India

Neutral *(no change)*

Highlighted Companies

Divi's Laboratories

ADD, TP Rs4707, Rs4545 close

The ongoing uncertainty around the Biosecure Act may present additional opportunities in the CCS business and lead to positive surprises.

Laurus Labs

REDUCE, TP Rs307, Rs427 close

Even though Laurus Labs has multiple business options, we feel the benefits may be back-ended and earnings are likely to languish in the interim.

Summary Valuation Metrics

P/E (x)	Mar24-A	Mar25-F	Mar26-F
Divi's Laboratories	75.42	61.42	48.28
Laurus Labs	141.9	60.29	36.8

P/BV (x)	Mar24-A	Mar25-F	Mar26-F
Divi's Laboratories	8.89	8.19	7.22
Laurus Labs	5.6	5.2	4.6

Dividend Yield	Mar24-A	Mar25-F	Mar26-F
Divi's Laboratories	0%	0%	0%
Laurus Labs	0.47%	0.47%	0.47%

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Pharmaceuticals

Biosecure Act: Is China's loss India's gain?

- The Biosecure Act will inhibit the ability of global pharmaceutical companies to outsource their work packages to China.
- Multiple US companies like Merck, Vertex and Gilead have declared in their SEC filings that this will have a serious impact on their business.
- Indian CDMO companies stand to benefit from it in the medium- to long-term.

Biosecure Act to bar US pharma cos from outsourcing work to China

A bipartisan group has introduced the Biosecurity Act in the US Senate and the House of Representatives. The Bill aims to reduce the dependence of the US biopharmaceutical industry on China and the transfer of technology to China. There are five Chinese companies that are specifically mentioned in the Act: WuXi Apptec, Wuxi Biologics, BGI, MGI, and Complete Genomics. Any company that collaborates with the above-mentioned companies will not qualify for any grants, loans, and contracts from executive agencies. A grandfather clause has been introduced which will allow the companies eight years to continue their existing contracts with Chinese players.

Biosecure Act to have a serious impact on global pharma industry

The Biosecure Act can impact 120 US biopharmaceutical drugs that are being developed in collaboration with Chinese CDMO companies. Wuxi is one of the largest manufacturing companies in the world, and there is bound to be a negative impact on the pharmaceutical industry like the price of drugs going up and an increase in the drug development timeline. Wuxi is involved in manufacturing several blockbuster drugs like Revilimid, Trikarfta, and Trizepatide. Multiple US companies like Iovance Biotherapeutics, Calbetta Bio, Merck, Gilead Sciences, and Vertex Pharmaceuticals have disclosed in their Securities and Exchange Commission or SEC filings the impact of the Biosecure Act on their business.

The CDMO landscape to change due to Biosecure Act

The CDMO market is growing at a faster pace than the global pharmaceutical market. A lot of this growth is driven by emerging biotech and biopharmaceutical companies that do not have the capital to invest in setting up manufacturing plants. Rival companies located in India, Japan, Europe, and America will benefit the most from the Biosecure Act. Several companies like Beigene and Eli Lilly have started looking for other CDMO partners. Management of CROs and CDMOs have commented that they are seeing an increase in enquiries after the introduction of the bill. Indian CDMOs will have a cost advantage while companies like Samsung Bio and Lonza will win contracts based on their capacity and capabilities. Samsung Bio and Lonza are two companies that will benefit the most from the Biosecure Act as their capabilities and services are very similar to that of Wuxi.

Indian CDMO cos to gain from Biosecure Act in medium- to long-term

Government incentives like the production-linked incentive or PLI scheme, foreign direct investments and low manufacturing costs have made India an attractive CDMO destination for companies seeking cost-friendly alternatives to China. Con-call comments by management indicate that new enquiries have increased due to the Biosecure Act. Indian players are also incurring capex and increasing their capacities and capabilities. India's strong regulatory track record and reputation will also help it gaining new contracts. The maximum growth is likely to be on the small molecules vs. biologics as Indian players have already established their reputation, skill, and capacity with small molecules and they currently do not have the capabilities in biologics like that of Wuxi, Lonza, and Samsung Bio. Enquiries, because of the Biosecure Act, will take medium- to long-term to materialize.

The Biosecure Act

An overview of the Act

- A Bill has been introduced by a bipartisan group of Select Committee Members in the Senate and the House of Representatives in the US. This bill will gravely influence the ability of US companies to outsource business to CRO and CDMO players located in **China, Russia, Iran, and North Korea**.
- The Biosecure Act will embargo executive (government) agencies from contracting with, extending loans, or grants to any company with current or future agreements with a "biotechnology company of concern." A "biotechnology company of concern" is a company that is headquartered in or is subject to jurisdiction of a foreign adversary's government and poses a threat to national security.
- The Bill further specifically mentions companies that are related to the People's Republic of China (PRC) as companies of concern. Some of the companies that are specifically mentioned in the Bill are Wuxi Apptec, BGI, Complete Genomics, MGI, and their affiliates.
- The Bill's co-sponsors assert that PRC has invested in furthering their AI and biotechnology capabilities and business collaborations enable PRC to access millions of Americans' genetic data. The Bill essentially opposes the use of US taxpayers' money for furthering foreign adversaries' hostile biotech pursuits. The Bill also aims at stopping the transfer of any American genomic data to the PRC government.
- The Bill sets forth 28 findings that prompted the proposed legislation, one of the reasons stated in the legislation is that the PRC government has unrestricted access to all the data that is collected by PRC companies, including the genomic data.
- The Bill concludes by stating that: "the time has come to stop United States taxpayer dollars from flowing to foreign adversary biotech companies…and prevent United States taxpayers from buying biotech equipment from foreign adversaries that facilitate the transfer of United States persons' genetic data to a foreign adversary."

What exactly will the Biosecure Act prohibit? ➤

- According to Section 3(a) of the Bill, an executive agency is prohibited to "(1) procure or obtain any biotechnology equipment or service produced or provided by a biotechnology company of concern; or (2) enter into a contract or extend or renew a contract with any entity that (a) uses biotechnology equipment or services produced or provided by a biotechnology company of concern…in performance of the contract, or (b) enters into any contract the performance of which will require the direct use of biotechnology equipment or services produced or provided by a biotechnology company of concern…."
- Furthermore, executive agencies cannot give loans or extend grants to purchase biotechnology services or equipment from a biotechnology company of concern.

What is a "biotechnology company of concern?" ➤

- In accordance with the concern expressed regarding PRC in the Bill's introductory statement, four Chinese companies are pointedly mentioned in it: WuXi Apptec, BGI, MGI, and Complete Genomics. As per the Bill, any subsidiaries of these companies, parent affiliates, or successors are also included. Wuxi Biologics, a sister company of Wuxi Apptec, is specifically mentioned in the Bill.
- Moreover, the definition in the Bill broadens the list of restricted companies by stating that a "biotechnology company of concern" is any establishment that is (i) "subject to the jurisdiction, direction, control, or operates on behalf of the

government of a foreign adversary," (ii) is involved in the manufacturing or distribution of a "biotechnology equipment or service", and (iii) poses a risk to US security, either by engaging in joint research with or being supported by a foreign adversary's military, or by providing genetic data to a foreign adversary's government, or by obtaining multiomic data without express and informed consent.

What falls under the category of "biotechnology equipment or services?" ➤

- A biotechnology equipment or service is any service or instrument that is used in "research, development, production, or analysis" relating to "biological materials."
- Data storage and analysis, software, disease detection, consulting services, and supporting services fall under this category as well.

Which agencies are categorized as executive agencies? ➤

- According to the Bill, an executive agency is "an executive department, a government corporation, and an independent establishment."
- The National Institutes of Health, Department of Défense, Department of Transportation, the Centre for Disease Control, and the Food and Drug Administration are some of the executive departments.

When will be the restrictions mentioned in the Biosecure Act come into force➤

- The Biosecure Act will come into effect in two stages. The timing of the House and Senate versions of the Act will be different.
- According to the Senate version of the Act, listed biotechnology companies will face the restrictions stated in the Act approximately six months post enactment. According to the House version of the Act, the restrictions will be implemented 18 months after enactment.

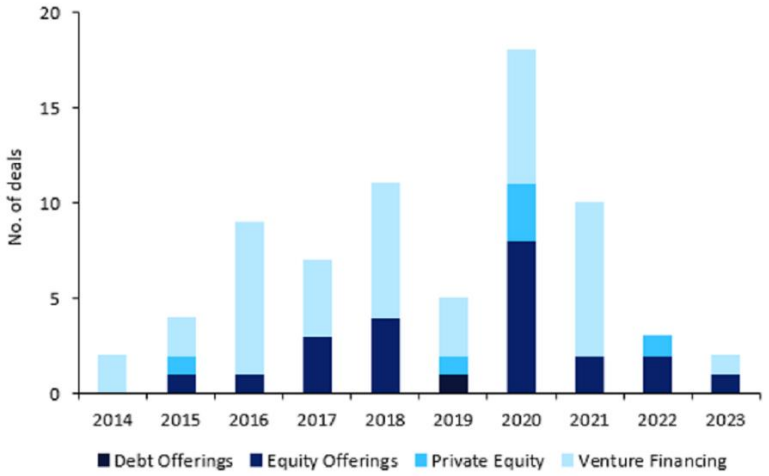
What are the initial reactions to the Biosecure Act? ➤

- **Reactions of Chinese CDMO players**
  - The capital-raising deals for the five companies mentioned in the Bill had already started declining in 2022 and 2023 due to the rising tensions between the US and China and increased interest rates and inflation. The Bill will adversely affect their ability to raise funds further.
  - Chinese biotech stocks fell to their lowest values since the Covid-19 pandemic. Wuxi AppTec and Wuxi Biologics, two of the companies that are explicitly mentioned in the Bill, were drastically impacted. **US companies contributed 46% and 66% to Wuxi Biologics and Wuxi AppTec's revenue, respectively, in 2023**. The Bill will have a momentous impact on their operations. Wuxi AppTec shares dropped by 32% and that of Wuxi Bioligics Cayman Inc fell by 28% in Hong Kong on 26 Jan 2024 when the Bill was introduced.
  - In its 2023 annual results presentation, Wuxi stated that its designation as a "biotechnology company of concern" will affect the company's ability to work with customers that do business with the US government.
  - Wuxi promptly responded to the Bill by publishing an open letter on its website on 2 Feb 2024. The letter was signed by the CEO, Ge Li, Ph.D., and co-CEOs Minzhang Chen, Ph.D. and Steve Yang, Ph.D. In the letter, the executives strongly objected to the allegations and pre-emptive actions that were taken against these companies.
  - Wuxi Bio, Wuxi AppTec's sister company, quickly defended themselves after the Bill's introduction by making an announcement on the Hong Kong Stock Exchange. Wuxi Biologics has asserted in the announcement that the Bill contains a misleading description of its CEO and Executive Director Zhisheng Chen. The company further stated that Mr. Chen has not worked

for China's Academy of Military Medical Sciences or an military-affiliated institution and that he has not received compensation from military-affiliated institutions in the country.

- MGI Tech released a filing to the Shanghai Stock Exchange in response to the Bill. The company stated that it is an upstream equipment provider in the gene sequencing industry and that its business does not involve data collection. The data that is generated using their platforms is collected, stored, processed, and controlled by the customer.
- Shanghai Stock Exchange-listed Pharmatech stated that its business activities did not include analysis of human genome and any of its technologies and samples were not subject to the restrictions stated in the Bill.

Figure 1: Capital raised by Complete Genomics, Wuxi Biologics, Wuxi AppTec, BGI Genomics, MGI Tech, and their subsidiaries



SOURCE: GLOBALDATA, INCRED RESEARCH

Figure 2: Wuxi AppTec and Wuxi Biologics stocks plunged after the introduction of the Bill in Jan 2024

SOURCE: BLOOMBERG, INCRED RESEARCH

- **Biotechnology Innovation Organization (BIO)**
  - BIO is one of the largest trade associations across the globe that represents biotechnology companies, state biology centres and related organizations, and academic institutions situated in the US and 30 other countries. The goal of this organization is to promote the business interests of the members.
  - Initially BIO opposed the Bill. BIO's CEO stated that the Bill presented a threat to the biotechnology industry and would negatively impact the biotechnology sector in the US.

- In a surprising turn of events, BIO changed its stance and openly supported the Bill in Mar 2024 stating that it is an important step to support US national security. Wuxi Apptec and BIO parted ways in Mar 2024 after BIO supported the Bill. Wuxi Biologics did not participate in BIO's 2024 conference.
- A BIO survey released in May 2024 brought to light the strong reliance of US drug and biotech companies on Chinese CDMOs and the drastic impact it will have on these companies if these companies are not given enough time to sever their ties with Chinese CDMOs.
- 100 out of 124 companies (79%) that participated in the survey responded that they had at least one contract or product agreement with a China-based or Chinese-owned manufacturing firm.

- **Amendment to the Bill**
  - Based on the responses to the BIO survey and recognizing the strong dependence of US pharmaceutical industry on Chinese CDMO, the US House of Representatives updated the draft of the Biosecure Act.
    - 52% of the respondents said that switching manufacturers for approved drugs could take two-to-eight years.
    - 85% respondents answered that switching the vendors for clinical and pre-clinical work could take somewhere between six months to six years, basis of the type, and size of service.
  - Based on the new amendment, a grandfather clause has been introduced that allows companies to continue ongoing contracts with Chinese CDMO companies for eight years, i.e., until 1 Jan 2032.
  - According to BIO's CEO John Crowley, the phase-out date that has been proposed in the revised draft will give companies time to cut their reliance on China-based manufacturers and it will ensure that life sciences research is not slowed down and the patients get uninterrupted access to life-saving drugs.

What are the prospects and timeline for passage of the Biosecure Act? ➤

- It is difficult to predict currently what will be the final provisions of the Bill and whether it will turn into a law but given the strong bipartisan support for it, some version of the Bill will come into effect.
- The US House Committee on Oversight and Accountability voted overwhelmingly (40-1) to approve the Biosecure Bill on 15 May 2024.
- Earlier there was an expectation that the National Defense Authorization Act (NDAA) will be a vehicle for the approval of the Act, but it was excluded from it. After touching new lows, Wuxi's Biologics stock jumped by 14% and Wuxi Apptec's stock jumped by 7% after the exclusion of the Act from the NDAA.
- Looking at previous precedents, where similar tactics were used to target Chinese telecommunication companies in 2010s, the Act will limit the ability of US life sciences companies to contract work to biotechnology companies on the ground of national security once the law is passed.
- The next step for the Bill is to go through the full House and Senate for further debate. As an earlier version of the Bill has been approved by the Senate in Mar 2024, the Congress must combine both versions in one before President Joe Biden signs it into a law.
- Even though the legislative process has kick-started, the process of making a Bill a part of a legal document is long and complex. Normally, it can take years for an initiative to turn into law. Furthermore, there are more details that need to be ironed out. More revisions can also be made over the course of time.

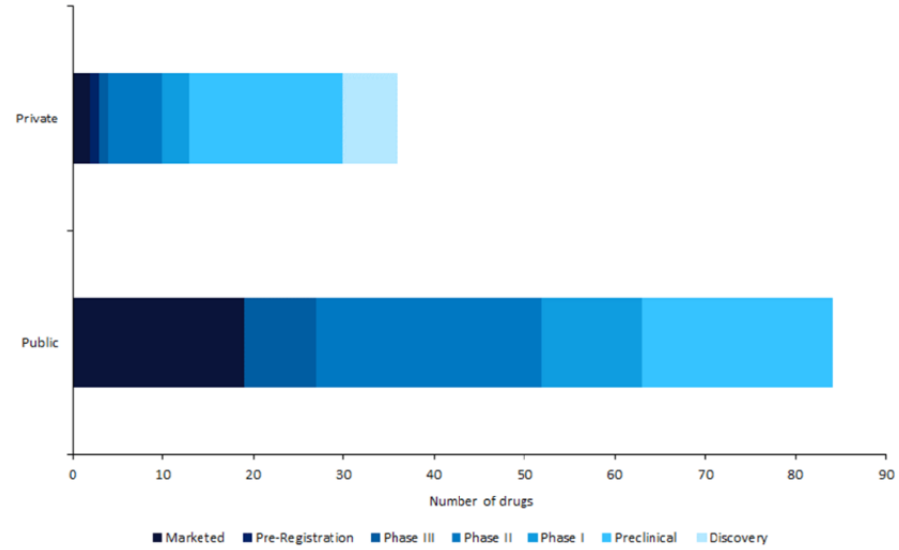
What is the impact of the Biosecure Act on the pharmaceutical industry? ➤

- Based on GlobalData's Pharma Intelligence Center Deals Database, the Bill can impact 120 US biopharmaceutical drugs under development by companies that have partnered with Chinese CDMOs and biotechnology companies. Approximately half of these drugs are in clinical stage development and a third are in early-stage discovery and preclinical trials.
- According to Thinktank Atlantic Council, US imports of Chinese pharmaceuticals and related products grew from US$2.1bn in 2020 to US$10.3 bn in 2022 (a 485% rise). The Biosecure Act will pose a significant hurdle to biotech manufacturing activity in China.
- Wuxi Biologics, Complete Genomics, Wuxi AppTec, and BGI Genomics have entered into licensing agreements, contract service agreements, or partnership deals with more than 45 companies headquartered in the US. Over two-thirds of the drugs being developed by public companies in the US, of which 60% are marketed or in late clinical stage, could be at risk because of the Biosecure Act.
- BGI Genomics, Complete Genomics, and MGI provide products and technologies for genetic sequencing, genotyping, gene expression, and proteomics markets. The restrictions imposed on these companies will have a minimal direct impact on the development and manufacturing of drugs. However, the restrictions placed on Wuxi will have a significant impact on the US pharmaceutical industry.
- Wuxi is one of the largest manufacturing companies in the world. US patients will face negative consequences if the Bill becomes a law owing to the number of manufacturing partnerships that Wuxi has.
- Based on GlobalData's Pharma Intelligence Center Drugs by Manufacturer Database, **Wuxi AppTec and Wuxi Bio manufacture 19 biosimilar and innovator drugs that are approved in the US**. Wuxi AppTec is also extensively used by cell and gene therapy companies.
    - Vertex's Trikafta/Kaftario and BeiGene's Brukinsa are examples of the drugs manufactured by Wuxi.
    - Tirzepatide – the active ingredient in Lilly's blockbuster weight loss drug Zepbound, is also produced by Wuxi Biologics.
- Multiple US companies have disclosed in their financial documents the impact of the Biosecure Act on their business.
    - **Iovance Biotherapeutics** won FDA approval for adoptive cell therapy, and Amtagvi to treat metastatic melanoma. The company depended on Wuxi to produce its therapy commercially. Iovance has declared in its SEC filing that the Biosecure Act will affect its production capabilities.
    - **Cabaletta Bio** has signed a contract with Wuxi to facilitate the development of its line of chimeric antigen receptor T-cells. The company has disclosed in its SEC filing that the inability to continue its business with Wuxi will negatively impact the operations.
    - **Merck** has noted in a Feb 2024 SEC filing that it has "significant research and manufacturing operations in China, including work with Chinese entities such as WuXi AppTec." If geopolitical tensions end up affecting this work, "such disruption could result in a material adverse effect on the company's product development, sales, business, cash flow, results of operations financial condition and prospects."
    - **Gilead Sciences and Vertex Pharmaceuticals** have declared in their company filings that the Biosecure Act will increase their manufacturing and development costs and result in a delay in clinical trials, regulatory submissions, and drug launch.
- Bristol Myers Squibb's or BMS' finance chief has stated that the company is working on a contingency plan to ensure the continuity of supply of medicines once the Bill is approved. According to GlobalData, BMS relies on Wuxi

Biologics to manufacture some active pharmaceutical ingredients in its blockbuster cancer pill, Revlimid. Revlimid generated a revenue of US$1.4bn in 1Q2022, despite coming off patent.

- The cost of drug development could go up if US pharmaceutical companies have to move their projects to European and US CDMOs, as the contract research and manufacturing services provided by Chinese companies have low costs and good margins.
    - Kojin Therapeutics' CEO Harvey Berger has said that Kojin's drug development costs would increase by 4x if it must outsource work to US CDMOs.

Figure 3: Contract service agreements, licensing agreements, and partnership deals globally between the five companies mentioned in the Bill and US-based companies



SOURCE: GLOBALDATA, INCRED RESEARCH

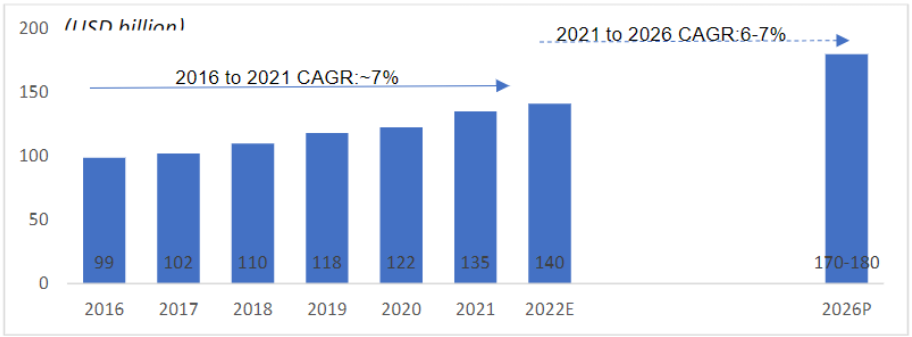
Global CDMO landscape

- The CDMO market was estimated at US$140bn in 2022 and is estimated to grow to US$170-180bn by 2026. The CDMO market grew at a faster pace than the CAGR of the pharmaceutical industry of 4-5% over 2016-2021. It grew at a CAGR of 7% from US$99bn in 2016 to US$135bn in 2021.
- The penetration of the CDMO market is expected to increase from 25-30% in 2021 to 30-32% in 2026.
- Emerging biopharma and small companies have been the major growth drivers in the CDMO and CRO space over the course of the last few years. Bernstein states that the **emerging biopharma-sponsored pipelines increased their CDMO industry share to 64% in 2022 compared to 50% in 2017.** Setting up a manufacturing facility can require a capital of billions of dollars and takes three-to-four years. Fixed costs of drugs can account for 50-60% and most emerging biopharma companies have only three-to-four drugs in their pipeline. This promotes the outsourcing of manufacturing.
- Even big pharmaceutical companies are facing pricing pressure due to the Inflation Reduction Act and the proposed Biosimilars Red Tape Elimination Act. This has driven even global pharmaceutical players towards outsourcing.
- Pharmaceutical companies are partnering with CDMOs to reduce their timeline and costs. Some other factors that have promoted CDMO outsourcing include innovation and access to specialized knowledge and technology. With rising outsourcing activity, contract manufacturing companies are likely to gain an advantage over in-house manufacturing facilities.
- CDMOs located in emerging countries offer an attractive option due to low-cost manpower.
- In the recent past, CDMOs have invested in innovation and are trying to cover more breadth beyond manufacturing. Companies have invested in specialized

areas such as developing new techniques for cell therapies, mRNA therapies, nucleic acid, and lipid-based formulations.

- Other than Wuxi, Lonza, Samsung Biologics, Catalent Inc. (now acquired by Novo Nordisk), and Fujifilm Diosynth are the major CDMO players. CDMO arms of big pharmaceutical companies like Boehringer Ingelheim GmbH's BioXcellence and Novartis AG's Novartis Global Biotech Cooperations also offer CDMO services.

Figure 4: Global CDMO market is expected to post a CAGR of 6-7% over 2021 to 2026F



SOURCE: COMPANY REPORTS, INCRED RESEARCH

Figure 5: Overview of major global CDMO players

Companies	Business overview	Plant locations
Lonza	Key services/products offered: small molecule, mammalian and microbial cell and gene technologies	Across the globe
Catalent*	Key services/products offered: protein, cell, and gene therapy biologics; and consumer health products.	USA, Europe
Recipharma	Services/products offered: sterile fill and finish, small molecule API, vaccine manufacturing.	USA, Europe, India
Boehringer Ingelheim BioXcellence (Patheon)	Services/products offered: small & large molecule development, oral solids, steriles and soft gels.	USA, Europe, China
Siegfried	Services/products offered: oral solids, sterile, ophthalmic, and inhalation capsules.	USA, Europe, China
Cambrex corporation	Services/products offered: generic API, conventional dosage forms, and analytical services.	USA, Europe
Aenova group	Services/products offered: manufacture of solid, semi-solids, steriles and packaging.	USA, Europe

SOURCE: COMPANY REPORTS, INCRED RESEARCH

Impact of the Biosecure Act on CDMO business

- It is highly likely that pharmaceutical companies investigate their supply chain and derisk them from having connections to China under the circumstance the Bill is not passed into a law due to the tensions building up between the US and China. However, a Bill like this will make it more challenging for the pharmaceutical industry to develop and manufacture drugs, taking into consideration the dependence on Chinese companies for clinical research and manufacturing support.
- Rival contract manufacturers located in India, Japan, Europe, and America stand to benefit from the bill.
- A total of 23 US biotech companies have flagged their reliance on Wuxi for their production facilities. Five companies, including ArriVent Biopharma and Dianthus Therapeutics, are exploring alternative manufacturing options.
- Companies, including Vertex, Eli Lilly, and BeiGene have initiated discussions with Wuxi's rival contract manufacturers to diversify their production away from Wuxi companies. BeiGene has stated that it is finalizing an API source outside China as a part of a process it started in 2019.
- Mario Polywka, interim chief executive of Evotec, a German CRO, has stated that the company is seeing increased engagement.
- Fujifilm Diosynth, a contract manufacturing company, has claimed that it has received "exploratory enquiries" about the "potential supply chain resiliency challenges" after the introduction of the Bill and the acquisition of contract manufacturer Catalent by Novo Holdings. Fujifilm has the third largest global mammalian capacity after Lonza and Samsung Biologics.
- Indian CDMO companies like Syngene and Aurobindo Pharma are positioned well to benefit from the Bill due to their cost effectiveness.
- Lonza and Samsung Biologics are two CDMO giants who are poised to see huge growth opportunities from the Biosecure Act:

- With the restrictions on Chinese CDMOs, a gap is expected to be created in the supply of biopharmaceutical medicines as many pharmaceutical companies rely on China for their manufacturing needs. Samsung Biologics, with its strong expertise and massive biologics production facilities, can grab this opportunity and fill the gap. According to GlobalData's Pharmaceutical Intelligence Center, Samsung Biologics and its subsidiaries manufacture 17 innovator and biosimilar drugs approved in the US, including Bristol Myers Squibb's Opdivo and Yervoy; Roche's Actemra & Rituxan; UCB's Bimzelx and Rystiggo; and TG Therapeutics' Briumvi.

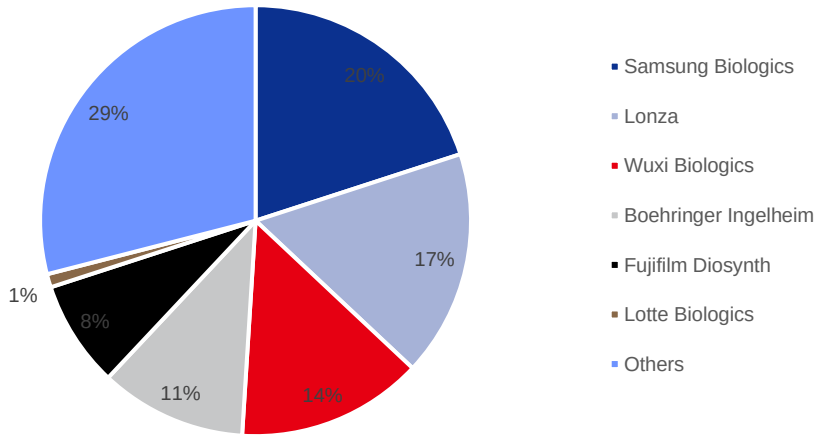
Figure 6: Comments of global CDMO players on the impact of the Biosecure Act

Company	Speaker	Comment
Lonza Group	Albert Baehny (Interim CEO)	"There is a lot of noise in general. The implementation of the Act remains unknown and uncertain. In this context, we are not willing to speculate and are not prepared to determine the magnitude and the timing of any potential impact on the business. It means that there is no Biosecure Act top line impact in our guidance today."
Charles River Labs	James Foster (CEO, Chairman)	"It is too early to determine the final outcome of this proposed legislation, both the content of the final Bill, if passed, and the potential impact on the broader biopharmaceutical industry. With approximately 95% of our revenue base in North America and Europe, we assume that the potential impact on Charles River would likely be a net positive, should the Bill be passed, but it's too early to determine the magnitude of the potential impact."
Thermo Fisher	Marc Casper	"We're likely to be a long-term beneficiary, not per se of the Act, but rather the fact that customers are thinking about who their partners are and where should those partners be based."
Samsung Biologics	John Rim (CEO)	"The number of enquiries for orders doubled since the proposal of the Biosecure Act this year."

SOURCE: COMPANY REPORTS, INCRED RESEARCH

- Lonza stands to benefit from the Biosecure Act, given its similar service package to Chinese companies, including support for small molecules, biologics, and cell and gene therapies. Lonza also has the largest mammalian manufacturing capacity globally after the acquisition of Roche's facility.

Figure 7: Mammalian capacity share of global CDMOs in 2022 (Lonza has now surpassed Samsung Biologics)

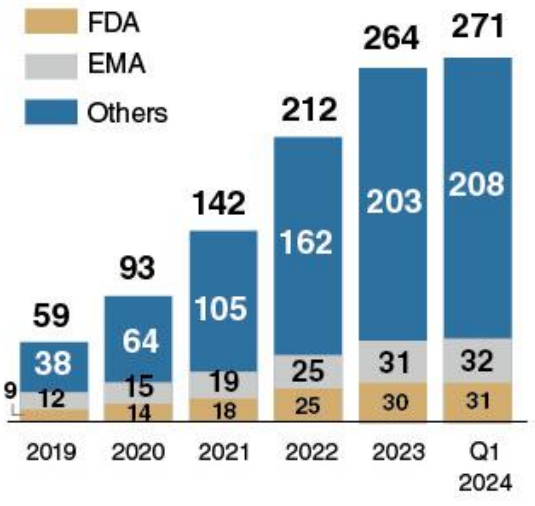


SOURCE: COMPANY REPORTS, INCRED RESEARCH

A closer look at Samsung Biologics and Lonza - global leaders in the CDMO business ➤

- Samsung Biologics:
  - Even though 2023 was a trying year for contract manufacturers across the globe due to challenges in biotech funding in the US and reduction in Covid-19 related contracts, Samsung Biologics became South Korea's first biotech company to generate a profit of 1tr won in 2023. Samsung's FY23 annual revenue was 3.7tr Korean won.
  - Samsung Biologics' facilities contributed largely to its success. Samsung Biologics' outstanding performance was largely driven by increased operations at its Plant-4 in Songdo, South Korea, and a "robust" sales backlog.
  - Plant-4 has a mammalian production capacity of 256,000L and 604kL total capacity. This plant is expected to contribute 30% to drug substances manufacturing business revenue by 2025. Plant-5 is expected to start its operations in Apr 2025F, which is five months prior to its expected timeline and will add 180kL to biomanufacturing capacity. With the addition of Plant-5, Samsung Biologics will have a total production capacity of 784,000L. Samsung Biologics is also starting an antibody-drug conjugate (ADC) facility, which is slated to begin its operations this year. The company will also be starting a dedicated mRNA manufacturing facility and adding aseptic filling capacity.
  - The company has also signed contracts valued over US$12bn and partnered with 14 out of 20 global pharmaceutical companies in 2023. The company also signed four new contracts with global pharmaceutical companies this year. It signed a US$381.9bn contract with Union Chimique Belge, 92.8bn won and 154.6bn won contracts with Merck Sharp and Dohme, and a 256.2bn won contract with Eli Lilly and Co.
  - Samsung Biologics has shown excellent capability through the entire pipeline, from manufacturing to management. The company has 271 regulatory agency approvals in 1Q2024 and a 99% batch success rate last year.
  - Moreover, as global companies compete for orders with China losing out due to the Biosecure Act, Samsung Biologics is well-positioned due to its long-standing cooperation with the US government dating back to the 1970s. Samsung Biologics was one of the most heavily invested companies when foreign investment opened in the US, and the company has an US public communications office located in Washington.

Figure 8: Samsung Biologics has received 271 manufacturing approvals from different regulatory agencies as of 1Q2024-end



SOURCE: COMPANY REPORTS, INCRED RESEARCH

- **Lonza**
  - Lonza, the Swiss CDMO player, is the world's largest contract manufacturer of monoclonal antibodies produced from genetically modified mammalian cells and possess capabilities across small molecules, ADCs, mRNA, cell and gene, etc.
  - Lonza's reported earnings surpassed expectations in 4Q2023, thereby allowing it to maintain its guidance through 2028F. Lonza's revenue in 2023 stood at US$7.7bn, a 11% increase compared to 2022.
  - The company saw softer sales and margin performance in Cell & Gene and Capsules & Health Ingredients, but a strong performance was observed in the biologics and Small Molecules divisions. The Biologics and Small Molecules division contributed over 70% to revenue and delivered a margin of over 30%.
  - The company has observed strong visibility in its commercial contracts, with an average length of seven years. This trend will drive high-capacity utilization over the next five years, with the new-wave of therapies driving forward the long-term demand. The company signed 130 new CDMO customers and approximately 350 new clinical and commercial customers in 2023.
  - In 2023, Lonza's facility for Vertex's Type I portfolio and small molecules plant dedicated to Aurinia became operational. The company has also started a new filing line for ADCs. The acquisition of Synaffix has brought new ADC licensing opportunities for the company. The company also has bioconjugates and microbial capabilities. The fact that the company was a supplier of mRNA vaccines to Moderna makes its mRNA capabilities quite evident. In cell and gene category, the company used its GS Gene expression system to cater to 500 customers with 80 approved therapies. In terms of small molecules, the company has a strong track record and expertise to work with HP APIs. The company has also seen progress in its personalized medicine division.
  - Lonza acquired Roche's large-scale biologics division in Vacaville, California for US$1.2bn in Mar 2024. This facility is one of the largest biologics manufacturing sites in the world, with a capacity of 330,000L.

How will Indian CDMOs benefit from the Biosecure Act? ➤

- Indian CDMO market is expected to grow to a value of US$44.69bn in 2029F compared to US$19.63bn in 2023, posting a CAGR of 14.67%. API and contract research opportunities are expected to fuel the growth.
- China's loss of market share is one of the major factors fuelling India's CDMO business growth. China became a dominant CDMO player because of its strong API and drug supply chain, huge facilities, and drug development capabilities. 25-30% cheaper labour and liberal government funding also made China rise to its number one rank as a global CDMO player. However, China started losing market share after the erstwhile US President Donald Trump levied trade sanctions and the supply chain got disrupted due to the Covid-19 pandemic. This was a major advantage and a turning point for India's CDMO companies as large companies started derisking by giving contracts to Indian companies. India also became an attractive destination due to its huge English-speaking population.

1. Government incentives like the PLI scheme and an increase in FDI and private equity investment have also led to India's establishment as a major CDMO player.
   - Goldman Sach's acquired a 33% stake in Aragen for Rs24,000m in May 2021.
   - US-based Carlyle acquired a 20% stake in Piramal's pharma business for Rs37,000m in May 2020.

  - Advent's acquisition of Suven Pharmaceuticals in 2020, after its demerger from its parent company Suven Life Sciences for over Rs95,000m, was the biggest deal in India's CDMO history at that time.
- Indian CDMOs are expected to gain further advantage now due to the Biosecure Act. Recent con-call comments from managements of Indian CDMO companies indicate that the enquiries coming to Indian CDMOs have increased due to the Biosecure Act.
- When we look at the installed capacity of Indian CDMO players, it is lesser than the big global giants like Samsung Biologics and Lonza. However, Indian players are keen on capitalizing on the CDMO opportunity and are making investments and expansions to capture the growing demand.
  - Dr. Reddy's Laboratories' subsidiary, Aurigene is developing a facility to produce proteins, viral vectors, and antibodies. The company is aiming to provide services for small and large molecules, starting from clinical research to commercial manufacturing.
  - Divi's Laboratories is building a facility over 500 acres of land at Kona in Andhra Pradesh.
  - Jubilant Pharmova is investing in expanding its double sterile injectables capacity in Montreal and Spokane.
- The benefit and growth of the Biosecure Act will be seen more towards the API synthesis side vs. biologics. Biologics involves complex skills and capabilities, which Indian companies are just starting to build and companies like Samsung Biologics and Lonza are already way ahead of India in that space. **Over the course of time, Indian companies have built technical skill sets and gained strong expertise in small molecule manufacturing, which will play to their advantage.**
  - Even though the trend is likely to shift towards biologics in the coming years, currently small molecules dominate the CDMO space. 75% of the global CDMO revenue comes from APIs.
- Indian CDMO players are also investing in new areas and cutting-edge technologies:
  - According to Frost and Sullivan, the global ADC discovery, development, and manufacturing outsourcing rate has reached about 70%. WuXi XDC is the second-largest CDMO globally in the XDC category - which encompasses ADCs and other (X) bioconjugates beyond ADCs - with a 9.8% revenue market share in 2022.Piramal Pharma is one of the first Indian players to make an entry in the ADC space. It has made timely investments in this arena and increased its ADC capacity by 70-80% at the Grangemouth facility.
  - Along with ADCs, Syngene has been offering advanced next generation technology platforms for clients like PROTACS. The company's service offerings also include peptides and oligonucleotides.
- Indian companies are also doing mergers and acquisitions with other companies to further enhance their service offerings.
  - Piramal Pharma invested in Allergan, Yapan Bio, and Hemmo Pharmaceuticals.
  - Syngene acquired Stellis Biologics facility for Rs6,170m, thereby increasing its biologics production capacity to 20,000L.
- Cost will be a major winning factor for Indian CDMOs in this arena. India can develop drugs at one-fourth of the cost compared to Western countries.
  - India has emerged as one of the lowest-cost countries in terms of manufacturing leaving behind China.
  - Even when it comes to managers and supervisors, India is a better performer than other countries.
- India has the largest number of US FDA-approved plants outside the US and Indian companies have built a good track record over a period.

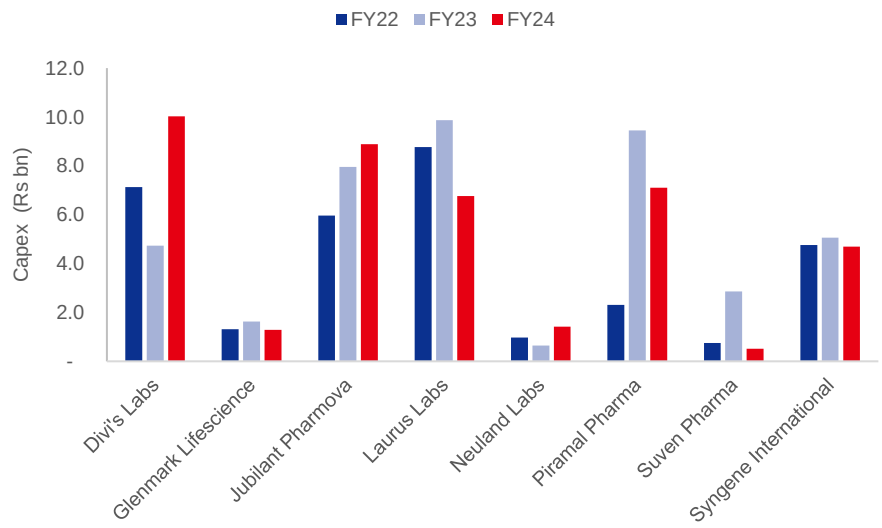
- Even though cost, technical skills, and quality assurance play a major role in selecting CDMO partners, geography influences the decision as well. Companies that are in Europe and the US will have an advantage in the geographic aspect.
- We strongly believe that India's CDMO business is bound to have an advantage from the Biosecurity Act and its market share will increase due to the factors explained above such as: capex to increase capacity and skillsets, cost competitiveness (cheap labour and managers), and strong regulatory track record. However, these positive effects will start showing in the medium- to long-term as companies will take time to transition from China and find the right CDMO partners.
- Companies like Syngene and Piramal Pharma with CRO capabilities, which allow them to work on smaller projects and early-stage assets, will start to see the benefits before the companies with large-scale manufacturing capacities. However, we need to consider the biotechnology funding scenario when we look at the timeline of the inflow of the orders to India. Even though the situation has improved when compared to last year, it will still take a few years until things get back to normal. Currently, most of the funding is coming from M&A activities, but these activities are more focused on medium- and late-stage assets. Even the IPO market is rewarding companies with more mature assets in their pipeline.

Figure 9: Management commentary on the impact of the Biosecure Act

Company	Source	Event	Commentary
Divi's Labs	Dr. Kiran S. Divi (WTD & CEO)	4QFY24 Concall	"We are seeing opportunities coming our way. But it is not something that says we're exiting China and they're coming to India. We are seeing a lot of Phase II, Phase III new molecules coming to us where we are working on, some of them are on the fast track." "Its (increased enquiries) a mix of everything. Its existing clients, new MNCs and also other niche product companies."
Glenmark Lifescience			
Jubilant Pharmova	Shyam S. Bhartia (Chairman) & Investor Presentation	4QFY24 earnings Press Release	"In the drug discovery business, the proposed Biosecure Act is expected to shift a lot of business to companies in 'friend sourcing' locations such as India." "(The company is) Uniquely positioned to take advantage of Biosecure Act." "Large pharma companies to derisk their supply chain by adding 'friend sourcing' locations. Biosecure Act is proposing to prohibit US govt. and US life sciences companies, (who are receiving federal grant money) to work with biotechnology service providers that are connected to foreign adversaries." "We are very bullish on the prospects of CRO industry in India due to talent availability & gradual shifting of demand due to preference of friend 'sourcing' locations."
Laurus Labs	Dr. Satyanarayana Chava (CEO & Executive Director)	4QFY24 Concall	"This (sic) shift in big pharma to diversify their vendor base has sorted (sic), I think all Indian CDMO companies are at the beginning of that shift, so few companies will definitely be benefited from this, but it will take its own time. If the partner is an existing customer, then onboarding is easier. If they have to onboard a new vendor, it will take its own time, but the benefit of their diversification has started showing results. It is also very clear we got more RFPs in the last 12 months for late-phase projects when compared to previous years. That is an indication that there is a diversification effort from big pharma, and it is clearly visible."
Neuland Labs	Saharsh Davuluri (Vice Chairman & MD)	4QFY24 Con-call	"For us, we have to wait and watch what will happen. **I think, obviously, the narrative is very favourable. I think a lot of American companies are talking to Neuland and other CDMOs about opportunity, about projects and perhaps these conversations would have been fewer if this whole Biosecure Act was not being discussed.** So that way, I think it's a positive thing. We have to see whether it will translate to actual business. So that is something that we are going to wait and watch." "**We could see a lot of requests. A lot of requests for information request of proposals.** There are definitely a lot of conversations. I think this something that I think post pandemic have become more precious. People don't this kind of come and visit facilities unless there is a quality audit or a EHS audit, product or something like that. So, I would not say that we have seen a surge in business. But definitely, we are seeing surge in RFI, RFP kind of activity.
Piramal Pharma	Peter De Young (CEO-Global Pharma, Piramal Pharma)	3QFY24 Con-call	"We see the geopolitical and geographic preferences of our customers being complex and varied. We see some clients who would like more onshore production and for them their shores may vary, but it would largely be in the US or Europe. **We see other clients for whom they have larger volumes and cost of goods is important and then they want to derisk from China and then we see increased inflows for customers with that profile.** And we see other customers who continue to be comfortable with China as a place to source from. And so we see the entire mix. And our go-to-market strategy is not to try and convince the client to go to a particular place because what we found is they typically know where they want to go and then we provide an offer from the location that they want at a price that is competitive and a technology level is competitive, then a service level is competitive for that geography. **And so, we see demand actually in both our overseas and our Indian offerings at the moment.**"
Suven Pharma	Dr Prasada Raju (MD)	4QFY24 Con-call	"Throughout the FY'24 we have been hearing, but we started getting the positive signal more from Q4FY'24 onwards."
Syngene International	Jonathan Hunt (MD & CEO)	4QFY24 Con-call	"**I'm starting to sense a material shift, not an acceleration, just a shift that big -- particularly the large cap companies are taking this much more seriously.** And to some extent it's been elevated from being a procurement or purchasing issue to being an audit and risk committee topic. And therefore, you're getting a very different lens and a different tone to some of the discussions. **People are now saying, well look, even if we've got great partnerships with some of our Chinese vendors, we don't want all of our supply coming from one geography, particularly one that's certainly the focus of all sorts of discussion and legislation in the US and that's moving them to look for alternatives.**"
Biocon	Peter Bains (Group CEO)	4QFY24 Con-call	"Syngene is very well positioned to capitalize on demand recovery across research, but also from the tailwinds in biomanufacturing and the fallout from the U.S. Biosecurity Act, which will gradually accelerate the China+1 opportunity."

SOURCE: COMPANY REPORTS, INCRED RESEARCH

Figure 10: Capex incurred by Indian CDMO players to expand their capacities



SOURCE: COMPANY REPORTS, INCRED RESEARCH

Figure 11: The cost of production workers in India is lower than in China

SOURCE: RESHORING INSTITUTE USA, INCRED

Figure 12: Inspection data of Indian CDMO players over the last two years

Company	Facility Location	Inspection End Date	Classification	Project Area
Jubilant Pharmova	Spokane, US	07/Jun/2024	Under Process	NA
	Roorkee, India	02/Feb/2024	VAI	Drug Quality Assurance
	Kirkland, Canada	28/Feb/2023	OAI	Drug Quality Assurance
	Mysuru, India	13/Dec/2022	VAI	Drug Quality Assurance
	Kirkland, Canada	07/Oct/2022	NAI	Bioresearch Monitoring
	Roorkee, India	01/Aug/2022	OAI	Drug Quality Assurance
	Kirkland, Canada	10/Jun/2022	VAI	Drug Quality Assurance
	Spokane, US	31/Aug/2021	VAI	Vaccines and Allergenic Products
	Roorkee, India	12/Mar/2021	OAI	Drug Quality Assurance
	Spokane, US	05/Mar/2021	NAI	Drug Quality Assurance
Laurus Labs	Synthesis Division, Visakhapatnam, India	12/Dec/2023	OAI	Drug Quality Assurance
	Anakapalli, India	10/Feb/2023	VAI	Drug Quality Assurance
	Unit-5, Anakapalli, India	28/Oct/2022	VAI	Pre-Approval Eval. of Animal Drugs and Food Additives
Neuland Labs	Unit-I, Bonthapalle, India	22/Mar/2024	NAI	Drug Quality Assurance
	Sangareddy, India	26/May/2023	VAI	Drug Quality Assurance
Piramal Pharma	Lexington, US	23/Feb/2024	VAI	Pre-Approval Eval. of Animal Drugs and Food Additives
	Bethlehem, US	27/Sep/2023	VAI	Drug Quality Assurance
	Bethlehem, US	27/Sep/2023	VAI	Monitoring of Marketed Animal Drugs, Feed, and Devices
	Pithampur, India	19/May/2023	NAI	Drug Quality Assurance
	Sangareddy, India	31/Mar/2023	NAI	Drug Quality Assurance
	Lexington, US	10/Jan/2023	VAI	Drug Quality Assurance
	Grangemouth, UK	18/Mar/2022	VAI	Drug Quality Assurance
	Morpeth, UK	18/Jun/2021	VAI	Drug Quality Assurance
Suven Pharma	Isnapur, India	23/Feb/2024	NAI	Drug Quality Assurance
	Isnapur, India	23/Feb/2024	NAI	Pre-Approval Eval. of Animal Drugs and Food Additives
Syngene International	Mangaluru, India	26/May/2023	NAI	Drug Quality Assurance
	Bengaluru, India	15/Nov/2022	NAI	Pre-Approval Eval. of Animal Drugs and Food Additives
	Bengaluru, India	28/Oct/2022	NAI	Bioresearch Monitoring

NAI - No Action Indicated
OAI - Official Action Indicated
VAI - Voluntary Action Indicated

SOURCE: COMPANY REPORTS, INCRED RESEARCH

Figure 13: Management commentary on biotech funding scenario

Company	Source	Event	Commentary
Jubilant Pharmova	Press Release	4QFY24 earnings call	"Lower biotech funding stalled growth, however early signs of recovery with further recovery expected by late FY'25".
Neuland Labs	Saharsh Davuluri (Vice Chairman & MD)	4QFY24 Con-call	"I think the biotech funding crunch is still prevalent." "We're seeing some challenges in the early-stage pipeline, drugs which are kind of either in preclinical or maybe in the early clinic. There are some challenges. I think even from the top of my head, I can recall 2 or 3 projects which have not moved forward in the last six months because the companies are still unable to raise funds."
Piramal Pharma	Nandini Piramal (Chairperson)	4QFY24 Con-call	"Biotech funding environment impacting early-stage orders in discovery and development is yet to return to full normalcy. Also, the clinical and regulatory attrition of our customers pipeline is a material challenge in the CDMO business." "And once the biotech funding improves, I think we should see more growth coming back, but it is too early to say yet for that."
Syngene International	Jonathan Hunt (MD & CEO)	4QFY24 Con-call	"The slowdown in biotech funding was most visible in discovery services." "In the last 12 weeks, I think we've seen a marked improvement in their funding environment. And looking forward, I'm pretty encouraged by some of the positive signals in the market." "US$23 billion of new funding went into the US biotech sector in the last 12 weeks."

SOURCE: COMPANY REPORTS, INCRED RESEARCH

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