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 13, 2019

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 Number)**

500 Totten Pond Road **Waltham, MA**	**02451**
(Address of registrant's principal executive office)	**(Zip code)**

(781) 209-6400
(Registrant's telephone number, including area code)

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))

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.01 Par Value	**DCPH**	**The 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 8.01 Other Events.

Corporate Update

On August 13, 2019, Deciphera Pharmaceuticals, Inc. (the "Company" or "we") announced positive top-line data from its INVICTUS pivotal Phase 3 clinical study of ripretinib, a broad-spectrum KIT and PDGFRα inhibitor, in patients with fourth-line and fourth-line plus gastrointestinal stromal tumor, or GIST. The Company also announced positive updated data from its ongoing Phase 1 clinical study of ripretinib.

Top-line Results from INVICTUS Phase 3 Study in Fourth-Line and Fourth-Line Plus GIST

The INVICTUS Phase 3 clinical study is a randomized, double-blind, placebo-controlled, international, multicenter study to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in patients with advanced GIST whose previous therapies have included imatinib, sunitinib, and regorafenib.

On August 13, 2019, we announced top-line data from the INVICTUS Phase 3 clinical study, including that the trial achieved its primary endpoint of improved progression free survival, or PFS, compared to placebo in patients with fourth-line and fourth-line plus GIST, as determined by blinded independent central radiologic review using modified Response Evaluation Criteria in Solid Tumors, or RECIST, version 1.1.

In the INVICTUS study, ripretinib demonstrated a median PFS of 6.3 months (27.6 weeks) compared to 1.0 month (4.1 weeks) in the placebo arm and significantly reduced the risk of disease progression or death by 85% (HR of 0.15, p<0.0001) compared to placebo.

For the key secondary endpoint of objective response rate, or ORR, as determined by blinded independent central radiologic review using modified RECIST version 1.1, ripretinib demonstrated an ORR of 9.4% compared with 0% for placebo (p-value=0.0504), which was not statistically significant. Ripretinib in this study also showed a clinically meaningful improvement over placebo in terms of the secondary endpoint of overall survival, or OS (median OS 15.1 months with ripretinib compared to 6.6 months with placebo, HR = 0.36, nominal p-value=0.0004). Since statistical significance was not achieved for ORR, the hypothesis testing of OS was not formally performed. According to the pre-specified hierarchical testing procedure of the endpoints, the hypothesis testing of OS cannot be formally conducted unless the test of ORR is statistically significant. The OS data for the placebo arm includes patients taking placebo who, following progression, were crossed-over to ripretinib treatment.

Ripretinib was generally well tolerated and the adverse event results in INVICTUS were consistent with data from previously presented Phase 1 study results. Grade 3 or 4 treatment-emergent adverse events, or TEAEs, occurred in 42 patients (49%) on the ripretinib arm compared to 19 patients (44%) on the placebo arm. Grade 3 or 4 TEAEs in greater than 5% of patients in the ripretinib arm were anemia (9%; n=8), abdominal pain (7%; n=6) and hypertension (7%; n=6). Grade 3 or 4 TEAEs in greater than 5% of patients in the placebo arm were anemia (14%; n=6). The below table lists all TEAEs greater than 15% in the ripretinib arm compared to the placebo arm in INVICTUS.

INVICTUS Phase 3 Clinical Study

Treatment Emergent Adverse Event	Placebo (N=43)(1)	Ripretinib 150mg Daily (N=85)(1)
Any event	42 (98%)	84 (99%)
Alopecia	2 (5%)	44 (52%)
Fatigue	10 (23%)	36 (42%)
Nausea	5 (12%)	33 (39%)
Abdominal pain	13 (30%)	31 (36%)
Constipation	8 (19%)	29 (34%)
Myalgia	5 (12%)	27 (32%)
Diarrhea	6 (14%)	24 (28%)
Decreased appetite	9 (21%)	23 (27%)
Palmar-plantar erythrodysaesthesia syndrome	0	18 (21%)
Vomiting	3 (7%)	18 (21%)
Headache	2 (5%)	16 (19%)
Weight decreased	5 (12%)	16 (19%)
Arthralgia	2 (5%)	15 (18%)
Blood bilirubin increased	0	14 (16%)
Oedema peripheral	3 (7%)	14 (16%)
Muscle spasms	2 (5%)	13 (15%)

(1) Safety population includes 128 patients. One patient was randomized to placebo but did not receive study drug.

Based on the positive INVICTUS data, the Company expects to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib and regorafenib in the first quarter of 2020.

Additional results from the INVICTUS Phase 3 clinical study are expected to be presented at an upcoming medical meeting.

Updated Data from Ongoing Phase 1 Study in GIST Patients

We are studying ripretinib in an ongoing Phase 1 trial in patients with advanced malignancies, including, without limitation, GIST. On August 13, 2019, we announced an update to the results from our ongoing Phase 1 study of ripretinib in 178 GIST patients who received at least one dose at or above 100 mg of ripretinib daily, with a cut-off date of March 1, 2019, with data based on investigator assessment. We observed an ORR by best response, which is the proportion of patients with either complete responses, or CRs, or partial responses, or PRs, by RECIST version 1.1, in each line of GIST as summarized below.

In addition, we observed a disease control rate, or DCR, defined as the proportion of patients with either stable disease or a PR at a point in time, at three months in each line of patients as summarized below. Disease control includes stable disease, PRs and CRs, measured by computerized tomography, or CT scan, or magnetic resonance imaging, or MRI scan, and assessed locally by RECIST. We also observed median progression free survival, or mPFS, and treatment duration.

Updated interim results, including those announced on August 13, 2019, are summarized in the below table.

Line of Therapy(1)	Objective Response Rate by Best Response Includes Unconfirmed (Confirmed Only)	Disease Control Rate at 3 Months	Median Progression Free Survival (mPFS)	Censored Patients for mPFS	Mean Treatment Duration(2)(3)
Second-Line (n=37)	30% (22%)	81%	42 weeks	38%	43 weeks
Third-Line (n=31)	23% (13%)	80%	40 weeks	32%	48 weeks
Fourth-Line (n=60)	15% (8%)	73%	30 weeks	30%	49 weeks
[3]Fourth-Line (n=110)(4)	11% (7%)	66%	24 weeks	22%	41 weeks

(1) Overall number of patients (n=178) remains the same as prior data presented at ESMO 2018; based on additional data cleaning, one patient from each of 2nd line and 4th/[3]4th line were reclassified as 3rd line patients; (2) Median treatment durations were: 2nd line = 44 weeks, 3rd line = 48 weeks, 4th line = 46 weeks and [3]4th line = 29 weeks; (3) Includes 60 patients who elected for intra-patient dose escalation from 150 mg QD to 150 mg BID; (4) Number of patients includes 60 patients from 4th line.

In the Phase 1 study, ripretinib was generally well tolerated and the updated adverse events were consistent with previously presented Phase 1 data in patients with GIST. Grade 3 or 4 TEAEs in greater than 5% of patients were lipase increased (18%; n=33), anemia (11%; n=20), hypertension (7%; n=13) and abdominal pain (6%; n=11). 13% of patients (n=24) experienced TEAEs leading to study treatment discontinuation, 17% of patients (n=31) experienced TEAEs leading to dose reduction and 49% of patients (n=88) had TEAEs leading to study drug interruption. The TEAEs in greater than 10% of GIST patients at or above 100 mg daily (n=179) by Grades 1/2 and Grades 3/4 are summarized in the table below.

GIST PATIENTS @ [3] 100 MG DAILY
Treatment Emergent Adverse Events (TEAEs) >10%

Treatment Emergent Adverse Event	GRADE 1-2 (N=179)(1)	GRADE 3-4 (N=179)(1)	GRADE 1-4 (N=179)(1)
Alopecia	102 (57%)	0 (0%)	102 (57%)
Fatigue	94 (53%)	4 (2%)	98 (55%)
Myalgia	79 (44%)	0 (0%)	79 (44%)
Nausea	77 (43%)	1 (1%)	78 (44%)
Palmar-plantar erythrodysaesthesia syndrome	71 (40%)	1 (1%)	72 (40%)
Constipation	67 (37%)	0 (0%)	67 (37%)
Decreased appetite	60 (34%)	2 (1%)	62 (35%)
Diarrhea	50 (28%)	3 (2%)	53 (30%)
Weight decreased	51 (29%)	1 (1%)	52 (29%)
Lipase increased	18 (10%)	33 (18%)	51 (29%)
Muscle spasms	47 (26%)	0 (0%)	47 (26%)
Abdominal pain	33 (18%)	11 (6%)	44 (25%)
Vomiting	42 (24%)	2 (1%)	44 (25%)
Arthralgia	40 (22%)	0 (0%)	40 (22%)
Anemia	18 (10%)	20 (11%)	38 (21%)
Hypertension	25 (14%)	13 (7%)	38 (21%)
Cough	37 (21%)	0 (0%)	37 (21%)
Dry skin	37 (21%)	0 (0%)	37 (21%)
Dyspnea	32 (18%)	4 (2%)	36 (20%)
Headache	33 (18%)	1 (1%)	34 (19%)
Back Pain	30 (17%)	2 (1%)	32 (18%)
Dizziness	29 (16%)	0 (0%)	29 (16%)
Rash	27 (15%)	0 (0%)	27 (15%)
Hypokalaemia	21 (12%)	5 (3%)	26 (15%)
Hypophosphataemia	17 (10%)	8 (5%)	25 (14%)
Actinic keratosis	25 (14%)	0 (0%)	25 (14%)
Blood bilirubin increase	16 (9%)	5 (3%)	21 (12%)
Amylase increased	19 (11%)	2 (1%)	21 (12%)
Insomnia	21 (12%)	0 (0%)	21 (12%)
Seborrhoeic keratosis(2)	21 (12%)	0 (0%)	21 (12%)
Urinary tract infection	16 (9%)	4 (2%)	20 (11%)
Dysgeusia	20 (11%)	0 (0%)	20 (11%)
Pain in extremity	18 (10%)	1 (1%)	19 (11%)
Blood creatine phosphokinase increased	13 (7%)	5 (3%)	18 (10%)
Upper respiratory tract infection	18 (10%)	0 (0%)	18 (10%)
Rash maculo-papular	18 (10%)	0 (0%)	18 (10%)
Hypomagnesaemia	18 (10%)	0 (0%)	18 (10%)
Pruritus	18 (10%)	0 (0%)	18 (10%)
Skin papilloma(2)	17 (10%)	0 (0%)	17 (10%)
Vision blurred	17 (10%)	0 (0%)	17 (10%)

(1) Includes one patient that only participated in the food effect portion of the Phase 1 study; (2) Dermatology skin exams were implemented to better evaluate skin lesions.

Additional results from the Phase 1 clinical study in these patients are expected to be presented at an upcoming medical meeting.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this document, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plan, objectives of management and expected market growth are forward-looking statements. You can identify these forward-looking statements by the use of words such as “outlook,” “believes,” “expects,” “potential,” “continues,” “may,” “will,” “should,” “seeks,” “approximately,” “predicts,” “intends,” “plans,” “estimates,” “anticipates” or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include but are not limited to those described under “Risk Factors” and include, among other things:

- the success, cost and timing of our product development activities and clinical trials, including the timing of our ongoing Phase 3 trials and results therefrom;
- our ability to obtain and maintain regulatory approval for ripretinib (DCC-2618) or any of our other current or future drug candidates, and any related restrictions, limitations, and/or warnings in the label of an approved drug candidate;
- preliminary or “top-line” data from our clinical trials based on a preliminary analysis of then-available top-line data in a summary format being perceived differently from additional data disclosed at a later time due to more patient data becoming available or audit and verification procedures resulting in material changes in the final data;
- the timing and release of additional results from our clinical trials, including from the INVICTUS Phase 3 clinical study, and their interpretation;

- acceptance by the public or regulatory agencies of our assumptions, estimates, calculations, conclusions or analyses of our data, and differences in interpretation or weight of importance of our data;
- our expectations regarding the size of target patient populations for our drug candidates, if approved for commercial use, and any additional drug candidates we may develop;
- our ability to obtain funding for our operations;
- our ability to manufacture or obtain sufficient quantities of our drug candidates, including, without limitation, ripretinib, to support our planned clinical trials and, if approved, commercialization;
- the commercialization of our drug candidates, if approved;
- our plans to research, develop and commercialize our drug candidates, including the timing of our ongoing Phase 3 trials and the timing of investigational new drug, or IND, applications, including, without limitation, the success of IND-enabling studies for, and the expected timing of, an IND application for our DCC-3116 program;
- the performance and experience of our licensee, Zai Lab (Shanghai) Co., Ltd., or Zai, to successfully develop and, if approved, commercialize ripretinib in Greater China under the terms and conditions of our license agreement;
- our ability to attract additional licensees and/or collaborators with development, regulatory and commercialization expertise;
- our expectations regarding our ability to obtain, maintain, enforce and defend our intellectual property protection for our drug candidates;
- future agreements with third parties in connection with the commercialization of ripretinib, or any of our other current or future drug candidates;
- the size and growth potential of the markets for our drug candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our drug candidates, as well as the reimbursement coverage for our drug candidates;
- regulatory and legal developments in the United States and foreign countries;
- the performance and experience of our third-party suppliers and manufacturers;
- the success and timing of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- our expectations related to the use of proceeds from our public offerings.

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included elsewhere in our filings with the SEC. The forward-looking statements contained in this document are made as of the date of this document, and we undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise.

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: August 13, 2019

DECIPHERA PHARMACEUTICALS, INC.

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