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GlobalData MediPoint

CORONARY STENTS – GLOBAL ANALYSIS AND MARKET FORECASTS

Executive Summary

The table below provides the key metrics for coronary stents in the 10 major markets (10MM) (US, France, Germany, Italy, Spain, UK, Japan, Brazil, China, and India) during the forecast period from 2013–2020.

Coronary Stents Market, Key Metrics in the 10MM, 2013–2020	
2013 Coronary Stents Market Sales ($m)	
US	$2,065.3m
EU	$573.1m
APAC	$2,123.3m
Brazil	$124.0m
Total	**$4,885.7m**
2013 Global Market Sales by Type of Stent ($m)	
Drug-eluting stents (DES)	$4,335.6m
Bare metal stents (BMS)	$530.1m
Pipeline Assessment (Stage of Clinical Development)	
Number of stents in the early development stage	4
Number of stents in in the preclinical stage	13
Number of stents in the early clinical stage	6
Number of stents in the late clinical stage	5
Key Events (2013–2020)	**Level of Impact**
(2013) Boston Scientific Corporation receives FDA approval for and launches the Promus PREMIER everolimus-eluting platinum-chromium (PtCr) stent in the US.	↑
(2013) Approval and launch of the next generation of DES, such as BioFreedom (Biosensors International) and Coroflex ISAR (B. Braun) in the EU	↑↑
(2013) Elixir Medical Corporation receives a CE Mark for the DESolve bioabsorbable stent (BAS) in the EU.	↑↑
(2014) MicroPort Scientific Corporation receives approval for Firehawk, the world's first targeted drug-eluting coronary stent system, in China.	↑↑
(2014) Approval and launch of the STENTYS sirolimus-eluting, self-expanding stent in the EU	↑
(2015) Commercial launch of the CE-Marked DESolve 100, a novolimus-eluting, thin-strut BAS, in the EU	↑
(2015–2016) Expected commercial launch of BAS, such as DREAMS by Biotronik and Fantom by REVA Medical, in the EU	↑↑
(2016–2017) Commercial launch of Absorb BVS in the US and APAC, including in Japan and China	↑↑↑
(2019–2020) Expected commercial launch of BAS, such as DREAMS by Biotronik and Fantom by REVA Medical, in the US	↑↑
2020 Coronary Stents Market Sales ($m)	
US	$1,849.9m
EU	$555.2m
APAC	$3,023.5m
Brazil	$187.8m
Total	**$5,616.4m**

Source: GlobalData
CE Mark = Conformité Européene (European Conformity) Mark
EU = France, Germany, Italy, Spain, and UK
APAC = Asia-Pacific (Japan, China, and India)

Coronary Stent Sales by Region

Coronary stents can be used for a wide range of indications in coronary artery disease (CAD), including *de novo* lesions, small-vessel disease (SVD), bifurcation lesions, and tortuous and narrow lesions. Coronary stents can improve the clinical outcomes for all of these indications as well as quality of life for patients suffering from this debilitating disease.

The figure below shows the sales of coronary stents for treating CAD in each of the 10 countries covered in this report during the forecast period. In 2013, sales of DES and BMS in the 10MM were $4.89 billion. GlobalData estimates the 2014 sales

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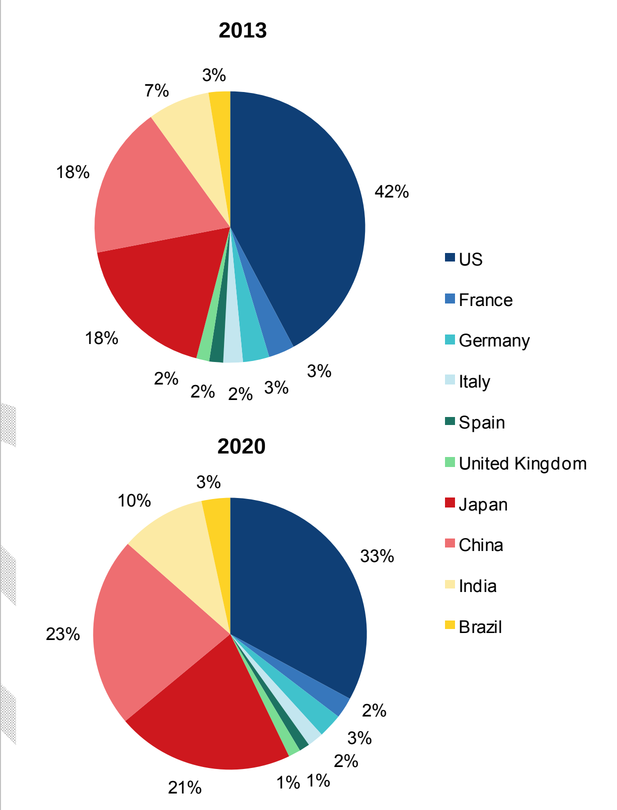
of DES and BMS in the 10MM to be $4.99 billion. By 2020, sales of coronary stents, including bare metal and drug-eluting stents, will grow to $5.62 billion, at a Compound Annual Growth Rate (CAGR) of 2.0%. To date, BAS have not received regulatory approval and been launched in the US, Japanese, and Chinese markets, but are expected to enter these markets in the near future.

Of the 10MM covered in the report, the US currently has and will continue to have the largest share in the coronary stents market. Together, the US, the 5EU countries, and Japan will account for 64% of the coronary stents market for BMS and DES in 2020. Collectively, the 5EU countries are forecast to have only 10% market share in the future. Among the emerging markets, China has captured significant market share, which is expected to increase in the future. The emerging markets, including Brazil, China, and India, are expected to demonstrate the greatest growth in the market over the forecast period and will serve as an outlet of expansion for stent manufacturers to increase their global presence.

Global Coronary Stents Market Revenue ($bn), 2013 and 2020



Source: GlobalData

Global = US, EU (France, Germany, Italy, Spain, and UK), APAC (Japan, China, and India), and Brazil

The key drivers for the coronary stents market during the forecast period are:

- The rising prevalence of CAD in the major markets covered in this report
- The need for effective therapies that reduce the risk of complications, such as restenosis (re-narrowing of the coronary artery), chronic inflammation, and thrombosis, and the need for target lesion revascularization (TLR)

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associated with bare metal and drug-eluting stenting

- The cost savings for healthcare payers resulting from the reduced need for repeat revascularization procedures and prolonged dual antiplatelet therapy
- Reducing the need for stent-in-stent procedures and improving the technical feasibility of future interventions
- Innovations in stent technology with regard to the platform, material, and coating
- The increase in patients' disposable income and government insurance coverage in the emerging markets, such as China and India
- The approval and launch of BAS, such as the Absorb BVS, in the US, Japan, and China

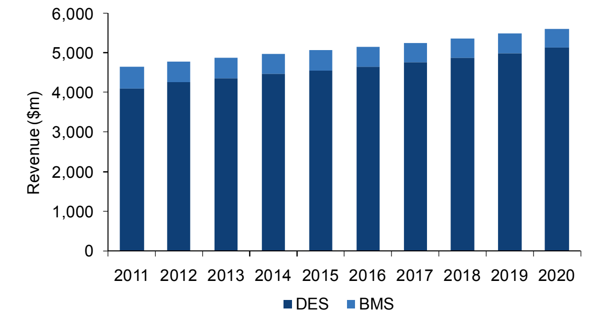
Market Dynamics

Stenting for coronary applications has been widely adopted in clinical practice and is associated with improved outcomes. BMS and DES are effectively commodities, where the physician has a handful of stents from which to choose. Within the coronary stents market, DES currently dominate the market and will continue to do so throughout the forecast period, as they are considered the gold standard of treatment. The DES market is a vast and double-digit market, accounting for nearly 90% of the total coronary stent market, as shown in the figure below. In fact, DES sales for coronary applications are nearly eight times those of BMS market sales.

Given this large market potential and the rising prevalence of CAD worldwide, device manufacturers have focused primarily on the research and development (R&D) and commercialization of innovative DES systems. The larger market sales of DES can be attributed to physicians' extensive clinical experience and expertise in using these stents, improved outcomes, and the reduced need for repeat intervention. BMS are used in cases where the patient is not a good candidate to receive a DES, such as those planning to undergo other major surgeries in the near future.

Covered stents (CS) are used less often in practice and only in select cases, such as patients with artery perforations. BAS have only recently entered the market and are not widely adopted in clinical practice, due to the lack of clinical evidence and the high cost of these devices.

Global Coronary Stents Market Revenue ($m) by Type of Stent, 2011–2020



Source: GlobalData

Global = US, EU (France, Germany, Italy, Spain, and UK), APAC (Japan, China, and India), and Brazil

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Technological Trends

Over the years, a plethora of BMS and DES have been developed, featuring innovative materials, designs, structures, coatings, and drug-elution components. The development and optimization of DES has become a primary focus for many stent manufacturers, where they utilize the BMS they have developed as the platform and foundation for their DES. These innovations in technology aim to ensure high radial strength and flexibility, low elastic recoil, optimal vessel coverage, minimal foreshortening, and rapid strut endothelialization.

Although stent technology has evolved over the years, several types of complications remain, such as late thrombosis and restenosis, negative vessel remodeling, delayed endotholelialization and healing, lack of homogenous drug distribution, and the need for prolonged dual antiplatelet therapy. Therefore, low-profile drug-delivery systems need to be developed to reduce the risk of restenosis and thrombosis, and improve long-term patency. Effective therapies also need to be developed to treat complex lesions and challenging patient populations, such as chronic total occlusions (CTOs), long lesions, acute myocardial infarction (AMI) (heart attack), and diabetes mellitus.

Emerging stent technologies in the coronary stent market, including BAS and the third generation of DES with biodegradable polymer/polymer-free coatings, aim to address these unmet needs. However, these emerging technologies have only recently entered the market and will encounter strong competition from the contemporary stents. The third generation of DES has been developed to eliminate concerns associated with the permanent polymer coating, which is a cause of late and very late stent thrombosis. Drug-eluting BAS represent the fourth generation of DES in the evolution of DES technology. Given that the stent scaffold degrades over a period of time, BAS offer several benefits, including a reduced risk of restenosis, avoiding the implantation of multiple layers of metal inside the vessel, improving the feasibility of future interventions, and enabling for late lumen gain.

Key Players in the Global Coronary Stents Market

The coronary stents market is a vast and dynamic market that is saturated with numerous players worldwide, as illustrated in the figure below. The competitive landscape consists of large, mid-size, and small companies that have developed different types of coronary stents to target various indications, such as *de novo* lesions and bifurcation lesions. The coronary stents market is largely dominated by a few key players, including Abbott Vascular, Medtronic, and Boston Scientific, followed by Biosensors International and Terumo Corporation.

Companies such as B. Braun, Sahajanand Medical Technologies, MicroPort Scientific Corporation, and Balton are potential competitors to these large corporations, as they develop innovative coronary stent platforms. As the next generation of DES and

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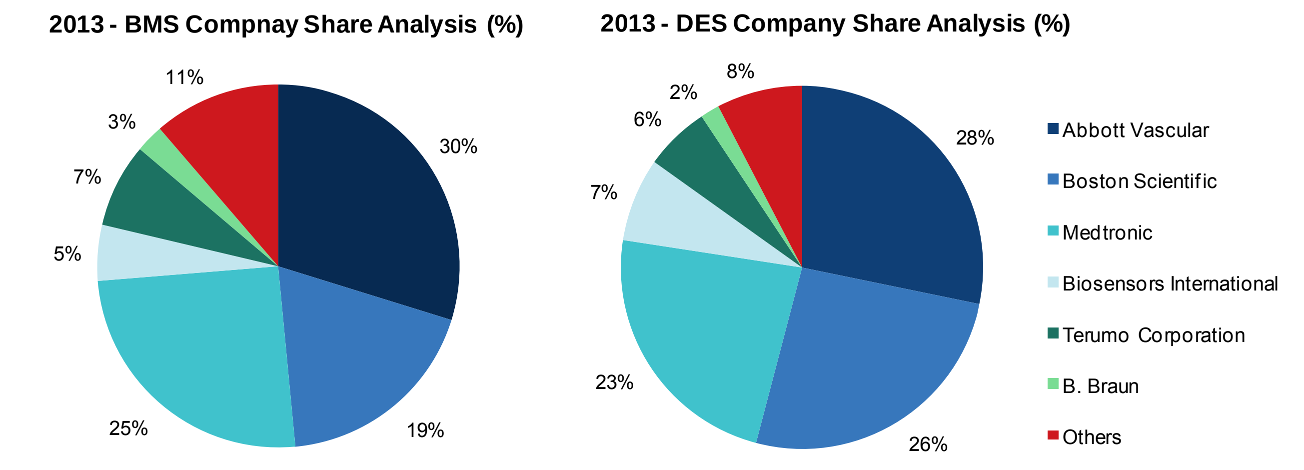
BAS enter the market, the current key players will need to retain and acquire market share by improving the clinical performance of their existing products. In addition, they will need to expand into or increase their presence in the emerging markets in order to take revenue away from their competitors in the future.

The top players in the coronary stent market offer a broad product portfolio with regard to the type of stent and the number of products within each stent category. Within this market, stent manufacturers can customize the type of stent they develop for specific types of lesions in the coronary vasculature.

Global Coronary Stents (BMS and DES) Market for Treating CAD, Company Share Analysis (%), 2013



Source: GlobalData

"Others" category includes Alvimedica, Balton, Biotronik, Envision Scientific, Innovative Health Technologies, Meril Life Science, MicroPort Scientific Corporation, Minvasys, OrbusNeich Medical, Sahajanand Medical Technologies, Translumina, and Vascular Concepts.

Future Outlook

Each year, millions of individuals worldwide are affected by CAD. Given the high burden of the disease, it is important to develop innovative technologies that can improve outcomes and disease management. Currently, DES are widely adopted in clinical practice, given the clinical evidence, improved outcomes, and physician experience with using these devices. In the US and 5EU, the coronary stents market value is expected to decline slowly in the future, given the decline in the average selling price (ASP) and number of BMS and DES used per procedure. As medical costs continue to rise, healthcare providers are implementing cost-containment policies and "appropriateness criteria" to reduce costs and overstenting.

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Unlike in the west, the coronary stents market in the APAC and South American regions is expected to increase and demonstrate steady growth in the future. The APAC countries, including Japan, China, and India, have diverse populations, ethnicities, and clinical practices. Most device manufacturers regard Japan and China as their chief targets, due to their economic growth, pricing structure, and vast populations. In particular, China, with its high proportion of aging individuals and procedure volume, is expected to become a prime market for coronary stents.

Many stent manufacturers have ventured into the R&D of BAS, which is a high-growth market segment. However, BAS technology is in the early stages, where robust, long-term clinical evidence of its therapeutic benefits needs to be shown. Currently, the adoption of BAS in the clinical setting is low, which is attributable to the lack of clinical data and appropriate reimbursement, as well as the high cost of these devices. In real-world practice, the majority of patients with CAD are treated with DES, and this will continue in the future. In addition, the development and commercialization of the next generation of DES with bioresorbable polymer coatings, polymer-free coatings, and innovative platforms indicates the continued value of DES in the coronary market.

What Do Physicians Think?

- Physicians interviewed by GlobalData believe that coronary stents will continue to be widely adopted for treating patients with CAD, especially in the emerging markets. DES are the gold standard of treatment for CAD and will continue to dominate the market in the future. Device manufacturers have developed innovative stent platforms to improve outcomes and the patient prognosis.

"Coronary stents will absolutely continue to be widely adopted in the future; just look at the numbers….In the emerging markets, as logistical issues with reimbursement and development issues are addressed, we will see increased adoption in the future. Markets like China and India are huge markets with huge populations, where stenting is still underused. I do see a trend towards an increase in coronary stenting procedures in the future, especially in the emerging markets…."

Key Opinion Leader

"I think BMS will almost disappear in five years' time; DES will be the gold standard, and adoption of [the Absorb] BVS will increase with its entry into the market. Stents design will improve with the incorporation of limus drugs, [the] development of innovative platforms, and reimbursement."

Key Opinion Leader

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- Coronary stents such as DES and BMS are effectively commodities, where physicians have a handful of stents from which to choose. The cost of the device plays an important role in the adoption of each type of stent.

"Most of the vendors retail a similar stent product, where there is little difference between them. It comes down to price."

Key Opinion Leader

- Physicians are cautiously optimistic about BAS technology with regard to the adoption of these devices in real-world practice. Currently, BAS are not widely adopted in clinical practice, which can be attributed to the lack of clinical data and reimbursement, and well as the high cost of these devices.

"I think the Holy Grail is having a completely absorbable stent. No doctor or patient will ever say that they want permanent implants. Having a completely degradable stent is the best thing that you can have.....So, I feel the next development has to be a better [more] absorbable stent."

Key Opinion Leader

"I believe in the concept of bioabsorbable stents, but I think that it has not been proven enough to be fully incorporated into practice. I think they are likely to present benefits and may be used in the future as the first line of therapy for certain indications, compared with the currently used second-generation DES. At present, I do not see any clinical benefit [of BAS] compared to the contemporary coronary stents…, but we don't have data supporting that [the use of BAS], and I think we will not have it in the next few years. I believe in the potential of BAS technology, but it has not been proven yet."

Key Opinion Leader

- The current design of BAS platforms, such as the Absorb Bioresorbable Vascular Scaffold (BVS), needs to be improved in terms of its deliverability and performance compared with DES and BMS.

"There are some limitations with the currently available BAS because of product strength. The current BVS scaffolds have big struts of about 140 microns. So, if you put that in a 2mm vessel, I think that the limiting loss will be quite big. Maybe when the device will be improved and we arrive at the next generation of BVS, we can tackle these kinds of lesions. However, I do not think we will start with that within the next few months."

Key Opinion Leader

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"The acute results are not good with the Absorb BVS because the stent struts are thicker than [those of the] contemporary stents, where you do not get optimal expansion of the lesion….There are concerns that the flow is not streamline flow, and there is an increased chance for thrombosis. That is what we have seen with the results, where [the] stent thrombosis rates of the Absorb BVS are a little higher than [those of] the current gold-standard DES."

Key Opinion Leader

- As cost-containment policies are implemented, the widespread adoption of expensive coronary stent technologies is questioned.

"I think price and access to devices are going to be issues. The current financial environment in healthcare is very uncertain….I would not be surprised that in a year or two, we will be told to prove [that] using one device over another [is better] for cost-containment purposes."

Key Opinion Leader

"Cost and availability are what will drive the usage of stents. There is a lot of excitement about the technology, and [it] has a lot of potential, where a lot of people are willing to test BAS technology. However, I think that the cost will be a big issue here, and [also, the] logistics."

Key Opinion Leader

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2 Introduction

Coronary artery disease (CAD) is a global public health and socioeconomic problem that affects millions of lives each year. Percutaneous coronary interventions (PCIs), such as stenting and angioplasty, have been widely adopted worldwide to treat a range of CAD indications. The coronary stent market is a dynamic and competitive one that is saturated with numerous players trying to gain share by developing innovative technologies. Coronary stents, which include bare metal, drug-eluting, covered, and bioabsorbable stents (BAS), can be used for a range of indications in CAD, including *de novo* stenosis, acute myocardial infarction (AMI) (heart attack), bifurcation lesions, SVD, saphenous vein grafts (SVGs), left main coronary artery disease (LMCAD) and chronic total occlusions (CTOs).

Among the different types of stents, drug-eluting stents (DES) are considered to be the gold standard of treatment and will continue to dominate the global coronary stents market in the future. Since the development of the first generation of DES, manufacturers have focused on optimizing and developing innovative low-profile platforms, stent coatings, drug-eluting components, and materials. These innovations have improved the deliverability, performance, and safety profile of stents, leading to better outcomes and reducing the risk of restenosis and complications such as chronic inflammation and late stent thrombosis. Emerging stent technologies, such as DES with biodegradable polymer/polymer-free coatings and BAS, are viable alternatives to and can address the complications associated with the contemporary stents. BAS are a breakthrough technology that can provide transient support to the vessel and completely degrade over time.

Drug-eluting stents are considered to be the gold standard of treatment and will continue to dominate the global coronary stents market in the future.

This report focuses on the global coronary stents market for treating CAD. The global coronary stents market is determined for the 10 countries covered in the report, which are the US, France, Germany, Italy, Spain, the UK, Japan, Brazil, China, and India. This report identifies the unmet needs in the market for treating CAD that are associated with current stent technologies, provides an understanding of physicians' perceptions and decision-making process in using different types of stents, and evaluates the adoption of the different types of coronary stents in the future. From GlobalData's analysis, it is evident that DES currently have and will continue to command the largest share in the global coronary stents market. The widespread adoption of DES can be attributed to improved outcomes, the availability of long-term clinical evidence, and the reduced need for repeat intervention, thereby incurring cost savings for healthcare providers. In addition, the current adoption of emerging stent technologies, such as the next generation of DES and BAS, is

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slow. BAS, such as the Absorb BVS and DESolve, have received only CE Mark approval and are available only in selected markets. Large-scale, long-term cost-effectiveness studies need to be conducted to demonstrate their clinical efficacy, so that these innovative technologies can be integrated appropriately into the existing reimbursement systems.

2.1 Catalyst

Stent technology has revolutionized the field of interventional cardiology such that coronary stenting has become the standard of care for patients with CAD. Modern developments in PCI have led to a paradigm shift in the treatment of CAD towards stenting. Among the coronary stents, DES dominate the coronary stents market worldwide, and physicians have extensive clinical experience using these devices. Unlike bare metal stents (BMS) and covered stents (CS), DES elute an antiproliferative agent, which can significantly reduce restenosis and target lesion revascularization (TLR) rates.

Modern developments in PCI have led to a paradigm shift in the treatment of CAD towards stenting.

Vascular stent technology has evolved over the years and is used in clinical practice for different types of lesions/indications, such as *de novo* stenosis, bifurcation lesions, and small-vessel disease (SVD). Although stent technologies such as DES have reduced the risk of restenosis and the need for repeat revascularization, and also provide mechanical support to the vessel, complications such as late and very late stent thrombosis, chronic inflammation, and dependency on prolonged dual antiplatelet therapy reiterate the need for new treatment modalities. In addition, the presence of polymer coatings on DES can lead to chronic inflammation and hypersensitivity reactions, resulting in poor clinical outcomes and endangering patient safety. The next generation of coronary stents is being developed with innovative stent structures, thinner struts, more effective antiproliferative drugs, durable metal alloys, biodegradable polymer coatings, bioactive and polymer-free coatings, and fully-absorbable stent platforms. BAS offer several benefits, including eliminating the need for stent-in-stent procedures, thereby potentially reducing the need for prolonged dual antiplatelet therapy, enhanced vessel healing, and improving the feasibility of future interventions.

As more long-term clinical data demonstrating the superior therapeutic benefits of BAS and reimbursement become available, the adoption of BAS by the medical community will increase slowly in the future. As CAD is an enormous global public health and socioeconomic problem, and the use of stents continues to increase, it is important to find effective treatment modalities that ensure long-term quality results for patients. This report looks at the current coronary stents market

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for CAD in various regions, and evaluates the adoption and opportunities for these technologies in the 10 major markets (10MM).

2.2 Related Reports

- GlobalData (2012). Bioabsorbable Stents – Global Market Analysis and Forecasts, December 2012, GDME0164MAR
- GlobalData (2013). Drug Eluting Balloons – Global Market Analysis and Forecasts, September 2013, GDME0179MAR

Appendix

12.8 About MediPoint

MediPoint is the flagship product for GlobalData's Medical team. Each MediPoint report is built from the ground up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading KOLs. Running throughout each report in the series, the "What Physicians Think" quotes provide unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

12.9 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

GlobalData has offices in New York, San Francisco, Boston, London, India, Korea, Tokyo, Japan, Singapore, and Australia.

12.10 Disclaimer