

CELYAD ONCOLOGY SA

FORM 6-K

(Report of Foreign Issuer Pursuant to Rule 13a-16 or 15d-16)

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the Month of May 2021

Commission File Number: 001-37452

CELYAD ONCOLOGY SA

(Translation of registrant's name into English)

**Rue Edouard Belin 2
1435 Mont-Saint-Guibert, Belgium
(Address of principal executive offices)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Financial and Operating Results

On May 6, 2021, Celyad Oncology SA (the “Company”) issued a press release announcing its financial and operating results for the first quarter of 2021. A copy of the Company’s press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The Company’s interim consolidated statement of comprehensive income and interim consolidated statement of financial position for the first quarter of 2021 are attached hereto as Exhibit 99.2 and are incorporated herein by reference.

Update on Horizon Discovery

As previously disclosed, Horizon Discovery Group plc / PerkinElmer, Inc. (Horizon/PKI) informed us they believe we are in material breach of our 2018 research and development collaboration and license agreements. Horizon/PKI recently informed us that unless we are able to reach agreement regarding the purported material breach they may elect to serve us a notice of termination. We continue to believe that any formal notice of termination would be without merit and we would expect to vigorously contest the validity and effectiveness of any such notice and the existence of any material breach. Any dispute under these agreements would be subject to arbitration in The Hague under the International Chamber of Commerce Rules. We are currently in discussions with Horizon/PKI to settle the matter.

The information contained in this Current Report on Form 6-K, including Exhibits 99.1 and 99.2, except for the quote of Filippo Petti contained in Exhibit 99.1, is hereby incorporated by reference into the Company’s Registration Statements on Forms F-3 (File No. 333-248464) and S-8 (File No. 333-220737).

EXHIBITS

Exhibit

Description

99.1 [Press release issued by the registrant on May 6, 2021](#)

99.2 [Interim consolidated statement of comprehensive income and interim consolidated statement of financial position](#)

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, thereunto duly authorized.

CELYAD ONCOLOGY SA

Date: May 7, 2021

By: /s/ Filippo Petti

Filippo Petti

Chief Executive Officer and Financial Officer



Celyad Oncology Announces First Quarter 2021 Financial Results and Recent Business Highlights

- *Enrollment continues in second dose cohort of Phase 1 dose-escalation IMMUNICY-1 trial for lead shRNA-based allogeneic CAR T candidate, CYAD-211, for relapsed/refractory multiple myeloma (r/r MM); additional proof-of-concept data anticipated in second quarter 2021.*
- *Expansion segment of Phase 1 alloSHRINK trial evaluating allogeneic CYAD-101 administered concurrently with preconditioning chemotherapy for the treatment of advanced metastatic colorectal cancer (mCRC) ongoing; preliminary data expected in mid-2021.*
- *Phase 1b KEYNOTE-B79 trial evaluating CYAD-101 with KEYTRUDA® in patients with microsatellite stable mCRC expected to be initiated in first half of 2021.*

Mont-Saint-Guibert, Belgium – Celyad Oncology SA (Euronext & Nasdaq: CYAD) (the “Company”), a clinical-stage biotechnology company focused on the discovery and development of chimeric antigen receptor T cell (CAR T) therapies for cancer, today announced an update on its financial results and recent business developments for the fiscal quarter ended March 31, 2021.

“We have entered 2021 with ever-increasing enthusiasm around the progress of our programs,” commented Filippo Petti, Chief Executive Officer of Celyad Oncology. “Our lead shRNA-based allogeneic candidate, CYAD-211, which is currently being evaluated in the Phase 1 IMMUNICY-1 trial for the treatment of multiple myeloma, has shown no safety concerns nor evidence of Graft-versus-Host Disease (GvHD) at dose level 1. We look forward to announcing additional proof-of-concept data from this trial by the end of second quarter of 2021. In addition, we have continued to enroll patients in the alloSHRINK expansion trial for CYAD-101 and will turn our attention to the KEYNOTE-B79 trial. Lastly, we are planning an R&D day for this summer that will provide an opportunity for our broader team to offer an in-depth overview of our clinical programs and strategy for advancing our next-generation shRNA platform and allogeneic pipeline.”

Recent Highlights

- Appointment of Dr. Charles Morris as Chief Medical Officer to lead and provide strategic direction for Celyad Oncology’s medical, regulatory, and clinical development activities.
- Appointment of Marina Udier, Ph.D. to Board of Directors
- Announced a committed equity purchase agreement for up to \$40 million in American Depositary Shares (ADSs) with Lincoln Park Capital Fund, LLC (“LPC”)

First Quarter 2021 Financial Review

As of March 31, 2021, the Company had cash and cash equivalents of €12.2 million (\$14.3 million). Net cash burn during the first quarter of 2021 amounted to €5.1 million (\$5.9 million), in line with expectations. In April 2021, the Company raised proceeds of €3.3 million (\$4.0 million) from the sale of ADSs to LPC. The Company confirms its previous guidance that its existing cash and cash equivalents combined with the remaining access to the equity purchase agreement established with LPC should be sufficient, based on the current scope of activities, to fund operating expenses and capital expenditure requirements until mid-2022.

Update on Clinical Programs

CYAD-211 – Allogeneic shRNA-based, anti-BCMA CAR T for r/r MM

CYAD-211 is an investigational, shRNA-based allogeneic CAR T candidate engineered to co-express a BCMA-targeting chimeric antigen receptor and a single shRNA, which interferes with the expression of the CD3ζ component of the T-cell receptor (TCR) complex. The Company is currently conducting the first-in-human, open-label, dose-escalation Phase 1 IMMUNICY-1 trial to evaluate the safety and efficacy of a single infusion of CYAD-211 following preconditioning chemotherapy cyclophosphamide and fludarabine in patients with r/r MM. The trial seeks to determine the recommended dose of CYAD-211 for the treatment of patients with r/r MM for further development as well as to establish proof-of-concept that single shRNA-mediated knockdown can generate allogeneic CAR T cells in humans without inducing GvHD. In March, the Company announced that no safety concerns nor evidence of GvHD had been reported in the first three patients treated at dose level 1 (30×10⁶ cells per infusion) of CYAD-211 in the IMMUNICY-1 trial. In first quarter 2021, the Company initiated enrollment in dose level 2 (100×10⁶ cells per infusion). The Company expects to announce additional proof-of-concept data from the IMMUNICY-1 trial by the end of the second quarter of 2021.

CYAD-101 – Allogeneic TIM-based NKG2D CAR T for mCRC

The Company's first-in-class, non-gene edited clinical candidate, CYAD-101, which co-expresses the NKG2D receptor and the novel inhibitory peptide TCR Inhibitory Molecule (TIM), is currently in the expansion segment of the alloSHRINK Phase 1 trial for the treatment of advanced mCRC. To the Company's knowledge, CYAD-101 is the first investigational allogeneic CAR T candidate to generate evidence of clinical activity for the treatment of a solid tumor indication.

- Phase 1 alloSHRINK trial is ongoing, in which the Company is evaluating CYAD-101 following FOLFIRI (combination of 5-fluorouracil, leucovorin and irinotecan) preconditioning chemotherapy in refractory mCRC patients, at the recommended dose of one billion cells per infusion. The Company expects to announce preliminary data from the expansion cohort of the trial in mid-2021.
- Celyad Oncology will also conduct the Phase 1b KEYNOTE-B79 clinical trial, which will evaluate Celyad Oncology's investigational non-gene edited allogeneic CAR T candidate, CYAD-101, following FOLFIRI chemotherapy, with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in refractory metastatic colorectal cancer (mCRC) patients with microsatellite stable (MSS) / mismatch-repair proficient (pMMR) disease. The Phase 1b KEYNOTE-B79 trial is expected to be initiated during first half of 2021.

CYAD-02 – Autologous NKG2D receptor-based CAR T for relapsed/refractory acute myeloid leukemia (r/r AML) and myelodysplastic syndromes (MDS)

Enrollment is ongoing in dose level 3 of the Phase 1 CYCLE-1 trial for the next-generation, autologous NKG2D receptor-based CAR T candidate CYAD-02. The dose-escalation Phase 1 CYCLE-1 trial is evaluating the safety and clinical activity of CYAD-02 following preconditioning chemotherapy in patients with r/r AML and MDS. To date, treatment with CYAD-02 has been generally well-tolerated. Of seven patients evaluable for clinical activity, five patients demonstrated anti-leukemic activity (at least 50% bone marrow blasts decrease), including a very-high risk MDS patient treated at dose level 3 who achieved a marrow complete response.

Next-generation shRNA Multiplex Platform

In 2020, the Company began developing a proprietary shRNA platform utilizing a novel framework to optimize and expand the expression of multiple shRNAs with our All-in-One vector approach. The Company's novel framework has the capability to knockdown or silence up to six genes simultaneously, while providing several key advantages beyond the Company's first-generation approach. The Company believes its next-generation shRNA multiplex platform will form the backbone for future allogeneic CAR T candidates, including several programs which are in the discovery phase of development. Our next-generation shRNA platform does not incorporate any of the Horizon Discovery technology.

Upcoming Milestones

- Additional proof-of-concept data from the initial dose cohorts of the Phase 1 IMMUNICY-1 trial of CYAD-211 for r/r MM are expected by the end of second quarter of 2021.
- Preliminary data from the expansion segment of the alloSHRINK trial evaluating CYAD-101 following FOLFIRI preconditioning chemotherapy in refractory mCRC patients are expected in mid-2021.
- Initiation of the Phase 1b KEYNOTE-B79 trial evaluating CYAD-101 with KEYTRUDA® in mCRC patients with MSS/pMMR disease is anticipated in the first half of 2021.
- Additional data from dose level 3 of Phase 1 CYCLE-1 trial of CYAD-02 for r/r AML and MDS are anticipated in the first half of 2021.

Financial Calendar

First Half 2021 Financial Results	August 4, 2021
Third Quarter 2021 Financial Results	November 10, 2021

About Celyad Oncology SA

Celyad Oncology SA is a clinical-stage biotechnology company focused on the discovery and development of chimeric antigen receptor T cell (CAR T) therapies for cancer. The Company is developing a pipeline of allogeneic (off-the-shelf) and autologous (personalized) CAR T cell therapy candidates for the treatment of both hematological malignancies and solid tumors. Celyad Oncology was founded in 2007 and is based in Mont-Saint-Guibert, Belgium and New York, NY. The Company has received funding from the Walloon Region (Belgium) to support the advancement of its CAR T cell therapy programs. For more information, please visit www.celyad.com.

Forward-looking statements

This release may contain forward-looking statements, within the meaning of applicable securities laws, including the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding: the planned announcement of proof-of-concept data from the Phase 1 IMMUNICY-1 trial by the end of second quarter of 2021, the planned initiation of the KEYNOTE-B79 trial in the second half of 2021, the expected announcement of preliminary data from the expansion cohort of the alloSHRINK Phase 1 trial in mid-2021, the announcement of additional data from dose level 3 of Phase 1 CYCLE-1 trial of CYAD-02 for r/r AML and MDS are anticipated in the first half of 2021, the safety and clinical activity of Celyad Oncology's pipelines and financial condition, results of operation and business outlook. Forward-looking statements may involve known and unknown risks and uncertainties which might cause actual results, financial condition, performance or achievements of Celyad Oncology to differ materially from those expressed or implied by such forward-looking statements. Such risk and uncertainty includes the expected date of the Phase 1 trial results in 2021, our continued clinical development of CYAD-211, CYAD-101 and CYAD-02, our expectations about possible amendments to our collaboration and license agreements with Horizon Discovery, our financial and operating results and the duration and severity of the COVID-19 pandemic and government measures implemented in response thereto. A further list and description of these risks, uncertainties and other risks can be found in Celyad Oncology's U.S. Securities and Exchange Commission (SEC) filings and reports, including in its Annual Report on Form 20-F filed with the SEC on March 24, 2021 and subsequent filings and reports by Celyad Oncology. These forward-looking statements speak only as of the date of publication of this document and Celyad Oncology's actual results may differ materially from those expressed or implied by these forward-looking statements. Celyad Oncology expressly disclaims any obligation to update any such forward-looking statements in this document to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which such statement is based, unless required by law or regulation.

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Source: Celyad Oncology SA

Celyad Oncology SA
Interim consolidated statement of comprehensive income

(€'000)	For the Three-month period ended March 31, 2021
Revenue	—
Cost of sales	—
Gross profit	—
Research and Development expenses	(4,739)
General & Administrative expenses	(2,341)
Change in fair value of contingent consideration	(2,220)
Other income	670
Other expenses	(145)
Operating Loss	(8,774)
Financial income	140
Financial expenses	(66)
Loss before taxes	(8,701)
Income taxes	—
Loss for the period	(8,701)
Basic and diluted loss per share (in €)	(0.61)
Other comprehensive income/(loss)	—
Items that will not be reclassified to profit and loss	—
Remeasurement of post-employment benefit obligations, net of tax	—
Items that may be subsequently reclassified to profit or loss	8
Currency translation differences	8
Other comprehensive income / (loss) for the period, net of tax	8
Total comprehensive loss for the period	(8,693)
Total comprehensive loss for the period attributable to Equity Holders	(8,693)

Celyad Oncology SA
Interim consolidated statement of financial position

(€'000)	March 31, 2021
NON-CURRENT ASSETS	46,268
Intangible assets	36,181
Property, Plant and Equipment	3,807
Non-current Trade and Other receivables	2,199
Non-current Grant receivables	3,837
Other non-current assets	244
CURRENT ASSETS	15,833
Trade and Other Receivables	590
Current Grant receivables	816
Other current assets	2,294
Short-term investments	—
Cash and cash equivalents	12,133
TOTAL ASSETS	62,101
EQUITY	25,319
Share Capital	50,123
Share premium	44,188
Other reserves	31,535
Accumulated deficit	(100,527)
NON-CURRENT LIABILITIES	25,667
Bank loans	—
Lease liabilities	2,341
Recoverable Cash advances (RCAs)	4,701
Contingent consideration payable and other financial liabilities	17,746
Post-employment benefits	614
Other non-current liabilities	264
CURRENT LIABILITIES	11,115
Bank loans	19
Lease liabilities	1,039
Recoverable Cash advances (RCAs)	341
Trade payables	4,532
Other current liabilities	5,185
TOTAL EQUITY AND LIABILITIES	62,101