

**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): November 30, 2020

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

Delaware
(State or other jurisdiction
of incorporation)

001-38219
(Commission
File Number)

30-1003521
(IRS Employer
Identification No.)

200 Smith Street, Waltham, Massachusetts
(Address of principal executive offices)

02451
(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 November 30, 2020, Deciphera Pharmaceuticals, Inc. (the “Company”) announced the completion of its target enrollment in the INTRIGUE Phase 3 clinical study evaluating the efficacy and safety of QINLOCK® compared to sunitinib in patients with second-line gastrointestinal stromal tumor (“GIST”). A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K and 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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On November 30, 2020, the Company announced the completion of its target enrollment in the INTRIGUE Phase 3 clinical study evaluating the efficacy and safety of QINLOCK compared to sunitinib in patients with second-line GIST. The Company expects to announce top-line results for INTRIGUE in the second half of 2021.

Cautionary Note Regarding Forward-Looking Statements

Statements in this Current Report on Form 8-K contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, the Company’s expectations regarding timing for top-line data from the Company’s INTRIGUE study. Any forward-looking statements in this report 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 report, including, without limitation, risks and uncertainties related to the severity and duration of the impact of COVID-19 on the Company’s business and operations, the Company’s ability to successfully demonstrate the efficacy and safety of the Company’s drug candidates and in additional indications for the Company’s existing drug, the preclinical or clinical results for the Company’s product candidates, which may not support further development of such product candidates, the Company’s ability to manage its reliance on sole-source third parties such as its third party drug substance and drug product contract manufacturers, actions of regulatory agencies, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and the Company’s ability to obtain additional regulatory approvals, and other risks identified in the Company’s Securities and Exchange Commission (SEC) filings, including the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, and subsequent filings with the SEC. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company disclaims 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 report represent the Company’s views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on November 30, 2020, 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: November 30, 2020

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter

Name: Steven L. Hoerter

Title: President and Chief Executive Officer



Deciphera Pharmaceuticals Completes Target Enrollment in the INTRIGUE Phase 3 Clinical Study of QINLOCK® (Ripretinib) in Patients with Second-Line Gastrointestinal Stromal Tumor

– Top-line Results Expected in Second Half of 2021 –

– Study Designed to Evaluate the Efficacy and Safety Profile of QINLOCK Compared to Sunitinib in Patients Previously Treated with Imatinib –

WALTHAM, Mass.—(BUSINESS WIRE)—November 30, 2020— Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced the completion of its target enrollment in the INTRIGUE Phase 3 clinical study evaluating the efficacy and safety of QINLOCK in patients with second-line gastrointestinal stromal tumor (GIST). QINLOCK, the Company’s switch-control tyrosine kinase inhibitor, is currently approved in the U.S., Canada, and Australia for patients with fourth-line GIST.

“We are pleased to announce the completion of target enrollment for our Phase 3 INTRIGUE study in patients with second-line GIST,” said Matthew L. Sherman, MD, Executive Vice President and Chief Medical Officer of Deciphera Pharmaceuticals. “This marks an important step forward to potentially bringing QINLOCK to an early-stage GIST population and establishing QINLOCK as the best-in-class treatment for this disease. We look forward to announcing top-line results for this study in the second half of 2021. I am grateful to the patients and their families, investigators, and our employees who have helped us reach this milestone.”

The INTRIGUE Phase 3 clinical study is a randomized, global, multicenter, open-label study to evaluate the efficacy and safety of QINLOCK compared to sunitinib in patients with GIST previously treated with imatinib. This study was designed to support regulatory approvals in second-line GIST patients in the United States, Europe, and other major markets. Approximately 426 patients were randomized 1:1 to either QINLOCK 150 mg once daily or sunitinib 50 mg once daily for four weeks followed by two weeks without sunitinib. The primary efficacy endpoint is median progression-free survival (mPFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). Secondary endpoints as determined by independent radiologic review using modified RECIST include Objective Response Rate (ORR) and Overall Survival (OS). The study is being conducted at 122 investigational sites in 22 countries.

About QINLOCK (ripretinib)

QINLOCK 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. QINLOCK 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. QINLOCK also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

QINLOCK 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 and 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.



About GIST

Gastrointestinal stromal tumor (GIST) is a cancer affecting the digestive tract or nearby structures within the abdomen, most often presenting in the stomach or small intestine. GIST is the most common sarcoma of the gastrointestinal tract, with approximately 4,000 to 6,000 new GIST cases each year in the United States and a similar incidence rate in European and other countries. Most cases of GIST are driven by a spectrum of mutations. The most common primary mutations are in KIT kinase, representing approximately 80% of cases, or in PDGFRA kinase, representing approximately 6% of cases. Current therapies are unable to inhibit the full spectrum of primary and secondary mutations, which drives resistance and disease progression. Estimates for 5-year survival range from 48% to 90%, depending on the stage of the disease at diagnosis.

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, QINLOCK is Deciphera's FDA-approved switch-control kinase inhibitor for the treatment of fourth-line gastrointestinal stromal tumor (GIST). QINLOCK is also approved for fourth-line GIST in Canada and Australia. For more information, visit www.deciphera.com and follow us on [LinkedIn](#) and Twitter (@Deciphera).

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 regarding timing for top-line data from our INTRIGUE study, the potential to bring QINLOCK to an early-stage GIST population and the potential to establish QINLOCK as the best-in-class treatment for this disease. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "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, 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, 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 September 30, 2020, 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.

QINLOCK and the QINLOCK logo are registered trademarks, and Deciphera, Deciphera Pharmaceuticals, and the Deciphera logo are trademarks, of Deciphera Pharmaceuticals, LLC.

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