

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 5, 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 Number)

200 Smith Street
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
Common Stock, \$0.01 Par Value

Trading Symbol
DCPH

Name of exchange on which registered
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 May 5, 2020, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 2020. 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 May 5, 2020, furnished herewith. |

EXHIBIT INDEX

Exhibit No.

Description

99.1

[Press Release issued by Deciphera Pharmaceuticals, Inc. on May 5, 2020, 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.

DECIPHERA PHARMACEUTICALS, INC.

Date: May 5, 2020

By: /s/ Steven L. Hoerter

Steven L. Hoerter

President and Chief Executive Officer



Deciphera Pharmaceuticals, Inc. Announces First Quarter 2020 Financial Results

- NDA for Ripretinib for the Treatment of Advanced GIST Under Review by U.S. FDA with PDUFA Date of August 13, 2020; Commercial Preparations Underway to Support Potential Launch -

- COVID-19 Business Update Provided; Clinical and Commercial Milestone Timing Affirmed -

- First Quarter 2020 Ended with Cash, Cash Equivalents and Marketable Securities of \$691.5 Million; Cash Runway Expected into the Second Half of 2022 -

- Company to Host Conference Call Today at 4:30 PM ET -

Waltham, MA – May 5, 2020 – Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced financial results for the first quarter ended March 31, 2020 and provided an update on clinical and corporate developments.

“Work is underway across the company as we prepare for the potential approval and launch of ripretinib later this year,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “We continue to make progress against our planned 2020 company milestones, including advancing our broad clinical-stage pipeline and completing enrollment in the ongoing, pivotal Phase 3 INTRIGUE study of ripretinib in second-line GIST.”

Mr. Hoerter continued, “In these unprecedented times, we remain steadfast in our mission to bring important new medicines to patients for the treatment of cancer. Our employees have done a tremendous job adapting to the COVID-19 related challenges we are facing as a company, and as an industry, to carry out this mission. We are continuing to actively evaluate the potential impact of the pandemic on our business and proactively explore and implement mitigation measures.”

COVID-19 Business Update

Deciphera is continuously assessing and adapting its business operations in an effort to mitigate interruption from the COVID-19 pandemic on its clinical programs, research efforts and other business activities and to ensure the well-being of its employees, as well as the physicians and patients participating in its clinical studies. At this stage of the COVID-19 pandemic, the operating environment remains fluid and uncertain. The full impact on the Company and its business is not known at this time, and the Company’s outlook assumes the COVID-19 impact on its business will be shorter-term over the next few months and not prolonged.

Clinical Trials and Research and Development Efforts

- The Company is monitoring risks associated with potential interruptions to its clinical studies and is in frequent communication with clinical study sites and contract research organizations to address the individual circumstances at each site. At this stage, Deciphera can confirm previously announced milestone timing guidance:
 - o Deciphera continues to believe that it will be able to achieve full enrollment in its Phase 3 INTRIGUE study in second-line gastrointestinal stromal tumor (GIST) patients in the second half of 2020.
 - o The Company also continues to believe it will be able to present updated clinical data, select a recommended Phase 2 dose and open the expansion cohort for its DCC-3014 program in tenosynovial giant cell tumor patients in the second half of 2020.

The Company also continues to expect to present updated clinical data from its rebastinib program in the second half of 2020.

- o The Company is continuing its discovery research, preclinical efforts and early development activities, and expects to file an IND for DCC-3116, its ULK kinase inhibitor, in the second half of 2020.

Drug Supply

- Deciphera has commercial drug supply sufficient to support the potential launch of ripretinib in fourth-line GIST. Based on current inventories and supply plans, the Company does not anticipate any COVID-19-related supply interruptions to its clinical programs at this time.

Commercial Activities

- In preparation for a potential launch of ripretinib, the Company has been preparing for the possible need to launch and promote using a virtual interaction model, if necessary.

Recent Program Highlights

- **Ripretinib**

- o Today announced that two posters containing results from the Company's pivotal Phase 3 INVICTUS study will be featured at the American Society for Clinical Oncology (ASCO) Annual Meeting, being held May 29-31, 2020 in a virtual format. The posters will be made available on-demand via the ASCO20 Virtual Scientific Program beginning on Friday, May 29, 2020 at 8:00 AM ET. Titles of the poster presentations can be found below:
 - "Quality of life (QoL) and self-reported function with ripretinib in 3rd-line therapy for patients with gastrointestinal stromal tumors (GIST): Analyses from INVICTUS"
 - "Safety profile of ripretinib, including impact of alopecia and palmar-plantar erythrodysesthesia syndrome (PPES) on patient reported outcomes (PROs), in 3rd-line advanced gastrointestinal stromal tumors (GIST): Analyses from INVICTUS"
- o Today announced that a poster containing health economics and outcomes research regarding what constitutes meaningful change for patients in gastrointestinal-related cancer will be featured at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Annual Meeting, being held May 18-20, 2020 in a virtual format in a poster session on Tuesday, May 19, 2020 at 3:30-7:00 PM ET. The title of the poster presentation can be found below and a copy of the abstract can be found online here.
 - "Thresholds for meaningful change for the EQ-5D VAS and EORTC QLQ-C30 physical and role functioning scale in gastrointestinal-related cancer"
- o As previously announced, the New Drug Application (NDA) seeking approval for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib, is currently under Priority Review by the U.S. Food and Drug Administration (FDA), with a Prescription Drug User Fee Act (PDUFA) target action date of August 13, 2020. The NDA is being reviewed by the FDA under the Oncology Center of Excellence Real-Time Oncology Review pilot program. Commercial preparations are currently underway to support the potential approval and launch of ripretinib.

- **Rebastinib**
 - o Today announced that the endometrial and ovarian cancer cohorts in Part 2 of the Phase 1b/2 study of rebastinib in combination with paclitaxel advanced into the second stage of the Simon two-stage design based on achievement of more than 4 responses in each cohort.
 - o A poster containing data from the endometrial cancer cohort in Part 2 of the Company's ongoing Phase 1b/2 study of rebastinib in combination with paclitaxel will be presented at the ASCO Annual Meeting. The poster will be made available on-demand via the ASCO20 Virtual Scientific Program beginning on Friday, May 29 at 8:00 AM ET. The title of the poster presentation can be found below:
 - "An open-label, multicenter, phase 1b/2 study of rebastinib in combination with paclitaxel in a dose expansion cohort to assess safety and preliminary efficacy in patients with advanced or metastatic endometrial cancer"
 - o Additional updates announced today from the Company's rebastinib program include:
 - The addition of a carcinosarcoma cohort in Part 2 of the Phase 1b/2 study of rebastinib in combination with paclitaxel based on the clinical activity observed in Part 1 of the study.
 - In the Phase 1b/2 study of rebastinib in combination with carboplatin, Part 2 of the study is continuing to enroll patients with breast cancer, ovarian cancer, and mesothelioma at the recommended Phase 2 dose of 50 mg twice daily (BID), which was reduced from 100 mg BID based on the observed frequency of muscular weakness in preliminary data from the ongoing Part 2 portion of the study.

First Quarter 2020 Financial Results

- **Cash Position:** As of March 31, 2020, cash, cash equivalents and marketable securities were \$691.5 million, compared to \$579.6 million as of December 31, 2019. The increase was primarily due to the Company's follow-on public offering in February 2020 that raised net proceeds of \$188.4 million. Deciphera expects its current cash, cash equivalents and marketable securities will enable the Company to fund its operating and capital expenditures into the second half of 2022.
- **R&D Expenses:** Research and development expenses for the first quarter of 2020 were \$51.4 million, compared to \$35.8 million for the same period in 2019. The increase was primarily due to personnel costs, clinical trial costs related to ripretinib, DCC-3014, and rebastinib, and preclinical costs related to DCC-3116. Non-cash stock-based compensation was \$3.3 million and \$1.7 million for the first quarters of 2020 and 2019, respectively.
- **SG&A Expenses:** Selling, general and administrative expenses for the first quarter of 2020 were \$23.9 million, compared to \$13.2 million for the same period in 2019. The increase was primarily a result of personnel costs as well as external spend associated with commercial readiness, increased expenses incurred in connection with our new headquarters that commenced in October 2019, and technology related costs to support the growth of the business. Non-cash stock-based compensation was \$3.7 million and \$4.5 million for the first quarters of 2020 and 2019, respectively.

- **Net Loss:** For the first quarter of 2020, Deciphera reported a net loss of \$72.8 million, or \$1.36 per share, compared with a net loss of \$47.4 million, or \$1.25 per share, for the same period in 2019. The increase in net loss was primarily related to increases in R&D and SG&A expenses, as discussed above.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, May 5, 2020 at 4:30 PM ET. To access the live call by phone please dial (866) 930-5479 (domestic) or (409) 216-0603 (international); the conference ID is 5381739. A live audio webcast of the event may also be accessed through the “Investors” section of Deciphera’s website at www.deciphera.com. A replay of the webcast will be available for 30 days following the event.

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.

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 the impact of COVID-19 on our operations, our goals of obtaining FDA approval for and bringing ripretinib to patients with advanced GIST, working with the FDA through its review of our NDA application, preparing for the potential commercial launch of ripretinib in the United States, if approved, including the potential for a virtual launch in light of COVID-19, the progress and potential of our clinical and preclinical development programs for ripretinib, DCC-3014, rebastinib, and DCC-3116, and corporate guidance for 2020, including timing of completion of enrollment in the INTRIGUE Phase 3 study, progress on the pipeline, presentation of updated clinical data, and cash guidance. 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 the Company’s business and operations, including, without limitation, the progress of our clinical studies and 2020 guidance, commercial and clinical drug supply chain continuity, and the potential commercial launch of ripretinib if approved, our ability to monitor the impact of COVID-19 on our business operations, take mitigation actions to minimize any impact and take steps to ensure the safety of patients and employees, our expectations regarding when COVID-19 impacts may not be as severe, any

delays and impact of COVID-19 on clinical study sites, patient enrollment, study timelines and data, and regarding drug supply for clinical studies and potential commercialization, the delay of any current or planned clinical studies or the development of our product candidates, including ripretinib, our ability to successfully demonstrate the efficacy and safety of our product candidates including in later-stage studies, the preclinical and 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 plan for potential commercialization of our product candidates, such as ripretinib, and if approved, execute on our marketing plans, the inherent uncertainty in estimates of patient populations and incidence and prevalence estimates, 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 regulatory approval, if at all, and make our investigational drugs, including ripretinib, available to patients, and, once commercial, to derive revenue from product sales, and other risks identified in our Securities and Exchange Commission (SEC) filings, including our Annual Report on Form 10-K for the year ended December 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.

DECIPHERA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands, except share and per share amounts)

| | March 31, 2020 | December 31, 2019 |
|--|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 229,652 | \$ 120,320 |
| Marketable securities | 461,848 | 459,256 |
| Prepaid expenses and other current assets | 11,979 | 13,832 |
| Total current assets | 703,479 | 593,408 |
| Long-term investment—restricted | 2,125 | 1,510 |
| Property and equipment, net | 6,693 | 6,333 |
| Operating lease assets | 20,630 | 21,158 |
| Total assets | <u>\$ 732,927</u> | <u>\$ 622,409</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 11,337 | \$ 19,575 |
| Accrued expenses and other current liabilities | 32,234 | 38,716 |
| Operating lease liabilities | 1,501 | 1,747 |
| Total current liabilities | 45,072 | 60,038 |
| Operating lease liabilities, net of current portion | 15,595 | 15,904 |
| Total liabilities | 60,667 | 75,942 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.01 par value per share; 5,000,000 shares authorized; no shares issued or outstanding | — | — |
| Common stock, \$0.01 par value per share; 125,000,000 shares authorized; 55,681,027 shares and 51,617,639 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively | 557 | 516 |
| Additional paid-in capital | 1,231,726 | 1,033,819 |
| Accumulated other comprehensive income (loss) | 763 | 111 |
| Accumulated deficit | (560,786) | (487,979) |
| Total stockholders' equity | 672,260 | 546,467 |
| Total liabilities and stockholders' equity | <u>\$ 732,927</u> | <u>\$ 622,409</u> |

DECIPHERA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands, except share and per share amounts)

| | <u>Three Months Ended March 31,</u> | |
|--|-------------------------------------|--------------------|
| | <u>2020</u> | <u>2019</u> |
| Revenues | \$ 62 | \$ — |
| Operating expenses: | | |
| Research and development | 51,388 | 35,789 |
| Selling, general, and administrative | 23,936 | 13,236 |
| Total operating expenses | <u>75,324</u> | <u>49,025</u> |
| Loss from operations | <u>(75,262)</u> | <u>(49,025)</u> |
| Other income (expense): | | |
| Interest and other income, net | 2,455 | 1,654 |
| Interest expense | — | (13) |
| Total other income (expense), net | <u>2,455</u> | <u>1,641</u> |
| Net loss | <u>\$ (72,807)</u> | <u>\$ (47,384)</u> |
| Net loss per share—basic and diluted | <u>\$ (1.36)</u> | <u>\$ (1.25)</u> |
| Weighted average common shares outstanding—basic and diluted | 53,567,434 | 38,057,018 |

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