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 9, 2023

Deciphera Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38219**	**30-1003521**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Smith Street, Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(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 9, 2023, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended June 30, 2023 and provided a corporate update. 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.

99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on August 9, 2023
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 9, 2023

DECIPHERA PHARMACEUTICALS, INC.

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

Exhibit 99.1

Deciphera Pharmaceuticals Announces Second Quarter 2023 Financial Results

– Second Quarter 2023 Total Revenue of $38.3 Million; Net Product Revenue for QINLOCK® (ripretinib) Increased 18% to $37.3 Million Compared to Second Quarter 2022 –

– Top-line Results for MOTION Pivotal Phase 3 Study of Vimseltinib Expected in Fourth Quarter 2023 –

– INSIGHT Pivotal Phase 3 Study of QINLOCK in Second-line GIST Patients with Mutations in KIT Exon 11 and 17/18 Initiated with First Sites Open for Enrollment –

– DCC-3116 Combination Escalation Cohorts with QINLOCK and with Encorafenib and Cetuximab Initiated with First Site Open for Enrollment; Combination Dose Escalation Cohorts with MEK and KRAS G12C Inhibitors Ongoing –

WALTHAM, Mass.— (BUSINESS WIRE)—August 9, 2023—Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer, today announced financial results for the second quarter ended June 30, 2023 and provided a corporate update.

“QINLOCK delivered record performance in the second quarter based on continued growth in the U.S. and around the world. Moving into a significant second half of 2023, we are looking forward to the top-line results from the MOTION study of vimseltinib in patients with tenosynovial giant cell tumor (TGCT), which has the potential to become our second approved medicine,” said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. “Additionally, we have opened the first sites for INSIGHT, the pivotal Phase 3 study of QINLOCK versus sunitinib in second-line gastrointestinal stromal tumor (GIST) patients with mutations in KIT exon 11 and 17 or 18 and for additional combination cohorts of our ULK inhibitor DCC-3116, one in combination with QINLOCK and another in combination with encorafenib and cetuximab. We are on track to submit an Investigational New Drug application to the FDA for DCC-3084, a potential best-in-class pan-RAF inhibitor, in the fourth quarter.”

Mr. Hoerter continued, “We are proud of the significant progress across both our early-stage and late-stage programs that we have already achieved in the first half of 2023. In addition to the INTRIGUE Phase 3 ctDNA analysis presented at the ASCO Plenary Session in the first quarter, we also presented eight poster presentations at AACR that showcased the depth and breadth of our kinase switch-control research engine along with the nomination of our newest development candidate, DCC-3009, a potential best-in-class pan-KIT inhibitor. At ASCO in June, we had one encore presentation of our INTRIGUE Phase 3 ctDNA analysis and three poster presentations, including overall survival and long-term safety data from the INTRIGUE Phase 3 study of QINLOCK. Finally, on behalf of everyone at Deciphera, I would like to thank Dan Flynn for his dedication to Deciphera’s founding vision of improving the lives of people with cancer, and for trailblazing the innovations that have made all these advancements possible. We are excited to build upon this foundation with Dash Dhanak as our new Chief Scientific Officer.”

Second Quarter 2023 Highlights and Upcoming Milestones

QINLOCK® (ripretinib)

- Recorded $37.3 million in QINLOCK net product revenue in the second quarter of 2023, including $28.9 million in U.S. net product revenue and $8.4 million in international net product revenue, an increase of 18% compared to net product revenue of $31.5 million in the second quarter of 2022. In addition, QINLOCK generated $1.0 million in collaboration revenue driven by royalties for sales of QINLOCK by Zai Lab, the Company's partner in Greater China.
- Presented one encore presentation and three poster presentations at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting featuring an update from the ASCO Plenary Series Session presenting circulating tumor DNA (ctDNA) analysis results from the INTRIGUE Phase 3 study of QINLOCK, updated overall survival (OS) and long-term safety results, and outcome data on patients without detectable ctDNA at baseline from the INTRIGUE Phase 3 study of QINLOCK in patients with advanced GIST previously treated with imatinib, and information on the study design for the upcoming INSIGHT pivotal Phase 3 study of QINLOCK versus sunitinib in second-line GIST patients with KIT exon 11 and 17/18 mutations.
- Initiated the INSIGHT Phase 3 study by opening the first sites for enrollment comparing QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18.
- Completed reimbursement negotiations process in Italy; launch expected shortly. Completed negotiations with the pan-Canadian Pharmaceutical Alliance (pCPA) in April 2023, which will enable broad access to fourth-line GIST patients in Canada.
- Received regulatory approval for QINLOCK in Singapore in May 2023.

Vimseltinib

- Expects to announce top-line results from the MOTION pivotal Phase 3 study of vimseltinib, an investigational, orally administered, potent, and highly selective switch-control kinase inhibitor of CSF1R for the potential treatment of tenosynovial giant cell tumor (TGCT) in the fourth quarter of 2023.
- Expects to present updated data from the Phase 1/2 study of vimseltinib in the fourth quarter of 2023.

DCC-3116

- Presented preclinical data on combinations with DCC-3116, an investigational, orally administered, selective, and potent switch-control kinase inhibitor of ULK1/2-mediated autophagy, at the American Association for Cancer (AACR) Annual Meeting 2023, including preclinical models in combination with QINLOCK in GIST models and with encorafenib and cetuximab in colorectal cancer (CRC) models.
- Completed the Phase 1 single agent dose escalation (n=28) of DCC-3116 at doses from 50 mg—300 mg BID; no maximum tolerated dose was reached with one dose limiting toxicity (DLT) observed (Grade 3 increased ALT at 100 mg BID) and no treatment-related serious adverse events observed.
    - As of August 4, 2023, combination dose escalations of DCC-3116 are ongoing with MEK inhibitors trametinib (n=11) and binimetinib (n=10), and with KRAS G12C inhibitor, sotorasib (n=6) in patients with advanced solid tumors. Evaluation of trametinib and binimetinib cohorts in combination with 50 mg QD of DCC-3116 is ongoing after dose reduction from 50 mg BID based on observed DLTs for the trametinib combination (Grade 3 skin rash and diarrhea in one patient and Grade 3 diarrhea in one patient) and the binimetinib combination (Grade 3 decreased ejection fraction in one patient and Grade 2 blurred vision in one patient).

- Evaluation of sotorasib cohort in combination with 200 mg QD of DCC-3116 is ongoing; combination of sotorasib and DCC-3116 at 50 mg BID was well tolerated with no DLTs observed in three evaluable patients.

- Initiated new combination escalation cohorts with the first site open for enrollment evaluating DCC-3116 (100 mg QD starting dose) in combination with QINLOCK in patients with GIST and in combination with encorafenib and cetuximab in patients with CRC. Under the terms of the clinical trial collaboration and supply agreement with Pfizer, Inc., Deciphera will sponsor the study and Pfizer will supply encorafenib at no cost.

DCC-3084

- Presented preclinical data for DCC-3084, a pan-RAF inhibitor, at the AACR Annual Meeting 2023, which demonstrated a potential best-in-class profile based on its inhibition of Class I, II, and III BRAF mutations, and BRAF fusions, and optimized pharmaceutical properties.
- Expects to submit an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) for DCC-3084 in the fourth quarter of 2023.

DCC-3009

- Presented preclinical data for DCC-3009, a potential best-in-class pan-KIT inhibitor, at the AACR Annual Meeting 2023, which demonstrated its ability to potently and selectively inhibit the broad spectrum of known primary and secondary drug-resistant mutations in GIST models, spanning KIT exons 9, 11, 13, 14, 17, and 18.
- Expects to submit an IND to the FDA for DCC-3009 in the first half of 2024.

Kinase Switch-Control Research Engine

- Presented new preclinical data in eight poster presentations at the AACR Annual Meeting 2023 from development candidates DCC-3116 (ULK), DCC-3084 (pan-RAF), DCC-3009 (pan-KIT) and research programs focused on GCN2 and PERK, novel targets in the integrated stress response pathway.

Corporate Update

- Announced that the Company's Founder, Executive Vice President, and Chief Scientific Officer, Daniel L. Flynn, Ph.D., will retire effective September 5, 2023, and will transition to a role as Senior Advisor to the Company. Dashyant Dhanak, Ph.D., has been appointed Executive Vice President and Chief Scientific Officer effective September 5, 2023. Dr. Dhanak brings over 30 years of experience in pharmaceutical research and discovery including most recently as Executive Vice President and Chief Scientific Officer at Incyte Corporation.
- Announced that Ron Squarer has been appointed Chairperson of the Board of Directors. Mr. Squarer has over 30 years of experience in the pharmaceutical and biotechnology industry and joined Deciphera as a Director in December 2019. James A. Bristol, Ph.D., who has served as either Chairperson or Co-Chairperson since 2007, will remain a Board member of Deciphera.

Second Quarter 2023 Financial Results

- **Revenue:** Total revenue for the second quarter of 2023 was $38.3 million, which includes $37.3 million of net product revenue of QINLOCK and $1.0 million of collaboration revenue compared to $32.5 million of total revenue, including $31.5 million of net product revenue of QINLOCK and $1.0 million of collaboration revenue, for the same period in 2022.

- **Cost of Sales:** Cost of sales were $0.2 million in the second quarter of 2023 compared to cost of sales of $1.8 million for the second quarter of 2022. In the third quarter of 2022, Deciphera completed the sale of zero cost inventories of QINLOCK that had been expensed prior to FDA approval.
- **R&D Expenses:** Research and development expenses for the second quarter of 2023 were $58.3 million, compared to $44.9 million for the same period in 2022. The increase was primarily due to an increase in clinical study costs related to the Phase 1/2 study of DCC-3116, the MOTION Phase 3 study and Phase 1 /2 study of vimseltinib, and clinical study costs for QINLOCK. Non-cash, stock-based compensation was $5.7 million and $5.4 million for the second quarters of 2023 and 2022, respectively.
- **SG&A Expenses:** Selling, general, and administrative expenses for the second quarter of 2023 were $32.6 million, compared to $29.6 million for the same period in 2022. The increase was primarily due to an increase in professional, consulting, and other expenses as well as personnel-related costs. Non-cash, stock-based compensation was $7.1 million and $7.6 million for the second quarters of 2023 and 2022, respectively.
- **Net Loss:** For the second quarter of 2023, Deciphera reported a net loss of $48.6 million, or $0.57 per share, compared with a net loss of $43.1 million, or $0.60 per share, for the same period in 2022.
- **Cash Position:** As of June 30, 2023, cash, cash equivalents, and marketable securities were $389.4 million, compared to $426.3 million as of March 31, 2023. Based on its current operating plans, Deciphera expects its current cash, cash equivalents, and marketable securities together with anticipated product, royalty, and supply revenues, but excluding any potential future milestone payments under its collaboration or license agreements, will enable the Company to fund its operating and capital expenditures into 2026.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, August 9, 2023, at 8:00 AM ET. The conference call may be accessed via this link: https://register.vevent.com/register/BI74ff2d04fe8541f48da1cf0ad35339ae. A live webcast of the conference call will be available in the “Events and Presentations” page in the “Investors & News” section of the Company’s website at https://investors.deciphera.com/events-presentations. A replay will be available on the Company’s website approximately two hours after the conference call and will be available for 30 days following the call.

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 switch-control inhibitor for the treatment of fourth-line GIST. QINLOCK is approved in Australia, Canada, China, the European Union, Hong Kong, Israel, Macau, New Zealand, Singapore, Switzerland, Taiwan, the United Kingdom, and the United States. 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 the potential for our preclinical and/or clinical stage pipeline assets to be first-in-class and/or best-in-class treatments; our Phase 3 INSIGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18; plans to announce top-line results from the pivotal Phase 3 MOTION study of vimseltinib in TGCT patients in the fourth quarter of 2023 and the potential for vimseltinib to become our second approved medicine; plans to present updated data from the phase 1/2 study of vimseltinib in TGCT patients in the fourth quarter of 2023; plans for our ongoing phase 1/2 studies of DCC-3116; and cash guidance. 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, our ability to successfully demonstrate the efficacy and safety of our drug or drug candidates, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, 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, 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 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, 2023, 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.

Deciphera Pharmaceuticals, Inc.

Consolidated Balance Sheets

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 81,394	$ 64,741
Short-term marketable securities	247,346	259,745
Accounts receivable, net	23,200	22,429
Inventory	25,343	20,561
Prepaid expenses and other current assets	27,767	25,482
Total current assets	405,050	392,958
Long-term marketable securities	60,683	14,550
Long-term investments—restricted and other long-term assets	3,339	3,277
Property and equipment, net	6,213	6,707
Operating lease assets	34,333	36,547
Total assets	$ 509,618	$ 454,039
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 18,211	$ 18,612
Accrued expenses and other current liabilities	59,455	64,622
Operating lease liabilities	3,368	3,235
Total current liabilities	81,034	86,469
Operating lease liabilities, net of current portion	24,154	25,879
Total liabilities	105,188	112,348
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; 78,772,870 shares and 67,637,351 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	788	676
Additional paid-in capital	1,736,143	1,575,361
Accumulated other comprehensive income (loss)	(967)	(983)
Accumulated deficit	(1,331,534)	(1,233,363)
Total stockholders' equity	404,430	341,691
Total liabilities and stockholders' equity	$ 509,618	$ 454,039

Deciphera Pharmaceuticals, Inc.

Consolidated Statements of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenues:				
Product revenues, net	$ 37,320	$ 31,497	$ 70,542	$ 60,306
Collaboration revenues	984	997	1,207	1,411
Total revenues	38,304	32,494	71,749	61,717
Cost and operating expenses:				
Cost of sales	173	1,799	661	2,181
Research and development	58,296	44,858	113,061	92,270
Selling, general, and administrative	32,610	29,625	64,059	57,946
Total cost and operating expenses	91,079	76,282	177,781	152,397
Loss from operations	(52,775)	(43,788)	(106,032)	(90,680)
Other income (expense):				
Interest and other income, net	4,213	727	7,861	727
Total other income (expense), net	4,213	727	7,861	727
Net loss	$ (48,562)	$ (43,061)	$ (98,171)	$ (89,953)
Net loss per share—basic and diluted	$ (0.57)	$ (0.60)	$ (1.17)	$ (1.31)
Weighted average common shares outstanding—basic and diluted	85,020,344	72,133,428	83,854,959	68,441,998

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