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 3, 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 May 3, 2023, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 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 May 3, 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: May 3, 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 First Quarter 2023 Financial Results

– First Quarter 2023 Total Revenue of $33.4 Million; Net Product Revenue for QINLOCK® Increased 15% to $33.2 Million Compared to First Quarter 2022 –

– Enrollment Complete in the MOTION Pivotal Phase 3 Study of Vimseltinib; Top-line Results Expected in the Fourth Quarter of 2023 –

– QINLOCK Granted FDA Breakthrough Therapy Designation in Second-line GIST Patients with Mutations in KIT Exon 11 and 17/18 and Included in NCCN Guidelines as a Preferred Regimen for Second-line GIST Patients Intolerant to Sunitinib; INSIGHT Study in Second-line GIST Patients with Mutations in KIT Exon 11 and 17/18 Expected to Initiate in Second Half 2023 –

– Preclinical Data at AACR Supporting DCC-3116 (ULK inhibitor) in Combination with QINLOCK in GIST and in Combination with Encorafenib and Cetuximab in Colorectal Cancer; Two New Combination Escalation Studies Expected to Initiate in Second Half of 2023 –

– Generated Gross Proceeds of Approximately $143.7 Million from Public Offering in January 2023; Cash Expected to Fund Operating and Capital Expenditures into 2026 –

WALTHAM, Mass.— (BUSINESS WIRE)—May 3, 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 first quarter ended March 31, 2023 and provided a corporate update.

“We have had a very strong start to 2023, achieving significant milestones including the completion of enrollment for the MOTION pivotal Phase 3 study of vimseltinib in TCGT patients, presentation of the ctDNA data for QINLOCK in second-line GIST patients with mutations in KIT Exon 11 and 17/18, and receiving Breakthrough Therapy Designation from the FDA for QINLOCK in this patient population,” said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. “These advancements in our late-stage pipeline position us for a catalyst-rich remainder of 2023, in which we expect top-line results from the MOTION study and plan to initiate INSIGHT, the pivotal Phase 3 study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18.”

Mr. Hoerter continued, “We continue to complement this impressive momentum with progress in our early-stage programs, including the recent presentations at AACR, which highlighted the productivity of our kinase switch-control research engine. We were excited to present the preclinical data for DCC-3084, a potential best-in-class pan-RAF inhibitor, and announce the nomination of our newest development candidate, DCC-3009, a potential best-in-class pan-KIT inhibitor. We also presented preclinical data supporting the study of DCC-3116 in combination with QINLOCK in GIST and with encorafenib and cetuximab in colorectal cancer. This encouraging progress demonstrates that, as we work toward becoming a company with multiple approved medicines, our proprietary drug discovery platform continues to fuel our pipeline with innovative, potential first- and best-in-class kinase inhibitors.”

First Quarter 2023 Highlights and Upcoming Milestones

QINLOCK® (ripretinib)

- Recorded $33.2 million in QINLOCK net product revenue in the first quarter of 2023, including $24.6 million in U.S. net product revenue and $8.6 million in international net product revenue, an increase of 15% compared to net product revenue of $28.8 million in the first quarter of 2022.
- Granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumor (GIST) who received prior treatment with imatinib, and who harbor a KIT exon 11 mutation and co-occurring KIT exon 17 and/or 18 mutations. The Company expects to initiate the INSIGHT study in the second half of 2023.
- Included in the latest National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology as a preferred regimen for second-line GIST patients intolerant to sunitinib.
- Will present posters at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting featuring updated overall survival (OS) and outcome data on patients without circulating tumor DNA (ctDNA) at baseline from the INTRIGUE Phase 3 study of QINLOCK in patients with advanced GIST previously treated with imatinib, along with information on the upcoming INSIGHT pivotal Phase 3 study of QINLOCK versus sunitinib in second-line GIST patients with KIT exon 11 and 17/18 mutations.
- Concluded successful price negotiations in Germany. In 2022, QINLOCK received a “major additional benefit” rating from Germany’s Federal Joint Committee (G-BA). QINLOCK is the first orphan oncology treatment in Germany to receive this rating for its lead indication and the only GIST treatment awarded with this recognition.

Vimseltinib

- Completed enrollment for 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) and expects to announce top-line results from the study in the fourth quarter of 2023.
- Expects to present updated data from the Phase 1/2 study of vimseltinib in the second half 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 ripretinib in GIST models and with encorafenib and cetuximab in colorectal cancer (CRC) models.
- Expects to initiate new combination escalation studies evaluating DCC-3116 in combination with ripretinib in patients with GIST and in combination with encorafenib and cetuximab in patients with CRC in the second half of 2023. 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.

- Expects to initiate one or more expansion cohorts in the ongoing Phase 1/2 study of DCC-3116 in the second half of 2023 in combination with the MEK inhibitors trametinib or binimetinib, or the KRAS G12C inhibitor sotorasib.

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, BRAF fusions, and BRAF/CRAF heterodimers, and optimized pharmaceutical properties.
- Expects to submit an investigational new drug (IND) application to the FDA for DCC-3084 in the second half 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 from research programs focused on GCN2 and PERK, novel targets in the integrated stress response pathway, at the AACR Annual Meeting 2023.

Corporate Update

- Announced the closing in January 2023 of its underwritten public offering of 7,986,111 shares of its common stock at a public offering price of $18.00. The aggregate gross proceeds to Deciphera from this offering were approximately $143.7 million, before deducting underwriting discounts and commissions and other estimated offering expenses.

First Quarter 2023 Financial Results

- **Revenue:** Total revenue for the first quarter of 2023 was $33.4 million, which includes $33.2 million of net product revenue of QINLOCK and $0.2 million of collaboration revenue compared to $29.2 million of total revenue, including $28.8 million of net product revenue of QINLOCK and $0.4 million of collaboration revenue, for the same period in 2022.
- **Cost of Sales:** Cost of sales were $0.5 million in the first quarter of 2023, which includes $0.4 million in cost of product sales, compared to cost of sales of $0.4 million for the first 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 first quarter of 2023 were $54.8 million, compared to $47.4 million for the same period in 2022. The increase was primarily due to an increase in clinical study costs related to the MOTION Phase 3 study of vimseltinib, the Phase 1/2 study of DCC-3116, and clinical study costs for QINLOCK, including the Phase 3 INTRIGUE study. Non-cash, stock-based compensation was $5.4 million and $6.3 million for the first quarters of 2023 and 2022, respectively.

- **SG&A Expenses:** Selling, general, and administrative expenses for the first quarter of 2023 were $31.4 million, compared to $28.3 million for the same period in 2022. The increase was primarily due to an increase in professional, consulting, and other expenses, partially offset by a decrease in personnel-related costs. Non-cash, stock-based compensation was $7.0 million and $8.0 million for the first quarters of 2023 and 2022, respectively.
- **Net Loss:** For the first quarter of 2023, Deciphera reported a net loss of $49.6 million, or $0.60 per share, compared with a net loss of $46.9 million, or $0.80 per share, for the same period in 2022.
- **Cash Position:** As of March 31, 2023, cash, cash equivalents, and marketable securities were $426.3 million, compared to $339.0 million as of December 31, 2022. 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, May 3, 2023, at 8:00 AM ET. The conference call may be accessed via this link: https://register.vevent.com/register/BI75fb53c225a648b486e50d922b166468. 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, 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 planned Phase 3 INSIGHT study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18; plans to present posters at the 2023 ASCO Annual Meeting; plans to announce top-line results from the pivotal Phase 3 MOTION study of vimseltinib in TGCT patients in the fourth quarter of 2023; plans to present updated data from the phase 1/2 study of

vimseltinib in TGCT patients in the second half of 2023; plans to initiate one or more expansion cohorts in the Phase 1/2 study of DCC-3116 in the second half of 2023 in combination with trametinib, binimetinib, or sotorasib; plans to initiate two new dose escalation studies evaluating DCC-3116 in combination with ripretinib in GIST patients and in combination with encorafenib and cetuximab in patients with CRC; the anticipated benefits of our collaboration and supply agreement with Pfizer; plans to submit an IND for DCC-3084 in the second half of 2023; plans to submit an IND for DCC-3009 in the first half of 2024; 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 Annual Report on Form 10-K for the year ended December 31, 2022, 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)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 114,637	$ 64,741
Short-term marketable securities	283,996	259,745
Accounts receivable, net	22,439	22,429
Inventory	25,528	20,561
Prepaid expenses and other current assets	29,559	25,482
Total current assets	476,159	392,958
Long-term marketable securities	27,627	14,550
Long-term investments—restricted and other long-term assets	3,277	3,277
Property and equipment, net	6,511	6,707
Operating lease assets	35,445	36,547
Total assets	$ 549,019	$ 454,039
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 19,670	$ 18,612
Accrued expenses and other current liabilities	60,942	64,622
Operating lease liabilities	3,301	3,235
Total current liabilities	83,913	86,469
Operating lease liabilities, net of current portion	25,022	25,879
Total liabilities	108,935	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; 78,507,752 shares and 67,637,351 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	785	676
Additional paid-in capital	1,722,452	1,575,361
Accumulated other comprehensive income (loss)	(181)	(983)
Accumulated deficit	(1,282,972)	(1,233,363)
Total stockholders' equity	440,084	341,691
Total liabilities and stockholders' equity	$ 549,019	$ 454,039

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

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Product revenues, net	$ 33,222	$ 28,809
Collaboration revenues	223	414
Total revenues	33,445	29,223
Cost and operating expenses:		
Cost of sales	488	382
Research and development	54,765	47,412
Selling, general, and administrative	31,449	28,321
Total cost and operating expenses	86,702	76,115
Loss from operations	(53,257)	(46,892)
Other income (expense):		
Interest and other income, net	3,648	—
Total other income (expense), net	3,648	—
Net loss	$ (49,609)	$ (46,892)
Net loss per share—basic and diluted	$ (0.60)	$ (0.80)
Weighted average common shares outstanding—basic and diluted	82,676,624	58,616,458

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