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): September 17, 2021

Deciphera Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38219**	**30-1003521**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Smith Street, Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (781) 209-6400
(Former name or former address, if changed from 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:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 203.425)

☐ 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 Exchange Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.01 Par Value	**DCPH**	**Nasdaq Global Select 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 7.01 Regulation FD Disclosure.

On September 17, 2021, Deciphera Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the European Medicines Agency's Committee for Medicinal Products for Human Use ("CHMP") adopted a positive opinion recommending the approval of QINLOCK® (ripretinib) for the treatment of adult patients with advanced gastrointestinal stromal tumor ("GIST") who have received prior treatment with three or more kinase inhibitors, including imatinib. A copy of the press release in connection with the CHMP announcement is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities 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 (the "Exchange Act"), except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On September 17, 2021, the Company announced that the CHMP adopted a positive opinion recommending the approval of QINLOCK for the treatment of adult patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. The CHMP opinion is a scientific recommendation for marketing authorization and is a step before the European Commission (the "EC"), which has the authority to grant marketing authorization for medicinal products in the European Union, issues a decision on the Company's marketing authorization application. The Company expects a final approval decision from the EC in the fourth quarter of 2021.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, our expectations and timing regarding the EC decision on marketing approval for QINLOCK in fourth-line GIST. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this Current Report on Form 8-K, including, without limitation, risks and uncertainties related to the severity and duration of the impact of COVID-19 on our business and operations, our ability to successfully demonstrate the efficacy and safety of our drug candidates and in additional indications for our existing drug, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, our ability to manage our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, comments, feedback and actions of regulatory agencies, our ability to commercialize QINLOCK and execute on our marketing plans for any drugs or indications that may be approved in the future, our ability to build and scale our operations to support growth in additional geographies, the inherent uncertainty in estimates of patient populations, competition from other products, our ability to obtain and maintain reimbursement for any approved product and the extent to which patient assistance programs are utilized, our ability to comply with healthcare regulations and laws, our ability to obtain, maintain and enforce our intellectual property rights, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain additional regulatory approvals, and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this Current Report on Form 8-K represent our views only as of the date hereof and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on September 17, 2021, furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Date: September 17, 2021

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter
Name: Steven L. Hoerter
Title: President and Chief Executive Officer

Exhibit 99.1

Deciphera Announces Positive CHMP Opinion for QINLOCK® for the Treatment of Fourth-line Gastrointestinal Stromal Tumor

– European Commission Decision Anticipated by the Fourth Quarter of 2021 –

Waltham, MA – September 17, 2021 – Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a commercial-stage biopharmaceutical company developing innovative medicines to improve the lives of people with cancer, today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of QINLOCK (ripretinib) for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib.

The positive CHMP opinion is a scientific recommendation for marketing authorization and one of the final steps before the European Commission (EC), which has the authority to approve medicines in the European Union (EU), issues a decision on Deciphera's marketing authorization application (MAA) for ripretinib.

"The majority of GIST patients who initially respond to traditional tyrosine kinase inhibitors eventually develop tumor progression due to secondary mutations, rendering this a disease area where novel treatment options are crucially needed," said Prof. Peter Reichardt, HELIOS Privatklinik Berlin-Buch, Germany. "In the Phase 3 INVICTUS study, ripretinib demonstrated significant clinical benefit in progression-free and meaningful overall survival."

"We are delighted that the CHMP has adopted a positive opinion for QINLOCK, which could lead to Deciphera's regulatory approval in the European Union," said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. "This positive opinion highlights the CHMP's recognition of the potential for QINLOCK to help GIST patients who have received three prior therapies. If approved by the EC, ripretinib will be commercialized under the brand name QINLOCK®."

The MAA is supported by efficacy results from the pivotal Phase 3 INVICTUS study of QINLOCK in patients with advanced GIST as well as combined safety results from INVICTUS and the Phase 1 study of QINLOCK. In INVICTUS, ripretinib demonstrated a median progression-free survival of 6.3 months compared to 1.0 month in the placebo arm and significantly reduced the risk of disease progression or death by 85% (hazard ratio of 0.15, $p<0.0001$). Secondary endpoints as determined by independent radiologic review using modified RECIST include Objective Response Rate (ORR) and Overall Survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo ($p =0.0504$). In addition, ripretinib demonstrated a median overall survival of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36) [1].

About QINLOCK (ripretinib)

Ripretinib is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRA mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop. Ripretinib inhibits primary and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18 involved in GIST, as well as the primary exon 17 D816V mutation. Ripretinib also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST [2].

Ripretinib is approved by the U.S. FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. It is also approved by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib; by the Australian Therapeutic Goods Administration for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib; and by the China National Medical Products Administration for the treatment of adult patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib[3,4,5,6].

About Deciphera Pharmaceuticals

Deciphera is a biopharmaceutical company focused on discovering, developing and commercializing important new medicines to improve the lives of people with cancer. We are leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. In addition to advancing multiple product candidates from our platform in clinical studies, ripretinib is Deciphera's FDA-approved switch-control kinase inhibitor for the treatment of fourth-line gastrointestinal stromal tumor (GIST)[3]. Ripretinib is also approved for fourth-line GIST in Australia[4], Canada[5], China[6], Hong Kong[7], and Taiwan[8].

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, our expectations and timing regarding European Commission decision on marketing approval for QINLOCK in fourth-line GIST and the potential for QINLOCK to help fourth-line GIST patients. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to the severity and duration of the impact of COVID-19 on our business and operations, our ability to successfully demonstrate the efficacy and safety of our drug candidates and in additional indications for our existing drug, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, our ability to manage our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, comments, feedback and actions of regulatory agencies, our ability to commercialize QINLOCK and execute on our marketing plans for any drugs or indications that may be approved in the future, our ability to build and scale our operations to support growth in additional geographies, the inherent uncertainty in estimates of patient populations, competition from other products, our ability to obtain and maintain reimbursement for any approved product and the extent to which patient assistance programs are utilized, our ability to comply with healthcare regulations and laws, our ability to obtain, maintain and enforce our intellectual property rights, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain additional regulatory approvals, and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any

such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

References

1. Blay JY, Serrano C, Heinrich MC et al. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): A double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol* 2020;21:923–934.
2. Schöffski P, Bauer S, Heinrich M, et al. Ripretinib demonstrated activity across all KIT/PDGFRA mutations in patients with fourth-line advanced gastrointestinal stromal tumor: analysis from the phase 3 INVICTUS study. Presented at: 2020 CTOS Virtual Meeting; November 18-21, 2020; Virtual. https://www.deciphera.com/sites/default/files/publication-files/CTOS-2020-Poster-INVICTUS-MutEfficacy.pdf.
3. Deciphera Press Release: FDA Grants Full Approval of Deciphera Pharmaceuticals' QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] May 15, 2020. Available from: https://investors.deciphera.com/news-releases/news-release-details/fda-grants-full-approval-deciphera-pharmaceuticals-qinlocktm [Last accessed: September 2021].
4. Deciphera Press Release: Deciphera Announces Australian Therapeutic Goods Administration's Approval of QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] July 14, 2020. Available from: https://investors.deciphera.com/news-releases/news-release-details/deciphera-announces-australian-therapeutic-goods-administrations [Last accessed: September 2021].
5. Deciphera Press Release: Deciphera Announces Health Canada's Authorization of QINLOCK™ (ripretinib) for the Treatment of Fourth-Line Gastrointestinal Stromal Tumor [online] June 22, 2020. Available from: https://investors.deciphera.com/news-releases/news-release-details/deciphera-announces-health-canadas-authorization-qinlocktm [Last accessed: September 2021].
6. Zai Lab Press Release: China NMPA Approves QINLOCK® (Ripretinib) for Treatment of Advanced Gastrointestinal Stromal Tumors (GIST) [online] March 31, 2021. Available from: https://zailab.gcs-web.com/news-releases/news-release-details/china-nmpa-approves-qinlockr-ripretinib-treatment-advanced [Last accessed: September 2021].
7. Zai Lab Press Release: Zai Lab Announces Financial Results for Second-half and Full-year 2020 [online] March 1, 2021. Available from: https://zailab.gcs-web.com/news-releases/news-release-details/zai-lab-announces-financial-results-second-half-and-full-year [Last accessed: September 2021].
8. Zai Lab Press Release: QINLOCK® (Ripretinib) Approved in Taiwan for Treatment of Advanced Gastrointestinal Stromal Tumors (GIST) [online] September 1, 2021. Available from: https://zailab.gcs-web.com/news-releases/news-release-details/qinlockr-ripretinib-approved-taiwan-treatment-advanced [Last accessed: September 2021].

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