
**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 8, 2018

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 Number)

500 Totten Pond Road
Waltham, MA
(Address of registrant's principal executive office)

02451
(Zip code)

(781) 209-6400
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since 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))

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 8, 2018, Deciphera Pharmaceuticals, Inc. announced its financial results for the quarter ended September 30, 2018. 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.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release issued by Deciphera Pharmaceuticals, Inc. on November 8, 2018, furnished herewith.</u>

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 8, 2018

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Michael D. Taylor

Michael D. Taylor
President and Chief Executive Officer



Deciphera Pharmaceuticals, Inc. Announces Third Quarter 2018 Financial Results

- Preliminary Phase 1 Clinical Study Results Presented at the European Society of Medical Oncology (ESMO) 2018 Congress Demonstrate the Potential of DCC-2618 to Provide Improved and Durable Clinical Outcomes in Second- and Third-Line Patients -

- Pivotal Phase 3 INTRIGUE Clinical Study in Second-Line GIST on Schedule to Initiate Later This Year -

- Ended Third Quarter 2018 with Cash and Cash Equivalents of \$321 Million -

Waltham, MA – November 8, 2018 – Deciphera Pharmaceuticals, Inc. (NASDAQ:DCPH), a clinical-stage biopharmaceutical company focused on addressing key mechanisms of tumor drug resistance, today announced financial results for the third quarter ended September 30, 2018 and provided an update on clinical and corporate developments.

“Recent clinical and corporate achievements support Deciphera’s transition to a late-stage, pre-commercial company,” said Michael D. Taylor, Ph.D., President and Chief Executive Officer of Deciphera. “Data presented at ESMO have bolstered our confidence in DCC-2618’s potential to transform the current treatment paradigm for GIST patients. As we approach the completion of enrollment for our pivotal Phase 3 INVICTUS study in the coming weeks, we look forward to the data readout from that study expected next year. In addition, we remain on track to initiate our Phase 3 INTRIGUE study later this year. We are building our commercial capabilities for DCC-2618 in the United States and are continuing to invest in our clinical-stage pipeline, with the recent initiation of our Phase 1b/2 clinical study of our investigational agent rebastinib in combination with paclitaxel.”

Clinical Programs

- **DCC-2618**

- At the European Society of Medical Oncology (ESMO) 2018 Congress in October 2018, Deciphera presented updated preliminary Phase 1 clinical study results of DCC-2618 in patients with gastrointestinal stromal tumors (GIST). Highlights from the presentation included:
 - Preliminary median progression free survival (mPFS) in second- and third-line GIST patients of 42 weeks and 40 weeks, respectively, that the Company believes demonstrates the potential for improved and durable clinical outcomes in patients with less advanced disease.
 - Updated objective response rates (ORR) and disease control rates (DCR) in second- and third-line GIST patients continue to exceed previously published results of registrational trials for currently approved therapies.
 - In fourth-line and fourth-line-plus GIST patients, for whom there are currently no approved therapies, the Company believes that the observed mPFS of 24 weeks demonstrates the potential for durable clinical outcomes in patients with advanced disease. Published studies have reported a mPFS of 4 to 6 weeks for similarly heavily pre-treated patients who did not receive an active therapy.



- Deciphera expanded the ongoing Phase 1 study to include additional cohorts for patients with: various solid tumors, including melanoma; non-small cell lung cancer; germ cell cancer; penile cancer; soft tissue sarcoma; GIST or other solid tumor patients with renal impairment.
- Deciphera will present preclinical data on the effects of the combination of DCC-2618 and MAPK pathway inhibitors on cell death and apoptosis in cellular assays of GIST and mastocytosis in a poster session at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Symposium on November 13, 2018.
- Data in GIST patients from the ongoing Phase 1 study that were presented at the ESMO 2018 Congress in October 2018 will also be presented at the Annual Meeting of the Connective Tissue Oncology Society (CTOS) on November 15, 2018.
- Deciphera previously announced that, following discussions with regulatory authorities in the United States and Europe, it is planning to initiate later this year a randomized, multicenter, open-label, pivotal Phase 3 INTRIGUE study evaluating DCC-2618 compared to sunitinib in second-line GIST patients.
- **Rebastinib**
 - Deciphera initiated a Phase 1b/2 clinical study of rebastinib, the Company's small molecule kinase switch control inhibitor of TIE2. In this two-part clinical study, rebastinib will be evaluated for the treatment of patients with advanced or metastatic solid tumors in combination with paclitaxel.
- **DCC-3014**
 - Deciphera continues to enroll patients in the Phase 1 dose escalation study of DCC-3014, a selective small molecule kinase switch control inhibitor of CSF1R and expects to provide an update on this study later this year.

Corporate Updates

- In September 2018, Deciphera appointed Daniel C. Martin as Chief Commercial Officer. Mr. Martin has more than 20 years of commercial experience within the biopharmaceutical industry with extensive background in oncology, including immuno-oncology.
- In November 2018, Oliver Rosen, M.D., informed Deciphera that effective November 30, 2018, he would leave his position as the Company's Chief Medical Officer to pursue another opportunity at an early-stage, private biotechnology company. The Company has commenced a search for his replacement.

"On behalf of the management team and board of directors, I want to thank Oliver for his many contributions to Deciphera over the past four and a half years," said Dr. Taylor. "During his tenure, Oliver was instrumental in developing DCC-2618 from a promising preclinical asset into a robust late-stage clinical program with a pivotal Phase 3 study expected to read out in 2019, a second Phase 3 study that is planned to initiate soon and a series of expansion studies in multiple indications. We wish Oliver all the best in his future endeavors."



“It has been a privilege to be a part of Deciphera’s successful growth since 2014 led by the rapid development of DCC-2618,” said Dr. Rosen. “I am proud of the progress the Company has made in translating the promise of its kinase switch control platform into an exciting pipeline of clinical-stage drug candidates designed to provide cancer patients with novel therapies that address unmet medical needs.”

Third Quarter 2018 Financial Results

- **Cash Position:** As of September 30, 2018, cash and cash equivalents were \$320.9 million, compared to cash and cash equivalents of \$196.8 million as of December 31, 2017. This increase was primarily related to proceeds obtained through the Company’s June 2018 underwritten public offering, offset by cash used in operating activities. We expect our current cash and cash equivalents will enable us to fund our operating and capital expenditures and debt service payments into the second half of 2020.
- **R&D Expenses:** Research and development expenses for the third quarter of 2018 were \$20.6 million, compared to \$9.8 million for the same period in 2017. The increase was primarily due to an increase in spending on the DCC-2618 program of \$6.1 million as a result of clinical trial costs related to the pivotal Phase 3 INVICTUS study that began enrollment in January 2018. Clinical trial costs also increased due to start-up activities related to a second Phase 3 INTRIGUE study in second-line GIST, which is expected to be initiated by the end of 2018. In addition, chemistry, manufacturing and controls development and manufacturing costs for the DCC-2618 program increased as a result of process development activities to support anticipated drug requirements for commercialization and the manufacture of registration lots to support the submission of a new drug application. Expenses related to the rebastinib program increased \$1.5 million, primarily due to start-up activities related to the Phase 1b/2 study of rebastinib in combination with paclitaxel, which initiated in October 2018. Personnel-related costs increased \$2.7 million due to increased headcount in our research and development functions. Personnel-related costs for the third quarters of 2018 and 2017 included non-cash share-based compensation expense of \$1.1 million and \$0.5 million, respectively.
- **G&A Expenses:** General and administrative expenses for the third quarter of 2018 were \$5.3 million, compared to \$2.4 million for the same period in 2017. The increase was primarily due to an increase in non-cash share-based compensation expense related to additional employee stock options and a higher value of our common stock and to an increase in legal and professional fees as a result of various advisory fees related to ongoing operations as a public company. Facility-related and other costs increased due to director and officer insurance costs and higher rent expense related to our new lease. Non-cash share-based compensation was \$1.5 million and \$0.6 million for the third quarters of 2018 and 2017, respectively.
- **Net Loss:** For the third quarter of 2018, Deciphera reported a net loss of \$24.4 million, or \$0.65 per share, compared with a net loss of \$12.0 million, or \$1.04 per share, for the same period in 2017.

About Deciphera Pharmaceuticals

Deciphera Pharmaceuticals is a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by tackling key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Our small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. We use our deep understanding of kinase biology together with a proprietary chemistry



library to purposefully design compounds that maintain kinases in a “switched off” or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic resistance causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. We have used our platform to develop a diverse pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate and/or durability of their responses to treatment.

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, statements regarding the planned initiation of our Phase 3 INTRIGUE study, expectations on the timing of updates on and data from our Phase 3 INVICTUS study and our Phase 1 DCC-3014 study, cash guidance, the potential for our drug candidates to treat cancers and our strategy, our commercial readiness plan, our business plans and our focus. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “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 delay of any current or planned clinical studies or the development of our drug candidates, including DCC-2618, rebastinib, and DCC-3014, our advancement of multiple early-stage and later-stage efforts, our ability to successfully demonstrate the efficacy and safety of our drug candidates including in later-stage studies, the preclinical and clinical results for our drug candidates, which may not support further development of such drug candidates, our efforts to scale up drug product manufacturing, our ability to implement commercial readiness, actions of regulatory agencies, any or all of which may affect the initiation, timing and progress of clinical studies and other risks identified in our SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, 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 its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.



CONSOLIDATED BALANCE SHEETS

(In thousands)

(Unaudited)

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Assets		
Cash and cash equivalents	\$ 320,875	\$ 196,754
Prepaid expenses and other current assets	4,734	1,428
Long-term investment restricted	1,069	—
Property and equipment, net ⁽¹⁾	19,238	838
Other assets	—	75
Total assets	<u>\$ 345,916</u>	<u>\$ 199,095</u>
Liabilities and Stockholders' Equity		
Accounts payable, accrued expenses and other liabilities	\$ 17,669	\$ 13,641
Debt obligations	1,341	1,481
Lease liability, net of current portion ⁽¹⁾	17,538	—
Total liabilities	<u>36,548</u>	<u>15,122</u>
Total stockholders' equity	<u>309,368</u>	<u>183,973</u>
Total liabilities and stockholders' equity	<u>\$ 345,916</u>	<u>\$ 199,095</u>

(1) In May 2018, we entered into a lease for office space in Waltham, MA. We are not the legal owners of the leased space, however, we are deemed to be the owner during the construction phase because of certain provisions within the lease. As a result, we recorded a \$17.9 million build-to-suit asset in property and equipment and a corresponding build-to-suit facility lease financing obligation as of September 30, 2018.



CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	20,630	9,751	55,531	23,856
General and administrative	5,259	2,430	14,738	6,741
Total operating expenses	25,889	12,181	70,269	30,597
Loss from operations	(25,889)	(12,181)	(70,269)	(30,597)
Other income (expense):				
Interest expense	(21)	(23)	(64)	(72)
Interest and other income, net	1,475	166	2,778	297
Total other income (expense), net	1,454	143	2,714	225
Net loss and comprehensive loss	\$ (24,435)	\$ (12,038)	\$ (67,555)	\$ (30,372)
Net loss per share—basic and diluted	\$ (0.65)	\$ (1.04)	\$ (1.95)	\$ (2.61)
Weighted average common shares outstanding—basic and diluted	37,654,324	11,626,287	34,623,773	11,626,287

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