

Celyad Reports 2017 Financial and Operating Results and Expected Key Milestones for 2018

Conference call scheduled for Friday, 23 March, at 2:00 p.m. CET / 9:00 a.m. EDT

- *NKG2D CARs demonstrate validity of the target with the clinical activity observed in solid and hematological cancers in the THINK¹ trial*
- *First ever Complete Response for a relapsed refractory AML patient and without preconditioning*
- *Stability of disease in ovarian and colorectal cancer provide first proof of potential importance in solid tumors*
- *Established feasibility of multiple dose CAR-T therapy*
- *Strengthened allogeneic CAR-T cell IP position through Novartis licensing*

Mont-Saint-Guibert, Belgium - Celyad (Euronext Brussels and Paris, and NASDAQ: CYAD), a clinical-stage biopharmaceutical company focused on the development of CAR-T cell therapies, today provides an update on its recent operations and reported consolidated financial results for the twelve-month period ended 31 December 2017, prepared in accordance with IFRS.

Christian Homsy, CEO of Celyad: *"2017 has been another milestone year for Celyad. The responses obtained to date in AML, and in solid tumors, we believe validate NKG2D as a target and allow us to move rapidly forward with the development of this product candidate in 2018.*

Our intellectual property related to the allogeneic technology, another of our core strengths, has been further strengthened: it was upheld by the US Patent and Trademark Office as part of multiple ex-parte re-examination requests and its importance has been recognized through our licensing agreement with Novartis.

As far as 2018 is concerned: we believe it will be an exciting year as we expect to – among other things– complete the dose escalation segment of THINK and explore the various conditions that could lead to a potential registrational Phase 2 trial."

¹ THINK: THERapeutic Immunotherapy with CAR-T NKG2D

Key 2017 Highlights

- First complete response by a CAR-T cell therapy reported in a patient with relapsed and refractory AML in the Phase 1 THINK trial. Complete response obtained without preconditioning therapy
- CYAD-01 (CAR-T NKG2D) well tolerated and clinical activity seen in AML patients treated in THINK trial to date
- First signs of clinical activity in Colorectal and Ovarian cancers
- Phase 1 SHRINK² study initiated to evaluate the synergetic effect of the concurrent administration of CYAD-01 with standard chemotherapy in metastatic colorectal cancer patients
- Non-exclusive license agreement signed with Novartis for its allogeneic TCR-deficient CAR-T cell patents
- New agreements with Celdara Medical LLC and Dartmouth College following encouraging results from the THINK trial, giving right to an increased share of future revenues generated by our CAR-T platform
- Strong central IP position in the allogeneic CAR-T cell field confirmed by USPTO

Expected Milestones for 2018 and Beyond

- Dose escalation segment of THINK trial; Enrolment according to plans
- Interim read-outs of the LINK³ and the SHRINK clinical trials
- Initiation of DEPLETHINK⁴ study (non-myeloablative preconditioning chemotherapy in relapse/refractory AML or myelodysplastic syndrome (MDS) patients)
- Initiation of EPITHINK⁵ study (CYAD-01 treatment administered concurrently with 5-azacytidine in treatment-naïve AML or MDS patients not candidates for intensive therapy).
- Investigational New Drug (IND) filing for our allogeneic CYAD-101 product candidate and enrolment of the first patient of the trial
- Finalization of preclinical development of CYAD-02, a CYAD-01 iteration aimed at enhanced *in-vivo* expansion and persistence

² SHRINK: Standard CHemotherapy Regimen and Immunotherapy with CAR-T NKG2D

³ LINK: Locoregional Immunotherapy with NKG2D

⁴ DEPLETHINK: LymphoDEPLEtion and THERapeutic Immunotherapy with NKG2D

⁵ EPITHINK: EPIgenetic drug treatment and THERapeutic Immunotherapy with NKG2D

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- Proof of concept of the CARGO platform, a next generation CAR-T engineered with tumor micro-environment targeting tools and enhanced tumor infiltration capabilities (a cargo CAR). CYAD-03 is the NKG2D CAR of the CARGO platform

Commenting on the 2017 results, Dr. Debasish Roychowdhury, Member of the Board, said: *"2017 was a watershed year for Celyad. We saw promising signs of tolerability and clinical activity in the THINK trial, validating NKG2D as a target, thus allowing us to be well positioned to broaden the scope of NKG2D platform and to initiate potential pivotal studies, respectively planned for 2018 and 2019."*

Conference Call Details

A conference call will be held on Friday, 23 March 2018, at 2:00 p.m. CET / 9:00am EDT to review the financial results. Christian Homsy, Chief Executive Officer, and Patrick Jeanmart, Chief Financial Officer will deliver a brief presentation followed by a Q&A session.

Joining the Conference Call:

1. In the 10 minutes prior to the call start time, call the appropriate **participant dial-in number**.
 - Standard International Dial-In Number: +44 (0) 2071 928338
 - Local Call Dial-In Numbers:
 - Belgium 027933847
 - France 0170700781
 - UK 08444819752
 - Netherlands 0207956614
 - US 18778709135
2. Provide the operator with the **conference ID: 4391809**

Helpful keypad commands: *0 - Operator assistance.

2017 Financial and Operating Results

Celyad reported steady progress in 2017 with the advancement of the clinical development of CYAD-01. Data collected thus far from the THINK trial, which started in early 2017, show that CYAD-01 has been well-tolerated, offers an excellent safety profile and validates the activity of the NKG2D receptor.

At year-end 2017, there were no critical toxicity events related to the CYAD-01 product candidate reported by the THINK trial investigators. More importantly, the first signs of clinical activity were reported in both arms of the trial.

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In the hematological arm of the THINK trial, Celyad announced in October 2017 a world's first with the complete response in a patient with refractory and relapsed AML, obtained without preconditioning chemotherapy or other anti-tumor treatments combined with CYAD-01. Furthermore, preliminary signs of clinical activity were observed in all AML patients dosed in 2017. In the solid arm, cases of stable disease (SD) were reported in patients suffering from ovarian cancer and colorectal cancer.

Celyad also made important progress on its IP position with the announcement of a non-exclusive license agreement with Novartis and three new patents covering the allogeneic CAR-T cell approach.

In terms of financing, Celyad reported €34 million at year end 2017. This, together with anticipated milestone payments expected to be received by Celyad in 2018 from its strategic partners, should enable the company to finance all its clinical programs and other needs through the first half of 2019.

Here are the operational and financial highlights of 2017 identified by the company's board of directors:

Clinical Developments

- Data collected in 2017 from the THINK trial showed that CYAD-01 has been well-tolerated to date and validated activity of the NKG2D CAR.
- In October, Celyad achieved an important milestone in oncology with the first ever complete response in a patient with refractory and relapsed AML, obtained without preconditioning chemotherapy or other anti-tumor treatments combined with CYAD-01. Importantly, clinical activity has been observed in AML patients dosed in 2017, with all patients seeing a reduction in their blast counts in the bone marrow and/or improvements in their hematological parameters.
- Data for the THINK trial showed preliminary signs of activity of CYAD-01 in solid tumors. Stabilization of the disease was observed in an ovarian patient and in colorectal cancer patients.
- In late-2017, Celyad initiated the SHRINK trial, an open-label Phase 1 trial evaluating the safety and clinical activity of multiple doses of CYAD-01, administered concurrently with the neoadjuvant standard FOLFOX chemotherapy treatment in patients with potentially resectable liver metastases from colorectal cancer. The trial includes a dose escalation and an extension stage.

The dose escalation design will include three dose-levels of CYAD-01: 1×10^8 , 3×10^8 and 1×10^9 CYAD-01 per administration. At each dose-level, patients will receive three successive administrations, two weeks apart, at the specified dose administered at a specific timing within the FOLFOX cycle. The dose escalation portion of the trial is

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designed to enrol three patients per dose level and the extension phase is expected to enrol twenty-one additional patients. SHRINK is being conducted in key oncology centers in Belgium.

Intellectual property

- In January, the U.S. Patent and Trade Office (USPTO) upheld, for a third time, Celyad's U.S. Patent No. 9,181,527 relating to allogeneic human primary T-cells that are engineered to be TCR-deficient and express a CAR. In March, the USPTO rejected another request for a re-examination of the same patent.
- In May, Celyad obtained a new patent related to its method of treating cancer by administering allogeneic primary human T cells that are engineered to be TCR-deficient and to express a CAR. U.S. Patent no. 9,663,763 is the third patent in Celyad's allogeneic intellectual property portfolio awarded by the USPTO. This new patent claims specific methods of treating cancer patients with allogeneic TCR-deficient CAR-T immunotherapies.

The combination of this patent with earlier granted U.S. patents, consolidates Celyad's strong intellectual property position in the allogeneic CAR-T field and strengthens the Celyad's IP portfolio covering key elements in the allogeneic TCR-deficient CAR-T cells production value chain.

Corporate and financial highlights

- In May, Celyad announced a non-exclusive license agreement with Novartis regarding U.S. patents related to allogeneic CAR-T cells. The agreement includes Celyad's intellectual property rights under U.S. Patent No. 9,181,527. This agreement is related to two undisclosed targets currently under development by Novartis.

Under the terms of the agreement, Celyad received an upfront payment and is eligible to receive payments in aggregate amounts of up to \$96 million. In addition, Celyad is eligible to receive single digit percentage royalties based on net sales of the licensed target. Celyad retains all rights to grant further licenses to third parties for the use of allogeneic CAR-T cells.

- In August, Celyad amended its agreements with Celdara Medical LLC and Dartmouth College related to the CAR-T NK cell drug product candidates and related technology licensed in January 2015 following the acquisition of OnCyte LLC. Under the amended agreements Celyad is entitled to receive an increased share of future revenues generated by these assets, including revenues from its sub-licensees. In return, Celyad paid Celdara Medical LLC and Dartmouth College an upfront payment of \$12.5 million (€10.6 million) and issued to Celdara Medical LLC \$12.5 million worth of Celyad's ordinary shares at a share price of €32.35.

Financial highlights

For the full year ended December 31, 2017, our revenues generated by our strategic collaborations amounted to €3.5 million and corresponded to the non-refundable upfront payment received from Novartis, as a result of the non-exclusive license agreement signed in May 2017. The revenues of 2016 corresponded to the payment received from ONO.

In 2017, our research and development expenses decreased by €4.7 million at €23.0 million compared to 2016. The general and administrative expenses are almost stable over the 2 periods.

As a result, the operating loss of our recurring operations (REBIT) amounted to €26.6 million compared to €25.6 million in 2016.

In 2017, we recognized non-recurring expenses related to the amendment of the agreements with Celdara Medical, LLC and Dartmouth College and the write-off of the C-Cure and Corquest assets together with the derecognition of related liabilities (respectively for €24.3 million, €0.7 million and €1.2 million). There were no non-recurring items in the income statement of 2016.

At year end 2017, the loss from operations before financial results and taxes (EBIT) amounted to €52.9 million versus €25.6 million in 2016.

The 2017 financial income & charges covered mainly interest received on cash deposits and currency exchange rates differences and bank charges. Due the depreciation of the USD compared to EUR, the Group recognized an unrealized loss on foreign exchange differences of €4.4 million in 2017. In 2016, the unrealized gain on foreign exchange differences amounted to €0.8 million.

Taking into account the net financial loss, the net loss of 2017 amounted to €56.4 million versus a net loss of €23.6 million for same period in 2016.

For 2018, we expect to receive additional sublicensing income from our strategic partners and a reasonable increase of our operating expenses, mainly research and development expenses as we will be running multiple clinical trials in parallel.

Cash and short-term deposits were €34 million as of 31 December 2017.



Press Release
22 March 2018
10:01 pm CET

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Celyad plans to publish its audited Annual Report for the year ended 31 December 2017 on 6 April 2018. The statutory auditor, BDO Réviseurs d'Entreprises SCCRL, represented by Bert Kegels, has confirmed that the audit, which is substantially complete, has not to date revealed any material misstatement in the draft consolidated financial statements, and that the accounting data reported in the press release are consistent, in all material respects, with the draft consolidated financial statements from which it has been derived.

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Consolidated statement of financial position

(€'000)	As of 31 December	
	2017	2016
NON-CURRENT ASSETS	41,232	53,440
Intangible assets	36,508	49,566
Property, Plant and Equipment	3,290	3,563
Other non-current assets	1,434	311
CURRENT ASSETS	36,394	85,367
Trade and Other Receivables	233	1,359
Other current assets	2,255	1,420
Short-term investment	10,653	34,230
Cash and cash equivalents	23,253	48,357
TOTAL ASSETS	77,626	138,806
EQUITY	47,535	90,885
Share Capital	34,337	32,571
Share premium	170,297	158,010
Other reserves	23,322	24,329
Retained loss	(180,421)	(124,026)
NON-CURRENT LIABILITIES	22,146	36,646
Bank loans	326	536
Finance leases	482	381
Advances repayable	1,544	7,330
Contingent consideration liability	19,583	28,179
Post employment benefits	204	204
Other non-current liabilities	7	16
CURRENT LIABILITIES	7,945	11,275
Bank loans	209	207
Finance leases	427	354
Advances repayable	226	1,108
Trade payables	4,800	8,098
Other current liabilities	2,282	1,508
TOTAL EQUITY AND LIABILITIES	77,626	138,806

⁽¹⁾ For 2017 and 2016, the Group does not have any non-controlling interests and the losses for the year are fully attributable to owners of the parent.

Consolidated statement of the comprehensive loss

(€'000)	For the year ended 31 December	
	2017	2016
Revenues	3,540	8,523
Cost of Sales	(515)	(53)
Gross profit	3,025	8,471
Research and Development expenses	(22,908)	(27,675)
General and administrative expenses	(9,310)	(9,744)
Other operating income	2,590	3,340
Operating Loss before non-recurring items - REBIT	(26,603)	(25,609)
Amendments of Celdara Medical and Dartmouth	(24,341)	-
Write-off C-Cure & Corquest assets and liabilities	(1,932)	-
Operating Loss - EBIT	(52,876)	(25,609)
Financial income	933	2,204
Financial expenses	(4,454)	(207)
Loss before taxes	(56,396)	(23,612)
Income taxes	1	6
Loss for the year ^[1]	(56,395)	(23,606)
Basic and diluted Loss per share (in €)	(5.86)	(2.53)
Other comprehensive Income		
Items that will not be reclassified to profit and loss	-	(107)
Remeasurements of post employment benefit	-	(107)
Items that may be subsequently reclassified to profit	(769)	277
Currency translation differences	(769)	277
Other comprehensive income/(loss) for the year, net	(769)	170
Total comprehensive loss for the year	(57,164)	(23,436)
Total comprehensive loss for the year attributable to Equity Holders ^[1]	(57,164)	(23,436)

^[1] For 2017 and 2016, the Group does not have any non-controlling interests and the losses for the year are fully attributable to owners of the parent.

Regulated Information

Consolidated statement of changes in equity

(€'000)	Share capital	Share premium	Other reserves	Retained loss	Total Equity
Balance as of 1st January 2016	32,571	158,010	21,205	(100,313)	111,473
Capital increase					-
Exercise of warrants					-
Share-based payments			2,848		2,848
Total transactions with owners, recognized directly in equity	-	-	2,848	-	2,848
Loss for the year				(23,606)	(23,606)
Currency Translation differences			277		277
Remeasurements of defined benefit obligation				(107)	(107)
Total comprehensive gain/(loss) for the year	-	-	277	(23,713)	(23,436)
Balance as of 31 December 2016	32,571	158,010	24,330	(124,026)	90,885
Balance as of 1st January 2017	32,571	158,010	24,330	(124,026)	90,885
Capital increase resulting from Celdara and Dartmouth College agreements amendment	1,141	9,479			10,620
Exercise of warrants	625				625
Share-based payments		2,808	(239)		2,569
Total transactions with owners, recognized directly in equity	1,766	12,287	(239)		13,814
Loss for the year				(56,395)	(56,395)
Currency Translation differences			(769)		(769)
Total comprehensive gain/(loss) for the year	-	-	(769)	(56,395)	(57,164)
Balance as of 31 December 2017	34,337	170,297	23,322	(180,421)	47,535

Regulated Information

Consolidated statement of Cash flows

(€'000)	For the year ended 31 December	
	2017	2016
<u>Cash Flow from operating activities</u>		
Net Loss for the year	(56,395)	(23,606)
Cash expense for amendment of Celdara Medical and Dartmouth College agreements	13,276	-
Non-cash adjustments		
Intangibles - Amortisation & Impairment	8,038	756
PP&E - Depreciation	966	760
Non-Cash expense for amendment of Celdara Medical and Dartmouth College agreements	10,620	
Post Employment Benefit	-	(24)
Change in fair value of Contingent consideration liability	(193)	1,633
Remeasurement of RCA's	(5,752)	(2,154)
RCA's and Grants income	(1,376)	(3,003)
Currency Translation Adjustment	-	(144)
Non-cash employee benefits expense – share based payments	2,569	2,847
Change in working capital		
Trade receivables, other receivables, other non-current assets	(161)	(1,018)
Trade payables, other payable and accruals	(2,524)	(740)
Net cash used in operations, before non-recurring items	(30,932)	(24,692)
Contingent consideration pay out	(5,341)	
Cash expense for amendment of Celdara Medical and Dartmouth College agreements	(13,276)	-
Net cash used in operations	(49,548)	(24,692)
<u>Cash Flow from investing activities</u>		
Acquisitions of Property, Plant & Equipment	(851)	(1,687)
Acquisitions of Intangible assets	(7)	(95)
Disposals of fixed assets	-	78
Acquisition of short term investments	(10,749)	(34,230)
Proceeds from short term investments	34,326	7,338
Acquisition of BMS SA	-	(1,560)
Net cash (used in)/from investing activities	22,720	(30,157)
<u>Cash Flow from financing activities</u>		

Regulated Information

Proceeds from finance leases and bank borrowings	543	1,165
Repayments of finance leases and bank borrowings	(576)	(399)
Proceeds from issuance of shares and exercise of warrants	625	-
Proceeds from RCAs & other grants	1,376	3,107
Repayment of advances	(1,364)	(842)
Net cash (used in)/from financing activities	605	3,031
Net cash and cash equivalents at beginning of the period	48,357	100,174
Change in Cash and cash equivalents	(26,224)	(51,818)
Effects of exchange rate changes on cash and cash equivalents	1,120	-
Net cash and cash equivalents at the end of the period	23,253	48,357

About Celyad

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized CAR-T cell based therapies. Celyad utilizes its expertise in cell engineering to target cancer. Celyad's Natural Killer Receptor based T-Cell (NKR-T) platform has the potential to treat a broad range of solid and hematologic tumors. Its lead oncology candidate, CYAD-01 (CAR-T NKG2D), has been evaluated in a single dose escalation Phase I clinical trial to assess the safety and clinical activity of multiple administrations of autologous CYAD-01 cells in seven refractory cancers including five solid tumors (colorectal, ovarian, bladder, triple-negative breast and pancreatic cancers) and two hematological tumors (acute myeloid leukemia and multiple myeloma). Celyad was founded in 2007 and is based in Mont-Saint-Guibert, Belgium, and Boston, Massachusetts. Celyad's ordinary shares are listed on the Euronext Brussels and Euronext Paris exchanges, and its American Depository Shares are listed on the NASDAQ Global Market, all under the ticker symbol CYAD.

For more information about Celyad, please visit: www.celyad.com

About the THINK trial

THINK (Therapeutic Immunotherapy with NKG2D) is a multinational (EU/US) open-label Phase I study to assess the safety and clinical activity of multiple administrations of autologous CYAD-01 cells in seven refractory cancers, including five solid tumors (colorectal, ovarian, bladder, triple-negative breast and pancreatic cancers) and two hematological tumors (acute myeloid leukemia and multiple myeloma). The trial will test three dose levels adjusted to body weight: up to 3×10^8 , 1×10^9 and 3×10^9 CYAD-01 cells. At each dose, the patients will receive three successive administrations, two weeks apart, of CYAD-01 cells. The dose-escalation part of the study will enroll up to 24 patients while the extension phase would enroll 86 additional patients.



Press Release
22 March 2018
10:01 pm CET

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Forward-looking statements

In addition to historical facts or statements of current condition, this press release contains forward-looking statements, including statements about the potential safety, activity, efficacy and feasibility of CYAD-01 cell therapy and other product candidates, including current and planned preclinical studies and clinical trials and regulatory filings for Celyad's product candidates; the clinical and commercial potential of these product candidates and the adequacy of Celyad's financial resources; the strength of Celyad's intellectual property portfolio and plans related thereto; Celyad's expectations regarding its strategic collaborations and license agreements with third parties, including Novartis, Celdara Medical, and Dartmouth College, and the potential impact of such collaborations on Celyad's future financial condition, including anticipated milestones and royalties and the timing thereof; Celyad's expected cash burn, which reflect Celyad's current expectations and projections about future events; and the anticipating timing of Celyad's 2017 annual report, and involve certain known and unknown risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These forward-looking statements are further qualified by important factors and risks, which could cause actual results to differ materially from those in the forward-looking statements, including risks associated with conducting clinical trials; the risk that safety, bioactivity, feasibility and/or efficacy demonstrated in earlier clinical trials or preclinical studies may not be replicated in subsequent trials or studies; risks associated with the timely submission and approval of anticipated regulatory filings; the successful initiation and completion of clinical trials, including its clinical trials for CYAD-01; risks associated with the successful manufacture of drug product for its clinical trials; risks associated with the satisfaction of regulatory and other requirements; risks associated with the actions of regulatory bodies and other governmental authorities; risks associated with obtaining, maintaining and protecting intellectual property, Celyad's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; risks associated with competition from others developing products for similar uses; risks associated with Celyad's ability to manage operating expenses; and risks associated with Celyad's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and business initiatives. A further list and description of these risks, uncertainties and other risks can be found in Celyad'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 April 4, 2017 and subsequent filings and reports by Celyad. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. Celyad 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.