

Celyad Reports 2016 Financial and Operating Results and Expected Key Milestones for 2017

First clinical trial of CAR-T NKR-2 cell therapy completed with encouraging safety profile and unexpected signals of clinical activity at the low doses tested.

Strong cash position expected to fund operations until mid-2019.

Key 2016 Highlights

- Completion of first CAR-T NKR-2 Phase I trial, confirming safety of CAR-T NKR-2 cells but also reporting unexpected clinical activity in patients suffering from AML and MM.
- Signature of strategic collaboration agreements with ONO Pharmaceuticals and Institut Curie to support development of immuno-oncology programs.
- Approval from Belgian regulatory authorities to start THINK Phase I trial in Belgium.
- Release of CHART-1 data 9-month primary endpoint. Results for the CHART-1 European Phase III clinical trial evaluating C-Cure® cell therapy did not meet the primary endpoint
- Strong cash position: EUR 82.6 million as of 31 December 2016.

Expected 2017 Milestones

- Initiation of THINK trial (USA) in Q1 2017.
- Initiation of SHRINK study (US/EU) in Q2 2017.
- Initiation of LINK study (EU) in Q3 2017.
- THINK dose-escalation results expected in Q4 2017.

Mont-Saint-Guibert, Belgium - Celyad (Euronext Brussels and Paris, and NASDAQ: CYAD), a leader in the discovery and development of engineered cell therapies, with clinical programs in immuno-oncology, today provides an update on its recent operations and reported consolidated financial results for the twelve-month period ended 31 December 2016, prepared in accordance with IFRS.

Commenting on the 2016 results, Christian Homsy, CEO of Celyad, said: "2016 has been a challenging year in which our CAR-T portfolio has continued to develop, with the company building its expertise in the field of immuno-oncology, and one in which we transitioned from a focus on cardiology to being one of the most promising prospects in the field of next generation CAR-T cells."



Conference Call Details

A conference call will be held on Thursday, 23 March 2017 at 2:00 p.m. CET / 8:00am EST 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) 1452 560304
 - Local Call Dial-In Numbers:
 - Belgium 024017052
 - France 0170700785
 - UK 08448719299
 - Netherlands 0207133453
 - US 16316215256
2. Provide the operator with the **conference ID 87117681**

Helpful keypad commands: *0 - Operator assistance.

2016 Financial and Operating Results

Celyad successfully completed the CM-CS1 trial, the first clinical trial using CAR-T NKR-2 cells in relapse refractory patients suffering from Acute Myeloid Leukemia (AML) or Multiple Myeloma (MM). No safety issues were reported and first unexpected signs of clinical activity were observed in both AML and MM patients, despite the low doses infused.

Celyad has a comfortable cash position at year end 2016 with more than EUR 82 million in treasury due to a successful NASDAQ IPO in June 2015. This should enable the Company to finance all its clinical programs and other needs until mid-2019.

Here are the operational and financial highlights of 2016 identified by the Board:

Clinical Developments in Oncology

- In March, Celyad substantially strengthened its allogeneic intellectual property portfolio with the granting by the USPTO of the US Patent No 9,273,283. This patent provides Celyad with broad protection for its proprietary method of producing allogeneic human T-cells that are engineered to be T-Cell Receptor (TCR)-deficient and express a Chimeric Antigen Receptor (CAR).
- Also in March, the company signed strategic collaboration agreement with Institut Curie's Immunity Cancer Unit (in France) for the development of the immuno-oncology program. The partnership will build on Institut Curie's first-in-class expertise and state-of-the-art translational, preclinical and clinical know-how in cancer biology and immunology.
- In July, Celyad announced the signing of an exclusive licensing agreement with leading Japanese immuno-oncology company, ONO Pharmaceutical Co. Ltd., for the development and commercialization of Celyad's allogeneic CAR-T NKR-2 immunotherapy in Japan, Korea and Taiwan. Celyad also granted to ONO an exclusive option to license its autologous NKR-2 T cell product in the above ONO territories. Total deal value of up to 31.325 JPYB (€282 million or \$311.5 million) plus double digit royalties on net sales in ONO territories.
- In September, the company completed the CAR-T NKR-2 Phase I trial with successful safety follow-up of all the dose level cohorts. No safety or toxicity issues were reported after the 21-day safety follow-up of the last patient enrolled in the fourth dose level cohort in its Phase I clinical trial – a study evaluating the safety and feasibility of its CAR-T NKR-2 cell therapy in Acute Myeloid Leukemia and Multiple Myeloma patients. The Phase I trial data (presented at the Annual Meeting of the American Society of Hematology) demonstrated the drug to be safe and well tolerated at the highest dose level tested to date (3×10^7). It also shows early signals of efficacy, including prolonged survival in both Acute Myeloid Leukemia (AML) and Multiple Myeloma (MM) patients.
- In November, the Belgian Regulatory Authorities approved the initiation of the THINK trial in Belgium. THINK (THERapeutic Immunotherapy with NKR-2) is a multinational open-label Phase I study aimed to assess the safety and clinical activity of multiple administrations of autologous NKR-2 T-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).

Clinical Developments in Cardiology – C-Cure®

- In June, we reported the CHART-1 9-month primary endpoint data release. Results for the CHART-1 European Phase III clinical trial evaluating C-Cure® cell therapy did not meet the primary endpoint. However, a statistically significant trend was observed in a subset representing 60% of the population of the CHART-1 study (baseline End Diastolic Volume (EDV) segmentation) for which primary endpoint was met ($p=0.015$).

Corporate

- Appointment of ten leading international immuno-oncology experts to the Scientific Advisory Board of the Company, as well as senior executives and directors in Belgium and in the U.S. to strengthen the Group managing bodies.
- Resignation of Prof. William Wijns and Mr. Danny Wong from Celyad's Board of Directors.

Finance

- ONO Pharmaceutical total deal value of up to 31.325 JPY B (€282 million or \$311.5 million) plus double digit royalties on net sales in ONO territories (Japan, Korea and Taiwan).
- Cash and short term deposit of €82.6 million as of 31 December 2016.

Highlights of 2017

The momentum generated by Celyad's progress during 2016 has carried through into the start of 2017. Most notably, the Company has reported the following highlights regarding its strong IP position in immuno oncology:

- USPTO decided to uphold 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. Celyad's U.S. patent (No. 9,181,527), and more precisely claim 1 of the said patent, was challenged by an anonymous third party through an *Ex Parte* Re-examination procedure. The request for *Ex Parte* re-examination was filed on February 10th, 2016 and an order granting *Ex Parte* Re-examination of claim 1 was issued by the USPTO on March 24th, 2016. The final decision of this *Ex Parte* procedure that was issued on January 6th, 2017 is not subject to appeal and upholds the validity of the patent.
- On March, 14th 2017, USPTO rejected new re-examination request against Celyad's US Patent for Production of Allogeneic TCR-Deficient CAR-T Cells, confirming once more, the validity of the patent.

Annual Report 2016

Celyad will publish its audited Annual Report for the year ended 31 December 2016 on or around 4 April 2017. The statutory auditor, PwC Réviseurs d'Entreprises SCCRL, represented by Patrick Mortroux, 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 is consistent, in all material respects, with the draft consolidated financial statements from which it has been derived.

END

Consolidated statement of financial position

(€'000)	For the year ended 31 December	
	2016	2015
NON-CURRENT ASSETS	53,440	50,105
Intangible assets	49,566	48,789
Property, Plant and Equipment	3,563	1,136
Other non-current assets	311	180
CURRENT ASSETS	85,367	109,419
Trade and Other Receivables	1,359	549
Grants receivables	-	104
Other current assets	1,420	1,254
Short term investments	34,230	7,338
Cash and cash equivalents	48,357	100,175
TOTAL ASSETS	138,806	159,525
EQUITY	90,885	111,473
Share Capital	32,571	32,571
Share premium	158,010	158,010
Other reserves	24,329	21,205
Retained loss	(124,026)	(100,313)
NON-CURRENT LIABILITIES	36,646	36,562
Bank loans	536	
Finance leases	381	427
Advances repayable	7,330	10,484
Contingent liabilities	28,179	25,529
Post-employment benefits	204	121
Other non current liabilities	16	
CURRENT LIABILITIES	11,275	11,490
Bank loans	207	
Finance leases	354	248
Advances repayable	1,108	898
Trade payables	8,098	8,576
Other current liabilities	1,508	1,768
TOTAL EQUITY AND LIABILITIES	138,806	159,525

Consolidated statement of comprehensive loss

(€'000)	For the year ended 31 December	
	2016	2015
Revenues	8,523	3
Cost of sales	(53)	(1)
Gross profit	8,471	2
Research and Development expenses	(27,675)	(22,766)
General administrative expenses	(9,744)	(7,230)
Other operating income	3,340	322
Operating Loss	(25,609)	(29,672)
Financial income	2,204	542
Financial expenses	(207)	(236)
Share of Loss of investments accounted for using the equity method	-	252
Loss before taxes	(23,612)	(29,114)
Income taxes	6	-
Loss for the year ^[1]	(23,606)	(29,114)
Basic and diluted loss per share (in €)	(2.53)	(3.43)
Other comprehensive loss		
Items that will not be reclassified to profit and loss	(107)	16
Remeasurements of post-employment benefit obligations, net of tax	(107)	16
Items that may be subsequently reclassified to profit or loss	277	485
Currency translation differences	277	485
Other comprehensive loss for the year, net of tax	170	501
Total comprehensive loss for the year	(23,436)	(28,613)
Total comprehensive loss for the year attributable to Equity Holders [1]	(23,436)	(28,613)

[1] For 2016 and 2015, 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 changes in equity

(€'000)	Share capital	Share premium	Other reserves	Retained loss	Total Equity
Balance as of 1st January 2015	24.615	53.302	19.982	(71.215)	26.684
Capital increase in cash	7,607	112,104			119,711
Capital increase (Acquisition Oncyte)	326	3,126			3,452
Exercise of warrants	23	196			219
Share-based payments		59	736		795
Transaction costs associated with capital increases		(10,776)	0		(10,776)
Total transactions with owners, recognized directly in equity	7,956	104,709	736	0	113,401
Loss for the year				(29,114)	(29,114)
Currency Translation differences			487		487
Remeasurements of defined benefit obligation				16	16
Total comprehensive gain/(loss) for the year			487	(29,098)	(28,611)
Balance as of 1st January 2016	32,571	158,010	21,205	(100,313)	111,473
Capital increase in cash					
Capital increase (Acquisition Oncyte)					
Exercise of warrants					
Share-based payments			2,848		2,848
Transaction costs associated with capital increases					
Total transactions with owners, recognized directly in equity	0	0	2,848	0	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	0	0	277	(23,713)	(23,436)
Balance as of 31 December 2016	32.571	158.010	24.330	(124.026)	90.885

Consolidated statement of Cash flows

(€'000)	For the year ended 31 December	
	2016	2015
<u>Cash Flow from operating activities</u>		
Net Loss for the year	(23,606)	(29,114)
Non-cash adjustments		
Depreciation	760	273
Amortisation	756	760
Post Employment Benefit	(24)	(45)
Deconsolidation of CELYAD Asia Ltd.	-	60
Change in fair value valuation of Contingent liabilities	1,633	
Change in fair value valuation of RCA's	(2,154)	(84)
Proceeds of grants and advances	(3,003)	(1,647)
Currency translation adjustment	(144)	(21)
Share-based payments	2,847	795
Change in working capital		
Trade receivables, other receivables	(1,018)	653
Trade payables, other payable and accruals	(740)	1,066
Net cash (used in)/from operations	(24,692)	(27,303)
<u>Cash Flow from investing activities</u>		
Acquisitions of Property, Plant & Equipment	(1,687)	(811)
Acquisitions of Intangible assets	(95)	(27)
Disposals of fixed assets	78	-
Acquisition of short term investment	(34,230)	(5,000)
Proceeds from Short Term Investments	7,338	333
Acquisition of BMS SA	(1,560)	-
Acquisition of Oncyte LLC	-	(5,186)
Net cash used in investing activities	(30,157)	(10,691)
<u>Cash flows from financing activities</u>		
Proceeds from borrowings	1,165	451
Repayments of finance leases	(399)	(188)
Proceeds from issuance of shares and exercise of warrants	-	109,154
Proceeds from RCAs & other grants	3,107	1,647
Repayment of advances	(842)	(529)
Net cash from financing activities	3,031	110,535
Net cash and cash equivalents at beginning of the period	100,174	27,633



Regulated Information
Press Release
23 March 2017
07:00 am CET

Change in net cash and cash equivalents	(51,818)	72,542
Net cash and cash equivalents at the end of the period	48,357	100,175



About Celyad

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialized cell-based therapies. The Company 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, the CAR-T NKR-2, has been evaluated in a single dose - escalation Phase I clinical trial to assess the safety and feasibility of CAR-T NKR-2 cells in patients suffering from AML or MM. This Phase I study was successfully completed in September 2016. 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 NASDAQ Global Market, all under the ticker symbol CYAD.

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

About the THINK trial

THINK (**T**herapeutic **I**mmunotherapy with **NKR-2**) is a multinational (EU/US) open-label Phase I study to assess the safety and clinical activity of multiple administrations of autologous CAR-T NKR-2 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 CAR-T NKR-2 cells. At each dose, the patients will receive three successive administrations, two weeks apart, of CAR-T NKR-2 cells. The dose-escalation part of the study will enroll up to 24 patients while the extension phase would enroll 86 additional patients.

About Celyad's NKR-T Cell Platform

Celyad is developing a unique CAR-T cell platform, using Natural Killer Receptor (NKR) transduced on to T lymphocytes. The platform targets a wide range of solid and hematological tumors. Unlike traditional CAR-T cell therapy, which target only one tumor antigen, Natural Killer (NK) cell receptors enable a single receptor to recognize multiple tumor antigens.

Celyad's lead candidate, CAR-T NKR-2, is a CAR-T-Cell engineered to express the human NK receptor, NKG2D, which is an activating receptor. CAR-T NKR-2 triggers cell killing through the binding of NKG2D to any of eight naturally occurring ligands that are known to be overexpressed on more than 80% of tumors.

Preclinical results indicate that CAR-T NKR-2 has multiple mechanisms of actions and goes beyond direct cancer cell killing. It inhibits the mechanisms that enable tumors to evade the immune system, activates and recruit anti-tumor immune cells and disrupts the blood supply to the tumor. These mechanisms promote the induction of adaptive immunity, meaning the development of a long-term immune memory against specific tumor antigens of the targeted tumor.

In contrast to traditional CAR-T therapeutic approaches, and based on strong preclinical evidence, Celyad's current CAR-T NKR-2 program does not use patient lymphodepleting pre-conditioning, thereby avoiding the toxicities associated with chemotherapy and allowing the immune system to remain intact.

Celyad is developing both autologous and allogeneic CAR-T NKR-2 approaches. For autologous CAR-T NKR-2, Celyad collects the patient's own T-Cells and engineers them to express NKG2D in order to target cancer cells effectively. Celyad's allogeneic platform engineers the T-Cells of healthy donors, to also express TCR Inhibitory Molecules (TIMs), to avoid having the donor cells rejected by the patient's normal tissues (also called Graft vs. Host Disease).



Regulated Information
Press Release
23 March 2017
07:00 am CET

The preclinical research underlying this technology was originally conducted at Dartmouth College by Dr. Charles Sentman and has been published extensively in peer-reviewed publications.

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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 and feasibility of CAR-T NKR-2 cell therapy, which reflect our current expectations and projections about future events, 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, 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 or pre-clinical studies may not be replicated in subsequent studies; risk associated with the timely submission and approval of anticipated regulatory filings; the successful initiation and completion of clinical trials, including Phase I clinical trial for CAR-T NKR-2; 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, our ability to enforce our patents against infringers and defend our patent portfolio against challenges from third parties; risks associated with competition from others developing products for similar uses; risks associated with our ability to manage operating expenses; and risks associated with our ability to obtain additional funding to support our 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 the Company's Securities and Exchange Commission filings and reports, including in the Company's Annual Report on Form 20-F filed with the SEC on April 8, 2016 and future filings and reports by the Company. 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. The Company 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.