

**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 3, 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 August 3, 2021, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended June 30, 2021 and other business highlights. 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 Current Report on 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 August 3, 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: August 3, 2021

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter

Name: Steven L. Hoerter

Title: President and Chief Executive Officer



Deciphera Pharmaceuticals, Inc. Announces Second Quarter 2021 Financial Results

- Second Quarter 2021 QINLOCK® Net Product Revenue of \$22.0 Million -

- Top-line Results from INTRIGUE Phase 3 Study of QINLOCK in Patients with Second-line Gastrointestinal Stromal Tumor (GIST) Expected in the Fourth Quarter of 2021 -

- First Patient Treated in Phase 1 Study of ULK Kinase Inhibitor DCC-3116 -

- Data from Vimseltinib in Patients with Tenosynovial Giant Cell Tumor (TGCT) and Rebastinib in Combination with Paclitaxel in Platinum-Resistant Ovarian Cancer to be Presented at the ESMO Congress 2021; Finalization of Pivotal Development Plans for both Programs Expected in the Second Half of 2021 -

Waltham, MA – August 3, 2021 – Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced financial results for the first quarter ended June 30, 2021 and provided a corporate update.

“We made significant progress against our goals in the first half of the year and we look forward to carrying this momentum through the rest of 2021,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “Building on the successful launch of QINLOCK for fourth-line GIST in the U.S., this best-in-class medicine has now been approved in China and Hong Kong and we expect approval from the European Medicines Agency later this year. In the fourth quarter, we look forward to reporting top-line data from the INTRIGUE Phase 3 study in second-line GIST. In addition, we expect to report updated data from the vimseltinib and rebastinib programs at the upcoming ESMO congress as well as finalize pivotal development plans for both programs later this year.”

Mr. Hoerter continued, “We also recently achieved a key milestone treating the first patient in our Phase 1 trial of DCC-3116, a first-in-class ULK kinase inhibitor designed to address mutant RAS and RAF cancers through the inhibition of autophagy.”

Second Quarter 2021 Highlights and Upcoming Milestones

- **QINLOCK (riporetinib)**
 - Recorded \$22.0 million in QINLOCK net product revenue in the second quarter of 2021, including \$20.7 million in U.S. sales of QINLOCK and \$1.3 million in ex-U.S. sales of QINLOCK.
 - Launched commercially in China, via our collaboration with Zai, for the treatment of adult patients with fourth-line GIST.
 - Presented 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.
 - Expects to announce top-line results from the INTRIGUE Phase 3 study in the fourth quarter of 2021.
 - Expects potential approval from the European Medicines Agency (EMA) for QINLOCK in the fourth quarter of 2021.



- Expects to initiate a Phase 1b/2 study of QINLOCK in combination with binimetinib, a commercially available MEK inhibitor, in post-imatinib GIST patients in the fourth quarter of 2021.
- **Vimseltinib**
 - Expects to present updated data from the ongoing Phase 1/2 study in patients with TGCT at the European Society for Medical Oncology (ESMO) Congress 2021 in September.
 - Plans to finalize the pivotal development plan for vimseltinib in patients with 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 platinum-resistant ovarian cancer cohort at the ESMO Congress 2021 in September.
 - Plans to finalize the pivotal development plan for rebastinib in combination with paclitaxel in the second half of 2021.
- **DCC-3116**
 - Initiated the Phase 1 study of DCC-3116 in June 2021. The study is evaluating 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.
 - Expects to present preclinical data on DCC-3116 in combination with approved, targeted oncology agents in multiple tumor models at an upcoming medical meeting in the second half of 2021.

Recent Corporate Updates

- Today announced an agreement with Sprint Bioscience to exclusively in-license worldwide rights to a research-stage program targeting VPS34, a key kinase in the autophagy pathway, strengthening the company's leading position in the development of regulators of autophagy for the potential treatment of cancer. VPS34 is involved in the endosomal trafficking of cellular cargo targeted for lysosomal degradation in cancer cells. Targeting VPS34 may provide an additional approach to regulating autophagy that is complementary to inhibition of ULK kinase by blocking VPS34-mediated immunosuppression in tumors.

Upcoming Scientific Congress Presentations

- **ESMO Congress 2021, September 16-21.** The following will be e-poster presentations and will be available on-demand via the ESMO Congress 2021 website beginning on September 16 at 8:30 AM CEST / 2:30 AM EST.
 - **QINLOCK**
 - Ripretinib as 3rdth-line treatment in patients with advanced gastrointestinal stromal tumor: long-term update from the Phase 3 INVICTUS study.



- Phase 1 study of ripretinib, a broad-spectrum KIT and PDGFRA inhibitor, in patients with KIT-mutated or KIT-amplified melanoma.
- **Vimseltinib**
 - Safety and preliminary efficacy of vimseltinib in tenosynovial giant cell tumor (TGCT).
- **Rebastinib**
 - A Phase 1b/2 study of rebastinib and paclitaxel in advanced/metastatic platinum-resistant ovarian cancer.

Second Quarter Financial Results

- **Revenue:** Total revenue for the second quarter of 2021 was \$23.6 million, which includes \$22.0 million of net product revenue from sales of QINLOCK and \$1.5 million of collaboration revenue comprised of commercial supply and royalty revenue under our license agreement with Zai Lab. Total revenue for the second quarter of 2020 was \$7.1 million, which includes \$4.8 million of net product revenue from sales of QINLOCK and \$2.3 million of collaboration revenue.
- **Cost of Sales:** Cost of sales was \$1.3 million in the second quarter of 2021, which includes \$0.4 million in cost of net product revenue for QINLOCK and \$0.9 million in cost of collaboration revenue. Cost of sales was less than \$0.1 million for the second quarter of 2020. Cost of net product sales is not expected to 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 second quarter were \$60.0 million, compared to \$46.1 million for the same period in 2020. The increase was primarily due to personnel and preclinical costs and an increase in clinical trial expenses related to our ongoing Phase 1/2 study of vimseltinib. Non-cash, stock-based compensation was \$5.6 million and \$5.3 million for the second quarters of 2021 and 2020, respectively.
- **SG&A Expenses:** Selling, general, and administrative expenses for the second quarter of 2021 were \$32.8 million, compared to \$29.9 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 \$6.8 million and \$5.3 million for the first quarters of 2021 and 2020, respectively.
- **Net Loss:** For the second quarter of 2021, Deciphera reported a net loss of \$70.4 million, or \$1.21 per share, compared with a net loss of \$67.2 million, or \$1.20 per share, for the same period in 2020. The increase in net loss was primarily a result of increased R&D expenses, as described above, partially offset by a full quarter of product sales during the second quarter of 2021.



- **Cash Position:** As of June 30, 2021, cash, cash equivalents, and marketable securities were \$451.0 million, compared to \$502.2 million as of March 31, 2021. Based on its current operating plans, Deciphera expects its current cash, cash equivalents, and marketable securities together with anticipated product and royalty revenues, 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, August 3, 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 9943767. 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 and timing regarding top-line data from our Phase 3 INTRIGUE study in second-line GIST, plans to initiate a phase 1b/2 study of QINLOCK with a MEK inhibitor in post-imatinib GIST patients, potential EMA approval of QINLOCK for the treatment of fourth-line GIST, finalizing pivotal study plans for vimseltinib in TGCT patients and for the rebastinib/paclitaxel combination, subject to favorable data and discussions with regulators, presenting updated data at ESMO 2021 from the Phase 1/2 study of vimseltinib in TGCT patients and from the Phase 1b/2 study of rebastinib in combination with paclitaxel for patients with platinum-resistant ovarian cancer, presenting e-posters at ESMO 2021 on several other programs, presenting preclinical data on DCC-3116 in combination with approved agents in multiple tumor models, planned expansion of our phase 1 study of DCC-3116 in patients with cancers driven by mutant RAS/RAF genes; the company’s leading position in the development of regulators of autophagy for the potential treatment of cancer and our belief that targeting VPS34 may provide an additional approach to regulating autophagy that is complementary to inhibition of ULK kinase by blocking VPS34-mediated immunosuppression in tumors, 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 June 30, 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)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 90,947	\$ 135,897
Short-term marketable securities	304,405	416,033
Accounts receivable, net	18,608	13,896
Inventory	8,206	5,716
Prepaid expenses and other current assets	14,977	12,489
Total current assets	437,143	584,031
Long-term marketable securities	55,605	9,375
Long-term investments—restricted	3,102	3,102
Property and equipment, net	9,588	9,583
Operating lease assets	35,128	36,341
Total assets	<u>\$ 540,566</u>	<u>\$ 642,432</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 14,022	\$ 12,308
Accrued expenses and other current liabilities	49,428	55,227
Operating lease liabilities	2,604	2,457
Total current liabilities	66,054	69,992
Operating lease liabilities, net of current portion	27,856	28,764
Total liabilities	<u>93,910</u>	<u>98,756</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value per share; 125,000,000 shares authorized; 58,033,984 shares and 57,596,144 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	580	576
Additional paid-in capital	1,332,249	1,297,557
Accumulated other comprehensive income (loss)	26	11
Accumulated deficit	(886,199)	(754,468)
Total stockholders' equity	446,656	543,676
Total liabilities and stockholders' equity	<u>\$ 540,566</u>	<u>\$ 642,432</u>



Deciphera Pharmaceuticals, Inc.
Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Revenues:				
Product revenues, net	\$ 22,048	\$ 4,825	\$ 42,010	\$ 4,825
Collaboration revenues	1,525	2,265	6,719	2,327
Total revenues	<u>23,573</u>	<u>7,090</u>	<u>48,729</u>	<u>7,152</u>
Cost and operating expenses:				
Cost of sales	1,275	8	1,497	8
Research and development	59,984	46,081	115,665	97,469
Selling, general, and administrative	32,828	29,933	63,575	53,869
Total cost and operating expenses	<u>94,087</u>	<u>76,022</u>	<u>180,737</u>	<u>151,346</u>
Loss from operations	<u>(70,514)</u>	<u>(68,932)</u>	<u>(132,008)</u>	<u>(144,194)</u>
Other income (expense):				
Interest and other income, net	81	1,691	277	4,146
Total other income (expense), net	<u>81</u>	<u>1,691</u>	<u>277</u>	<u>4,146</u>
Net loss	<u>\$ (70,433)</u>	<u>\$ (67,241)</u>	<u>\$ (131,731)</u>	<u>\$ (140,048)</u>
Net loss per share—basic and diluted	<u>\$ (1.21)</u>	<u>\$ (1.20)</u>	<u>\$ (2.28)</u>	<u>\$ (2.56)</u>
Weighted average common shares outstanding—basic and diluted	<u>57,987,095</u>	<u>55,920,122</u>	<u>57,867,795</u>	<u>54,743,778</u>