ASCEND™

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THE BIOMEDICAL INNOVATOR'S GUIDE TO SPACE

Insights from Industry and ISS Experts Pave the Way

Space offers compelling advantages for biomedical innovators.

Researchers have leveraged microgravity to conduct novel, fundamental studies in tissue engineering and regenerative medicine, including research on stem cell proliferation and differentiation, biofabrication, and disease modeling. Despite this progress, biomedical firms remain largely unaware of space's potential for their businesses.

ASCEND, the interdisciplinary community focused on building humanity's off-world future faster, offers this introductory guide to help you more clearly visualize the industry's future in space and confidently pursue off-world opportunities.

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Space embodies many things:

the ultimate proving ground for innovation and the focal point of humanity's future beyond Earth.

As an emerging economy, space continues to attract record investments from privately funded cutting-edge companies and new space investors.

Bank of America expects the space industry to triple to a $1.4 trillion market within a decade.[1] The Space team at Morgan Stanley points to key drivers being data demand growing at an exponential rate, while the cost of access to space (and, by extension, data) falls by orders of magnitude, according to a 2020 article, "Space: Investing in the Final Frontier."[2]

Thousands of low Earth orbit satellites coming online promise faster, universal broadband over the globe that will fuel new applications and intelligence about the planet and all moving assets.

In addition, an increasing number of microgravity experiments on the International Space Station (ISS) underscore the global realization that space can deliver lasting value to life on Earth.

That's especially true in the biomedical research area, which accounts for 40% of all experiments that have run on the space station, according to the Center for the Advancement of Science in Space (CASIS), which manages the ISS U.S. National Laboratory. CASIS aims to advance space-based research and development to bring value to the United States and foster a scalable and sustainable low Earth orbit economy.

"It's a good time to be on the ISS," Marc Giulianotti, a chemist-trained program director for the ISS U.S. National Laboratory, said in a recent interview with ASCEND.[3]

He pointed out that half of all U.S. resources for research and development on the ISS, including rides up and back to Earth, are targeted at non-NASA use. "A growing percentage of our portfolio is dedicated to companies that have ideas for space that have commercial potential."

[1] Katje, Chris. 2020. "Space Race: The Top Players in A Market That Could Be Worth $1.4 Trillion By 2030," (September 28, 2020). https://www.yahoo.com/now/space-race-top-players-market-175014708.html.

[2] "Space: Investing in the Final Frontier." Morgan Stanley (July 24, 2020). https://www.morganstanley.com/ideas/investing-in-space.

[3] Giulianotti, Marc (August 23, 2021). Personal interview with ASCEND staff.

Space-Driven Biomedical R&D – The Opportunity

From startup medical device firms to global pharma companies, many research teams are already discovering how microgravity experiments can boost their R&D efforts, validate their science, and accelerate their path to commercialization.

CASIS and the University of Pittsburgh's McGowan Institute for Regenerative Medicine hosted a Biomanufacturing in Space Symposium in 2020 to identify areas where industry and government could stimulate advances and overcome barriers to creating a biomanufacturing marketplace in low Earth orbit (LEO).

Read more in the post-symposium report, "Opportunities for Biomanufacturing in Low Earth Orbit: Current Status and Future Directions."[4]

"Key takeaways for the near-term are all aimed at generating more robust and relevant data that can enable the prioritization of investable opportunities," Giulianotti said of the report. "These will be met through the formation of public-private partnerships, standardization (materials, protocols, and processes), and critically the development of tools that utilize artificial intelligence, machine learning, and automation."[3]

In an interview with ASCEND, report co-author Anjali Gupta, life science lead in business development for Axiom Space, noted that despite all this promise, awareness of space's value across much of the biomedical community remains low.[5]

"Currently the emerging LEO economy enabled by human spaceflight, especially the bioeconomy, is still in its infancy," Gupta explained.

But with the cost of access to space coming down and with it, greater opportunities for the private sector to launch their own R&D projects into LEO, the tide is changing.

"Space is open to everyone – it's not just about missions to Mars or the moon. There are companies using space to develop or improve their products," said Gupta, who is quick to correct common misconceptions that space is only accessible to government users.

[4] Giulianotti, M., et al. (2021, July). "Opportunities for Biomanufacturing in Low Earth Orbit: Current Status and Future Directions," Preprints. 2021080044 (doi.org/10.20944/preprints202108.0044.v1).

[5] Gupta, Anjali (August 30, 2021). Personal interview with ASCEND staff.

Bio Breakthroughs in Space

Over the last decade, space-based research has demonstrated that living and conducting experiments in microgravity informs our understanding of fundamental biology in healthy and diseased individuals on Earth that accelerates advancements in health care and medical technologies.

Stanford University researchers recently examined microgravity's effects on heart function using 3D heart tissues derived from human cells. The results could improve the screening of potential new drugs to treat heart conditions on Earth, according to an ISS360 blog article.[6]

Drug giants Merck, Novartis, and Eli Lilly have invested in microgravity research. In fact, Merck is using microgravity to optimize its cancer-treatment drug Keytruda®, which turns on the immune system to fight cancer, and which is on track to becoming the best-selling cancer drug in history. Merck is taking advantage of microgravity to crystalize the drug in space because protein crystallization on Earth can be negatively impacted by gravity. In space, some crystals grow more uniformly and this knowledge can then be used to improve the formulation of the drug to increase its safety and efficacy.

"Merck has come up with novel formulations for monoclonal antibodies that may change the way they deliver this therapeutic, going from an in-clinic IV to a potential injectable that patients could do at the doctor's office and go home," said Giulianotti.[3]

Biotech startup LambdaVision is working to develop a protein-based artificial retina to restore vision in patients who are blind or have lost sight because of disease. The company is experimenting with producing the artificial retina in microgravity on the ISS National Lab with the hope of reducing the amount of materials needed, which lowers costs and accelerates production time, according to a April 2020 news report[7] on the company's $5 million award from NASA with implementation partner Space Tango.

LambdaVision's model turns on its ear the idea that the economics of manufacturing products in space is cost prohibitive.

In his interview Giulianotti was asked if a company's space investment business model could be grounded on Earth. "You don't necessarily have to continue experiments in space; you can take that learning and apply it terrestrially. However, there are opportunities for in-space manufacturing processes that are very low weight, low volume, and have a high market value, such as LambdaVision's," he said.[3]

Another important area of investigation is studying the effects of living in microgravity on astronauts, which could lead to medical outcomes for humans in orbit as well as on Earth.

"We know when we put astronauts in LEO [for months,] they experience muscle wasting, bone loss, immune systems dysfunction, cardiac dysfunction and they experience this rapidly. When they come back to Earth, most of these negative effects rapidly reverse," said Giulianotti.

Investigators are looking at how to use these studies to understand which genes and proteins turn on and off. "The big question is, 'Are these space diseases or are these really accelerated terrestrial diseases?'"

[6] "Having a Heart to Heart in Space." ISS360 (February 8, 2021). https://www.issnationallab.org/iss360/space-based-heart-research/.

[7] Burba. Kate. "LambdaVision Awarded $5 Million by NASA to Develop Artificial Retina," (April 27, 2020). Healio. https://www.healio.com/news/ophthalmology/20200427/lambdavision-awarded-5-million-by-nasa-to-develop-artificial-retina.

Bioresearch Is Key Building Block of Tomorrow's Space Infrastructure

Axiom Space, which was awarded a NASA contract to attach the beginnings of a commercial space station to the ISS, plans to establish its first foothold in 2024. Gupta said the company's long-term mission "is to build cities in space."[5]

She said companies that are poised to be successful in space are those that see its value. "We're still very much in the discovery phase, but we need companies like the instrument and the tool makers, who are very successful on the ground, to adapt their technology to the microgravity environment," she said.

The good news for biomedical firms: there will be more opportunities to get to space, with the likes of Axiom Space, Nanoracks, Sierra Space, and other firms planning new stations and destinations for innovators to do in-space product testing and development.

Nanoracks is ahead of most, as the first company to offer commercial hardware and services for small satellite deployment in low-Earth orbit.[8] It has delivered more than 1,000 research payloads and small satellites[9] to the International Space Station since its founding in 2009. Its Outpost program seeks to transform upper stages of launch vehicles into controllable destinations across multiple orbits.

Unlike open research announcements sponsored by government agencies, which typically require that proposals to address the nation's priority science goals, these commercial firms will have greater freedom to foster new markets and help firms scale up their efforts more quickly.

Gupta noted that Axiom sees this as a "bi-directional opportunity," where tools required to accelerate discovery in orbit can also be applied on Earth.

"Research is a stepping stone to manufacturing for benefit of humans on Earth, and exploration beyond," she said.[5]

She encourages biomedical firms to look at microgravity as a tool. "Our message to the pharmaceutical companies, to tool companies, to biotech companies is: 'How is space part of your innovation strategy?'"

[8] "Nanoracks Completes 17th Commercial Space Station CubeSat Deployment Mission." Nanoracks (February 19, 2020). https://nanoracks.com/nanoracks-completes-17th-commercial-space-station-cubesat-deployment-mission/#:~:text=Nanoracks%20was%20the%20first%20company,the%20SpaceX%20CRS%2D19%20mission

[9] "About Us." Nanoracks (retrieved on September 16, 2021). https://nanoracks.com/about-us/

Space as an Innovation Platform

Companies need to start thinking about microgravity "as an innovation platform" and adapt their intellectual property, such as existing hardware tools and devices, to work in space.

"There is a first-mover advantage by entering the new space economy early," Gupta added, pointing to the fact that Axiom Space's engineers are looking for companies to integrate with now.

"Now is the time to test a process, validate a hypothesis or demonstrate a business case."[5]

For its part, Axiom is improving in-space capabilities to the point that it hopes to minimize upmass and downmass by having end-to-end systems on orbit, so all they will return is the data.

"We are very much actively trying to reduce costs. Currently [astronaut] crew time is very limited. However, via our human spaceflight program, private astronauts will be trained to conduct complex tasks on orbit, so crew time will now be more available for these companies. Companies will also have the opportunity to send their own researchers into space."

She emphasized that newcomers who enter the market later will face "a much greater hurdle of learning because the pace of progress is not linear, it's exponential."

Techshot, an in-space research facility provider founded in 1988, plans to provide some of the "picks and shovels" that professional researchers across industry, academia, and government will need to uncover new discoveries in space. The company already operates one of the largest catalogs of privately-operated biomedical R&D devices on board the ISS and has signed agreements with private space station developers to transition its research and manufacturing equipment to those vehicles once the ISS is decommissioned in 2030.

In a recent ASCEND article, Techshot Vice President Rich Boling predicted that within a decade commercial companies will be flying industrial and institutional researchers to multiple space stations orbiting Earth.[10]

"We may see the creation of the first on-orbit commercial contract research organization for customers who just want the data, and commercial contract in-space manufacturers for biomedical products that still need to be made there," he stated.

In the nearer term, the ISS National Lab remains an option for companies with great ideas that can drive the LEO economy. CASIS publishes opportunities for ISS National Lab research solicitations online that include projects for biomedical research firms. CASIS also works with NASA, the National Institutes of Health, and National Science Foundation on joint solicitations, as well as through the Small Business Innovation Research (SBIR) program.

A good idea for any biomedical researcher is to think about the space station's unique attributes and how those environments could inform their research.

Smaller firms also should explore opportunities through tech accelerators like the MassChallenge business incubator program that looks for high-impact, high-potential startups. Texas Mass Challenge includes a space commercialization industry track. The organization also has established MassChallenge HealthTech, a digital health innovation hub that matches startups with at least one partnership.

"Companies can always contact us, and we'll walk through the process," said Giulianotti,[3] who also encourages interested companies to visit the ISS National Lab's website for the latest news.

[10] "10 Reasons Biomedical R&D Is the Next Big Growth Sector in Space." ASCEND (July 22, 2021). https://www.ascend.events/partners/10-reasons-biomedical-rd-is-the-next-big-growth-sector-in-space/.

From Accelerator to ISS:

Brian Hess on Getting his Bone Adhesive Validated in Space

So how do you launch your technology or breakthrough science into microgravity?

In an interview with ASCEND, Brian Hess, founder of Revolutionary Biologicals (RevBio), explained he is currently preparing an experiment for RevBio's second trip to the ISS in 2022 to test his breakthrough Tetranite® bone adhesive on rodents.[11]

Back in 2015, his company, then called Launchpad Medical, was part of the Boston MassChallenge accelerator network. MassChallenge business accelerator, which partners with CASIS and Boeing to award the Technology Space Prize, provided Hess with advisors, business curriculum, and testing facilities, and allowed his startup to hone and test its business plan. It was there he became aware of opportunities on the ISS National Lab for teams that could show evidence their research in space could have an impact on Earth.

Learning from space station visitors that astronauts can lose up to 2% of their bone mass per month in space without resistive exercise,[12] Hess's team proposed a simple question: "Does our material stimulate growth in poor quality bone, especially for people who may have conditions like osteopenia or osteoporosis?" he recalled. "We thought, 'Wow, what if we could actually demonstrate some evidence in space that our product influences bone growth in a positive way?'"[11]

CASIS liked Hess's proposal. He was assigned an implementation partner, slotted to fly his cell culture experiment leveraging the ISS National Lab, and as hypothesized, the experiment showed positive effects of bone growth in microgravity.

Hess said the ISS experiment was an inflection point for the company, giving it the credibility to attract additional grants and angel funding to advance his research.

"The Space Station project, while it was a project that we won in 2015, really was the start to us being able to raise a significant amount of funding, and enabled us to move forward after MassChallenge," Hess said. "The unique environment onboard the space station is absolutely a differentiator, to advance innovation and provide a competitive advantage. However, it takes time and effort. Patience is required."

Since the ISS mission, RevBio has won an NIH grant from the National Institute for Aging to develop an injectable, ready-to-use bone adhesive to treat fractured bones. Hess also was selected for the ISS National Lab User Advisory Committee to help provide input on what has worked and how to make it easier for commercial biotech firms to engage with the space station.

The company is currently pursuing several applications for its adhesive. The first use case focuses on dental implant stabilization. A second application will focus on arm and leg extremities, such as joints and knee replacement.

Before clinical evaluations, RevBio needs to do animal testing. Its next mission to the space station in October 2022 will involve testing on rodents in the ISS's rodent habitat, which will directly support the animal trial requirement. At the same time, RevBio has developed a product to treat dogs and cats suffering from severe periodontal disease since these animals, once a tooth is pulled, are susceptible to jaw fractures.

His advice for biomedical firms thinking about getting their research in microgravity?

"Put in the effort to understand the question you want answered.

Be resilient and patient. Space projects take time, and that timeline is not one you can control. Find advocates for your science, and put yourself out there. By doing so, opportunities may present themselves. We were fortunate. CASIS came to MassChallenge. They were looking for ideas and we seized that opportunity."

[11] Hess, Brian (2021, August 18). Personal interview with ASCEND staff.

[12] "What Happens to Bones in Space?" Canadian Space Agency (retrieved on September 16, 2021). https://www.asc-csa.gc.ca/eng/astronauts/space-medicine/bones.asp.

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https://arc.aiaa.org

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https://www.ascend.events/news

BryceTech
https://brycetech.com/reports

International Space Station U.S. National Laboratory / Center for the Advancement of Science in Space
www.issnationallab.org

Morgan Stanley
https://www.morganstanley.com/Themes/global-space-economy

NASA Resources (Available on www.nasa.gov)
- Space Station Research Explorer
- ISS National Lab Homepage
- Space Station Research and Technology
- International Space Station Benefits for Humanity (3rd Edition Book)

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If you are a biomedical leader looking at space's potential for your business, we invite you to join us at ASCEND. We are a growing global community dedicated to building on-ramps to space for everyone.

This November, we will hold our flagship event on-site in Las Vegas, as well as in Washington, DC, and online everywhere. Our unique format welcomes bio-R&D leaders along with other industries to engage in a thoughtful, dynamic conversation focused on moving us closer to a vibrant off-world future.

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