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): January 9, 2022

COHERUS BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36721**	**27-3615821**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

333 Twin Dolphin Drive, Suite 600
Redwood City, CA 94065
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 649-3530

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:

☐ 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(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**CHRS**	**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. ☐

Item 1.01 Entry into a Material Definitive Agreement.

TIGIT Exercise Letter Agreement related to Collaboration Agreement

On February 1, 2021, Coherus BioSciences, Inc. (the "Company") previously announced that the Company had entered into an Exclusive License and Commercialization Agreement (the "Collaboration Agreement") with Shanghai Junshi Biosciences, Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) for the co-development and commercialization of toripalimab, Junshi Biosciences' anti-PD-1 antibody in the United States and Canada. Under the Collaboration Agreement, the Company was also granted two options and two rights of first negotiation with respect to additional programs (the "Collaboration").

On January 9, 2022, the Company entered into a Letter Agreement with Junshi Biosciences related to the Collaboration Agreement (the "TIGIT Exercise Letter Agreement"). Under the TIGIT Exercise Letter Agreement, the Company notified Junshi Biosciences of its election to exercise the license option for the TIGIT program described in the Collaboration Agreement (the "TIGIT Program"), with the TIGIT Exercise Letter Agreement effective on the date that all applicable waiting periods and approvals required under antitrust laws with respect to such exercise by the Company of the license option for the TIGIT Program have expired or have been terminated (in the case of waiting periods) or been received (in the case of approvals), in each case, without the imposition of any conditions (the "TIGIT Exercise Letter Agreement Effective Date"). The Company will pay the option exercise payment of $35.0 million to Junshi Biosciences no later than 10 days following the TIGIT Exercise Letter Agreement Effective Date and, if applicable, will pay up to $255 million in development regulatory and sales milestones and an 18% royalty on net product revenue as set forth under the Collaboration Agreement. Pursuant to the TIGIT Exercise Letter Agreement, Coherus will lead further development of the TIGIT antibodies included in the TIGIT Program, including JS006, in the United States and Canada, after the date it makes the option exercise payment and will be responsible for the associated development costs as set forth in the Collaboration Agreement.

The foregoing summary of the TIGIT Exercise Letter Agreement does not purport to be complete and is qualified in its entirety by the full text of the TIGIT Exercise Letter Agreement, a copy of which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Item 8.01 Other Events.

On January 10, 2022, the Company issued a press release announcing the initiation of the process to exercise the license option for the TIGIT Program. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference. The information in this Item 8.01 shall not be deemed "filed" for purposes of Section 18 of the Security Exchange Act of 1934, as amended (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 of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated January 10, 2022
104	Cover page Interactive Data file (embedded within the Inline XBRL document)

SIGNATURES

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.

Date: January 13, 2022

COHERUS BIOSCIENCES, INC.

By: /s/ McDavid Stilwell
Name: McDavid Stilwell
Title: Chief Financial Officer

Exhibit 99.1

Coherus and Junshi Biosciences Expand Immuno-Oncology Collaboration to Include TIGIT-Targeted Antibody

- **Coherus and Junshi Biosciences plan to evaluate the toripalimab + JS006 combination in clinical trials in multiple tumor types**
- **Combinations of PD-1 + TIGIT inhibitors have potential to expand checkpoint inhibitor utilization to new tumors and lines of therapy**

REDWOOD CITY, Calif., and SHANGHAI, China, Jan. 10, 2022 (GLOBE NEWSWIRE) — Coherus BioSciences, Inc. (“Coherus”, Nasdaq: CHRS) and Shanghai Junshi Biosciences Co., Ltd. (“Junshi Biosciences”, HKEX: 1877; SSE: 688180) today announced that Coherus has initiated the process to exercise its option to license JS006, Junshi Biosciences’ TIGIT-targeted antibody, in the United States and Canada, expanding the companies’ 2021 immuno-oncology collaboration agreement. Coherus will pay Junshi Biosciences $35 million upfront, up to $255 million in development regulatory and sales milestones, and an 18% royalty on net product revenue, subject to terms and conditions agreed between the parties. Closing of the transaction is expected to follow receipt of any applicable regulatory clearances. Antibodies blocking TIGIT (T cell immunoglobulin and ITIM domain) have shown potential for synergistic anti-tumor activity in combination with PD-1/PD-L1 inhibitors. In pre-clinical studies, JS006 has demonstrated excellent binding affinity and strong inhibition of the TIGIT pathway. Investigational new drug (IND) applications allowing clinical development of JS006 have been approved in Chinese Mainland and in the United States. A dose escalation, dose expansion clinical trial (NCT05061628) evaluating the safety, tolerability and pharmacokinetic properties of JS006 as monotherapy and in combination with PD-1 inhibitor toripalimab in patients with advanced solid tumors is ongoing.

“TIGIT is a leading-edge immuno-oncology target with significant therapeutic potential across multiple major tumor types. The exercise of the option for JS006 marks the emergence of Coherus as an immuno-oncology development company with a rich clinical and preclinical pipeline of product candidates to drive long-term growth,” said Denny Lanfear, CEO of Coherus. “We are making rapid progress on our objective to become a leading immuno-oncology company, and the development of toripalimab combinations with therapeutics addressing novel targets such as TIGIT will allow us to access future growing markets. While toripalimab + JS006 is the first novel combination in our pipeline, our internal analytic, protein science and bioinformatics capabilities have generated additional toripalimab combination candidates. The first of these proprietary product candidates is expected to enter human clinical trials in 2023.”

“Blockade of the TIGIT pathway may be a crucial underlying mechanism for overcoming resistance to checkpoint inhibition. We believe the dual immuno-therapy approach of TIGIT with PD-1 could enhance PD-1 efficacy and create a new standard-of-care for multiple tumor types,” said Theresa LaVallee, Ph.D., Chief Development Officer at Coherus. “We recently reported that our PD-1 inhibitor, toripalimab, in combination with chemotherapy, extends both progression free survival and overall survival in patients with advanced non-small cell lung cancer. We look forward to working with our Junshi Biosciences colleagues to build upon this efficacy signal and to evaluate the potential of the JS006 and toripalimab combination to bring new, more efficacious immuno-oncology treatments forward for patients.”

“We are excited to extend our productive immuno-oncology collaboration with Coherus to include our anti-TIGIT monoclonal antibody JS006, after achieving several key milestones on toripalimab,” said Dr. Ning Li, CEO of Junshi Biosciences. “Following our ‘In China, For Global’ corporate strategy, we are actively conducting global clinical R&D programs in China, the U.S., Southeast Asia and European countries. We are grateful for the joint effort from our pre-clinical as well as clinical teams at the company’s innovation centers in China and the U.S. We believe the collaboration with Coherus will strengthen the development and commercialization of our products in the U.S. and Canada.”

“Since 2012, Junshi Biosciences has built a rich pipeline with complementary products in the area of immuno-oncology, which enable us to explore combination therapy of I-O drugs and combination of immunotherapy with other modalities, including traditional chemotherapy, radiotherapy, angiogenesis inhibitors and cytokine drugs, to provide patients with better treatment options,” said Dr. Sheng Yao, Senior Vice President of Junshi Biosciences. “The combination of anti-TIGIT and anti-PD-1 is quite promising with a potential to not only increase patients’ response to I-O therapy, but also expand the beneficial patient population. We look forward to working together with Coherus to quickly advance the combination therapy of JS006 with toripalimab across multiple tumor types.”

About JS006

JS006 is a recombinant humanized IgG4? monoclonal antibody specifically against human TIGIT, developed independently by Junshi Biosciences. Including back-up candidates, the JS006 program encompasses molecules with silent and active Fc functions. According to the results of preclinical studies, JS006 can specifically block the TIGIT-PVR pathway. Expressed by T cells and NK cells, TIGIT can be engaged and activated by PVR family ligands highly expressed on tumor cells and suppressive immune cells to directly inhibit the killing effect of T cells and NK cells directed at tumor cells. A number of pre-clinical and clinical studies have showed that activation of the TIGIT pathway could be a crucial underlying mechanism for the resistance to PD-1 blockade therapy. Combination of TIGIT and PD-1/PD-L1 antibodies showed a synergistic potential to enhance antitumor response to overcome anti-PD-1 resistance and broaden the cancer patient population that can benefit from immunotherapy.

In early 2021, JS006 was approved for clinical trials in both China and the United States. In the same year, Junshi Biosciences commenced a phase I trial to evaluate the safety and tolerability of JS006 as monotherapy and in combination with toripalimab in patients with advanced tumors who have failed standard therapies. Coherus and Junshi Biosciences are planning late-stage clinical development of JS006 in combination with toripalimab in North America.

About toripalimab

Toripalimab is an anti-PD-1 monoclonal antibody developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2, and for enhanced receptor internalization (endocytosis function). Blocking PD-1 interactions with PD-L1 and PD-L2 promote the immune system’s ability to attack and kill tumor cells.

More than thirty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted globally, including in China, the United States, Southeast Asia, and European countries. Ongoing or completed pivotal clinical trials evaluating the safety and efficacy of toripalimab cover a broad range of tumor types including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney and skin.

In China, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). Currently, there are 4 approved indications for toripalimab in China: unresectable or metastatic melanoma after failure of standard systemic therapy; recurrent or metastatic nasopharyngeal carcinoma (NPC) after failure of at least two lines of prior systemic therapy; locally advanced or metastatic urothelial carcinoma that failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy; in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic NPC.

The first three indications have been included in the National Reimbursement Drug List (NRDL) (2021 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for melanoma and NPC.

In addition, two supplemental New Drug Applications (NDAs) for toripalimab are currently under review by the National Medical Products Administration (NMPA) in China: in combination with chemotherapy as the first-line treatment of patients with advanced or metastatic esophageal squamous cell carcinoma (ESCC). in combination with chemotherapy as the first-line treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC) with no EGFR or ALK sensitizing mutations.

In the United States, the FDA has granted priority review for the toripalimab biologics license application (BLA) for the treatment of recurrent or metastatic NPC, an aggressive head and neck tumor which has no FDA-approved immuno-oncology treatment options. The FDA has assigned a Prescription Drug User Fee Act target action date for April 2022 for the toripalimab BLA. The FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC in 2021 as well as for toripalimab monotherapy in the second or third-line treatment of recurrent or metastatic NPC in 2020. Additionally, the FDA has granted Fast Track designation for toripalimab for the treatment of mucosal melanoma and orphan drug designation for the treatment of esophageal cancer, NPC, mucosal melanoma and soft tissue sarcoma. In 2021, Coherus in-licensed rights to develop and commercialize toripalimab in the United States and Canada. Coherus and Junshi Biosciences plan to file additional toripalimab BLAs with the FDA over the next three years for multiple other cancer types.

About Coherus BioSciences

Coherus is a commercial stage biopharmaceutical company building a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. A biologics license application for toripalimab for the treatment of metastatic or recurrent nasopharyngeal carcinoma is currently under priority review by the FDA, with a target action date of April 2022. Toripalimab is also being evaluated in pivotal clinical trials for the treatment of cancers of the lung, breast, liver, skin, kidney, stomach, esophagus, and bladder.
Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta® in the United States, and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the United States in 2023. The FDA is currently reviewing the biologics license application for CHS-201, a biosimilar of Lucentis® (ranibizumab), with a target action date of August 2022. Coherus is also developing CHS-305, a biosimilar of Avastin® (bevacizumab).

About Junshi Biosciences

Founded in December 2012, Junshi Biosciences (HKEX: 1877; SSE: 688180) is an innovation-driven biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapeutics. The company has established a diversified R&D pipeline comprising 45 drug candidates, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurological, and infectious diseases. Junshi Biosciences was the first Chinese pharmaceutical company that obtained marketing approval for anti-PD-1 monoclonal antibody in China. Its first-in-human anti-BTLA antibody for solid tumors was the first in the world to be approved for clinical trials by the FDA and NMPA and its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA. In early 2020, Junshi Biosciences joined forces with the Institute of Microbiology of Chinese Academy of Science and Eli Lilly to co-develop JS016 (etesevimab), China’s first neutralizing fully human monoclonal antibody against SARS-CoV-2. JS016 administered with bamlanivimab has been granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. The JS016 program is a part of our continuous innovation for disease control and prevention of the global pandemic. Junshi Biosciences has over 2,500 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.

Forward-Looking Statements

Except for the historical information contained herein, the matters set forth in this press release are forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Coherus’ ability to build its immuno-oncology franchise to achieve a leading market position; Coherus’ ability to generate cash; Coherus’ investment plans; Coherus’ expectations for the launch date of YUSIMRY™ (adalimumab-aqvh); expectations for the therapeutic potential of TIGIT; expectations for Coherus’ long-term growth; whether toripalimab combination candidates will enter human clinical trials in 2023; and the ability of TIGIT combinations to enhance PD-1 efficacy and create a new standard-of-care for multiple tumor types.

Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus’ actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties inherent in the clinical drug development process; risks relating to the COVID-19 pandemic; risks related to our existing and potential collaboration partners; risks of the drug development position of Coherus’ competitors; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review and the timing of Coherus’ regulatory filings; the risk of FDA review issues; the risk of Coherus’ execution of its change in strategy from a focus on biosimilars to a strategy using cash from biosimilars to fund an immuno-oncology franchise; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus’ drug candidates; and the risks and uncertainties of possible litigation. All forward-looking statements contained in this press release speak only as of the date of this press release. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the significant risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus’ business in general, see Coherus’ Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission on February 25, 2021, its subsequent Quarterly Reports on Form 10-Q, including the sections therein captioned “Risk Factors” and in other documents we file with the Securities and Exchange Commission.

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