

IRONWOOD PHARMACEUTICALS INC
Form DEFA14A
May 01, 2018

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

SCHEDULE 14A

**Proxy Statement Pursuant to Section 14(a) of
the Securities Exchange Act of 1934 (Amendment No.)**

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

- Preliminary Proxy Statement
- Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
- Definitive Proxy Statement
- Definitive Additional Materials
- Soliciting Material under §240.14a-12

IRONWOOD PHARMACEUTICALS, INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

- No fee required.
- Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.
 - (1) Title of each class of securities to which transaction applies:
 - (2) Aggregate number of securities to which transaction applies:
 - (3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):
 - (4) Proposed maximum aggregate value of transaction:
 - (5) Total fee paid:
- Fee paid previously with preliminary materials.
- Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form DEFA14A

- (1) Amount Previously Paid:
 - (2) Form, Schedule or Registration Statement No.:
 - (3) Filing Party:
 - (4) Date Filed:
-

FOR IMMEDIATE RELEASE

Ironwood Pharmaceuticals Announces Intent to Separate Soluble Guanylate Cyclase (sGC) Business from Commercial and Gastrointestinal Business

Separation designed to unlock value, increase operational performance and strategic flexibility, and tailor capital structure for each business

Separation expected to result in two independent, publicly traded companies

CAMBRIDGE, Mass., May 1, 2018 [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ: IRWD), a commercial biotech company, today announced that its Board of Directors has authorized an intent to separate into two independent, publicly traded companies (Ironwood and R&D Co.). The separation is expected to be completed in the first half of 2019 and is anticipated to be tax-free to Ironwood shareholders.

- Following the separation, Ironwood anticipates being a profitable company, building on its commercial success to-date to accelerate growth of its in-market products and advance development programs targeting treatments for gastrointestinal (GI) diseases, uncontrolled gout, and abdominal pain.
- R&D Co. will harness the pioneering work in cyclic guanosine monophosphate (cGMP) pharmacology to advance an innovative sGC pipeline expected to focus on the treatment of serious and orphan diseases, led by Phase II clinical compounds pralicyguat and olincyguat (IW-1701).

Peter Hecht, chief executive officer of Ironwood said, "Today's announcement marks a transformative milestone for Ironwood. Since our founding 20 years ago, we have been driven by a simple mission: create and commercialize innovative drugs that can change patients' lives and generate value for our shareholders. Ironwood today markets three commercial medicines, including LINZESS, a category leader, and is advancing a deep pipeline of drug candidates targeting severe and high unmet need diseases. We are pioneering two important areas: commercializing products in categories with millions of potential patients and innovating to discover and develop important new medicines. The positive Phase IIb data from IW-3718, combined with the significant progress within our sGC platform, including recent Phase IIa pralicyguat data, catalyzed our ability to separate into two focused, durable businesses poised for long-term growth."

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form DEFA14A

Terrance G. McGuire, Ironwood's chairman of the Board of Directors, commented, "There has never been a more exciting time for Ironwood, and our decision to separate these businesses underscores the strength of our in-market and development portfolio developed by the team's leadership and expertise. With our priority to maximize shareholder value, our Board and management team

regularly explore strategic opportunities. This particular strategic review, which began in the fall of 2017, included a focus on opportunities to best develop Ironwood's strong commercial platform and its rich drug discovery and development assets. Following a comprehensive review, the Board and management team unanimously determined that a separation of these platforms into two independent, publicly traded companies targeting differentiated markets presents the best way to drive operating performance, accelerate growth and unlock value.

Ironwood believes the planned separation will create, among other things:

- two nimbler, more productive businesses with strengthened competitive positions,
- separate and distinct management teams focused on each business's unique strategic priorities, target markets, and corporate development opportunities,
- specifically tailored capital allocation strategies for each company, and
- sharpened investment theses that attract a long-term shareholder base suited to each business.

Creating Two Focused, Growth Companies

Ironwood

Ironwood's assets are expected to continue to include its three in-market products and two development candidates targeting GI diseases and abdominal pain. Ironwood anticipates being profitable with strong revenue growth from its in-market products following the separation. It also intends to develop and commercialize (if approved) its core pipeline candidates. The in-market products include flagship product linaclotide, which is available in the U.S. and over 30 countries worldwide for the treatment of adults with irritable bowel syndrome with constipation (IBS-C) and/or chronic idiopathic constipation (CIC) under the brand names LINZESS® and CONSTELLA®. All of Ironwood's current linaclotide collaborations are expected to remain with Ironwood. Ironwood is expected to retain U.S. rights to the lesinurad franchise for uncontrolled gout, including recently introduced DUZALLO® (lesinurad and allopurinol) and ZURAMPIC® (lesinurad), and continues to evaluate the optimal mix of investments for this franchise. Additionally, Ironwood anticipates including IW-3718, which is being evaluated for the treatment of persistent gastroesophageal reflux disease (GERD) with Phase III trials expected to initiate in the third quarter of 2018, and linaclotide delayed release which is being evaluated for the treatment of abdominal pain associated with all forms of IBS. These assets are expected to have strong intellectual property coverage into the 2030s and are first-in-category therapies with the potential to serve markets with millions of patients suffering from serious and chronic disorders.

Following the separation, we believe Ironwood will:

- be profitable beginning in 2019 with the ability to tailor capital allocation to the growth of the commercial business,
- drive revenue growth with a focus on expanding operating leverage,
- use its distinctive skills in applying deep patient insights and bringing differentiated therapies to patients,
- employ more innovative consumer-led marketing techniques, such as digital advertising, to effectively engage, educate, and motivate patients and healthcare providers,

- secure broad market access through greater payer appreciation of product value,

- continue highly effective linaclotide collaborations, and
- execute on a multi-faceted business development strategy.

R&D Co.

R&D Co. s assets are expected to initially include numerous sGC stimulator programs targeting serious and orphan diseases, such as praliciquat in Phase II for heart failure with preserved ejection fraction (HFpEF) and for diabetic nephropathy, olinciguat in Phase II targeting sickle cell disease and achalasia, and tissue-targeted sGC stimulators, including IW-6463 in development for severe central nervous system diseases and other discovery programs targeting severe liver and lung diseases. sGC plays an important role in regulating many critical physiological processes; dysregulation of sGC may play a role in multiple serious diseases. Ironwood s sGC stimulators are believed to harness the nitric oxide/sGC/cyclic guanosine monophosphate (NO/sGC/cGMP) pathway by working synergistically with NO to improve blood flow and metabolism and decrease inflammation and fibrosis. R&D Co. is expected to develop and commercialize (if approved) drugs treating serious and orphan diseases and to out-license drugs targeting larger patient populations.

As an independent company, we believe R&D Co. will:

- apply its core competency in NO/sGC/cGMP pharmacology,
- rapidly advance its pipeline of clinical-stage assets, including praliciquat and olinciguat,
- accelerate drug development with more parallel programs and innovative trial designs,
- tailor its development approaches to serious and orphan diseases,
- simplify its capital allocation decision-making process, and
- enter strategic partnerships to achieve the full patient impact and value creation in the diverse markets its products could serve.

Leadership, Employees, Name and Location

Ironwood plans to have separate Boards and management teams for each business with specific details provided at a later date. The company intends to transition employees to the new businesses as the organization design is completed over the coming months. After separation, the commercial business will continue to be named Ironwood with the name of R&D Co. to be announced at a later date. Both businesses are anticipated to be headquartered in Cambridge, MA.

Approvals

The proposed separation is subject to customary conditions, including receipt of regulatory approvals, a favorable opinion with respect to the tax-free nature of the transaction, and final approval of Ironwood s Board of Directors. Ironwood may, for any or no reason and at any time until the proposed separation is complete, abandon the separation or modify or change its terms.

Guidance

Ironwood expects to incur charges related to the transaction. As a result, Ironwood plans to provide an update on the impact of the transaction charges on its 2018 financial guidance during the company's second quarter 2018 investor update.

Centerview Partners LLC is acting as financial advisor to Ironwood, and Ropes & Gray LLP is acting as legal counsel.

Conference Call

Ironwood will discuss today's announcement in more detail on its first quarter 2018 conference call, scheduled for 8:30 a.m. Eastern Time today, Tuesday, May 1, 2018. Individuals interested in participating in the call should dial (877) 643-7155 (U.S. and Canada) or (914) 495-8552 (international) using conference ID number 9859406.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is a commercial biotechnology company focused on creating medicines that make a difference for patients, building value for our fellow shareholders, and empowering our passionate team. We are commercializing two innovative primary care products: linaclotide, the U.S. branded prescription market leader for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC), and lesinurad, which is approved to be taken with a xanthine oxidase inhibitor (XOI), or as a fixed-dose combination with allopurinol, for the treatment of hyperuricemia associated with gout. We are also advancing a pipeline of innovative product candidates in areas of significant unmet need, including uncontrolled gastroesophageal reflux disease, diabetic nephropathy, heart failure with preserved ejection fraction, achalasia and sickle cell disease. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. For more information, please visit www.ironwoodpharma.com or www.twitter.com/ironwoodpharma; information that may be important to investors will be routinely posted in both these locations.

About LINZESS (linaclotide)

LINZESS® is the #1 prescribed brand for the treatment of adult patients with irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC), based on IQVIA data. Since its FDA approval in August of 2012 and subsequent launch in December 2012, greater than 2 million unique patients have filled approximately 10 million prescriptions for LINZESS, according to IQVIA.

LINZESS is a once-daily capsule that helps relieve the abdominal pain and constipation associated with IBS-C, as well as the constipation, infrequent stools, hard stools, straining, and incomplete evacuation associated with CIC. The recommended dose is 290 mcg for IBS-C patients and 145 mcg for CIC patients, with a 72 mcg dose approved for use in CIC depending on individual patient presentation or tolerability. LINZESS should be taken at least 30 minutes before the first meal of the day.

LINZESS is contraindicated in pediatric patients less than 6 years of age. The safety and effectiveness of LINZESS in pediatric patients less than 18 years of age have not been established. In neonatal mice, linaclotide increased fluid secretion as a consequence of GC-C agonism resulting in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences. In adults with IBS-C or CIC treated with LINZESS, the most commonly reported adverse event was diarrhea.

LINZESS is not a laxative; it is the first medicine approved by the FDA in a class called guanylate cyclase-C (GC-C) agonists. LINZESS contains a peptide called linaclotide that activates the GC-C receptor in the intestine. Activation of GC-C is thought to result in increased intestinal fluid secretion and accelerated transit and a decrease in the activity of pain-sensing nerves in the intestine. The clinical relevance of the effect on pain fibers, which is based on nonclinical studies, has not been established.

In the United States, Ironwood and Allergan plc co-develop and co-commercialize LINZESS for the treatment of adults with IBS-C or CIC. In Europe, Allergan markets linaclotide under the brand name CONSTELLA for the treatment of adults with moderate to severe IBS-C. In Japan, Ironwood's partner Astellas markets linaclotide under the brand name LINZESS for the treatment of adults with IBS-C. Ironwood also has partnered with AstraZeneca for development and commercialization of linaclotide in China, and with Allergan for development and commercialization of linaclotide in all other territories worldwide.

About ZURAMPIC (lesinurad) 200mg tablets

ZURAMPIC (lesinurad) works in combination with xanthine oxidase inhibitors (XOIs) to treat hyperuricemia associated with uncontrolled gout. ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy. XOIs reduce the production of uric acid; ZURAMPIC increases the excretion of uric acid. Together, the combination of ZURAMPIC and an XOI provides a dual mechanism of action that both decreases production and increases excretion of uric acid, thereby lowering serum uric acid (sUA) levels in patients who have not achieved target serum uric acid levels with XOI treatment alone. ZURAMPIC selectively inhibits the function of transporter proteins uric acid transporter 1 (URAT1) and organic anion transporter 4 (OAT4), involved in uric acid reabsorption in the kidney. The safety and efficacy of ZURAMPIC was established in three Phase III clinical trials that evaluated a once-daily dose of ZURAMPIC in combination with the XOI allopurinol or febuxostat compared to XOI alone. The boxed warning for ZURAMPIC states that acute renal failure has occurred with ZURAMPIC and was more common when ZURAMPIC was given alone and reinforces that ZURAMPIC should be used in combination with an XOI.

About DUZALLO (lesinurad and allopurinol)

DUZALLO (lesinurad and allopurinol) is a once-daily oral therapy that contains lesinurad 200 mg plus allopurinol 300 mg; it is also available in a lesinurad 200 mg plus allopurinol 200 mg dosage. DUZALLO is approved by the FDA as a once-daily oral treatment for hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with a medically appropriate daily dose of allopurinol alone. DUZALLO is not recommended for the treatment of asymptomatic hyperuricemia. Allopurinol is an XOI whose action differs from that of uricosuric agents such as lesinurad. Allopurinol reduces the production of uric acid (UA); lesinurad increases renal excretion of UA by selectively inhibiting the action of URAT1, the UA transporter responsible for the majority of renal UA reabsorption. The dual-mechanism combination of DUZALLO can address both inefficient excretion and overproduction of UA, thereby lowering sUA levels.

DUZALLO should be taken in the morning with food and water, and patients should be advised to stay well hydrated when taking DUZALLO (about 2 liters of liquid a day).

LINZESS Important Safety Information

INDICATIONS AND USAGE

LINZESS (linaclotide) is indicated in adults for the treatment of both irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC).

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

LINZESS is contraindicated in patients less than 6 years of age. In nonclinical studies in neonatal mice, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration. Use of LINZESS should be avoided in patients 6 years to less than 18 years of age. The safety and effectiveness of LINZESS have not been established in patients less than 18 years of age.

Contraindications

- LINZESS is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Pediatric Risk

- LINZESS is contraindicated in patients less than 6 years of age. The safety and effectiveness of LINZESS in patients less than 18 years of age have not been established. In neonatal mice, linaclotide increased fluid secretion as a consequence of GC-C agonism resulting in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences.
- Use of LINZESS should be avoided in pediatric patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, use of LINZESS should be avoided in pediatric patients 6 years to less than 18 years of age.

Diarrhea

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form DEFA14A

- Diarrhea was the most common adverse reaction in LINZESS-treated patients in the pooled IBS-C and CIC double-blind placebo-controlled trials. The incidence of diarrhea was similar in the IBS-C and CIC populations. Severe diarrhea was reported in 2% of 145 mcg and 290 mcg LINZESS-treated patients, and in <1% of 72 mcg LINZESS-treated CIC patients. If severe diarrhea occurs, dosing should be suspended and the patient rehydrated.

Common Adverse Reactions (incidence $\geq 2\%$ and greater than placebo)

- In IBS-C clinical trials: diarrhea (20% vs 3% placebo), abdominal pain (7% vs 5%), flatulence (4% vs 2%), headache (4% vs 3%), viral gastroenteritis (3% vs 1%) and abdominal distension (2% vs 1%).
- In CIC trials of a 145 mcg dose: diarrhea (16% vs 5% placebo), abdominal pain (7% vs 6%), flatulence (6% vs 5%), upper respiratory tract infection (5% vs 4%), sinusitis (3% vs 2%) and abdominal distension (3% vs 2%). In a CIC trial of a 72 mcg dose: diarrhea (19% vs 7% placebo) and abdominal distension (2% vs <1%).

Please see full Prescribing Information including Boxed Warning:

http://www.allergan.com/assets/pdf/linzess_pi

ZURAMPIC Important Safety Information and Limitations of Use

WARNING: RISK OF ACUTE RENAL FAILURE MORE COMMON WHEN USED WITHOUT A XANTHINE OXIDASE INHIBITOR (XOI)

- **Acute renal failure has occurred with ZURAMPIC and was more common when ZURAMPIC was given alone**
- **ZURAMPIC should be used in combination with an XOI**

Contraindications:

- Severe renal impairment (eCLcr less than 30 mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis
- Tumor lysis syndrome or Lesch-Nyhan syndrome

Warnings and Precautions:

- **Renal events:** Adverse reactions related to renal function have occurred after initiating ZURAMPIC. A higher incidence was observed at the 400-mg dose, with the highest incidence occurring with monotherapy use. Monitor renal function at initiation and during therapy with ZURAMPIC, particularly in patients with eCLcr below 60 mL/min or with serum creatinine elevations 1.5 to 2 times the pre-treatment value, and evaluate for signs and symptoms of acute uric acid nephropathy. Interrupt treatment with ZURAMPIC if serum creatinine is elevated to greater than 2 times the pre-treatment value or if there are symptoms that may indicate acute uric acid nephropathy. ZURAMPIC should not be restarted without another explanation for the serum creatinine abnormalities. ZURAMPIC should not be initiated in patients with an eCLcr less than 45 mL/min.
- **Cardiovascular events:** In clinical trials, major adverse cardiovascular events (defined as cardiovascular deaths, non-fatal myocardial infarctions, or non-fatal strokes) were observed with ZURAMPIC. A causal relationship has not been established.

Adverse Reactions:

- Most common adverse reactions with ZURAMPIC (in combination with an XOI and more frequently than on an XOI alone) were headache, influenza, blood creatinine increased, and gastroesophageal reflux disease

Indication and Limitations of Use for ZURAMPIC

ZURAMPIC is a URAT1 inhibitor indicated in combination with an XO1 for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with an XO1 alone.

- ZURAMPIC is not recommended for the treatment of asymptomatic hyperuricemia
- ZURAMPIC should not be used as monotherapy

Please see full Prescribing Information, including Boxed Warning, at:

http://irwdpi.com/zurampic/ZURAMPIC_PI_and_Medguide_2017.pdf#page=1

DUZALLO Important Safety Information

WARNING: RISK OF ACUTE RENAL FAILURE

- Acute renal failure has occurred with lesinurad, one of the components of DUZALLO

Contraindications:

- Severe renal impairment (estimated creatinine clearance [eCLcr] < 30 mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis
- Tumor lysis syndrome or Lesch-Nyhan syndrome
- Known hypersensitivity to allopurinol, including previous occurrence of skin rash

Warnings and Precautions:

- **Renal events:** Adverse reactions related to renal function, including acute renal failure, can occur after initiating DUZALLO. Renal function should be evaluated prior to initiation of DUZALLO and periodically thereafter, as clinically indicated. More frequent renal function monitoring is recommended in patients with eCLcr < 60 mL/min or with serum creatinine elevations 1.5 to 2 times the value when lesinurad treatment was initiated. DUZALLO should not be initiated in patients with an eCLcr < 45 mL/min. Interrupt treatment with DUZALLO if serum creatinine is elevated to > 2 times the pretreatment value or if there are symptoms that may indicate acute uric acid nephropathy, including flank pain, nausea, or vomiting. DUZALLO should not be restarted without another explanation for the serum creatinine abnormalities

- **Skin rash and hypersensitivity:** Skin rash is a frequently reported adverse event in patients taking allopurinol. In some instances, a skin rash may be followed by more severe hypersensitivity reactions associated with exfoliation, fever, lymphadenopathy, arthralgia, and/or eosinophilia including Stevens-Johnson syndrome and toxic epidermal necrolysis. Associated vasculitis and tissue response may be manifested in various ways including hepatitis, renal impairment, seizures, and on rare occasions, death. Hypersensitivity reactions to allopurinol may be increased in patients with decreased renal function who are receiving thiazide diuretics and DUZALLO concurrently. DUZALLO should be discontinued immediately at the first appearance of skin rash or other signs that may indicate an allergic reaction, and additional medical care should be provided as needed
- **Hepatotoxicity:** A few cases of reversible clinical hepatotoxicity have been reported in patients taking allopurinol and, in some patients, asymptomatic rises in serum alkaline phosphatase or serum transaminase have been observed. If anorexia, weight loss, or pruritus develops in

patients taking DUZALLO, evaluation of liver function should be performed. In patients with preexisting liver disease, periodic liver function tests are recommended

- **Cardiovascular events:** In clinical trials, major adverse cardiovascular events (defined as cardiovascular deaths, nonfatal myocardial infarctions, and nonfatal strokes) were observed with DUZALLO. A causal relationship has not been established
- **Bone marrow depression:** Bone marrow depression has been reported in patients receiving allopurinol, most of whom received concomitant drugs with the potential for causing this reaction. This has occurred as early as 6 weeks to as long as 6 years after the initiation of allopurinol therapy. Rarely, a patient may develop varying degrees of bone marrow depression, affecting one or more cell lines, while receiving allopurinol alone. Patients taking allopurinol and mercaptopurine or azathioprine require a reduction in dose to approximately one-third to one-fourth of the usual dose of mercaptopurine or azathioprine
- **Increase in prothrombin time:** It has been reported that allopurinol prolongs the half-life of dicumarol, a coumarin anticoagulant. The prothrombin time should be reassessed periodically in patients receiving coumarin anticoagulants (dicumarol, warfarin) concomitantly with DUZALLO
- **Drowsiness:** Occasional occurrence of drowsiness was reported in patients taking allopurinol. Patients should be alerted to the need for caution when engaging in activities where alertness is mandatory

Adverse Reactions:

- The most common adverse reactions in controlled studies (occurring in 2% or more of patients on lesinurad in combination with allopurinol and at least 1% greater than observed in patients on allopurinol alone) were headache, influenza, blood creatinine increased, and gastroesophageal reflux disease
- The most common adverse reactions identified during post-approval use of allopurinol are skin rash, nausea, and diarrhea

Indication and Limitations of Use:

DUZALLO, a combination of lesinurad, a URAT1 inhibitor, and allopurinol, a xanthine oxidase inhibitor, is indicated for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone.

- DUZALLO is not recommended for the treatment of asymptomatic hyperuricemia

Please see full Prescribing Information, including Boxed, at
<https://www.irwdpi.com/duzallo/DuzalloPIandMedguide2017.pdf#page=1>

Edgar Filing: IRONWOOD PHARMACEUTICALS INC - Form DEFA14A

LINZESS® and CONSTELLA® are registered trademarks of Ironwood Pharmaceuticals, Inc., and ZURAMPIC® and DUZALLO® are registered trademarks of AstraZeneca AB. Any other trademarks referred to in this press release are the property of their respective owners. All rights reserved.

Forward Looking Statements

This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about the benefits of a potential separation, including with respect to Ironwood's and R&D Co.'s competitive position, attractiveness to investors and enhanced operational, commercial and scientific effectiveness; the timing, leadership, structure, including the division of assets among Ironwood and R&D Co., and impact of a separation; capital allocation; the strategy, including the intended development and commercialization plans for each of Ironwood and R&D Co., and potential corporate development opportunities; the tax free nature of the separation; the market size, commercial potential, prevalence, and the growth in, and potential demand for, linaclotide, lesinurad and other product candidates (and the drivers, timing and impact thereof), for each of Ironwood and R&D Co., as applicable; the potential indications for, and benefits of, linaclotide, lesinurad and other product candidates, for each of Ironwood and R&D Co., as applicable; the strength of the intellectual property protection for linaclotide, lesinurad and other product candidates; growth in LINZESS prescriptions; the number of potential patients; the anticipated timing of preclinical, clinical and regulatory developments and the design, timing and results of clinical and preclinical studies; expected periods of patent exclusivity, durability and life of the respective patent portfolios for linaclotide, lesinurad and other product candidates; Ironwood's and R&D Co.'s financial performance and results, and guidance and expectations related thereto (including the drivers and timing thereof); and expectations related to revenue growth for in-market products, commercial margin, cash flow and profitability growth and LINZESS U.S. net sales. 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 possibility that we may not complete the separation on the terms or timeline currently contemplated if at all, achieve the expected benefits of a separation, and that a separation could harm our business, results of operations and financial condition; the risk that the transaction might not be tax-free; the risk that we may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as independent companies; R&D Co.'s lack of independent operating history and the risk that its accounting and other management systems may not be prepared to meet the financial reporting and other requirements of operating as an independent public company; the risk that a separation may adversely impact our ability to attract or retain key personnel; the effectiveness of development and commercialization efforts by us and our partners; preclinical and clinical development, manufacturing and formulation development; the risk that findings from our completed nonclinical and clinical studies may not be replicated in later studies; efficacy, safety and tolerability of linaclotide, lesinurad and our product candidates; decisions by regulatory and judicial authorities; the risk that we are unable to successfully commercialize lesinurad or realize the anticipated benefits of the lesinurad transaction; the risk that we may never get sufficient patent protection for linaclotide, lesinurad and our product candidates or that we are not able to successfully protect such patents; the outcomes in legal proceedings to protect or enforce the patents relating to our products and product candidates, including ANDA litigation; 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, linaclotide, lesinurad or our product candidates; the risk that we are unable to manage our operating expenses or cash use for operations, or are unable to commercialize our products, within the guided ranges or otherwise as expected; 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, 2017, and in our subsequent SEC filings. These forward-looking statements (except as otherwise

noted) speak only as of the date of this press release, and Ironwood undertakes no obligation to update these forward-looking statements.

Additional Information

Ironwood, its directors and certain of its officers may be deemed to be participants in the solicitation of proxies from shareholders in connection with the matters to be considered at the company's 2018 Annual Meeting of Shareholders. In connection with any such solicitation of proxies from shareholders, the company filed a preliminary proxy statement and a WHITE proxy card on April 16, 2018 and will file a definitive proxy statement and WHITE proxy card, each with the U.S. Securities and Exchange Commission (the "SEC"). **SHAREHOLDERS ARE STRONGLY ENCOURAGED TO READ ANY SUCH DEFINITIVE PROXY STATEMENT AND ACCOMPANYING WHITE PROXY CARD WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION.** Information regarding the identity of solicitation participants, and their direct or indirect interests, by security holdings or otherwise, is set forth in the preliminary proxy statement and will be set forth in the definitive proxy statement and other materials to be filed with the SEC in connection with the company's 2018 Annual Meeting of Shareholders. Shareholders will be able to obtain any proxy statement, any amendments or supplements to the proxy statement and other documents filed by the company with the SEC for no charge at the SEC's website at www.sec.gov. Copies will also be available at no charge at the company's website at www.ironwoodpharma.com. If you have any questions regarding this information or the proxy materials, please contact MacKenzie Partners, Inc., our proxy solicitor assisting us in connection with the annual meeting, toll-free at (800) 322-2885 or at (212) 929-5500 or via email to IRWD@mackenziepartners.com.

Investors:

Meredith Kaya, 617-374-5082

Vice President, Investor Relations and Corporate Communications
mkaya@ironwoodpharma.com

Media:

Andi Rose / Mahmoud Siddig

Joele Frank, Wilkinson Brimmer Katcher

212-355-4449