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 2, 2021

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 November 2, 2021, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended September 30, 2021 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.

The following exhibit relating to Item 2.02 of this Current Report on Form 8-K shall be deemed to be furnished and not filed:

Exhibit No.	Description
99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on November 2, 2021
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 2, 2021

DECIPHERA PHARMACEUTICALS, INC.

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

Deciphera Pharmaceuticals, Inc. Announces Third Quarter 2021 Financial Results

– Third Quarter 2021 Revenue of $23.2 Million, Including QINLOCK® (ripretinib) Net Product Revenue of $21.7 Million –

– Top-line Results from INTRIGUE Phase 3 Study of QINLOCK in Patients with Second-line Gastrointestinal Stromal Tumor (GIST) Expected in the Fourth Quarter of 2021 –

– Approval from the European Medicines Agency (EMA) for QINLOCK Expected in the Fourth Quarter of 2021 –

– Initiation of the Phase 3 MOTION Study of Vimseltinib in Patients with Tenosynovial Giant Cell Tumor (TGCT) Expected in the Fourth Quarter of 2021; Vimseltinib Granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) –

Waltham, MA – November 2, 2021 – Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH) today announced financial results for the third quarter ended September 30, 2021 and provided a corporate update.

“In the third quarter, we made tremendous progress expanding the reach of QINLOCK for patients with GIST around the world. In addition to obtaining the approval for this important medicine in Switzerland and Taiwan, we also received a positive CHMP opinion for QINLOCK in the EU, with approval expected before the end of the year. Finally, we remain on track to report top-line results from the Phase 3 INTRIGUE study in second-line GIST later this quarter.”

Mr. Hoerter continued, “At the European Society for Medical Oncology (ESMO) Congress 2021, we shared very encouraging data from both the vimseltinib and rebastinib programs demonstrating significant clinical activity in two diseases with high unmet medical needs. We plan to initiate the Phase 3 MOTION study of vimseltinib in tenosynovial giant cell tumor this quarter and expect to initiate a Phase 3 study of rebastinib in combination with paclitaxel in platinum-resistant ovarian cancer next year. The body of scientific evidence continues to build supporting the potential of our first-in-class ULK inhibitor, DCC-3116, to address a broad spectrum of cancers in which autophagy is upregulated and believed to play an important role in tumor growth and survival. The Phase 1/2 study of DCC-3116 is on track and, with the first-in-class program in this field, we are well positioned to explore the full potential of inhibiting autophagy in cancer.”

Third Quarter 2021 Highlights and Upcoming Milestones

- **QINLOCK (ripretinib)**
  - Recorded $21.7 million in QINLOCK net product revenue in the third quarter of 2021, including $20.0 million in U.S. sales of QINLOCK and $1.7 million in ex-U.S. sales of QINLOCK.
  - Presented data at the ESMO Congress 2021:
    - An exploratory evaluation of primary and secondary endpoints in the Phase 3 INVICTUS study, with a cutoff date of January 15, 2021, an additional 19

months after the primary analysis, demonstrated consistent progression-free survival (PFS) with no change since the primary data cut off, and improved median overall survival (OS) among patients receiving QINLOCK.

    - Median PFS was 6.3 months with QINLOCK compared to 1.0 month with placebo.
    - Median OS was 18.2 months with QINLOCK compared to 6.3 months with placebo.
  - Phase 1 study in patients with KIT-mutated or KIT-amplified melanoma.
- Received approvals in Switzerland and Taiwan for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.
- Expects approval from the EMA for QINLOCK in the fourth quarter of 2021**.**
- Expects to announce top-line results from the Phase 3 INTRIGUE study in the fourth quarter of 2021.
- Expects to initiate a Phase 1b/2 study of QINLOCK in combination with binimetinib, a commercially available MEK inhibitor, in post-imatinib GIST patients in the fourth quarter of 2021.

- **Vimseltinib**
  - Presented updated data from the ongoing Phase 1/2 study in patients with TGCT at the ESMO Congress 2021, showing an encouraging ORR of 47% across all cohorts and a manageable safety and tolerability profile.
  - Expects to initiate the pivotal Phase 3 MOTION study of vimseltinib in the fourth quarter of 2021. MOTION is a two-part, randomized, double-blind, placebo-controlled study of vimseltinib to assess the efficacy and safety in patients with symptomatic TGCT who are not amenable to surgery. The primary endpoint of the study is ORR at week 25 as measured by RECIST v1.1 by blinded independent central review.
  - Granted Fast Track Designation by the FDA for the treatment of patients with symptomatic TGCT who are not amenable to surgery. This designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.
- **Rebastinib**
  - Presented updated data from the ongoing Phase 1b/2 study of rebastinib in combination with paclitaxel in the platinum-resistant ovarian cancer (PROC) cohort at the ESMO Congress 2021. Data showed promising results including median PFS of 9.1 months and an ORR of 38% (confirmed and unconfirmed) in heavily pretreated patients with PROC.
  - Received Orphan Drug Designation in the EU for the treatment of ovarian cancer based on a positive opinion issued by the EMA Committee for Orphan Medicinal Products (COMP).
  - Announced that the Company has begun planning for a pivotal study in PROC that is anticipated to start in 2022, subject to feedback from regulators.

- **DCC-3116**
  - Presented preclinical data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics showing that DCC-3116 inhibits EGFR inhibitor-induced autophagy in multiple EGFR-mutant non-small cell lung cancer cell lines and decreased tumor burden in combination with osimertinib and afatinib in an EGFR mutant xenograft model.
  - Announced plans to present initial data from the dose escalation phase of the Phase 1 study in 2022.

Third Quarter Financial Results

- **Revenue:** Total revenue for the third quarter of 2021 was $23.2 million, which includes $21.7 million of net product revenue from sales of QINLOCK and $1.5 million of collaboration revenue comprised primarily of QINLOCK supply and royalty revenue under our license agreement with Zai Lab. Total revenue for the third quarter of 2020 was $15.5 million, which included $15.2 million of net product revenue from sales of QINLOCK and $0.3 million of collaboration revenue.
- **Cost of Sales**: Cost of sales was $0.9 million in the third quarter of 2021, which includes $0.2 million in cost of net product revenue for QINLOCK and $0.7 million in cost of collaboration revenue. Cost of sales was $0.1 million for the third quarter of 2020. Deciphera does not expect that the cost of sales as a percentage of net product sales of QINLOCK will increase significantly after the Company has sold all zero cost inventories and commenced the sales of inventories which will reflect the full cost of manufacturing. The Company expects to continue to sell the zero cost inventories of QINLOCK in the U.S. during 2021 and into 2022.
- **R&D Expenses:** Research and development expenses for the third quarter were $66.4 million, compared to $49.2 million for the same period in 2020. The increase was primarily due to personnel and preclinical costs, and a $4.0 million up-front payment to Sprint Bioscience (Sprint) pursuant to the terms of the agreement with Sprint to exclusively in-license worldwide rights to a research-stage program targeting VPS34, and an increase in clinical trial expenses related to start-up activities for the planned Phase 3 MOTION study of vimseltinib and Phase 1b/2 study of QINLOCK in combination with binimetinib. Non-cash, stock-based compensation was $5.4 million and $4.5 million for the third quarters of 2021 and 2020, respectively.
- **SG&A Expenses:** Selling, general, and administrative expenses for the third quarter of 2021 were $35.5 million, compared to $30.1 million for the same period in 2020. The increase was primarily due to personnel costs as well as external spend related to professional fees, including those associated with establishing a targeted commercial infrastructure and commercial preparedness in key European markets to support a launch of QINLOCK in Europe, if approved. Non-cash, stock-based compensation was $6.4 million and $5.3 million for the third quarters of 2021 and 2020, respectively.
- **Net Loss:** For the third quarter of 2021, Deciphera reported a net loss of $79.8 million, or $1.37 per share, compared with a net loss of $63.7 million, or $1.13 per share, for the same period in 2020. The increase in net loss was primarily a result of increased R&D expenses, as described above, partially offset by increased sales volume in the U.S.

- **Cash Position:** As of September 30, 2021, cash, cash equivalents, and marketable securities were $392.2 million, compared to $451.0 million as of June 30, 2021. Based on its current operating plans, Deciphera expects its current cash, cash equivalents, and marketable securities together with anticipated product, royalty, and supply revenues, excluding any potential future milestone payments under the Zai License Agreement, will enable the Company to fund its operating and capital expenditures into the first half of 2023.

Conference Call and Webcast

Deciphera will host a conference call and webcast to discuss this announcement today, November 2, 2021, at 4:30 PM ET. To access the live call by phone please dial (866) 930-5479 (domestic) or (409) 216-0603 (international); the conference ID is 8178994. A live audio webcast of the event may also be accessed through the "Investors" section of Deciphera's website at www.deciphera.com. A replay of the webcast will be available for 30 days following the event.

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, Hong Kong, Switzerland, Taiwan, 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 top-line data from our Phase 3 INTRIGUE study in second-line GIST, plans to initiate a phase 1b/2 study of QINLOCK with a MEK inhibitor in post-imatinib GIST patients, potential EMA approval of QINLOCK for the treatment of fourth-line GIST, plans to initiate pivotal studies for vimseltinib in TGCT patients and for the rebastinib/paclitaxel combination, subject to discussions with regulators, the potential benefits of fast track designation from the FDA, the potential of DCC-3116 to address a broad spectrum of cancers in which autophagy is upregulated and our timing for initial data from the dose escalation portion of the phase 1 study of DCC-3116, the company's leading position in the development of regulators of autophagy for the potential treatment of cancer, and cash runway expectations. 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 candidates and in

additional indications for our existing drug, the preclinical or clinical results for our product candidates, which may not support further development of such product candidates, our ability to manage our reliance on sole-source third parties such as our third party drug substance and drug product contract manufacturers, 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, our ability to build and scale our operations to support growth in additional geographies, 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, our ability to comply with healthcare regulations and laws, our ability to obtain, maintain and enforce our intellectual property rights, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain additional regulatory approvals, 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, 2021, 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. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing our views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

Deciphera Pharmaceuticals, Inc.

Consolidated Balance Sheets

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 53,189	$ 135,897
Short-term marketable securities	289,081	416,033
Accounts receivable, net	18,049	13,896
Inventory	7,253	5,716
Prepaid expenses and other current assets	17,722	12,489
Total current assets	385,294	584,031
Long-term marketable securities	49,926	9,375
Long-term investments—restricted	3,102	3,102
Property and equipment, net	10,820	9,583
Operating lease assets	34,276	36,341
Total assets	$ 483,418	$ 642,432
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 13,502	$ 12,308
Accrued expenses and other current liabilities	59,625	55,227
Operating lease liabilities	2,662	2,457
Total current liabilities	75,789	69,992
Operating lease liabilities, net of current portion	27,172	28,764
Total liabilities	102,961	98,756
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, $0.01 par value per share; 125,000,000 shares authorized; 58,327,889 shares and 57,596,144 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	583	576
Additional paid-in capital	1,345,746	1,297,557
Accumulated other comprehensive income (loss)	165	11
Accumulated deficit	(966,037)	(754,468)
Total stockholders' equity	380,457	543,676
Total liabilities and stockholders' equity	$ 483,418	$ 642,432

Deciphera Pharmaceuticals, Inc.

Consolidated Statements of Operations and Comprehensive Loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product revenues, net	$ 21,682	$ 15,164	$ 63,692	$ 19,989
Collaboration revenues	1,538	285	8,257	2,612
Total revenues	23,220	15,449	71,949	22,601
Cost and operating expenses:				
Cost of sales	917	90	2,414	98
Research and development	66,444	49,213	182,109	146,682
Selling, general, and administrative	35,527	30,143	99,102	84,012
Total cost and operating expenses	102,888	79,446	283,625	230,792
Loss from operations	(79,668)	(63,997)	(211,676)	(208,191)
Other income (expense):				
Interest and other income, net	(170)	296	107	4,442
Total other income (expense), net	(170)	296	107	4,442
Net loss	$ (79,838)	$ (63,701)	$ (211,569)	$ (203,749)
Net loss per share—basic and diluted	$ (1.37)	$ (1.13)	$ (3.65)	$ (3.68)
Weighted average common shares outstanding—basic and diluted	58,107,611	56,390,748	57,948,612	55,296,775

Contacts:

Investor Relations:

Jen Robinson
Deciphera Pharmaceuticals, Inc.
jrobinson@deciphera.com
781-906-1112

Media:

David Rosen
Argot Partners
David.Rosen@argotpartners.com
212-600-1902