

Ironwood Pharmaceuticals, Inc.

**2021**

Environmental, Social  
and Governance Report



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### What this report covers

This report provides information on our ESG progress in the year from January 1, 2021 to December 31, 2021.

For more information, please see [About this Report](#) on page 18.

# A Letter from Our CEO

Dear Stakeholders,

At Ironwood, we have been steadfast in our mission to advance the treatment of GI diseases and redefine the standard of care for GI patients. We have long believed that how we do things is just as important as what we do.

That principle has never been more critical, as the COVID-19 pandemic has presented unprecedented challenges to us all.

Our team has displayed great resilience throughout the pandemic, working tirelessly to advance the treatment of GI diseases and redefine the standard of care for GI patients while readily adapting to a new, largely remote way of working in 2020 and 2021. We are immensely proud that we continued to advance our research and development efforts and achieved blockbuster commercial success with LINZESS<sup>®</sup>, which surpassed \$1 billion in U.S. net sales in 2021 and reached more than 3.5 million U.S. patients.

Underpinning our success is our strong investment in a culture that prioritizes sustainability in everything we do. From recruiting and retaining our talented employees, to overseeing our internal processes, to remaining mindful of our environmental footprint on a daily basis, we know that delivering on our mission requires taking a broad view of success. While stockholder value remains our essential guidepost, we must always measure our performance against the backdrop of corporate social responsibility and sustainability.

These are things that we have done because it is core to who we are. Now, companies across all industries are being challenged to innovate and create more value while strengthening environmental, social, and governance (ESG) performance. For Ironwood's inaugural ESG Report, we embarked on a comprehensive company-wide project to identify our high-priority ESG issues and capture our progress and commitment.

In it, we highlight key Ironwood initiatives and philosophies that support our sustainability efforts. I'm extremely proud of the progress we're making and of the people who have worked hard to make our vision of an inclusive, ethical and responsible culture a reality. As we look to the future of Ironwood, we do so with hope for a brighter tomorrow that continues to elevate our ESG goals and priorities.

Sincerely,



Thomas A. McCourt  
Chief Executive Officer & Director



# Who We Are

Ironwood Pharmaceuticals is a leading gastrointestinal (GI) healthcare company on a mission to advance the treatment of GI diseases and redefine the standard of care for GI patients. We are pioneers in the development of LINZESS® (linaclotide), the U.S. branded prescription market leader for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC). Under the guidance of our seasoned industry leaders, we continue to build upon our history of GI innovation and challenge what has been done before to shape what the future holds. We keep patients at the heart of our R&D and commercialization efforts to reduce the burden of GI diseases and address significant unmet needs.

## Our Approach to Corporate Responsibility

Corporate responsibility is a key element of our corporate purpose and identity. We strive to manage our business in a manner that promotes transparent governance and strong ethics; maintains extensive patient, employee and other stakeholder engagement; and helps us grow our organization strategically, sustainably and responsibly, including with respect to our environmental, social and governance, or ESG, impacts.

Our Board of Directors oversees our corporate responsibility efforts through each of our standing Board committees. Our Governance & Nominating Committee has responsibility for overseeing our corporate social responsibility strategy, efforts and policies. Our Compensation and HR Committee oversees the Company's strategies, efforts and policies related to human capital management, including with respect to matters such as diversity and inclusion, workplace environment and culture, and talent development and retention. Our Audit Committee oversees compliance,

our enterprise risk management process and our cybersecurity program. Each of the foregoing matters are also routinely reviewed with our Board of Directors.

## Our Values

In 2022, we refreshed our core values based on extensive cross-functional collaboration and feedback across the entire organization. These values not only represent what's happening in the world around us, but they remain authentic to our unique mission, story and company culture. At the heart of our values is providing our employees with a more significant role in improving the lives of our patients.

# Our Values



## Transform Patient Lives

Leverage our insights, capabilities, and expertise to see the most critical patient needs

- Leveraging our insights, capabilities and expertise with a sense of urgency to serve the needs of GI patients
- Advancing bold opportunities to make a difference in patients' lives as a committed GI-innovator
- Striving continuously to be patient-centric to meet the most critical needs of our patients



## Innovate Meaningfully

Think boldly, experiment proactively, and take initiative to create new possibilities in the GI world

- Proactively experimenting, taking initiative to create new possibilities
- Acting with inclusion, pursuing, and exploring diverse perspectives
- Placing priority on continuously improving and investing in upping our skills and capabilities at all levels
- Being agile to quickly advance solutions aligned with how our customers seek to experience emerging healthcare trends
- Fostering a 'can do' environment by turning challenges/ setbacks into new ideas, services



## Challenge and Collaborate

Encourage different opinions and points of views in decision-making

- Proactively seeking input to better understand alternatives and/or opposing points of view to make rapid, compliant, timely decisions
- Cultivating relationships, networks within the GI/healthcare ecosystem to develop shared solutions
- Engendering trust and cooperation among and across teams
- Embracing differing ways of working together
- Being accountable to each other to accelerate progress, find solutions



## Practice Humanity

Recognize that our people are the cornerstone of Ironwood

- Recognizing that our people are the cornerstone of Ironwood's success
- Placing equality, diversity, and inclusion at the heart of everything we do
- Providing opportunities to have fun and maintain a flexible and healthy lifestyle
- Playing an active role in making our communities a better place to live and work



## Own the Outcome

Honor our commitments to our patients, stakeholders and one another by upholding a performance-driven culture

- Honoring our commitments to our patients, stakeholders and to one another, even when it is uncomfortable or hard
- Using metrics to objectively measure progress and results
- Delivering only the highest quality and compliant outcomes, on-time
- Committing to a performance-driven culture; rewarding for smart risk & results with high ethical standards

# Our People

Our highly skilled team of employees is paramount to our ability to research, develop and commercialize medicines for unmet medical need. Our team has extensive research and development experience in GI, industry-leading commercial expertise and deep relationships within the GI community.

By leveraging our capabilities alongside our leadership team's success building innovative and blockbuster medicines, Ironwood has built a formidable team uniquely capable of sourcing and evaluating GI portfolio opportunities that are aligned with Ironwood's mission. Our compensation, benefits and employee development opportunities are designed to attract and retain the highly skilled talent we rely on to drive our vision forward. In 2021 and 2022, Ironwood was named to Top Workplaces USA by Energage.

As of December 31, 2021, we had 219 employees. Approximately 40 were in our drug development team, 126 were in our sales and commercial team, and 53 were in general and administrative functions.

## Attracting the Best Talent

### Compensation and Benefits

Attracting the best talent starts with offering competitive compensation and benefits, and particularly compensation and benefits that give our employees a sense of ownership in our company and pride and determination to achieve our mission. All our employees receive long-term incentives in the form of equity and are encouraged to think and act as owners of Ironwood. Key benefits offered to all of our employees include the following:

- **Health and Wellness.** Because every employee's situation is different, we offer many choices when it comes to health benefits. Our health plans include HMO, PPO and PPO Saver plans through Blue Cross Blue Shield. We have FSA plans to help with medical and dependent care expenses. We also offer dental and vision programs, disability benefits and life insurance. To help our employees stay healthy, we also offer plenty of health perks like an on-site gym, virtual fitness classes, wellness stipend, discounted Blue Bikes membership and more.
- **Retirement Savings.** To help plan for a secure financial future, we offer a competitive 401(k) Savings & Retirement plan.
- **Commuting.** For the days when we come into our downtown Boston headquarters, New England-based employees are provided a generous commuter stipend, while headquarters employees living outside of New England can expense their travel. Our field sales employees receive a fleet vehicle – and we cover fuel, maintenance, and repairs.
- **Time Off.** We know the importance of taking time to relax and unwind. To help our employees relax and refresh, we offer generous vacation and sick time as well as weeklong, company-wide paid shutdowns to

recharge. We also offer generous leave benefits to help employees nurture new families.

- **Education.** Education is important. We're committed to helping our employees succeed through on-the-job training, professional development programs, and a generous tuition reimbursement program to support undergraduate or postgraduate studies.

## Hybrid Working Environment

During 2021, the majority of our headquarters-based employees performed their jobs remotely for at least part of the time due to the COVID-19 pandemic. Overwhelmingly, our employees told us that they valued the flexibility remote work afforded them. In response, we reimaged our plans to return to the office and laid the groundwork for a new hybrid working environment that we refer to as Workplace 2.0. As of April 2022, most headquarters employees continue to have the flexibility to work from home for the majority of the time and will spend three to five days in the office each month for headquarters-wide and team-based programming called Culture and Collaboration days.

Our Workplace 2.0 philosophy is the result of intensive employee surveys and cross-functional working group participation. It represents our support for a diversity of working styles at Ironwood, allowing us to continue to attract and retain our highly skilled work force as well as to draw on talent from a larger geography.

## Communication and Engagement

We strongly believe that our success depends on employees understanding how their work contributes to our ability to execute on our vision, mission and strategy. Communication and engagement have been especially critical in light of challenges brought on by macro events such as the COVID-19 pandemic, the competition for talent in the biopharmaceutical industry and employees' higher expectations on engagement by their employers. To this end, we utilize a variety of channels to facilitate open and direct communication, including frequent town hall meetings, Ironwood intranet, CEO blog, leadership engagement opportunities, regular communications regarding business updates, and employee engagement surveys.

We conduct an annual, anonymous employee survey, administered by Energage, a company focused on

employee engagement, to help us measure the overall confidence, engagement and satisfaction level of our team. Through this survey we collect direct and candid feedback to help leaders understand what drives engagement at Ironwood and to inform our overall culture and engagement strategy.

## Health, Wellness and Safety in the Face of the COVID-19 Pandemic

The health and safety of all our employees is a top priority for us. We have augmented certain healthcare, childcare and leave benefits in an effort to support our employees and their families in the face of the unique challenges brought on by the COVID-19 pandemic. We maintain a working group focused on creating and keeping employees well informed about the company's latest plans and guidance around COVID-19. We also have provided personal protective equipment, at-home COVID-19 test kits and safety trainings for field-based employees, a home supply stipend to create home office space, reallocated commuter benefits for home office use, extended additional wellness benefits including backup childcare, and resilience training for employees, among other efforts.

## Training and Development

We have developed and implemented a performance management program that includes career development planning and actions designed to create opportunities for personal growth, professional growth, and career mobility.

Senior leadership, in conjunction with our Talent, Team and Culture professionals, are responsible for ensuring that all personnel, including contractors and consultants, have the appropriate education, training, competency and credentials to perform their jobs effectively. In addition to formal development plans and training programs, our online learning and development portal offers a comprehensive educational curriculum including both job-specific and general business skills development training programs. Examples include trainings on:

- Communications skills
- Finance and Accounting
- Leadership
- Management
- Project Management
- Strategy and Innovation

We offer dedicated sales training to our entire sales team. In 2021, 100% of our salesforce participated in a remote selling skills training program.

An important aspect of career development and employee satisfaction is feedback. In addition to receiving frequent, informal check-ins with their managers, all employees are required to participate in formal performance reviews and generate annual goals in alignment with our company's mission. The goals each employee sets are individualized, and centered on five key pillars that are core to our company's success:

- Maximizing the impact of our products;
- Advancing our innovative pipeline;
- Driving value by creating ownership and partnership choices;
- Driving financial discipline; and
- Leveraging talent, team and culture within our organization.

## Co-Op and Fellowship Programs

We have implemented a co-op program allowing us to provide opportunities for students to apply their learnings in real world settings in areas of both R&D and our corporate functions. In 2020, we affiliated with a graduate pharmacy program to enable fourth year PharmD students to participate in industry rotations within our Global Patient Safety and Medical Scientific Affairs groups. This is now an ongoing program with five PharmD students participating during the 2021-2022 school year.

In 2020, we also launched a Post-Doc Fellowship program. The first Fellow started in July 2020, in Medical Scientific Affairs. In 2021, we expanded the program to include three fellows - one in Global Patient Safety/Regulatory Affairs and two in Medical Scientific Affairs/Clinical Development. In 2022, we expect the fellowship program to include four fellows in the same groups listed above.

## Equality, Diversity and Inclusion (ED&I)



We believe that creating an equitable, diverse, and inclusive culture is critical to attracting, motivating and retaining the talent necessary to deliver on our mission and to creating an ownership culture that gives us the best opportunity to deliver a sustained competitive advantage. For us, this means fostering a culture where every employee feels a sense of belonging and where employees encourage each other to share ideas for succeeding in a diverse environment.

Approximately 49% of our employees are women, and women represent approximately 29% of our senior leadership (vice president and above) and nearly 27% of our Board of Directors (including our Board chair and our Audit Committee chair). Additionally, approximately 19% of our employees are racially or ethnically diverse and, in 2021, approximately 24% of our new hires were racially or ethnically diverse. Our equality, diversity and inclusion principles are also reflected in our employee training and policies. For example, all employees receive annual harassment prevention training and biennial training in unconscious bias.

In 2021, we continued to advance our equality, diversity, and inclusion, or EDI, initiatives with strong advocacy by our leadership team and Board of Directors. In 2021, we incorporated into our corporate goals an EDI scorecard reflecting numerous metrics and deliverables. Over the course of the year, we achieved our target level of performance on these EDI metrics. We strove to ensure that our candidate pools were diverse and, as a result, both of the executive officers hired in 2021 represent diverse populations. For 2022, we are committed to furthering our EDI efforts consistent with our long-term



EDI strategy adopted in 2020. Our Board of Directors has approved a specific corporate goal for 2022 aimed at fostering an environment where employees feel included and empowered.

Current EDI initiatives include empowering our employee resource groups, such as W@IRWD (Women at Ironwood), and our employee-led initiatives, such as ISHINE, an internship program, and ISTAR (Ironwood Stands Together Against Racism). We have also introduced new learning and development opportunities, strengthened our talent acquisition strategies, supported equality programs in our local communities and sought to foster the career development of employees from diverse populations. All of these initiatives are key parts of fostering employee engagement and retention at Ironwood.

## W@IRWD

We have a longstanding employee resource group, W@IRWD, designed to empower, develop, and sponsor women at Ironwood. W@IRWD strives to build an inclusive space that advances women's leadership and unlocks their potential. W@IRWD is open to all employees of Ironwood regardless of gender and focuses on a specific development theme each year supported by a variety of learning channels such as speaker programs with external experts, internal networking, and book clubs. Additionally, W@IRWD recognizes and communicates with employees regarding key external events including, International Women's Day, Equal Pay Day, and Women's History month.

## ISHINE

In 2021, we developed and implemented a paid internship program, called ISHINE, that draws undergraduate candidates from Historically Black Colleges and Universities (HBCUs) and exposes students to careers in the healthcare field. This program provides students with education and experience in both our commercial and corporate activities, including sales operations, medical literature research, global patient safety, corporate communications and human resources. ISHINE interns spend eight weeks in the summer working on projects under the guidance of experienced mentors. At the end of the program, interns have the opportunity to present their work to the larger Ironwood community.

Three students participated in the ISHINE internship program in 2021. In 2022, we are expanding this program with the goal to recruit up to five interns to participate.

## ISTAR

Ironwood Stands Together Against Racism (ISTAR) is an employee-led initiative that was created in 2020 in response to racial equality movements and our employees' drive to take action. Through the ISTAR program, employees across the company are entrusted with Ironwood funds to donate to organizations working towards racial equality. ISTAR supports our employees' goal to take an active role in their communities and put resources in the hands of those engaged in the following areas: anti-discrimination, improving access to healthcare, improving access to education and technology, programs for equal opportunity to grow wealth, and programs enabling food access, housing security and criminal justice reform.

In 2021, the ISTAR program resulted in donations to more than 30 organizations, including the Black Women's Health Imperative, the Boston Chinatown Neighborhood Center and Citizens for Juvenile Justice.

# Our Commitments to Patients & Responsible Research

## LINZESS®

We discovered, developed and, together with our U.S. collaboration partner, are commercializing LINZESS® (linaclotide), the market leading prescription medicine in the U.S. for treating irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC), disorders that afflict millions of adults in the U.S. alone. We also have strong relationships with our collaboration partners who are developing and commercializing LINZESS outside the U.S. LINZESS is available to adult men and women suffering from IBS-C or CIC in Mexico, IBS-C or chronic constipation in Japan, and IBS-C in China. Linaclotide is available under the trademarked name CONSTELLA® to adults suffering from IBS-C or CIC in Canada, and to adults suffering from IBS-C in certain European countries.

LINZESS recently attained blockbuster status, and has reached more than 3.5 million unique patients in the U.S. since launch. We work closely with our U.S. collaboration partner to ensure class-leading market access to help appropriate patients continue to access to LINZESS through Medicare and commercial prescription coverage plans.

Even as the COVID-19 pandemic impacted patient care in 2021, LINZESS reached new patients, with a 12% increase in total prescription demand compared to 2020. Ensuring continued patient access during COVID-19 was an especially important goal for us, as survey findings we presented in 2021 highlighted that more than a third of surveyed IBS-C patients indicated their symptoms had worsened during the COVID-19 pandemic. For more information on this study, which was conducted in collaboration with research from the Mayo Clinic, Acumen Health Research Institute, and the International Foundation for Functional Gastrointestinal Disorders, please refer to our [press release](#) dated May 24, 2021.

In addition, we continue to work hard in an effort to expand the reach of LINZESS and address unmet patient need. For example, we and our U.S. collaboration partner have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatric patients. In August, 2021, the U.S. FDA approved a revised label for LINZESS based on clinical safety data that had been generated thus far in pediatric studies. The updated label modified the boxed warning for risk of serious dehydration and contraindication against use in children to those less than two years of age. The boxed warning and contraindication previously applied to all children less than 18 years of age and less than six years of age, respectively. The safety and effectiveness of LINZESS in patients less than 18 years of age have not been established. Clinical pediatric programs in IBS-C and functional constipation are ongoing.

## Our Pipeline



### Strengthening Our Leading GI Portfolio

#### CNP-104

In 2021, we expanded our pipeline by entering into a collaboration and option agreement with COUR Pharmaceuticals which grants us the right to acquire a license for the U.S. rights to CNP-104, a tolerizing immune modifying nanoparticle, that has the potential to transform the treatment of primary biliary cholangitis (PBC) – a rare autoimmune disease targeting the liver that affects an estimated 133,000 people in the U.S. In December 2021, the U.S. FDA granted Fast Track Designation for CNP-104. COUR has initiated a clinical study for CNP-104 to evaluate the safety, tolerability, pharmacodynamic effects and efficacy of CNP-104 in PBC patients, with the preliminary data readout estimated in 2023.

#### IW-3300

We are currently advancing our wholly-owned product candidate IW-3300 – a stable and potent GC-C agonist – into clinical development for the potential treatment of visceral pain conditions, such as interstitial cystitis/bladder pain syndrome (IC/BPS) and endometriosis, that affect millions of patients in the U.S. Currently there are a limited number of treatment options available and high unmet need among patients experiencing these conditions. We initiated a clinical program for IW-3300 in the first quarter of 2022 to evaluate the safety and tolerability of IW-3300 in healthy volunteers.

## Patient Engagement

We believe in bringing diverse patient voices to the forefront of what we do, and we are committed to reducing healthcare inequities. In 2021, we sponsored a workshop with the International Foundation for Gastrointestinal Disorders (IFFGD) focused on improving communication

between physicians and patients living with GI disease. We also partnered with the digital platform PatientsLikeMe to bolster support for patient advocacy. Our clinical trials are designed to minimize patient burden and improve access to investigational drugs by all demographics. It takes diverse patient experiences to inform our strategy, and we work hard to amplify those experiences both within Ironwood and in the broader GI community.

## Responsible Research

### Clinical Research Data Sharing

We meet industry and scientific standards in our clinical trial publication and data sharing practices and we believe providing access to such data strengthens opportunities for further scientific development and collaboration. All clinical trials results, including the results of terminated trials, when required, are published on [clinicaltrials.gov](https://clinicaltrials.gov).

To uphold our commitments to patient privacy, we have implemented and maintain a Clinical Research Data Sharing Policy, which requires that individual participant data that underlie the results reported in any publication of any Ironwood clinical study will be shared only after deidentification.

Data will be available from two years and ending four years after publication. Data will be shared with researchers who provide a methodologically sound proposal to achieve the aims outlined in the approved proposal. The study protocol, statistical analysis plan (when applicable), informed consent form (when applicable), and clinical study report (when applicable) will also be shared.

### Animal Welfare

We are committed to the ethical use of animals in medical research. All animal studies are carefully reviewed by an Institutional Animal Care and Use Committee (IACUC) which is charged with ensuring that a proposed study is essential. We comply with the “Three Rs” (Replace, Reduce and Refine), widely accepted ethical principles that are embedded in the conduct of animal-based science.

## Product Quality and Safety

The objective of the Ironwood Pharmaceutical Quality System (PQS) is to achieve product realization, establish and maintain a state of control, and facilitate continual improvement and effective knowledge transfer/management. This objective is enabled by a robust knowledge & Quality Risk Management program and is memorialized in the Ironwood Quality policy.

### Quality Policy

Ironwood maintains a Quality Policy (POL-000002, also known as a Quality Manual) which serves as the foundation of our Pharmaceutical Quality System (PQS). It requires that we meet industry standards, follow Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Pharmacovigilance Practices (GVP), and Good Clinical Practices (GCP) (all aspects combined are frequently referred to as GXP) wherever appropriate, and achieve and maintain regulatory compliance. Our Quality Policy reinforces that quality is the responsibility of every Ironwood employee and internal contractor and assigns ultimate accountability to our CEO.

### Quality Management System

Ironwood has implemented a comprehensive electronic Quality Management System (eQMS) which facilitates the execution and documentation of all aspects of GxP activities that are required by regulations. The QMS is independently evaluated and meets global industry standards and regulatory requirements.

### Elements of the Ironwood Pharmaceutical Quality System

#### Executive Management responsibility

Our Audit Committee, through its quarterly compliance updates, and our Board of Directors have ultimate accountability for Quality issues.

#### Quality Management responsibility

Our Chief Operating Officer, who reports directly to the CEO, has accountability to maintain the performance of the PQS. The PQS is supported by a senior level management representative (Head of Quality) who has

independent oversight and responsibility for all Quality matters. The Head of Quality is responsible for reporting to Executive Management on any Quality events that have the potential to impact product quality and safety. The Head of Quality is supported by a Quality Leadership Team, who are all responsible for:

- Ensuring that processes needed for the PQS are established, implemented, and maintained.
- Reviewing the suitability, adequacy, and effectiveness of the PQS with the Head of Quality through Quality Management Reviews conducted at defined intervals (e.g., quarterly). This review includes assessing opportunities for improvement and the need for changes to the PQS, including the quality policy and quality objectives.
- Ensuring the promotion of awareness, training, and remediation of regulatory requirements throughout the organization.

#### Employee Responsibility

Ironwood's GxP employees (including internal GxP contractors), individually and collectively, are responsible for operating within the guidelines of the PQS in all relevant parts of the organization.

#### Self-Inspections (Internal Audits)

Periodic, risk-based internal audits are carried out to ensure that our procedures are current and suitable for their intended use, and the internal policies and procedures are being executed as written. Audit results and any corrective actions (CAPA) are communicated to functional area management and the Head of Quality.

#### Personnel and Training

Ironwood hires personnel who are qualified by training, education, and experience to perform their duties. The GxP Training program ensures that basic training requirements are established for all GxP employees and are intended to ensure that GxP employees are properly trained and capable of performing all required job duties in compliance with applicable laws, rules, regulations, Ironwood policies and procedures, and industry best practices.

#### Quality Risk Management (QRM)

Ironwood's QRM program includes risk assessments and mitigation elements of all GxP activities, including those risks to computerized systems.

## **GxP Vendor Oversight and Management**

Ironwood cross-functional technical teams assess the technical capabilities, and Quality qualifies each GxP vendor. Ironwood Quality conducts routine audits to verify compliance, quality, and adequate vendor oversight by Ironwood functional areas.

## **Production and Process Controls and Monitoring**

Although Ironwood does not directly perform GMP manufacturing and testing on site, several procedures have been established within the Ironwood PQS to:

1. Outline the processes for ensuring GMP activities carried out at Ironwood GMP Vendors meet regulatory requirements, industry best practices and internal Ironwood standards, and,
2. Detail the GMP requirements of an Investigational New Drug (IND) sponsor or Marketing Application Holder (MAH) and describe how these requirements are met.

For outsourced GMP activities, Quality Agreements are established to ensure patient safety, product quality, continuous drug supply and data integrity, primarily through Vendor and manufacturing oversight. Ironwood Quality retains responsibility for disposition of finished drug products unless this responsibility has been delegated to a vendor in a Quality Agreement.

## **Quality Events Management**

Ironwood monitors and/or maintains processes for identification and management of deviations, change management, out-of-specification and out-of-trend results, and investigations.

## **Corrective and Preventive Action**

Inputs from process performance and product quality monitoring, deviations, product rejections, investigational product complaints, internal and external audits, and regulatory inspections are evaluated for level of risk, and are assessed and trended to determine the necessity of corrective and/or preventive actions. The CAPA approach is intended not only to correct or prevent recurrence or occurrence of an issue, but also to result in improvements in Ironwood product, processes, and Quality systems.

## **Commercialization**

### **Commercial Labeling, Marketing, Promotions and Advertising**

A process is defined for commercial product labeling development, review, and approval. Quality Operations is responsible for approving product labeling and oversight of the development, review, and approval process. Responsibility for compliance oversight of marketing, promotions and advertising lies with the Corporate Compliance function, including establishing and documenting procedures for marketing activities which comply with applicable law, regional requirements, and training qualified personnel on those procedures.

### **Commercial Drug Distribution and Returns**

Ironwood applies the same quality principles to drug distribution and returns as it does to other manufacturing activities. The key quality activities include Third Party Logistics (3PL) provider qualification, and subsequent ongoing oversight. Drug distribution processes, policies and procedures are established that are designed to meet applicable laws, rules, regulations and product pedigree requirements for product returns and reporting.

### **Product Process Quality Monitoring**

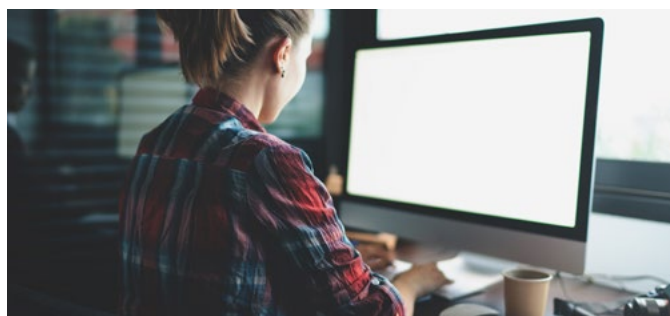
Critical, key and selected non-critical process parameters, material attributes, critical in-process controls, and critical quality attributes are continuously monitored, trended, and analyzed during commercial manufacture to assure product quality and that the process remains in a state of control. Process performance and product quality monitoring information is captured in product reviews that are generated on a routine basis.

### **Product Quality Complaint, Field Alert and Recall**

Product Complaint, Field Alert and Recall processes are established to ensure product quality and patient safety during marketing of commercial products. In instances when a Field Alert (FAR) or Product Recall action is required for a distributed, commercial product(s) for which Ironwood holds the regulatory responsibility (i.e., Marketing Authorization Holder) Quality is responsible for initiating Ironwood's process and monitoring progress, ensuring that all planned actions have been completed and communicated to applicable health authorities in a timely manner.

# Our Strong Oversight

## Cybersecurity



Ironwood implements a multilayered cybersecurity program designed to maintain the confidentiality and integrity of our data and systems and to protect our users from potential breaches. The program is overseen at multiple levels within our organization, including by our Audit Committee and Board of Directors. The program is reviewed annually by our Audit Committee with updates to our Board.

Our risk management procedures adopt Cybersecurity Security Framework controls (CSF) recommended by the National Institute of Standards and Technology (NIST). This framework is broadly accepted by private industry as a reliable source of security guidance, guidelines and practices and allows us to tailor our cybersecurity strategy to the specific needs of our business.

We employ a continuous process improvement approach to manage our cybersecurity risk. We perform annual penetration tests and monthly vulnerability scans, employ multifactor authentication where feasible, and we have deployed antimalware prevention in our enterprise systems. Since 2018, Ironwood has engaged an independent third-party auditor to review our approach to cybersecurity and to deliver strategic, enterprise-wide industry assessments and benchmarks of our systems. We perform these reviews biannually and implement mitigation measures on an ongoing basis.

All employees are required to take monthly, quarterly and annual cybersecurity training and participate in quarterly Phishing test campaigns. In addition, we have a comprehensive business continuity plan in place designed to ensure restored access to critical systems in the event of a disruption to our infrastructure.

## Ethics and Compliance

At Ironwood, compliance starts with, and is the responsibility and continuing obligation of, each Ironwood employee, officer, director, contractor or other third parties acting on behalf of Ironwood (Ironwood Representatives). We rely upon and expect that Ironwood Representatives will conduct themselves in compliance with Ironwood policies, and applicable laws, rules and regulations.

### Comprehensive Compliance Plan

In an effort to ensure that Ironwood Representatives remain abreast of and informed about these policies, and the laws, rules and regulations that impact and govern our business, Ironwood has developed a [Comprehensive Compliance Plan](#) (the Compliance Plan).

In addition to providing training and education, the Compliance Plan is designed to monitor, detect, correct, and as necessary take disciplinary action, in respect of activities or practices that do not comply with the law or Ironwood policies and expectations. The ultimate goal of the Compliance Plan is to ensure that Ironwood Representatives have the knowledge and resources necessary to comply with these policies, laws, rules and regulations. In developing the Compliance Plan, reference was made to and reliance placed upon the Compliance Program Guidance for Pharmaceutical Manufacturers issued in April 2003, as amended to date, by the Office of Inspector General of the Department of Health and Human Services (Compliance Program Guidance), the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare

Professionals, effective as of July 1, 2002, as amended to date (the PhRMA Code), the Prescription Drug Marketing Act, relevant guidelines of the American Medical Association, the guidelines of the Accreditation Council for Continuing Medical Education (ACCME), and other guidance issued by the US Food and Drug Administration and other government agencies. A current copy of our Comprehensive Compliance Plan is available on the Corporate Governance page of the Investors section of our website.

## Ironwood Code of Conduct and other Policies and Procedures

Ironwood has adopted a written [Code of Business Conduct and Ethics](#) that provides a general statement of the expectations of Ironwood regarding the ethical standards by which Ironwood Representatives are to adhere when acting on behalf of Ironwood. Although not a member of PhRMA, Ironwood supports and has implemented written policies and procedures that are consistent with the requirements of the PhRMA Code. A current copy of our Code of Business Conduct and Ethics is available on the Corporate Governance page of the Investors section of our website.

In addition, Ironwood has implemented various written policies and procedures designed to ensure compliance with applicable legal and regulatory requirements governing the advertising and promotion of pharmaceutical products as set forth in, without limitation, the Federal Food, Drug and Cosmetic Act, the False Claims Act, the Federal Anti-Kickback Statute, Compliance Program Guidance, the American Medical Association's Code of Professional Ethics Opinion 8.061 on Gifts to Physicians from Industry, Section 6002 of the Patient Protection and Affordable Care Act, commonly known as the Physician Payment Sunshine Act, and federal and state privacy laws, as well as other and applicable state laws. Ironwood Representatives are expected to comply with the Ironwood Code of Business Conduct and Ethics, the PhRMA Code, and any and all compliance policies and procedures applicable to their function at, and activities performed on behalf of, Ironwood.

## Compliance Officer and Compliance Committee

Ironwood has appointed a Head of Compliance to serve as a focal point for compliance activities and has established a Compliance Committee that is chaired by the Head of Compliance. In addition to the Head of Compliance, other standing members of the Compliance Committee include the Ironwood CEO, Chief Operating Officer, Chief Legal Officer, Chief Financial Officer, and Chief Medical Officer.

## Compliance Training and Education

Ironwood is committed to developing and providing Ironwood Representatives with effective compliance training. This training includes both new hire training as well as mandatory annual training on the Ironwood Code of Business Conduct and Ethics, as well as other company policies and procedures governing the conduct of Ironwood Representatives, and applicable state and federal laws, rules and regulations as is relevant for the particular job function.

## Monitoring and Auditing

To assess the efficacy of Ironwood's training and education program, as well as to confirm that Ironwood Representatives are acting in the expected compliant manner, Ironwood will periodically perform monitoring and auditing activities designed to evaluate compliance with company policies and applicable laws. The nature, frequency and extent of these reviews may vary according to factors such as internal risk assessments, regulatory requirements and developments, and changes in Ironwood's business practices. The Compliance Committee annually reviews and approves the monitoring and auditing plan.

## Employee Communications

Ironwood has developed and implemented a written Policy on Reporting Suspected Law and Company Policy Violations in an effort to promote the prevention, detection, reporting and correction of unlawful or improper conduct. Under this Policy, Ironwood Representatives are obligated to report any actual or suspected violation of law, regulation or company policy involving any Ironwood Representative to their managers, or to the Compliance, Legal or Talent, Team and Culture Departments. In addition, Ironwood Representatives are free to report concerns anonymously 24 hours a day, 7 days per week through the Ironwood Compliance Hotline. No retaliation will be taken against any Ironwood Representative for a good faith report of what they honestly believe to be an actual or suspected violation.



# Environmental Stewardship



Our impact on the environment matters to us and to our stakeholders. We continuously seek ways to use resources efficiently and to reduce our overall environmental footprint. For example, when we selected our new headquarters facility in 2019, we prioritized proximity to public transportation to enable the opportunity for employees to utilize alternative modes of commuting. We also furnished our headquarters facility with furniture that contains an estimated 52% recycled materials and meets BIFMA's LEVEL sustainability certification standards. As per our commitment to reduce resource consumption by practicing efficient use of energy, we have invested in various resource efficient technologies at our facilities, including:

- High efficiency LED light fixtures
- Automated lighting system, lowering energy consumption
- Elimination of hazardous chemical storage at our headquarters facility
- Automated water dispensing systems in all restrooms, lowering water consumption / processing
- Automated HVAC schedule allowing occupied and unoccupied modes, lowering power consumptions.

As part of our ongoing efforts to reduce all types of waste, we have implemented the following initiatives:

- Plastics Recycling
- Compost Recycling
- Paper Recycling
- 90% On-site Paper Elimination
- Compostable Paper and Utensil products

Through initiatives such as these, we demonstrate Ironwood's strong belief in environmental sustainability and our organization's drive to lessen the impacts of climate change.

# About This Report

This report, published in April 2022, covers data and activities undertaken from January 1, 2021 through December 31, 2021, and in certain instances, activities undertaken and events that have transpired to date in 2022 or prior to 2021. All presentations of data denote the time period covered.

The disclosures in this report were informed by the recommendations of the Sustainability Accounting Standards Board (SASB) biotechnology and pharmaceuticals standard. Relevant topics addressed include clinical trial safety, product safety, business ethics, and employee recruitment, development, and retention.

The inclusion of information and data in this report is not an indication that such information or data, or the subject matter of such information or data, is material to Ironwood for purposes of applicable securities laws or otherwise. The principles used to determine whether to include information or data in this report do not correspond to the principles of materiality or disclosure contained in U.S. securities laws used to determine whether disclosures are required to be made in filings with the U.S. Securities and Exchange Commission (SEC), or principles applicable to the inclusion of information in financial statements. The data contained herein are not based on generally accepted accounting principles and are not independently audited. Statements contained in this report regarding our corporate responsibility and ESG goals and future plans are aspirational and not guarantees or promises that such goals will be met or future plans achieved.

Ironwood Pharmaceuticals, Inc.  
2021 Environmental, Social and Governance Report

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