
**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 2, 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))

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 2.02 Results of Operations and Financial Condition.

On August 2, 2019, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended June 30, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on August 2, 2019, furnished herewith.

EXHIBIT INDEX

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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 2, 2019

DECIPHERA PHARMACEUTICALS, INC.

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



Deciphera Pharmaceuticals, Inc. Announces Second Quarter 2019 Financial Results

- *Top-line Data from INVICTUS Pivotal Phase 3 Clinical Study of Ripretinib in Fourth-line and Fourth-line Plus Gastrointestinal Stromal Tumor (GIST) Patients Expected this Month -*
- *Ripretinib Granted Fast Track Designation by the U.S. Food and Drug Administration for Treatment of Patients with Fourth-line and Fourth-line Plus GIST -*
- *Exclusive License Agreement with Zai Lab Ltd. Established for the Development and Commercialization of Ripretinib in Greater China -*
- *DCC-3116 Added to Pipeline as Potential First-in-Class Autophagy Inhibitor to Treat Mutant RAS Cancers -*
- *Ended Second Quarter 2019 with Cash, Cash Equivalents and Marketable Securities of \$225 Million -*

Waltham, MA – August 2, 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 second quarter ended June 30, 2019 and provided an update on clinical and corporate developments.

“In recent months, we’ve made substantial progress across our pipeline of novel candidates from our two Phase 3 GIST trials with ripretinib to the addition of DCC-3116, a potential first-in-class autophagy inhibitor aimed at treating mutant RAS cancers,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “Later this month, we expect to announce top-line data from the INVICTUS pivotal Phase 3 clinical study, the results of which, if favorable, could serve as the basis for our first new drug application, or NDA, filing. We also recently established our first license agreement for ripretinib outside of the U.S., which we believe reflects the growing recognition that ripretinib has the potential to alter the treatment landscape for patients with GIST.”

Recent Pipeline Updates

- **Ripretinib**
 - 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 PDGFRA inhibitor, in fourth-line and fourth-line plus GIST patients in August 2019. The Company is building its commercial and medical affairs capabilities to support the planned launch of ripretinib in the United States, if approved.
 - In June 2019, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for ripretinib for the investigation of the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib and regorafenib.
 - Deciphera continues to activate sites and enroll 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. As of July 26, 2019, 45 sites have been activated.



- **Rebastinib**
 - Deciphera previously 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 43 patients in Part 1 of the Phase 1b/2 combination study of rebastinib with paclitaxel. Part 2 of the Phase 1b/2 study is now enrolling patients. The Company expects to report initial data from Part 1 of this study in the second half of 2019.
- **DCC-3014**
 - The Company plans to present updated 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, in the second half of 2019.
 - The Company continues to enroll patients diagnosed with tenosynovial giant cell tumors (TGCT) in the Phase 1 study evaluating DCC-3014.
- **DCC-3116**
 - In June 2019, Deciphera announced the addition of a new candidate to its pipeline, DCC-3116, a potential first-in-class small molecule designed to inhibit cancer autophagy, a key tumor survival mechanism, by inhibiting the ULK kinase. Subject to favorable investigational new drug (IND)-enabling studies and filing and activation of an IND, expected in mid-2020, Deciphera intends to develop DCC-3116 for the potential treatment of mutant RAS cancers in combination with inhibitors of downstream RAS effector targets including RAF, MEK, or ERK inhibitors as well as with direct inhibitors of mutant RAS.

Corporate Updates

- **Ripretinib License Agreement for Greater China.**
 - In June 2019, Deciphera announced an exclusive license agreement with Zai Lab (Shanghai) Co., Ltd. (Zai) to advance the development and commercialization of ripretinib in Greater China, including mainland China, Hong Kong, Macau and Taiwan. Under the terms of the agreement, Deciphera has received an upfront cash payment of \$20 million and will be eligible to receive up to \$185 million in potential development and commercial milestone payments, including \$5 million for an INTRIGUE study-related milestone the Company achieved. In addition, Zai will be obligated to pay Deciphera royalties ranging from low to high teens on annual net sales of ripretinib in Greater China.
- **New Member of the Board of Directors**
 - In July 2019, Deciphera announced the appointment of Susan L. Kelley, M.D. to its Board of Directors. Dr. Kelley has over 25 years of experience across all stages of oncology drug research and development.



Second Quarter 2019 Financial Results

- **Cash Position:** As of June 30, 2019, cash, cash equivalents and marketable securities were \$225.4 million, compared to cash and cash equivalents of \$293.8 million as of December 31, 2018. Deciphera expects its cash, cash equivalents and marketable securities as of June 30, 2019, along with the \$20.0 million up-front payment from the Company's recent license agreement with Zai received in the third quarter of 2019, will enable the Company to fund its operating expenses, capital expenditure requirements and debt service payments into the fourth quarter of 2020. This excludes any potential milestone or royalty payments, if any, under Deciphera's license agreement with Zai.
- **Revenue:** Revenue for the second quarter of 2019 was \$25.0 million which was related to the Company's exclusive license agreement with Zai to advance the development and commercialization of ripretinib in Greater China. Deciphera recognized license revenue of \$20.0 million for an upfront fee and \$5.0 million for a development milestone related to the INTRIGUE study.
- **R&D Expenses:** Research and development expenses for the second quarter of 2019 were \$34.8 million, compared to \$18.0 million for the same period in 2018. The increase was primarily due to the INTRIGUE Phase 3 clinical study in second-line GIST, which the Company initiated in December 2018, and to the INVICTUS Phase 3 clinical study in fourth-line and fourth-line plus GIST, which the Company initiated in January 2018. The Company also incurred costs related to other supporting clinical trials for ripretinib. Additionally, expenses related to the rebastinib program increased primarily as a result of an increase in clinical trial costs related to the Phase 1b/2 trial 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 \$4.0 million primarily due to increased headcount and stock-based compensation expense in research and development functions. Personnel-related costs for the second quarters of 2019 and 2018 included non-cash stock-based compensation expense of \$1.8 million and \$1.0 million, respectively. Facility-related and other costs included in unallocated expenses increased \$2.3 million primarily due to increased consultant fees and other costs in connection with our early-stage drug discovery programs.
- **G&A Expenses:** General and administrative expenses for the second quarter of 2019 were \$13.2 million, compared to \$4.5 million for the same period in 2018. The increase was primarily due to an increase in professional, consultant and various advisory fees, including those related to commercialization preparedness. Non-cash stock-based compensation was \$2.3 million and \$1.2 million for the second quarters of 2019 and 2018, respectively. The increase in non-cash stock-based compensation expense was primarily related to the granting of additional employee stock option awards.
- **Net Loss:** For the second quarter of 2019, Deciphera reported a net loss of \$21.5 million, or \$0.56 per share, compared with a net loss of \$21.7 million, or \$0.65 per share, for the same period in 2018.



About Deciphera Pharmaceuticals

Deciphera Pharmaceuticals (NASDAQ: DCPH) 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 clinical study, the potential for ripretinib (DCC-2618) and our other drug candidates (DCC-3116, rebastinib and DCC-3014) based on our kinase switch control inhibitor platform to provide clinical benefit and treat cancers such as GIST and other possible indications, preparations for a possible NDA, pending positive study results, and commercial launch of ripretinib in fourth-line and fourth-line plus GIST, if approved, expectations for timing of filing and activation of an IND for DCC-3116, expectations of timing of data for, and enrollment with respect to, the Company’s rebastinib and DCC-3014 programs and expectations of benefits from the Company’s license agreement with Zai. 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 delay of any current or



planned clinical studies or the development of our drug candidates, including ripretinib, rebastinib, DCC-3014 and DCC-3116, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, 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)

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
Assets		
Cash and cash equivalents and marketable securities	\$ 225,416	\$ 293,764
Accounts receivable and unbilled receivable	25,000	—
Prepaid expenses and other current assets	6,010	7,273
Long-term investment restricted	1,510	1,069
Property and equipment, net	1,595	13,453
Operating lease, right-of-use assets	476	—
Total assets	<u>\$ 260,007</u>	<u>\$ 315,559</u>
Liabilities and Stockholders' Equity		
Accounts payable, accrued expenses and other liabilities	\$ 35,451	\$ 22,398
Debt obligations	1,201	1,294
Operating lease liabilities	477	11,886
Total liabilities	<u>37,129</u>	<u>35,578</u>
Total stockholders' equity	222,878	279,981
Total liabilities and stockholders' equity	<u>\$ 260,007</u>	<u>\$ 315,559</u>



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	\$ 25,000	\$ —	\$ 25,000	\$ —
Operating expenses:				
Research and development	34,811	17,976	70,600	34,901
General and administrative	13,164	4,453	26,400	9,479
Total operating expenses	47,975	22,429	97,000	44,380
Loss from operations	(22,975)	(22,429)	(72,000)	(44,380)
Other income (expense):				
Interest expense	(25)	(21)	(38)	(43)
Interest and other income, net	1,540	760	3,194	1,303
Total other income (expense), net	1,515	739	3,156	1,260
Net loss	\$ (21,460)	\$ (21,690)	\$ (68,844)	\$ (43,120)
Net loss per share—basic and diluted	\$ (0.56)	\$ (0.65)	\$ (1.81)	\$ (1.30)
Weighted average common shares outstanding—basic and diluted	38,200,288	33,567,314	38,129,049	33,083,383

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