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): February 6, 2024

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 February 6, 2024, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter and fiscal year ended December 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 February 6, 2024
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: February 6, 2024

DECIPHERA PHARMACEUTICALS, INC.

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

Deciphera Pharmaceuticals Announces Fourth Quarter and Full Year 2023 Financial Results

– Fourth Quarter 2023 Total Revenue of $48.3 Million and Full Year 2023 Revenue of $163.4 Million; QINLOCK® Net Product Revenue Increased 27% to $159.1 Million in 2023 Compared to 2022 –

– Expects to Submit NDA for Vimseltinib in the Second Quarter of 2024 and MAA in the Third Quarter of 2024 in Tenosynovial Giant Cell Tumor (TGCT) –

– Results from Exploratory ctDNA Analysis from INTRIGUE Phase 3 Study in 2L GIST Patients with Mutations in KIT Exon 11+17/18 Published in Nature Medicine; Final Overall Survival (OS) Results from INTRIGUE Study in 2L GIST Patients Presented at ASCO GI –

– Cash Expected to Fund Operating and Capital Expenditures into the Second Half of 2026 –

WALTHAM, Mass.—(BUSINESS WIRE)—February 6, 2024—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 fourth quarter and year ended December 31, 2023 and provided a corporate update.

"We are proud of the significant progress we made across our company throughout 2023, particularly in our late-stage programs as we continue on our path to becoming a self-sustaining, fully integrated biotechnology company. I am excited to announce another record quarter of QINLOCK revenue, demonstrating the proven commercial capabilities that position us well as we continue to evolve into a company with multiple approved medicines," said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. "Looking ahead, we plan to build upon this momentum in 2024 as we work to file regulatory submissions for vimseltinib, which has the potential to be a much-needed treatment option for patients with tenosynovial giant cell tumor, continue enrollment of our INSIGHT Phase 3 study of QINLOCK, and progress our early-stage pipeline of potential first- or best-in-class candidates."

Fourth Quarter 2023 and Upcoming Milestones

QINLOCK® (ripretinib)

- Recorded $46.7 million in QINLOCK net product revenue in the fourth quarter of 2023, including $35.3 million in U.S. net product revenue and $11.4 million in international net product revenue, an increase of 42% from net product revenue of $32.9 million in the fourth quarter of 2022.
- Published results in *Nature Medicine* from an exploratory circulating tumor DNA (ctDNA) analysis of the INTRIGUE Phase 3 study demonstrating the substantial clinical benefit of QINLOCK in second line gastrointestinal stromal tumor (GIST) patients with mutations in KIT exon 11 and 17/18.
- Presented final OS results from the INTRIGUE Phase 3 clinical study in second-line GIST patients at the 2024 American Society of Clinical Oncology Gastrointestinal Cancers (ASCO GI) Symposium showing that the median OS was similar with QINLOCK (35.5 months) versus sunitinib (31.5 months) (HR 0.86; 95% CI, 0.65 to 1.13; nominal p= 0.275). Treatment with QINLOCK continued to show a favorable safety profile compared to treatment with sunitinib, with fewer patients

experiencing Grade 3/4 drug-related treatment emergent adverse events with QINLOCK (27.4%) compared with sunitinib (57.9%). The results also showed that patient outcomes in the third line setting were comparable for patients that were treated with either QINLOCK or sunitinib in the second line. The presentation is available on the Company's website at www.deciphera.com/presentations-publications.

- Entered into a supply and distribution agreement with GENESIS Pharma, a leading regional biopharma company, in Central and Eastern Europe under which GENESIS Pharma will be the exclusive distributor of QINLOCK in 14 countries in the European Union with a combined population of 118 million including Czech Republic, Greece, Hungary, Romania, and Poland.
- Continue to enroll the INSIGHT Phase 3 study comparing QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18.

Vimseltinib

- Expects to submit a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the second quarter of 2024 and a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA) in the third quarter of 2024.
- Expects to present additional results from Part 1 of the MOTION pivotal Phase 3 study of vimseltinib at a medical meeting in the second quarter of 2024.
- Expects to present updated results from the Phase 1/2 study of vimseltinib in TGCT in the second half of 2024.
- Expects to initiate a Phase 2 proof-of-concept study of vimseltinib for the treatment of chronic graft versus host disease (cGVHD) in the fourth quarter of 2024.

DCC-3116

- Expects to select a recommended Phase 2 dose for expansion cohort(s) for DCC-3116, an investigational switch-control kinase inhibitor of ULK1/2 designed to inhibit autophagy, in 2024.

DCC-3084

- Expects to initiate a Phase 1 study for DCC-3084, a potential best-in-class pan-RAF inhibitor, in the first half of 2024.

DCC-3009

- Expects to submit an Investigational New Drug (IND) application with the FDA for DCC-3009, a potential best-in-class pan-KIT inhibitor, in the first half of 2024 and initiate a Phase 1 study in the second half of 2024.

Fourth Quarter and Full Year 2023 Financial Results

- **Revenue:** Total revenue for the fourth quarter of 2023 was $48.3 million, which includes $46.7 million of net product revenue of QINLOCK and $1.6 million of collaboration revenue compared to $36.3 million of total revenue, including $32.9 million of net product revenue of QINLOCK and $3.4 million of collaboration revenue, for the same period in 2022. Total revenue for the year ended December 31, 2023 was $163.4 million, which includes $159.1 million of net product revenue of QINLOCK and $4.3 million of collaboration revenue compared to $134.0 million of total revenue, including $125.5 million of net product revenue of QINLOCK and $8.5 million of collaboration revenue, for the same period in 2022.

- **Cost of Sales:** Cost of sales were $1.8 million in the fourth quarter of 2023, which includes $0.9 million in cost of product sales, compared to cost of product sales of $0.7 million for the fourth quarter of 2022. For the year ended December 31, 2023, cost of sales were $3.7 million, including $2.0 million in cost of product sales, compared to cost of sales of $8.7 million in 2022, including cost of product sales of $2.7 million. In the third quarter of 2022, the Company completed the sales of zero cost inventories of QINLOCK that had been expensed prior to FDA approval.
- **R&D Expenses:** Research and development expenses for the fourth quarter of 2023 were $58.6 million, compared to $48.1 million for the same period in 2022, and $234.1 million for the year ended December 31, 2023 compared to $187.8 million for the same period in 2022. The increase was primarily due to higher clinical study costs related to QINLOCK, an increase in clinical study costs related to the Phase 1/2 study of DCC-3116, and the Phase 3 study of vimseltinib. Non-cash, stock-based compensation was $21.8 million and $22.2 million for the year ended December 31, 2023 and 2022, respectively.
- **SG&A Expenses:** Selling, general, and administrative expenses for the fourth quarter of 2023 were $39.1 million, compared to $32.2 million for the same period in 2022 and $136.5 million for the year ended December 31, 2023, compared to $120.2 million for the same period in 2022. The increase was primarily due to an increase in professional and consultant fees and personnel-related costs. Non-cash, stock-based compensation was $28.8 million and $29.7 million for the year ended December 31, 2023 and 2022, respectively.
- **Net Loss:** For the fourth quarter of 2023, Deciphera reported a net loss of $47.2 million, or $0.54 per share, compared with a net loss of $45.9 million, or $0.60 per share, for the same period in 2022. Net loss for the year ended December 31, 2023 was $194.9 million, or $2.29 per share, compared with a net loss of $178.9 million, or $2.37 per share, for the year ended December 31, 2022.
- **Cash Position:** As of December 31, 2023, cash, cash equivalents, and marketable securities were $352.9 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 the second half of 2026.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, February 6, 2024, at 8:00 AM ET. The conference call may be accessed via this link: https://register.vevent.com/register/BI7a0bbbeb53864df9a854d959bbbae709. 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, Iceland, Israel, Liechtenstein, Macau, New Zealand, Norway, Singapore, Switzerland, Taiwan, the United Kingdom, and the United States. For more information, visit www.deciphera.com and follow us on LinkedIn and X (@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, the ability to become a company with multiple approved medicines, plans to continue our geographic expansion of QINLOCK in European and international markets, our Phase 3 INSIGHT clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18, the timing of our NDA and MAA submission for vimseltinib, plans to present additional data from our Phase 3 MOTION study and Phase 1/2 study of vimseltinib, each in TGCT patients, plans to initiate a Phase 2 study of vimseltinib in patients with cGVHD, subject to FDA feedback, plans for our on-going phase 1/2 study of DCC-3116 and to select a recommended Phase 2 dose for expansion cohort(s), subject to favorable data, initiating a Phase 1 study of DCC-3084 in the first half of 2024, and submitting an IND for DCC-3009 in the first half of 2024 and initiating a Phase 1 study in the second half of 2024, each subject to FDA feedback. 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, 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
(In thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 83,507	$ 64,741
Short-term marketable securities	222,709	259,745
Accounts receivable, net	31,952	22,429
Inventory	21,210	20,561
Prepaid expenses and other current assets	21,718	25,482
Total current assets	381,096	392,958
Long-term marketable securities	46,699	14,550
Long-term investments—restricted and other long-term assets	8,277	3,277
Property and equipment, net	5,421	6,707
Operating lease assets	32,073	36,547
Total assets	$ 473,566	$ 454,039
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 26,476	$ 18,612
Accrued expenses and other current liabilities	70,295	64,622
Operating lease liabilities	3,504	3,235
Total current liabilities	100,275	86,469
Operating lease liabilities, net of current portion	22,375	25,879
Total liabilities	122,650	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; 80,503,338 shares and 67,637,351 shares issued and outstanding as of December 31, 2023 and 2022, respectively	805	676
Additional paid-in capital	1,777,839	1,575,361
Accumulated other comprehensive income	577	(983)
Accumulated deficit	(1,428,305)	(1,233,363)
Total stockholders' equity	350,916	341,691
Total liabilities and stockholders' equity	$ 473,566	$ 454,039

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Revenues:				
Product revenues, net	$ 46,712	$ 32,880	$ 159,074	$ 125,504
Collaboration revenues	1,582	3,465	4,282	8,532
Total revenues	48,295	36,345	163,356	134,036
Cost and operating expenses:				
Cost of sales	1,785	3,245	3,732	8,770
Research and development	58,599	48,066	234,123	187,821
Selling, general, and administrative	39,148	32,195	136,459	120,167
Total cost and operating expenses	99,532	83,506	374,314	316,758
Loss from operations	(51,237)	(47,160)	(210,958)	(182,722)
Other income (expense):				
Interest and other income, net	4,478	1,926	16,447	4,513
Total other income (expense), net	4,478	1,926	16,447	4,513
Loss before income tax expense	(46,759)	(45,234)	(194,511)	(178,209)
Income tax expense	431	700	431	722
Net loss	$ (47,190)	$ (45,934)	$ (194,942)	$ (178,931)
Net loss per share—basic and diluted	$ (0.54)	$ (0.60)	$ (2.29)	$ (2.37)
Weighted average common shares outstanding—basic and diluted	86,702,025	76,440,793	85,059,962	75,500,148

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