# 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): May 9, 2019

# **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 Number)

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

02451 (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))

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  $\square$ 

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.  $\square$ 

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.01 Par Value	DCPH	The Nasdaq Global Select Market

#### Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 2019. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in 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, 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 issued by Deciphera Pharmaceuticals, Inc. on May 9, 2019, furnished herewith.

## EXHIBIT INDEX

## Description

Exhibit No. 99.1 Press Release issued by Deciphera Pharmaceuticals, Inc. on May 9, 2019, furnished herewith.

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: May 9, 2019

### DECIPHERA PHARMACEUTICALS, INC.

By: <u>/s/ Steven L. Hoerter</u> Steven L. Hoerter

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President and Chief Executive Officer



#### Deciphera Pharmaceuticals, Inc. Announces First Quarter 2019 Financial Results

- Top-line Data from INVICTUS Pivotal Phase 3 Clinical Study of Ripretinib in Fourth-line and Fourth-line Plus GIST Patients Expected in Mid-2019 -

- Recommended Phase 2 Dose Selected for Part 2 of Phase 1b/2 Study of Rebastinib plus Paclitaxel; Enrollment in Part 2 with Expansion Cohorts Expected to Commence Second Quarter 2019 -

- Ended First Quarter 2019 with Cash, Cash Equivalents and Marketable Securities of \$262 Million -

Waltham, MA – May 9, 2019 – Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), a clinical-stage biopharmaceutical company focused on addressing key mechanisms of tumor drug resistance, today announced financial results for the first quarter ended March 31, 2019 and provided an update on clinical and corporate developments.

"Our team made significant progress during the first quarter of 2019 advancing our portfolio of novel drug candidates from our proprietary kinase switch control inhibitor platform," said Steve Hoerter, President and Chief Executive Officer of Deciphera. "We expect top-line data from our INVICTUS pivotal Phase 3 study of ripretinib for the treatment of fourth-line and fourth-line plus GIST patients in mid-2019 and pending favorable results from this study, we look forward to our first NDA submission and laying the groundwork for our first potential launch in the United States. In addition, we continue to advance key clinical trials of DCC-3014 and rebastinib and we expect to announce the initiation of IND-enabling preclinical studies for a new clinical candidate later this year."

#### **Recent Clinical Updates**

- Ripretinib (DCC-2618)
  - Deciphera expects to report top-line data from the INVICTUS pivotal Phase 3 clinical study evaluating the safety and efficacy of ripretinib, the Company's investigational broad-spectrum KIT and PDGFRα inhibitor, in fourth-line and fourth-line plus gastrointestinal stromal tumor (GIST) patients in mid-2019. The Company is building its commercial and medical affairs capabilities to support the planned launch of ripretinib in the United States, if approved.
  - Deciphera is actively enrolling patients in the INTRIGUE Phase 3 clinical study comparing ripretinib to sunitinib for the treatment of second-line GIST patients who have previously received imatinib.

#### Rebastinib

- Deciphera announced the initiation of an open-label, multicenter, Phase 1b/2 combination study of rebastinib, the Company's investigational small molecule switch control inhibitor of TIE2 kinase, with carboplatin in patients with advanced or metastatic solid tumors.
- Deciphera completed enrollment of 40 patients in Part 1 of the Phase 1b/2 combination study of rebastinib with paclitaxel. In April 2019, Deciphera selected a 100 mg BID dose of rebastinib in combination with a weekly dose of 80 mg/m<sup>2</sup> of paclitaxel as the recommended Phase 2 dose for Part 2 of the study, which is expected to begin enrollment later this quarter. The Company expects to report initial data from Part 1 of this study in the second half of 2019.



#### • DCC-3014

- Deciphera announced positive, preliminary top-line data from the ongoing dose escalation portion of the Phase 1 clinical study of DCC-3014, the Company's investigational small molecule switch control inhibitor of CSF1R, in patients with advanced malignancies. The Company plans to present a review of further data from this Phase 1 study in the second half of 2019.
- The Company is currently enrolling patients diagnosed with tenosynovial giant cell tumors (TGCT) in its expanded Phase 1 study evaluating DCC-3014.

#### **Corporate Update**

Deciphera announced the appointment of Steve Hoerter as President & Chief Executive Officer, effective March 18, 2019. Mr. Hoerter has
served as a member of the Deciphera Board of Directors since May 2018. He joined the Company from Agios, where he was Chief
Commercial Officer. He succeeded Michael D. Taylor, Ph.D., who retired as President & Chief Executive Officer of the Company.
Dr. Taylor remains as senior advisor to the Company and a member of the Company's Board of Directors.

#### First Quarter 2019 Financial Results

- Cash Position: As of March 31, 2019, cash, cash equivalents and marketable securities were \$262.3 million, compared to cash and cash equivalents of \$293.8 million as of December 31, 2018. Deciphera expects its current cash, cash equivalents and marketable securities will enable the Company to fund its operating, capital expenditures and debt service payments into the second half of 2020.
- **R&D Expenses:** Research and development expenses for the first quarter of 2019 were \$35.8 million, compared to \$16.9 million for the same period in 2018. The increase was primarily due to an increase in spending on the ripretinib program of \$10.7 million as a result of clinical trial costs related to the Phase 3 INTRIGUE study in second-line GIST, which the Company initiated in December 2018, and includes \$5.3 million for comparator drug to be used in this trial. Expenses related to the rebastinib program increased \$3.2 million, primarily due to the Phase 1b/2 study of rebastinib in combination with paclitaxel, which the Company initiated in October 2018, and the second Phase 1b/2 clinical trial of rebastinib in combination with carboplatin, which the Company initiated in January 2019. Personnel-related costs increased \$3.7 million due primarily to increased headcount and stock-based compensation expense in research and development functions. Personnel-related costs for the first quarters of 2019 and 2018 included non-cash stock-based compensation expense of \$1.7 million and \$1.0 million, respectively. Facility-related and other costs included in unallocated expenses increased \$1.7 million primarily due to increased costs incurred in connection with early-stage drug discovery programs and increased consulting fees.



- **G&A Expenses:** General and administrative expenses for the first quarter of 2019 were \$13.2 million, compared to \$5.0 million for the same period in 2018. The increase was primarily a result of increases in stock-based compensation expense and headcount in general and administrative functions. Non-cash stock-based compensation was \$4.5 million and \$1.1 million for the first quarters of 2019 and 2018, respectively. The increase in stock-based compensation expense was primarily related to the modification of stock options pursuant to the transition agreement with the Company's former President and Chief Executive Officer and additional employee stock options. In addition, professional and consultant fees increased due to various advisory fees, including those related to commercialization preparedness.
- Net Loss: For the first quarter of 2019, Deciphera reported a net loss of \$47.4 million, or \$1.25 per share, compared with a net loss of \$21.4 million, or \$0.66 per share, for the same period in 2018.

#### **About Deciphera Pharmaceuticals**

Deciphera Pharmaceuticals is a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Our small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. We use our deep understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a "switched off" or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic resistance causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. We have used our platform to develop a diverse pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate and/or durability of their responses to treatment.

#### Availability of Other Information About Deciphera Pharmaceuticals

Investors and others should note that Deciphera Pharmaceuticals communicates with its investors and the public using its company website (www.deciphera.com), including but not limited to investor presentations and scientific presentations, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Deciphera Pharmaceuticals posts on these channels and websites could be deemed to be material information. As a result, Deciphera Pharmaceuticals encourages investors, the media and others interested in Deciphera Pharmaceuticals to review the information that it posts on these channels, including Deciphera Pharmaceuticals' investor relations website, on a regular basis. This list of channels may be updated from time to time on Deciphera Pharmaceuticals' investor relations website and may include other social media channels than the ones described above. The contents of Deciphera Pharmaceuticals' website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

#### **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, statements regarding our



expectations regarding timing of reporting top-line data from our INVICTUS pivotal Phase 3 study, the potential for ripretinib (DCC-2618) and our other drug candidates based on our kinase switch control inhibitor platform to provide clinical benefit and treat cancers such as GIST and other possible indications, initiation of and enrollment for our INTRIGUE pivotal Phase 3 study, expectations for, progress with respect to and the timing of enrollment and data from our clinical trials with our investigational agent rebastinib, including, without limitation, our study of rebastinib in combination with carboplatin and in combination with paclitaxel, and the potential for rebastinib, alone or in combination with other agents or chemotherapy to treat cancers, expectations for presenting data from our studies of DCC-3014, enrollment of TGCT patients in our ongoing Phase 1 trial for DCC-3014, expectations regarding cash guidance, preparations for a possible NDA, pending positive study results, and commercial launch of ripretinib in fourthline and fourth-line plus GIST, if approved, and expectations regarding designating a new clinical candidate and IND-enabling studies to support such candidate. The words "may," "will," "could," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "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 delay of any current or planned clinical studies or the development of our drug candidates, including ripretinib, rebastinib, and DCC-3014, our advancement of multiple early-stage and later-stage efforts, our ability to successfully demonstrate the efficacy and safety of our drug candidates including in later-stage studies, the preclinical and clinical results for our drug candidates, which may not support further development of such drug candidates, our efforts to scale up and manage drug product manufacturing, our ability to implement commercial readiness, actions of regulatory agencies, any or all of which may affect the initiation, timing and progress of clinical studies and other risks identified in our SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2018, 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 its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.



#### CONSOLIDATED BALANCE SHEETS (In thousands) (Unaudited)

	March 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents and marketable securities	\$262,342	\$ 293,764
Prepaid expenses and other current assets	4,103	7,273
Long-term investment restricted	1,069	1,069
Property and equipment, net	1,504	13,453
Operating lease, right-of-use assets	670	
Total assets	\$269,688	\$ 315,559
Liabilities and Stockholders' Equity		
Accounts payable, accrued expenses and other liabilities	\$ 27,751	\$ 22,398
Debt obligations	1,263	1,294
Operating lease liabilities	678	11,886
Total liabilities	29,692	35,578
Total stockholders' equity	239,996	279,981
Total liabilities and stockholders' equity	\$269,688	\$ 315,559

#### CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (In thousands, except share and per share data) (Unaudited)

		Three Months Ended March 31,	
	2019	2018	
Revenue	\$ —	\$ —	
Operating expenses:			
Research and development	35,789	16,925	
General and administrative	13,236	5,026	
Total operating expenses	49,025	21,951	
Loss from operations	(49,025)	(21,951)	
Other income (expense):			
Interest expense	(13)	(22)	
Interest and other income, net	1,654	543	
Total other income (expense), net	1,641	521	
Net loss	\$ (47,384)	\$ (21,430)	
Net loss per share—basic and diluted	\$ (1.25)	\$ (0.66)	
Weighted average common shares outstanding—basic and diluted	38,057,018	32,594,074	



#### **Contacts:**

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