

**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 4, 2021

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 2.02 Results of Operations and Financial Condition.

On May 4, 2021, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 2021 and other corporate updates. 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.

The following exhibit relating to Item 2.02 of this Form 8-K shall be deemed to be furnished and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on May 4, 2021
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: May 4, 2021

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter

Name: Steven L. Hoerter

Title: President and Chief Executive Officer



Deciphera Pharmaceuticals, Inc. Announces First Quarter 2021 Financial Results

- *First Quarter 2021 QINLOCK® Net Product Revenue of \$20.0 Million; QINLOCK Approved in China and Hong Kong for Fourth-line GIST -*
 - *Top-line Results from INTRIGUE Phase 3 Study of QINLOCK in Patients with Second-line GIST Expected in the Fourth Quarter of 2021; Plans to Initiate a Phase 1b/2 Study of QINLOCK in Combination with Binimetinib in Patients with Post-Imatinib GIST -*
 - *Updated Data from Phase 1b/2 Study of Rebastinib in Combination with Paclitaxel in Patients with Endometrial Cancer to be Presented at ASCO -*
 - *Initiation of Phase 1 Study of DCC-3116, Potential First-in-Class ULK Kinase Inhibitor for the Treatment of Patients with Mutant RAS and RAF Cancers, Expected in the Second Quarter of 2021 –*
- *Company to Host Conference Call Today at 4:30 PM ET –*

Waltham, MA – May 4, 2021 – Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced financial results for the first quarter ended March 31, 2021, and provided a corporate update.

“We are excited by the continuing successful commercial launch of QINLOCK in the U.S. as we solidify its position among GIST prescribers and patients and expand access to this important medicine globally. We also remain focused on realizing QINLOCK’s potential in earlier lines of therapy,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “We expect the INTRIGUE Phase 3 top-line results in the fourth quarter of this year and believe QINLOCK has the potential to transform the treatment of GIST for this larger, second-line patient population. Building on our commitment to fully explore the potential of QINLOCK to benefit patients with GIST, we are excited to announce today our plans to initiate a Phase 1b/2 study combining QINLOCK with binimetinib, an approved MEK inhibitor. Our enthusiasm for this combination is based on compelling pre-clinical data showing that this combination can induce apoptosis and has the potential to deepen and prolong responses.”

Mr. Hoerter continued, “We remain very pleased with the progress and growth for the balance of our pipeline, including the upcoming initiation of the Phase 1 study for our potential first-in-class ULK kinase inhibitor, DCC-3116, in patients with cancers driven by mutant RAS or RAF genes. We look forward to presenting updated data from both the vimseltinib and rebastinib programs in the coming months and plan to finalize registration-enabling studies for both programs before the end of the year.”

First Quarter 2021 Highlights and Upcoming Milestones

- **QINLOCK (ripretinib)**
 - Recorded \$20.0 million in QINLOCK net product revenue in the first quarter of 2021, including \$19.3 million in U.S. net product revenue.
 - Received approval in China from the China National Medical Products Administration (NMPA) and from the Hong Kong Department of Health, via our collaboration with Zai Lab, for the treatment of adult patients with fourth-line gastrointestinal stromal tumors (GIST).
 - Expects potential approval from the European Medicines Agency (EMA) for QINLOCK in the fourth quarter of 2021.
 - Expects to announce top-line results from the INTRIGUE Phase 3 study in the fourth quarter of 2021.

- Expects to present data for QINLOCK patients undergoing intra-patient dose escalation after disease progression in the INVICTUS Phase 3 study at the American Society of Clinical Oncology (ASCO) Annual Meeting in June.
- Today announced that the Company plans to initiate a Phase 1b/2 study of QINLOCK in combination with binimetinib, an approved MEK inhibitor, to address one of the potential mechanisms of resistance to kinase inhibition, reactivation of the MAPK pathway, in post-imatinib GIST patients.
 - A publication supporting this approach was recently published online by *Molecular Cancer Therapeutics*. The results showed that treatment with QINLOCK in combination with MEK inhibitors effectively induced and enhanced apoptotic responses and prevented growth of resistant colonies in both imatinib-sensitive and -resistant GIST cell lines.
- **Vimseltinib**
 - Expects to present updated data from the ongoing Phase 1/2 study in patients with tenosynovial giant cell tumor (TGCT) in the third quarter of 2021.
 - Plans to finalize the pivotal development plan for vimseltinib in TGCT in the second half of 2021.
- **Rebastinib**
 - Expects to present updated data from the ongoing Phase 1b/2 study of rebastinib in combination with paclitaxel in the endometrial cancer cohort at the ASCO Annual Meeting in June.
 - Expects to present updated data from the ongoing Phase 1b/2 study of rebastinib in combination with paclitaxel in the platinum-resistant ovarian cancer cohort in the third quarter of 2021.
 - Plans to finalize the pivotal development plan for rebastinib in combination with paclitaxel in the second half of 2021.
- **DCC-3116**
 - Expects to initiate the Phase 1, multicenter, open-label, first-in-human study of DCC-3116 in the second quarter of 2021. The study will evaluate DCC-3116 as a single agent and in combination with trametinib in patients with advanced or metastatic tumors with a mutant RAS or RAF gene. Currently, expansion cohorts are planned in patients with advanced or metastatic pancreatic ductal adenocarcinoma with KRAS or BRAF mutations, non-small cell lung cancer with KRAS, NRAS, or BRAF mutations, colorectal cancer with KRAS, NRAS, or BRAF mutations, and melanoma with NRAS or BRAF mutations.

Upcoming Scientific Congress Presentations

- **2021 ASCO Annual Meeting, June 4-8.** E-poster presentations will be available on-demand via the ASCO Meeting Library beginning on Friday, June 4 at 9:00 AM ET.
 - **QINLOCK**
 - E-poster presentation: Intra-patient dose escalation (IPDE) of ripretinib after disease progression in patients with advanced gastrointestinal stromal tumor (GIST): Analyses from the phase 3 INVICTUS study.
 - **Rebastinib**
 - E-poster presentation: Open-label, multicenter, phase 1b/2 study of rebastinib in combination with paclitaxel to assess safety and efficacy in patients with advanced or metastatic endometrial cancer.



First Quarter Financial Results

- **Revenue:** Total revenue for the first quarter of 2021 was \$25.2 million, which includes \$20.0 million of net product revenue from sales of QINLOCK and \$5.2 million of collaboration revenue. Net product revenues for the first quarter of 2021 included U.S. sales of QINLOCK of \$19.3 million and ex-U.S. sales of QINLOCK of \$0.7 million. The Company also recognized \$5.0 million in collaboration revenue under its license agreement with Zai Lab based on the approval of QINLOCK in China. In the first quarter of 2020, the Company did not generate product revenue.
- **Cost of Sales:** Cost of sales were \$0.2 million in the first quarter of 2021. There were no cost of sales in the first quarter of 2020 as no product sales were generated during that period. Cost of sales will not be significant until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold.
- **R&D Expenses:** Research and development expenses for the first quarter were \$55.7 million, compared to \$51.4 million for the same period in 2020. The increase was primarily due to personnel and preclinical costs, partially offset by a decrease in clinical trial expenses related to the INTRIGUE Phase 3 study in second-line GIST and the INVICTUS Phase 3 study in fourth-line and fourth-line plus GIST. Non-cash, stock-based compensation was \$5.0 million and \$3.3 million for the first quarters of 2021 and 2020, respectively.
- **SG&A Expenses:** Selling, general and administrative expenses for the first quarter of 2021 were \$30.7 million, compared to \$23.9 million for the same period in 2020. The increase was primarily due to personnel costs as well as external spend related to professional fees, including those associated with establishing a targeted commercial infrastructure in key European markets to support a potential launch of QINLOCK in Europe, if approved. Non-cash, stock-based compensation was \$6.2 million and \$3.7 million for the first quarters of 2021 and 2020, respectively.
- **Net Loss:** For the first quarter of 2021, Deciphera reported a net loss of \$61.3 million, or \$1.06 per share, compared with a net loss of \$72.8 million, or \$1.36 per share, for the same period in 2020. The decrease in net loss was primarily a result of product sales during the first quarter of 2021, partially offset by an increase in R&D and SG&A expenses as described above.
- **Cash Position:** As of March 31, 2021, cash, cash equivalents and marketable securities were \$502.2 million, compared to \$561.3 million as of December 31, 2020. Based on its current operating plans, Deciphera expects its current cash, cash equivalents, and marketable securities together with anticipated product and royalty revenues, but excluding any potential future milestone payments or other payments under its collaboration or license agreements, will enable the Company to fund its operating and capital expenditures into the first half of 2023.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, May 4, 2021 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 5470938. 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 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 Australia, Canada, China, and Hong Kong. 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 Phase 3 INTRIGUE study in second-line GIST, expanding access to QINLOCK globally, the potential of QINLOCK in earlier lines of therapy such as second-line GIST and the potential to transform the treatment for such patients, plans to initiate a phase 1b/2 study of QINLOCK with a MEK inhibitor in post-imatinib GIST patients and the potential for a deeper and prolonged response, plans to present data on patients undergoing intra-patient dose escalation following disease progression from the phase 3 INVICTUS study, potential EMA approval of QINLOCK for the treatment of fourth-line GIST, finalizing pivotal study plans for vimseltinib (DCC-3014) in TGCT patients and for the rebastinib/paclitaxel combination, presenting updated data from the Phase 1/2 study of vimseltinib (DCC-3014) in TGCT patients, presenting updated data from the Phase 1b/2 study of rebastinib in combination with paclitaxel for patients with endometrial cancer and also from patients with platinum-resistant ovarian cancer, initiating a phase 1 study of DCC-3116 in patients with cancers driven by mutant RAS/RAF genes; and cash runway expectations. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “seek,” “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, comments, feedback and 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, our ability to build and scale our operations to support growth in additional geographies, 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 March 31, 2021, 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 and the Deciphera logo are trademarks, of Deciphera Pharmaceuticals, LLC.



Deciphera Pharmaceuticals, Inc.

Consolidated Balance Sheets

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 201,648	\$ 135,897
Short-term marketable securities	300,527	416,033
Accounts receivable, net	21,821	13,896
Inventory	7,090	5,716
Prepaid expenses and other current assets	15,546	12,489
Total current assets	546,632	584,031
Long-term marketable securities	—	9,375
Long-term investments—restricted	3,102	3,102
Property and equipment, net	9,633	9,583
Operating lease assets	35,879	36,341
Total assets	<u>\$ 595,246</u>	<u>\$ 642,432</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,905	\$ 12,308
Accrued expenses and other current liabilities	49,344	55,227
Operating lease liabilities	2,540	2,457
Total current liabilities	63,789	69,992
Operating lease liabilities, net of current portion	28,444	28,764
Total liabilities	<u>92,233</u>	<u>98,756</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 125,000,000 shares authorized; 57,901,020 shares and 57,596,144 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	579	576
Additional paid-in capital	1,318,157	1,297,557
Accumulated other comprehensive income (loss)	43	11
Accumulated deficit	(815,766)	(754,468)
Total stockholders' equity	<u>503,013</u>	<u>543,676</u>
Total liabilities and stockholders' equity	<u>\$ 595,246</u>	<u>\$ 642,432</u>



Deciphera Pharmaceuticals, Inc.

Consolidated Statements of Operations and Comprehensive Loss
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Product revenues, net	\$ 19,962	\$ —
Collaboration revenues	5,194	62
Total revenues	25,156	62
Cost and operating expenses:		
Cost of sales	222	—
Research and development	55,681	51,388
Selling, general, and administrative	30,747	23,936
Total cost and operating expenses	86,650	75,324
Loss from operations	(61,494)	(75,262)
Other income (expense):		
Interest and other income, net	196	2,455
Total other income (expense), net	196	2,455
Net loss	\$ (61,298)	\$ (72,807)
Net loss per share—basic and diluted	\$ (1.06)	\$ (1.36)
Weighted average common shares outstanding—basic and diluted	57,747,168	53,567,434

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