

CELYAD ONCOLOGY SA

FORM 6-K

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

Filed 11/10/21 for the Period Ending 11/10/21

| | |
|-------------|------------------------------------|
| Telephone | 32 10 394 100 |
| CIK | 0001637890 |
| Symbol | CYAD |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Medical Research |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

**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 November 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):

Celyad Oncology SA

On November 10, 2021, Celyad Oncology SA (the “Company”) issued a press release announcing its financial and operating results for the third quarter of 2021. A copy of the Company’s press release is attached hereto as Exhibit 99.1 and a copy of the Company’s interim financial report for the third quarter of 2021 is attached hereto as Exhibit 99.2. Exhibits 99.1 and 99.2 are incorporated herein by reference.

The information contained in this Current Report on Form 6-K, including Exhibits 99.1 and 99.2, except for the quotes 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

| <u>Exhibit</u> | <u>Description</u> |
|----------------|--|
| 99.1 | Press release issued by the registrant on November 10, 2021 |
| 99.2 | Interim Financial Report issued by the registrant on November 10, 2021 |

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: November 10, 2021

By: /s/ Filippo Petti

Filippo Petti

Chief Executive Officer and Financial Officer



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

- *Phase 1b KEYNOTE-B79 trial set to evaluate CYAD-101 followed by KEYTRUDA® in metastatic colorectal cancer (mCRC) patients with microsatellite stable disease on track to begin by year-end 2021*
- *Enrollment continues at the highest dose level in Phase 1 IMMUNICY-1 trial evaluating CYAD-211 in relapsed/refractory multiple myeloma (r/r MM); next clinical update will be presented at the 63rd American Society of Hematology (ASH) Annual Meeting*
- *Additional data from CYCLE-1 trial evaluating CYAD-02 in relapsed/refractory acute myeloid leukemia/myelodysplastic syndromes (r/r AML / MDS) will be presented at the 63rd ASH Annual Meeting*
- *Exclusive patent license agreement signed with the University of Pennsylvania for an engager targeting Glypican 3 (GPC3)*
- *Company awarded €3.5 million Grants and Non-Dilutive Funding by the Walloon Region*

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 September 30, 2021.

“Our team continues to take major strides towards the development of a differentiated, next-generation CAR T pipeline based on novel non-gene edited technologies which we believe offer potential advantages over gene-editing approaches. During our R&D Day in the third quarter, we provided an in-depth review of our platforms, including our proprietary shRNA and TIM technologies, as well as our ‘armored’ CAR franchise focused on the co-expression of secreting IL-18. These key capabilities are reflected across our allogeneic clinical programs and highlight the advancements we’re making. Overall, we’ve treated more than 30 patients with our allogeneic CAR T product candidates without evidence of GvHD while observing encouraging early signals of clinical activity, which we believe is a promising validation that our non-gene edited strategy for allogeneic CAR T has the potential to be a game-changer for the field,” commented Filippo Petti, Chief Executive Officer of Celyad Oncology. “There are several data readouts scheduled at this year’s ASH and SITC annual meetings, and we believe the updates from the Phase 1 IMMUNICY-1 trial of CYAD-211, as well as the pending initiation of the Phase 1b KEYNOTE-B79 trial will further position us as leaders in the allogeneic CAR T space.”

Recent Highlights

- Research & Development Day held on July 20, 2021, during which the management team provided:
 - Updates on the allogeneic CAR T clinical candidates CYAD-211 and CYAD-101.
 - Highlights from the latest research from the Company’s proprietary short hairpin RNA (shRNA) platform, including the introduction of CYAD-203 – a novel allogeneic, Interleukin-18 (IL-18)-armored CAR T candidate currently in IND-enabling studies.
- Acquisition of an exclusive patent license from the University of Pennsylvania for an engager targeting Glypican 3 (GPC3), which will be tested with the Company’s proprietary shRNA technology platform.
- Three abstracts to be presented at the Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting, which will include information about:
 - Celyad Oncology’s multiplexing capabilities using shRNA technology.
 - The Company’s first non-gene edited allogeneic, IL-18-armored CAR T candidate CYAD-203.
 - Phase 1b KEYNOTE-B79 trial of CYAD-101 followed by KEYTRUDA® (pembrolizumab) in refractory metastatic colorectal cancer patients.
- Two abstracts to be presented at the 63rd ASH Annual Meeting to be held from December 11-14, 2021, which will include additional data for CYAD-211 and CYAD-02.

Third Quarter 2021 Financial Review

As of September 30, 2021, the Company had cash and cash equivalents of €6.1 million (\$7.1 million), representing a decrease in cash and cash equivalents of €5.9 million as compared to June 30, 2021. The Company believes that its existing cash and cash equivalents combined with the remaining access to the equity purchase agreement established with Lincoln Park Capital Fund, LLC should be sufficient, based on the current scope of activities, to fund operating expenses and capital expenditure requirements to the end of the third quarter of 2022.

Update on Clinical and Preclinical Programs

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

- CYAD-101 is the Company's allogeneic CAR T candidate engineered to co-express a chimeric antigen receptor (CAR) based on the NKG2D receptor and the novel inhibitory peptide TCR Inhibitory Molecule (TIM).
- 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.
- The Phase 1b KEYNOTE-B79 trial, which will evaluate CYAD-101 following FOLFOX preconditioning chemotherapy, with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in refractory mCRC patients with microsatellite stable (MSS) / mismatch-repair proficient (pMMR) disease, is on track to begin by year-end 2021.
- This KEYNOTE-B79 trial is part of a clinical trial collaboration involving Celyad Oncology and MSD, a tradename of Merck & Co., Inc., Kenilworth, NJ., USA, through a subsidiary.

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

- CYAD-211 comprises a B cell maturation antigen (BCMA) targeting CAR co-expressed with a shRNA that targets the CD3ζ component of the T-cell receptor (TCR) complex.
- The dose-escalation, Phase 1 IMMUNICY-1 trial is evaluating the tolerability and clinical activity of a single infusion of CYAD-211 following preconditioning with cyclophosphamide and fludarabine given for three consecutive days.
- In July 2021, preliminary data from the Phase 1 IMMUNICY-1 trial was presented from a total of seven patients (three patients at dose level one, three patients at dose level two and one patient at dose level three) demonstrating no evidence of Graft-versus-Host disease (GvHD) along with initial evidence of clinical response in the form of two partial responses. Importantly, CYAD-211 cells were detected within the peripheral blood of all patients analyzed with an apparent stepwise engraftment across the three dose levels.
- Enrollment in the trial is ongoing with plans to explore higher doses of preconditioning regimens in future cohorts. A clinical update will be presented at the upcoming ASH meeting in December 2021.

CYAD-203 – Allogeneic shRNA-based, IL-18-armed NKG2D CAR T for Solid Tumors

- CYAD-203 is the Company's first armored CAR T candidate engineered to co-express the cytokine IL-18 with the NKG2D CAR receptor. To the Company's knowledge, CYAD-203 is the first allogeneic IL-18 secreting CAR T candidate.
- Investigational New Drug (IND)-enabling studies are currently in progress alongside production of the clinical grade vector.
- Submission of the IND application for CYAD-203 is expected in mid-2022.
- At the SITC 36th Annual Meeting, preclinical data will be presented demonstrating the enhanced anti-tumor activity of NKG2D CAR T cells armored with IL-18.

CYAD-02 – Autologous NKG2D receptor CAR T for r/r AML / MDS

- CYAD-02, the Company's autologous CAR T candidate with shRNA technology that targets the NKG2D ligands MICA and MICB, is currently being evaluated for the treatment of r/r AML / MDS in the Phase 1 CYCLE-1 dose-escalation trial.
- Additional safety and efficacy data from the trial will be presented at the upcoming ASH meeting in December 2021.

Upcoming Anticipated Milestones

- Initiation of the Phase 1b KEYNOTE-B79 trial evaluating CYAD-101 with KEYTRUDA® in mCRC patients with MSS/pMMR disease is anticipated by year-end 2021.
- Additional data from the Phase 1 IMMUNICY-1 trial of CYAD-211 and the Phase 1 CYCLE-1 trial of CYAD-02 are expected at the upcoming ASH meeting in December 2021.
- Submission of the IND application for CYAD-203 for treatment of solid tumors is expected in mid-2022.

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 initiation of the KEYNOTE-B79 trial, the timing and outcomes of additional data from Phase 1 IMMUNICY-1 trial of CYAD-211 and the Phase 1 CYCLE-1 trial of CYAD-02, the timeline and outcome of the submission of the IND application for CYAD-203, the safety and clinical activity of Celyad Oncology's pipelines, Celyad Oncology's financial condition and cash runway, and 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, 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 the latest Annual Report on Form 20-F filed with the SEC 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 any such statement is based, unless required by law or regulation.

Investor and Media Contacts:

Sara Zerkovic
Communications & Investor Relations Director
Celyad Oncology
investors@celyad.com

Daniel Ferry
Managing Director
LifeSci Advisors, LLC
daniel@lifesciadvisors.com



Source: Celyad Oncology SA

Celyad Oncology SA
Interim consolidated statement of comprehensive income

| (€'000) | For the Nine-month period ended September 30, | |
|---|--|-----------------|
| | 2021 | 2020 |
| Revenue | — | 5 |
| Cost of sales | — | — |
| Gross profit | — | 5 |
| Research and Development expenses | (15.233) | (15.687) |
| General & Administrative expenses | (7.193) | (7.308) |
| Change in fair value of contingent consideration | (3.219) | (2.117) |
| Other income | 3.548 | 3.360 |
| Other expenses | (226) | (132) |
| Operating Loss | (22.324) | (21.880) |
| Financial income | 282 | 215 |
| Financial expenses | (199) | (363) |
| Loss before taxes | (22.241) | (22.028) |
| Income taxes | (0) | — |
| Loss for the period | (22.241) | (22.028) |
| Basic and diluted loss per share (in €) | (1,49) | (1,58) |
| Other comprehensive income/(loss) | | |
| Items that will not be reclassified to profit and loss | — | — |
| Remeasurements of post-employment benefit obligations, net of tax | — | — |
| Items that may be subsequently reclassified to profit or loss | 35 | 2 |
| Currency translation differences | 35 | 2 |
| Other comprehensive income / (loss) for the period, net of tax | 35 | 2 |
| Total comprehensive loss for the period | (22.206) | (22.026) |
| Total comprehensive loss for the period attributable to Equity Holders (1) | (22.206) | (22.026) |

Celyad Oncology SA
Interim consolidated statement of financial position

| (€'000) | September 30, 2021 | December 31, 2020 |
|--|-------------------------------|------------------------------|
| NON-CURRENT ASSETS | 46.028 | 46.379 |
| Intangible assets | 36.074 | 36.171 |
| Property, Plant and Equipment | 3.419 | 4.119 |
| Non-current Trade and Other receivables | 2.165 | 2.117 |
| Non-current Grant receivables | 4.164 | 3.679 |
| Other non-current assets | 206 | 293 |
| CURRENT ASSETS | 12.169 | 19.705 |
| Trade and Other Receivables | 574 | 615 |
| Current Grant receivables | 3.333 | 145 |
| Other current assets | 2.164 | 1.711 |
| Short-term investments | — | — |
| Cash and cash equivalents | 6.098 | 17.234 |
| TOTAL ASSETS | 58.197 | 66.084 |
| EQUITY | 19.043 | 30.994 |
| Share Capital | 54.951 | 48.513 |
| Share premium | 2.142 | 43.349 |
| Other reserves | 32.668 | 30.958 |
| Accumulated deficit | (70.718) | (91.826) |
| NON-CURRENT LIABILITIES | 26.625 | 23.256 |
| Bank loans | — | — |
| Lease liabilities | 1.914 | 2.525 |
| Recoverable Cash advances (RCAs) | 5.323 | 4.220 |
| Contingent consideration payable and other financial liabilities | 18.745 | 15.526 |
| Post-employment benefits | 614 | 614 |
| Other non-current liabilities | 29 | 371 |
| CURRENT LIABILITIES | 12.529 | 11.834 |
| Bank loans | — | 37 |
| Lease liabilities | 953 | 1.076 |
| Recoverable Cash advances (RCAs) | 350 | 371 |
| Trade payables | 5.624 | 4.736 |
| Other current liabilities | 5.602 | 5.614 |
| TOTAL EQUITY AND LIABILITIES | 58.197 | 66.084 |