# 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): January 8, 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 January 8, 2024, Deciphera Pharmaceuticals, Inc. (the "Company") disclosed that, based on preliminary unaudited financial information, it had preliminary unaudited total revenue of approximately $47 million for the fourth quarter ended December 31, 2023, and approximately $162 million for the full year ended December 31, 2023. Preliminary unaudited QINLOCK® (ripretinib) net product revenue for the fourth quarter 2023 is estimated to be approximately $46 million, including approximately $35 million in U.S. QINLOCK net product revenue and approximately $11 million in international QINLOCK net product revenue, in addition to approximately $1 million in collaboration revenue. The Company's preliminary unaudited U.S. QINLOCK net product revenue for the fourth quarter and year ended December 31, 2023 increased an estimated 37% and 25%, respectively, over the same periods in 2022.

Year-over-year growth was primarily due to increased demand volume with the remainder from net price growth. The increased demand observed in the U.S. for the year ended December 31, 2023 was driven by several factors, including fourth-line gastrointestinal stromal tumor (GIST) sales, unpromoted use in earlier lines of therapy based on physician decision, and an increase in average duration of therapy. Outside the U.S., year-over-year growth was driven by increased demand and continued geographic expansion. In 2024, we expect overall growth to continue based on the core factors experienced in 2023 as described above, with typical quarter-to-quarter variability. The growth observed in the fourth quarter of 2023, compared to the same period in 2022, was primarily due to increased demand based on the factors described above, increased net price, and geographic expansion.

The Company also disclosed that it had preliminary unaudited cash, cash equivalents, and marketable securities of approximately $352 million as of December 31, 2023, which, based on current operating plans, is expected to fund operating and capital expenditures into the second half of 2026.

These amounts are preliminary and are subject to completion of financial closing procedures. As a result, these amounts may differ materially from the amounts that will be reflected in the Company's consolidated financial statements for the quarter and year ended December 31, 2023. A copy of the press release disclosing this information is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 2.02 by reference.

The preliminary financial data included in this Current Report on Form 8-K has been prepared by, and is the responsibility of, the Company's management. PricewaterhouseCoopers LLP has not audited, reviewed, examined, compiled, nor applied agreed-upon procedures with respect to the preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto.

The information in Item 2.02 of this Current Report on Form 8-K 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 8.01 Other Events.**

*Planned 2024 Corporate Milestones*

On January 8, 2024, the Company also announced the following planned 2024 corporate milestones and expects to:

**QINLOCK® (ripretinib)**

- Continue enrolling the INSIGHT pivotal Phase 3 clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18 only.
- Publish in *Nature Medicine* in January 2024 data from the INTRIGUE Phase 3 study supporting the study of QINLOCK in second-line GIST patients with mutations in KIT exon 11 and 17/18 only.

- Continue the geographic expansion of QINLOCK in fourth-line GIST, with planned commercial launches following conclusion of pricing and reimbursement negotiations in European and international markets.

**Vimseltinib**

- Submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second quarter of 2024 and a Marketing Authorisation (MAA) to the European Medicines Agency in the third quarter of 2024 for vimseltinib, an investigational, orally administered, potent, and highly selective switch-control kinase inhibitor of CSF1R, for the potential treatment of TGCT.
- Present additional results from Part 1 of the pivotal Phase 3 MOTION study of vimseltinib in TGCT patients at a medical meeting in the second quarter of 2024.
- Present updated data from the Phase 1/2 study of vimseltinib in TGCT in the second half of 2024.
- 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, subject to FDA feedback.

**Early-Stage Pipeline**

**DCC-3116**

- Select a recommended Phase 2 dose for potential expansion cohort(s) for DCC-3116, an investigational switch-control kinase inhibitor of ULK1/2 designed to inhibit autophagy, in 2024, subject to favorable data.
- Operationalize its announced prioritization of the development of DCC-3116 in combination with sotorasib and with QINLOCK and to discontinue development of the encorafenib and cetuximab combination cohort prior to enrollment in any clinical studies as well as the two MEK combination cohorts.

**DCC-3084**

- Initiate a Phase 1 study for DCC-3084, the Company’s pan-RAF inhibitor, in the first half of 2024.

**DCC-3009**

- Submit an investigational new drug (IND) application with the FDA for DCC-3009, the Company’s pan-KIT inhibitor, in the first half of 2024 and initiate a Phase 1 study in the second half of 2024, each subject to FDA feedback.

*Potential U.S. Market Opportunity for Vimseltinib Incident Population*

In addition, based on an internal analysis of U.S. claims data, the Company disclosed that it estimates the addressable market opportunity in the United States for vimseltinib, if approved, to be approximately $700 million for the incident population alone (defined as diagnosed, drug-treated, and recently engaged with a medical oncologist (or a surgeon)). This estimate is based on the previously disclosed 1,400 incident TGCT patients in the U.S., and an estimated 24 months average duration of treatment. The above does not include the potential addressable market opportunity for prevalent TGCT patients, patients who may not have recently engaged with an oncologist (or surgeon), or patients in Europe. Estimates are inherently uncertain. The total addressable market opportunity for vimseltinib and any other drug candidates we may develop will ultimately depend upon, among other things, the diagnosis criteria included in the final label for our current and future drugs for sale for these indications, acceptance by the medical community, patient access, drug pricing, and reimbursement. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, our expected duration of therapy or treatment may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drug, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

*Cautionary Note Regarding Forward-Looking Statements*

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the Company's preliminary unaudited net product revenue for the fourth quarter and year ended December 31, 2023, preliminary unaudited cash, cash equivalents, and marketable securities for the year ended December 31, 2023, our expectations regarding future year-over-year and quarter-over-quarter growth factors, and cash guidance; our Phase 3 INSIGHT clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18, plans to publish clinical data from our Phase 3 INTRIGUE study in second-line GIST patients with mutations in KIT exon 11 and 17/18, plans to continue our geographic expansion of QINLOCK in European and international markets; the timing of our NDA and MAA submission for vimseltinib, subject to FDA feedback, the total addressable market opportunity for vimseltinib, if approved, 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 potential expansion cohort(s), subject to favorable data; initiating a Phase 1 study of DCC-3084 in the first half of 2024, 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. Forward-looking statements are based on current expectations of management and upon what management believes to be reasonable assumptions based on information currently available to it, and are subject to risks and uncertainties. Such risks and uncertainties may cause actual results to differ materially from the expectations set forth in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks related to preliminary financial results, including the risks that actual product and collaboration revenues may differ from the Company's current expectations, and risks that the preliminary financial results reported herein reflect information available to the Company only at this time and may differ from actual results, including in connection with the Company's completion of financial closing procedures, as well as other risks detailed in the Company's recent filings on Forms 10-K and 10-Q with the Securities and Exchange Commission. The Company undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

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|---|---|
| 99.1 | Press Release issued by Deciphera Pharmaceuticals, Inc. on January 8, 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: January 8, 2024

**DECIPHERA PHARMACEUTICALS, INC.**

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

**Exhibit 99.1**

**Deciphera Pharmaceuticals Announces Planned 2024 Corporate Milestones Supporting Evolution to a Self-Sustaining, Multi-Product Company**

*– Preliminary Unaudited Fourth Quarter 2023 QINLOCK® Net Product Revenue of Approximately $46.0 Million, an Increase of 40% Compared to the Fourth Quarter of 2022 –*

*– Expects to Submit Vimseltinib New Drug Application (NDA) in the Second Quarter of 2024 and Marketing Authorisation Application (MAA) in the Third Quarter of 2024 in Tenosynovial Giant Cell Tumor (TGCT); Commercial Launch Preparations Underway –*

*– 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 –*

*– Preliminary Unaudited Cash, Cash Equivalents, and Marketable Securities of Approximately $352.0 million as of December 31, 2023; Cash Runway Extended into the Second Half of 2026 –*

Waltham, MA – January 8, 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 highlighted its strategic outlook for 2024 and planned 2024 corporate milestones, and announced preliminary unaudited fourth quarter and full year 2023 revenue.

"2023 was a year of important progress across our organization, in which we demonstrated our ability to drive commercial growth while advancing our clinical pipeline and strategically investing in key earlier-stage programs," said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. "Thanks to our late-stage clinical execution and global commercial excellence, we have the potential to reach $1 billion in peak revenue with QINLOCK and vimseltinib, and we look forward to continuing this exciting evolution as we work to become a self-sustaining, multi-product company."

Planned 2024 corporate milestones and business updates include:

**QINLOCK® (ripretinib)**

- Continue enrolling the INSIGHT pivotal Phase 3 clinical study of QINLOCK versus sunitinib in second-line gastrointestinal stromal tumor (GIST) patients with mutations in KIT exon 11 and 17/18 only.
- Publication in *Nature Medicine* in January 2024 of the results of a ctDNA analysis from the INTRIGUE Phase 3 study demonstrating substantial clinical benefit of QINLOCK in second-line GIST patients with mutations in KIT exon 11 and 17/18 only.
- Continue the geographic expansion of QINLOCK in fourth-line GIST, with planned commercial launches following conclusion of pricing and reimbursement negotiations in European and international markets.
- The Company has 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.

**Vimseltinib**

- Submit an NDA to the U.S. Food and Drug Administration (FDA) in the second quarter of 2024 and a MAA to the European Medicines Agency in the third quarter of 2024 for vimseltinib, an investigational, orally administered, potent, and highly selective switch-control kinase inhibitor of CSF1R, for the potential treatment of TGCT.
- Present additional results from Part 1 of the pivotal Phase 3 MOTION study of vimseltinib at a medical meeting in the second quarter of 2024.
- Present updated data from the Phase 1/2 study of vimseltinib in TGCT in the second half of 2024.
- Initiate a Phase 2 proof-of-concept study of vimseltinib for the treatment of cGVHD in the fourth quarter of 2024.

**Early-Stage Pipeline**

**DCC-3116**

- The Company 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.
- The Company has prioritized the development of DCC-3116 in combination with sotorasib and with QINLOCK and discontinued development of the encorafenib and cetuximab combination cohort prior to enrollment in any clinical studies as well as the two MEK combination cohorts.

**DCC-3084**

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

**DCC-3009**

- 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.

**Preliminary 2023 Financial Results**

Based on preliminary unaudited financial information, Deciphera expects total fourth quarter 2023 revenue to be approximately $47 million and total full year 2023 revenue to be approximately $162 million. QINLOCK net product revenue is estimated to be approximately $46 million in the fourth quarter 2023, including approximately $35 million in U.S. net product revenue and approximately $11 million in international net product revenue, in addition to approximately $1 million in collaboration revenue.

In addition, preliminary unaudited cash, cash equivalents, and marketable securities was approximately $352 million as of December 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 the second half of 2026.

Preliminary selected financial information presented in this release are unaudited, subject to adjustment, and provided as an approximation in advance of the Company’s announcement of complete financial results expected in February 2024.

**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 multi-product, self-sustaining company, plans to continue our geographic expansion of QINLOCK in European and international markets, plans to publish clinical data from our Phase 3 INTRIGUE study in second-line GIST patients with mutations in KIT exon 11 and 17/18, our Phase 3 INSIGHT clinical study of QINLOCK versus sunitinib in second-line GIST patients with mutations in KIT exon 11 and 17/18, our expectations regarding the aggregate potential revenue opportunity for QINLOCK, our ability to expand the market opportunity for QINLOCK in second-line GIST in our INSIGHT Phase 3 study; the timing of our NDA and MAA submission for vimseltinib, the potential revenue opportunity for vimseltinib, if approved, 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 at least one potential expansion cohort, subject to favorable data; initiating a Phase 1 study of DCC-3084 in the first half of 2024, 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; statements regarding the Company's preliminary unaudited fourth quarter, year-end, and net product revenue for the quarter and year-ended December 31, 2023 and preliminary unaudited cash, cash equivalents, and marketable securities for the quarter and year-ended December 31, 2023, 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, risks and uncertainties related to, 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

September 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.

The Deciphera logo and the QINLOCK® word mark and logo are registered trademarks and the Deciphera word mark is a trademark of Deciphera Pharmaceuticals, LLC.

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