge as an important business and profitability driver for the Company.

SUVEN PHARMACEUTICALS LIMITED ANNUAL REPORT 2019-20

# N-1... API... FORMULATIONS



There is no API as of today. But we can manufacture APIs if our customers desire so.





There is only one formulation as of today (March 31, 2020) Creating a basket of formuations for our CDMO customers could be an opportunity.



It is only the penultimate intermediate until now. But straddling the phama value is the new customer mandate.









# Economic performance and prospects

Global economy: Growth across economies worldwide decelerated markedly in 2019 with a sustained weakness in international trade and investments. Global trade contracted for most part of the year, leading to a slowdown in manufacturing, and financial markets remained fragile. In the backdrop of such turmoil, global growth weakened to an estimated 2.9% during the year — the lowest rate of expansion since the 2008 financial crisis. The year 2020 became a year of nightmare not for businesses alone, but for the entire human race. The loss in businesses because of the Covid-19 pandemic and the containment measures possibly dwarfed the losses that the two global financial crises had caused. The bleeding in the economy didn't stop with the losses, and it drove the entire world into a state of severe uncertainty of unpredictable length. The mayhem has pushed the ailing global economy into one of its worst recessions.

Indian economy: The Corona virus outbreak came like a dreaded blow to an economy grappling with a sustained slowdown. The growth in the gross domestic product (GDP) hit an 11-year low of 4.2% in 2019-20 from 6.1% a year ago. The country's fiscal metrics worsened beyond the government estimates, with the fiscal deficit for FY20 widening to 4.6% of the GDP as against a finance ministry projection of 3.8%.

The slowdown was triggered by a mix of both internal as well as external factors such as a synchronised global slowdown, historically poor automobile sales, and a flat growth in core sectors. On the output front, agriculture and mining could survive the headwinds with the farm sector putting up a 3.7% growth. Government spending helped save the day when manufacturing and gross fixed capital formation threw up disappointing figures. The overall demand in the economy slumped with the three main drivers - consumption demand, investments and exports teetering on the edge. At a time when the wobbly economy spotted some green shoots of recovery towards the end of 2019-20, the Covid-19 pandemic hit India. The consequent lockdowns paralysed lives and froze all economic activities, setting stage for the GDP to see yet another year of contraction. But as every crisis begins, matures, summits and then dissipates, paving the way for a revival, the Indian economy, too, is resilient enough, supported by its strong pillars of growth, to rebound with the lifting of the restrictions and the easing of business activities.

### SECTORAL PERFORMANCE AND PROSPECTS

The global spend on medicines is consistent with an increased use of drugs likely to help it surpass the \$1.1-trillion mark by 2024. The rise in spending is also driven by changes in the specialty and innovative product composition of new brands reaching the market. Adoption of specialty medicines is leading to higher spending and these products now account for 36% of the global drug spend. Specialty spending is projected to account for 40% of the global spending in 2024, when it will reach 52% in developed markets. New product growth is projected to contribute \$165 billion over the next five years – up from \$126 billion in the past five years (2015-2019). It also reflects the effects of market access and price controls

**Global pharmaceutical industry** in many markets that may contribute to slower growth. The IQVIA Institute estimates that approximately 270 (~54 per year) new molecular entities (NMEs) are expected to be approved between 2020 and 2024, compared to 236 during 2015-2019, and 200 in 2010-2014, contributing to the rise in new brand spending.

### Global outsourcing - A growing need

The The pharmaceutical market is going through a radical change, mostly driven by price and cost pressures that the industry could not control. Both innovators and generic companies are challenged in the highly competitive environment to bring new products to the market that provide real therapeutic value — treatments that achieve measurable results in terms of improved health and quality of life for patients at reasonable costs.

Despite the increasing complexity of both small molecules and biological drug substances, new drugs must not only be safe and efficacious but also be patient-friendly leading to an increase in medication adherence Also, in addition to greater efficiency and productivity, access to novel technologies - from digital tools and manufacturing platforms to deliver solutions – has emerged as the new operational mandate. Entrepreneurial pharma and biotech companies will continue to lead innovation in nextgeneration medicines, driving further growth of licensing deals and co-development partnerships. For all of these reasons, significant growth in outsourcing will be a dominant theme in the pharmaceutical industry going forward.

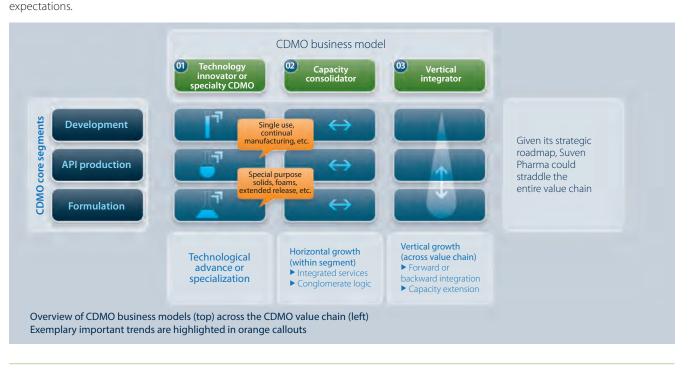
Prospects: The current outsourcing market is estimated at \$90 billion (2019) and is projected to record a CAGR of about 7% to approximately \$117.3 billion by 2023 and represent

about 30% of the overall manufacturing requirements. (Source: The Future of the CDMO Market, March 19, 2020)

**Contract Development and** Manufacturing (CDMO) – a concept that has evolved into a business mandate

Globally, the demand for pharmaceutical products has been increasing steadily as the population ages and healthcare standards in developing countries rise. In response to market trends, the landscape for contract development and manufacturing organisations (CDMOs) is changing to meet the evolving customer

CDMOs are increasingly being seen as extensions of pharmaceutical companies, more specifically their development and manufacturing wings, providing capabilities that are fully integrated with their own preexisting services. Majority of them rely on CMDO partners to avoid the high fixed costs of in-house development, manufacturing capabilities and expertise required to drive their molecules through clinical development. Increasing



### **Emerging trends** 1) Small enterprises are making it large

R&D has shifted from large pharmaceutical companies to emerging biopharma enterprises, which also include start-ups. Also, there has been an increase in virtual companies which, thanks to their business models, outsource clinical development.

2) Integration is the new ask A multi-capability CDMO that provides the entire basket of services is considered vital for new product introduction (NPI) and technology transfer.

The processes require to progress from drug discovery to commercialisation.

### 3) Niche development

Small molecules continue to dominate FDA approvals – almost 70% of NMEs approved over the last five years were small molecules. In light of this reality, small molecule outsourcing trend will continue to strengthen in the coming years. As a result, CDMOs that focus on the development and production of small molecule APIs are growing.

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- complexity in the development of new molecular entities (NMEs) has created a need for niche capabilities and competencies that drug makers prefer to outsource rather than incorporate in-house.
- The CDMO industry is largely fragmented with the top five companies owning less than a 15% share of the market. But this has begun changing with more and more consolidations taking place across the CDMO sector. Most pharma companies prefer

one full-service CDMO to several niche providers to ensure a more simplified and efficient supply chain and, in turn, a reduced time to market.

As such, outsourcing has evolved from being a transactional function to a business strategy.

### Prospects over the horizon:

The year 2019 proved to be a stellar year for the biopharma industry in general and the CDMO sector in particular. Many CDMOs experienced doubledigit growth. Until February, there were good reasons to expect a strong 2020 since many prospects of the CDMO business of the conditions that made 2019 successful remained in place

Emerging biopharma companies raised \$5.7 billion in initial public offerings (IPOs) in the US and were on pace to raise \$15

billion in venture capital, again a historical second best. But the global pandemic that engulfed the entire regulated market – the US, Japan and key markets of Europe being the worst hit by Covid-19 – has cast a shadow of uncertainty over the for the immediate short-term. According to a recent report by Technavio, the CDMO outsourcing market is poised to grow by \$36.51 billion during 2019-2023, progressing at a CAGR of almost 8%.