

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): August 9, 2022

GEMINI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39438
(Commission
File Number)

85-1612845
(IRS Employer
Identification No.)

297 Boston Post Road #248, Wayland, MA¹
(Address of principal executive offices)

01778
(Zip Code)

Registrant's telephone number, including area code: (617) 401-4400

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	GMTX	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

¹ The Company does not currently maintain a physical headquarters but maintains a mailing address at 297 Boston Post Road #248, Wayland, MA 01778.

Item 7.01. Regulation FD Disclosure.

As previously announced, on August 9, 2022, Gemini Therapeutics, Inc., a Delaware corporation (“Gemini” or the “Company”), Gemstone Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Gemini (“Merger Sub”), and Disc Medicine, Inc., a Delaware corporation (“Disc”), entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Disc, with Disc continuing as a wholly owned subsidiary of Gemini and the surviving corporation of the merger (the “Merger”).

On August 10, 2022, Gemini and Disc hosted a webcast presentation regarding the proposed Merger between Gemini and Disc. (the “Presentation”). A transcript of the Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference, and a copy of the investor presentation was previously furnished as Exhibit 99.2 to that certain Current Report on Form 8-K filed by Gemini on August 10, 2022, and which is incorporated herein by reference.

Additionally, on August 10, 2022, Disc issued a press release announcing the initiation of BEACON (the “Study”), a Phase 2 clinical study of Bitopertin in patients with Erythropoietic Protoporphyrinemia (EPP) and X-linked Protoporphyrinemia (XLP). The press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference, except that the information contained on the websites referenced in the press release is not incorporated herein by reference.

Furnished as Exhibit 99.3 hereto and incorporated herein by reference are social media posts posted by Disc on LinkedIn and Twitter on August 10, 2022 regarding the announcement of the Merger and the Study.

On August 10, 2022, Arix Bioscience plc, an investor in Disc and a participant in the concurrent financing to the Merger, issued the press release attached as Exhibit 99.4.

The information in this Item 7.01 and Exhibits 99.1, 99.2, 99.3 and 99.4 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements (including within the meaning of Section 21E of the Exchange Act and Section 27A of the Securities Act of 1933, as amended (the “Securities Act”)) concerning Gemini, Disc, the proposed transaction and other matters. These forward-looking statements include express or implied statements relating to Gemini’s and Disc’s management team’s expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting Gemini, Disc or the proposed transaction will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Gemini’s or Disc’s control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that the conditions to the closing of the transaction are not satisfied, including the failure to obtain stockholder approval for the transaction; the risk that the concurrent financing is not completed in a timely manner or at all; uncertainties as to the timing of the consummation of the transaction and the ability of each of Gemini and Disc to consummate the transaction, including the

concurrent financing; risks related to Gemini's continued listing on the Nasdaq Stock Market until closing of the proposed transaction; risks related to Gemini's and Disc's ability to correctly estimate their respective operating expenses and expenses associated with the transaction, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company's cash resources; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement; the effect of the announcement or pendency of the merger on Gemini's or Disc's business relationships, operating results and business generally; costs related to the merger; the outcome of any legal proceedings that may be instituted against Gemini, Disc or any of their respective directors or officers related to the merger agreement or the transactions contemplated thereby; the ability of Gemini or Disc to protect their respective intellectual property rights; competitive responses to the transaction; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; legislative, regulatory, political and economic developments; uncertainties related to the initiation of Disc's BEACON clinical study; and those factors described under the heading "Risk Factors" in the Gemini's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors included in later filings, including any Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and the proxy statement/prospectus included in the registration statement on Form S-4 to be filed with the SEC in connection with the Merger. Should one or more of these risks or uncertainties materialize, or should any of Gemini's or Disc's assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the ongoing COVID-19 pandemic and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. Gemini's and Disc's forward-looking statements only speak as of the date they are made, and Gemini and Disc do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

No Offer or Solicitation

This Current Report on Form 8-K is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

Important Additional Information Will be Filed with the SEC

In connection with the proposed transaction between Gemini and Disc, Gemini intends to file relevant materials with the SEC, including a registration statement on Form S-4 that will contain a proxy statement/prospectus of Gemini and information statement of Disc. **GEMINI URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT GEMINI, DISC, THE PROPOSED TRANSACTION AND RELATED**

MATTERS. Investors and shareholders will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Gemini with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In addition, investors and shareholders should note that Gemini communicates with investors and the public using its website (www.geminitherapeutics.com) and the investor relations website (<https://investors.geminitherapeutics.com/>) where anyone will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Gemini with the SEC and stockholders are urged to read the proxy statement/prospectus/information statement and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transaction.

Participants in the Solicitation

Gemini, Disc and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Gemini's directors and executive officers is included in Gemini's most recent Annual Report on Form 10-K, including any information incorporated therein by reference, as filed with the SEC. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement/prospectus/information statement relating to the transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of webcast presentation held by Gemini Therapeutics, Inc. and Disc Medicine, Inc. on August 10, 2022
99.2	Press release issued by Disc Medicine, Inc. on August 10, 2022
99.3	Social media posts, posted by Disc Medicine, Inc. on August 10, 2022
99.4	Press release issued by Arix Bioscience plc on August 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GEMINI THERAPEUTICS, INC.

Date: August 10, 2022

By: /s/ Dr. Georges Gemayel

Name: Dr. Georges Gemayel

Title: Interim President and Chief Executive Officer

CONFIDENTIAL

Conference Call Transcript

Gemini Therapeutics and Disc Medicine Merger Agreement Announcement

August 10, 2022 / 08:00 AM ET

CORPORATE PARTICIPANTS

Georges Gemayal—Gemini Therapeutics, Chair of the Board and Interim CEO

John Quisel—President and CEO of Disc Medicine

PRESENTATION

Operator

Welcome to today's joint call with Gemini Therapeutics and Disc Medicine. Our speakers today are Georges Gemayal, Chair of the Board and Interim CEO of Gemini Therapeutics, and John Quisel, President and CEO of Disc Medicine.

Georges Gemayal—Gemini Therapeutics, Chair of the Board and Interim CEO

Gemini's strategic review was a thorough and thoughtful process. We believe that this transaction presents an exciting opportunity for our shareholders, as Disc has built a diversified, clinical-stage pipeline of product candidates, and we believe in the ability of Disc's experienced management team to lead the combined company. We look forward to its continued success. John will now provide an overview of Disc Medicine and the company's hematology drug development programs.

John Quisel—President and CEO of Disc Medicine

Thank you, Georges, and good morning everyone. Before I begin, I want to remind everyone that this discussion and the accompanying presentation will contain forward-looking statements based upon the current expectations of Gemini Therapeutics and Disc Medicine, which include, but are not limited to statements regarding the expected timing, completion, effects and potential benefits of the transaction and our future expectations, plans and prospects for the combined company. Such statements represent management's judgment and intention as of today and involve assumptions, risks and uncertainties. Gemini and Disc undertake no obligation to update any or revise any forward-looking statements. This slide provides an overview of these forward-looking statements and the risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated in these forward-looking statements. Please refer to the accompanying slide for more details on these forward-looking statements.

Further, as indicated on this slide, Gemini intends to file a registration statement and accompanying proxy statement and prospectus with the SEC relating to the proposed merger. Please be advised to read, when available, the proxy statement and prospectus and other relevant documents filed with the SEC as these will contain important information about Gemini, Disc and the transaction. Once available, these documents can be obtained free of charge from the SEC at sec.gov or on Gemini's website.

Now with those preliminaries completed, I'm delighted that we'll be joining with Gemini through this merger. I will briefly summarize the components of the reverse merger transaction first and then discuss the business plans here at Disc Medicine.

We believe this merger will be transformative. At Disc we have now become a mid-stage clinical biotech company with multiple drug development programs focused on hematologic disorders. With two first-in-class molecules in patient trials across three disease areas, we anticipate near term clinical catalysts in the next 6 to 12 months. The combined financial strength of Gemini and Disc is expected to finance our business plan into 2025 with an expected approximate \$175 million cash and cash equivalents at close.

As an overview on the merger terms, upon the closing of the transaction the company will be renamed Disc Medicine and will begin trading on NASDAQ under the ticker symbol IRON. The ticker symbol is a reference to our therapeutic focus on modulating iron metabolism. After the merger, the currently expected ownership breakdown is projected to be as shown on the slide, and we expect approximately \$92 million raised from Gemini plus an additional \$53.5 million from a concurrent financing. There will be a contingent value rights agreement, or CVR, associated with the legacy Gemini programs that are referred to as GEM103 and GEM307, and any net value received from future transactions for these assets will flow to the pre-existing Gemini shareholders. We expect the merger transaction to close in the fourth quarter of 2022, subject to approval of shareholders at both companies. The merged company will be managed by the existing Disc Medicine team and board, and we are delighted that Georges Gemayal will be continuing as a director of the combined company

Now I will summarize the Disc Medicine business plan. We have been working for many years to build a great hematology company. We think this is an excellent therapeutic area for building a company. Unmet patient needs are high and the tools for clinical development include readily measurable and objective endpoints. Our approach focuses on fundamental components of red blood cells, particularly the metabolism of heme and iron, which are universal and critical components of these cells. There is evidence from studies in humans that both of our clinical-stage molecules engage their respective targets and cause the desired effect on iron metabolism and heme biosynthesis. There is also strong evidence in human genetics for the importance of our targets in iron metabolism. Because of the universal need for heme and iron in red blood cells, we believe each program has potential to address a broad range of multiple indications.

I will focus on our two clinical-stage programs. One is called bitopertin which was in-licensed from Roche in 2021 and is now starting a Phase 2 trial in an indication that we refer to in brief as EPP, or erythropoietic protoporphyria. We have also now initiated one of two near term phase 1b/2a studies for our DISC-0974 antibody program. The first of these, for the treatment of myelofibrosis patients with anemia is now open and enrolling, and later this year we expect to be opening a trial in anemic patients with chronic kidney disease. This clinical activity puts us in a position to have many potential near-term catalysts. We expect across the next 6-12 month to have readouts on bitopertin in the EPP trials and DISC-0974 in the two trials of anemia of inflammation in myelofibrosis and chronic kidney disease. As I mentioned, we also believe that both of these drugs have the potential to expand into other indications.

I believe we've built a fantastic team with strong experience in drug discovery and development. So we are positioned to take our programs deep into clinical development and potentially transition to a fully integrated biotech company should we be successful.

Our investors are a group of top-tier biotech specialist investors. We were founded and seeded at Atlas Ventures. Novo Holdings led the Series A along with Access Biotechnology and OrbiMed led the Series B along with Arix. They were joined by a host of other top-flight groups such as Janus Henderson, Rock Springs and 5AM. We also benefit from an experienced Board of Directors and a scientific advisory board representing top names in our field.

What we're doing at Disc is engaging fundamental biology in red blood cells and if you think about it, what is a red blood cell other than a cell that's full of hemoglobin to carry oxygen. The key components of hemoglobin are iron and heme, so our programs are designed to control the incorporation of iron and heme into newly forming red blood cells, thereby controlling fundamental aspects of red blood cell biology. We believe that these targets and this approach will allow us to address a wide range of indications, examples of which are listed at the bottom of the slide. You'll hear about three or four of these indications over the course of this discussion where we have clinical trials either open or in near-term planning, and we expect to be able to access this full range of indications over the lifecycle of these programs.

In terms of our pipeline chart, we have our heme biosynthesis portfolio led by bitopertin, a molecule that, as I said previously, we in-licensed from Roche. This is a small molecule, given orally, once daily. Bitopertin inhibits heme biosynthesis by targeting GlyT1, a glycine transporter expressed on red blood cells. We are now open and enrolling on a Phase 2 trial in Australia in EPP patients and we expect to be opening a similar trial in the US shortly, referred to as the BEACON and AURORA trials, respectively. We are also in planning for a trial in a rare anemia called Diamond-Blackfan Anemia, as well as other potential indications.

The founding portfolio of the company was around iron metabolism where there's a central regulator called hepcidin. We have a set of programs that suppress hepcidin and associated programs that induce hepcidin and each have different uses in hematology. DISC-0974 is an antibody against a target called hemojuvelin or HJV that we in-licensed from AbbVie in 2019. It is given subcutaneously and, based on phase 1 data, it appears to be suitable for once monthly dosing. The Phase 1 data for DISC-0974 was recently presented at the European Hematology Association, and showed promising evidence of activity, which I will go through later. We've now opened a trial in patients with anemia of myelofibrosis, a severe and difficult-to-treat form of anemia, and we are also working to open a trial in patients with anemia as a consequence of chronic kidney disease, focusing particularly on the non-dialysis population. We expect to get data flowing from these two trials across 2023.

We also have some earlier pipeline programs as you can see here. The first is a follow-on molecule to DISC-0974 called DISC-0998 with an extended half-life, which is positioned for indication expansion as well as lifecycle management.

We have another discovery program against a compelling target called matriptase-2 and this would be designed for treating polycythemia vera and also diseases of iron overload. There, we're in the discovery stage, working on our lead candidate optimization.

This next slide shows the Disc vision of growth. We've established a track record of exceptional operational capability moving from a preclinical company in 2019 to a company with multiple programs in patient trials here in 2022. As you can see, we are entering an exciting period in our company's story, which this financing will support.

So now I will turn to each individual program, starting with bitopertin.

This molecule is an inhibitor of glycine uptake through a transporter called GlyT1. What's interesting about glycine uptake is that it is fundamental for red blood cell formation. Glycine is the first metabolite that's converted into heme, and heme, of course, is a critical component of newly forming red blood cells, so what has been shown in the clinic is that by suppressing glycine uptake there's inhibition of the flow of metabolites through the heme biosynthesis pathway. The objective is to use this mechanism to address diseases where the heme biosynthesis pathway is driving disease.

First and foremost are diseases called the porphyrias. These are diseases caused by the accumulation of toxic porphyrins, which are intermediate metabolites in heme biosynthesis that accumulate to toxic levels in these patients. In particular, we are focusing on two forms of porphyria, erythropoietic protoporphyria and X-linked porphyria, or EPP and XLP. For brevity, throughout this talk, I have referred and will continue to refer to both of these together as EPP. As we announced earlier today, the Phase 2 BEACON trial is open and recruiting in these two forms of porphyria, and then we expect to expand from there to disorders caused by heme toxicity, disorders caused by hemoglobin toxicity and those caused by an excess of red blood cells.

Our Phase 2 trial that's up and running is in patients with EPP, which is a rare debilitating lifelong condition characterized by extreme pain and damage to skin caused by sunlight. It is a genetic condition driven by a toxic metabolite called protoporphyrin IX, or PPIX, which, as I mentioned earlier is a metabolite of the heme biosynthesis pathway. In addition to the skin phototoxicity, the other major symptom of disease is hepatobiliary complications with gallstones, liver dysfunction, and in some cases liver failure and death. There are also substantial psychosocial issues that these patients face.

Today, there is only one FDA approved agent, a surgically implanted agent called afamelanotide that stimulates skin pigmentation or tanning and thereby causes some resistance to sunlight. From a patient prevalence point of view, there are approximately 7,000-8,000 EPP and XLP patients in the US and Europe. These numbers represent identifiable patients, but recent genetic studies suggest that there may be additional patients who have not been properly diagnosed. This is a disease that impacts multiple aspects of patients' lives, and the impacts are severe, even leading to fatalities.

This slide shares testimonials from patients of a variety of ages and their caregivers illustrating the degree of pain and lifestyle impacts that EPP patients face.

So again this disease is driven by the molecule shown in the center of the slide, protoporphyrin IX. This is produced by the heme biosynthesis pathway and accumulates due to mutations in that pathway in these patients. This ring structure leads to absorption of light energy and as that energy is released inside the body, it causes intense pain in the skin. This molecule also accumulates in the bile canaliculi, leading to significant rates of liver damage and gallstone formation as well as a small percentage of liver failure and even fatality.

So again this disease is caused by mutations in the first or last enzymes of the heme biosynthesis pathway and those genetic defects leads to the buildup of the metabolite PPIX. Our hypothesis is that by reducing the flow of glycine into the top of the heme biosynthesis pathway, we can reduce the amount of PPIX and this would have the potential to be the first disease modifying treatment for EPP.

We have been able to run a variety of pre-clinical models ourselves and with collaborators at Boston Children's Hospital and this data has all been presented at various scientific conferences. As a quick summary, in cellular models of EPP where we introduced the disease causative mutation, we see a dramatic dose response decrease in PPIX levels and then in two different mouse models we see decreases in PPIX of 45 to 73% depending on the model that's run. Based on several clinical publications, we expect a 30% percent or greater decrease in PPIX to really cause significant modification of all aspects of the disease. I should also mention that our collaborators have observed that, in mouse models, bitopertin reduced liver fibrosis as well, which is an expected consequence so the available pre-clinical data suggests that by reducing the flow of glycine into the heme biosynthesis pathway we can achieve what appears to be a meaningful impact.

We in-licensed bitopertin from Roche, which had failed Phase 3 trials in neuropsychiatric indications but in that process Roche had established a thorough package in anticipation of commercialization. So we are the beneficiaries of extensive non-clinical, CMC, and clinical information including a safety profile collected in over 4,000 patients and 30 clinical trials. Many late-stage risks have already been addressed like carcinogenicity studies and long-term toxicology, so we do not expect to face problems on these aspects of the program.

We are up and running now with the BEACON trial. This is an open label Phase 2 trial where we're looking at two dose groups—20 mg and 60 mg once daily for six months plus a potential extension. These doses bracket where we saw efficacy in the mouse models and are predicted to reach 70-90% target engagement in humans. The primary endpoint will be changes in PPIX levels and secondary endpoints will include the clinically relevant metrics of light tolerance as well as measures of hepatobiliary health. We expect to be able to report interim open label PPIX data from this trial as early as year-end 2022, ranging possibly to mid-year 2023, depending on the speed of enrollment and other factors.

We also plan to be opening a US trial called the AURORA trial soon. This is a randomized double-blind placebo-controlled study in approximately 75 patients. Here we'll have three arms—placebo plus the same 20 and 60 mg once daily doses over a four month period. This will give us a placebo-controlled data set to design a pivotal trial.

Collectively we think we've made great progress on this program since we in-licensed it from Roche in 2021. We've completed the GMP clinical supply, we've opened the BEACON trial, we plan to open the AURORA trial in the coming months, and we expect to have data flow in the next 6 to 12 months for both trials. We're also working on a Phase 2 trial in Diamond Blackfan anemia through an investigator-initiated mechanism and, as I mentioned earlier, we believe this mechanism has potential across many different additional indications that we are looking forward to exploring.

Now let me turn to our iron metabolism program. These were the founding programs of the company.

It is well known that a hormone-like molecule called hepcidin is the key gatekeeper for iron in the body. Normally, about 70% of your iron is in your red blood cells and there's a tremendous flow of iron from the stores in the spleen to enable new red blood cell formation. Of course, iron comes into the body from the diet through the G.I. tract as well. Both of these processes are regulated by hepcidin and when hepcidin becomes high, both iron absorption in the G.I. tract and the flow of iron from the spleen are impaired and as a consequence new red blood cells cannot be formed efficiently because there's not sufficient iron available. Inflammation causes elevated hepcidin levels, so, elevated hepcidin leads to a form of anemia generally referred to as anemia of inflammation.

We have a program designed to reduce high hepcidin, releasing iron, which is to address anemias of inflammatory disease where iron is restricted. We also have an early-stage program designed to increase low hepcidin, which can restrict iron availability and this is expected to address disorders like polycythemia vera, as well as disorders of iron overload.

DISC-0974 is our antibody that targets hemojuvelin.

This is designed to suppress hepcidin, increasing iron and enabling red blood cell production in the setting of inflammatory disease. We in-licensed this program as a pre-clinical molecule from AbbVie in 2019.

With DISC-0974, we expect to be able to address one of the major causes of anemia in the world referred to as anemia of inflammation. An estimated 40% of all anemias are driven by an inflammatory component.

Hepcidin has been a target of interest for many years in the pharmaceutical industry, however there are only two targets defined by human genetics that appear to be highly specific and highly potent. These are hepcidin itself and hemojuvelin, both of which, when the function is lost in humans, lead to a syndrome of iron overload, and that's because hepcidin is not being produced. Now targeting hepcidin itself has been tried and it's not successful because the body's able to make compensatory levels of hepcidin. Hemojuvelin is a very attractive target because it actually controls the pathway by which hepcidin is produced, and this pathway is shown on the slide.

It's a BMP signaling pathway, in the liver, which I'm very familiar with from my 14 years at Acceleron Pharma. BMP signals through transcription factors called SMADs which drive expression from the gene that encodes hepcidin which is called the *Hamp* gene. BMPs and their receptors which are called the ALKs are generally involved in many tissues in the body and therefore represent rather pleiotropic targets for therapeutic intervention. By contrast, Hemojuvelin is a so-called co-receptor of this pathway as it has tissue restricted expression and as I mentioned before it has a very selective role in iron metabolism as demonstrated by the phenotype of knockouts in both humans and rodents. So, we chose this target as being genetically defined to have a combination of potency and selectivity.

We tested this pre-clinically in nonhuman primates where our antibody was administered at a single high dose. As shown in the right panel in the blue line, you can see the levels of antibody decreasing and then gray triangles of hepcidin immediately suppressed to undetectable levels and that results in the release of iron from internal stores into the bloodstream which is measured as what's called transferrin saturation or a percent TSAT. You can see that the TSAT levels approach 100%, which is the theoretical maximum amount of iron that can be released into the bloodstream. So it is highly potent and as the antibody is eliminated you can see hepcidin levels return to normal as does iron. So this is an example of the kind of data we could see clinically and we hoped to replicate in our Phase 1 trial in humans.

We've conducted a standard Phase 1 trial design with six patients for each cohort receiving DISC-0974 and 2 patients on placebo. In addition to looking at safety, we were able to take advantage of our target engagement measurements such as hepcidin, serum iron levels and percent TSAT. We had stopping rules generally based on safety, but also based on the degree of iron mobilization looking at TSAT. So we had a very clean study where we started at a 7 mg dose intravenously, or IV, and then transitioned over to a subcutaneous, or SC, dose and stopped the study at the 56 mg dose, not due to safety issues but because we had stopping rules around iron mobilization.

This slide shows our phase 1 data. In the left panel, you can see a dose dependent decrease in hepcidin as a result of our drug and relative to placebo, which is shown in the dotted line, we had a marked affect from the highest dose, of 56 mg, shown as the red line. You can see that reduction in hepcidin led to release of iron into the bloodstream as measured by transferrin saturation. We were seeing the increase in TSAT of almost 40 points in the 56 mg group, so if you think of the baseline as being roughly around 20 on average then we're talking about a 200% increase, which is a profound effect.

Now our therapeutic objective is to increase hemoglobin levels in anemic patients. We did not expect to see this in healthy volunteers because iron is not necessarily viewed as a limiting factor for red blood cell formation in healthy people. But we did actually see this effect. Here in the left-hand panel, as I showed you previously with the nonhuman primates, we show data from the 56 mg subcutaneous dose cohort. There's an increase in the antibody and you see it has a good half life with antibody levels enduring over a month. The reduction in hepcidin and the attendant increase in TSAT levels are notable. This resulted quite remarkably in more than a gram per deciliter increase in hemoglobin levels on average, which is statistically significant over the placebo group. That's shown in the upper right panel and increases in red blood cell numbers are shown in the bottom right panel.

This is very promising evidence of the potential for this mechanism to increase hemoglobin in patients that do have a pathology of elevated hepcidin. The data compare favorably to all of the hepcidin suppressing agents that have come before us and that have published placebo-controlled Phase 1 data, so we're proceeding now with a lot of confidence.

I'll also mention that our safety profile is favorable so far, and this is consistent with the human genetics. There were no adverse events above Grade 1 and there was no pattern for any adverse event in particular. So, based on the Phase 1 data we would appear to have a good target engagement and very potent effect on iron at doses that are well tolerated.

We are proceeding now to clinical trials in patients with one trial in patients with myelofibrosis initiated and plans for a trial in patients with anemia of chronic kidney disease due to start shortly. These two diseases both represent forms of anemia of inflammation with excellent rationale for using a hepcidin lowering approach and both are associated with significant unmet medical need.

Myelofibrosis represents about 16,000 to 18,000 patients in the US and hepcidin is elevated due to inflammation. Anemia is a hallmark of MF – it is both highly prevalent and severe, with most patients requiring transfusions. Moreover, standard therapies such as the so-called JAK inhibitors tend to worsen the anemia. This is a severe and difficult to treat anemia and there are no approved therapies for the anemia of myelofibrosis.

We are also attempting to treat anemia of chronic kidney disease where there are millions of patients in the US alone. Patients with CKD suffer from a range of chronic diseases that drive inflammation, elevating hepcidin. hepcidin levels are also elevated directly due to the loss of kidney function because hepcidin is normally cleared through the kidney, so a natural consequence of this disease is to lead to elevated hepcidin, abnormal iron metabolism and anemia. Recent papers show that these patients tend to be under-treated. The ESAs as a class of drug are effective but have a blackbox warning that restricts use. The result is that most non-dialysis patients that go on to dialysis have a remarkably low hemoglobin level at 9.3 grams per deciliter, reflecting a need for effective therapies in the space.

Turning first to anemia of myelofibrosis, a study from the Mayo Clinic demonstrated that hepcidin levels in these patients are 12 times higher than in normal people and that increases with disease severity, as you can see progressing from right to left on the graph in the left hand panel. On the right hand panel is a proof of concept, if you will, from a molecule called momelotinib developed by Sierra Oncology, which was recently acquired by GSK. This compound is a JAK inhibitor with a side effect of suppressing hepcidin and for this reason it is probably not suitable to be used as a pure anemia therapy but it shows that reduction of hepcidin in these patients has the potential to deliver transfusion independence in over 40% of patients treated with 85% or more receiving a transfusion burden reduction. Notably, JAK inhibition typically causes anemia, so the effects of momelotinib in these patients is even more surprising. Momelotinib's unprecedented effects on transfusion burden in these patients is significant and represents rationale for why an agent such as ours that suppresses hepcidin could lead to significant impact on anemia in myelofibrosis patients.

Another way of evaluating this is through a pre-clinical model. There are no great models for myelofibrosis anemia, but it is thought to be driven by a number of inflammatory cytokines including IL-6 that cause elevated hepcidin. So we tested a model in nonhuman primates where we have administered IL-6 either with or without our antibody on board at different doses. We can see that the IL-6 itself led to considerable elevation of hepcidin in the left panel and considerable reduction in serum iron levels in the right panel. However, if DISC-0974 was administered at the low or high-dose of 0.6 or 6 mg per kg, respectively, we saw reduction in the hepcidin levels and normalization of the serum iron. This demonstrates that our mechanism has potential to normalize iron metabolism in patients. So, we're now open enrolling on our Phase 1b/2a study in these anemic myelofibrosis patients.

This slide shows the study design. We will initially do dose escalation starting with our 14 mg subcutaneous dose given once monthly. This dose is what we viewed as the lowest active dose from the healthy volunteer study. We are authorized to progress through seven cohorts, doubling the dosage each time and we expect to escalate with a single patient per cohort using our iron metrics to assess the degree of target engagement. When we see significant changes in iron metabolism we will expand to a larger group of patients and look for a change in hemoglobin and transfusion independence as key endpoints. We expect the data from part one of the study to be available in 2023.

Turning now to chronic kidney disease, as I mentioned before hepcidin elevation is a natural consequence of disease pathology; hepcidin is eliminated through the kidney, so as kidney function declines, hepcidin accumulates and there's also inflammation that drives it further such that you have about 20 times higher hepcidin in CKD patients. Here again there's clinical precedent— on the righthand panel is data from a discontinued molecule from Eli Lilly, an antibody against BMP6, which is mechanistically similar to anti-hemojuvelin, and achieves in a single dose about a 1 gram per deciliter increase in hemoglobin in sicker, dialysis patients, which is close to the target of what will be needed to achieve a desired therapeutic effect. This suggests that DISC-0974 should be appropriate for the non-dialysis CKD patients.

We've also run a standard mouse model of CKD anemia, which showed that our drug can markedly decrease hepcidin and increase or normalize serum iron. The effect of this is to increase hemoglobin by 1.7 grams per deciliter, which again, is precisely the kind of magnitude of effect that would be desired in these patients and underscores the role of hepcidin in CKD anemia.

So we've designed a single ascending dose study where we expect the single-dose can cause a change in hemoglobin, and then expand to a familiar phase 2 design and here we expect the interim data to be available in 2023.

We've made tremendous progress on DISC-0974. We completed our phase 1 study with a positive tolerability profile and proof of mechanism for hepcidin in iron modulation. We've now started the MF anemia trial, which is open and enrolling, and we're working on our non-dialysis chronic kidney disease trial, which is expected to be open by the end of the year. We are expecting data from both trials to come in 2023 and are also working on a wide range of other indications for this mechanism.

Now, the last program in our pipeline is our matriptase two inhibitor, which is a pre-clinical discovery program

We are trying to induce hepcidin because increased hepcidin limits iron availability and modulates red blood cell production. This restriction of iron availability has been demonstrated to have benefit in patients with polycythemia vera and is also expected to benefit disorders of iron overload.

This program is the opposite of the DISC-0974 antibody that we just discussed, as matriptase-2 is actually a negative regulator of hemojuvelin. It is well-known that a human knockout phenotype of the mat-2 target leads to iron refractory iron deficiency anemia. So we have here from human genetics what appears to be a very potent target and we don't expect to see additional undesirable biologic effects.

We are making small molecule inhibitors of this protease and on this slide we have some of the compelling data from our lead compounds where we demonstrate dose-responsive increases in hepcidin levels leading to decreases in serum iron and transferrin saturation. We continue to work to hit our target profile aiming for oral bioavailability and durable effects on iron metabolism.

When successful, we expect to be able to develop this molecule across the range of indications mentioned here. Polycythemia vera is a likely initial indication, where iron restriction has been shown to provide benefits to patients, and then several disorders such as hereditary hemochromatosis should also be relevant.

So thank you for listening to our story today. I want to emphasize the key aspects that we believe make Disc Medicine a great hematology company. We are clinical stage focused on fundamental and well-validated pathways that affect heme biosynthesis and iron homeostasis. All of our programs therefore have potential applicability to multiple indications and have a pipeline in a product potential. Bitopertin in Phase 2 is potentially the first disease-modifying treatment for EPP and XLP. DISC-0974 is an antibody in phase 1B/2 trials targeting anemia of inflammation through an anti-HJV mechanism and, lastly, our pre-clinical program is a matriptase-2 inhibitor in order to restrict iron. We are now entering catalyst-rich period with data readouts from our three different disease areas, all of which are expected in the next 6 to 12 months. We think it's a strong foundation and now the merger with Gemini and the concurrent financing puts us in a strong position to drive all these programs forward without real need for intervening financing until early 2025. We've built a great team to do this with. So thank you again for your time today

Operator

Thank you everyone, this concludes today's call. You may now disconnect your lines.

Disc Medicine Initiates BEACON, a Phase 2 Clinical Study of Bitopertin in Patients with Erythropoietic Protoporphyrin (EPP) and X-linked Protoporphyrin (XLP)

- *BEACON study will evaluate bitopertin as a potential disease-modifying treatment for patients with Erythropoietic Protoporphyrin (EPP) or X-linked Protoporphyrin (XLP)*
- *Key assessments include changes in protoporphyrin IX levels, safety, tolerability and measures of photosensitivity; preliminary data expected by 1H 2023*

WATERTOWN, Mass. (August 10, 2022) – Disc Medicine, a clinical-stage biotechnology company dedicated to the discovery and development of novel therapeutic candidates for the treatment of serious and debilitating hematologic diseases, announced today the initiation of BEACON, a phase 2 clinical study of bitopertin in patients with Erythropoietic Protoporphyrin (EPP) or X-linked Protoporphyrin (XLP). Bitopertin is an oral, selective inhibitor of glycine transporter 1 (GlyT1) designed to modulate heme biosynthesis, and has been shown in preclinical studies to reduce accumulation of protoporphyrin IX (PPIX), the toxic metabolite that causes disease pathology in EPP and XLP patients.

“The initiation of the BEACON phase 2 study is an important milestone as it marks the first time bitopertin will be evaluated as a potential, disease-modifying therapy in patients with porphyria. It builds upon our previous studies in animal models of EPP and XLP, which demonstrated that bitopertin can significantly reduce protoporphyrin IX,” said John Quisel, JD, PhD, Chief Executive Officer at Disc Medicine. “This is the second development program that Disc has successfully advanced into patient studies in the past few months. I want to thank our entire team for the tremendous effort that has brought us to this point and for their tireless dedication to patients.”

The BEACON Phase 2 study is a randomized, open-label, multiple dose clinical trial designed to evaluate the safety, tolerability, and efficacy of bitopertin in patients with EPP or XLP. It is designed to enroll approximately 20 patients at sites in Australia. The study will primarily assess changes in levels of PPIX as well as the pharmacokinetic profile, safety and tolerability of bitopertin in EPP or XLP patients. It will also include measures of photosensitivity, daylight tolerance, pain and exploratory biomarkers of hepatobiliary disease. Patients will receive orally-administered bitopertin for 24 weeks at doses of either 20 mg once-daily or 60 mg once-daily. Upon completion of the 24-week treatment period, patients may continue on bitopertin for an additional 24 weeks.

“EPP and XLP are severe, debilitating and rare diseases that impact multiple dimensions of patients’ lives, spanning severe and painful phototoxic reactions, complications of hepatobiliary disease, and a major toll on psychosocial development and quality of life. There is an immense need for novel therapies, particularly ones that address the underlying pathophysiology,” said Robert Desnick, MD, Ph.D, Inaugural Chair Emeritus of the Department of Genetics and Genomics at Mount Sinai. “We are excited by the initiation of this clinical trial of bitopertin and its potential effects on PPIX, the molecular driver of these porphyrias and a major determinant of disease severity.”

About Bitopertin

Bitopertin is a clinical-stage, orally administered inhibitor of glycine transporter 1 (GlyT1) that is designed to modulate heme biosynthesis. GlyT1 is a membrane transporter expressed on developing red blood cells and is required to supply sufficient glycine for heme biosynthesis and support erythropoiesis. The safety profile and effects of bitopertin on heme biosynthesis were previously established in a comprehensive clinical program comprising over 4,000 individuals across multiple clinical studies. Disc Medicine is planning to develop bitopertin as a potential treatment for a range of hematologic diseases beginning with erythropoietic protoporphyria (EPP) and X-linked protoporphyria (XLP). In preclinical models of EPP and XLP, bitopertin was shown to significantly decrease PPIX, a toxic intermediate of heme biosynthesis and which is the underlying cause of the disease.

Bitopertin is an experimental agent and is not approved for use as a therapy in any jurisdiction worldwide. Disc obtained global rights to bitopertin under a license agreement from Roche in May 2021.

About Erythropoietic Protoporphyrin (EPP) and X-linked Protoporphyrin (XLP)

Erythropoietic protoporphyria (EPP) and X-linked Protoporphyrin (XLP) are rare, debilitating and potentially life-threatening diseases caused by mutations that affect heme biosynthesis, resulting in the accumulation of a toxic, photoactive intermediate called protoporphyrin IX (PPIX). This causes severe reactions when patients are exposed to sunlight, characterized by excruciating pain, edema, burning sensations and potential blistering and disfigurement. PPIX also accumulates in the hepatobiliary system and can result in complications including gallstones, cholestasis, and liver damage in 20-30% of patients and in extreme cases liver failure. Current standard of care involves extreme measures to avoid sunlight, including restricting outdoor activities to nighttime, use of protective clothing and opaque shields, and pain management. This has a significant impact on the psychosocial development, quality of life, and daily activities of patients, particularly in young children and families. There is currently no cure for EPP and only one FDA-approved therapy, a surgically implanted synthetic hormone designed to stimulate melanin production called Scenesse® (afamelanotide).

About Disc Medicine

Disc Medicine is a clinical-stage biopharmaceutical company that is dedicated to transforming the lives of patients with hematologic disorders. We are building a portfolio of innovative, first-in-class therapeutic candidates that affect fundamental pathways of red blood cell biology. We are committed to developing treatments that empower and bring hope to the many patients who suffer from hematologic diseases. For more information, please visit www.discmedicine.com.

Disc Medicine Cautionary Statement Regarding Forward-Looking Statements

Certain statements in this press release may constitute “forward-looking statements” for purposes of the federal securities laws concerning the proposed transaction between Disc and Gemini Therapeutics, Inc. (Gemini) and other matters, including Disc’s expectations with respect to its BEACON clinical study. These forward-looking statements include express or implied statements relating to Disc’s management team’s expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting Disc, Gemini or the proposed transaction will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Disc’s control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that the conditions to the closing of the transaction are not satisfied, including the failure to obtain stockholder approval for the transaction; the risk that the concurrent financing is not completed in a timely manner or at all; uncertainties as to the timing of the consummation of the transaction and the ability of each of Gemini and Disc to consummate the transaction, including the concurrent financing; risks related to Gemini’s continued listing on the Nasdaq Stock Market until closing of the proposed transaction; risks related to Gemini’s and Disc’s ability to correctly estimate their respective operating expenses and expenses associated with the transaction, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company’s cash resources; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement; the effect of the announcement or pendency of the merger on Gemini’s or Disc’s business relationships, operating

results and business generally; costs related to the merger; the outcome of any legal proceedings that may be instituted against Gemini, Disc or any of their respective directors or officers related to the merger agreement or the transactions contemplated thereby; the ability of Gemini or Disc to protect their respective intellectual property rights; competitive responses to the transaction; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; and legislative, regulatory, political and economic developments. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties described in the “Risk Factors” section of the proxy statement/prospectus included in the registration statement on Form S-4 to be filed with the SEC in connection with the transaction and other documents filed by Gemini from time to time with the SEC. Should one or more of these risks or uncertainties materialize, or should any of Disc’s assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the ongoing COVID-19 pandemic and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. Disc’s forward-looking statements only speak as of the date they are made, and Gemini and Disc do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

No Offer or Solicitation

This press release is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

Important Additional Information Will be Filed with the SEC

In connection with the proposed transaction between Gemini and Disc, Gemini intends to file relevant materials with the SEC, including a registration statement on Form S-4 that will contain a proxy statement/prospectus of Gemini and information statement of Disc. **DISC URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT GEMINI, DISC, THE PROPOSED TRANSACTION AND RELATED MATTERS.** Investors and shareholders will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Gemini with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In addition, investors and shareholders should note that Gemini communicates with investors and the public using its website (www.geminitherapeutics.com), the investor relations website (<https://investors.geminitherapeutics.com/>) where anyone will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Gemini with the SEC and stockholders are urged to read the proxy statement/prospectus/information statement and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transaction.

Participants in the Solicitation

Gemini and its directors and executive officers may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Gemini’s directors and executive officers is included in Gemini’s most recent Annual Report on Form 10-K, including any information incorporated therein by reference, as filed with the SEC. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement/prospectus/information statement relating to the transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

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Disc Medicine | Gemini Merger + Bitopertin BEACON Social Media

Date	LinkedIn	Image
Weds, August 10 at 7:30 am ET (after PR crosses wires)	We are delighted to announce that Disc has entered into a definitive merger agreement with Gemini Therapeutics. The merger will create a NASDAQ-listed, clinical-stage biopharmaceutical company focused on advancing Disc's portfolio of first-in-class hematology programs. Upon close, the combined company is expected to have approximately \$175 million of cash or cash equivalents which is expected to provide funding into 2025. Read more: [link to press release]	An abstract graphic consisting of several concentric, curved lines in shades of yellow and red, resembling a stylized sun or a series of overlapping arcs.

Wednes
day,
August
10 at
1:00 pm
ET

Disc is excited to announce the initiation of the BEACON Phase 2 study, a randomized, open-label, clinical trial designed to evaluate bitopertin as a potential disease-modifying therapy for patients with Erythropoietic protoporphyria (EPP) or X-linked Protoporphyrin (XLP). Learn more about bitopertin and the BEACON trial here: [\[LINK TO PR\]](#)


Bitopertin is an experimental agent and is not approved for use as a therapy in any jurisdiction worldwide.



disc)medicine



Disc Medicine | Bitopertin BEACON Social Media

Date	LinkedIn	Image
Wednesday, August 10 at 1:00 pm ET	<p>Disc is excited to announce the initiation of the BEACON Phase 2 study, a randomized, open-label, clinical trial designed to evaluate bitopertin as a potential disease-modifying therapy for patients with Erythropoietic protoporphyria (EPP) or X-linked Protoporphyrin (XLP). Learn more about bitopertin and the BEACON trial here: [LINK TO PR]</p> <p>Bitopertin is an experimental agent and is not approved for use as a therapy in any jurisdiction worldwide.</p>	



Arix Bioscience plc

Portfolio Company Disc Medicine Enters Definitive Merger Agreement with Gemini Therapeutics

Merger to create a Nasdaq-listed, clinical stage biopharmaceutical company focused on advancing Disc Medicine's portfolio of haematology programmes

Transaction will fund multiple clinical studies, including clinical trials of bitopertin for erythropoietic porphyrias, DISC-0974 for anaemia of myelofibrosis, and DISC-0974 for anaemia of chronic kidney disease

LONDON, 10 August 2022: Arix Bioscience plc (LSE: ARIX), a global venture capital company focused on investing in breakthrough biotechnology companies, notes that its portfolio company, Disc Medicine, Inc. ("Disc"), has entered into a definitive merger agreement with Gemini Therapeutics, Inc. (Nasdaq: GMTX) ("Gemini") to create a Nasdaq-listed clinical-stage biopharmaceutical company in an all-stock transaction. The combined company will focus on advancing Disc's pipeline of haematology programmes, including multiple patient studies for its clinical stage programmes. Upon shareholder approval, the combined company is expected to operate under the name Disc Medicine, Inc. and trade on the Nasdaq Global Market under the ticker symbol IRON.

In support of the merger, Arix will participate in a \$53.5 million financing in a syndicate of healthcare investors led by Access Biotechnology and including OrbiMed, Atlas Venture, 5AM Ventures, Novo Holdings A/S, Rock Springs Capital and Janus Henderson Investors. With the cash expected from both companies at closing and the proceeds of the concurrent financing, the combined company is expected to have approximately \$175 million of cash or cash equivalents, which will be used to advance Disc's pipeline through multiple clinical studies and provide runway into 2025. The merger and related financing are expected to close in the fourth quarter of 2022.

Disc also announced the initiation of BEACON, a Phase 2 clinical study of bitopertin in patients with Erythropoietic Protoporphyrin (EPP) or X-linked Protoporphyrin (XLP). Bitopertin is an oral, selective inhibitor of glycine transporter 1 (GlyT1) designed to modulate heme biosynthesis and has been shown in preclinical studies to reduce accumulation of protoporphyrin in IX (PPIX), the toxic metabolite that causes disease pathology in EPP and XLP patients.

Robert Lyne, CEO of Arix Bioscience, stated: "The merger with Gemini represents an exciting opportunity for Disc Medicine. Led by a highly credible management team, Disc has built a diversified, clinical stage pipeline of products focused on diseases of unmet medical need. In less than one year since our initial investment, Disc has made rapid clinical progress, advancing two programmes into patient studies in the past few months. Today's announcement of the merger agreement follows a thorough and thoughtful strategic review process by Gemini and is validation of our refocused strategy to invest in companies with nearer-term value inflection points."

[ENDS]

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Notes to Editors



About Gemini Therapeutics, Inc.

Gemini Therapeutics is a clinical-stage precision medicine company previously focused on developing novel therapeutic compounds to treat genetically defined age-related macular degeneration (AMD).

For more information, visit www.gemini therapeutics.com.

About Disc Medicine, Inc.

Disc Medicine is a clinical-stage biopharmaceutical company that is dedicated to transforming the lives of patients with hematologic disorders. Disc is building a portfolio of innovative, first-in-class therapeutic candidates that affect fundamental pathways of red blood cell biology. Disc Medicine is committed to developing treatments that empower and bring hope to the many patients who suffer from hematologic disease. For more information, please visit www.discmedicine.com.

About Disc Medicine's Haematology Portfolio

Disc has a clinical-stage development pipeline composed of investigational product candidates that affect heme biosynthesis and iron metabolism. Disc's programs are designed to target pathways with established, clinically-validated biology and have the potential to address multiple indications. This includes:

Bitopertin (Heme Synthesis Modulator): Bitopertin is an inhibitor of glycine transporter, GlyT1, and has demonstrated effects on heme biosynthesis in clinical studies. Bitopertin was in-licensed by Disc from Roche in 2021 and has been extensively studied, including a safety data package reflecting clinical experience in over 4,000 individuals. Inhibition of heme biosynthesis has the potential to address a wide range of hematologic disorders. Disc has initiated BEACON, an open-label, phase 2 trial of bitopertin in patients with erythropoietic porphyria, a rare, debilitating and potentially fatal genetic disorder that results in dysregulated heme biosynthesis and where bitopertin has the potential to become the first disease-modifying treatment. Additional clinical studies in Diamond-Blackfan Anemia (DBA) and other indications are being planned.

DISC-0974 (Hepcidin Suppression): DISC-0974 is a monoclonal antibody targeting a co-receptor called hemojuvelin (HJV) and is designed to suppress hepcidin production and increase serum iron levels in patients suffering from the anemia of inflammation. DISC-0974 was in-licensed by Disc from AbbVie in 2019. Anemia of inflammation arises from abnormally elevated hepcidin and is the most common form of anemia, affecting millions of patients across numerous diseases such as chronic kidney disease, myelofibrosis, cancer, autoimmune diseases, and other conditions with an inflammatory component. Disc has established clinical proof-of-mechanism of DISC-0974 in a phase 1 study of healthy volunteers and initiated a phase 1b/2 clinical study of DISC-0974 in patients with anemia of myelofibrosis. Disc plans to initiate a phase 1b/2 clinical study of DISC-0974 in patients with anemia of chronic kidney disease (non-dialysis) in late 2022.

Matriptase-2 Inhibitor (Hepcidin Induction): Disc has a research program designed to identify orally-available, small molecules to inhibit Matriptase-2 (referred to as Mat-2 or TMPRSS6) and increase the production of hepcidin and restrict iron availability. The therapeutic role of hepcidin has been established in patients with polycythemia vera and hereditary hemochromatosis, and is being studied for the treatment of diseases associated with iron overload, including beta-thalassemia, myelodysplastic syndromes, and sickle cell disease.

About Arix Bioscience plc

Arix Bioscience plc is a global venture capital company focused on investing in breakthrough biotechnology companies around cutting-edge advances in life sciences.

We collaborate with exceptional entrepreneurs and provide the capital, expertise, and global networks to help accelerate their ideas into important new treatments for patients. As a listed company, we are able to bring this exciting growth phase of our industry to a broader range of investors.

www.arixbioscience.com