

**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): November 3, 2022

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 November 3, 2022, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended September 30, 2022 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.

- 99.1 [Press Release issued by Deciphera Pharmaceuticals, Inc. on November 3, 2022](#)
- 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: November 3, 2022

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter

Name: Steven L. Hoerter

Title: President and Chief Executive Officer



Deciphera Pharmaceuticals, Inc. Announces Third Quarter 2022 Financial Results

- *Third Quarter 2022 Total Revenue of \$36.0 Million; QINLOCK® Net Product Revenue Increases 49% to \$32.3 Million Compared to Third Quarter 2021 –*
- *Presented Updated Results from Phase 1/2 Study of Vimseltinib in TGCT Patients at the ESMO Congress 2022 Demonstrating Best-in-Class Potential; Pivotal Phase 3 MOTION Study Actively Enrolling –*
- *Presented Initial Phase 1 Single Agent Dose Escalation Data for DCC-3116 in Oral Presentation at the ESMO Congress 2022; Opened Enrollment in Combination Dose Escalation Cohorts with MEK and KRAS G12C Inhibitors and Treated First Patient in Fourth Quarter 2022 –*
- *Nominated Potential Best-in-Class Pan-RAF Inhibitor, DCC-3084, as the Next Clinical Development Candidate from Proprietary Switch Control Kinase Inhibitor Platform –*

WALTHAM, Mass.—(BUSINESS WIRE)—November 3, 2022— 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 third quarter ended September 30, 2022 and provided a corporate update.

“Our strong third quarter results continue the exceptional progress we have made across our business in 2022: QINLOCK® delivered another quarter of record revenue, we reported exciting data at ESMO for our two clinical programs and we nominated the next clinical development candidate from our proprietary research platform,” said Steve Hoerter, President and Chief Executive Officer of Deciphera Pharmaceuticals. “We have already begun building upon this momentum in the fourth quarter with key milestones including our announcement today of the opening of enrollment in our combination escalation cohorts in the Phase 1 study of DCC-3116 and the treatment of the first patient.”

Mr. Hoerter continued, “We remain inspired by QINLOCK’s impact on the treatment of patients with GIST, in the U.S., Europe, and other countries around the world, as we focus on expanding the geographic reach of this breakthrough medicine. We achieved important milestones in the third quarter in our two clinical programs, vimseltinib and DCC-3116, with exciting data updates at the ESMO Congress in September. The best-in-class potential of vimseltinib in TGCT was underscored by the high response rates and the preliminary patient-reported outcome results, which found clinically meaningful improvements in both pain and stiffness. We also presented first-in-human data for DCC-3116 demonstrating a favorable safety and pharmacokinetic profile and strong target inhibition across all dose levels studied. Building upon this quarter’s clinical success and leveraging the full potential of our switch control kinase inhibitor discovery platform, we are excited to announce our new clinical development candidate, DCC-3084, that has best-in-class potential as a pan-RAF inhibitor.”

Third Quarter 2022 Highlights and Upcoming Milestones

QINLOCK (ripretinib)

- Recorded \$32.3 million in QINLOCK net product revenue in the third quarter of 2022, including \$24.5 million in U.S. net product revenue and \$7.8 million in international net product revenue, an increase of 49% from net product revenue of \$21.7 million in the third quarter of 2021.
- Announced that the *Journal of Clinical Oncology* published results from the Company's INTRIGUE Phase 3 study of QINLOCK in patients with advanced gastrointestinal stromal tumor (GIST) previously treated with imatinib. Although QINLOCK did not offer a statistically significant improvement in progression-free survival (PFS) compared to sunitinib, QINLOCK showed meaningful clinical activity with fewer Grade 3/4 treatment-emergent adverse events (TEAEs) and improved tolerability.

Vimseltinib

- Presented updated results from the ongoing Phase 1/2 study of vimseltinib in tenosynovial giant cell tumor (TGCT) in two poster presentations at the European Society for Medical Oncology (ESMO) Congress 2022 in September. The results showed an objective response rate of 69% in Phase 1, 53% in Phase 2 Cohort A, and 46% in Phase 2 Cohort B, with a demonstrated clinical benefit rate of 100% across all Phase 1/2 patients. Preliminary patient-reported outcome data in the Phase 2 portion demonstrated clinically meaningful improvements in pain and stiffness at week 25 compared to baseline. Treatment with vimseltinib across all Phase 1/2 patients was well-tolerated. Duration of treatment continued to increase from the data cut at ESMO 2021 including 17.5 months of median treatment duration for patients in the Phase 1 portion of the study.
- Continued patient enrollment in the pivotal Phase 3 MOTION study of vimseltinib for the treatment of TGCT. MOTION is a two-part, randomized, double-blind, placebo-controlled study of vimseltinib to assess the efficacy and safety in patients with TGCT who are not amenable to surgery. The primary endpoint of the study is objective response rate at week 25 as measured by RECIST v1.1 by blinded independent radiologic review.

DCC-3116

- Presented initial clinical data in an oral presentation as a Proffered Paper at the ESMO Congress 2022 from the single agent dose escalation portion of the Phase 1 study of DCC-3116 in patients with advanced or metastatic tumors with a mutant RAS or RAF gene. The results showed DCC-3116 was well-tolerated at doses from 50 to 300 mg twice daily with no dose limiting toxicities or treatment-related serious adverse events observed. Pharmacokinetic and pharmacodynamic data across all dose levels demonstrated exposure and ULK 1/2 inhibition associated with anti-cancer efficacy in preclinical studies.
- Completed enrollment in the single agent dose escalation Phase 1 study in the fourth quarter of 2022; single-agent DCC-3116 did not reach a maximum tolerated dose; and selected 50 mg twice daily as the starting dose for the combination dose escalation cohorts.
- Opened enrollment in three Phase 1b combination dose escalation cohorts and treated the first patient in the fourth quarter of 2022:



- In combination with trametinib, a Food and Drug Administration (FDA)-approved MEK inhibitor, in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations.
- In combination with binimetinib, an FDA-approved MEK inhibitor, in patients with advanced or metastatic solid tumors with RAS, NF1, or RAF mutations.
- In combination with sotorasib, an FDA- approved KRAS^{G12C} inhibitor, in patients with advanced or metastatic solid tumors with KRAS^{G12C} mutations.

DCC-3084

- Nominated DCC-3084 as the Company's new pan-RAF clinical development candidate. DCC-3084 is a selective inhibitor of BRAF/CRAF kinases that inhibits Class I, II and III BRAF mutants, BRAF fusions and NRAS mutant cell lines using the Company's novel switch-control kinase inhibitor platform. Preclinical studies of DCC-3084 demonstrate both single-agent and combination activity and favorable pharmaceutical properties, a key potential differentiator from other pan-RAF programs in development.

Corporate Update

- Appointed Lisa Amaya Price as Senior Vice President and Chief Human Resources Officer to lead the Company's human resources, recruitment, and talent development strategy. Ms. Amaya Price brings over 20 years of experience with a strong track record of developing human resource strategies and leading talent recruitment, selection, and development in the biopharmaceutical industry.

Third Quarter 2022 Financial Results

- **Revenue:** Total revenue for the third quarter of 2022 was \$36.0 million, which includes \$32.3 million of net product revenue of QINLOCK and \$3.7 million of collaboration revenue compared to \$23.2 million of total revenue, including \$21.7 million of net product revenue of QINLOCK and \$1.5 million of collaboration revenue, for the same period in 2021.
- **Cost of Sales:** Cost of sales were \$3.3 million in the third quarter of 2022, which includes \$0.7 million in cost of product sales, compared to \$0.9 million for the third quarter of 2021, which included \$0.2 million in cost of product sales. 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 third quarter of 2022 were \$47.5 million, compared to \$66.4 million for the same period in 2021. The decrease was primarily due to lower clinical trial costs related to QINLOCK, including INTRIGUE, the Phase 3 study for the treatment of second-line GIST for which top-line results were announced in November 2021, the discontinuation of the rebastinib program following the corporate restructuring implemented in the fourth quarter of 2021, and preclinical costs including the recognition of a \$4.0 million up-front payment to Sprint Bioscience (Sprint) in the prior year, partially offset by an increase in clinical trial costs related to the Phase 3 study of vimseltinib and the Phase 1 study of DCC-3116. Non-cash, stock-based compensation was \$5.3 million and \$5.4 million for the third quarters of 2022 and 2021, respectively.



- **SG&A Expenses:** Selling, general, and administrative expenses for the third quarter of 2022 were \$30.0 million, compared to \$35.5 million for the same period in 2021. The decrease was primarily due to a decrease in personnel-related costs and professional and consultant fees. Non-cash, stock-based compensation was \$7.1 million and \$6.4 million for the third quarters of 2022 and 2021, respectively.
- **Net Loss:** For the third quarter of 2022, Deciphera reported a net loss of \$43.0 million, or \$0.55 per share, compared with a net loss of \$79.8 million, or \$1.37 per share, for the same period in 2021.
- **Cash Position:** As of September 30, 2022, cash, cash equivalents, and marketable securities were \$371.6 million, compared to \$393.1 million as of June 30, 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 2025.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, November 3, 2022, at 8:00 AM ET. The conference call may be accessed via this link: <https://register.vevent.com/register/B1ddf165cd801a473885dd3605fd55f7da>. A live webcast of the conference call will be available in the “Events and Presentations” page in the “Investors” 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, 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 our plans to expand the geographic reach of QINLOCK, the potential for our pre-clinical and/or clinical stage pipeline assets to be first-in-class and/or best-in-class treatments, enrollment of three



combination dose escalation cohorts in the Phase 1 study of DCC-3116, enrollment in the pivotal Phase 3 MOTION study of vimseltinib in TGCT patients, the potential for DCC-3084 to be a key differentiator from other pan-RAF programs in development, 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 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 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, 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, the Deciphera logo, QINLOCK, and the QINLOCK logo are registered trademarks of Deciphera Pharmaceuticals, LLC.



Deciphera Pharmaceuticals, Inc.

Consolidated Balance Sheets

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 82,538	\$ 87,063
Short-term marketable securities	282,039	198,571
Accounts receivable, net	23,278	20,595
Inventory	19,129	14,125
Prepaid expenses and other current assets	13,895	18,660
Total current assets	420,879	339,014
Long-term marketable securities	7,006	41,950
Long-term investments—restricted and other long-term assets	3,276	3,110
Property and equipment, net	7,152	8,610
Operating lease assets	37,639	36,800
Total assets	<u>\$ 475,952</u>	<u>\$ 429,484</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 12,800	\$ 13,130
Accrued expenses and other current liabilities	59,498	80,773
Operating lease liabilities	3,170	2,870
Total current liabilities	75,468	96,773
Operating lease liabilities, net of current portion	26,708	27,991
Total liabilities	<u>102,176</u>	<u>124,764</u>
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; 67,429,720 shares and 58,549,644 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	674	585
Additional paid-in capital	1,562,572	1,358,516
Accumulated other comprehensive income (loss)	(2,042)	51
Accumulated deficit	(1,187,428)	(1,054,432)
Total stockholders' equity	373,776	304,720
Total liabilities and stockholders' equity	<u>\$ 475,952</u>	<u>\$ 429,484</u>



Deciphera Pharmaceuticals, Inc.

Consolidated Statements of Operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product revenues, net	\$ 32,318	\$ 21,682	\$ 92,624	\$ 63,692
Collaboration revenues	3,656	1,538	5,067	8,257
Total revenues	35,974	23,220	97,691	71,949
Cost and operating expenses:				
Cost of sales	3,344	917	5,525	2,414
Research and development	47,485	66,444	139,755	182,109
Selling, general, and administrative	30,026	35,527	87,972	99,102
Total cost and operating expenses	80,855	102,888	233,252	283,625
Loss from operations	(44,881)	(79,668)	(135,561)	(211,676)
Other income (expense):				
Interest and other income, net	1,838	(170)	2,565	107
Total other income (expense), net	1,838	(170)	2,565	107
Net loss	\$ (43,043)	\$ (79,838)	\$ (132,996)	\$ (211,569)
Net loss per share—basic and diluted	\$ (0.55)	\$ (1.37)	\$ (1.82)	\$ (3.65)
Weighted average common shares outstanding—basic and diluted	78,206,647	58,107,611	73,129,804	57,948,612

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