



Ironwood Pharmaceuticals, Inc.

2022

Environmental, Social and Governance Report



Safe Harbor Statement

This report contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about our ability to execute on our vision; our strategy, business, and operations, including with respect to the demand, development, commercial availability and commercial potential of linaclotide and the drivers, timing, impact and results thereof; the potential indications for, and benefits of, linaclotide and our ability to drive LINZESS® growth; expectations the progress of ongoing clinical trials and the timing of related data readouts; the size of the pediatric population affected by FC, and IBS-C/CIC, IC/BPS, endometriosis and PBC estimated affected populations; the potential for LINZESS to be the first and only FDA approved Rx therapy to treat functional constipation in pediatric patients aged 6-17; our anticipation for a mid-2023 FC indication with existing 72 mcg dose assuming FDA priority review and approval of the related supplemental new drug application; the timing data for the POC study for CNP-104 and of reaching a clear decision point on whether to exercise our option to acquire an exclusive license for CNP-104; the potential for CNP-104 to be the first PBC disease modifying therapy; the potential of IW3300 to be an effective treatment of visceral pain conditions, as well as our plans to and begin patient enrollment for POC study in IC/BPS for IW-3300 (including the timing and results thereof). These forward-looking statements speak only as of the date this report is published, and Ironwood undertakes no obligation to update these forward-looking statements. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include those related to the effectiveness of development and commercialization efforts by us and our partners; preclinical and clinical development, manufacturing and formulation development of linaclotide, IW-3300, CNP-104 and our product candidates; the risk that clinical programs and studies, including for the linaclotide pediatric program, CNP-104 and IW-3300, may not progress or develop as anticipated, including that studies are delayed or discontinued for any reason, such as safety, tolerability, enrollment, manufacturing, economic or other reasons; the risk that findings from our completed nonclinical and clinical studies may not be replicated in later studies; the risk that we or our partners are unable to obtain, maintain or manufacture sufficient LINZESS or our product candidates, or otherwise experience difficulties with respect to supply or manufacturing; the efficacy, safety and tolerability of linaclotide and our product candidates; the risk that the therapeutic opportunities for LINZESS or our product candidates are not as we expect; decisions by regulatory and judicial authorities; the risk that we may never get additional patent protection for linaclotide and other product candidates, that patents for linaclotide or other products may not provide adequate protection from competition, or that we are not able to successfully protect such patents; the risk that we are unable to manage our expenses or cash use, or are unable to commercialize our products as expected; the risk that the development of any of our clinical pediatric programs in IBS-C and functional constipation in 6 to 17 year-olds, CNP-104 and/or IW-3300 are not successful or that any of our product candidates is not successfully commercialized; the risk that the FDA will not accept our supplemental new drug application and request for priority review for the potential indication in functional constipation in pediatric patients aged 6-17; outcomes in legal proceedings to protect or enforce the patents relating to our products and product candidates, including abbreviated new drug application litigation; the risk that financial and operating results may differ from our projections; developments in the intellectual property landscape; challenges from and rights of competitors or potential competitors; the risk that our planned investments do not have the anticipated effect on our company revenues; developments in accounting guidance or practice; Ironwood's or AbbVie's accounting practices, including reporting and settlement practices as between Ironwood and AbbVie; the risk that we are unable to manage our expenses or cash use, or are unable to commercialize our products as expected; the impact of the COVID-19 pandemic; and the risks listed under the heading "Risk Factors" and elsewhere in Ironwood's Annual Report on Form 10-K for the year ended December 31, 2022, and in our subsequent SEC filings. LINZESS® is a registered trademark of Ironwood Pharmaceuticals, Inc. Any other trademarks referred to in this presentation are the property of their respective owners. All rights reserved.

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What this report covers

This report provides information on our ESG progress in the year from January 1, 2022 to December 31, 2022.

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

A Letter From Our CEO

Dear Stakeholders,

I am pleased to introduce Ironwood Pharmaceuticals' latest Environmental, Social, and Governance (ESG) Report. This report reflects how we work—challenging ourselves, innovating regularly, and managing risks—to advance the treatment of GI diseases to create a healthier and brighter future for people with GI diseases. It also demonstrates our commitment to being a sustainable business on behalf of our stakeholders for years to come.

Powered by our incredible team, it is our privilege to serve the GI patients of today and tomorrow and the communities in which we operate and reside. This remains our North Star—and it is a responsibility we do not take lightly because we know that people with GI diseases are counting on us to help improve and redefine their standard of care.

We are excited about our journey as we continue to help drive and enable our business strategy in ways that make us an even better company and corporate citizen. Critically, we have intensified our efforts to integrate ESG initiatives into our daily business, making progress in understanding and managing environmental, social, and governance opportunities in our business practices. Our goal is to be valued not only for our mission to advance the treatment of GI diseases and redefine the standard of care for GI patients—but to do that in an environmentally and socially responsible way.

This year, our ESG focus was on answering two critical questions: how can we improve the GI health of patients? And how can we cultivate an even more diverse, equitable, and inclusive workplace for our Ironwood team?

Improving the GI Health of Patients

Over the past year, we have centered on maximizing the potential benefit of our in-market product, LINZESS, reaching more appropriate adult patients in the U.S. who suffer from IBS-C or CIC, advancing our scientific pipeline, and expanding our scientific pipeline our portfolio with innovative GI assets. As of the end of 2022, LINZESS had treated more than 4 million unique patients—a number that represents the true magnitude of our impact. And LINZESS, a guanylate cyclase-C (GC-C) agonist, is strongly recommended by treatment guidelines of the American Gastroenterological Association (AGA) and American College of Gastroenterology (ACG) for the treatment of adult patients with IBS-C.



We pursued new opportunities for our blockbuster treatment LINZESS to address unmet patient needs, including submitting a supplemental New Drug Application (sNDA) with the FDA for Functional Constipation in children and adolescents 6 to 17 years of age. And in February 2023, the FDA granted Priority Review to this sNDA and assigned the application a Prescription Drug User Fee Act (PDUFA) date of June 14th, 2023, four months earlier than the standard review cycle.

If approved, LINZESS would be the first and only FDA-approved prescription therapy for Functional Constipation in this patient population—an estimated 6 million in the U.S.

In addition, we continued to advance clinical trial programs for potential treatments for primary biliary cholangitis (PBC) and interstitial cystitis/bladder pain syndrome (IC/BPS), and endometriosis. These important milestones are steps toward potentially bringing new medications to meet the needs of patients with these GI diseases.

Cultivating a More Diverse, Equitable & Inclusive Workplace

We also have remained focused on keeping our people at the heart of who we are and what we offer our worlds. We do this by fostering a culture of ownership and belonging—which has long been one of our biggest priorities—and we made meaningful strides to advance this goal this year.

We have enhanced our focus on building Diversity, Equity, and Inclusion (DE&I) into our daily business. In 2022, our strategy focused on hiring and engaging a diverse workforce, expanding our Employee Resource Groups (ERGs), promoting health equity, and introducing new learning, training, and career development opportunities.

We also developed and launched a new DE&I vision, mission statement, and set of DE&I principles deeply embedded into our corporate values and daily life at Ironwood. We will continue focusing on accelerating and expanding our efforts in this area while learning from the challenges we face. The opportunities ahead of us are energizing.

Lastly, I want to thank all my colleagues for their passion and dedication to making Ironwood a unique, supportive company and upholding the highest standards of ethics and integrity. We have the best people and the highest levels of GI expertise, diligently focused on advancing scientific innovation in the pursuit of progress. Our future is ripe with possibilities to deliver many exciting milestones for our business and people and continue making our world a better, healthier place.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom McCourt", written in a cursive style.

Thomas A. McCourt
Chief Executive Officer & Director

Who We Are

Ironwood Pharmaceuticals is a leading gastrointestinal (GI) health-care 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. Accordingly, 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 concerning 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 and nominating committee have responsibility for overseeing our corporate social

responsibility strategy, efforts, and policies. Our compensation and HR committee oversee the Company's strategies, efforts, and policies related to human capital management, including concerning matters such as diversity, equity, and inclusion, workplace environment and culture, talent development, and retention. Finally, our audit committee oversees compliance, our enterprise risk management process, and our cybersecurity program. The foregoing matters also are routinely reviewed with our board of directors.

Our Values

Our core values are based on extensive cross-functional collaboration and feedback across the entire organization. These values represent what's happening in the world around us and 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
- Continuously improving and investing in upskilling our professional development 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 needs. 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 in 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. In addition, 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, 2022, and 2023, Ironwood was named to Top Workplaces USA by Energage, and in 2022 was named to *Boston Globe's* Top Places to Work.

As of December 31, 2022, we had 219 employees. Of these employees, 45 were on our drug development team, 125 were on our sales and commercial team, and 49 were in general and administrative functions.

Attracting the Best Talent

Compensation and Benefits

Attracting the best talent starts with offering competitive compensation and benefits, 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 regarding health benefits. Our health plans include HMO, PPO, and PPO Saver plans through Blue Cross Blue Shield. In addition, 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 provide plenty of health perks like an on-site gym, virtual fitness classes, well-being stipend, a remote work stipend for headquarters employees, and access to discounted backup child and elder care, Blue Bikes bike sharing membership, and more.
- **Retirement Savings.** To help plan for a secure financial future, we offer a competitive 401(k) Savings & Retirement plan, including company matching contributions.
- **Commuting.** For the days when we come into our downtown Boston headquarters, New England-based employees are provided with contributions towards parking and transit costs. In addition, 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 and weeklong, company-wide paid shutdowns to recharge. We also provide 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

In 2022, we launched a new, hybrid working environment that we refer to as Workplace 2.0. While working remotely during the COVID-19 pandemic, our employees overwhelmingly told us that they value the benefits that remote work affords them. In response, we invested in our technology infrastructure. We carefully planned a shift in our culture so that most headquarters employees can continue to have the flexibility to work from home for the majority of the time. However, most headquarters employees still spend several days in the office each month to collaborate with team members and to participate in headquarters-wide Culture and Collaboration Days. These pre-planned days offer the opportunity to connect with colleagues, collaborate toward achieving important goals, and participate in team-based learning and development.

Our philosophy behind this hybrid environment results from 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 workforce and draw on talent from a more extensive geography.

Communication and Engagement

We strongly believe that our success depends on employees understanding how their work contributes to our ability to execute our vision, mission, and strategy. To this end, we utilize a variety of channels to facilitate open and direct communication, both in-person and while working remotely. These channels include frequent town hall meetings, the Ironwood intranet, the CEO blog,

leadership engagement opportunities, regular communications regarding business updates, and employee engagement surveys. Members of our management actively participate in each of our communication channels.

We conduct an annual anonymous employee survey administered by Energage, a company focused on employee engagement, to help us measure our team's overall confidence, engagement, and satisfaction level. 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.

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, along 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. For example, in 2022, 100% of our salesforce participated in a combination of remote and in-person training.

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 and to executing our commitment to patients:

- 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.

Practical Experience and Fellowship Programs

We operate a co-op program, allowing us to provide opportunities for students to apply their learnings in real-world settings in R&D and our corporate functions. In 2022, we also affiliated with two graduate pharmacy programs to enable fourth-year PharmD students to participate in industry rotations within our Global Patient Safety group. Four PharmD students participated during the 2022-2023 school year.

Our Post-Doc Fellowship program operated for the third consecutive year in 2022 and has grown to support four full-time fellowships in our Global Patient Safety/Regulatory Affairs and Medical Scientific Affairs/Clinical Development groups.

Diversity, Equity, and Inclusion (DE&I)



Creating a diverse, equitable, and inclusive culture is critical to attracting, motivating, and retaining the talent necessary to deliver on our mission and creating an ownership culture that gives us the best opportunity to have 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. We aspire to create an inclusive environment that values and respects our people's diverse ideas and life experiences in our collective efforts to improve the lives of people living with GI diseases.

Approximately 52% of our employees are women, representing approximately 27% of our leadership team (vice president and above) and 33% of our board of directors (including our board and audit committee chairs). Additionally, approximately 18% of our employees are racially or ethnically diverse, and, in 2022, approximately 28% of our new hires were racially or ethnically diverse. Our diversity, equity, and inclusion principles are also reflected in our employee training and policies. For example, all employees receive harassment prevention training at least every other year. And in 2022, approximately 90% of our regional sales managers attended a workshop on unconscious bias.

Our board of directors approved a specific corporate goal for 2022 to foster an environment where employees feel included and empowered. We tracked our progress toward this goal using a DE&I scorecard reflecting numerous quantitative measures (tracking of internal diversity metrics) and qualitative (goals set by the ERGs and ELIs).

We also introduced new learning and development opportunities, strengthened our talent acquisition strategies, and sought to foster the career development of employees from diverse populations. These initiatives are key to fostering employee engagement and retention at Ironwood.

Employee Resource Groups and Employee-Led Initiatives

Our employee resource groups and employee-led initiatives aim to provide opportunities for professional development, networking, and building deeper connections with our communities and each other. We've put key initiatives in place to ensure that all employees can be part of our culture of belonging.

W@IRWD

Our longest-standing employee resource group, W@IRWD, is 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. In 2022, W@IRWD focused on the development theme "Building Career Confidence and Positive Mindset," which was supported by various learning channels, including book reviews and several panel discussions featuring leaders at Ironwood and members of our board of directors. W@IRWD sponsors a membership with Women in the Enterprise of Science and Technology (WEST), which provides members with events and networking opportunities to grow their careers. 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.

PRIDE@IRWD

PRIDE@IRWD seeks to foster LGBTQ+ visibility for all Ironwood employees and raise awareness about the current workplace and social issues that affect the LGBTQ+ community. Through PRIDE@IRWD, we aim to empower LGBTQ+ members, allies, and advocates to be their authentic selves at work while maintaining a culture of inclusion and dispelling assumptions and phobias. PRIDE@IRWD has created multiple opportunities to engage in meaningful conversations and action at Ironwood, including a discussion series on "Allyship in the Workplace" facilitated by the advocacy organization PFLAG to ensure diverse identities across the company are understood and affirmed. PRIDE@IRWD also works to advocate for LGBTQ+ employees in all Ironwood policies and business practices, to reflect better and address the experiences of our LGBTQ+ employees.



IMPACT

IMPACT offers a space for bettering our communities and engaging deeper with one another. IMPACT meets monthly, and employees use this time to share ways they can serve as stewards for good, both as individuals and as a company. One of our most successful, company-wide give-back efforts, Operation Giving, was created by IMPACT, and involved a month-long community service challenge. Our employees volunteered 208 hours of community service, including urban farming with Boston Area Gleaners, running the American College of Gastroenterology's Diversity in GI 5k, donating and packing for local women's shelter Rosie's Place, community cleaning with Boston Chinatown Neighborhood Center, and much more.

ISHINE

ISHINE is a paid internship program that draws undergraduate and select graduate school 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. It has historically included internships in sales operations, medical literature research, global patient safety, corporate communications, and human resources. ISHINE interns spend eight weeks working with Ironwood on substantive, impactful projects under the guidance of experienced mentors. Five students participated in the ISHINE internship program in 2022 and presented their work to Ironwood's executive team and the larger Ironwood community.

In a survey conducted at their completion of the program, the interns reported an increased understanding of the pharmaceutical industry. They believed that their experience at Ironwood had enhanced their career preparation.

ISTAR

Ironwood Stands Together Against Racism (ISTAR) was created in 2020 as an employee-led initiative in response to racial equality movements and our employees' drive to take action. Through the ISTAR program, teams of employees across the company meet to identify how systemic racism impacts our communities and are entrusted with Ironwood funds to donate to local organizations working to combat those issues. 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 2022, ISTAR financially supported more than 30 organizations working to achieve greater racial justice and equity, with over 50% of Ironwood employees involved in the review and selection process. Our largest financial contributions went to Citizens for Juvenile Justice (a third-time donation recipient), Artists for Humanity, and The Food Project.

Health Equity Sponsorship Committee

Ironwood has committed resources to increase Ironwood's impact on reducing health disparity by providing grants and sponsorships to programs that foster awareness and education around expanding healthcare access, support diversity in healthcare and clinical research, and help build a diverse pipeline of GI leaders. This dedicated funding has been used for activities including "Investing in the Future" and "Visiting EDI Professor" grants to the American Gastroenterological Association, "Leadership Education and Development (LEAD)" and "GI Organizational Leadership Development (GOLD)" grants to the American Society for Gastrointestinal Endoscopy, and International Foundation for Gastrointestinal Disorders' "2022 IFFGC Advocacy Day". Ironwood is also a sponsor of the American College of Gastroenterology's "Diversity in GI 5k".

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 adult men and women suffering from IBS-C or CIC in Canada, and to adult men and women suffering from IBS-C in certain European countries.

In 2022, LINZESS attained blockbuster status, and has reached approximately 4 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 LINZESS through Medicare, Medicaid, and commercial prescription coverage plans.

In addition, we continue to work hard to expand the reach of LINZESS and address unmet patient needs. In September 2022, we announced positive topline data from a Phase III clinical trial evaluating linaclotide 72 mcg in pediatric patients aged 6-17 years with functional constipation, or FC. In December 2022, we and AbbVie submitted a Supplemental New Drug Application, or sNDA, to the U.S. FDA seeking approval of a new indication of linaclotide for FC in pediatric patients aged 6-17 years. In February 2023, the U.S. FDA granted priority review to our sNDA and assigned a Prescription Drug User Free Act, or PDUFA, date of June 14, 2023. Additional clinical

pediatric programs in IBS-C and FC are ongoing. There are currently no U.S. FDA approved prescription therapies for FC.

Our Pipeline



Strengthening Our Leading GI Portfolio

CNP-104

Through our collaboration and option license agreements with COUR Pharmaceuticals, we and COUR are developing CNP-104 for the potential treatment of primary biliary cholangitis, or PBC, a rare autoimmune disease targeting the liver that affects approximately 130,000 people in the U.S., according to a study published in Clinical Gastroenterology and Hepatology in 2018. If successful, CNP-104 has the potential to be the first approved PBC disease-modifying therapy. In December 2021, the U.S. FDA granted Fast Track Designation to CNP-104. COUR is currently conducting a clinical study for CNP-104 to evaluate the safety, tolerability, pharmacodynamic effects, and efficacy of CNP-104 in PBC patients, with early data assessing T-cell response from patients enrolled in the clinical study expected in the second half of 2023. We expect that such early data will inform the timing of topline data readout.

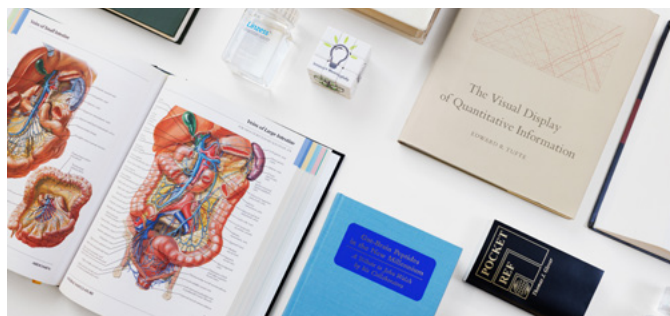
IW-3300

We are advancing IW-3300, a GC-C agonist, for the potential treatment of visceral pain conditions, including interstitial cystitis/bladder pain syndrome, or IC/BPS, and endometriosis. IC/BPS affects an estimated 4 to 12 million Americans, according to the Interstitial Cystitis Association, as of 2022. An estimated 4 million reproductive-age women in the U.S. have been diagnosed endometriosis, according to a study published in Gynecologic and Obstetric Investigation in 2017. Both diseases have a limited number of treatment options available. We successfully completed Phase I studies to evaluate the safety and tolerability of IW-3300 in healthy volunteers and expect to begin patient dosing for the Phase II proof of concept study in IC/BPS in early 2023.

Patient Engagement

We believe in bringing diverse patient voices to the forefront of what we do and are committed to reducing healthcare inequities. 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 within Ironwood and 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. Therefore, results from Ironwood-sponsored clinical trials, including the results of terminated trials, when required, are published on clinicaltrials.gov.

In addition, we will make these results available to researchers who provide a methodologically sound, approved research proposal. As applicable, the study protocol, statistical analysis plan, informed consent form, and clinical study report will also be shared.

To uphold our commitments to patient privacy, we share individual participant data that underlie the results reported in any publication of any Ironwood clinical study only after de-identification.

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 ensures that a proposed study is essential. Furthermore, we comply with the "Three Rs" (Replace, Reduce and Refine), widely accepted ethical principles embedded in the conduct of animal-based science.

Product Quality and Safety

The Ironwood Pharmaceutical Quality System (PQS) aims 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 is 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. In addition, 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 for maintaining the performance of the PQS. The PQS is supported by a senior-level management representative (Head of Quality) with 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 the following:

- Ensuring 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 that 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 qualified personnel 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. In addition, 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 promote patient safety, product quality, continuous drug supply, and data integrity, primarily through Vendor and manufacturing oversight. Ironwood Quality retains responsibility for the 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 identifying and managing 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. They 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 the 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 that comply with applicable law, and 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 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 control. Process performance and product quality monitoring information are 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 the 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 our data and systems' confidentiality and integrity and 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. In addition, 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, and deployed anti-malware prevention in our enterprise systems. Since 2018, Ironwood has engaged an independent third-party auditor to review our cybersecurity approach and 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 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

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 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 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 Business 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 and 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. These reviews' nature, frequency and extent, 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 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, seven 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 our stakeholders and us. 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 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 reducing 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 consumption.

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

- Plastics Recycling
- Paper Recycling
- 90% On-site Paper Elimination

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 2023, covers data and activities undertaken from January 1, 2022, through December 31, 2022, and in certain instances, activities undertaken and events that have transpired to date in 2023 or prior to 2022. 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, 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.
2022 Environmental, Social and Governance Report

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