

Admission to trading of up to 1.781.395 new shares (the "New Shares") to Euronext Brussels and Euronext Paris

Investing in shares involves a high degree of risks. An investor is exposed to the risk to lose all or part of his investment. Before any investment in shares, the investor must read the "Risk Factors Section". Our main assets are intellectual property rights concerning technologies that have not led to the commercialization of any product. We have never been profitable and we have never commercialised any products.

This prospectus contains the minimum disclosure requirements for the share securities note in accordance with Annex III of the prospectus Regulation. As this prospectus relates to an application for the admission to trading on a regulated market of shares by an issuer which qualifies as SME, the level of disclosure of this prospectus is proportionate to this type of transaction in accordance with Annex XXV of the Prospectus Regulation.

For a description of certain restrictions on transfers of the shares, see section 2 "DISCLAIMERS AND NOTICES".

Prospectus dated 19 June 2015

Christian Homsy, CEO

Patrick Jeanmart, CFO

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SUMMARY

Summaries are made up of disclosure requirements known as "Elements." These Elements are numbered in Section A - E (A.1 - E.7).

This summary contains all the Elements required to be included in a summary for this type of securities and company. Because some Elements are not required to be addressed, there may be gaps in the numbering sequence of the Elements.

Even though an Element may be required to be inserted in the summary because of the type of securities and company, it is possible that no relevant information can be given regarding the Element. In this case a short description of the Element is included in the summary with the mention of "Not applicable."

Section A - Introduction and warnings

Element	Disclosure requirement
A.1	Introduction and warnings
	This summary must be read as an introduction to this prospectus and is provided to aid investors when considering whether to invest in the shares, but is not a substitute for this prospectus. Any decision to invest in the shares should be based on consideration of this prospectus as a whole, including any documents incorporated by reference. Following the implementation of the relevant provisions of the Prospectus Directive (Directive 2003/71/EC) in each Member State of the European Economic Area, no civil liability will attach to the persons responsible for this summary in any such Member State solely on the basis of this summary, including any translation thereof, unless it is misleading, inaccurate or inconsistent when read together with the other parts of this prospectus or it does not provide, when read together with the other parts of this prospectus, key information in order to aid investors when considering whether to invest in the shares. Where a claim relating to this prospectus is brought before a court in a Member State of the European Economic Area, the plaintiff may, under the national legislation of the Member State where the claim is brought, be required to bear the costs of translating this prospectus before the legal proceedings are initiated.
A.2	Consent for use of this prospectus for subsequent resale
	Not applicable. We do not consent to the use of this prospectus for the subsequent resale or final placement of securities by financial intermediaries.

Section B - Issuer

Element	Disclosure requirement
B.1	The legal and commercial name of the Company
	The legal and commercial name of the Company is Celyad SA (previously called Cardio3 BioSciences SA).
B.2	Registered office and legal form of the Company
	We are a limited liability company incorporated in the form of a société anonyme under the laws of Belgium. We are registered with the legal entities register (Nivelles) under number 0891.118.115. Our registered office is located at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

Element	Disclosure requirement
B.3	Current operations and principal activities of the Company and the principal markets in which it competes We consider we are a leader in engineered cell therapy treatments with clinical programs initially targeting indications in cardiovascular disease and oncology. All of our current drug product candidates are autologous cell therapy treatments. In autologous procedures, a patient's cells are harvested, selected, reprogrammed and expanded, and then infused back into the same patient. A benefit of autologous therapies is that autologous cells are not recognized as foreign by patients' immune systems. We believe that we are well situated to effectively advance autologous cell therapy treatments for cancer and other indications as a result of the expertise and knowhow that we have acquired through our development of C-Cure.
B.4a	Significant recent trends affecting the Company and the industries in which it operates Our lead drug product candidate in cardiovascular disease is C-Cure, an autologous cell therapy for the treatment of patients with ischemic heart failure, or HF. We completed enrollment in our first Phase 3 clinical trial of C-Cure in Europe and Israel, or CHART-1, in March 2015. On March 30, 2015, we announced that the Data Safety Monitoring Board, or DSMB, reviewed unblinded safety data from CHART-1 and determined that there was no evidence of obvious differences in safety profiles of patients in the two arms of the trial, which means that the data did not support discontinuation of the trial on the basis of safety. The full data readout from this trial is expected in the middle of 2016. We anticipate initiating our second Phase 3 clinical trial of C-Cure in the United States and Europe, or CHART-2, pending U.S. Food and Drug Administration, or FDA, lifting of the existing clinical hold, which we expect in the second half of 2015. Our lead drug product candidate in immuno-oncology is CAR-NKG2D, an autologous chimeric antigen receptor, or CAR, an artificial, lab engineered receptor, which is used to graft a given protein onto an immune cell, T lymphocyte, or CAR T-cell, therapy. We are currently enrolling patients with refractory or relapsed acute myeloid leukemia, or AML, or multiple myeloma, or MM, in a Phase 1 clinical trial of CAR-NKG2D in the United States. Interim data from this trial is expected to be reported at various times during the trial, with the full data readout expected in the middle of 2016.
B.5	Description of the Group and the Company's position within the Group We and our subsidiaries are a biotechnology group specialising in stem cell-based therapies for the treatment of cardiovascular diseases. The group has two fully owned subsidiaries in the US, Cardio3 Inc and Corquest Medical Inc, and has incorporated a joint venture in Hong-Kong in July 2014, Cardio3 BioSciences Asia Ltd, with its Hong-Kong based partner Medisun International Ltd. Corquest Medical Inc. was acquired in November 2014.
B.6	Relationship with major shareholders Based on information known to us or ascertained by us from public filings made by the shareholders as of the date of this Prospectus, updated, as the case may be, on the basis of the written answers provided by these shareholders to our questionnaires in view of

Element Disclosure requirement

the Nasdaq listing, our major shareholders are Tolefi SA (28.90%), Medisun International Ltd (7.24%), PMV-TINA (5.45%) and SRIW SA (5.10%).

The following relationships exist between us and, Medisun, one of our significant shareholders:

- we entered into an investment agreement with Medisun International Limited, pursuant to which Medisun purchased 568,180 of our ordinary shares for an aggregate purchase price of €25.0 million;
- we and Medisun also entered into a joint venture agreement, pursuant to which
 we agreed to form Cardio3 Biosciences Asia Holdings Limited to conduct clinical
 trials of C-Cure in the Peoples Republic of China, Hong Kong, Macau and Taiwan,
 and other territories mutually agreed upon by us and Medisun, with the goal of
 obtaining marketing authorization for C-Cure in the applicable territories;

we obtained a 40.0% initial ownership interest in Cardio3 Asia in exchange for our entry into a license agreement with Cardio3 Asia pursuant to which we granted an exclusive, royalty-free and non-transferable license to Cardio3 Asia for C-Cure and certain knowhow for conducting clinical trials in the applicable territories.

B.7 Selected historical key financial information

In March 2015, we had successfully raised €32 million through a private placement of ordinary shares to qualified institutional investors in the United States and Europe at a price of €44.50 per share. The consolidated net equity of the company (under IFRS) is therefore increased by €32 million following this private placement.

The selected key information is summarized here below:

(€'000)	For the year ended 31 December	
	2014	2013
		(as restated)
Consolidated statement of comprehensive loss		
Revenue	146	_
Cost of sales	(115)	_
Gross Profit	31	
Research and development expenses	(15,865)	(9,046)
General and administrative	(5,016)	(3,972)
Other operating income	4,413	64
Operating loss	(16,437)	(12,954)
Financial income	277	60
Financial expenses	(41)	(1,595)
Share of loss of investments accounted for using the equity method	(252)	_
Loss for the year.	(16,453)	(14,489)

(€'000)	Por the year ended 31 December,	
	2014	2013 (as restated)
Consolidated statement of financial position		
Non-current assets	11,041	9,783
Intangible assets	10,266	9,400
Property, Plant and Equipment	598	243
Investment accounted for using the equity method	68	-
Other non-current assets	109	140
Current assets	32,935	22,603
Trade and Other Receivables	830	422

Element	Disclosure requirement		
	Grant receivables	1,009	-
	Other current assets	792	123
	Short term investment	2,671	3,000
	Cash and cash equivalents	27,633	19,058
	Total assets	43,976	32,386
	Share capital	24,615	22,138
	Share premium	53,302	30,474
	Other reserves	19,982	18,894
	Retained loss	(71,215)	(54,608
	Total shareholders' equity	26,684	16,898
	Finance leases	279	27
	Non-current advances repayable	10,778	12,072
	Other non-current liabilities	182	· -
	Total non-current liabilities	11,239	12,099
	Finance leases	[^] 134	[^] 79
	Advances repayable	777	429
	Trade payables	4,042	2,169
	Other current liabilities	1,100	712
	Total current liabilities	6,053	3,389
	Total liabilities	17,292	15 <u>,</u> 488
	Total equity and liabilities	43,976	32,386

B.8 Selected key pro forma financial information

The unaudited pro forma condensed combined financial information gives effect to the Oncyte acquisition as if it had been completed on 1 January 2014 for purposes of the statement of operations and 31 December 2014 for purposes of the statement of financial position. The pro forma financial information and adjustments are preliminary and have been made solely for purposes of providing these unaudited pro forma condensed combined statements of operations and balance sheet. Differences between these preliminary estimates and the final acquisition accounting may occur and these differences could have a material impact on the pro forma financial information presented and the combined company's future results of operations and financial position.

(€'000)	For the year ended 31 December
	2014
Consolidated statement of comprehensive loss	
Revenue	146
Cost of sales	(115)
Gross Profit	
Research and development expenses	(16,793)
General and administrative	(5,016)
Other operating income	5,169
Operating loss	(16,609)
Financial income	277
Financial expenses	(41)
Share of loss of investments accounted for using the equity method	(252)
Loss for the year	(16,625)
•	For the year
	ended 31
(€'000)	December,
	2014
Consolidated statement of financial position	
Non-current assets	55,941
Intangible assets	•
Property, Plant and Equipment	,

Element	Disclosure requirement
	Investment accounted for using the equity method 68 Other non-current assets 109 Current assets 27,754 Trade and Other Receivables 830 Grant receivables 1,009 Other current assets 792 Short term investment 2,671 Cash and cash equivalents 22,452 Total assets 83,695 Share capital 24,940 Share premium 56,428 Other reserves 19,982 Retained loss (71,215)
	Total shareholders' equity 30,135 Finance leases 279 Non-current advances repayable 10,778 Other non-current liabilities 182 Contingent liabilities 36,268 Total non-current liabilities 47,507 Finance leases 134 Advances repayable 777 Trade payables 4,042 Other current liabilities 1,100 Total current liabilities 6,053 Total liabilities 53,560 Total equity and liabilities 83,695
B.9	Profit forecast or estimate Not applicable. No profit forecast has been included in this Prospectus.
B.10	A description of the nature of any qualifications in the audit report on the historical financial information Not applicable. There are no qualifications to the audit report on the historical financial information.
B.11	Working capital
	On the date of this prospectus, we are of the opinion that it has sufficient working capitate to meet its present requirements and cover the working capital needs for a period of a least 12 months as of the date of this prospectus.

Section C - Securities

Element	Disclosure requirement
C.1	Type and class of the securities being admitted to trading
	The shares offered to be admitted to trading (the "New Shares") are ordinary shares without nominal value. All of our shares belong to the same class. They are in registered or dematerialized form.
	The following codes have been assigned to our shares:
	ISIN: BE0974260896
	National code: 974260.89
C.2	Currency of the New Shares
	The currency of the New Shares is euro.
C.3	Number of shares issued

Element	Disclosure requirement					
	On the date of this prospectus, our registered capital is represented by 7,847,687 shares without nominal value. The number of shares for which the admission to trading on Euronext Brussels and Euronext Paris is requested is maximum 1.781.395 shares, which have been or will be					
	 93,087 shares were issued on 21 January 2015 in the context of our acquisition of OnCyte, LCC (the "OnCyte acquisition"); 9,308 shares were issued on 3 March 2015 in the context of a private placement with qualified investors (the "March private placement"); and maximum 1.679.000 new shares are expected to be issued on 24 June 2015 in the context of our U.S. initial public offering (the "Global offering"), including (i) an offering of ordinary shares in the form of American Depositary Shares, or ADSs in the U.S. (the "U.S. offering") and (ii) a concurrent private placement of ordinary shares with qualified investors in Europe and countries outside the United States and Canada (the "Concurrent private placement"). 					
C.4	Rights attached to the New Shares All New Shares will have the same rights and benefits attached to them as our other ordinary shares and will be issued with coupons 1 and following attached.					
	An ADS holder will not be treated as one of our shareholders and will not have shareholder rights. The depositary will be the holder of the ordinary shares underlying ADSs. A holder of ADSs will have ADS holder rights. A deposit agreement among us, the depositary and all persons directly and indirectly holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADRs.					
C.5	Restrictions on the free transferability of the New Shares					
	All of our outstanding shares are fully paid-up and freely transferable, subject to any contractual restrictions.					
C.6	Applications for admission to trading on a regulated market and identity of all the regulated markets where the New Shares are or are to be traded					
	An application has been made to have the New Shares listed on the regulated market of Euronext Brussels and the regulated market of Euronext Paris under the symbol "CYAD". On 5 May 2015, the Extraordinary Shareholders meeting of the Company approved the new name "Celyad". The rebranding of the Company was triggered by the acquisition on Oncyte, the new immune-oncology asset of the Company, hence the name change from Cardio3 BioSciences to Celyad. The estimate costs of the rebranding amount to €0.1 million.					
	We intend to apply to have our ADSs listed on the NASDAQ Global Market under the symbol "CYAD."					
C.7	A description of dividend policy					
	We have never declared or paid any cash dividends on our ordinary shares. We do not anticipate paying cash dividends on our equity securities in the foreseeable future and					

Element Disclosure requirement

intend to retain all available funds and any future earnings for use in the operation and expansion of our business. In general, distributions of dividends proposed by our board of directors require the approval of our shareholders at a meeting of shareholders with a simple majority vote, although our board of directors may declare interim dividends without shareholder approval, subject to the terms and conditions of the Belgian Company Code.

Section D - Risks

Element Disclosure requirement

D.1 Key Risks Relating to our Business

Investing in securities involves a high degree of risk. You should carefully consider the following risks and all other information contained in this prospectus, including our consolidated financial statements and the related notes, before making an investment decision regarding our securities. The risks and uncertainties described below are those significant risk factors, currently known and specific to us, that we believe are relevant to an investment in our securities. If any of these risks materialize, our business, financial condition or results of operations could suffer, the price of the securities could decline and you could lose part or all of your investment.

- We have incurred net losses in each period since our inception and anticipate that we will continue to incur net losses in the future.
- We have generated only limited revenue from sales of C-Cathez to date, and do not expect to generate material revenue until we receive regulatory approval for one of our drug product candidates.
- We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities. For example, our IND for C-Cure was originally submitted to the FDA in January 2012 and is now subject to a clinical hold that prevents the initiation of CHART-2.
- Our drug product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.
- Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials as well as data from any interim analysis of ongoing clinical trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.
- Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- There has been no prior active market for the ADSs and an active and liquid market for the ADSs may fail to develop, which could harm the market price of the ADSs.

Element	Disclosure requirement						
	Our future results will suffer if we do not effectively manage our expanded operations as a result of our recent acquisition of OnCyte.						
D.3	Key Risks Relating to the Securities						
	 If securities or industry analysts do not publish research or publish inaccurate research or unfavorable research about our business, the price of the securities and trading volume could decline. 						
	 Future sales of ordinary shares or ADSs by existing shareholders could depress the market price. 						
	After the completion of the U.S. initial public offering, we may be at an increased risk of securities class action litigation.						

Section E - The Issue

Element	Disclosure requirement					
E.1	Net proceeds and expenses of the issuing of the New Shares					
	We estimate that our net proceeds from the envisaged Global offering will be approximately \$90 million (€ 79 million), after deducting the underwriting commissions and estimated offering expenses payable by us: the net proceeds of the U.S. offering will be approximately \$72 million (€ 63 million) and the net proceeds of the Concurrent private placement of ordinary shares with qualified investors in Europe and countries outside the United States and Canada will be approximately amounted to \$18 million (€16 million).					
E.2a	Use of proceeds					
	We expect to use the net proceeds from the Global offering to advance the development of C-Cure through Phase 3 clinical development as a treatment for ischemic HF, to advance the development of CAR-NKG2D through Phase 1 clinical development as a treatment for AML and MM, to advance additional CAR T-cell therapy drug product candidates for the treatment of additional blood cancers and solid tumors, to support our growth globally by expanding general, administrative and operational functions in our headquarters in Belgium and in the United States, and the remainder for working capital and other general corporate purposes.					
E.3	Terms and conditions of the issuing of the New Shares					
	The maximum 1.781.395 New Shares for which admission to trading on Euronext Brussels and Euronext Paris has been requested, have been or will be issued by us in the context of the following transactions:					
	• 93,087 New Shares were issued on 21 January 2015 at EUR 37.08 per share in the context of OnCyte acquisition;					
	 9,308 New Shares were issued on 3 March 2015 at EUR 44.50 per share in the context of the March private placement; and 					
	 maximum 1.679.000 New Shares are expected to be issued on 24 June 2015, at a purchase price to be determined in the context of the Global offering, including (i) the U.S. offering and (ii) the Concurrent private placement. 					

Element	Disclosure requirement				
E.4	Material interests to the issuing of the New Shares				
	Save for the fees payable to the underwriters in the context of the Global offering, so far as we are aware, no person involved in the issue of the New Shares has an interest that could be material to the issue.				
E.5	Entity offering the New Shares and Lock-ups				
	In the context of our U.S. initial public offering we, the members of our board of directors and our executive management team, and certain of our shareholders have entered into lock-up agreements with the underwriters. Under the lock-up agreements, subject to certain exceptions, we and each of these persons may not, without the prior written approval of UBS Securities LLC, offer, sell, contract to sell, pledge, or otherwise dispose of, directly or indirectly, or hedge our ADSs or securities convertible into or exchangeable or exercisable for our ADSs. These restrictions will be in effect for a 90-day period after 18 May 2015. UBS Securities LLC may, at any time, without public notice and in its sole discretion, release some or all the securities from these lock-up agreement.				

E.6 Dilution resulting from the issuing of the New Shares

The table below provide an overview of the shareholding of the significant shareholders of the Company after the completion of the Global offering and listing of the Company's new shares. The number of outstanding shares and warrants after the completion of the Global offering and listing of the new shares assumes that the over-allotment option has been fully exercised and that as a result, the number of offered shares amounts to 9.526.687. The simulation is merely for information purposes only. Prospective investors should note that the final number of New Shares could be lower than assumed for the table below.

Share- / Warrantholder	Number of shares	%	Warrants in number of shares	%	Total number of shares and	%
A. Executive Management Tean		70	or snares	70	warrants	70
CEO and other members of the Executive Management Team	81.378	0.85	199.725	61.70	281.103	2.85
B. (Independent) Directors						
Independent Directors	125.753	1.32	10.000	3.09	135.753	1.38
C. Other shareholders						
Tolefi SA	2.267.844	23.81	2.504	0.77	2.270.348	23.05
Medisun Ltd	568.180	5.96	-	-	568.180	5.77
PMV-Tina NV	428.071	4.49	-	-	428.071	4.35
SRIW Techno and Sofipôle	400.000	4.20	-	-	400.000	4.06
Mayo Foundation for Education and Research	211.135	2.22	-	-	211.135	2.14
Cardiovasculair Onderzoek Aalst CVBA	160.062	1.68	-	-	160.062	1.62
Mr Michel Lussier	162.370	1.70	400	0.12	162,370	1.65
Other shareholders	3.340.499	35.60	1.871	0.58	3,342,370	33.93
Subtotal	7.538.161	79.13	4.775	1.47	7.542.936	76.58
D. Personnel						

Element	Disclosure requirement							
	Personnel	-	-	109.197	33.73	109.197	1.11	
	E. Shares issued in January and March 2015	102.395	1.07	-	-	102.395	1.04	
	Subtotal A+B+C+D+E	7.847.687	82.38	323.697	100%	8.171.384	82.95	
	E. As a result of the Global offering	1.679.000	17.62			1.679.000	17.05	
	New shares	1.460.000	15.33			1.460.000	14.82	
	Exercise over-allotment option	219.000	2.30			219.000	2.22	
	Total A+B+C+D+E+F	9.526.687	100%	323.697	100%	9.850.384	100%	
E.7	Estimated expenses charg	ed to the inv	estor by	us				
	Not applicable. No fees or expenses in connection with the admission to trading will be charged to investors by us.							

1 RISK FACTORS

Investing the shares involves a high degree of risk. You should carefully consider the following risks and all other information contained in this prospectus before making an investment decision regarding our securities. The risks and uncertainties described below are those significant risk factors, currently known and specific to us, which we believe are relevant to an investment in our securities. If any of these risks materialize, our business, financial condition or results of operations could suffer, the price of the shares could decline and you could lose part or all of your investment.

The prospectus also contains forward-looking statements that involve risks and uncertainties. The risks and uncertainties that we believe are material are further described below. However, these risks and uncertainties may not be the only ones faced by us and are not intended to be presented in any assumed order of priority. Additional risks and uncertainties, including those currently unknown, or deemed immaterial, could have the effects set forth above.

1.1 Risks Related to Our Financial Position and Need for Additional Capital

We have incurred losses in each period since our inception and anticipate that we will continue to incur losses in the future.

We are not profitable and have incurred losses in each period since our inception. For the years ended 31 December 2014 and 2013, we incurred a loss for the year of €16.5 million and €14.5 million, respectively. As of 31 December 2014, we had a retained loss of €71.2 million. We expect these losses to increase as we continue to incur significant research and development and other expenses related to our ongoing operations, continue to advance our drug product candidates through pre-clinical studies and clinical trials, seek regulatory approvals for our drug product candidates, scale-up manufacturing capabilities and hire additional personnel to support the development of our drug product candidates and to enhance our operational, financial and information management systems.

Even if we succeed in commercializing one or more of our drug product candidates, we will continue to incur losses for the foreseeable future relating to our substantial research and development expenditures to develop our technologies. We anticipate that our expenses will increase substantially if and as we:

- continue our research, pre-clinical and clinical development of our drug product candidates;
- expand the scope of therapeutic indications of our current clinical trials for our drug product candidates;
- initiate additional pre-clinical studies or additional clinical trials of existing drug product candidates or new drug product candidates;
- further develop the manufacturing processes for our drug product candidates;
- seek regulatory and marketing approvals for our drug product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval, in the European Union and the United States;
- make milestone or other payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio; and
- create additional infrastructure to support our operations as a U.S. public company.

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital. Further, the losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period to period comparison of our results of operations may not be a good indication of our future performance.

We have generated only limited revenue from sales of C-Cath_{ez} to date, and do not expect to generate material revenue until we receive regulatory approval for one of our drug product candidates.

We have generated only limited revenue from sales of C-Cath_{ez}, our proprietary catheter for injecting cells into the heart, to research laboratories and clinical stage companies. We expect that revenue from sales of C-Cath_{ez} will remain insignificant as we sell C-Cath_{ez} only to research laboratories and clinical stage companies. We have no drug products approved for commercial sale, have not generated any revenue from drug product sales, and do not anticipate generating any revenue from drug product sales until after we have received regulatory approval, if at all, for the commercial sale of a drug product candidate. As of the date of this prospectus, C-Cure, our lead drug product candidate in cardiovascular disease, is in Phase 3 clinical development for the treatment of ischemic heart failure, or HF, while CAR-NKG2D, our lead drug product candidate in oncology, is in Phase 1 clinical development for the treatment of refractory or relapsed acute myeloid leukaemia, or AML, and multiple myeloma, or MM. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including:

- completing research regarding, and pre-clinical and clinical development of, our drug product candidates;
- pursuing regulatory approvals and marketing authorizations for drug product candidates for which we complete clinical trials;
- developing a sustainable and scalable commercial-scale manufacturing process for our drug product candidates, including establishing our own manufacturing capabilities and infrastructure or establishing and maintaining commercially viable supply relationships with third parties;
- launching and commercializing drug product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our drug product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new drug product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the drug product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved drug product candidate. Our expenses could increase beyond expectations if we are required by the European Medicines Agency, or EMA, the U.S. Food and Drug Administration, or the FDA, or other applicable regulatory agencies, to change our manufacturing processes or assays, or to perform clinical, pre-clinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our drug product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the drug product, the ability to get coverage and adequate reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved drug products, we may never become profitable.

If we fail to obtain additional financing, we will be unable to complete the development and commercialization of our drug product candidates.

Our operations have required substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of our drug product candidates, including our ongoing and planned clinical trials for C-Cure, CAR-NKG2D and any of our future drug product candidates. If approved, we will require significant additional amounts in order to launch and commercialize our drug product candidates.

As of 31 December 2014, we had €27.6 million in cash and €2.7 million in short term investments. In March 2015, we raised an additional €31.7 million though a private placement. We estimate that our net proceeds from the envisaged Global offering (including the U.S offering and the Concurrent private placement) will be approximately \$ 104.2 million (€ 91.5 million), after deducting the underwriting commissions and estimated offering expenses payable by us. We expect to use the net proceeds from the Global offering to advance the development of C-Cure through Phase 3 clinical development as a treatment for ischemic HF, to advance the development of CAR-NKG2D through Phase 1 clinical

development as a treatment for AML and MM, to advance additional CAR T-cell therapy drug product candidates for the treatment of additional blood cancers and solid tumors, to support our growth globally by expanding general, administrative and operational functions in our headquarters in Belgium and in the United States, and the remainder for working capital and other general corporate purposes.

We believe that such proceeds, together with our existing cash, will be sufficient to fund our operations until at least the end of 2017. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our drug product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our drug product candidates or other research and development initiatives. Our licenses may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for our drug product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our drug product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any these events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our Shares to decline.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our drug product candidates or technologies.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and/or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. The incurrence of indebtedness and/or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt and/or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of the Shares to decline. In the event that we enter into collaborations and/or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

1.2 Risks Related to Product Development, Regulatory Approval and Commercialization

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining regulatory approval or marketing authorization from regulatory authorities for the sale of our drug product candidates, if at all, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in raising, or inability to raise, sufficient capital to fund the planned clinical trials;
- delays in reaching a consensus with regulatory agencies on trial design;
- identifying, recruiting and training suitable clinical investigators;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- delays in obtaining required Investigational Review Board, or IRB, approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;

- delays due to changing standard of care for the diseases we are studying;
- adding new clinical trial sites;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical trial operations or trial sites;
- failure by our CROs, other third parties or us to adhere to clinical trial requirements;
- catastrophic loss of drug product candidates due to shipping delays or delays in customs in connection with delivery to foreign countries for use in clinical trials;
- failure to perform in accordance with the FDA's good clinical practices, or GCPs, or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of our drug product candidates to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a trial;
- occurrence of serious adverse events associated with the drug product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

For example, our Investigational New Drug application, or IND, for the use of C-Cure in our planned Phase 3 clinical trial of C-Cure for the treatment of ischemic HF in the United States and Europe, or CHART-2 was initially submitted to the FDA in January 2012. This IND became effective in December 2013 for administration of the cells with Myostar, a Biologics catheter used for the injection of therapeutic agents into the heart, and manufactured by Biologics Delivery Systems Group, Cordis Corporation, a Johnson & Johnson company. Prior to initiating the trial, in August 2014, we filed an amendment to the IND requesting among other changes to the initial submission, the use of our proprietary cell injection catheter called C-Cathez. In January 2015, the FDA issued a clinical hold on CHART-2. Most of the clinical hold questions request clarifications on the design dossier of C-Cathez, while the remaining questions relate to providing updated safety information on CHART-1, defining CHART-2 stopping rules, and a request to measure troponin, a cardiac marker of injury, at day 30 post baseline procedure. We anticipate responding to the clinical hold questions in the third quarter of 2015 once all safety data from CHART-1 is available, and pending the FDA's lifting of the clinical hold, initiating CHART-2 during the second half of 2015. However, we cannot be certain that FDA will accept our response and lift the clinical hold.

Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our drug product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our drug product candidates and may harm our business and results of operations.

If the results of our clinical trials are inconclusive or if there are safety concerns or adverse events associated with our drug product candidates, we may:

- be delayed in obtaining marketing approval for our drug product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a risk evaluation and mitigations strategy, or REMS, plan;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug product candidates could potentially cause other adverse events that have not yet been predicted. As described above, any of these events could prevent us from achieving or maintaining market acceptance of our drug product candidates and impair our ability to commercialize our products if they are ultimately approved by applicable regulatory authorities.

Our drug product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

As with most biological drug products, use of our drug product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our drug product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials. The FDA, EMA, or comparable foreign regulatory authorities could delay or deny approval of our drug product candidates for any or all targeted indications and negative side effects could result in a more restrictive label for any product that is approved. Side effects such as toxicity or other safety issues associated with the use of our drug product candidates could also require us or our collaborators to perform additional studies or halt development or sale of these drug product candidates.

Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or could result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff. Any of these occurrences may materially and adversely harm our business, financial condition and prospects.

Additionally, if one or more of our drug product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a REMS plan which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular drug product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the drug product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and

the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials will compete with other clinical trials for drug product candidates that are in the same therapeutic areas as our drug product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our drug product candidates represent a departure from more commonly used methods for ischemic HF and cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, rather than enroll patients in our clinical trials.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug product candidates.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials as well as data from any interim analysis of ongoing clinical trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Although drug product candidates may demonstrate promising results in early clinical (human) trials and pre-clinical (animal) studies, they may not prove to be effective in subsequent clinical trials. For example, testing on animals may occur under different conditions than testing in humans and therefore the results of animal studies may not accurately predict human experience. Likewise, early clinical trials may not be predictive of eventual safety or effectiveness results in larger-scale pivotal clinical trials. The results of pre-clinical studies and previous clinical trials as well as data from any interim analysis of ongoing clinical trials of our drug product candidates, as well as studies and trials of other products with similar mechanisms of action to our drug product candidates, may not be predictive of the results of ongoing or future clinical trials. For example, the positive results generated in our Phase 2 clinical trial of C-Cure for the treatment of patients with ischemic HF do not ensure that our ongoing Phase 3 clinical trial of C-Cure for the treatment of patients with ischemic HF in Europe and Israel, or CHART-1, will demonstrate similar results or observations. Drug product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and earlier clinical trials. In addition to the safety and efficacy traits of any drug product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and it is possible that we will as well. Based upon negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or pre-clinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

The regulatory approval processes of the FDA, EMA and other comparable regulatory authorities is lengthy, time-consuming, and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval, if any, of our drug product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA, EMA and other comparable regulatory authorities. We are not permitted to market any biological drug product in the United States until we receive a Biologics License Application, or BLA, from the FDA or a marketing authorization application, or MAA, from the EMA. We have not previously submitted a BLA to the FDA, MAA to the EMA, or similar approval filings to comparable foreign authorities. A BLA must include extensive pre-clinical and clinical data and supporting information to establish that the drug product candidate is safe, pure, and potent for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. We expect the nature of our drug product candidates to create further challenges in obtaining regulatory approval. For example, the FDA and EMA have limited experience with commercial development of genetically modified T-cell therapies for cancer. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the drug product candidates based on the completed clinical trials. Accordingly, the regulatory approval pathway for our drug product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained.

Obtaining and maintaining regulatory approval of our drug product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our drug product candidates in other jurisdictions.

If we obtain and maintain regulatory approval of our drug product candidates in one jurisdiction, such approval does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or EMA grants marketing approval of a drug product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the drug product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the European Union or in the United States, including additional pre-clinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions, a drug product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our drug product candidates will be harmed.

We may seek Orphan Drug Designation for some of our drug product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we may seek Orphan Drug Designation for some of our drug product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate products for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the European Union, the EMA's Committee for Orphan Medicinal Products grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention or treatment of lifethreatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the product in the European Union would be sufficient to justify the necessary investment in developing the product. In the European Union, Orphan Drug Designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a drug product candidate with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europea. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition or the same products can be approved for different conditions. If one of our drug product candidates that receives an orphan drug designation is approved for a particular indication or use within the rare disease, the FDA may later approve the same product for additional indications or uses within that rare disease that are not protected by our exclusive approval. Even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was

materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition or if another product with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a product nor gives the product any advantage in the regulatory review or approval process. While we intend to seek Orphan Drug Designation for some of our drug product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

Even if we receive regulatory approval of our drug product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug product candidates.

If our drug product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including requirements of regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, and in certain cases Good Tissue Practices, or cGTP, regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance, to the extent applicable, with cGMP and adherence to commitments made in any marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our drug product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the drug product candidate. The regulatory authorities may also require a REMS program as a condition of approval of our drug product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if a regulatory authority approves our drug product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval.

The regulatory authorities may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our drug product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or holds on clinical trials;
- refusal by the regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our drug product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The regulatory authorities strictly regulate marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with approved label. The agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to

maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Even if we obtain regulatory approval of our drug product candidates, the products may not gain market acceptance among physicians, patients, hospitals and others in the medical community.

Our autologous engineered-cell therapies may not become broadly accepted by physicians, patients, hospitals, and others in the medical community. Numerous factors will influence whether our drug product candidates are accepted in the market, including:

- the clinical indications for which our drug product candidates are approved;
- physicians, hospitals, and patients considering our drug product candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, EMA, or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or EMA;
- the timing of market introduction of our drug product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing embryonic stem cells in our drug product candidates, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance our drug product candidates due to the perceived similarity between our drug product candidates and these other therapies. If our drug product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, or others in the medical community, we will not be able to generate significant revenue.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and reimbursement may be limited or unavailable in certain market segments for our drug product candidates, which could make it difficult for us to sell our drug product candidates profitably.

Successful sales of our drug product candidates, if approved, depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our drug product candidates represent novel approaches to the treatment of ischemic HF and cancer, we cannot accurately estimate the potential revenue from our drug product candidates. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;

- cost-effective; and
- neither experimental nor investigational.

In the United States and in other jurisdictions, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our products. Patients are unlikely to use our drug product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drug product candidates. Because our drug product candidates have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

We intend to seek approval to market our drug product candidates in the United States, European Union, and in selected other foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our drug product candidates, we will be subject to rules and regulations in those jurisdictions. For example, in the countries of the European Union, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a drug product candidate. In addition, market acceptance and sales of our drug product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our drug product candidates and may be affected by existing and future health care reform measures.

Healthcare legislative reform measures and constraints on national budget social security systems may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain other jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably.

There have been, and likely will continue to be, legislative and regulatory proposals in several jurisdictions directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our drug product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any denial in coverage or reduction in reimbursement government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

Our drug product candidates are biologics, which are complex to manufacture, and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our drug product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our drug product candidates are biologics and the process of manufacturing our products is complex, highly-regulated and subject to multiple risks. The manufacture of our drug product candidates involves complex processes, including harvesting cells from patients, selecting and expanding certain cell types, engineering or reprogramming the cells in a certain manner to create either cardiopoietic cells or CAR T-cells, expanding the cell population to obtain the desired dose, and ultimately infusing the cells back into a patient's body. As a result of the complexities, the cost to manufacture our drug product candidates, is higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing process is susceptible to

product loss or failure due to logistical issues associated with the collection of blood cells, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. For example, we were only able to produce C-Cure for 70% of the patients that we attempted to produce drug product candidate for in our Phase 2 clinical trial. If for any reason we lose a patient's starting material or later-developed product at any point in the process, the manufacturing process for that patient will need to be restarted and the resulting delay may adversely affect that patient's outcome. If microbial, viral, or other contaminations are discovered in our drug product candidates or in the manufacturing facilities in which our drug product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Because our drug product candidates are manufactured for each particular patient, we are required to maintain a chain of identity with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as drug product candidates are developed through pre-clinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our drug product candidates to perform differently and affect the results of ongoing clinical trials or other future clinical trials.

We are currently manufacturing C-Cure for CHART-1 in our pilot manufacturing plant in Belgium. We are also planning to build a pilot manufacturing facility in the United States to reduce our overall logistical costs for CHART-2 and to allow redundancy between manufacturing sites. The cells for our ongoing Phase 1 clinical trial of CAR-NKG2D are being manufacturing at the Dana Farber Cancer Institute's cell manufacturing facility. In the future, we plan to operate two commercial manufacturing sites, one in the United States and one in the European Union. We believe this will allow increased flexibility and reduced logistical costs and will allow for the necessary redundancy in case of site or geography-related failure. However, we are very early in the process of locating sites for these commercial manufacturing facilities and may be unsuccessful in our ability to find appropriate sites for such facilities.

Although we are working, or will be working, to develop commercially viable processes for the manufacture of our drug product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for later-stage clinical trials and commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. We may ultimately be unable to reduce the cost of goods for our drug product candidates to levels that will allow for an attractive return on investment if and when those drug product candidates are commercialized.

In addition, the manufacturing process that we develop for our drug product candidates is subject to regulatory authorities' approval process, and we will need to make sure that we or our contract manufacturers, or CMOs, if any, are able to meet all regulatory authorities requirements on an ongoing basis. If we or our CMOs are unable to reliably produce drug product candidates to specifications acceptable to the regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such drug product candidates. Even if we obtain regulatory approval for any of our drug product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could have an adverse effect on our business, financial condition, results of operations and growth prospects.

We may face competition from biosimilars, which may have a material adverse impact on the future commercial prospects of our drug product candidates.

Even if we are successful in achieving regulatory approval to commercialize a drug product candidate faster than our competitors, we may face competition from biosimilars. "Biosimilarity" means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product. To meet the higher standard of "interchangeability," an applicant must provide sufficient information to show biosimilarity and demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administrated more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of

the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

A reference biological product is granted 12 years of exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after first licensure. First licensure typically means the initial date the particular product at issue was licensed in the United States. This does not include a supplement for the biological product or a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, unless that change is a modification to the structure of the biological product and such modification changes its safety, purity, or potency. Whether a subsequent application, if approved, warrants exclusivity as the first licensure of a biological product is determined on a case-by-case basis with data.

This data exclusivity does not prevent another company from developing a product that is highly similar to the innovative product, generating its own data, and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the application for the reference biological product to support the biosimilar product's approval.

In the European Union, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In the European Union, a competitor may reference data supporting approval of an innovative biological product, but will not be able do so until eight years after the time of approval of the innovative product and to get its biosimilar on the market until ten years from the aforementioned approval. This 10-year marketing exclusivity period will be extended to 11 years if, during the first eight of those ten years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

We currently have no marketing and sales organization and have no experience in marketing drug and biological products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our drug product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing, or commercial product distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all products we develop, we will likely pursue collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug product candidates.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the European Union, the United States, overseas, and as a result, we may not be able to generate product revenue.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug product candidates.

We face competition both in the United States and internationally, including from major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. In addition, many universities and private and public research institutes are active in our target disease areas. As of the date of this prospectus, our main competitors for C-Cure include Aldagen, Inc., Athersys, Inc., Cytori Therapeutics, Inc., Mesoblast Ltd and Vericel Corporation. As of the date of this prospectus, our main competitors for CAR-NKG2D and our other CAR T-cell product candidates include Bellicum Pharmaceuticals, Inc., bluebird bio, Inc., Cellectis S.A., Juno Therapeutics, Inc., Kite Pharma Inc., Novartis AG and Ziopharm Oncology, Inc.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any drug product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential drug product candidates uneconomical or obsolete, and we may not be successful in marketing our drug product candidates against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

1.3 Risks Related to our Reliance on Third Parties

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Engineered-cell therapies require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an inspection of the regulatory authorities or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose.

We rely on third parties to conduct, supervise and monitor our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug product candidates and our business could be substantially harmed.

We rely on CROs and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the GCPs for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities, enforce these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA, the EMA, or other foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA the EMA, or other foreign regulatory authorities may determine that our clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our drug product candidates. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are therefore unable to directly monitor whether or not they devote sufficient time and resources to our clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities that could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our drug product candidates. If any such event were to occur, our financial

results and the commercial prospects for our drug product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Further, switching or adding additional CROs involves additional costs and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

1.4 Risks Related to Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how, and proprietary technology, both our own and licensed from others. We license technology from the Mayo Foundation for Medical Education and Research, or the Mayo Clinic, and the Trustees of Dartmouth College, or Dartmouth College. The Mayo Clinic may terminate our license agreement with them, or the Mayo License, on a product-by-product basis or licensed invention-by-licensed invention basis if we default in making payment when due and payable or under other circumstances specified in the Mayo License, subject to 120 days' prior written notice and opportunity to cure. The Mayo Clinic may also terminate the Mayo License if we deliberately make false statements in reports delivered to the Mayo Clinic. Further, the Mayo Clinic may terminate the Mayo License immediately for our insolvency or bankruptcy. Dartmouth College may terminate either our 2010 license or 2014 license, if we fail to meet a milestone within the specified time period, unless we pay the corresponding milestone payment. Dartmouth College may terminate either the 2010 license or 2014 license in the event we default or breach any of the provisions of the applicable license, subject to 30 days' prior notice and opportunity to cure. In addition, each of the 2010 license and 2014 license automatically terminates in the event we become insolvent, make an assignment for the benefit of creditors or file, or have filed against us, a petition in bankruptcy. Furthermore, Dartmouth College may terminate our 2010 license, after April 30, 2024, if we fail to meet the specified minimum net sales obligations for any year, unless we pay to Dartmouth College the royalty we would otherwise be obligated to pay had we met such minimum net sales obligation. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our drug product candidates. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues:
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- the amount and timing of milestone and royalty payments;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our drug product candidates; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected drug product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our drug product candidates.

The patent application process is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our drug product candidates or deliver technologies at a reasonable cost, in a timely fashion, or at all. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore,

our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. Under our existing license agreements with the Mayo Foundation for Medical Education and Research and the Trustees of Dartmouth College, we have the right, but not the obligation, to enforce our licensed patents. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

We currently have issued patents and patent applications directed to our drug product candidates and medical devices, and we anticipate that we will file additional patent applications in several jurisdictions, including several European Union countries and the United States, as appropriate. However, we cannot predict:

- if and when any patents will issue from patent applications;
- the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose.

We cannot be certain, however, that the claims in our pending patent applications will be considered patentable by patent offices, or that the claims in any of our issued patents will be considered valid and enforceable by local courts.

The strength of patents in the biotechnology and pharmaceutical field can be uncertain, and evaluating the scope of such patents involves complex legal and scientific analyses. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our drug product candidates or uses thereof in the European Union, in the United States or in other jurisdictions. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our drug product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, our drug product candidates. Further, because patent applications in most countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our drug product candidates.

Patents have a limited lifespan. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Further, the extensive period of time between patent filing and regulatory approval for a drug product candidate limits the time during which we can market a drug product candidate under patent protection, which may particularly affect the profitability of our early-stage drug product candidates. If we encounter delays in our clinical trials, the period of time during which we could market our drug product candidates under patent protection would be reduced. Without patent protection for our drug product candidates, we may be open to competition from biosimilar versions of our drug product candidates.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on drug product candidates in all countries throughout the world would be prohibitively expensive., In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the European Union or the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing products made using our inventions in and into other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in a number of jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, an April 2014 report from the Office of the United States Trade Representative identified a number of countries, including India and China, where challenges to the procurement and enforcement of patent rights have been reported. Several countries, including India and China, have been listed in the report every year since 1989. Proceedings to enforce our patent rights in some jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some countries do not protect proprietary rights to the same extent or in the same manner as the laws of the European Union or the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the European Union, the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Third-party claims of intellectual property infringement against us or our collaborators may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, opposition and re-examination proceedings. Recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. This reform adds uncertainty to the possibility of challenge to our U.S. patents in the future.

Numerous issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our drug product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug product candidates may give rise to claims of infringement of the patent rights of others.

Although we have conducted analyses of the patent landscape with respect to our drug product candidates, and based on these analyses, we believe that we will be able to commercialize our drug product candidates, third parties may nonetheless assert that we infringe their patents, or that we are otherwise employing their proprietary technology without authorization, and may sue us. There may be third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture, or methods of use or treatment that cover our drug product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our drug product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies or the manufacture, use, or sale of our drug product candidates infringes upon these patents. If any such third-party patents were held by a court of competent jurisdiction to cover our technologies or drug product candidates, the holders of any such patents may be able to block our ability to commercialize the applicable drug product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a

license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, our ability to commercialize our drug product candidates may be impaired or delayed, which could in turn significantly harm our business.

Third parties asserting their patent rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our drug product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our drug product candidates, which could harm our business significantly.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding or a declaratory judgment action against us, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable, interpreted narrowly, or amended such that they do not cover our drug product candidates. Such results could also put our pending patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Interference or derivation proceedings provoked by third parties may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, or derivation proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in some jurisdictions in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ordinary shares.

Issued patents covering our drug product candidates could be found invalid or unenforceable if challenged in court or before relevant authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our drug product candidates, the defendant could counterclaim that the patent covering our drug product candidate is invalid or unenforceable. Third parties may also raise similar claims before administrative bodies, even outside the context of litigation. Such mechanisms include \ opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drug product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug product candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to patent agencies in several stages over the lifetime of the patent. Various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

1.5 Risks Related to Our Organization, Structure and Operation

Our future results will suffer if we do not effectively manage our expanded operations as a result of our recent acquisition of OnCyte.

We obtained access to our CAR T-cell drug product candidates and related technology, including technology licensed from Dartmouth College, in January 2015, through our acquisition of OnCyte, LLC, or OnCyte, from Celdara Medical, LLC, a privately-held U.S. biotechnology company. Our acquisition of OnCyte significantly changed the composition of our operations, markets and drug product candidate mix. Our future success depends, in part, on our ability to address these changes, and, where necessary, to attract and retain new personnel that possess the requisite skills called for by these changes.

Our failure to adequately address the financial, operational or legal risks of the OnCyte acquisition, or any future acquisitions, license arrangements, other strategic transactions could harm our business. Financial aspects of these transactions that could alter our financial position, reported operating results or ADS price include:

- use of cash resources;
- higher than anticipated acquisition costs and expenses;
- potentially dilutive issuances of equity securities;
- the incurrence of debt and contingent liabilities, impairment losses or restructuring charges;
- large write-offs and difficulties in assessing the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount that must be amortized over the appropriate life of the asset; and
- amortization expenses related to other intangible assets.

Operational risks that could harm our existing operations or prevent realization of anticipated benefits from these transactions include:

- challenges associated with managing an increasingly diversified business;
- disruption of our ongoing business;
- difficulty and expense in assimilating the operations, products, technology, information systems or personnel of the acquired company;
- diversion of management's time and attention from other business concerns;
- entry into a geographic or business market in which we have little or no prior experience;
- inability to maintain uniform standards, controls, procedures and policies;
- the assumption of known and unknown liabilities of the acquired business or asset, including intellectual property claims; and
- subsequent loss of key personnel.

Our future success depends, in part, upon our ability to manage our expansion opportunities. Integrating new operations into our existing business in an efficient and timely manner, successfully monitoring our operations, costs, regulatory compliance and customer relationships, and maintaining other necessary internal controls pose substantial challenges for us. As a result, we cannot assure you that our expansion or acquisition opportunities will be successful,

or that we will realize our expected operating efficiencies, cost savings, revenue enhancements, synergies or other

We are highly dependent on our Chief Executive Officer and members of our management team, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on members of our executive management team, particularly our chief executive officer, Christian Homsy,. We do not maintain "key man" insurance on the life of Christian Homsy, or the lives of any of our other employees. The loss of the services of any members of our executive management team and our inability to find suitable replacements, could result in delays in product development and harm our business.

Competition for skilled personnel in the biotechnology and pharmaceutical industries is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided warrants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of the date of this prospectus, we had 82 full-time and three part-time employees. As our drug product candidates move into later stage clinical development and towards commercialization, we must add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our drug product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Our future financial performance and our ability to commercialize our drug product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or drug product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We do not currently carry biological or hazardous waste insurance coverage.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities.

Risks from the improper conduct of employees, agents, contractors, consultants or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation. In particular, our business activities may be subject to anti-bribery or anti-corruption laws, regulations or rules of countries in which we operate, including the Foreign Corrupt Practices Act, or FCPA, or the U.K. Bribery Act.

Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we will operate in an increasingly demanding regulatory environment that requires us to comply with, among things, the Sarbanes-Oxley Act of 2002, and related rules and regulations of the Securities and Exchange

Commission's substantial disclosure requirements, accelerated reporting requirements and complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We have limited accounting personnel and other resources to address our internal controls and procedures. Our independent registered public accounting firm has not conducted an audit of our internal control over financial reporting. However, in connection with the reaudit of our consolidated financial statements as of and for year ended 31 December 2013 and audit of our consolidated financial statements as of and for the year ended 31 December 2014, we identified three material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, such that there is reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis by our employees. The material weaknesses identified were related to a lack of:

- accounting resources required to fulfill the reporting requirements of International Financial Reporting Standards, or IFRS, and financial reporting requirements;
- comprehensive knowledge of IFRS accounting policies and financial reporting procedures; and
- segregation of duties given the size of our finance and accounting team.

As described in Note 4.36 of our consolidated financial statements referred to in this prospectus, we have restated our consolidated financial statements as of and for the year ended 31 December 2013 as a result of errors in the accounting treatment of shareholders convertible loans and share-based payments. We believe that the material weaknesses identified contributed to the restatement.

We have taken several remedial actions to address these material weaknesses, which are described under "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS"

Our management may conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue a report that is qualified if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, after we become a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation, testing and any required remediation.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, CROs, CMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our drug product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our drug product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our drug product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any drug product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Although we currently carry €100,000 of clinical trial insurance, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Our international operations subject us to various risks, and our failure to manage these risks could adversely affect our results of operations.

We face significant operational risks as a result of doing business internationally, such as:

- fluctuations in foreign currency exchange rates;
- potentially adverse and/or unexpected tax consequences, including penalties due to the failure of tax planning or due to the challenge by tax authorities on the basis of transfer pricing and liabilities imposed from inconsistent enforcement;
- potential changes to the accounting standards, which may influence our financial situation and results;
- becoming subject to the different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- reduced protection of, or significant difficulties in enforcing, intellectual property rights in certain countries;
- difficulties in attracting and retaining qualified personnel;
- restrictions imposed by local labor practices and laws on our business and operations, including unilateral cancellation or modification of contracts; and

rapid changes in global government, economic and political policies and conditions, political or civil unrest or instability, terrorism or epidemics and other similar outbreaks or events, and potential failure in confidence of our suppliers or customers due to such changes or events; and tariffs, trade protection measures, import or export licensing requirements, trade embargoes and other trade barriers.

We are subject to certain covenants as a result of certain non-dilutive financial support we have received to date.

We have received non-dilutive financial support totalling €18.7 million as of 31 December 2014, to support various research programs from the Walloon Region, or the Region. The support has been granted in the form of recoverable cash advances, or RCAs, and subsidies.

In the event we decide to exploit any discoveries or products from the research funded by under an RCA, the relevant RCA becomes refundable, otherwise the RCA is not refundable. We own the intellectual property rights which result from the research programs partially funded by the Region, unless we decide not to exploit, or cease to exploit, the results of the research in which case the results and intellectual property rights are transferred to the Region. Subject to certain exceptions, however, we cannot grant to third parties, by way of license or otherwise, any right to use the results without the prior consent of the Region. We also need the consent of the Region to transfer an intellectual property right resulting from the research programs or a transfer or license of a prototype or installation. Obtaining such consent from the Region could give rise to a review of the applicable financial terms. The RCAs also contain provisions prohibiting us from conducting research for any other person which would fall within the scope of a research program of one of the RCAs. Most RCAs provide that this prohibition is applicable during the research phase and the decision phase but a number of RCAs extend it beyond these phases.

Subsidies received from the Region are dedicated to funding research programs and patent applications and are not refundable. We own the intellectual property rights which result from the research programs or with regard to a patent covered by a subsidy. Subject to certain exceptions, however, we cannot grant to third parties, by way of license, transfer or otherwise, any right to use the patents or research results without the prior consent of the Region. In addition, certain subsidies require that we exploit the patent in the countries where the protection was granted and to make an industrial use of the underlying invention. In case of bankruptcy, liquidation or dissolution, the rights to the patents covered by the patent subsidies will be assumed by the Region by operation of law unless the subsidy is reimbursed. Furthermore, we would lose our qualification as a small or medium-sized enterprise, the patent subsidies will terminate and no additional expenses will be covered by such patent subsidies.

We may be exposed to significant foreign exchange risk.

We incur portions of our expenses, and may in the future derive revenues, in currencies other than the euro, in particular, the U.S. dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. Therefore, for example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euros at a reduced value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

The requirements of being a U.S. public company may strain our resources and divert management's attention.

Upon closing of our U.S. initial public offering, we will be required to comply with various corporate governance and financial reporting requirements under the Sarbanes-Oxley Act of 2002, the Securities and Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations adopted by the Securities and Exchange Commission and the Public Corporation Accounting Oversight Board. Further, compliance with various regulatory reporting requires significant commitments of time from our management and our directors, which reduces the time available for the performance of their other responsibilities. Our failure to track and comply with the various rules may materially adversely affect our reputation, ability to obtain the necessary certifications to financial statements, lead to additional regulatory enforcement actions, and could adversely affect the value of our securities.

1.6 Risks Related to Ownership of Shares

If securities or industry analysts do not publish research or publish inaccurate research or unfavorable research about our business, the price of the securities and trading volume could decline.

The trading market for the securities depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover our company, the trading price would be negatively impacted. If one or more of the analysts who covers us downgrades the securities or publishes incorrect or unfavorable research about our business, the price of the securities would likely decline. If one or more of these

analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades the securities, demand for the securities could decrease, which could cause the price of the securities or trading volume to decline.

We have no present intention to pay dividends on our ordinary shares in the foreseeable future and, consequently, your only opportunity to achieve a return on your investment during that time is if the price of the securities increases.

We have no present intention to pay dividends in the foreseeable future. Any recommendation by our board of directors to pay dividends will depend on many factors, including our financial condition (including losses carried-forward), results of operations, legal requirements and other factors. Furthermore, pursuant to Belgian law, the calculation of amounts available for distribution to shareholders, as dividends or otherwise, must be determined on the basis of our non-consolidated statutory accounts prepared in accordance with Belgian accounting rules. In addition, in accordance with Belgian law and our articles of association, we must allocate each year an amount of at least 5% of our annual net profit under our non-consolidated statutory accounts to a legal reserve until the reserve equals 10% of our share capital. Therefore, we are unlikely to pay dividends or other distributions in the foreseeable future. If the price of the securities or the underlying ordinary shares declines before we pay dividends, you will incur a loss on your investment, without the likelihood that this loss will be offset in part or at all by potential future cash dividends.

Future sales of ordinary shares or ADSs by existing shareholders could depress the market price.

If our existing shareholders sell, or indicate an intent to sell, substantial amounts of ordinary shares or ADSs in the public market after the 90-day contractual lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of the securities could decline significantly and could decline below the public offering price. Upon completion of the U.S. initial public offering, we will have outstanding ordinary shares, approximately 4.037.675 of which are subject to the 90-day contractual lock-up referred to above. The representatives of the underwriters may permit us, our directors and members of our executive committee to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements pertaining to this offering expire, and based on the number of ordinary shares outstanding upon completion of the U.S. initial public offering, additional shares will be eligible for sale in the public market, all of which shares are held by directors and members of the executive committee and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, the ordinary shares subject to outstanding warrants under our equity incentive plans and the shares reserved for future issuance under our equity incentive plans will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations.

Following the U.S. initial public offering, we intend to file one or more registration statements with the SEC covering ordinary shares available for future issuance under our equity incentive plans. Upon effectiveness of such registration statements, any shares subsequently issued under such plans will be eligible for sale in the public market, except to the extent that they are restricted by the lock-up agreements referred to above and subject to compliance with Rule 144 in the case of our affiliates. Sales of a large number of the shares issued under these plans in the public market could have an adverse effect on the market price of the securities.

We are a Belgian public limited liability company, and shareholders of our company may have different and in some cases more limited shareholder rights than shareholders of a U.S. listed corporation.

We are a public limited liability company incorporated under the laws of Belgium. Our corporate affairs are governed by Belgian corporate and securities law. The rights provided to our shareholders under Belgian corporate law and our articles of association differ in certain respects from the rights that you would typically enjoy as a shareholder of a U.S. corporation under applicable U.S. federal and state laws. Under Belgian corporate law, other than certain information that we must make public and except in certain limited circumstances, our shareholders may not ask for an inspection of our corporate records, while under Delaware corporate law any shareholder, irrespective of the size of its shareholdings, may do so. Shareholders of a Belgian corporation have more limited rights to initiate a derivative action, a remedy typically available to shareholders of U.S. companies, in order to enforce a right of our Company, in case we fail to enforce such right ourselves.

A liability action can be instituted for our account by one or more of our shareholders who, individually or together, hold securities representing at least 1.0% of the votes or a part of the capital worth at least €1.25 million and have not approved of the discharge from liability that was granted to the directors. If the court orders the directors to pay damages, they are due to us, though the amounts advanced by the minority shareholders (for example attorney's fees) are to be reimbursed by us. If the action is disallowed, the minority shareholders may be ordered to pay the costs, and, should there be grounds therefor, to pay damages to the directors, for example for having conducted provocative and reckless legal proceedings.

In addition, a majority of our shareholders present or represented at our meeting of shareholders may release a director from any claim of liability we may have, provided that the financial position of the company is accurately

reflected in the annual accounts. This includes a release from liability for any acts of the directors beyond their statutory powers or in breach of the Belgian Company Code, provided that the relevant acts were specifically mentioned in the convening notice to the meeting of shareholders deliberating on the discharge. In contrast, most U.S. federal and state laws prohibit a company or its shareholders from releasing a director from liability altogether if he or she has acted in bad faith or has breached his or her duty of loyalty to the company. Finally, Belgian corporate law does not provide any form of appraisal rights in the case of a business combination. See "DESCRIPTION OF THE SHARE CAPITAL AND CORPORATE STRUCTURE". As a result of these differences between Belgian corporate law and our articles of association, on the one hand, and the U.S. federal and state laws, on the other hand, in certain instances, you could receive less protection as an ADS holder of our company than you would as a shareholder of a listed U.S. company.

Takeover provisions in the national law of Belgium may make a takeover difficult.

Public takeover bids on our shares and other voting securities, such as warrants or convertible bonds, if any, are subject to the Belgian Act of 1 April 2007 on public takeover bids, as amended and implemented by the Belgian Royal Decree of 27 April 2007, or Royal Decree, and to the supervision by the Belgian Financial Services and Markets Authority, or FSMA. Public takeover bids must be made for all of our voting securities, as well as for all other securities that entitle the holders thereof to the subscription to, the acquisition of or the conversion into voting securities. Prior to making a bid, a bidder must issue and disseminate a prospectus, which must be approved by the FSMA. The bidder must also obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of our company. The Belgian Act of 1 April 2007 provides that a mandatory bid will be required to be launched for all of our outstanding shares and securities giving access to ordinary shares if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting on their account, directly or indirectly holds more than 30% of the voting securities in a company that has its registered office in Belgium and of which at least part of the voting securities are traded on a regulated market or on a multilateral trading facility designated by the Royal Decree. The mere fact of exceeding the relevant threshold through the acquisition of one or more shares will give rise to a mandatory bid, irrespective of whether or not the price paid in the relevant transaction exceeds the current market price.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose important shareholdings and merger control, that may apply to us and which may make an unfriendly tender offer, merger, change in management or other change in control, more difficult. These provisions could discourage potential takeover attempts that third parties may consider and thus deprive the shareholders of the opportunity to sell their shares at a premium (which is typically offered in the framework of a takeover bid).

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from NASDAQ corporate governance listing standards. We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on 30 June 2016. In the future, we would lose our foreign private issuer status if we to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and more than 50% of the members of our executive committee or members of our board of directors are residents or citizens of the United States, we could lose our foreign private issuer status.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, rather than IFRS, and modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP will involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

After the completion of the U.S. initial public offering, we may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical

companies have experienced significant share price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Holders of the shares outside Belgium and France may not be able to exercise pre-emption rights (notice for non-Belgian resident investors).

In the event of an increase in our share capital in cash, holders of shares are generally entitled to full pre-emption rights unless these rights are excluded or limited either by a resolution of the general meeting, or by a resolution of the board of directors (if the board of directors has been authorised by the general meeting in the articles of association to increase the share capital in that manner). Certain holders of shares outside Belgium or France may not be able to exercise pre-emption rights unless local securities laws have been complied with. In particular, U.S. holders of the shares may not be able to exercise pre-emption rights unless a registration statement under the Securities Act is declared effective with respect to the shares issuable upon exercise of such rights or an exemption from the registration requirements is available. The Company does not intend to obtain a registration statement in the U.S. or to fulfil any requirement in other jurisdictions (other than Belgium and France) in order to allow shareholders in such jurisdictions to exercise their pre-emptive rights (to the extent not excluded or limited).

Any sale, purchase or exchange of the shares may become subject to the Financial Transaction Tax (the "FTT").

On 14 February 2013, the European Commission published a proposal (the "Commission's Proposal") for a Directive for a common FTT in Belgium, Germany, Estonia, Greece, Spain, France, Italy, Austria, Portugal, Slovenia and Slovakia (the "participating Member States").

The Commission's Proposal has very broad scope and could, if introduced, apply to certain dealings in our shares in certain circumstances.

Under the Commission's Proposal the FTT could apply in certain circumstances to persons both within and outside of the participating Member States. Generally, it would apply to certain dealings in our shares where at least one party is a financial institution, and at least one party is established in a participating Member State. A financial institution may be, or be deemed to be, "established" in a participating Member State in a broad range of circumstances, including (a) by transacting with a person established in a participating Member State or (b) where the financial instrument which is subject to the dealings is issued in a participating Member State.

A joint statement issued in May 2014 by ten of the eleven participating Member States indicated an intention to implement the FTT progressively, such that it would initially apply to shares and certain derivatives, with this initial implementation occurring by 1 January 2016. However, full details are not available. Therefore it is not known to what extent the elements of the Commission's Proposal outlined in the preceding paragraph will be followed in relation to the taxation of shares.

The FTT proposal remains subject to negotiation between the participating Member States. It may therefore be altered prior to any implementation. Additional EU Member States may decide to participate. Prospective holders of the Shares are advised to seek their own professional advice in relation to the FTT.

We were subject to an investigation by the Belgian Financial Services and Markets Authority.

The Belgian Financial Services and Markets Authority, or the FSMA, opened an investigation against us on 22 April 2014. Such investigation was related to whether we had failed to timely disclose inside information to the market in relation to the IND clearance from the FDA for our CHART-2 Phase III heart-failure trial received on 26 December 2013 and reported on 9 January 2014. In April 2015, we notified the FSMA our agreement to settle its investigation by paying the proposed settlement amount of €175,000. Although such settlement does not provide for any admission of guilt on our part, the fact that we have entered into a settlement with the FSMA could cause investors to have a negative perception of our governance structure, which would have a material adverse effect on our business. Further, any future allegations (based on other facts and circumstances) that we failed to comply with applicable securities laws, whether or not true, may subject us to fines, claims and/or sanctions, which could impair our ability to offer our securities or restrict trading in our securities. The occurrence of any of the foregoing could have a material adverse effect on the trading price of our securities and our business.

2 DISCLAIMERS AND NOTICES

2.1 No public offering

This prospectus has been approved for the purposes of the admission to trading of the New Shares on the regulated market of Euronext Brussels and Euronext Paris and does not constitute an offer to sell or the solicitation of an offer to buy any New Shares. This prospectus can be distributed in Belgium and France, where it has been approved by the FSMA and passported by the AMF.

The distribution of this prospectus in any country other than Belgium or France may be restricted by law. We do not represent that this prospectus may be lawfully distributed in compliance with any applicable registration or other requirements in any jurisdiction other than Belgium or France, or pursuant to any exemption available thereunder, or assume any responsibility for facilitating such distribution or offering. In particular, no action has been taken by us which is intended to permit a public offering of any shares or distribution of this prospectus. Persons in whose possession this prospectus or any shares may come must inform themselves about, and observe, any such restrictions on the distribution of this prospectus. Any person that, for any reason whatsoever, circulates or allows circulation of this prospectus, must draw the addressees' attention to the provisions of this section.

2.2 Notice to investors in the EEA

No actions have been or will be made, in any Member state that has implemented the Prospectus Directive (each a "Relevant Member State"), to make an offer to the public of our securities that requires the publication of a prospectus in such Relevant Member State.

For the purposes of this provision, the expression an "offer to the public" in relation to New Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the New Shares to be offered so as to enable an investor to decide to purchase New Shares, as the same may be varied in that Relevant Member State by any measure implementing the prospectus Directive in that Relevant Member State, and the expression "prospectus Directive" means Directive 2003/71/EC (and any amendments thereto, including the Directive 2010/73/EU amending the prospectus Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State.

2.3 Notice to investors in the United States

This prospectus does not constitute an offer to sell nor a solicitation of an offer to buy any New Shares in the United States. The New Shares have not been registered in the United States under the United States Securities Act of 1933, as amended (the "Securities Act") or under other applicable securities laws and are subject to restrictions on transfer on the basis of such laws. The New Shares may not be offered, sold, resold, or otherwise transferred in or into the United States, except pursuant to registration with the U.S. Securities and Exchange Commission ("SEC") or pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and applicable state securities laws.

A Form F-1 Registration Statement under the Securities Act for the offering in the United States of American Depositary Shares ("ADSs") representing in ordinary shares, has been filed with the SEC, but has not yet become effective. Application has been made to list the ADSs on the NASDAQ Global Select Market. The ADSs may not be sold, nor may offers to buy be accepted in the United States, prior to the time the F-1 Registration Statement becomes effective. When declared effective, a copy of the F-1 Registration Statement will be available via the SEC's website at www.sec.gov.

2.4 Notice to investors in Australia, Canada or Japan

This prospectus may not be circulated or otherwise made available in Australia, Canada or Japan and our securities may not be offered or sold, directly or indirectly, by any person in Australia, Canada or Japan unless such circulation, offering, sale or exercise is allowed under applicable legislation of the relevant jurisdiction.

2.5 Decision to invest

In making an investment decision, investors must rely on their own examination of our company, including the merits and risks involved as described in this prospectus, including the information incorporated by reference. The information appearing in this prospectus is provided as of the date shown on the front cover of this prospectus only.

Our business, financial condition, results of operations and the information set forth in this prospectus may have changed since that date.

None of the information in this prospectus should be considered investment, legal or tax advice. Investors should consult their own counsel, accountant and other advisors for legal, tax, business, financial and related advice regarding purchasing any shares.

This prospectus is intended to provide information in the context of the admission to trading of the New Shares. It contains selected and summarised information, does not express any commitment or acknowledgement or waiver and does not create any right expressed or implied towards anyone other than a potential investor. The content of this prospectus is not to be construed as an interpretation of our rights and obligations, of the market practices or of contracts entered into by us.

2.6 Presentation of financial and other information

This prospectus includes extract of our audited financial statements as per 31 December 2014 and 31 December 2013 and for the years then ended prepared in accordance with Belgian GAAP and our consolidated audited financial statements as per 31 December 2014 and 31 December 2013 and for the years then ended prepared in accordance with IFRS as adopted by the European Union (together "the annual financial statements"). The annual financial statements (as prepared under Belgian GAAP and IFRS) were audited by our statutory auditor.

Their reports are incorporated by reference in this prospectus.

In this prospectus, references to " \in " are to the currency of the member states of the European Union participating in the European Monetary Union and references to " \in " or are to the currency of the United States.

Some numerical figures included in this prospectus have been subject to rounding adjustments. Accordingly, numerical figures shown as totals in certain tables may not be an exact arithmetic aggregation of the figures that precede them.

2.7 Third party information

Information relating to markets and other industry data pertaining to our business contained in this prospectus has been obtained from internal surveys, industry sources and publicly available information. The main sources for industry information were industry publications such as those published by Data Monitor and other publicly available sources. We accept responsibility for having correctly reproduced information obtained from publications or public sources, and, so far as we are aware and have been able to ascertain from information published by those industry publications or public sources, no facts have been omitted which would render the reproduced information inaccurate or misleading. However, we have not independently verified information obtained from industry and public sources. Certain other information in this prospectus regarding the industry reflects our best estimates based upon information obtained from trade and business organisations and associations and other contacts within the industry. Information from our internal estimates and surveys has not been verified by any independent sources.

2.8 Forward-looking statements

This prospectus, particularly the sections of this prospectus titled "prospectus summary," "Risk factors," "Management's discussion and analysis of financial condition and results of operations" and "Business," contains forward-looking statements. All statements other than present and historical facts and conditions contained in this prospectus, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this prospectus, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- our ability to advance drug product candidates into, and successfully commence and complete, clinical trials;
- our reliance on the success of our drug product candidates;
- the timing or likelihood of regulatory filings and approvals;
- our ability to develop sales and marketing capabilities;
- the commercialization of our drug product candidates, if approved;

- the pricing and reimbursement of our drug product candidates, if approved;
- the implementation of our business model, strategic plans for our business, drug product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug product candidates and technology;
- our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- cost associated with defending intellectual property infringement, product liability and other claims;
- regulatory development in the United States, the European Union and other jurisdictions;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations or obtain additional grant funding;
- the rate and degree of market acceptance of our drug product candidates;
- developments relating to our competitors and our industry, including competing therapies;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- our ability to build our finance infrastructure, improve our accounting systems and controls and remedy the material weaknesses identified in our internal control over financial reporting;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance;
- our expected use of proceeds of this offering;
- our expectations regarding our PFIC status;
- the future trading price of our securities and impact of securities analysts' reports on these prices; and
- other risks and uncertainties, including those listed under the caption "RISK FACTORS."

You should refer to the section of this prospectus titled "RISK FACTORS" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

2.9 Documents incorporated by reference

This prospectus should be read and construed in conjunction with:

- our annual report and our audited annual financial statements for the financial year ended 31 December 2014 (statutory in accordance with Belgian GAAP as well as consolidated in accordance with IFRS), together with in each case the audit reports thereon;
- our annual report and our audited annual financial statements for the financial year ended 31 December 2013 (statutory in accordance with Belgian GAAP as well as consolidated in accordance with IFRS), together with in each case the audit reports thereon; and

our articles of association.

These documents shall be incorporated in, and form part of, this prospectus, save that any statement contained in the document which is incorporated by reference shall be modified or superseded for the purpose of this prospectus to the extent that the statement contained herein modifies or supersedes such earlier statement (whether expressly, by implication or otherwise). Any statement so modified or superseded shall not, except as so modified or superseded, constitute part of this prospectus.

Copies of the documents incorporated by reference in the prospectus may be obtained without charge from our website (www.celyad.com) or from our registered office.

3 GENERAL INFORMATION AND INFORMATION CONCERNING RESPONSIBILITY FOR THIS PROSPECTUS AND FOR AUDITING THE ACCOUNTS

3.1 Proportionate disclosure

This prospectus relates to an application for the admission to trading on a regulated market of shares by an issuer which qualifies as SME and, as a result, the level of disclosure of this prospectus is proportionate to this type of transaction in accordance with Annex XXV of the prospectus Regulation.

3.2 Responsibility for the content of this prospectus

The Company, having its registered offices at Axisparc Business Center, Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium, represented by its board of directors, assumes responsibility for the content of this prospectus. We declare that, having taken all reasonable care to ensure that such is the case, the information contained in this prospectus is, to our knowledge, in accordance with the facts and contains no omission which would affect its import.

3.3 Statutory auditors

PricewaterhouseCoopers Reviseurs d'Entreprises scrl, organised and existing under the laws of Belgium, with registered office at Woluwe Garden, Woluwedal 18, 1932 Sint-Stevens-Woluwé, Belgium, represented by Patrick Mortroux, has been appointed as our statutory auditor on 5 May 2014 for a term of three years. Patrick Motroux is a member of the Belgian Institute of Certified Auditors ("Institut des Réviseurs d'Entreprises") (membership number A01995).

Our statutory financial statements as per 31 December 2014 and 31 December 2013 and the years then ended were prepared in accordance with Belgian GAAP. The statutory financial statements in accordance with Belgian GAAP have been audited by PricewaterhouseCoopers Reviseurs d'Entreprises scrl, represented by Patrick Mortroux, who delivered unqualified opinions with emphasis of matter paragraph.

Our consolidated financial statements as of 31 December 2014 and 31 December 2013 and the years then ended have also been prepared in accordance with IFRS. The annual financial statements in accordance with IFRS have been audited by PricewaterhouseCoopers Reviseurs d'Entreprises scrl, represented by Patrick Mortroux, who delivered unqualified opinions with emphasis of matter paragraph.

On 5 May 2014, our annual shareholder's meeting decided not to renew the independent public accounting firm mandate of Ernst & Young. At the time of shareholders decision, Ernst & Young had been our auditor for six years.

Ernst & Young's reports (under International Standards on Auditing) on our consolidated financial statements for the years ended 31 December 2013 and 2012 did not contain an adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles. In connection with the audits of our financial statements for each of the years ended 31 December 2013 and 2012 there were no disagreements with Ernst & Young on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure during the two years ended 31 December 2013 and 2012, that if not resolved to the satisfaction of Ernst & Young, would have caused it to make reference to the subject matter of the disagreements in connection with its report.

3.4 Approval of this prospectus

On 23 June 2015, the FSMA approved the English version of this prospectus for the purposes of the admission to trading of the New Shares on Euronext Brussels and Euronext Paris in accordance with Article 23 of the Belgian Act of 16 June 2006 on the public offerings of investment instruments and the admission of investment instruments to trading on a regulated market ("Loi relative aux offres publiques d'instruments de placement et aux admissions d'instruments de placement à la négociation sur des marchés réglementés"). The FSMA's approval does not imply any judgment on the merits or the quality of our shares or us. The FSMA has notified this prospectus to the AMF in accordance with the European passport mechanism provided for the prospectus Directive. This passport does not imply any judgment by the AMF on the merits or the quality of our shares or us.

This prospectus has been prepared and approved in English and the summary has been translated in French. The Company is responsible for verifying the consistency between the language versions of this prospectus. The English version of this prospectus is legally binding

This prospectus has not been submitted for approval to any supervisory body or governmental authority outside Belgium and France.

3.5 Available information

Prospectus

This prospectus is available in English and a summary in French. This prospectus will be made available to investors at no cost at our registered office, at Axisparc Business Center, Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium and can be obtained upon request by phone at +32 10 394100 and by email (<u>investors@celyad.com</u>). Subject to certain conditions regarding the location of the reader, this prospectus is also available on our website <u>www.celyad.com</u>.

Posting this prospectus and the summary on the internet does not constitute an offer to sell or a solicitation of an offer to purchase, and there shall not be a sale of any of shares in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to its registration or qualification under the laws of such jurisdiction or to or for the benefit of any person to whom it is unlawful to make such offer, solicitation or sale. The electronic version may not be copied, made available or printed for distribution. Other information on our website or any other website does not form part of this prospectus.

Company documents and other information

We must file our (amended and restated) articles of association and all other deeds that are to be published in the Annexes to the Belgian Official Gazette with the clerk's office of the Commercial Court of Nivelles (Belgium), where they are available to the public. A copy of our most recently restated articles of association and our corporate governance charter are available on our website.

In accordance with Belgian law, we must prepare annual audited statutory financial statements. Our statutory financial statements and the reports of our board of directors and of our statutory auditor relating thereto are filed with the National Bank of Belgium, where they are available to the public.

Furthermore, as a listed company, we must publish our annual statutory financial statements and semi-annual interim financial statements (in the form provided by the Belgian Royal Decree of 14 November 2007 relating to the obligations of issuers of financial instruments admitted to trading on a Belgian regulated market (as amended from time to time) ("Arrêté royal relatif aux obligations des émetteurs d'instruments financiers admis à la négociation sur un marché réglementé"), prepared under Belgian GAAP. In addition, we also provide such financial statements and interim financial statements as prepared under IFRS. Copies thereof will also be available on our website.

We also have to disclose price-sensitive information, information about our shareholders' structure, and certain other information to the public. In accordance with the Belgian Royal Decree of 14 November 2007, such information and documentation will be made available through press releases, the financial press in Belgium, our website, the communication channels of Euronext Brussels and Euronext Paris or a combination of these media.

Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC has been implemented in Belgian law by, *inter alia*, the Belgian Act of 2 May 2007 on the disclosure of large shareholdings in issuers whose securities are admitted to trading on a regulated market ("Loi du 2 mai 2007 relative à la publicité des participations importantes dans des émetteurs dont les actions sont admises à la négociation sur un marché réglementé et portant des dispositions diverses") and the Royal Decree of 14 February 2008 on the disclosure of important shareholdings ("Arrêté royal du 14 février 2008 relatif à la publicité des participations importantes").

Our website address is www.celyad.com.

4 INFORMATION ON THE TRANSACTIONS IN THE CONTEXT OF WHICH THE NEW SHARES ARE ISSUED

The maximum 1.562.395 New Shares for which admission to trading on Euronext Brussels and Euronext Paris has been requested, have been or will be issued by us in the context of (i) our acquisition of Oncyte closed in January 2015 (93,087 New Shares) described in section 4.1 below, (ii) a private placement with qualified investors closed in March 2015 (9,308 New Shares) described in section 4.2 below and (iii) our U.S. offering and concurrent private placement with qualified investors outside the U.S. and Canada expected to be closed on or around 24 June 2015 (maximum 1.460.000 New Shares) described in section 4.3 below.

4.1 Information related to the Oncyte acquisition

On 21 January 2015, we closed the acquisition of the outstanding membership interests in Oncyte LLC ("Oncyte") the oncology division of Celdara Medical, LLC ("Celdara"), a privately-held biotechnology company based in Lebanon, New Hampshire, USA. The acquisition establishes our entry into the field of immuno-oncology with a portfolio of drug product candidates including three autologous CAR T-Cell cell therapy products and an allogeneic T-Cell platform, targeting a broad range of cancer indications. Pursuant to the terms of the Stock Purchase Agreement and the Asset Purchase Agreement, we made a cash payment of \$6.0 million at closing and issued new shares to Celdara with a value of \$4.0 million. Additional contingent payments with an estimated fair value of \$42.0 million may be due upon reaching various clinical and sales milestones. We financed the acquisition with existing cash and authorized share capital.

On 21 January 2015, our board of directors decided to increase our capital, in the framework of the authorized capital, by way of a contribution in kind of 26.7% of the shares issued by OnCyte, LLC, valued at $\le 3,451,680$ (of which $\le 325,504.50$ in share capital and $\le 3,125,875.50$ in issue premium), and issued 93,087 New Shares to Celdara Medical, LLC.

4.2 Information related to the March private placement

On 3 March 2015, following a private placement with institutional investors internationally (i) outside the United States in reliance on Regulation S under the Securities Act and (ii) within the United States only to persons reasonably believed to be qualified institutional buyers within the meaning of and pursuant to Rule 144A under the Securities Act in transactions exempt from the registration requirements of the Securities Act, our capital was increased by way of a contribution in cash of €31,745,410 (of which €2,496,830 in share capital and €29,248,580 in issue premium), represented by 713,380 new shares (the "March private placement"). Of the 713,380 shares issued in the context of the private placement, 704,072 shares (i.e. 10% of the then listed shares) were immediately admitted to trading on Euronext Brussels and Euronext Paris. The admission to trading on Euronext Brussels and Euronext Paris of the remaining shares (i.e. 9,308 New Shares) is the subject of this listing prospectus.

4.3 Information related to the Global offering

On 12 June 2015, our board of directors decided to increase our capital, in the framework of the authorized capital, with restriction of the preferential subscription rights of our existing shareholders and to issue maximum 1.679.000 New Shares in view of our U.S. initial public offering and listing on NASDAQ.

In the context of our U.S. initial public offering, we are offering maximum 1.460.000 ordinary shares in a Global offering, including (i) an offering of ordinary shares in the form of 1.168.000 American Depositary Shares, or ADSs in the U.S. (the "U.S. offering") and (ii) a private placement of ordinary shares with qualified investors in Europe and countries outside the United States and Canada ("Concurrent private placement"). The ADSs may be evidenced by American Depositary Receipts, or ADRs, and each ADS represents the right to receive one ordinary share. We have granted the underwriters an option to purchase up to an additional 175.200 ordinary shares in the form of ADSs and 43.800 additional ordinary shares.

We have applied to have the ADSs listed on the NASDAQ Global Market under the symbol "CYAD."

No public offering is being made in Belgium, France or in any other jurisdiction than the U.S. This prospectus has been approved for the purposes of the admission to trading of the New Shares on the regulated market of Euronext Brussels and Euronext Paris and does not constitute an offer to sell or the solicitation of an offer to buy any New Shares.

We are an "emerging growth company" as defined under the United States federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for the U.S. prospectus and future filings.

The public offering price is 60.25 € per share, equivalent to a price of 68.56 \$ per ADS, assuming an exchange rate of 1.1380 € per U.S.

The issue of the New Shares and delivery of the ADSs to purchasers is expected to occur on or about 24 June 2015.

The exact number of New Shares to be issued in the context of our U.S. offering and the Concurrent private placement will be announced on our website on or about 19 June, 2015.

Each ADS represents the right to receive one ordinary share. The ADS holders will have the rights as provided in the deposit agreement among us, the depositary (Citibank, N.A.) and all holders and beneficial owners of ADSs issued thereunder.

We are offering our ordinary shares in the context of the Concurrent private placement and ADSs in the context of the U.S. offering through the underwriters named below. UBS Securities LLC and Piper Jaffray & Co are acting as joint bookrunners and as representative of the underwriters. On 18 June 2015, we have entered into an underwriting agreement with the representative. Subject to the terms and conditions of the underwriting agreement, each of the underwriters will severally agree to purchase, and we will agree to sell to the underwriters, in their own name but for the account of the investors, the number of ADSs and ordinary shares listed next to each such underwriters' name in the following table.

Underwriters	Number of shares or ADSs
Piper Jaffray & Co	458.857
UBS Securities LLC	709.144
Petercam NV/SA	104.286
Bryan, Garnier & Co	104.286
LifeSci Capital, LLC	62.571
Lake Street Capital Markets LLC	20.856
Total	1.460.000

We have granted the underwriters an option to buy up to an aggregate of 219.000 additional ADSs and ordinary shares. The underwriters will have 30 days from the date of the U.S. prospectus to exercise this option. If the underwriters exercise this option, they will each purchase additional ADSs and ordinary shares approximately in proportion to the amounts specified in the table above.

The underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our ADSs and our ordinary shares during and after the U.S. initial public offering, including stabilizing transactions, short sales, purchases to cover positions created by short sales, imposition of penalty bids, and syndicate covering transactions. Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our ADSs and our ordinary shares while this offering is in progress. Stabilization transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. These transactions may also include making short sales of our ADSs and our ordinary shares, which involve the sale by the underwriters of a greater number of ADSs and our ordinary shares than they are required to purchase in this offering and purchasing ADSs and our ordinary shares on the open market to cover short positions created by short sales. Short sales may be "covered short sales," which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked short sales," which are short positions in excess of that amount. The underwriters may close out any covered short position by either exercising their option, in whole or in part, or by purchasing ordinary shares or ADSs in the open market. In making this determination, the underwriters will consider, among other things, the price of ordinary shares or ADSs available for purchase in the open market as compared to the price at which they may purchase ordinary shares or ADSs through the options to purchase additional ordinary shares or ADSs. Naked short sales are short sales made in excess of the option to purchase additional ordinary shares or ADSs. The underwriters must close out any naked short position by purchasing ordinary shares or ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ordinary shares or the ADSs in the open market that could adversely affect investors who purchased in this offering. Any naked short position will not exceed an amount equal to 5% of the original number of ordinary shares or ADSs offered. The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased ordinary shares or ADSs sold by or for the account of that underwriter in stabilizing or short covering transactions. These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or maintaining the market price of our ADSs and our ordinary shares or preventing or retarding a decline in the market price of our

ADSs and our ordinary shares. As a result of these activities, the price of our ADSs and our ordinary shares may be higher than the price that otherwise might exist in the open market. The underwriters may carry out these transactions on the NASDAQ, on Euronext, in the over-the-counter market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the ADSs or the ordinary shares. Neither we, nor any of the underwriters make any representation that the underwriters will engage in these stabilization transactions or that any transaction, once commenced, will not be discontinued without notice. Stabilization will not be executed above the offer price. Within five business days of the end of the stabilization period, the following information will be made public:

- (i) whether or not stabilization was undertaken;
- (ii) the date at which stabilization started;
- (iii) the date on which stabilization last occurred;
- (iv) the price range within which stabilization was carried out, for each of the dates on
- (v) which stabilization transactions were carried out; and
- (vi) the final size of the U.S. initial public offering, including the result of the stabilization and the exercise of the over-allotment option, if any.

5 USE OF PROCEEDS

The principal purposes of the Global offering are to increase our financial flexibility, create a public market for our securities in the United States and facilitate our access to the public equity markets.

We estimate that we will receive net proceeds from the Global offering (including the U.S. offering and the Concurrent private placement) of approximately \$90 million (\in 79 million), after deducting underwriting commissions and estimated offering expenses payable by us, and assuming no exercise of the underwriters' option to purchase additional ordinary shares and ADSs. The net proceeds of the U.S. offering will be approximately \$72 million (\in 63 million). The net proceeds of the Concurrent private placement of ordinary shares with qualified investors in Europe and countries outside the United States and Canada will be approximately \$18 million (\in 16 million). If the underwriters exercise in full their options to purchase additional ordinary shares and ADSs in this Global offering, we estimate that we will receive net proceeds from the Global offering of approximately \$104 million, after deducting underwriting commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from the Global offering as follows:

- approximately \$ 15.0 million to advance the development of C-Cure through Phase 3 clinical development as a
 treatment for ischemic HF. The full data readout of CHART-1, the ongoing Phase 3 clinical trial currently
 conducted in Europe and Israel, is expected to occur in Q2-Q3 2016. The initiation of CHART-2, the second
 Phase 3 clinical trial of C-Cure, to occur in the US and in other countries is expected in H2 2015;
- approximately \$ 5.0 million to advance the development of CAR-NKG2D through Phase 1 clinical development
 as a treatment for AML and MM. The full data readout of CAR-NKG2D Phase 1 trial is expected to occur in Q2Q3 2016;
- approximately \$ 40.0 million to advance additional CAR T-cell therapy drug product candidates for the treatment of additional blood cancers and solid tumors. The target identification of additional CAR T-cell therapies is expected to occur in 2015 and the start of Phase 2b in 2016;
- approximately \$ 5.0 million to support our growth globally by expanding general, administrative and operational functions in our headquarters in Belgium and in the United States.

We expect to use the remainder of any net proceeds for working capital and other general corporate purposes.

We may also use a portion of the net proceeds to in-license, acquire or invest in complementary technologies, products or assets. However we have no current plan, commitments or obligations to do so.

Based on our current operation plans and assumptions, we believe that such proceeds, together with our existing cash, will be sufficient to fund our operations until at least the end of 2017. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our drug product candidates and may need to raise additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our drug product candidates or other research and development initiatives. Our licenses may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for our drug product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or% license on unfavorable terms our rights to our drug product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any these events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our securities to decline.

We currently have no specific plans as to how the net proceeds from this offering will be allocated beyond the uses specified above and therefore management will retain discretion to allocate the remainder of the net proceeds of this offering among these uses.

This expected use of the net proceeds from the Global offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of

and results from pre-clinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our drug product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from the U.S. initial public offering.

Pending our use of the net proceeds from the Global offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

We estimated the total fees associated to the Global offering to \$10 million, representing 10% % of the base amount, assuming no exercise of the underwriters' option to purchase additional ordinary shares and ADSs. The fees associated to the transaction could be breakdown as followed; 7% placement fee due to the underwriters, 2.0% counsel and audit fees and 1.0% fee associated to printing, communication and regulatory expenses.

5.1 Interest of natural persons and legal persons involved in the issue

Save for the fees payable to the underwriters in the context of private placement and our U.S. initial public offering, so far as we are aware, no person involved in the issue of the New Shares has an interest that could be material to the issue.

6 INFORMATION CONCERNING THE SECURITIES TO BE ADMITTED TO TRADING

6.1 Form of the New Shares

All New Shares will have the same rights and benefits attached to them as our other ordinary shares and will be issued with coupons 1 and following attached. For a further description of our shares and the rights and benefits attached thereto, see section 17 "DESCRIPTION OF THE SHARE CAPITAL AND CORPORATE STRUCTURE".

All of our shares belong to the same class. They are in registered or dematerialized form.

Investors who wish to have their shares in registered form in our share register, should ask us to do this, and we will thereupon within a reasonable period of time record the shares in our share register. Any costs incurred in connection with the conversion of shares in dematerialized form into registered form will be borne by the converting shareholder.

Our shares are listed on Euronext Brussels and Euronext Paris under the symbol "CYAD" and international code number BE0974260896. We intend to apply to have our ADSs listed on the NASDAQ Global Market under the symbol "CYAD."

All of our outstanding shares are fully paid-up and freely transferable, subject to any contractual restrictions.

Our share capital, which is represented by our outstanding ordinary shares, is denominated in euros. The shares are issued under Belgian law.

6.2 Listing and first trading

We have made an application of admission to trading for all New Shares on Euronext Brussels and Euronext Paris.

Trading of the New Shares is expected to commence on or about 24 June 2015.

6.3 Financial service

The financial service for our shares is provided in Belgium and in France by BNP Paribas Securities Services. Should we alter our policy in this respect, this will be announced in accordance with applicable law.

6.4 Lock-up and standstill arrangements

In the context of the U.S. initial public offering we, the members of our board of directors and our executive management team, and several shareholders have entered into lock-up agreements with the underwriters. Under the lock-up agreements, subject to certain exceptions, we and each of these persons may not, without the prior written approval of UBS Securities LLC, offer, sell, contract to sell, pledge, or otherwise dispose of, directly or indirectly, or hedge our ADSs or securities convertible into or exchangeable or exercisable for our ADSs. These restrictions will be in effect for a 90-day period after 18 May 2015. UBS Securities LLC may, at any time, without public notice and in its sole discretion, release some or all the securities from these lock-up agreement; provided, that in the case of a release given to any of our officers or directors, we will be required to announce such a release in a press release at least two business days prior to the effective date of such release as long as we are notified at least three business days in advance thereof. There are no agreements between the representative, on the one hand, and our officers or directors, on the other hand, releasing any such officer or director from these lock-up agreements prior to the expiration of the 90-day period. If the restrictions under the lock-up agreements are waived, our ADSs may become available for resale into the market, subject to applicable law, which could reduce the market price of our ADSs.

7 SELECTED FINANCIAL INFORMATION

You should read the following selected historical consolidated financial data in conjunction with our audited consolidated financial statements and related notes incorporated by reference in this prospectus and the section of this prospectus titled "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS". We derived the consolidated statement of comprehensive loss data for the years ended 31 December 2014 and 2013 and consolidated statement of financial position data as of 31 December 2014 and 2013 from our audited consolidated financial statements. Our audited consolidated financial statements have been prepared in accordance with IFRS, as issued by the IASB. Our historical results are not necessarily indicative of the results to be expected in the future.

The restatement of our previously issued consolidated financial statements as of and for the year ended 31 December 2013 relates to errors in our accounting for convertible debentures and certain share-based payments. For additional information regarding the restatement, see Note 2.36 to our consolidated financial statements incorporated by reference in this prospectus.

(€'000)	For the year ended		
	2014	2013	
		(as restated)	
Consolidated statement of comprehensive loss			
Revenue	146	_	
Cost of sales	(115)	_	
Gross Profit	31	_	
Research and development expenses	(15,865)	(9,046)	
General and administrative	(5,016)	(3,972)	
Other operating income	4,413	64	
Operating loss	(16,437)	(12,954)	
Financial income	277	60	
Financial expenses	(41)	(1,595)	
Share of loss of investments accounted for using the equity method	(252)	_	
Loss for the year	(16,453)	(14,489)	
Basic and diluted loss per shares ⁽¹⁾	(2.44)	(3.53)	
Number of shares used for computing basic and diluted loss for the year ⁽²⁾	6750,383	4,099,216	

Basic and diluted net loss per share are the same in these periods because outstanding warrants would be anti-dilutive due to our net loss in these periods.

(E1000)

000) For the year endo		31 December,
	2014	2013 (as restated)
Consolidated statement of financial position		
Non-current assets	11,041	9,783
Intangible assets	10,266	9,400
Property, Plant and Equipment	598	243
Investment accounted for using the equity method	68	-
Other non-current assets	109	140
Current assets	32,935	22,603
Trade and Other Receivables	830	422
Grant receivables	1,009	-
Other current assets	792	123
Short term investment	2,671	3,000
Cash and cash equivalents	27,633	19,058
Total assets	43,976	32,386
Share capital	24,615	22,138
Share premium	53,302	30,474
Other reserves	19,982	18,894
Retained loss	(71,215)	(54,608
Total shareholders' equity	26,684	16,898
Finance leases	279	27
Non-current advances repayable	10,778	12,072
Other non-current liabilities	182	- -
Total non-current liabilities	11,239	12,099
Finance leases	134	79

Weighted-average number of shares for the period then ended.

(€'000)	For the year ended 31 December,		
	2014	2013 (as restated)	
Advances repayable	777	429	
Trade payables	4,042	2,169	
Other current liabilities	1,100	712	
Total current liabilities	6,053	3,389	
Total liabilities	17,292	15,488	
Total equity and liabilities	43,976	32,386	

8 WORKING CAPITAL AND CAPITALISATION AND INDEBTEDNESS

8.1 Working capital statement

On the date of this prospectus, we are of the opinion that it has sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this prospectus.

Reference is also made to section 5 "USE OF PROCEEDS".

8.2 Capitalisation and indebtedness

The following table sets forth certain preliminary selected financial data of 31 March 2015. All amounts are presented in their nominal value.

The preliminary financial data presented below are subject to the completion of our consolidated financial closing procedures. Those procedures have not been completed. This information should be read in conjunction with the financial statements as of and for the years ended 31 December 2014 and the related notes thereto.

The preliminary financial data included in this registration statement has been prepared by and is the responsibility of Celyad S.A. management. PricewaterhouseCoopers Reviseurs d'Entreprises sccrl has not audited, reviewed, compiled or performed any procedures with respect to the accompanying preliminary financial data. Accordingly, PricewaterhouseCoopers Reviseurs d'Entreprises sccrl does not express an opinion or any other form of assurance with respect thereto.

(€'000)	As of 31 March 2015
Total Current financial indebtedness (1)	869
Secured	92
Unsecured	777
Total Non-Current financial indebtedness (2)	11,464
Secured	279
Unsecured	11,185
Capital and share premium	
Share capital	27,438
Share premium	83,768
Cash and cash equivalents	49,202
Current financial indebtedness	(869)
Net Cash and cash equivalents in excess of Current financial indebtedness	48,333
Non-Current financial indebtedness	(11,464)
Net Cash and cash equivalents in excess of Current and non- Current financial indebtedness	36,869

⁽¹⁾ Current financial indebtedness consists of financial leases and advances repayable that is to be paid within twelve months from 31 March 2015.

⁽²⁾ Non-current financial indebtedness consists of financial leases and advances repayable that is expected to be paid at a date that is more than twelve months from 31 March 2015.

9 DIVIDENDS AND DIVIDEND POLICY

9.1 Entitlement to dividends

The New Shares are entitled to dividends, if and when declared, for the financial year ended on 31 December 2015 and the following financial years.

9.2 Dividend policy

We have never declared or paid any cash dividends on our ordinary shares. We do not anticipate paying cash dividends on our equity securities in the foreseeable future and intend to retain all available funds and any future earnings for use in the operation and expansion of our business. In general, distributions of dividends proposed by our board of directors require the approval of our shareholders at a meeting of shareholders with a simple majority vote, although our board of directors may declare interim dividends without shareholder approval, subject to the terms and conditions of the Belgian Company Code.

Pursuant to Belgian law, the calculation of amounts available for distribution to shareholders, as dividends or otherwise, must be determined on the basis of our non-consolidated statutory financial accounts prepared under Belgian GAAP, and not on the basis of IFRS consolidated accounts. In addition, under the Belgian Company Code, we may declare or pay dividends only if, following the declaration and issuance of the dividends, the amount of our net assets on the date of the closing of the last financial year according to our statutory annual accounts (i.e., the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all as prepared in accordance with Belgian accounting rules), decreased with the non-amortized costs of incorporation and expansion and the non-amortized costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the called capital), increased with the amount of non-distributable reserves. Finally, prior to distributing dividends, we must allocate at least 5% of our annual net profits (under our non-consolidated statutory accounts prepared in accordance with Belgian accounting rules) to a legal reserve, until the reserve amounts to 10% of our share capital.

10 DILUTION

We are applying for admission to trading on Euronext Brussels and Euronext Paris of maximum 1.781.395 New Shares, of which 93,087 New Shares were issued in January 2015 in the context of our acquisition of Oncyte, 9,308 New Shares were issued in March 2015 in the context of a private placement and maximum 1.679.000 New Shares will be issued on or around 24 June 2015 in the context of our U.S. initial public offering (see section 4.3).

The table sets out the percentage of dilution resulting from the issue of the New Shares.

10.1 Shareholders prior to the completion of the Global offering and listing of the shares and ADSs

The table below provides an overview of our significant shareholders prior to the completion of the Global offering (including the U.S. offering and Concurrent private placement) and the listing of our shares. The overview must be read together with the notes referred to below.

	Name I am a f		Warrants		Total number of	
Share- / Warrantholder	Number of shares	%	in number of shares ^[1]	%	shares and warrants	%
A. Executive Management Team [2]						
CEO and other members of the Executive Management Team	81,378	1.04	199,725	61.70	281,103	3.44
B. (Independent) Directors [2]						
Independent Directors	125,753	1.60	10,000	3.09	135,753	1.66
C. Other shareholders						
Tolefi SA [3]	2,267,844	28.90	2,504	0.77	2,270,348	27.78
Medisun Ltd	568,180	7.24	-	-	568,180	6.96
PMV-Tina NV	428,071	5.45	-	-	428,071	5.24
SRIW Techno and Sofipôle	400,000	5.10	-	-	400,000	4.89
Mayo Foundation for Education and Research	211,135	2.69	-	-	211,135	2.58
Cardiovasculair Onderzoek Aalst CVBA	160,062	2.04	-	-	160,062	1.96
Mr Michel Lussier	162,370	2.07	400	0.12	162,370	1.99
Other shareholders	3,340,499	42.57	1,871	0.58	3,342,370	40.91
Subtotal	7,538,161	96.06	4,775	1.47	7,542,936	92.31
D. Personnel						
Personnel [4]	-	-	109,197	33.73	109,197	1.34
Subtotal A+B+C+D	7,745,292	98.69	323,697	100.00	8,068,989	98.75
E. Shares issued in January and March 2015	102,395	1.31	-	-	102,395	1.25
Total A+B+C+D+E	7,847,687	100.00	323,697	100.00	8,171,384	100.00

^[1] For an overview of all Warrants issued by the Company, reference is made to section Error! Reference source not found. "Error! ference source not found.".

10.2 Shareholders after completion of the Global offering and listing of the shares and ADSs

The table below provide an overview of the shareholding of our significant shareholders after the completion of the Global offering (including the U.S. offering and Concurrent private placement) and listing of our shares. The number of

^[2] For a detailed overview of the shares and warrants held by the members of the Board of Directors and by the members of the Executive Management Team, reference is made to section 14.8 "Compensation of Directors and Executive Management Team".

^[3] Tolefi SA is controlled, within the meaning of Article 5 BCC, by Mr Serge Goblet, who is a Director of the Company. For a detailed overview of the shares and warrants held by Serge Goblet, reference is made to the previous footnote.

^{[4] &}quot;Personnel" includes the persons providing services to the Company on the basis of an employment or a consultancy agreement and who are not a member of the Executive Management Team or a member of the Board of Directors.

outstanding shares and warrants after the completion of the Global offering and listing of the shares assumes that the over-allotment option has been fully exercised and that as a result, the number of offered shares amounts to 219.000.

The simulation is merely for information purposes only. Prospective investors should note that the final number of offered Shares could be lower than assumed for the table below.

The overview must be read together with the notes referred to below.

Share- / Warrantholder	Number of shares	0/2	Warrants in number of shares [1]	%	Total number of shares and warrants	%
A. Executive Management Team [2]	snares	/0	or shares	/0	warrants	/0
CEO and other members of the Executive Management Team	81,378	0.85	199,725	61.70	281,103	2.85
B. (Independent) Directors [2]						
Independent Directors	125.753	1.32	10.000	3.09	135,753	1.38
C. Other shareholders						
Tolefi SA [3]	2.267.844	23.81	2.504	0.77	2.270.348	23.05
Medisun Ltd	568.180	5.96	-	-	568.180	5.77
PMV-Tina NV	428.071	4.49	-	-	428.071	4.35
SRIW Techno and Sofipôle	400.000	4.20	-	-	400.000	4.06
Mayo Foundation for Education and Research	211.135	2.22	-	-	211.135	2.14
Cardiovasculair Onderzoek Aalst CVBA	160.062	1.68	-	-	160.062	1.62
Mr Michel Lussier	162.370	1.70	400	0.12	162.370	1.65
Other shareholders	3.340.499	35.60	1.871	0.58	3.342.370	33.93
Subtotal	7.538.161	79.13	4.775	1.47	7.542.936	76.58
D. Personnel						
Personnel [4]	-	-	109.197	33.73	109.197	1.11
E. Shares issued in January and March 2015	102.395	1.07	-	-	102.395	1.04
Subtotal A+B+C+D+E	7.847.687	82.38	323.697	100.00	8.171.384	82.95
F. Global offering	1.679.000	17.62			1.679.000	17.05
New shares	1.460.000	15.33	-	=	1.460.000	14.82
Exercise over allotment option	219.000	2.30			219.000	2.22
Total A+B+C+D+E+F	9.526.687	100%	323.697	100%	9.850.384	100%

^[1] For an overview of all Warrants issued by the Company, reference is made to section Error! Reference source not found. "Error! ference source not found.".

^[2] For a detailed overview of the shares and warrants held by the members of the Board of Directors and by the members of the Executive Management Team, reference is made to section 14.8 "Compensation of Directors and Executive Management Team".

^[3] Tolefi SA is controlled, within the meaning of Article 5 BCC, by Mr Serge Goblet, who is a Director of the Company. For a detailed overview of the shares and warrants held by Serge Goblet, reference is made to the previous footnote.

^{[4] &}quot;Personnel" includes the persons providing services to the Company on the basis of an employment or a consultancy agreement and who are not a member of the Executive Management Team or a member of the Board of Directors.

11 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of our financial condition and results of operations in conjunction with our audited consolidated financial statements and related notes incorporated by reference in this prospectus. The following discussion contains forward-looking statements that involve certain risks and uncertainties. Our actual results could differ materially from those discussed in these statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly under the "Risk factors" and "Forward-looking statements" sections.

All amounts included herein with respect to the years ended 31 December 2013 and 2014 are derived from our audited consolidated financial statements. The audited consolidated financial statements for the years ended 31 December 2013 and 2014 are prepared pursuant to International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB.

11.1 Overview

We consider we are a leader in engineered cell therapy treatments with clinical programs initially targeting indications in cardiovascular disease and oncology. Our lead drug product candidate in cardiovascular disease is C-Cure, an autologous cell therapy for the treatment of patients with ischemic heart failure, or HF. We completed enrollment in our first Phase 3 clinical trial of C-Cure in Europe and Israel, or CHART-1, in March 2015. On 30 March 2015, we announced that the Data Safety Monitoring Board, or DSMB, reviewed unblinded safety data from CHART-1 and determined that there was no evidence of obvious differences in safety profiles of patients in the two arms of the trial, which means that the data did not support discontinuation of the trial on the basis of safety. The full data readout from this trial is expected in the middle of 2016. We anticipate initiating our second Phase 3 clinical trial of C-Cure in the United States and Europe, or CHART-2, pending U.S. Food and Drug Administration, or FDA, lifting of the existing clinical hold, which we expect in the second half of 2015. Our lead drug product candidate in oncology is CAR-NKG2D, an autologous chimeric antigen receptor or CAR, an artificial, lab engineered receptor, which is used to graft a given protein onto an immune cell, T lymphocyte, or CAR T-cell, therapy We are currently enrolling patients with refractory or relapsed acute myeloid leukemia, or AML, or multiple myeloma, or MM, in a Phase 1 clinical trial of CAR-NKG2D in the United States. The first patient was treated in this trial in April 2014 and no treatment-related safety concerns were reported during the 30-day follow-up period. Interim data from this trial is expected to be reported at various times during the trial, with the full data readout expected in the middle of 2016.

All of our current drug product candidates are autologous cell therapy treatments. In autologous procedures, a patient's cells are harvested, selected, reprogrammed and expanded, and then infused back into the same patient. A benefit of autologous therapies is that autologous cells are not recognized as foreign by patients' immune systems. We believe that we are well situated to effectively advance autologous cell therapy treatments for cancer and other indications as a result of the expertise and know-how that we have acquired through our development of C-Cure. We also believe that there are numerous operational synergies between our product platforms, including that, prior to commercialization, our existing pilot manufacturing plant can accommodate both of our cell therapy programs without significant capital expenditure.

On 5 November 2014, we acquired CorQuest Medical, Inc., a private U.S. company, or CorQuest, for a single cash payment of €1.5 million and .a potential earn-out payment to the sellers if the intellectual property acquired from CorQuest is sold, in whole or in part, to a third party within ten years of November 5, 2014. The earn-out payment shall be 2.0% of the value of the cash and non-cash consideration from such sale, or Net Revenue, if the Net Revenue is €10.0 million or less, and 4.0% of the Net Revenue, if the Net Revenue is greater than €10.0 million.

On 21 January 2015, we purchased OnCyte, LLC, or OnCyte, a wholly-owned subsidiary of Celdara Medical, LLC, a privately-held U.S. biotechnology company for an upfront payment of \$10.0 million, of which, \$6.0 million was paid in cash and \$4.0 million was paid in the form of 93,087 of our ordinary shares. Additional contingent payments with an estimated fair value of \$42.0 million are payable upon the attainment of various clinical and sales milestones. As a result of this transaction we acquired our CAR T-cell drug product candidates and related technology, including technology licensed from the Trustees of Dartmouth College.

As of 31 December 2014, we have been funded through the following transactions:

proceeds of €42.0 million from private financing rounds;

- proceeds of €26.5 million from an initial public offering of our ordinary shares on Euronext Brussels and Euronext Paris, or the Euronext IPO;
- proceeds of €25.0 million from a private financing by Medisun International Limited, or Medisun; and
- proceeds of €18.7 million from non-dilutive financing sources, such as government grants and recoverable cash advances, or RCAs.

As of 31 December 2014, we had cash and cash equivalents of €27.6 million and short term investments of €2.7 million. In March 2015, we completed a €31.7 million private placement of 713,380 ordinary shares to institutional investors in the United States, bringing our total cash and cash equivalents after this financing as of 31 March 2015, to € 46.6 millions.

We have incurred net losses in each year since our inception. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administration expenses associated with our operations. For the years ended 31 December 2014 and 2013, we incurred a loss for the year of €16.5 million and €14.5 million, respectively. As of 31 December 2014, we had a retained loss of €71.2 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- continue the development of our drug product candidates, including planned and future clinical trials;
- conduct additional research and development for drug product candidate discovery and development;
- seek regulatory approvals for our drug product candidates;
- prepare for the potential launch and commercialization of our drug product candidates, if approved;
- establish a sales and marketing infrastructure for the commercialization of our drug product candidates, if approved;
- in-license or acquire additional drug product candidates or technologies;
- build-out additional manufacturing capabilities; and
- hire additional personnel, including personnel to support our drug product development and commercialization efforts and operations as a U.S. public company.

We generate limited revenue from sales of $C-Cath_{ez}$, our proprietary catheter for injecting cells into the heart. We believe that $C-Cath_{ez}$ revenue will remain immaterial in the future as we intend to sell $C-Cath_{ez}$ to research laboratories and clinical-stage companies only.

We do not expect to generate material revenue from drug product sales unless and until we successfully complete development of, and obtain marketing approval for, one or more of our drug product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital, in addition to the net proceeds from this offering, prior to commercialization of C-Cure. Until such time that we can generate substantial revenue from drug product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, including government grants and RCAs, and collaborations and licensing arrangements. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market drug product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full.

11.2 Financial Operations Overview

The successful development of research programs and drug product candidates is uncertain and we expect to continue to incur operating losses for the foreseeable future as we develop C-Cure and our other drug product candidates. At this time, we cannot reasonably estimate the precise timing or detailed costs of the efforts that will be necessary to complete the remainder of the development of our drug product candidates and their research and development programs. We are also unable to predict when material cash inflows will commence from sales of C-Cure or any of our other drug product candidates.

Set forth below is a discussion of factors that we believe will materially impact our results of operations in future periods.

Revenue

For the periods presented in this prospectus, the only revenue we generated was for third-party sales of C-Cath_{ez} in 2014 that are immaterial in comparison to our operating expenses. We expect revenue from C-Cath_{ez} sales to remain immaterial compared to our operating expenses for the foreseeable future.

Cost of Sales

For the periods presented in this prospectus, costs of sales are related to the cost of manufacturing C-Cathez.

We expect the costs of sales related to sales of C-Cath_{ez} will remain immaterial compared to our operating expenses for the foreseeable future.

Recoverable cash advances

RCAs support specific development programs and are typically granted by regional governmental entities, and in our case, the Walloon Region. RCA contracts consist of three phases: the research phase, the decision phase and the exploitation phase. During the research phase, we receive funds from the Walloon Region based on statements of expenses.

RCAs are recognized as "Other operating income" on a systematic basis over the periods in which we recognize the costs compensated by the RCAs as expenses.

At the end of the research phase, we generally decide within a period of six months whether or not to exploit the results of the research phase; this phase is known as the decision phase. If we elect to exploit the results achieved under a RCA, we enter the exploitation phase, which may have a duration of up to ten years. If we elect to exploit the results under an RCA, the relevant RCA becomes contingently refundable, and we recognize a liability when it is probable that all or a portion of the RCA will be refunded and the amount to be refunded is estimable. The provision of the liability for amounts to be refunded under our RCA programs are recognized as a reduction of other operating income in the income statement.

In 2015, we will be required to make exploitation decisions on our remaining outstanding RCAs. As a result, we may potentially recognize an additional undiscounted liability of €2.5 million. This amount is based on the amount effectively perceived by us as of 31 December 2014.

When we decide not to exploit, or cease to exploit, the results under an RCA, we notify the Walloon Region of our decision. The RCA related to such decision will no longer be refundable as of the calendar year following such decision, and the research data and intellectual property rights related to such results are transferred to the Walloon Region. Also, when we decide to renounce our rights to patents which may result from the research, title to such patents are transferred to the Walloon Region.

When we decide to discontinue the development program for which a financial liability has been accounted for, or decide not to exploit, or cease to exploit, the results of a program previously recognized as a financial liability, the outstanding liability is derecognized at the end of the period and credited to the income statement as other operating income.

We are now in the exploitation phase with of RCAs paid related to C-Cath_{ez} and C-Cure. As of 31 December 2014, the total cumulative reimbursements associated with the RCAs related to C-Cath_{ez} and C-Cure amounted to €0.5 million.

Other government grants

Since inception through 31 December 2014, we received grants totaling €1.7 million and we expect to continue to apply for grants from FP7 and Walloon Region authorities. These grants are used to partially finance early stage projects such as fundamental research, applied research and prototype design.

As of the date of this prospectus, none of the grants received are subject to any conditions. As per our agreements with these governmental authorities, grants are paid upon our submission of a statement of expenses. We incur project expenses first and ask for partial reimbursement according to the terms of the agreements.

The government grants are recognized in profit or loss on a systematic basis over the periods in which we recognize as expenses the related costs for which the grants are intended to compensate.

Research and development expenses

The following expenses are aggregated and presented under the caption "Research and development expenses":

- Manufacturing expenses;
- Clinical, quality and regulatory expenses; and

Other research and development expenses.

Manufacturing expenses

Manufacturing expenses represented 25% and 19% of our total operating expenses for the years ended 31 December 2014 and 2013, respectively. For the periods presented in this prospectus, manufacturing expenses only included the costs to manufacture C-Cure, but will include the cost of manufacturing our other clinical-stage drug product candidates in the future. These costs are mainly comprised of the salaries of the manufacturing team, production raw material and supplies, maintenance and calibration charges of equipment and the rental of Good Manufacturing Practices laboratory facilities. Raw materials are the main component to the current cost of production of C-Cure and will remain as such in the future as they are closely associated to the production of clinical batches. Most of our raw material suppliers are large companies, and pursuant to our internal procedures, we are trying to have an alternative supplier for each critical material, to limit risk of disruption and price sensitivity. The second largest caption in manufacturing expenses is the salaries of our production team. We expect salaries will increase in 2015 and plateau thereafter. We lease our production facility from Biological Manufacturing Services SA. Manufacturing expenses are mostly driven by the number and the size of clinical trials that we conduct on our drug product candidates. We expect these expenses will remain significant in the near future and will increase as our clinical trials include a greater number of patients and we potentially commence commercialization of our drug product candidates, if approved.

Clinical, quality and regulatory expenses

Our clinical, quality and regulatory expenses relate to our C-Cure clinical trial activities and represented 37% and 34% of our total operating expenses for the years ended 31 December 2014 and 2013, respectively.

Our clinical, quality and regulatory expenses include employee expenses, costs of setting up quality procedures, as well as the preparation and supervision of our clinical trials. These expenses also include the costs of maintaining and overseeing our intellectual property portfolio, such as the costs of intellectual property legal counsel and associated filing and maintenance fees. We expect that these expenses will increase in the near future given the expected clinical trial activities associated with our drug product candidates, including our CAR T-cell drug product candidates.

All clinical, quality and regulatory costs related to our C-Cure clinical program incurred to date have been expensed as incurred, and we have not capitalized any such costs. We may review this policy in the future depending on the outcome of our current development programs.

We cannot determine with certainty the duration and completion costs of our current or future clinical trials of our drug product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our drug product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our drug product candidates. The duration, costs and timing of clinical trials and development of our drug product candidates will depend on a variety of factors, including:

- per patient clinical trial costs;
- the number of patients that participate in clinical trials;
- the drop-out or discontinuation rates of patients;
- the duration of patient follow-up;
- the scope, rate of progress and expense of our ongoing as well as any additional non-clinical studies, clinical trials and other research and development activities;
- clinical trial and early-stage results;
- the terms and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance of C-Cure or any of our other product candidates.

A change in the outcome of any of these variables with respect to the development of C-Cure or any other drug product candidate that we are developing could mean a significant change in the costs and timing associated with the development of C-Cure or such other drug product candidate. For example, if FDA, European Medicines Agency, or EMA, or other regulatory authority were to require us to conduct additional pre-clinical studies and clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of our drug product candidates, or if we experience significant delays in enrollment in any clinical trials, we would be required to

spend significant additional financial resources and time on the completion of the clinical development of the applicable drug product candidate.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

We have not received regulatory approval from the FDA, EMA or any other regulatory authority to market any of our drug product candidates. The successful development of our drug product candidates is highly uncertain. Our drug product candidates are tested in numerous pre-clinical studies for safety, pharmacology and efficacy. We then conduct clinical trials for those drug product candidates that are determined to be the most promising. We fund these trials ourselves or through non-dilutive funding. As we obtain results from clinical trials, we may elect to discontinue or delay trials for some drug product candidates in order to focus resources on drug product candidates that we believe are more promising. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a drug product candidate. The cost of clinical trials for a particular drug product candidate may vary significantly.

At this time we cannot reasonably estimate the time and costs necessary to complete the development of any of our drug product candidates or the period, if any, in which we will generate drug product revenue. There are numerous risks and uncertainties associated with drug product development, including:

- terms and timing of regulatory approvals and authorizations; and
- the number, the design and the size of the clinical trials required by the regulatory authorities to seek marketing approval.

Other research and development expenses

Other research and development expenses represented 14% and 17% of our total operating expenses for the years ended 31 December 2014 and 2013, respectively.

Other research and development expenses reflect costs incurred for our research and development projects related to our pre-clinical drug product candidates. These expenses include the salaries of scientists and technicians, our laboratory supplies, depreciation of our license with the Mayo Foundation for Medical Education and Research, or Mayo License, and the costs of our outsourced research and development studies and services. With the exception of the Mayo License, which has been capitalized and amortized over 20 years, and C-Cath_{ez} development costs capitalized since May 2012, we expense all research and development costs as they are incurred. The €0.9 million development costs of C-Cath_{ez} have been capitalized since 1 May 2012, the month following our receipt of the CE mark for C-Cath_{ez}.

We utilize our research and development staff and infrastructure resources across projects in our programs and many of our costs historically have not been specifically attributable to a single project. Accordingly, we cannot state precisely our total costs incurred on a project-by-project basis. In addition, our research and development expense may vary substantially from period to period based on the timing and scope of our research and development activities, the timing of regulatory approvals or authorizations and the rate of commencement and enrollment of patients in clinical trials.

Other research and development activities are central to our business. We expect that our other research and development expenses will continue to grow in the future with our development of drug product candidates from our cardiovascular disease program and our CAR T-cell program.

The expected increase in research and development expenditures will mostly relate to higher personnel costs, outsourcing costs and additional in house pre-clinical studies.

General and administrative expenses

General and administrative expenses represented 24% and 31% of our total operating expenses for the years ended 31 December 2014 and 2013, respectively.

Our general and administrative expenses consist of salaries and other share-based compensation costs not related to research and development activities for personnel in executive, finance, accounting and communication functions. It also includes costs related to professional fees for auditors and lawyers and consulting fees not related to research and development operations and fees related to functions that are outsourced by us such as information technology, or IT. General and administrative expenses are expected to increase in the near future with the expansion of our executive management team to include new personnel responsible for legal, IT, sales and marketing, as well as with the additional responsibilities related to becoming a U.S. public company.

Other operating income

During the periods presented in this prospectus, our other operating income is primarily generated from (i) government grants received from the European Commission under the Seventh Framework Program, or FP7, and (ii) government grants received from the Regional government, or Walloon Region, in the form of RCAs.

From inception through 31 December 2014, we have received subsidies totaling €1.7 million and RCAs totaling €17.0 million. In the future, we expect to generate income from a combination of subsidies, RCAs, products sales and upfront fees, research and development support, milestone payments from potential collaborations and royalties from the licensing of intellectual property. We expect that future income will continue to fluctuate from period to period as a result of the timing of future regional funding, the terms and timing of potential collaboration agreements and, to the extent that any drug products are approved and successfully commercialized, the volume and timing of drug product sales.

Finance Income

Finance income relates to interest income earned on bank accounts and from currency exchange rate differences. Our cash and cash equivalents have been deposited primarily in savings and deposit accounts with original maturities of three months or less. Savings and deposit accounts generate a modest amount of interest income. We expect to continue this investment philosophy.

Finance Expenses

Finance expenses relate to interest payable on shareholder loans and finance leases, as well as interest on overdrafts and current exchange rate differences.

Restatement of 2013 Financial Statements

Our financial statements for the year ended 31 December 2013 were restated to reflect errors in the IFRS recognition and measurement of shareholders convertible loans and share-based payments. The restatement of the shareholders convertible loans is a result of classifying such loans as financial debt, instead of equity, previously called 'quasi equity', as originally posted in our 2013 financial statements. We decided that the shareholders convertible loans should have been accounted for as a financial debt, because the loans were convertible into a variable number of shares. The restatement of the share-based payment is a result of recognizing the fair value of the warrants issued under our May 2013 warrants plan based on the initial public offering price of our ordinary shares in the Euronext IPO. For further details on these adjustments, see Note 2.36 of our consolidated financial statements.

Consolidated financial data

The following is a summary of our consolidated financial data.

Revenue

(€'000)	For the year ended 31 December,		
	2014	2013 (as restated)	
C-Cath _{ez} Sales	146	· -	
Total Revenue	146	_	

In the year ended 31 December 2014, the total revenue generated through sales of C-Cath_{ez} was € 0.1 million. No revenue was generated from sales of C-Cath_{ez} in 2013.

Cost of Sales

(€'000)	For the year ended 31 December,		
	2014	2013	
		(as restated)	
C-Cath _{ez} Cost of Sales	(115)	_	
Total Cost of Sales	(115)	_	

In 2014, the total cost of sales associated with sales of C-Cath_{ez} amounted to 0.1 million. There were no costs of sales in 2013 as there were no sales of C-Cath_{ez}.

Research and development expenses

The following is a summary of manufacturing expenses, clinical, quality and regulatory expenses and other research and development expenses, which are aggregated and presented as research and development expenses in our consolidated financial statements.

Manufacturing expenses

(€'000)	For the year ended 31 December,		
	2014	2013	
		(as restated)	
Employee expenses	1,501	842	
Contractor fees	402	76	
Pilot Plan consulting fees	348	289	
Raw materials	2,060	988	
Rent &utilities	234	133	
Other manufacturing costs	591	87	
Total manufacturing expenses	5,136	2,415	

Manufacturing expenses increased by €2.7 million in 2014 as compared to 2013. In 2014, manufacturing expenses were primarily related to the production of clinical lots of C-Cure for CHART-1, which was initiated in 2013. The first clinical lots were produced in the middle of 2013 with a slow ramp-up over the second part of 2013, whereas in 2014, all our production resources were used at full capacity.

The employee expenses increase year over year is a result of the hiring of 13 additional employees in 2014 due to higher production needs.

Increase of production associated with the ramp-up of CHART-1 also explained the increase of €1.1 million of raw materials cost year over year. This increase is mostly related to the volume of raw materials consumed during CHART-1 as purchase prices remained stable throughout 2014.

The contractor fees are comprised primarily of the supply of C-Cathez, manufactured by Creganna. The increase in such fees in 2014 compared to 2013 is due to the number of catheters used in CHART-1.

Clinical, quality and regulatory expenses

	For the year ended 31 December,			
(61000)	2014	2013		
(€'000)		(as restated)		
Employee expenses	1,780	1,460		
Study cost	4,924	2,169		
IP filing & living	351	360		
Travel & living	249	180		
Consulting fees	436	269		
Other costs	12	34		
Total clinical, quality and regulatory expenses	7,752	4,472		

All clinical, quality and regulatory expenses for the periods presented relate to CHART-1. The €3.3 million increase in these expenses in 2014 as compared to 2013 is primarily related to the initiation of CHART-1 in the middle of 2013, resulting in only six months of trial expenses in 2013, as compared to 12 months of trial expenses in 2014. Trial costs are mainly driven by the costs of clinical vendors and investigators associated with clinical trial management. Trial management costs increased year over year due to the higher number of patients enrolled in CHART-1 in 2014.

The employee expenses increase between 2013 and 2014 is due to an increase in the number of employees in our clinical and quality teams.

The increased number of patients in CHART-1 also explained the increase in consulting fees. Such fees are mainly comprised of fees paid to regulatory affairs and quality assurance consultants, and the outsourced quality control testing performed on incoming materials and in process-controls.

Clinical, quality and regulatory expenses are expected to grow in the near future with the initiation of CHART-2 and our Phase 1 clinical trial of CAR-NKG2D.

Other research and development expenses

For the year ended 31 December,

•	2014	2013
(€'000)		(as restated)
Employee expenses	954	898
Mayo research project	751	4
Pre-clinical studies	273	275
Delivery systems	51	459
Other costs	121	67
R&D consultant fees	13	29
Capitalization C-Cath _{ez} development costs	(50)	(459)
Subtotal	2,113	1,273
Depreciation and amortization	864	886
Total other research and development expenses	2,977	2,159

For 2014 and 2013, our other research and development expenses reflect costs incurred for research and development projects related to C-Cure, including the salaries of scientists and technicians, our laboratory supplies, depreciation of the Mayo License and the costs of the outsourced research and development services.

In 2014, pre-clinical research and development expenses increased by €0.8 million as compared to 2013 primarily related to direct research that we funded at the Mayo Clinic for €0.7 million. Under the Mayo License, we participate in a three year direct research program. Payments are triggered by initiation of research programs agreed upon by us and Mayo Clinic. This ongoing research was limited in 2013 and was reactivated in 2014.

As a result of our acquisition of Oncyte and CAR T-cell technology, pre-clinical research and development expenses are expected to increase significantly in future periods.

General and Administrative

	For the year ended 31 Dece		
(£'000)	2014	2013	
(€'000)		(as restated)	
Employee expenses	1,408	910	
Share-based payment	1,528	1,258	
Rent	315	323	
Communication & Marketing	394	206	
Consulting fees	741	975	
Travel & Living	399	147	
Post employment benefits	28	_	
Other	203	153	
Total General and administration	5,016	3,972	

General and administrative expenses increased by €1.0 million in 2014 as compared in 2013 primarily related to our recruitment of additional employees to strengthen our executive management team and other support functions such as finance, accounting and investor relations. In addition, there was an increase in our share-based payments in 2014 as compared to 2013, as a result of warrants granted to new employees, members of our executive management team and directors under our May 2014 warrant plan.

Consulting fees are composed of legal, audit, human resources and other fees. The decrease in consulting fees in 2014 as compared to 2013 is due to fees related to the Euronext IPO in 2013.

Other operating income

	For the year ended 31 December,		
	2014	2013	
(€'000)		(as restated)	
Recoverable cash advances (RCA)	2,791	955	
Subsidies	636	129	
Recognition of provision for reimbursement RCA	_	(1,020)	
Reversal of provision for reimbursement RCA	507	_	
Realized gain on contribution of IP into joint venture	312	_	
Other movements	167	_	
Total Other Operating Income	4,413	64	

Other operating income increased by €4.3 million in 2014 as compared to 2013.

The increase in other operating income in 2014 compared to 2013 is mainly due to the receipt of funds from RCA contracts and subsidies. We received funding and notification of funding from RCAs amounting to €2.8 million in 2014, mainly related to RCAs for the use of C-Cath_{ez} as an investigational device in the United States and additional preclinical studies of C-Cure, compared to €1.0 million in 2013. We also received subsidies and grants from the Walloon Region for a total of €0.6 million in 2014 compared to €0.1 million in 2013. Such subsidies and grants support our research and development projects.

During the year ended 31 December 2014, we abandoned one RCA program previously recognized as a liability, resulting in a reversal of a provision of €0.5 million.

In 2013, we elected to exploit an RCA, triggering the recognition of a €1.0 million liability.

In 2014, we recorded another liability for €0.2 million reflecting amounts to reimburse the Walloon Region under grant contract 6305, corresponding to the amount received but not expensed by us at the time of entry into the grant agreement.

We expect to receive the remainder of the existing cash advance agreements outstanding as of 31 December 2014, of approximately €1.7 million in 2015 and 2016. We also plan to submit further applications for additional Walloon Region non-dilutive funding in 2015 and thereafter to partially finance new research and development programs.

In 2015, we will decide whether to exploit one of our RCAs, triggering a potential recognition of an additional liability of €2.5 million.

Operating loss

As a result of the foregoing, our operating loss increased by €3.5 million in 2014 as compared to 2013, totaling €16.4 million in 2014.

Financial income and Financial expenses

	For the year ended 31 December,	
	2014	2013
(€'000)		(as restated)
Interest shareholders convertibles loans	_	401
Interest finance leases	6	6
Interest on overdrafts and other finance costs	16	19
Fair value convertible loans	_	1,158
Exchange differences	19	11
Finance expenses	41	1,595
Interest income bank account	277	47
Exchange differences	_	12
Other	_	1
Finance income	277	60

Financial expenses represent interest paid, bank charges and the fair value of convertible loans. Most of the financial expenses in 2013 related to shareholder convertible loans. An expense of €1.2 million was posted on such loans to reflect their fair value at the time of their conversion in May 2013.

Interest income on short term deposits increased significantly from 2013 to 2014, reflecting the increase of our average cash position over the periods, primarily resulting from the Euronext IPO.

Income tax expense

As we incurred losses in all of the relevant periods, we had no taxable income and therefore incurred no corporate taxes.

Loss for the year

As a result of the foregoing, our loss for the year increased by €2.0 million from €14.5 million in 2013 to €16.5 million in 2014.

11.3 Operating Capital Requirements

We believe that the net proceeds of the U.S. initial public offering, together with our existing cash and cash equivalents, and short term investments will enable us to fund our operating expenses and capital expenditure requirements, based on the current scope of our activities, until at least the end of 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. In any event, we will require additional capital to pursue pre-clinical and clinical activities, obtain regulatory approval for, and to commercialize our drug product candidates.

Until we can generate a sufficient amount of revenue from our drug product candidates, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, government, including RCAs and subsidies, or other third-party financings and collaborations. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our drug product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and these securities may have rights senior to those of our ordinary shares. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our present and future funding requirements will depend on many factors, including, among other things:

- the size, progress, timing and completion of our clinical trials for any current or future drug product candidates, including C-Cure and CAR-NKG2D;
- the number of potential new drug product candidates we identify and decide to develop;
- the costs involved in filing patent applications, maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the time and costs involved in obtaining regulatory approval for drug products and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these drug products;
- selling and marketing activities undertaken in connection with the anticipated commercialization of C-Cure and any other current or future drug product candidates and costs involved in the creation of a sales and marketing organization; and
- the amount of revenue, if any, we may derive either directly or in the form of royalty payments from future potential partnership agreements on our technology platforms.

For more information as to the risks associated with our future funding needs, see the section of this prospectus entitled "RISK FACTORS ."

11.4 Liquidity and capital resources

Our liquidity requirements primarily relate to the funding of manufacturing expenses, clinical quality and regulatory expenses, research and development expenses, general and administrative expenses, capital expenditures, repayments of finance leases and working capital requirements.

We monitor our risk to a shortage of funds using a recurring liquidity planning tool. Our objective is to maintain a balance between continuity of funding and flexibility through the use of bank deposits and finance leases.

Since May 2012, we have expensed all our clinical and research and development costs with the exception of the development costs for C-Cath_{ez}, which were capitalized following our receipt of the CE mark for C-Cath_{ez}.

As of December 2014, we have funded our operations through several private investments for a total of €42.0 million, the Euronext IPO which resulted in proceeds of €26.5 million, and a private placement of €25.0 million conducted in June 2014. We also received non-dilutive funding from governmental bodies and received cash proceeds from subsidies and RCAs totaling €18.7 million.

As of 31 December 2014, we had cash and cash equivalents of €27.6 million and short term investments of €2.7 million. Our cash and cash equivalents have been deposited primarily in savings and deposit accounts that have original maturities of three months or less and generate only minimal interest income.

On 21 January 2015, we purchased of OnCyte, for an upfront payment of \$10.0 million, of which \$6.0 million was paid in cash and \$4.0 million was paid in the form of 93,087 our ordinary shares. Additional contingent payments with an estimated fair value of \$42.0 million are payable upon the attainment of various clinical and sales milestones.

We are exposed to liabilities and contingent liabilities as a result of the RCAs we have received from the Walloon Region. Out of the RCAs contracted as of 31 December 2014, €17.0 million has been effectively paid out.

In 2015 and 2016, we will have to make an exploitation decision on the remaining RCAs with a potential recognition of an additional liability of €3.5 million based on the advances effectively paid out as of 31 December 2014.

Please see our consolidated financial statements included elsewhere in this prospectus for an analysis of our non-derivative financial liabilities into relevant maturity groupings based on the remaining period at the balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

The following table sets forth our consolidated cash flows information for the years ended 31 December 2014 and 2013.

	Year ended 31 December,	
	2014	2013
(€'000)		(as restated)
Net cash used in operations	(17,414)	(10,638)
Net cash used in investing activities	(1,768)	(3,532)
Net cash from financing activities	27,757	31,583
Net increase in cash and cash equivalents	8,575	17,413

Cash flow from operating activities represented at year end 2014 a net cash outflow of €17.4 million. Compared to the period ended 31 December 2013, the net cash outflow from operating activities increased by €6.8 million. This increase primarily resulted from the initiation of CHART-1 in the middle of 2013, which significantly increased our expenditures for our manufacturing and clinical operations by €2.7 million and €3.3 million, respectively.

Cash flow from investing activities represented a net cash outflow amounting to €1.8 million in 2014 mainly due to the acquisition of CorQuest for a cash payment of €1.5 million. In 2013, most of the cash outflow from investing activities resulted from a €3.0 million investment in a three-year short term deposit account.

Cash flow from financing activities represented a net cash inflow of €27.8 million in 2014 compared to €31.6 million in 2013. In 2014, the proceeds we received from our issuance of our shares were less than in 2013, €25.3 million compared to €30.6 million, respectively, whereas the proceeds received from RCAs and subsidies from the Walloon Region increased in 2014 compared to 2013, €2.4 million compared to €1.1 million, respectively.

11.5 Cash and Funding Sources

During 2013 and 2014, we obtained new financing mostly through the issuance of our shares. A summary of our financing activities during 2014 and 2013 is as follows:

		Equity	Finance	
(€'000)	Total	capital	leases	Other debt
2013	31,643	30,623	_	1,020
2014	25,749	25,305	444	_
Total Financing	57,392	55,928	444	1,020

In March 2015, we completed a €31.7 million capital increase via a private placement subscribed by qualified institutional investors in the United States and Europe at a price of €44.50 per share. The net proceeds, after deduction of the placement fees amounted to €29.8 million.

During 2014, our capital was increased in June 2014 by way of a capital increase of €25.0 million, represented by 568,180 new shares. Our capital was also increased by way of exercise of warrants. Over four different exercise periods, 139,415 warrants were exercised resulting in the issuance of 139,415 new shares. Our capital and share

premium were therefore increased respectively by 0.5 million each. Also, we financed part of our capital expenditures with a bank lease of 0.4 million.

Over the course of 2013, we conducted a private placement of $\[\in \]$ 7.0 million in May 2013 and closed our Euronext IPO in July 2013 for proceeds of $\[\in \]$ 26.5 million. Net proceeds from these capital increases amounted to $\[\in \]$ 30.6 million. We also recognized a new cash advance of $\[\in \]$ 1.0 million from a RCA from the Walloon Region as we decided to exploit a RCA related to C-Cath_{ez} development.

Since inception, we have not incurred any bank debt. Some of our capital expenditures related to laboratory and office equipment are financed with 3-year maturity finance leases.

In 2013, we decided to exploit the results associated with an RCA related to C-Cath_{ez} and therefore recognized a €1.0 million debt.

Amounts due to the Walloon Region, booked as advances repayable, at the end of 2014 correspond to funding received under several RCAs, dedicated to supporting specific development programs related to C-Cure and C-Cath_{ez}.

The movements of the advances repayable recorded in 2014 and 2013 are summarized in the table below:

(€'000)	
Balance of 1 January 2013	11,842
+ liability recognition	+1,020
-repayments	-211
+/- other transactions	-150
Balance at 31 December 2013	12,501
Balance of 1 January 2014	12,501
+ liability recognition	_
-repayments	-272
+/- other transactions	-674
Balance at 31 December 2014	11,555
—	

11.6 Contractual Obligations and Commitments

The following table discloses aggregate information about material contractual obligations and periods in which payments were due as of -31 December 2014. Future events could cause actual payments to differ from these estimates.

(€'000)	Total	Less than one year	One to three years	Three to five years	More than five years
As of 31 December 2014					
Finance leases	413	134	245	34	_
Operating leases	1,683	751	679	88	165
Pension obligations	182	_	_	_	182
Advances repayable (current and non-current)	11,555	777	1,570	1,846	7,362
Total	13,833	1,662	2,494	1,968	7,709

On 21 January 2015, we acquired OnCyte from Celdara for an upfront payment of \$10.0 million, of which \$6.0 million was paid in cash and \$4.0 million was paid in the form of 93,087 our ordinary shares. Additional contingent payments with an estimated fair value of \$42.0 million are payable upon the attainment of various clinical and sales milestones. The liability for the estimated contingent consideration is not reflected in the consolidated statement of financial position as of 31 December 2014.

11.7 Capital Expenditures

We do not capitalize our research and development expenses until we receive marketing authorization for the applicable product candidate. As of end of 2014, all clinical, research and development expenditures related to the development of C-Cure and are accounted for as operating expenses.

Our capital expenditures were €0.6 million and €0.1 million for the years ended 31 December 2014 and 2013, respectively. There are no material capital projects planned in 2015. In addition, we completed the acquisition of CorQuest in November 2014, resulting in recognition of patent intangible assets of €1.5 million.

	As of 31 December,		
(€'000)	2014	2013	
		(as restated)	
Intangible assets	10,266	9,400	

As of		31 December,	
(€'000)	2014	2013	
		(as restated)	
Property, plant and equipment	598	243	
Other long term financial assets	109	140	
Total	10,973	9,783	

11.8 Off-Balance Sheet Arrangements

As of the date of this prospectus and also for the periods presented, we did not have any off-balance sheet arrangements.

11.9 Critical accounting estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited financial statements, which we have prepared in accordance with IFRS as issued by the IASB. The preparation of our financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities and the disclosure of contingent liabilities, at the end of the reporting period.

Our significant accounting policies are more fully described in Note 2.2 to our consolidated financial statements appearing elsewhere in this prospectus. We have identified these policies as critical to understanding and evaluating the estimates and judgments important to the presentation of our financial condition and results of operations and require us to make judgments and estimates on matters that are inherently uncertain and may change in future periods.

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that we believe are reasonable under the circumstances. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods.

In the process of applying our accounting policies, management has made judgments and has used estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are addressed below.

Advances received from the Walloon Region: recognition of a liability

The advances received only become contingently reimbursable if certain conditions are met. Assessing if these conditions are met (or not) can only reasonably be performed at the end of the research phase. At the end of this research phase, we should, within a period of six months, decide whether or not to exploit the results of the research programs. In the event we decide to exploit the results under a RCA, the relevant RCA becomes contingently refundable to the Walloon Region and we apply the recognition and measurement criteria of IAS 37 related to liability recognition, with any amounts being recognized as a reduction of other operating income in our statement of comprehensive income (loss).

The total estimated amount to be reimbursed includes the sales-independent reimbursements as well as the sales-dependent reimbursements and interest (if applicable) if the reimbursement of these amounts is probable. The contingent liability is discounted using a discount rate made up of two components: a risk free rate reflecting the maturity of the advances repayable and the spread reflecting our credit risk.

At the time of a liability recognition, an estimate is made of the amount to be reimbursed including the sales-independent reimbursements (an annual lump-sum), the sales-dependent reimbursements and the interest to be paid. These estimated future (outgoing) cash flows are discounted as the liability is a long-term liability.

When a liability is recognized, significant estimates are required to determine the discount rate used to calculate the present value of those liabilities as well as the determination of the estimated cash flow relating to the exploitation. The estimates triggering the discount rate are the assessment of own credit risk as well as the risk profile of the financial instruments. At the end of 2014, we estimated the total liabilities using a discount rate of 12.5%.

After initial recognition this liability is measured at amortized cost using the effective interest method. An interest expense is recognized based on the discount rate used.

Each year, we reassess the amounts to be reimbursed based upon (i) progress made in the pre-clinical and clinical development of all projects partially financed by RCAs and, (ii) on the updated sales projections over the reimbursement period.

In 2014 no new advances were recognized as contingently repayable.

In 2014, we notified the Walloon Region of our decision to not exploit the outcome of two RCAs related to the industrialization of the C-Cure production process in bioreactors, resulting in a decrease of estimated amounts to be reimbursed of €0.5 million.

Share-based payment transactions

We have established share-based compensation plans as an incentive for our employees, members of our executive management team and independent directors, as well as certain consultants and advisors. Warrants are granted by the board of directors in accordance with authorizations given by our shareholders. Warrant grants are based on the merits of the individual grantee and no employee is entitled to receive warrants simply by virtue of being employed.

Under the terms of our warrant programs, warrants are granted at an exercise price equal to the market price as determined by our board of directors on the grant date. The vesting of warrants is generally conditioned on the grantee completing a period of service. Each warrant grant vests in installments after the date of grant, subject to continued service of the grantee. Warrant exercises are settled with the delivery of shares.

For all plans issued before July 2013, warrants were granted at an exercise price equal to share price used at the occasion of the last capital increase as determined by the board of directors on the grant date. Before becoming a public company, we issued warrants in 2008, 2010 and 2013.

In May 2013 and May 2014, respectively, we issued 266,641 and 100,000 warrants to our employees, members of our executive management team and directors. Out of the warrants issued, 302,150 were granted and 282,750 were outstanding as of 31 December 2014.

We measure the cost of these equity-settled transactions by reference to the fair value of the equity instruments at the date on which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them.

The variables, used in this model are:

Fair Value of Our Ordinary Shares: In connection with our listing on Euronext Brussels and Euronext Paris in July 2013, we established a policy to determine the fair value of our warrants. Pursuant to Belgian law, the exercise price of warrants is established at the lower of a) the 30 days average closing stock price and b) the closing stock price for the day preceding the issuance of warrants. Prior to our listing on Euronext Brussels and Euronext Paris, the fair value of the respective warrant plans was determined as the price paid for our shares during the last private financing round. For the warrants issued in May 2013, because of the proximity to our Euronext IPO, the warrants were valued using price as which our ordinary shares were sold in the Euronext IPO.

Expected Term: The expected term represents the period that the share-based awards are expected to be outstanding. As we do not have sufficient historical experience for determining the expected term of the share-based awards granted, we have based the expected term on the simplified method, which represents the period from the grant of the award to the expiration of the award.

Expected Volatility: We are using the volatility of our share price on Euronext Brussels and Euronext Paris observed since the Euronext IPO. Prior to the Euronext IPO, we used the volatility of our peers.

Risk-Free Interest Rate: The risk-free interest rate is based on the yields of Belgian government bonds with maturities similar to the expected term of the warrants for each warrant group.

Dividend Yield: We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

For the purpose of estimating the fair value per share of the warrants, we believe the expected volatility and the estimated fair value per underlying share are the most critical assumptions. Changes in these assumptions could significantly affect the fair value of warrants and, as a result, the amount of share-based compensation that we recognize in our consolidated financial statements. If any of the assumptions used in the Black-Scholes option-pricing model changes significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

The fair value of warrants granted to the participants is recorded as an expense against a credit in equity. The total amount to be expensed is determined by reference to the fair value, using the Black-Scholes option-pricing model, of the warrants at the time of grant. For allocation of the share-based compensation expenses to be recorded, we treat each installment of a graded vesting award as a separate grant.

The following table presents the weighted-average assumptions used to estimate the fair value of warrants granted during the periods presented:

	As of 31 December,		
	2014	2013	
Expected dividend yield	_	_	
Expected share value volatility	68%	36% - 40%	
Risk-free interest rate	1%	2%	
Expected life (in years)	10	10	

For 2014 and 2013, the share-based compensation expenses recorded in our income statement amounted to €1.5 million and €1.3 million, respectively.

Consolidation

We periodically undertake transactions that may involve obtaining control, joint control or significant influence of other companies. These transactions include equity acquisitions and asset purchases. In all such cases management makes an assessment as to whether we have control, joint control or significant influence of the other company, and whether such company should be consolidated as a subsidiary or accounted for as a joint venture or as an associated company. In making this assessment management considers the underlying economic substance of the transaction in addition to the contractual terms.

At year end 2014, an assessment was completed to decide if we had obtained control or joint control of Cardio3 Biosciences Asia. Our subscription and joint venture agreement with Medisun stipulates that:

- We acquired 40% of the share capital of Cardio3 BioSciences Asia in return for an outlicense for the development of C-Cure in Greater China.
- Medisun acquired 60% of the shares of Cardio3 Biosciences Asia for HK\$ 5 million. Medisun will make additional cash contributions for additional shares over the next three years to fund research.
- The agreement stipulates that unanimous consent is required from both parties to the agreements over relevant activities, for example approving budgets and business plans, declaring dividends, borrowing money, applying for registration of intellectual property, etc.
- Our arrangement is structured as a limited company and provides us and the parties to the agreements with rights to the net assets of the limited company under the arrangements.

Based on the above, we have assessed there is joint control and that Cardio3 Biosciences Asia is a joint venture.

Business combinations

In respect of acquired businesses by us, significant judgment is made to determine whether these acquisitions are to be considered as an asset deal or as a business combination. Determining whether a particular set of assets and activities is a business should be based on whether the integrated set is capable of being conducted and managed as a business by a market participant. Moreover, management judgment is particularly involved in the recognition and fair value measurement of the acquired assets, liabilities, contingent liabilities and contingent consideration. In making this assessment management considers the underlying economic substance of the items concerned in addition to the contractual terms.

Contingent consideration provisions

We make provision for the estimated fair value of contingent consideration arrangements arising from business combinations. The estimated amounts are the expected payments, determined by considering the possible scenarios of forecast sales and other performance criteria, the amount to be paid under each scenario, and the probability of each scenario, which is then discounted to a net present value. The estimates could change substantially over time as new facts emerge and each scenario develops.

Deferred Tax Assets

Deferred tax assets for unused tax losses are recognised to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgment is required to determine the

amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits together with future tax planning strategies.

Once we will obtain market approval for C-Cure, or another drug product candidate, and when we will have more certainty on the generation of taxable income, we will recognize deferred tax assets accordingly.

11.10 Quantitative and Qualitative Disclosures about Market Risk

We are exposed to a variety of financial risks: market risk (including foreign exchange risk and interest rate risk), credit risk and liquidity risk. Our overall risk management program focuses on preservation of capital given the unpredictability of financial markets.

Foreign exchange risk

We are exposed to foreign exchange risk as certain collaborations or supply agreements of raw materials are denominated in USD. Moreover we have also investments in foreign operations, whose net assets are exposed to foreign currency translation risk (USD). So far, because of the materiality of the exposure, we did not enter into any currency hedging arrangements. No sensitivity has been performed on the foreign exchange risk as up till now we still consider this risk as immaterial.

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the USD. Our functional currency is the Euro, but we have several of our product suppliers and clinical vendors invoicing U.S. in USD or in other currencies. In addition, we plan to convert a substantial portion of the proceeds from this offering to Euro.

We have not established any formal practice to manage the foreign exchange risk against our functional currency. As of 31 December 2014, we had no trade receivables denominated in USD and had trade payables denominated in USD of \$0.9 million.

Foreign exchange rate movements had no material effect on our results for the years ended 31 December 2014 and 2013. Because of our growing activities in the United States, the foreign exchange risk may increase in the future.

Liquidity risk

Based on our current operating plans, we believe that the anticipated net proceeds of this offering, together with our existing cash and cash equivalents and short term investments, will be sufficient to fund our operations through at least the end of 2017.

11.11 Internal Control Over Financial Reporting

We have determined the existence of three material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, such that there is a reasonable possibility that a material misstatement of our annual consolidated financial statements will not be prevented or detected on a timely basis by our employees. The material weakness identified were a lack of knowledge of:

- accounting resources required to fulfill the reporting requirements of International Financial Reporting Standards, or IFRS, and financial reporting requirements;
- comprehensive IFRS accounting policies and financial reporting procedures; and
- segregation of duties given the size of our finance and accounting team.

As described in Note 2.36 of our consolidated financial statements referred to in this prospectus, we have restated our consolidated financial statements as of and for the year ended 31 December 2013 as a result of errors in the accounting treatment of shareholders convertible loans and share-based payments. We believe that the material weaknesses identified contributed to the restatements.

We have not yet undertaken and our independent registered public accounting firm has not yet conducted a comprehensive assessment of our internal control over financial reporting for purposes of identifying and reporting material weaknesses, significant deficiencies and control deficiencies in our internal control over financial reporting. We anticipate being first required to issue management's annual report on internal control over financial reporting, pursuant to Section 404 of the Sarbanes-Oxley Act, in connection with issuing our consolidated financial statements as of and for the year ending 31 December 2016.

We believe it is possible that, if we had performed a formal assessment of our internal control over financial reporting, or if our independent registered public accounting firm had performed an audit of our internal control over financial reporting, other material weaknesses, significant deficiencies or control deficiencies may have been identified.

We have taken several remedial actions to address the material weaknesses identified. In particular, we have hired additional staff for the finance department, including a corporate controller, and we are planning to hire a compliance financial officer with experience with external financial reporting, IFRS and establishing appropriate financial reporting policies, controls and procedures.

The process of designing and implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments, as well as to expend significant resources to maintain a financial reporting system that is adequate to satisfy our reporting obligations. See "RISK FACTORS - Risks Related to Our Business Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies."

12 UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On 21 January 2015, we acquired the outstanding membership interests in Oncyte LLC ("Oncyte") the oncology division of Celdara Medical, LLC ("Celdara"), a privately-held biotechnology company based in Lebanon, New Hampshire, USA. The acquisition establishes our entry into the field of immuno-oncology with a portfolio of drug product candidates including three autologous CAR T-Cell cell therapy products and an allogeneic T-cell platform, targeting a broad range of cancer indications. Pursuant to the terms of the Stock Purchase Agreement and the Asset Purchase Agreement, we made a cash payment of \$6.0 million at closing and issued new shares to Celdara with a value of \$4.0 million. Additional contingent payments with an estimated fair value of \$42.0 million may be due upon reaching various clinical and sales milestones. We financed the acquisition with existing cash and authorized share capital.

The unaudited pro forma condensed combined financial information gives effect to the acquisition as if it had been completed on 1 January 2014 for purposes of the statement of operations and 31 December 2014 for purposes of the statement of financial position. The historical consolidated financial information of us and Oncyte has been adjusted in the unaudited pro forma condensed combined financial information to give effect to events that are (1) directly attributable to the acquisition, (2) factually supportable, and (3) with respect to the statements of operations, expected to have a continuing impact on the combined results. The unaudited pro forma adjustments are based upon currently available information and assumptions that we believe to be reasonable. The pro forma adjustments and related assumptions are described in the notes accompanying the unaudited pro forma condensed combined financial information.

The pro forma financial information and adjustments are preliminary and have been made solely for purposes of providing these unaudited pro forma condensed combined statements of operations and balance sheet. Differences between these preliminary estimates and the final acquisition accounting may occur and these differences could have a material impact on the pro forma financial information presented and the combined company's future results of operations and financial position. The actual results reported in future periods may differ significantly from that reflected in these pro forma financial information for a number of reasons, including but not limited to differences between the assumptions used to prepare this pro forma financial statements and actual amounts, as well as cost savings from operating and expense efficiencies and potential income enhancements.

The unaudited pro forma condensed combined statement of operations does not reflect any prospective income enhancements or operating synergies that the combined company may achieve as a result of the acquisition or the costs to integrate the operations or the costs necessary to achieve these income enhancements and operating synergies. In addition, the unaudited pro forma condensed combined statements of operations do not give effect to the consummation of this offering. As a result, the pro forma information does not purport to be indicative of what the financial condition or results of operations would have been had the transactions been completed on the applicable dates of this pro forma financial information. The unaudited pro forma condensed combined statements of operations and balance sheet are for informational purposes only and do not purport to project the future financial condition and results of operations after giving effect to the transactions.

The following unaudited pro forma condensed financial information is derived from our audited historical consolidated financial statements as of and for the year-ended 31 December 2014 prepared in accordance with IFRS as issued by the IASB and the audited financial statements of the OnCyte Clinical Trials Program as of and for the year-ended 31 December 2014 prepared in accordance with accounting principles generally accepted in the United States of America, or US GAAP, each included elsewhere in this prospectus. You should read this unaudited pro forma condensed combined financial information in conjunction with the accompanying notes, the audited financial statements of the Company and Oncyte referred to above, as well as with "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS", included elsewhere in this prospectus.

Statement of Financial Position	Celyad SA	Oncyte			Proforma combined
				Pro Forma	
	As of 31	As of 31	Reclassification	Adjustment	As of 31
(€'000)	December 2014	December 2014	(Note 2)	(Note 4)	December 2014
NON-CURRENT ASSETS	11,041	83	_	44,817	55,941
Intangible assets	10,266	61	_	44,839(a)(b)	55,166
Property, Plant and Equipment	598	22		(22)(b)	598
Investment accounted for using the equity					
method	68	_		_	68
Other non-current assets	109	_		_	109
CURRENT ASSETS	32,935	145	_	(5,326)	27,754

Statement of Financial Position	Celyad SA	Oncyte			Proforma combined
	·	•		Pro Forma	
	As of 31	As of 31	Reclassification	Adjustment	As of 31
(€'000)	December 2014	December 2014	(Note 2)	(Note 4)	December 2014
Trade and Other Receivables	830	141		(141)(b)	830
Grant receivables	1,009	_			1,009
Other current assets	792	4		(4)(b)	792
Short-term investment	2,671	_			2,671
Cash and cash equivalents	27,633	_		(5,181)(c)	22,452
TOTAL ASSETS	43,976	228	_	39,491	83,695
EQUITY	26,684	20	_	3,431	30,135
Share Capital	24,615	208	_	117(b)(d)	24,940
Share premium	53,302	_		3,126(d)	56,428
Other reserves	19,982	(16)		16(b)	19,982
Retained loss	(71,215)	(172)		172(b)	(71,215)
NON-CURRENT LIABILITIES	11,239	24		36,244	47,507
Financial leases	279	_		_	279
Advances repayable	10,778	_		_	10,778
Other non-current liabilities	182	24		(24)(b)	182
Contingent liabilities	_	_		36,268(e)	36,268
CURRENT LIABILITIES	6,053	184	_	(184)	6,053
Financial leases	134	_		_	134
Advances repayable	777	_		_	777
Trade payables	4,042	_		_	4,042
Other current liabilities	1,100	184		(184)(b)	1,100
TOTAL EQUITY AND LIABILITIES	43,976	228	_	39,491	83,695

IFRS Statement of operations	Celvad SA	Oncyte			Proforma combined
	For the year	For the year		Pro Forma	For the year
	ended 31	ended 31	Reclassification	Adjustment	ended 31
(€'000)	December 2014	December 2014	(Note 2)	(Note 4)	December 2014
Revenue	146	_	_	_	146
Grant income	_	756	(756)	_	_
Cost of sales	(115)				(115)
Gross profit	31				31
Costs of Operations	_	(928)	928	_	_
Research and Development	(15,865)	` _ ´	(928)		(16,793)
General and administrative	(5,016)	_	_	_	(5,016)
Other operating income	4,413	_	756	_	5,169
Operating Loss	(16,437)	(172)			(16,609)
Financial (income)	277	_	_	_	277
Financial expenses	(41)	_	_	_	(41)
Share of Loss of investment accounted for					
using the equity method	(252)				(252)
Loss before taxes	(16,453)	(172)	_		(16,625)
Income taxes		_		_	
Loss for the year	(16,453)	(172)	_		(16,625)
Basic and diluted loss per share (in €)	(2.44)				(2.43)

Oncyte LLC-Notes to Unaudited Pro Forma Condensed Combined Financial Information

Note 1: Basis of preparation

The acquisition is accounted for in accordance with the acquisition method of accounting for business combinations with Celyad SA as the acquiring entity. The unaudited pro forma condensed combined financial information is based on the historical consolidated financial statements of the Celyad SA and Oncyte after giving effect to the consideration paid by Celyad SA to consummate the acquisition, as well as pro forma adjustments as described in Note 4. In accordance with the acquisition method of accounting for business combinations, tangible and intangible assets acquired and liabilities assumed are required to be recorded at their respective fair market values as of the date of the acquisition, with any excess purchase price allocated to goodwill.

The unaudited pro forma condensed combined statement of operations for the twelve months ended 31 December 2014 is presented as if the acquisition had occurred on 1 January 2014. The unaudited pro forma condensed combined statement of financial position is presented as if the acquisition had occurred on 31 December 2014.

The fair values assigned to the intangible assets acquired from Oncyte are based on management's estimates and assumptions with the assistance of an independent valuation specialist. The estimated fair values of these assets acquired are considered preliminary. We believe that the information provides a reasonable basis for estimating the fair values of assets acquired; however, the provisional measurements of fair value are subject to change. We expect to finalize the valuation of the intangible assets as soon as practicable, but not later than one-year from the acquisition date.

The Oncyte' balance sheet positions initially expressed in USD have been translated in EUR by using the closing EUR/USD exchange rate as at 31 December 2014 (1EUR = 1.21548USD); whereas the Oncyte' statement of operations positions initially expressed in USD have been translated in EUR by using the average EUR/USD exchange rate over the year 2014 (1EUR = 1.32947USD).

Under the acquisition method, acquisition-related transaction costs (e.g. advisory, legal, valuation and other professional fees) are not included as consideration transferred but are accounted for as expenses in the periods in which the costs are incurred. These costs are not presented in the unaudited pro forma combined consolidated statements of operations because they will not have a continuing impact on the combined results. Total acquisition-related transaction costs of the combined company were immaterial.

Note 2. Accounting Policies

The historical financial information extracted from the financial statements of Oncyte is prepared in accordance with U.S. GAAP. For the purpose of presenting the historical information of Oncyte in a reporting format that is consistent with that of the Company, certain components of Oncyte's statement of operations and comprehensive income have been reclassified. The following reclassifications have been made in the unaudited proforma combined statement of operations for the year ended 31 December 2014:

Amounts historically included in Grant income on Oncyte's statements of operations and comprehensive income (loss) have been reclassified to Other operating income in order to conform with our financial statement presentation. Amounts historically included in Cost of Operations on Oncyte's statements of operations and comprehensive income (loss) have been reclassified to Research and Development in order to conform with our financial statement presentation. The unaudited pro forma condensed combined financial information does not assume any differences in accounting policies. We believe there are no differences between US GAAP and IFRS as issued by the IASB that would have a material impact on the unaudited pro forma condensed combined financial information.

Note 3. Calculation of Estimated Consideration Transferred and Preliminary Allocation of Consideration to Net Assets Acquired

The following table summarizes the preliminary reconciliation of upfront payment in accordance to the Share Purchase Agreement and the total purchase price:

Cash consideration according to the Share Purchase Agreement	\$ 6.0 million	€ 5.2 million
Issuance of ordinary shares of the Group according to the Share		
Purchase Agreement	\$ 4.0 million	€ 3.4 million
Premiliminary estimate of fair value of contingent consideration	\$42.0 million	€36.3 million
Total Purchase Price	\$52.0 million	€44.9 million

^[1] Converted using the following exchange rate as of 21 January 2015: 1EUR = 1

The value of the 93,087 ordinary shares issued as part of the consideration paid for Oncyte was based on a share price of €37.08, our share price at the date of the acquisition.

The preliminary fair value estimate of contingent consideration of \$42.0 million (€36.3 million) relates to the achievement of certain regulatory and sales milestones and are based on the contractual terms defined in the Share Purchase Agreement. The preliminary fair value estimate of contingent consideration was obtained using several discount rates and probability rates of success over the different products candidates acquired and is subject to change.

Following the terms of the Share Purchase Agreement, assuming successful development of the lead product CAR-NKG2D, Celdara could receive up to \$45.0 million in development and regulatory milestones until market approval. Celdara will also be eligible to additional payments on the other products in development upon achievement of development and regulatory milestones totaling up to \$21.0 million per product. In addition, the seller will receive per product up to \$80.0 million in sales milestones when total net sales will exceed \$1 billion and royalties ranging from 5% to 8% on net sales.

The transaction was accounted for as a business combination under the acquisition method of accounting.

For purposes of these unaudited pro forma condensed financial statements, the above consideration transferred will be assigned to the fair value of acquired assets and is based on preliminary estimates and is subject to change. The following table summarizes the estimated fair values of the assets acquired as if the transaction occurred on 31 December 2014:

In process research and development	\$52.0 million	€44.9 million
Assets acquired	\$52.0 million	€44.9 million
Liabilities assumed	_	
Net assets acquired	\$52.0 million	€44.9 million

^[1] Converted using the following exchange rate as of 21 January 2015: 1EUR = 1.15806USD

No deferred tax liability has been recorded on the fair value of the intangible assets acquired. We intend to make an election to treat the share acquisition as the acquisition of assets for U.S. federal income tax purposes resulting in tax deductible amortization of the intangible assets acquired.

The fair value of the acquired assets and liabilities assumed was determined on a provisional basis. The provisional fair value of acquired assets and liabilities assumed can change when the final fair value of the acquired assets and liabilities assumed is established.

Note 4. Pro Forma Adjustments

- a) To consider the estimated fair value of the intangible asset of Oncyte. The acquired assets have been recognized at an estimated fair value determined by us with the assistance of an independent valuation specialist in an amount of €44.9 million—\$52.0 million translated by using the closing EUR/USD exchange rate as at 21 January 2015 (1EUR = 1.15806USD).
- b) The Oncyte business has been acquired through a special purpose vehicle especially created for this transaction which only the intangible assets related to the CAR-T-cell technology have been transferred in. We have not acquired the underlying property, plant and equipment, working capital and long term liabilities of the Oncyte business. The historical figures reflected in the unaudited condensed consolidated statement of financial position is a carve-out of the financial statements of the Sellers' activities related to CAR T-cell technology as at 31 December 2014 including all the assets and liabilities. Consequently, the elements not related to the intangible assets have been eliminated in the pro forma combined financial information.
- c) To record the use of cash and cash equivalents to fund the cash consideration paid according the Share Purchase Agreement amounting to €5.2 million—\$6.0 million translated by using historical exchange rate (1 EUR = 1.15806USD) as at the acquisition date (21 January 2015).
- d) To record the issuance of our new shares for a total value of ≤ 3.4 million—\$4.0 million translated by using historical exchange rate (1 EUR = 1.15806USD) as at the acquisition date (21 January 2015), split between the share capital (≤ 0.3 million) and the share premium (≤ 3.1 million).
- e) To reflect the preliminary fair value estimate of the contingent consideration: €36.3 million—\$42.0 million translated by using the closing EUR/USD exchange rate as at 21 January 2015 (1EUR = 1.15806USD).

13 BUSINESS

13.1 Overview

We consider we are a leader in engineered cell therapy treatments with clinical programs initially targeting indications in cardiovascular disease and oncology. Our lead drug product candidate in cardiovascular disease is C-Cure, an autologous cell therapy for the treatment of patients with ischemic heart failure, or HF. We completed enrollment in our first Phase 3 clinical trial of C-Cure in Europe and Israel, or CHART-1, in March 2015. On 30 March 2015, we announced that the Data Safety Monitoring Board, or DSMB, reviewed unblinded safety data from CHART-1 and determined that there was no evidence of obvious differences in safety profiles of patients in the two arms of the trial, which means that the data did not support discontinuation of the trial on the basis of safety. The full data readout from this trial is expected in the middle of 2016. We anticipate initiating our second Phase 3 clinical trial of C-Cure in the United States and Europe, or CHART-2, pending U.S. Food and Drug Administration, or FDA, clearance to initiate the trial, which we expect in the second half of 2015. Our lead drug product candidate in oncology is CAR-NKG2D, an autologous chimeric antigen receptor T lymphocyte, or CAR T-cell, therapy. We are currently enrolling patients with refractory or relapsed acute myeloid leukemia, or AML, or multiple myeloma, or MM, in a Phase 1 clinical trial of CAR-NKG2D in the United States. The first patient was treated in this trial in April 2014 and no treatment-related safety concerns were reported during the 30-day follow-up period. Interim data from this trial is expected to be reported at various times during the trial, with the full data readout expected in the middle of 2016.

All of our current drug product candidates are autologous cell therapy treatments. In autologous procedures, a patient's cells are harvested, selected, reprogrammed and expanded, and then infused back into the same patient. A benefit of autologous therapies is that autologous cells are not recognized as foreign by patients' immune systems. We believe that we are well situated to effectively advance autologous cell therapy treatments for cancer and other indications as a result of the expertise and know-how that we have acquired through our development of C-Cure. We also believe that there are numerous operational synergies between our product platforms, including that, prior to commercialization, our existing pilot manufacturing plant can accommodate both of our cell therapy programs without significant capital expenditure.

HF is a condition in which the heart is unable to pump enough blood to meet the body's metabolic needs, affects 1% to 2% of the adult population in developed countries and approximately 5.7 million patients were diagnosed with HF in the United States in 2012, according to the American Heart Association. HF can either be of ischemic origin linked to impairment of blood flow to the heart muscle, or non-ischemic origin, linked to other causes such as hypertension and metabolic disorders. In the Bromley heart failure study, 52% of the patients had HF of ischemic origin. Other studies and timing of when the study was completed. The long-term prognosis associated with HF is dire, with approximately 50% mortality at five years following initial diagnosis, according to a report from the American Heart Association. HF is classified according to the severity of the symptoms experienced by the patient. The classification most commonly, used in the New York Heart Association, or NYHA, classification, where patients are classified from Class I, where there is no limitation on a patient's physical activity to Class IV, where the patient is unable to carry on any physical activity without discomfort. Although existing therapies have been somewhat effective in the treatment of HF, there is still great unmet medical need. In particular, in the case of ischemic HF, which is caused by insufficient oxygen to the heart, current treatments fail to address the decrease in the number of functional myocytes, or heart cells, in the heart that result from this lack of oxygen. Over time this functional decrease modifies the dynamics of cardiac contractions leading to tissue remodeling and loss of cardiac function. We believe that cellular therapies have the potential to repair or replace the non-functioning myocytes of ischemic HF patients.

To guide cardiac tissue formation, our C-Cure therapy reprograms multipotent stem cells harvested from a patient into cardiopoietic cells, cells that can myocytes, using naturally occurring cytokines, small proteins that play an important role in celle signalling, and growth factors that mimic the signaling that occurs in embryonic heart tissue development. Based on pre-clinical studies, we have identified both direct and indirect possible modes of action for C-Cure. The direct mode may replace non-functioning myocytes. In the indirect modes, factors secreted by the cardiopoietic cells may cause patients' resident stem cells to begin pooling, regenerating and differentiating into cardiac cells, with the resulting favorable environment inducing the non-functioning myocytes to regain function. We have developed C-Cure predominantly on technology that we licensed from the Mayo Foundation for Medical Education and Research, or the Mayo Clinic. To assist in the reinjection of cardiopoietic cells, we have also developed C-Cath_{ez}, which we believe may be able to achieve a higher retention rate of cells in the heart relative to the commercial catheter we used in our prior clinical trial.

Positive outcomes were observed in ischemic HF patients treated with C-Cure in our Phase 2 clinical trial in Europe. Patients treated with C-Cure showed a 25% relative improvement of median left ventricular ejection fraction, or LVEF,

which is the percentage of blood that is pumped out of the heart at each beat, at six months versus baseline, whereas untreated patients showed a relative improvement of 0.7% versus baseline. Patients treated with C-Cure also demonstrated an improved exercise capacity as measured by the six minutes walking distance test, or six minutes WDT, which measures the distance a patient can walk in a six-minute period. The C-Cure treatment group's walking distance improved by 77 meters compared to the control group.

Cancer is the second leading cause of death in the United States after cardiovascular diseases, according to the U.S. Centers for Disease Control and Prevention. According to the American Cancer Society, in 2014, there were an estimated 1.6 million new cancer cases diagnosed and over 550,000 cancer deaths in the United States alone. In the past decades, the cornerstones of cancer therapies have been surgery, chemotherapy and radiation therapy. Since 2001, small molecules that specifically target cancer cells have emerged as standard treatments for a number of cancers. For example, Gleevec is marketed by Novartis AG for the treatment of leukemia, and Herceptin is marketed by Genentech, Inc. for the treatment of breast and gastric cancer. Although these targeted therapies have significantly improved the outcomes for certain patients with these cancers, there is still a high unmet need for the treatment of these and many other cancers.

While the immune system has a natural response to cancer, automatically recognizing and eliminating cancer cells, cancer cells can develop the ability to evade immune response, resulting in the formation of potentially dangerous cancerous tumors and blood cancers. CAR T-cell therapy is a new technology that broadly involves engineering patients' own T-cells to express CAR, so that these re-engineered cells recognize and kill cancer cells, overcoming cancer cells' ability to evade immune response. According to a January 2015 review article published in Immunological Reviews, several early clinical trials involving CAR T-cell therapies have suggested potentially high clinical responses in difficult to treat relapsed or refractory B lymphocyte, or B-cell, malignancies.

For example, results of a clinical trial reported in the New England Journal of Medicine in October 2014 demonstrated that CAR T-cell therapy that targets the CD19 antigen, or CD19 CAR Therapy, was effective in treating patients with relapsed and refractory acute lymphoblastic leukemia. Treatment was associated with a complete remission rate of 90% and sustained remissions of up to two years after treatment.

Our lead CAR T-cell drug product candidate is CAR-NKG2D, which has shown promising data in pre-clinical solid and blood cancer models, including for the treatment of lymphoma, ovarian cancer and myeloma. CAR-NKG2D is constructed using the native sequence of non-engineered natural killer, or NK, cell receptors that target ligands, which are antigens or antigens complexed with other molecules, present on numerous cancer cells. Ligands are substances bound together to form a larger complex, such as an antigen bound to other molecules. Accordingly, our technology has the potential to attack and kill a broad range of solid and blood cancers, CD19 CAR Therapy, is typically only effective in B-cell malignancies. In pre-clinical studies, treatment with CAR-NKG2D significantly increased survival. In some studies, 100% of treated mice survived through the follow-up period of the applicable study, which in one study was 325 days. All untreated mice died during the follow-up period of the applicable study. We obtained access to our CAR T-cell drug product candidates and related technology, including technology licensed from the Trustees of Dartmouth College, or Dartmouth College, in January 2015, through our purchase of OnCyte, LLC, a wholly-owned subsidiary of Celdara Medical, LLC, or Celdara, a privately-held U.S. biotechnology company.

13.2 Strategy

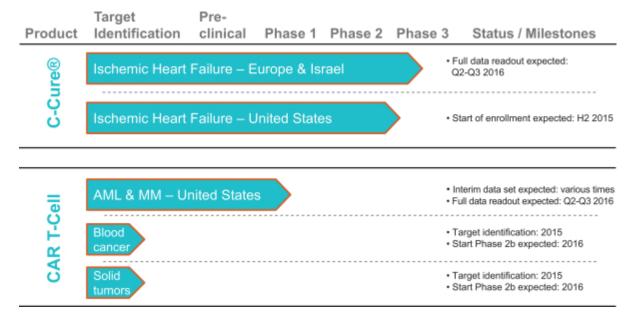
Our goal is to be a leader in engineered cell therapy treatments, initially focused on cardiovascular disease and oncology. The key elements of our strategy are as follows:

- Complete our Phase 3 clinical program for C-Cure and thereafter file for, marketing applications and begin commercialization, of C-Cure for patients with ischemic HF. Based on the favorable safety and efficacy profile demonstrated in our Phase 2 clinical trial, we believe that C-Cure is a promising candidate for the treatment of ischemic HF. We completed enrollment in CHART-1 in March 2015 and, pending FDA clearance of the existing clinical hold, anticipate initiating CHART-2 in the second half of 2015. If our Phase 3 clinical program for C-Cure is successful, we plan to submit a marketing authorization application to the European Medicines Agency, or EMA, and a biologics license application to the FDA and thereafter to actively pursue commercialization of C-Cure.
- Rapidly advance CAR-NKG2D through clinical development and into commercialization for the treatment of AML and MM. CAR T-cell therapy is an emerging therapy for the treatment of some cancers, such as B-cell malignancies. We are currently enrolling patients with refractory or relapsed AML or MM in a Phase 1 clinical trial of CAR-NKG2D in the United States. If this clinical trial is successful, we intend to progress CAR-NKG2D into later clinical trials. We believe that the knowledge that we have gained through the development of C-Cure will allow us to more efficiently progress CAR-NKG2D through clinical development.

- Leverage our expertise and knowledge of engineered-cell therapies to expand our CAR T-cell therapy drug product candidate pipeline. The NKG2D receptor has ligands that are expressed in numerous types of cancer cells, including those associated with ovarian, bladder, breast, lung and liver cancers, as well as leukemia, lymphoma and myeloma, while CD19 CAR Therapy is typically only effective in treating B-cell malignancies. Accordingly, we plan to target the treatment of cancers beyond AML and MM, where the cancer cells express NKG2D receptor ligands, with CAR-NKG2D, in the near future. We are currently conducting pre-clinical studies to determine which other cancers to pursue with CAR-NKG2D. In addition, we are continuing pre-clinical studies of our other preclinical product candidates, NKp30, which is another activating receptor of NK cells, and B7H6, which is a NKp30 ligand expressed on cancer cells.
- Develop our allogeneic CAR T-cell technology. We also have technology that we believe may enable the development of an allogeneic CAR T-cell therapy, where T-cells harvested from one patient are engineered into CAR T-cells that can be used in the treatment other patients without triggering an immune response. This could allow for the manufacture of an off the shelf CAR T-cell therapy product, which has the potential to transform the treatment of cancer.
- Select, develop and advance cell therapies in additional therapeutic areas with high unmet need. We believe that we are well situated to effectively advance cell therapy treatments for additional indications, such as acute myocardial infarction, or heart attack, and non-ischemic HF, as a result of the expertise and know-how that we have acquired through the development of C-Cure. Additional new indications may be identified through our relationship with the Mayo Clinic, and we will consider developing autologous cell therapy treatments for additional indications in which there is high unmet medical need.

13.3 Drug product candidates

We consider we are a leader in engineered cell therapy treatments with clinical programs initially targeting indications in cardiovascular disease and oncology. We currently hold worldwide rights to all of our drug product candidates, which are summarized in the table below.



13.3.1 Cardiovascular Disease

Cardiovascular diseases, which are diseases of the heart and blood vessels, are the largest cause of mortality in the world and, in 2012, approximately 31% of all global deaths were attributable to cardiovascular diseases, according to the World Health Organization. A subset of cardiovascular diseases, cardiac diseases, which are diseases of the heart, represent the single largest cause of death in the cardiovascular diseases population, according to the American Heart Association. If left untreated, cardiac diseases can lead to HF, a condition in which the heart is unable to pump enough blood to meet the body's metabolic needs.

HF affects 1% to 2% of the adult population in developed countries and approximately 5.7 million patients were diagnosed with HF in the United States in 2012, according to the American Heart Association. HF can either be of ischemic origin, linked to impairment of blood flow to the heart muscle, or non-ischemic origin, linked to other causes

such as hypertension and metabolic disorders. In the Bromley heart failure study, 52% of the patients had HF of ischemic origin. Other studies have reported lower rates of ischemic HF, but such differences can be explained by differences in study population, definitions and timing of when the study was completed.

The prevalence of HF is increasing due to an aging population and the increasing prevalence of major cardiovascular risk factors, such as obesity and diabetes. Population studies published in Nature Reviews Cardiology have estimated that one in five people over the age of 40 will develop HF during his or her lifetime. The long-term prognosis associated with heart failure is dire, with approximately 50% mortality at five years following initial diagnosis, according to a 2014 report from the American Heart Association.

HF is classified according to the severity of the symptoms experienced by the patient. The classification most commonly used is the New York Heart Association, or NYHA, classification. The table below summarizes the NYHA Functional Classification.

NYHA Functional Classification*	Functional Capacity						
Class I	No limitation of physical activity. Ordinary physical activity does not cause undue breathlessness, fatigue, or palpitations.						
Class II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in breathlessness, fatigue, or palpitations.						
Class III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary physical activity causes breathlessness, fatigue, or palpitations.						
Class IV	Unable to carry on any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken, discomfort is increased.						

In addition, the level of objective evidence of the cardiovascular disease is also classified as A, B, C, or D, representing, no evidence of disease, evidence of minimal disease, evidence of moderate disease, and evidence of severe disease, respectively.

Hospitalizations of HF patients are expensive and are particularly problematic, as the risk of death is increased with each recurrent HF-related hospitalization, according to an article in the Journal of American College of Cardiology. As of 2013, there were one million primary HF-related hospitalizations annually in the United States, according to a report in the Journal of American College of Cardiology. The estimated direct cost of HF in the United States in 2012 was \$60.2 billion, half of which was related to hospitalizations, according to a 2014 review article published in Clinical Cardiology. By 2030, the total cost of HF in the United States is projected to increase to \$70 billion, according to a Policy Statement from the American Heart Association.

Current Treatments of Heart Failure

Patients with HF are treated with medications such as angiotensin-converting enzyme inhibitors, angiotensin-2 receptor blockers, beta blockers and diuretics. Patients with HF may also be equipped with certain implantable devices, such as Implantable Cardioverter Defibrillators, or ICDs, or Cardiac Resynchronization Therapy Devices. Current treatment options for patients in severe stages of the disease include heart transplant surgery or implantation of a left ventricular assist device, or LVAD, a battery operated mechanical circulatory device used to partially or completely replace the function of the left ventricle of the heart. Both of these end-stage treatment options require invasive open-chest surgery, can be associated with numerous complications, including risk of thrombosis and infection in the case of LVADs, and can require lifetime immunosuppressive therapy in the case of transplant. In 2012, approximately 2,300 HF patients in the United States underwent heart transplant according to a report from the American Heart Association. In 2013, approximately 2,500 patients had a primary LVAD implanted, according to the Sixth INTERMACS annual report.

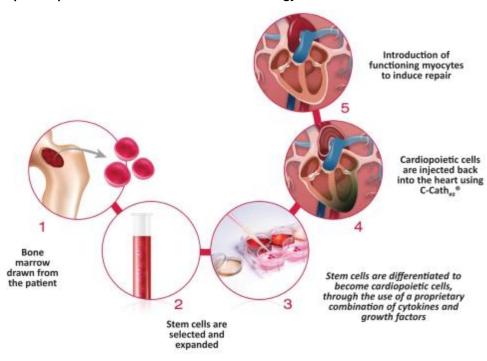
Although existing therapies have been somewhat effective in the treatment of HF, there is still great unmet medical need. In particular, in the case of ischemic HF, which is caused by insufficient oxygen to the heart, current treatments fail to address the decrease in the number of functional myocytes in the heart that result from this lack of oxygen. Over time this functional decrease modifies the dynamics of cardiac contractions leading to tissue remodeling and loss of cardiac function. We believe that cellular therapies have the potential to repair or replace the non-functioning myocytes of ischemic HF patients.

Our Approach

Our lead drug product candidate, C-Cure, is an autologous cell therapy that we believe has the potential to treat patients with NYHA Classes II, III and IV ischemic HF through both direct and indirect modes of action. The direct mode may replace non-functioning myocytes. In the indirect modes, factors secreted by the cardiopoietic cells may cause patients' resident stem cells to begin pooling, regenerating and differentiating into cardiac cells, with the resulting favorable environment inducing the non-functioning myocytes to regain function. We have developed C-Cure based predominantly on technology that we licensed from the Mayo Clinic.

Since the heart does not harbor large quantities of stem cells, it cannot rely on self-repair mechanisms to address damage to the myocardium. Accordingly, in order to repair or replace non-functioning myocytes, the introduction of cardiopoietic cells is necessary. To guide cardiac tissue formation, our C-Cure therapy reprograms multipotent stem cells harvested from a patient into cardiopoietic cells, cells that become myocytes, using naturally occurring cytokines, small proteins that play an important role in cell signalling, and growth factors that mimic the signaling that occurs in embryonic heart tissue development. In the C-Cure process, stem cells are collected from an ischemic HF patient through bone marrow aspiration during an outpatient procedure. The stem cells are then harvested, selected, expanded and differentiated into cardiopoietic cells at our manufacturing facility, yielding a homogeneous and pure cardiopoietic cell population. The cardiopoietic cells are then re-injected into the heart of the ischemic HF patient with our C-Cath_{ez} cell injection catheter.

Graphic representation of the C-Cure technology.¹



1. Behfar et al., "Cardiopoeitic programming of embryoinic stem cells for tumor-free heart

Clinical Development

Phase 2 Clinical Trial

The first human clinical Phase 2 trial for C-Cure was completed in 2012. This trial was initially designed as a Phase 2/3 trial, but only the Phase 2 portion of this trial was completed. The Phase 2 portion was a prospective, randomized, open parallel two-arm study and consisted of 45 ischemic HF patients, with the primary endpoint being the safety and feasibility of C-Cure. Safety was assessed based on occurrence of cardiovascular events and arrhythmias. Feasibility was assessed based on assessment of cell expansion, manufacturing, phenotye release, in addition to catheter-based delivery. Measures of efficacy included cardiac function and structure as assessed by LVEF, left ventricular end systolic volume, left ventricular end diastolic volume, as well as clinical exercise capacity as assessed by the six minutes WDT and quality-of-life measures.

Patients between 18 and 75 years of age with NYHA Class II or III ischemic HF, an LVEF \geq 15% and \leq 40%, and who had not experienced a heart attack within two months prior to enrollment were candidates for the trial. The 45 patients

enrolled in the trial were randomly assigned to either the control group or the C-Cure treatment group, with each patient having a 67% chance of being assigned to the C-Cure treatment group and a 33% chance of being assigned to the control group. Baseline data demonstrated a similar distribution of age, sex, body mass index, prevalence of cardiovascular risk factors and cardiac disease history in both the C-Cure treatment group and control group, and no difference in medications or hemodynamics was observed. Both groups received optimal standard of care as defined by the American College of Cardiology guidelines and the European Society of Cardiology guidelines, including the implantation of an ICD if the patient did not already have one. Patients assigned to the C-Cure treatment group received C-Cure in addition to the optimal standard of care. Where patient factors such as medications and comorbidities prevented us from producing sufficient cells to obtain the C-Cure dose necessary for treatment, patients were assigned to the control group per the trial protocol. This trial was performed at nine clinical trial sites located in Europe.

At six months following treatment, patients treated with C-Cure showed a 25% relative improvement of median LVEF versus baseline (p<0.0001), whereas patients in the control group showed a relative improvement of 0.7% versus baseline. Furthermore, all patients in the C-Cure treatment group showed improved LVEF beyond the optimal standard of care, with 76% of patients demonstrating an absolute increase of over 3% and 57% showing an absolute increase of over 5%. Patients in the C-Cure treatment group also had a significant reduction in left ventricular end systolic volume as compared to patients in the control group, with patients in the C-Cure treatment groups showed a reduction of -8.8 ml (p < 0.001). In addition, patients in the C-Cure treatment group demonstrated an improved exercise capacity as measured by the six minutes WDT. The C-Cure treatment group's walking distance improved by 77 meters compared to the control group (p<0.01). Patients in the C-Cure treatment group also had a reduction in end diastolic volume as compared to patients in the control group, and patients in the C-Cure treatment group also demonstrated a reduction in heart mass as compared to patients in the control group, although neither of these results reached statistical significance.

The Minnesota Living with Heart Failure Quality-of-Life questionnaire was used to score the extent to which patients' lives were affected by ischemic HF. A higher score on the test represents a lower quality-of-life, with the maximum score being 105. Over the course of six months, the score of the patients in the C-Cure treatment group improved by 7.1 points, whereas the score of the control group patients improved by 0.4 points. In addition, the C-Cure treatment group had 30% of patients improve by a 10 point difference or more while no patients in the control group improved by that difference. These results did not reach statistical significance.

A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for measuring the statistical significance of a result is known as the "p-value", which represents the probability that random chance caused the result (e.g., a p-value = 0.001 means that there is a 0.1% or less probability that the difference between the control group and the treatment group is purely due to random chance). A p-value = 0.05 is a commonly used criterion for statistical significance, and may be supportive of a finding of efficacy by regulatory authorities. However, regulatory authorities, including the FDA and EMA, do not rely on strict statistical significance thresholds as criteria for market approval and maintain the flexibility to evaluate the overall risks and benefits of a treatment. Accordingly, treatments may receive market approval from the FDA or EMA even if the p-value of the primary endpoint is greater than 0.05, or may fail to receive market approval from the FDA or EMA even if the p-value of the primary endpoint is less than 0.05.

No unanticipated serious adverse events definitely attributed to C-Cure or the trial procedure were reported in this trial. One patient experienced a serious adverse reaction, migraine with aura, one day post-procedure, but was subject to similar migraine episodes in the past. Another patient experienced rapid and irregular heartbeat resolved by applying an electrical stimulation to the heart during the procedure. A third patient experienced atrial fibrillation approximately a year and a half after the study procedure, but records of arrhythmia prior to treatment support that atrial fibrillation was a pre-existing condition.

We produced C-Cure for 21 out of the 30 patients attempted as patient factors such as medications and co-morbidities prevented us from producing sufficient cells for certain patients in the trial. However, we have made improvements to our manufacturing process, which we believe will allow us to have a greater than 80% manufacturing success rate in our Phase 3 clinical trials. These changes include:

- > adopting cryopreserved, a process whereby cells that are susceptible to damage caused by time are preserved by cooling to subzero temperatures, product storage to extend the shelf life of the cells;
- modifying improving the release criteria to ensure that desirable cells are not incorrectly rejected. In our Phase 2 trial of C-Cure, some production lots were rejected because the tests used identified the presence of impurities such as osteoblasts, or bone precursor cells, adipocytes, or fat cells, or chondrocytes, or cartilage

cells. Upon further examination, it appeared that the methods used were overly sensitive. New methods have been developed that are more specific, while at the same time remaining as sensitive; and

developing predictive tests that allow us to reject patient bone marrow, that is unsuitable to yield the required number of cells for effective treatment. In CHART-1, patients bone marrow that does not reach 24 million cells are rejected from the manufacturing process, resulting in such patients not being randomized for treatment and discontinued from the trial. Therefore, only bone marrow that is capable of good cell expansion proceeds to the next culture phase, leading to randomization of the patient in the trial.

Phase 3 Clinical Program

We are pursuing clinical development of C-Cure through a comprehensive Phase 3 program comprised of two Phase 3 clinical trials, CHART-1 and CHART-2.

CHART-1

CHART-1 is being conducted in Europe and Israel and was first authorized in November 2012. CHART-1 is a 240 patient prospective controlled randomized double-blinded trial, including NYHA Class III and IV ischemic HF patients, with each patient having a 50% chance of being assigned to the C-Cure treatment group or the control group. The primary endpoint of this trial is an improvement in the composite hierarchical endpoint using the Finkelstein-Schoenfeld statistical method. The elements of this endpoint are, in hierarchical order, mortality, morbidity, quality of life, six minutes WDT, left ventricular end systolic volume and LVEF. Each patient in the C-Cure treatment group will be compared to each patient in the control group and a comprehensive score will be derived to compare one group against the other.

We received a pediatric waiver across all subsets of the pediatric population for C-Cure for the treatment of ischemic HF from the EMA in February 2015, therefore all clinical trials of C-Cure will be restricted to the adult population. In April 2014, the EMA issued a certificate of quality data for C-Cure. This Advanced Therapy Medicinal Products, or ATMP, certification recognizes that the data generated for C-Cure in its development programs to date meet the standards imposed by the EMA. The ATMP's certificate for quality data will facilitate the EMA's review of our anticipated future application for marketing authorization for C-Cure. On 30 March 2015, we announced that DSMB reviewed unblinded safety data from CHART-1 and determined that there was no evidence of obvious differences in safety profiles of patients in the two arms of the trial, which means that the data did not support discontinuation of the trial on the basis of safety. The full data readout from this trial is expected in the middle of 2016.

As of the date of this prospectus, we have completed enrollment of all patients in this trial at over 30 trial sites in Europe and Israel. We anticipate reporting interim futility data from this trial in the second quarter of 2015, with the full data readout expected in the middle of 2016.

CHART-2

On January 27, 2012, we, as the sponsor, filed our Investigational New Drug Application, or IND, for the use of C-Cure in CHART-2 with the FDA (NCT02317458). The subject of the IND is the efficacy and safety of bone marrow-derived mesenchymal cardiopoietic cells for improving exercise capacity in subjects with advanced chronic ischemic HF.

CHART-2 is expected to be conducted in the United States and Europe. CHART-2 is a 240 patient prospective controlled randomized double-blinded trial, including NYHA Class III and IV ischemic HF patients, with each patient having a 50% chance of being assigned to the C-Cure treatment group or the control group. The primary efficacy endpoint of CHART-2 is the change in the six-minute WDT from pre-procedure to nine months. Our IND became effective in December 2013 for administration of the cells with Myostar, a catheter used for the injection of therapeutic agents into the heart, and manufactured by e we filed an amendment to the IND requesting among other changes to the initial submission, the use of our proprietary cell injection catheter called C-Cathez. In January 2015, the FDA issued a clinical hold on CHART-2. Most of the clinical hold questions request clarifications on the design dossier of C-Cathez, while the remaining questions relate to providing updated safety information on CHART-1, defining CHART-2 stopping rules, and a request to measure troponin, a cardiac marker of injury, at day 30 post baseline procedure. We anticipate responding to the clinical hold questions in the third quarter of 2015 once all safety data from CHART-1 is available, and pending the FDA's lifting of the clinical hold, initiating CHART-2 during the second half of 2015.

13.3.2 Oncology

Cancer is the second leading cause of death in the United States after cardiovascular diseases, according to the U.S. Centers for Disease Control and Prevention. Cancer accounts for nearly one out of every four deaths in the United

States, according to the American Cancer Society. In 2014, there were an estimated 1.6 million new diagnosed cancer cases and over 550,000 cancer deaths in the United States alone. According to the Leukemia and Lymphoma Society, the approximate prevalence of AML in the United States as of 1 January 2011 was 37,726 and the incidence rate of MM in the United States as from 2007 to 2011 was 7.7 per 100,000 population for men and 4.9 per 100,000 population for women.

CAR T-Cell Therapy

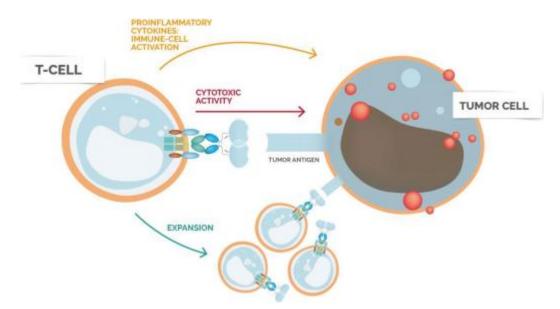
The immune system has a natural response to cancer, as cancer cells express antigens that can be recognized by cells of the immune system. Upon recognition of an antigen, activated T-cells release substances that kill cancer cells and attract other immune cells to assist in the killing process. However, cancer cells can develop the ability to release inhibitory factors that allow them to evade immune response, resulting in the formation of potentially dangerous cancerous tumors and blood cancer.

CAR T-cell therapy is a new technology that broadly involves engineering patients' own T-cells to express CARs so that these re-engineered cells recognize and kill cancer cells, overcoming cancer cells' ability to evade the immune response. CARs are comprised of the following elements:

- binding domains that encode proteins, such as variable fragments of antibodies that are expressed on the surface of a T-cell and allow the T-cell to recognize specific antigens on cancer cells;
- intracellular signaling domains derived from T-cell receptors that activate the signaling pathways responsible for the immune response following binding to cancer cells; and
- costimulatory and adaptor domains, which enhance the effectiveness of the T-cells in their immune response.

Once activated, CAR T-cells proliferate and kill cancer cells directly through the secretion of cytotoxins that destroy cancer cells, and these cytokines attract other immune cells to the tumor site to assist in the killing process.

Illustration of CAR T-cell binding to a ligand, triggering mechanisms to eliminate cancer cells.



The CAR T-cell therapeutic process starts with collecting cells from a patient's bone marrow. T-cells are then harvested and selected from the collected cells, following which the CAR is introduced into the T-cells using retrovirus vectors, a widely used technology to transfer genes into immune cells using the natural capacity of a retrovirus to deliver genes into cells. The CAR T-cells are then expanded prior to injection back into the patient.

Current Investigational Treatments of Cancer using CAR T Cells

In the past decades, the cornerstones of cancer therapies have been surgery, chemotherapy and radiation therapy. Since 2001, small molecules that specifically target cancer cells have emerged as standard treatments for a number of cancers. For example, Gleevec is marketed by Novartis AG for the treatment of leukemia, and Herceptin is marketed by Genentech, Inc. for the treatment of breast and gastric cancer. Although these targeted therapies have significantly improved the outcomes for certain patients with these cancers, there is still a high unmet need for the treatment of

these and many other cancers. CAR T-cell therapy is an emerging therapy for the treatment of some cancers, such as B-cell malignancies.

CAR19 is a widely used CAR, which has an antigen binding domain that recognizes the normal B-cell marker CD19. CD19 CAR Therapies have demonstrated high clinical responses in difficult to treat refractory B-cell malignancies. For example, results of a clinical trial reported in the New England Journal of Medicine in October 2014 demonstrated that CD19 CAR Therapy was effective in treating patients with relapsed and refractory acute lymphoblastic leukemia. Treatment was associated with a complete remission rate of 90 %and sustained remissions of up to two year after treatment. Despite its promise, CD19 CAR Therapy is inherently limited to the treatment of B-cell malignancies.

Our Approach to CAR T-Cell Therapy

Our approach to CAR T-cell therapy has the potential to treat a wider range of cancers than CD19 CAR Therapy because, in certain cases, we employ natural receptors that target multiple ligands, at least one of which is found in numerous cancers, as opposed to targeting a single ligand. Our primary CAR technologies use activated receptors of NK cells, lymphocytes of the innate immune system that kill cancer cells directly and also secrete cytokines that attract other immune cells to assist in the killing process. The receptors used in our therapies target ligands that are activated in cancer cells, but absent or expressed at low levels in normal cells, resulting in therapies that are intended to be less destructive to normal cells.

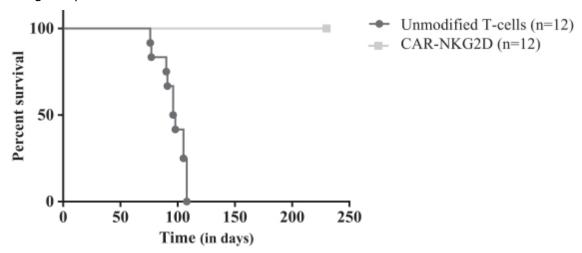
Our lead CAR T-cell drug product candidate is CAR-NKG2D. CAR-NKG2D uses the native sequence of NKG2D in the CAR construct, thereby avoiding linker sequences that could be recognized as "non-self" by the immune system and thereby trigger an immune response. Accordingly, CAR-NKG2D does not require re-engineering to allow it to bind to cancer cell ligands with high affinity. CAR-NKG2D also makes use of DAP10, a naturally occurring adaptor molecule that is normally is expressed by T-cells, to aid in the immune response.

Ligands for the NKG2D receptor are expressed either individually or together with other ligands at the surface of cancer cells, allowing for the targeting of multiple tumor types given the higher likelihood of expression of at least one ligand. NKG2D receptor ligands, such as ULBP, MICA and MICB, are expressed in numerous solid tumors and blood cancers, including ovarian, bladder, breast, lung and liver cancers, as well as leukemia, lymphoma and myeloma. MICA and MICB may be induced in association with cell stress, infection or malignant transformation. Within a given cell population, we have shown *in vitro* effectiveness of CAR-NKG2D even when as few as 7% of the cancer cells expressed a NKG2D receptor ligand.

Pre-Clinical Development

CAR-NKG2D has been tested in pre-clinical models of solid and blood cancers, including lymphoma, ovarian cancer and myeloma. In pre-clinical studies, treatment with CAR-NKG2D significantly increased survival. In some studies, 100% of treated mice survived through the follow-up period of the applicable study, which in one study was 325 days. All untreated mice died during the follow-up period of the applicable study.

In one representative study, as shown in the figure below, the treatment with CAR-NKG2D completely prevented tumor development in mice injected with ovarian cancer cells and followed over a period of 225 days. In contrast, all mice injected with ovarian cancer cells that were treated with unmodified T-cells developed cancerous tumors and died during that period.



Our pre-clinical models have also shown that treatment with CAR-NKG2D is followed by changes in a tumor's microenvironment resulting from the local release of chemokines, a family of small cytokines. In a pre-clinical study, mice that had been injected with cancer cells and treated with CAR-NKG2D were rechallenged either with the 5T33MM cancer cells or a different tumor type (RMA lymphoma cells). The mice that were rechallenged with the same tumor type survived, while the mice that were challenged with a different tumor type died, as shown in the figure below. We believe that the mechanism by which the mice in the former group survived may be linked to T-cell memory against the tumor antigen, independent of the continued presence of CAR-NKG2D. We believe that this continued protection may be a result of the type of chemokines released at the time of the initial CAR-NKG2D treatment, and we do not believe that this effect has been demonstrated with other CARs.

Moreover, pre-clinical studies have suggested that CAR-NKG2D could potentially have a direct effect on tumor vasculature. Tumor vessels express ligands for the NKG2D receptor that are not generally expressed by normal vessels. We believe that this expression may be linked to genotoxic stress, hypoxia and reoxygenation in tumors and therefore that CAR-NKG2D could potentially inhibit tumor growth by decreasing tumor vasculature, which could possibly render it effective in the treatment of NKG2D-negative tumors.

Pre-clinical studies also demonstrate that CAR-NKG2D is effective without lymphodepletion conditioning, which is the destruction of lymphocytes and T-cells, normally by radiation. We believe this absence of a pre-conditioning regimen may expand the range of patients eligible for CAR T-cell treatment, reduce costs, reduce toxicity and thereby improve patient experience and acceptance.

No significant toxicology findings were reported from pre-clinical multiple-dose studies at dose levels below 10,000,000 CAR-NKG2D per animal. Some temporary weight loss was noted in animals treated with CAR-NKG2D. At this dose, histology showed there was no accumulation of infused cells in any organ other than the lungs. We believe that this accumulation of infused cells in the lungs was likely due to the large number of cells infused into the animals.

Clinical Development

On June 9 2014, Celdara filed an IND with the FDA (NCT02203825) related to the CAR-NKG2D trial. The subject of the IND is evaluating the safety and feasibility of administering a single intravenous dose of CAR-NKG2D to patients with AML, Myelodysplastic Syndrome and MM.

We are currently enrolling patients with (i) AML who are not in remission and for which standard therapy options are not available or (ii) relapsed or refractory progressive MM, in a Phase 1 clinical trial to test the safety and feasibility of single-dose intravenous administration of CAR-NKG2D T-cells without prior lymphodepletion conditioning. This is a dose escalation trial to test four different dose levels. Patients may receive doses anywhere from 1,000,000 up to 30,000,000 CAR-NKG2D T-cells in a single intravenous injection. For each dose level, three patients, one with AML, one with MM, and one with either AML or MM, will be recruited, until a toxicological response is demonstrated or we reach a dose of 30,000,000 cells. Once a dose has been selected, an additional 12 patients, six AML patients and six MM patients, will be included in the dose expansion part of the trial, to probe efficacy signals. This trial is being conducted at the Dana Farber Cancer Institute in the United States. Interim data is expected to be reported throughout this trial, with the full data readout expected in the middle of 2016. The first patient was treated in this trial in April 2014 and no treatment-related safety concerns were reported during the 30-day follow-up period. A pre-defined, staggered enrolment of two additional patients at the same dose level as the first patient is expected to occur now that the 30-day follow-up period for the first patient has ended.

We are currently conducting pre-clinical studies to determine which other cancers to pursue with CAR-NKG2D.

Other CAR T-Cell Development

Allogeneic Platform

We also Autologous CAR T-cells must be manufactured for each individual patient. As a result this form of treatment presents cost and logistical challenges. We have technology that we believe may enable the development of an allogeneic CAR T-cell therapy, the patients , the host, without triggering an immune response. This could allow for the manufacture of Functioning T-cell receptors on a donor T-cell are responsible for eliciting an adverse immune reaction in the host, which is known as a graft-versus-host response. The goal of our allogeneic platform is to eliminate the graft-versus host response. Our allogeneic platform is based on the engineering of T-cells that lack expression of a functional T-cell receptor, while at the same time expressing a CAR that can trigger the killing of cancer cells. We believe that our allogeneic platform may allow us to manufacture an off the shelf CAR T-cell therapy product, which has the potential to transform the treatment of cancer. We also have two additional CAR T-cell programs that are in very early pre-clinical development. The first program focuses on another activating receptor of NK cells, NKp30, which could expand the range of cancers that can be targeted by our technology. The second program targets the ligand of NKp30, B7H6, expressed on cancer cells. In this latter case, we anticipate that the CAR would be similar to the CAR19 construct.

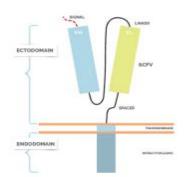
Additional Autologous Programs

We also have two additional autologous CAR T-cell programs that are in pre-clinical development. The first program involves the use of a CAR T-cell expressing NKp30, another activated receptor of NK cells. CAR T-cells expressing NKp30 target ligands, which are expressed on many types of cancer cells, including lymphoma, leukemia and gastrointestional stromal tumors. The primary ligand of NKp30 is B7H6. Previous pre-clinical studies performed at Dartmouth College and reported in the Journal of Immunology in 2012 demonstrated that CAR-T cells expressing NKp30 were able to kill cancer cells expressing NKp30 ligands both in vitro and in vivo. The second program involves the specific targeting of B7H6 to kill cancer cells that express B7H6. Previous pre-clinical studies performed at Dartmouth College and reported in the Journal of Immunology in 2015 demonstrated that therapy targeting B7H6 decreased tumor burden of melanoma-and ovarian cancer-bearing mice.

Comparison of our CAR T-cell therapy approach to CD19 CAR Therapy.

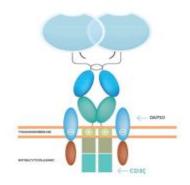
Classical CAR construct

- One CAR construct targets one tumor
- · May not be suitable for repeated injections
- Mostly autologous
- · Many potential therapies under development



Our CAR construct

- Uses NK cell receptors
- One CAR construct has the potential to target multiple tumors
- Suitable for repeated injections
- Autologous and possibly allogeneic



13.3.3 Our Complementary Devices

We developed C-Cath_{ez}, which is CE-marked, with the goal of overcoming limitations of existing cell injection devices that we discovered during our development of C-Cure. Due to continuous heart movements, we believe that injecting cells into the heart requires a stable needle that anchors into the tissue during injection. In addition, excess pressure on cells during injection has an adverse impact on cell retention. To respond to these challenges, C-Cath_{ez} features a curved needle that provides stability during the injection and multiple holes along the needle that increase the exit surface, reducing the pressure exerted on cells during the injection procedure. In pre-clinical studies, we obtained a high retention rate of injected cells through the use of C-Cath_{ez} as compared to other commercially available catheters. In a pre-clinical study of C-Cath_{ez}, use of C-Cath_{ez} did not cause myocardial perforation or clinically relevant increases in the blood levels of cardiac enzymes were observed in pigs or dogs. We also market C Cath_{ez} in the European Union as a stand-alone medical device for delivery of diagnostic and therapeutic agents indicated for delivery into the heart to research laboratories and clinical-stage companies only.

In addition, we believe our heart access technology will enable cardiologists to take a unique access route directly to the patient's left atrium, which may potentially enable the deployment of catheters or other necessary instruments for use in the treatment of various indications such as mitral valve disorders and structural heart diseases, conditions often linked to HF. This heart access technology includes the heart access sheath, mitral valve neo-chordae, and closure device. These devices are either in the discovery phase or preclinical development.

13.4 Manufacturing

We plan to use our pilot manufacturing facility, located in Belgium, for the manufacture of C-Cure until commercial launch. This facility has a production capacity of approximately 250 patients per year. We are also building a second pilot manufacturing facility in Rochester, Minnesota to reduce our overall logistical costs for patients in CHART-2 and to provide redundancy.

In the future, we plan to operate two commercial manufacturing sites, one in the United States and one in the European Union. We believe that this will provide us with increased flexibility, reduced logistical costs and necessary redundancy, as well as allowing us to comply with contractual obligations that require us to manufacture in the European Union.

We have been working on the optimization of our manufacturing processes to reduce our cost of production. For example, we are currently developing a closed system that may allow for the manufacture of C-Cure in vessels that prevent contact with the environment, which we expect will reduce our need for Class B clean rooms and the associated expense.

The cells for our ongoing Phase 1 clinical trial of CAR-NKG2D are being manufactured at the Dana Farber Cancer Institute's cell manufacturing facility.

13.5 Commercialization

We currently intend to market C-Cure using a sales model focused on leading catheterization laboratories and referral networks. We believe that C-Cure would first be adopted by high-volume key-opinion-leader catheterization laboratories, and progressively by a broader segment of the market. We expect to establish or acquire a specialty sales force to increase physician familiarity with our treatments and field technicians to assist sites during adoption. While we maintain all commercial rights to our C-Cure technology and currently intend to commercialize C-Cure directly, we may in the future adopt a partnering strategy for C-Cure in the United States and/or the European Union.

Given the developmental stage our CAR T-cell platform, we have not yet developed a commercialization plan for our CAR T-cell drug product candidates.

13.6 Licensing and Collaboration Agreements

Academic and clinical collaborations

We have core relationships and collaborations with the Mayo Foundation for Medical Education and Research, or the Mayo Clinic, and the Trustees of Dartmouth College, or Dartmouth.

Mayo Clinic

C-Cure is based on technology discovered at the Molecular Pharmacology and Experimental Therapeutics lab at the Mayo Clinic, led by Dr. Andre Terzic. Under our technology license agreement with the Mayo Clinic entered into in June 2007 and amended in July 2008 and October 2010, or Mayo License, we were granted an exclusive, worldwide license to make, use, modify, enhance, promote, market and/or sell the "Cardiogenic Cocktail for the production of Cardiac Cells" and "Stem Cell Based Therapy for Non-ischemic Cardiomyopathic Heart Failure" within the field of cardiovascular regeneration or protection, including certain related patents. In addition, we were granted a non-exclusive, worldwide license to licensed know-how in connection with the licensed inventions within the same field. The exclusive license is subject to the Mayo Clinic's right to make and use the licensed inventions and licensed know-how within its affiliates' own programs, and to the rights, if any, of the United States government. The Mayo Clinic has the right to purchase quantities of licensed invention from us at cost to meet its and its affiliates' internal needs.

In consideration for the rights granted to us under the Mayo License, we were required to pay an upfront fee to Mayo Clinic of €9,500,000 upon the initial agreement and \$3,193,125 upon the execution of the second amendment, which were subsequently converted into our share capital. We also paid the Mayo Clinic \$337,000 for the purchase of equipment for research purposes. Additionally, we are required to pay to the Mayo Clinic a low single-digit royalty on net commercial sales by us or by our permitted sublicensees from the commercialization of licensed products, on a licensed product-by-licensed product basis, beginning on the date of the first commercial sale of the relevant licensed product and extending until the earlier of (i) the 15 year anniversary of the first commercial sale of such licensed product, (ii) the date on which the licensed product is no longer covered by a valid claim of a licensed patent in the applicable territory, or (iii) termination of the Mayo License. The Mayo License permits a reduction of these royalties, not to exceed a specified floor, for amounts payable to third parties as required to in-license necessary third-party technology.

Under the Mayo License, we are responsible for the development, manufacture and commercialization of the licensed inventions. We committed to provide the Mayo Clinic with \$500,000 of directed research funding per year for the years 2012 through 2014. Any results of this research will automatically be included as licensed inventions under the Mayo License. We will also fund research at the Mayo Clinic in the amount of \$1,000,000 per year for four years in the area of regeneration or protection for cardiovascular applications. Such payments will begin once we have achieved both commercial sale of a licensed product and a positive cash flow from operations in the previous financial year. We will have an exclusive right of first negotiation to acquire an exclusive license to inventions that are the direct result of

work carried out under these grants, in accordance with the mechanism described in the Mayo License. The Mayo Clinic provided us with directed research and conducted a dose finding study for us at no additional cost. Subject to pre-existing obligations, until 18 October 2015, we also have an exclusive right of first negotiation to obtain an exclusive license from the Mayo Clinic on any guided cardiopoiesis technology developed by Dr. Andre Terzic or developed or co-developed by Dr. Atta Behfar, the senior investigator involved in the discovery of the cardiopoiesis technology. With respect to both of the foregoing rights of first negotiation, if we and the Mayo Clinic do not reach agreement for a license for the applicable invention within the prescribed negotiation period or permitted extension, the Mayo Clinic is prohibited from entering into a license agreement for such invention with a third party for a period of nine months.

The Mayo License will continue until the later of ten years or as long as the Mayo Clinic has any rights to any part of the licensed inventions. The Mayo Clinic may terminate the license on a product-by-product basis or licensed invention-by-licensed invention basis if we default in making payment when due and payable or under other circumstances specified in the Mayo License, subject to 120 days' prior written notice and opportunity to cure. The Mayo Clinic may also terminate the Mayo License if we deliberately make false statements in reports delivered to Mayo Clinic. Additionally, Mayo Clinic may convert the license to non-exclusive or terminate the license upon final decision of an arbitral tribunal that we breached our diligence obligations under the Mayo License. Further, Mayo Clinic may terminate the agreement immediately for our insolvency or bankruptcy, as described in the Mayo License.

In November 2014, we entered into a Preferred Access Agreement with the Mayo Clinic. Pursuant to this agreement, the Mayo Clinic will review with us, on a quarterly basis, technologies arising from the Mayo Center for Regenerative Medicine, and we may review certain other technologies upon request. If, as a result of such reviews, we and the Mayo Clinic decide to advance a certain technology, we will enter into a separate exclusive license agreement with respect to such technology. This agreement remains in effect until December 2017, and may be extended by mutual agreement.

Dartmouth College and Celdara

In January 2015, we entered into a stock purchase agreement, or the Celdara Agreement, with Celdara Medical, LLC, or Celdara, pursuant to which we purchased all of the outstanding membership interests of OnCyte, LLC, or OnCyte, for a \$10.0 million upfront payment to Celdara, \$6.0 million of which was paid in cash and \$4.0 million of which was paid in the form of 98,087 of our ordinary shares. After this transaction we, Celdara and OnCyte entered into an asset purchase agreement, or OnCyte APA, pursuant to which Celdara sold to OnCyte, data, protocols, regulatory documents and intellectual property, including the rights and obligations under license agreements between Celdara and Dartmouth College, related to our CAR T-cell therapy programs, or the Transferred Assets. Pursuant to the OncCyte APA, we are obligated to make development-based milestone payments to Celdara of \$40.0 million for clinical products and of \$36.5 million for pre-clinical products, as well as sales-based milestone payments of up to \$80.0 million for products based on the Transferred Assets, or CAR Products. The OnCyte APA also requires us to make tiered single-digit royalty payments to Celdara in connection with the sales of CAR Products. Such royalties are payable on a CAR Productby CAR Product and country-by-country basis until the later of (i) the last day that at least one valid patent claim covering the CAR Product exists, or (ii) the tenth anniversary of the day of the first commercial sale of the CAR Product in such country. Under the OnCyte APA, we can opt out of the development of any CAR Product if the data does not meet the scientific criteria of success. We may also opt out of development of any CAR Product for any other reason upon payment of a termination fee of \$2.0 million to Celdara.

2010 Dartmouth License Agreement

Under the exclusive license agreement with Dartmouth College entered into in April 2010 and amended in February 2012, July 2013 and January 2015, Dartmouth College granted us (as successor in interest to Celdara) an exclusive, worldwide, royalty-bearing license to certain know-how and patent rights to make, have made, use, and/or sell any product or process for human therapeutics, the manufacture, use or sale of which, is covered by such patent rights. Dartmouth College reserves the right to use the licensed patent rights and licensed know-how, in the same field, for education and research purposes only. The patent rights covered by this agreement are related, in part, to methods for treating cancer involving chimeric NK and NKP30 receptor targeted therapeutics and T cell receptor-deficient T cell compositions in treating tumor, infection, GVHD, transplant and radiation sickness.

In consideration for the rights granted to us under the agreement, we are required to pay to Dartmouth College an annual license fee of \$20,000 as well as a low single-digit royalty based on annual net sales of the licensed products by us and by our permitted sublicensees, with certain minimum net sales obligations beginning 30 April 2024 and continuing for each year of sales thereafter. We are also obligated to pay to Dartmouth College a certain tiered percentage of sublicensing income ranging from the mid-single digits to the mid-teens based on the development stage of the technology at the time the sublicense is granted. We are not required to pay sublicensing income on transactions in which we form a new spin-off entity and transfer at least a portion of our assets. Additionally, the agreement requires that we exploit the licensed products, and we have agreed to meet certain developmental and regulatory

milestones. Upon successful completion of such milestones, we are obligated to pay to Dartmouth College certain milestone payments up to an aggregate amount of \$1.5 million. We are responsible for all expenses in connection with the preparation, filing, prosecution and maintenance of the patents covered under the agreement.

After 30 April 2024, Dartmouth College may terminate the license if we fail to meet the specified minimum net sales obligations for any year, unless we pay to Dartmouth College the royalty we would otherwise be obligated to pay had we met such minimum net sales obligation. Dartmouth College may also terminate the license if we fail to meet a milestone within the specified time period, unless we pay the corresponding milestone payment. Either party may terminate the agreement in the event the other party defaults or breaches any of the provisions of the agreement, subject to 30 days' prior notice and opportunity to cure. In addition, the agreement automatically terminates in the event we become insolvent, make an assignment for the benefit of creditors or file, or have filed against us, a petition in bankruptcy. Absent early termination, the agreement will continue until the expiration date of the last to expire patent right included under the agreement in the last to expire territory. We expect that the last to expire patent right included under this agreement will expire in 2033, absent extensions or adjustments.

2014 Dartmouth License Agreement

Under the exclusive license agreement with Dartmouth College entered into in June 2014 and amended in January 2015, Dartmouth College granted us (as successor in interest to Cerldara) an exclusive, worldwide, royalty-bearing license under certain know-how and patent rights to make, have made, use, modify, exploit, distribute, and/or sell any product or process for human therapeutics, the manufacture, use or sale of which, is covered by such patent rights. Our license is subject to any rights that may be required to be granted to the government of the United States, and Dartmouth College reserves the right to use the licensed patent rights and licensed know-how, in the same field, for education and research purposes only. The patent rights covered by this agreement are related, in part, to anti-B7-H6 antibody, fusion proteins and methods of using the same.

In consideration for the rights granted to us under the agreement, we are required to pay to Dartmouth College a license maintenance fee of \$10,000 upon the first anniversary of the agreement and an annual license maintenance fee of \$20,000 thereafter. We are also required to pay to Dartmouth College a low single-digit royalty based on annual net sales of the licensed products by us and by our permitted sublicensees, with a specified minimum royalty payment for each year of sales. We are obligated to pay to Dartmouth College a certain tiered percentage of sublicensing income ranging from the mid-single digits to the mid-teens based on the time or development stage of the technology at the time the sublicense is granted. We are not required to pay sublicensing income on transactions in which we form a new spin-off entity and transfer at least a portion of our assets. Additionally, the agreement requires that we exploit the licensed products, and we have agreed to meet certain developmental and regulatory milestones. Upon successful completion of such milestones for each licensed product, we are obligated to pay to Dartmouth College certain milestone payments up to an aggregate amount of \$1.6 million. We are responsible for all expenses in connection with the preparation, filing, prosecution and maintenance of the patents covered under the agreement.

Dartmouth College may, at its option, terminate the license, upon thirty days written notice, if we fail to pay at least the minimum royalty payment amount or make such minimum payment within such thirty day period. In addition, Dartmouth College has the right to terminate if we fail to meet a milestone within the specified time period or fail to make the corresponding milestone payment, subject to 30 days' prior written notice and opportunity to cure. We may unilaterally terminate the agreement by giving three months advance written notice to Dartmouth College and paying a termination fee of \$2,500. Either party may terminate the agreement in the event the other party defaults or breaches any of the provisions of the agreement, subject to 30 days' prior notice and opportunity to cure. In addition, the agreement automatically terminates in the event we become insolvent, make an assignment for the benefit of creditors or file, or have filed against us, a petition in bankruptcy. Absent early termination, the agreement will continue until the expiration date of the last to expire patent right included under the agreement in the last to expire territory. We expect that the last to expire patent right included under this agreement will expire in 2033, absent extensions or adjustments.

13.7 Intellectual Property

Patents and patent applications

Patents, patent applications and other intellectual property rights are important in the sector in which we operate. We consider on a case-by-case basis filing patent applications with a view to protecting certain innovative products, processes, and methods of treatment. We may also license or acquire rights to patents, patent applications or other intellectual property rights owned by third parties, academic partners or commercial companies which are of interest to us.

Our patent portfolio includes pending patent applications and issued patents in a number of European Union countries, in the United States and in other countries. These patents and applications generally fall into four broad categories:

- patents and pending patent applications relating to cardiopoiesis, a subset of which are licensed from the Mayo Clinic;
- patents and pending applications we own that relate to cardiac injection catheter technology;
- patent applications owned by our subsidiary Corquest that relate to cardiac medical device technology; and
- patents and patent applications licensed from Dartmouth that relate to our CAR-T platform.

In some countries, including the United States and the European Union countries, the term of a patent may be eligible for patent term extension to account for at least some of the time the drug or device is under development and regulatory review after the patent is granted.

In particular, the term of a U.S. patent may be eligible for patent term extension under the Hatch-Waxman Act to account for at least some of the time the drug or device is under development and regulatory review after the patent is granted. With regard to a drug or device for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the drug or device. Some foreign jurisdictions have analogous patent term extension provisions that allow for extension of the term of a patent that covers a device approved by the applicable foreign regulatory agency.

Cardiopoiesis Platform Patents

As of 15 May 2015, our cardiopoiesis platform portfolio includes seven patent families, four of which are owned by the Mayo Clinic, which we refer to as the Mayo Cardiopoiesis Patents and are exclusively licensed to us, and three of which are owned by us, which we refer to as the Celyad's Cardiopoiesis Patents.

The Mayo Cardiopoiesis Patents include three issued U.S. patents; 17 other patents issued in other jurisdictions including Australia, China, Europe, Hong Kong, Israel, Mexico, New Zealand, Russia, Singapore and South Africa; three pending U.S. patent applications; and 24 patent applications pending in other jurisdictions, including Europe, Australia, Brazil, Canada, China, Israel, India, Japan, Mexico, New Zealand, Singapore, South Korea, Taiwan and Thailand. These patents and patent applications relate to compositions and methods for inducing cardiogenesis in embryonic stem cells, methods of identifying cardiopoietic stem cells, and methods of using cardiopoietic stem cells to treat cardiovascular tissue. The Mayo Cardiopoiesis Patents will begin to expire in 2025, absent any adjustments or extensions. We expect that any patents that eventually issue from currently patent applications in the Mayo Cardiopoiesis patent portfolio will begin to expire in 2025, absent any adjustments or extensions.

Our Cardiopoiesis Patents include one issued patents in each of Europe, New Zealand and Singapore; a pending U.S. patent application; and 14 patent applications pending in other jurisdictions including, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Russia, , South Korea, Taiwan and Thailand, as well as one application filed under the Patent Cooperation Treaty. These patents and patent applications relate to pharmaceutical compositions containing cardiopoietic stem cells and methods of their production, as well as therapeutic targets and agents for treating ischemia reperfusion injury. Our Cardiopoiesis Patents will begin to expire in 2030, absent any adjustments or extensions. We expect that any patents that eventually issue from currently patent applications our Cardiopeisis patent portfolio will begin to expire in 2030, absent any adjustments or extensions.

CAR T-cell Platform Patents

As of 15 May 2015, our CAR T-cell portfolio includes three patent families exclusively licensed to us by Dartmouth. This portfolio includes two issued U.S. patents; four pending U.S. patent applications; and 12 patent applications pending in other jurisdictions including Australia, Brazil, Canada, China, Europe, India, Japan, Mexico and Russia. These patents and patent applications relate to particular chimeric antigen receptors and to T-cell receptor-deficient T-cells. After a pending U.S. patent application relating to T-cell receptor-deficient T-cells was allowed, we amended the claims of the patents application and submitted additional prior art references to the U.S. Patent and Trademark Office with a request to reopen examination of the application. As such, the application is not currently allowed and there is no guarantee that the application will again be allowed in the future. Patents in our CAR T-cell portfolio will begin to expire in 2025, absent any adjustments or extensions. We expect that any patents that eventually issue from currently pending application in the CAR T-cell Platform patent portfolio will begin to expire in 2025, absent any adjustments or extensions.

Cardiac Injection Catheter Technology Patents

As of 15 May 2015, our cardiac injection catheter technology portfolio includes two patent families we own. This portfolio includes a pending U.S. patent application; eight patents issued in jurisdictions including Australia, Belgium, Europe, Israel, Japan, Mexico, New Zealand and /Taiwan; and nine patent applications pending in jurisdictions including Australia, Brazil, Canada, China, Hong Kong, India, , Russia, Singapore, South Korea, and the United Kingdom, as well as an application filed under the Patent Cooperation Treaty. These patents and patent applications relate to injection catheters and processes for their use. Patents in this portfolio will begin to expire in 2029, absent any adjustments or extensions. We expect that any patents that eventually issue from currently pending application in the Cardiac Injection Catheter Technology patent portfolio will begin to expire in 2030, absent any adjustments or extensions.

Heart Access Technology Patents

As of 15 May 2015, our heart access technology portfolio includes five patent families owned by Corquest, our wholly owned subsidiary. This portfolio includes ten pending U.S. patent applications and nine patent applications pending in other jurisdictions including Australia, Brazil, Canada, Europe, Israel, Mexico, Russia, and the Republic of Korea, as well as four applications filed under the Patent Cooperation Treaty. These patents and patent applications relate to devices, assemblies and methods for treating cardiac injuries and defects. Patents in this portfolio, if issued, will begin to expire in 2032.

Patent Portfolio owned by or licensed to the Company¹.

Title	Jurisdiction	Amuliantian Number	Filing Date	Ctatus
Title	Jurisaiction	Application Number	Filing Date	Status
	USA	US 8,173,118 B2	29/07/2005	Granted
Treating cardiovascular tissue	USA	13/433,095	28/03/2012	Notice of Allowance
	EP EP	EP1786471	29/07/2005	Intention to Grant
	EP	EP2269461	24/09/2010	Examination Response
			, ,	
Methods and materials for providing cardiac cells	USA	US 11/674,461	3/02/2007	Office Actions
	T			
	Australia	2009257801		Granted
	Australia	2013201427		Granted
	Australia	2013201429		Examination Report
	Brazil	PI0912292-3		Filed & Published
	Canada	20092724694)		Filed & Published
	China	200980118954)		Granted
	China Div	20130269183.2)		Filed
	Europe	09763198.0		Filed & Published
Compositions and methods for using cells to treat heart tissue	Hong Kong	1152225A / 11104901.7	20/05/2009	Granted
J	Hong Kong Div	TBC / 1410337.4		Filed & Published
	Israel	209555		Granted
	Israel Div 1	223453		Granted
	Israel Div 2	TBC		Filed
	India	08393CN2010 / 2010CN08393		Filed & Published
	Japan	2011521645 / 20110511722		Filed & Published
	Mexico	2010012998		Granted
	Mexico	MX/a/2014/006017)		Filed
	New Zealand	589415		Granted
	New Zealand Div1	600920		Granted

¹ Situation: 26 January 2015.

	7			1
	New Zealand Div 2	607933		Filed
	Russia	201053243		Granted
	Singapore	166319 / 201008105-7		Granted
	Singapore Div	179523 / 201202077-2		Filed & Published
	South Africa	2010/08046		Granted
	South Africa Div 1	2011/09313		Granted
	South Africa Div 2	TBC / 2013/04418		Filed
	South Korea	20110034617 / 20107029313		Filed & Published
	United States	US 8,835,384 / 12/994,626		Granted
	United States Div	TBD / 14/453,231		Filed
	Thailand	TBC / 0901002241		Filed
	1		1	
	Australia	TBC / 2010249821		Filed
	Brazil	TBC/PI1010684-7		Filed
	Canada	TBC / 2,761,807		Filed
	China	CN 102498399 / 201080021551.6		Filed
	Europe	2433125 / 10721224.3		Filed
Method for determining the	Israel	TBC/ 216368	20/05/2010	Filed
cardio-generative potential of mammalian cells	Japan	2012-527245/2012-512038		Filed
mammalian cells	New Zealand	595919 / 595919		Granted
	Russia	TBC / 2011143063		Filed
	South Korea	TBC / 10-2011-7027716		Filed
	USA	TBC / US 13/321100		Filed & Published
	Taiwan	·		Filed & Published
	Talwall	201105965 / 099116051		Filed & Published
	D. L. L.	DE4.04.0E24 / DE2.000/0274	20/04/2000	Control
	Belgium	BE1018521 / BE2009/0271	29/04/2009	Granted
	Australia	TBC / 2010243530		Filed
	Brazil	TBC/ PI1014628-8)		Filed
	Canada	TBC/2,777,475		Filed
	China	CN 102596304 A / 201080018740.8		Filed & Published
	Europe	2424606 / 10719593.5		Filed & Published
	Hong Kong	12102411.3/12102411.3		Filed
	India	TBC / 2286/MUMNP/2011		Filed
Injection catheter for delivering	Israel	215815/215815		Granted
a therapeutic agent into a	Japan	TBC/ JP 2012-507775	29/04/2010	Filed
substrate	Mexico	TBC / 2011011008		Filed
	New Zealand	TBC / 595721		Granted
	Russia	TBC / 201141789		Filed
	Singapore	TBC / 201107670-0		Filed
	Singapore Div	TBC / 10201404282T		Filed
	South Korea	TBC / 10-2011-7028533		Filed
	USA	TBC / US 13/265,961)		Filed
	Taiwan	201043283 / 099113613		Filed & Published
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	Australia	TBC / 2010251151)	4	Filed
	Brazil	TBC/PI1012116-1	4	Filed
	Canada	TBC / 2,762,584	4	Filed
	China	CN 10248636 / 201080021110.6	4	Filed
	Europe	2432482 / 10723556.6	4	Filed
	Hong Kong	12103832.2/12103832.2	1	Filed
Pharmaceutical composition for	India	TBC / 2358/MUMNP/2011	1	Filed
the treatment of heart diseases	Israel	216399 / 216399	20/05/2010	Filed
and dedunient of fical tuiseases	Japan	2012-527432/2012-511301	_	Filed
	Mexico	TBC / MX/a/2011/012183		Filed
	New Zealand	TBC / 596162		Granted
	New Zealand Div	TBC / TBC	1	Filed
	Russia	TBC / 2011145370	1	Filed
	Singapore	TBC / 201108107-2)	1	Filed
	South Korea	TBC / 10-2011-7028912	1	Filed
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	Thailand	TBC / 1101003209		Filed
	USA	US20120128638A1 / US 13/321224		Filed
	Taiwan	201108935 / 099116052		Filed & Published
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Biomarker Methods and Compositions	None	WO 2014/096248 / PCT/EP2013/077476	19/12/2013	Filed & Published
Steering Control Mechanism for	United Kingdom	TBC / 1306341.7		Filed
Catheter	None	WO 2014/166968 / PCT/EP2014/057093		Filed & Published
Therapeutic targets and agents	EP	EP 13197532.8	16-déc-13	Examination Pending
useful in treating ischemia	EP	PCT/EP2014/062890	18-juin-14	International Search Report
reperfusion injury	JP	JP 2013-262642	19-déc-13	Requesting Examination
	T	T	T	T
	Europe	128228509		Pending Examination
	USA	13/442,230		Office Actions
	USA	13/570,347		Office Actions
Introductory assembly and	Brazil	1120140028036	9-août-14	Pending Examination
method for inserting	Canada	2844285	9-a0ut-14	Pending Examination
intracardiac instruments	Mexico Russian	MXa2014001480		Pending Examination
	Federation	2014105115		Pending Examination
	Republic of Korea	1020147005899		Pending Examination
	USA	14/174,212	6-févr-14	Pending Examination
Closure system for atrial wall	USA	14/065,613	29/OCT/2013	Pending Examination
Closure system for atrial wall	PCT	PCTUS1462856	29/OCT/2014	Entering National Phase 2016
	1104	42/504 007	20	Office Actions
Device and method for treating	USA	13/691,087	30-nov-12	Office Actions
heart valve malfunction	USA PCT	13/967,647 PCTUS1370972	15-août-13 20/11/2013	Pending Examination Entering National Phase 2015
	101	1 01031370372	20/11/2013	Littering National Friase 2015
	US	13/714,989	14-déc-12	Pending Examination
Assembly and method for left	US	13/838,199	15/mar/2013	Pending Examination
atrial appendage occlusion	PCT	PCTUS1370254	15-nov-13	Entering National Phase 2015
System for treating heart valve	US	14/090,383	26-nov-13	Pending Examination
malfunction including mitral regurgitation	PCT	PCTUS1467264	25-nov-14	Entering National Phase 2016
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Pericardial cutting assembly	US	13/875,664	2/may/2013	Office Actions
Pericardial cutting assembly	PCT	PCTUS1436487	2/may/2014	Entering National Phase 2015
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	USA	PCT/US2005/031100	31/08/2005	Filed
Chimeric NK receptor and	USA	US 11/575,878	19/04/2007	Granted
methods for treating cancer	USA	US 12/407,440	19/03/2009	Pending
	USA	US 13/155,909	8/06/2011	Granted
	USA	US 13/502,978	29/10/2010	Pending
	USA	US 13/459,664	30/04/2012	Pending
	USA	PCT/US2013/038921	30,0 1,2012	Entered National Phases
	Europe	EP13784744.8		Pending
	Canada	CA2871955		Pending
T cell receptor-deficient T cell	Australia	AU2013256424		Pending
compositions	Mexico	MX/a/2014/013118		Pending
,	India	2530/KOLNP/2014	30/04/2013	Pending
	Brazil	BR112014027155-0		Pending
	China	TBC		Entered National Phase
	Japan	TBC		Pending
	Russia	TBC		Pending
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	USA	PCT/US2013/039812	7/05/2012	Entered National Phases	
Anti-B7-H6 antibody, fusion proteins, and methods of using the same	ion Europe	EP13787935.9		Pending	İ
	using USA	US 14/399,835	7/05/2013	Pending	İ
	China	TBC	//05/2013	Pending	
	Japan	Not Available		Pending	İ

Trade Secrets

In addition to our patents and patent applications, we keep certain of our proprietary information as trade secrets, which we seek to protect by confidentiality agreements with our employees and third parties, and by fragmenting know-how between different individuals, in accordance with standard industry practices.

Trademarks & Designs

On the date of this Prospectus, the Company has notably sought protection on the "C-Cure", "C-Cath", "Cath $_{\rm ez}$ " names as well as the Company name and logo by having these registered, or is in the process of registering these names as trademarks in most relevant countries, including but not limited to all European Union Member States (EU Community trademark) and the US. Trademark protection for "C-Cure" was applied for but refused in Russia and China. The Company also applied in April 2013 for a European Community design right covering its proprietary "-Cath $_{\rm ez}$ " catheter handle.

The name "C-Cure" used by the Company to describe the first autologous cardiopoietic cell therapy clinical trial for HF and by extension, the cardiopoietic cell therapy program itself, is not being used in the commercialisation of any product. In most countries, including the European Union and the US, prior regulatory clearance by the competent authorities of the commercial name(s) of a pharmaceutical product is required. In view of the therapeutic connotations of the word "C-Cure", the Company is likely not to be authorized to use this mark to identify its products or services

Conflicts and litigation concerning Intellectual Property

As of the date of this Prospectus and as far as the Company is aware, its intellectual property has not been challenged otherwise than by patent offices in the normal course of examination of its patent applications or misappropriated. The Company received a "cease and desist" request letter from SMB SA (Belgium) for the C-Cure trademark limited to the Benelux market in the event it would be authorized by EMA to use this trademark for an approved pharmaceutical product.

Competition

The industry in which we operate is subject to rapid technological change. We face competition from pharmaceutical, biopharmaceutical and medical devices companies, as well as from academic and research institutions. Some of these competitors are pursuing the development of medicinal products and other therapies that target the same diseases and conditions that we are targeting.

Some of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety and convenience.

C-Cure

We have identified several companies that are active in cardiac cell therapy as of the date of this prospectus, including Aldagen, Inc., Athersys, Inc., Cytori Therapeutics, Inc., Mesoblast Ltd and Vericel Corporation.

CAR T-Cell Therapy

Early results from clinical trials have fueled continued interest in CAR T-cell therapies and our competitors include Bellicum Pharmaceuticals, Inc., bluebird bio, Inc., Cellectis S.A., Juno Therapeutics, Inc., Kite Pharma Inc., Novartis AG and Ziopharm Oncology, Inc.

13.8 Government Regulation

13.8.1 Drug development

Government authorities in the European Union, in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labelling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, or biologics, such as our drug product candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and an application for marketing authorization must be approved by the regulatory authority.

Certain products may be comprised of components that are regulated under separate regulatory authorities and by different centers at the FDA. These products are known as combination products. A combination product is comprised of a combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, a device, and a biological product. Under regulations issued by the FDA, a combination product includes:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, device, or biological packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

One of our drug product candidates is a combination product that is comprised of a biologic and a device (an endocardial injection catheter) that is used for delivery of the biologic. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product, which means the single mode of action that provides the most important therapeutic action of the combination product, i.e., the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biologic product, that is, if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, the FDA center responsible for premarket review of the biologic product (the Center for Biologics Evaluation and Research, or CBER) would have primary jurisdiction for the combination product. CBER is the agency component with primary jurisdiction for the premarket review and regulation for our C-Cure investigational product. Because C-Cure utilizes a catheter as a delivery system to the heart, CBER may consult or collaborate with the agency center that is responsible for the premarket review of that device, the Center for Devices and Radiological Health, or CDRH.

U.S. Biological Product Development

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or withdrawals from the market,

product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our drug product candidates must be approved by the FDA through the Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices, or GCPs, and other clinical trial-related regulations to establish the safety and efficacy of the proposed drug product candidate for its proposed indication;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the BLA;
 and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

The data required to support a BLA is generated in two distinct development stages; pre-clinical and clinical. The preclinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the preclinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, as well as other information, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug product candidate at any time before or during clinical trials due to safety concerns, non-compliance, or other issues affecting the integrity of the trial. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated. Where a trial is conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research, prior to the submission of an IND to the FDA, a protocol and related documentation is submitted to and the trial is registered with the NIH Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, however many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. The NIH is responsible for convening the Recombinant NDA Advisory Committee, or RAC, a federal advisory committee, which discusses protocols that raise novel or particularly important scientific, safety or ethical considerations at one of its quarterly public meetings. The OBA will notify the FDA of the RAC's decision regarding the necessity for full public review of a gene therapy protocol. RAC proceedings and reports are posted to the OBA web site and may be accessed by the public.

The clinical stage of development involves the administration of the drug product candidate to healthy volunteers and patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be

reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of trial-related information, and it is possible that data and other information from trials involving biologics that never garner approval could in the future require disclosure. In addition, publication policies of major medical journals mandate certain registration and disclosures as a pre-condition for potential publication, even if not currently mandated as a matter of law. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap. Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the drug product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug product candidate and, if possible, to gain early evidence on effectiveness. Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase 3 clinical trials generally involve large numbers of patients at multiple sites, in multiple countries, and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the biologic, findings from animal or in vitro testing that suggest a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified where organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug product candidate does not undergo unacceptable deterioration over its shelf life.

Following trial completion, trial data are analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the drug product candidate, and other relevant information. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application may include both negative or ambiguous results of pre-clinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. PDUFA also imposes an annual product fee for human drugs and an annual establishment fee on facilities used to manufacture prescription drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Once a BLA has been accepted for filing, which occurs, if at all, sixty days after the BLA's submission, the FDA's goal is to review BLAs within 10 months of the filing date for standard review or six months of the filing date for priority review, if the application is for a product intended for a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness. The review process is often significantly extended by FDA requests for additional information or clarification.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed drug product candidate is safe and effective for its intended use, and whether the drug product candidate is being manufactured in accordance with cGMP to assure and preserve the drug product candidate's identity, strength, quality, purity and potency. The FDA may refer applications for novel drug product candidates or drug product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely reanalyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of a BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase IV testing which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of

approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and non-clinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product concurrently with, or at any time after, submission of an IND, and the FDA must determine if the product qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review, or review within a six-month timeframe from the date a complete BLA is accepted for filing, if it has the potential to provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review.

Additionally, a product may be eligible for accelerated approval. An investigational drug may obtain accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions as it deems necessary to assure safe use of the drug, such as:

- distribution restricted to certain facilities or physicians with special training or experience; or
- distribution conditioned on the performance of specified medical procedures.

The limitations imposed would be commensurate with the specific safety concerns presented by the product. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Breakthrough Designation

The Food and Drug Administration Safety and Innovation Act, or FDASIA, amended the FDCA to require the FDA to expedite the development and review of a breakthrough therapy. A product can be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a drug product candidate be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the drug product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather pre-clinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an

efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable.

Pediatric Trials

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. FDASIA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers.

Post-Marketing Requirements

Following approval of a new product, a manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP requirements for constituent parts of cross-labeled combination products that are manufactured separately and not co-packaged are the same as those that would apply if these constituent parts were not part of a combination product. For single-entity and co-packaged combination products, there are two ways to demonstrate compliance with cGMP requirements, either compliance with all cGMP regulations applicable to each of the constituent parts included in the combination product, or a streamlined approach demonstrating compliance with either the drug/biologic cGMPs or the medical device quality system regulation rather than demonstrating full compliance with both, under certain conditions. These conditions include demonstrating compliance with specified provisions from the other of these two sets of cGMP requirements. Because the C-Cure device comprises a biologic and a cathether that are not co-packaged, we need to comply with the cGMPs requirements for each constituent part. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result

in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-approval testing, sometimes referred to as Phase IV testing, risk minimization action plans and post-marketing surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with federal and state fraud and abuse laws, data privacy and security laws, transparency laws, and pricing and reimbursement requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable childresistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or

BPCI Act, which was part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. This amendment to the PHSA attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times, that the product and the reference product may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. However, complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted twelve years of exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after first licensure. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. This does not include a supplement for the biological product or a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, unless that change is a modification to the structure of the biological product and such modification changes its safety, purity, or potency. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which attaches to both the twelve-year and four-year exclusivity periods for reference biologics, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

European Union Drug Development

In the European Union, our future drug product candidates will also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization, or MA, from the competent regulatory agencies has been obtained.

Clinical Trials

Similar to the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the European Union clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the European Union Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, a new Regulation No. 536/2014 on clinical trials on medicinal drug product candidates for human use, which repealed Directive 2001/20/EC, was adopted on 16 April 2014, and published in the European Official Journal on 27 May 2014. The new Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency. The new Regulation entered into force on 16 June 2014, but will apply not earlier than 28 May 2016. Until then the Clinical Trials Directive 2001/20/EC will still apply. In addition, the transitory provisions of the new Regulation offer the sponsors the possibility to choose between the requirements of the Directive and the Regulation for one year from the entry into application of the Regulation.

Under the current regime, before a clinical trial can be initiated it must be approved in each of the European Union countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. More specifically, a clinical trial may not be started until the relevant EC has issued a favorable opinion, and the NCA has not informed the Sponsor of the trial of any grounds for non-acceptance or confirmed that no such grounds exist. Approval will only be granted if satisfactory information demonstrating the quality of the investigational agent and its non-clinical safety has been provided, together with a study plan that details the manner in which the trial will be carried out.

ECs determine whether the proposed clinical trial will expose participants to unacceptable conditions of hazards, while considering, among other things, the trial design, protocol, facilities, investigator and supporting staff, recruitment of clinical trial subjects, the Investigator's Brochure, or IB, indemnity and insurance, etc. The EC also determines whether

clinical trial participants have given informed consent to participate in the trial. Following receipt of an application (which must be submitted in the national language), ECs must deliver their opinion within 60 days (or sooner if the Member State has implemented a shorter time period). For clinical trials of gene therapy, somatic cell therapy, and all medicinal products containing genetically modified organisms, this timeline may be extended (with an additional 120 days).

Similarly, a valid request for authorization (in the national language) must be submitted to the NCA of each Member State where the trial will be conducted. Sponsors must be notified of the decision within 60 days of receipt of the application (unless shorter time periods have been fixed), in the absence of which, the trial is considered approved. However, for clinical trials of gene therapy, somatic cell therapy, and all medicinal products containing genetically modified organisms, a written authorization by the competent NCA is required. Similar timeline extensions as for ECs exist.

Studies must comply with ethical guidelines and Good Clinical Practice (GCP) guidelines. Monitoring of adverse reactions that occur during clinical trials, including, where applicable, notification of the same to the competent NCA and ECs, is also required. Trials can be terminated early if a danger to human health is established or continuing the trial would be considered unethical. Consequently, the rate of completion of clinical trials may be delayed by many factors, including slower than anticipated patient enrollment or adverse events occurring during clinical trials.

Drug Review and Approval

In the European Economic Area, or EEA (which is comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

The Centralized MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines, and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions, and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in other Member State(s) through the Mutual Recognition Procedure, or MRP. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure, or DCP. Under the DCP an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of product characteristics, or SmPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States, or CMSs) for their approval. If the CMSs raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the relevant Member States (i.e. in the RMS and the CMSs).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Marketing Authorization Application

Following positive completion of clinical trials, pharmaceutical companies can submit a MA application. The MA application shall include all information that is relevant to the evaluation of the medicinal products, whether favorable or unfavourable. The application dossier must include, among other things, the results of pharmaceutical (physicochemical, biological, or microbiological) tests, preclinical (toxicological and pharmacological) tests, and clinical trials, including the therapeutic indications, contra-indications, and adverse reactions, and the recommended dosing regimen or posology.

In addition to demonstrating the safety and efficacy of the medicinal product, pharmaceutical companies are required to guarantee the consistent quality of the product. Therefore, the conditions for obtaining a MA include requirements

that the manufacturer of the product complies with applicable legislation including Good Manufacturing Practice, or GMP, related implementing measures and applicable guidelines that involve, amongst others, ongoing inspections of manufacturing and storage facilities.

Early Access Mechanisms

Several schemes exist in the EU to support earlier access to new medicines falling within the scope of the Centralized Procedure, in particular (i) accelerated assessment; (ii) conditional MAs; and (iii) MAs granted under exceptional circumstances.

For a medicine which is of "major public health interest" (in particular, in terms of therapeutic innovation), accelerated assessment can be requested, taking up to 150 days instead of the usual period of up to 210 days. There is no single definition of what constitutes major public health interest. This should be justified by the applicant on a case-by-case basis. The justification should present the arguments to support the claim that the medicinal product introduces new methods of therapy or improves on existing methods, thereby addressing to a significant extent the greater unmet needs for maintaining and improving public health.

Conditional MAs may be granted on the basis of less complete data than usual in order to meet unmet medical needs of patients and in the interest of public health, subject to specific obligations with regard to further studies and intended to be replaced by a full unconditional MA once the missing data is provided. A conditional MA is valid for one year on a renewable basis.

Medicines for which the MA applicant can demonstrate that the normally required comprehensive efficacy and safety data cannot be provided (for example because the disease which the medicine treats is extremely rare) may be eligible for a MA under exceptional circumstances. These are medicines for which it is never intended that a full MA will be obtained. MAs under exceptional circumstances are reviewed annually to reassess the risk-benefit balance.

Supplementary Protection Certificates and data/market exclusivity

In Europe, the extension of effective patent term to compensate originator pharmaceutical companies for the period between the filing of an application for a patent for a new medicinal product and the first MA for such product, has been achieved by means of a Supplementary Protection Certificate (SPC) which can be applied for by the originator pharmaceutical company within 6 months from the granting of the first MA and comes into effect on expiry of the basic patent. Such SPC attaches only to the active ingredient of the medicinal product for which the MA has been granted. The SPC for an active ingredient has a single last potential expiry date throughout the EEA, and cannot last for more than five years from the date on which it takes effect (i.e., patent expiry. Furthermore, the overall duration of protection afforded by a patent and a SPC cannot exceed 15 years from the first MA. The duration of a medicinal product SPC can be extended by a single six-month period, or pediatric extension, when all studies in accordance with a pediatric investigation plan, or PIP, have been carried out.

Innovative medicines benefit from specific data and marketing exclusivity regimes. These regimes are intended to provide general regulatory protection to further stimulate innovation. The current rules provide for (i) an 8-year data protection (from the MA of an innovative medicine) against the filing of an abridged application for a follow-on product, referring to the data supporting the MA of the innovative medicine (data exclusivity); and (ii) a 10-year protection against the marketing of a follow-on product (marketing exclusivity), with a possible extension by 1 year if, during the first 8 years, a new therapeutic indication (which is considered to bring a significant clinical benefit in comparison with existing therapies) is approved. This protection is often referred to as the "eight, plus two, plus one" rule. Additional reward mechanisms exist, most notably a 10-year orphan medicines' marketing exclusivity, and a 1-year data exclusivity for developing a new indication for an old substance and for switch data supporting a change in prescription status.

The current rules also provide for a system of obligations and rewards and incentives intended to facilitate the development and accessibility of pediatric medicinal products, and to ensure that such products are subject to high quality ethical research. Pursuant to such rules, pharmaceutical companies are often required to submit a Pediatric Investigation Plan, or PIP, at a relatively early stage of product development, which defines the pediatric studies to be completed before a MA application can be submitted. Upon completion of the studies in the agreed PIP, the company may be entitled to a "reward", *i.e.*, the afore-mentioned 6-month pediatric extension of the SPC for non-orphan medicinal products; or a two-year extension of the 10-year marketing exclusivity period for orphan medicines.

Post-marketing and pharmacovigilance requirements

When granting a MA, competent authorities (i.e., the EMA or the relevant NCAs) may impose an obligation to conduct additional clinical testing, sometimes referred to as Phase IV clinical trials, or other post-approval commitments, to monitor the product after commercialization. Additionally, the MA may be subjected to limitations on the indicated uses for the product.

Also, after a MA has been obtained, the marketed product and its manufacturer and MA holder will continue to be subject to a number of regulatory obligations, as well as to monitoring/inspections by the competent authorities.

Under applicable pharmacovigilance rules, pharmaceutical companies must, in relation to all their authorized products, irrespective of the regulatory route of approval, collect, evaluate and collate information concerning all suspected adverse reactions and, when relevant, report it to the competent authorities. This information includes both suspected adverse reactions signaled by healthcare professionals, either spontaneously or through post-authorization studies, regardless of whether or not the medicinal product was used in accordance with the authorized SmPC and/or any other marketing conditions, and suspected adverse reactions identified in worldwide-published scientific literature. To that end, a MA holder must have (permanently and continuously) at its disposal an appropriately qualified person responsible for pharmacovigilance and establish an adequate pharmacovigilance system. All relevant suspected adverse reactions, including suspected serious adverse reactions, which must also be reported on an expedited basis, should be submitted to the competent authorities in the form of Periodic Safety Update Reports, or PSURs. PSURs are intended to provide an update for the competent authorities on the worldwide safety experience of a medicinal product at defined time points after authorization. PSURs must therefore comprise a succinct summary of information together with a critical evaluation of the risk/benefit balance of the medicinal product, taking into account any new or changing information. The evaluation should ascertain whether any further investigations need to be carried out, and whether the SmPC or other product information needs to be modified.

To ensure that pharmaceutical companies comply with pharmacovigilance regulatory obligations, and to facilitate compliance, competent authorities will conduct pharmacovigilance inspections. These inspections are either routine (i.e. aimed at determining whether the appropriate personnel, systems, and resources are in place) or targeted to companies suspected of being non-compliant. Reports of the outcome of such inspections will be used to help improve compliance and may also be used as a basis for enforcement action.

Other regulatory matters

Advertising of medicines is subject to tighter controls than general consumer goods and specific requirements are set forth in Directive 2001/83/EC, which apply in addition to the general rules. In general, advertising of unapproved medicinal products or of unapproved uses of otherwise authorized medicinal products (e.g., off-label uses) is prohibited, and advertising for prescription medicinal products must be directed only towards health care professionals (i.e., advertising of these products to the general public is prohibited). Member States have implemented the advertising rules differently and the requirements vary significantly depending on the specific country. Advertising of medicinal products in an online setting, including social media, can be particularly challenging given the strict rules in place.

13.8.2 Pricing & Reimbursement

United States

Sales of our products will depend, in part, on the extent to which our products, once approved, will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product, including a biologic, typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any drug product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the drug product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our drug product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs, including biologics, have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment

measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug product candidate or a decision by a third-party payor to not cover our drug product candidate could reduce physician usage of the drug product candidate and have a material adverse effect on our sales, results of operations and financial condition.

For example, the ACA, enacted in March 2010, has had, and is expected to continue to have, a significant impact on the health care industry. The ACA has expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program. We cannot predict the full impact of the ACA on bio-pharmaceutical companies as many of the ACA reforms require the promulgation of additional detailed regulations implementing the statutory provisions which has not yet completely occurred. Further, new legislation is currently pending before the U.S. Supreme Court seeking to invalidate certain provisions of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On 2 August 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On 2 January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country.

European Union

In Europe, pricing and reimbursement for pharmaceutical products are not harmonized and fall within the exclusive competence of the national authorities, provided that basic transparency requirements (such as maximum timelines) defined at the European level are met as set forth in the EU Transparency Directive 89/105/EEC. A Member State may approve a specific price for a medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. For example, in France, effective access to the market assumes that our future products will be reimbursed by social security. The price of medications is negotiated with the Economic Committee for Health Products, or CEPS.

As a consequence, reimbursement mechanisms by public national healthcare systems, or private health insurers also vary from country to country. In public healthcare systems, reimbursement is determined by guidelines established by the legislator or a competent national authority. In general, inclusion of a product in reimbursement schemes is dependent upon proof of the product efficacy, medical need, and economic benefits of the product to patients and the healthcare system in general. Acceptance for reimbursement comes with cost, use and often volume restrictions, which again vary from country to country.

The pricing and reimbursement level for medicinal products will depend on the strength of the clinical data set and, as for most novel therapies, restrictions may apply. In most countries, national competent authorities ensure that the prices of registered medicinal products sold in their territory are not excessive. In making this judgment, they usually compare the proposed national price either to prices of existing treatments and/or to prices of the product at issue in other countries - so-called "international reference pricing" - also taking into account the type of treatment (preventive, curative or symptomatic), the degree of innovation, the therapeutic breakthrough, volume of sales, sales forecast, size of the target population and/or the improvement (including cost savings) over comparable treatments. Given the growing burden of medical treatments on national healthcare budgets, reimbursement and insurance coverage is an important determinant of the accessibility of medicines.

The various public and private plans, formulary restrictions, reimbursement policies, patient advocacy groups, and cost-sharing requirements may play a role in determining effective access to the market of our product candidates. The national competent authorities may also use a range of policies and other initiatives intended to influence pharmaceutical consumption. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our drug product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be priced at a significantly lower level.

13.8.3 Other Healthcare Laws and Compliance Requirements

Our business operations in the United States and our arrangements with clinical investigators, healthcare providers, consultants, third-party payors and patients may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws. These laws may impact, among other things, our research, proposed sales, marketing and education programs of our drug product candidates that obtain marketing approval. The laws that may affect our ability to operate include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, an item, good, facility or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which impose penalties and provide for civil whistleblower or qui tam actions against individuals and entities for, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, obtaining money or property of the health care benefit program through false representations, or knowingly and willingly falsifying, concealing or covering up a material fact, making false statements or using or making any false or fraudulent document in connection with the delivery of or payment for healthcare benefits or services.
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interest held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements on covered entities and their business associates relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

The ACA broadened the reach of the federal fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and certain applicable federal criminal healthcare fraud statutes. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant administrative, civil, and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they

also may be subject to administrative, civil, and/or criminal sanctions, including exclusions from government funded healthcare programs.

13.9 Employees

As of the date of the prospectus, we employed 82 full-time and three part-time employees, including 75 in research and development and 10 in general and administrative. Fourteen of our employees have either an M.D. or a Ph.D. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

The table below summarises the evolution of employment (Full Time Equivalent) since 2013.

	2014	2013
Research and development	66	46
Administrative	9	5
Total	75	51

13.10 Facilities

We rent a 1,120 square meter office and laboratory space from the Axis Parc developer located at the Axis Parc in Mont-Saint-Guibert pursuant to a lease agreement dated 31 October 2007, as amended from time to time, which expires on 30 September 2017. In addition, clean-room environments are available to use from Biological Manufacturing Services SA in the same building pursuant to a service agreement dated 11 April 2011, which will automatically renew for three years on 31 December 2015. We believe that our current office and laboratory space is sufficient to meet our clinical needs until the expiration of our lease.

We plan to identify additional facilities in the Flemish region of Belgium to construct our contemplated future European manufacturing plant. We have committed to maintain our headquarters and registered office in the Walloon region of Belgium and all of our existing activities will continue to be performed in the Walloon region.

13.11 Legal Proceedings

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

14 MANAGEMENT AND GOVERNANCE

14.1 Our board of directors

Board composition

Pursuant to the Belgian Company Code, we are managed by a board of directors acting as a collegiate body. We have opted for a one-tier governance structure. Pursuant to the Belgian Company Code, the board of directors is our ultimate decision-making body, except with respect to those areas that are reserved by law or by our articles of association to the shareholders' meeting.

Under our articles of association, our board of directors must be composed of at least three members, who may be natural persons or legal entities. Under our corporate governance charter and in accordance with the Belgian Corporate Governance Code, at least half of the board members must be non-executive directors and at least three must be independent directors as defined by the Belgian Company Code. Subject to this, the number of directors is determined by our shareholders. Directors are elected, re-elected and may be removed at a shareholders' general meeting with a simple majority vote of our shareholders.

Pursuant to the Belgian Company Code, if the mandate of a director becomes vacant, the remaining directors have the right to temporarily appoint a new director to fill the vacancy until the first shareholders' meeting after the mandate became vacant. The new director completes the term of the director whose mandate became vacant.

Pursuant to our corporate governance charter, our directors are elected for a maximum term of four years.

Under our articles of association, PMV-TINA Comm. V and Sofipôle SA are each entitled to nominate a candidate for appointment as a member of the our board of directors as long as such entity (or any of its affiliates) continues to hold a minimum number of shares. As of 31 December 2014, the number of shares was 427,929 shares for PMV-TINA and 495,879 shares for Sofipôle).

The following table sets forth certain information with respect to the current members of our board of directors, including their ages, as of 15 March 2015:

Name	Age	Term(1)	Position(s)
Michel Lussier ⁽²⁾	58	2016	Chairman of the board of directors
LSS Consulting SPRL, represented by its permanent representative Christian Homsy	56	2016	Executive Director, CEO
William Wijns	63	2016	Non-executive Director
Pienter-Jan BVBA, represented by its permanent representative Chris Buyse $^{(2,\ 3)}$	50	2016	Independent Director
R.A.D. Life Sciences BVBA, represented by its permanent representative Rudy Dekeyser $^{(2, 3)}$	53	2016	Independent Director
Jean-Marc Heynderickx	56	2019	Independent Director
Chris De Jonghe ⁽³⁾	42	2017	Non-executive Director
Hanspeter Spek ⁽²⁾	65	2018	Independent Director
Danny Wong	52	2018	Non-Executive Director
Serge Goblet	57	2016	Non-Executive Director
TOLEFI SA, represented by its permanent representative Serge Goblet	57	2018	Non-Executive Director

The term of the mandates of the directors will expire immediately after the annual meeting of shareholders held in the year set forth next to the director's name, except for Jean-Marc Heynderickx's mandate which will expire on 31 January 2019 and Chris De Jonghe's mandate which will expire on 25 September 2017.

(2) Member of the nomination and remuneration committee.

Unless otherwise stated, the address for our directors is Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

The following is the biographical information of the members of our board of directors or of their permanent representatives:

Michel Lussier has served as Chairman of our board of directors since 2007 and is also our co-founder. Mr. Lussier was also the Chairman of the board of directors and co-founder of our predecessor entity, Celyad SA, until 2008. Mr. Lussier recently founded Medpole Ltd, the North American satellite of MedPole SA, a European incubator for medical technology start-up companies located in Belgium, and serves as the Chief Executive Officer for the group. In this capacity, he is a managing director of Fjord Ventures, a Laguna Hills, California based medical technology accelerator / incubator. Since May 2014, Mr. Lussier has served as the Chief Executive Officer of Metronom Health Inc, an early stage medical device company created by Fjord Ventures, developing a continuous glucose monitoring system. Prior to that, from 2002 to 2013, he worked for Volcano Corporation, where he served in a number of positions, most recently as President, Clinical and Scientific Affairs from 2012 to 2013, and prior to that from 2007 to 2012, Group President, Advanced Imaging Systems, Global Clinical & Scientific Affairs and General Management of Europe, Africa and the Middle East. Mr. Lussier obtained a Bachelor of Sciences degree in Electrical Engineering and Master's degree in Biomedical Engineering at the University of Montreal. He also holds an MBA from INSEAD (European Institute of Business Administration), France. In addition to serving on our board of directors, he also serves on the boards of directors of several early stage medical devices companies.

Christian Homsy (representative of LSS Consulting SPRL) has served as a member of our board of directors since 2007 and has been our Chief Executive Officer since its inception. Mr. Homsy gained his business experience in senior research and development, marketing, business development and sales positions at Guidant Corporation, a leading medical device company active in the treatment of cardiovascular disease. He was also founder of Guidant Institute for Therapy Development, a landmark facility for physician and health care professionals' education. Before joining us, Mr. Homsy was General Manager of Medpole, a European incubator dedicated to initiating the European operations for start-up companies in the medical device or biotechnology fields. He also holds a director mandate in Medpole SA. Mr. Homsy obtained his Medical Doctorate at the University of Louvain and holds an M.B.A. from the IMD (International Institute for Management Development) in Lausanne (Switzerland).

William Wijns has served as a member of our board of directors since 2007 and is also our co-founder. Since 1994, Dr. Wijns has been the co-Director of the Cardiovascular Center Aalst and active as an interventional cardiologist. More recently, he has been involved with the clinical applications of non-invasive coronary angiography with the use of multislice computed tomography as well as innovative therapies for cardiovascular diseases, including heart failure. He has authored 500 publications in peer-reviewed journals and holds several positions in national and international professional and scientific organizations. He is currently Deputy Editor of the European Heart Journal (impact factor 14,723). Dr. Wijns previously worked at the Thorax Center in Rotterdam, where he was actively involved with the first applications of nuclear cardiology, thrombolysis and coronary dilatation, and the University of Louvain in Brussels, where he directed the cardiac PET program and became Clinical Professor of Cardiology. His research there focused on the regulation of coronary blood flow and cardiac metabolism in ischemic heart disease. Dr. Wijns graduated in 1976 from the University of Louvain in Belgium where he trained as a cardiologist until 1981. In the past five years, he has held board memberships in the European Society of Cardiology and the World Heart Federation. He is currently Chairman of PCR, co-Director of Africa PCR and EuroPCR, the official congress of the European Association of Percutaneous Cardiovascular Interventions.

Serge Goblet (permanent representative of TOLEFI SA) has served as a member of our board of directors since 2008. He holds a Master Degree in Business and Consular Sciences from ICHEC Brussels Management School, Belgium and has many years of international experience as director in Belgian and foreign companies. He is the managing director of TOLEFI SA, a Belgian holding company, and holds director mandates in subsidiaries of TOLEFI. Mr. Goblet has two voting rights at our board of directors, one in his own name and one on behalf of TOLEFI SA, as its permanent representative.

Chris Buyse (permanent representative of Pienter-Jan BVBA) has served as a member of our board of directors since 2008. He brings more than 25 years of international financial expertise and experience in introducing best financial management practices. He is currently Managing Director of Life Sciences Research Partners VZW, a non-profit organization supporting and investing in innovative companies active in life sciences. He is also setting up Fund+NV/SA, a fund that will be investing in Belgian biotech companies. Between August 2006 and June 2014, Mr. Buyse served as the Chief Financial Officer and board member of ThromboGenics NV, a leading biotech company that is listed on NYSE Euronext Brussels. Before joining ThromboGenics, he was the Chief Financial Officer of the Belgian biotech company CropDesign, where he coordinated the acquisition by BASF in July 2006. Prior to joining CropDesign he was financial

⁽³⁾ Member of the audit committee.

manager of WorldCom/MCI Belux, a European subsidiary of one of the world's largest telecommunication companies and he was also the Chief Financial Officer and interim Chief Executive Officer of Keyware Technologies. Mr. Buyse holds a master degree in applied economic sciences from the University of Antwerp and an MBA from Vlerick School of Management in Gent. He currently serves, in his own name or as permanent representative of a management company, as member of the board of directors of the following publicly and privately held companies: Bone Therapeutics SA, Orgenesis Inc. Iteos SA, Bioxodes SA, Bio Incubator NV, Immo David NV, Pinnacle Investments SA, CreaBuild NV, Sofia BVBA, Pienter-Jan BVBA, Life Sciences Research Partners VZW (a shareholder of the Company) and Keyware Technologies NV.

Rudy Dekeyser (permanent representative of R.A.D. Life Sciences BVBA) has served as a member of our board of directors since 2007. Since 2012, Mr. Dekeyser has been managing partner of the LSP Health Economics Fund, a private equity fund investing in late stage European and North American health care companies. Prior to joining LSP Health Economics Fund, Mr. Dekeyser was managing director of VIB (Flanders Institute for Biotechnology), where he was also responsible for the intellectual property portfolio, business development and new venture activities. He obtained a Ph.D. in molecular biology at the University of Ghent. He holds non-executive director positions in Curetis AG, Sequana Medical AG and Remynd NV, and held non-executive director positions in Devgen NV, CropDesign NV, Ablynx NV, Actogenix NV, Pronota NV, Flandersbio VZW, Bioincubator Leuven NV and Multiplicom NV. He is a co-founder of ASTP (the European associations of technology transfer managers) and Chairman of EMBLEM (EMBL's business arm). Mr. Dekeyser has been an advisor to several seed and venture capital funds and to multiple regional and international committees on innovation.

Jean-Marc Heynderickx has served as a member of our board of directors since 2013. Mr. Heynderickx spent his career in the Louis Delhaize Group of which he was Chief Executive Officer from 1995 to 2010. As such, he was also chairman of sub holding companies in France, Luxemburg and in The Netherlands. In 2006 he co-founded the Budapest Food Bank. From 2000 to 2005, he was board member of Comeos (Fedis) national retail organization and the Charleroi Chamber of Commerce. Mr. Heynderickx is now Chief Executive Officer of Nextgen group, a private venture capital holding managing 18 companies active in Belgium, France, Hungary and Romania. He holds a degree in Marketing from Charleroi University (Belgium) and completed the Solvay executive program in Real Estate. He holds non-executive director positions FRI (First Retail International), Stanley&Stella, Medi-Market, Claris Clinic and CBO Territoria.

Chris De Jonghe has served as a member of our board of directors since 2013. She is Group Manager Venture Capital at PMV (ParticipatieMaatschappij Vlaanderen). She was first Licensing Manager then Business Development Manager of VIB (Flanders Institute for Biotechnology), before joining PMV in 2013, initially as Senior Investment Manager in January 2013. Since August 2013 she joined the Group Management Committee, responsible for daily management at PMV, as Group Manager Venture Capital. She obtained a Ph.D. in Science (Biochemistry) and a Bachelor degree in Laws at the University of Antwerp. She is a member of the board of directors of AgroSavfe NV, eSaturnus NV, Vesalius Biocapital I Sicar and Vesalius Biocapital II Sicar. She is member of Flanders'Bio and IFB Network.

Hanspeter Spek has served as a member of our board of directors since 2014. He started his career at Pfizer where, over more than ten years and after a thorough comprehensive training in commercial general management, he held positions of increasing responsibility. He then joined Sanofi as Marketing Director and rose through the organization to become the Executive Vice President, International in 2000. When Sanofi and Aventis merged in 2004, he took on the responsibility of Executive Vice President, Operations. In 2009, he was nominated President Global Operations. He retired from Sanofi in mid-2013. He has since joined Advent as a Senior Advisor for Healthcare. He continues to serve on the board of Sanofi, Germany, as chairman.

Danny Wong has served as a member of our board of directors since 2014. Since May 2007, Mr. Wong has served as an executive director of the National Investments Fund Limited, and was appointed chairman in June 2007. As the executive director and chairman of National Investments Fund Limited, he is responsible for the strategic development of National Investments Fund Limited. Prior to that from 2001 to 2005, he was the executive director of Sun Hung Kai International Limited, where he was in charge of investment banking and responsible for the public listing of companies, as well as fundraising for private and public companies. Recently, Mr. Wong established Medisun Holdings Limited, a group of companies which commits to the stem cell regenerative bio-medical industry. He holds a Bachelor degree in Economics and Accounting from China Central University of Finance and Economics.

Director Independence

The independence criteria of Article 526ter of the Belgian Company Code can be summarized as follows:

the director has not been an executive member of the board of directors, member of the management board ("directiecomité / comité de direction") (should such corporate body be created) or daily manager of the company (or an affiliate of the company, if any), during a term of five years prior to his or her election;

- the director has not been a non-executive director for more than three consecutive terms or during a period of more than 12 years;
- the director has not been a member of the managerial staff of the company (or an affiliate of the company, if any) during a term of three years prior to his or her election;
- the director does not receive and has not received any remuneration or other significant financial advantage from the company (or an affiliate of the company, if any), other than the profit share ("tantièmes") and remuneration received in his or her capacity as a non-executive director or as a member of the supervisory body;
- the director does not own any corporate rights that represent 10% or more of the share capital, of the corporate funds or of a category of our shares. If the director has corporate rights which represent less than 10%, then:
 - such rights, taken together with rights in the same company held by companies over which the director has control, may not represent 10% or more of the share capital, the corporate funds or of a category of our shares;
 - or the disposal of these shares, or the exercise of the rights attached thereto, may not be subject to agreements or unilateral commitments entered into by the director.
- the independent director in any case cannot represent a shareholder who falls under the conditions set forth in this criterion;
- the director does not and, during the past financial year, did not, have a significant business relationship with the company (or an affiliate of the company, if any), either directly or as a partner, shareholder, member of the board of directors or member of the managerial staff of a company or of a person that maintains such a relationship;
- the director is not and has not been at any time during the past three years, a partner or an employee of our current or former statutory auditor or of a company or person affiliated therewith;
- the director is not an executive director of another company in which an executive director of the company is a non-executive director or a member of the supervisory body, and has no other significant ties with executive directors of the company through his or her involvement in other companies or bodies;
- the director's spouse, unmarried legal partner and relatives (via birth or marriage) up to the second degree do not act as a member of the board of directors, member of the management board ("directiecomité / comité de direction") (should such corporate body be created) or daily manager or member of the managerial staff in the company (or an affiliate of the company, if any), and do not meet one of the criteria set out above.

Role of the Board in Risk Oversight

Our board of directors is primarily responsible for the oversight of our risk management activities and has recently delegated to the audit committee the responsibility to assist our board of directors in this task. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Board Practices

Our board of directors can set up specialized committees to analyze specific issues and advise the board of directors on those issues.

The committees are advisory bodies only and the decision-making remains within the collegial responsibility of the board of directors. The board of directors determines the terms of service of each committee with respect to the organization, procedures, policies and activities of the committee.

Our board of directors has set up and appointed an audit committee and a nomination and remuneration committee. The composition and function of all of our committees will comply with all applicable requirements of the Belgian Company Code, the Belgian Corporate Governace Code, the Exchange Act, the applicable rules of the NASDAQ Stock Market and SEC rules and regulations.

14.2 Committees

Audit Committee

Our board of directors has recently established an audit committee. Our audit committee consists of three members: Pienter-Jan BVBA, represented by its permanent representative, Chris Buyse, R.A.D. Life Sciences BVBA, represented by its permanent representative, Rudy Dekeyser and Chris De Jonghe.

Our board of directors has determined that one member of the audit committee is independent under Rule 10A-3 of the Exchange Act and the applicable rules of the NASDAQ Stock Market and that Chris Buyse qualifies as an "audit committee financial expert" as defined under the Exchange Act.

As a result we plan to rely on the phase-in rules of the NASDAQ Stock Market pursuant to which we must have one independent director on our audit committee at the time of listing, a majority of independent directors on our audit committee within 90 days of the effectiveness of the registration statement for our U.S. initial public offering, and all independent directors on our audit committee within one year of the effectiveness of the registration statement for our U.S. initial public offering.

The role of our audit committee is to ensure the effectiveness of our internal control and risk management systems, the internal audit (if any) and its effectiveness and the statutory audit of the annual and consolidated accounts, and to review and monitor the independence of the external auditor, in particular regarding the provision of additional services to the company. The committee reports regularly to our board of directors on the exercise of its functions. It informs our board of directors about all areas in which action or improvement is necessary in its opinion and produces recommendations concerning the necessary steps that need to be taken. The audit review and the reporting on that review cover us and our subsidiaries as a whole. The members of the audit committee are entitled to receive all information which they need for the performance of their function, from our board of directors, executive committee and employees. Every member of the audit committee shall exercises this right in consultation with the chairman of the audit committee.

Our audit committee's duties and responsibilities to carry out its purposes include, among others: our financial reporting, internal controls and risk management, and our internal and external audit process. These tasks are further described in the audit committee charter as set out in our corporate governance charter and in Article 526bis of the Belgian Company Code.

Nomination and Remuneration Committee

Our nomination and remuneration committee consists of four members: Michel Lussier (Chairman), Pienter-Jan BVBA, represented by its permanent representative Chris Buyse, RAD Life Sciences BVBA, represented by its permanent representative and Rudy Dekeyser and Hanspeter Spek.

The role of the nomination and remuneration committee is to assist the board of directors in all matters:

- relating to the selection and recommendation of qualified candidates for membership of the board of directors;
- relating to the nomination of the CEO;
- relating to the nomination of the members of the executive management team, other than the CEO, upon proposal by the CEO;
- relating to the remuneration of independent directors;
- relating to the remuneration of the CEO;
- relating to the remuneration of the members of the executive management team, other than the CEO, upon proposal by the CEO; and
- on which the board of directors or the chairman of the board of directors requests the nomination and remuneration committee's advice.

Additionally, with regard to matters relating to remuneration, except for those areas that are reserved by law to the board of directors, the nomination and remuneration committee will at least have the following tasks:

- preparing the remuneration report (which is to be included in the board of director's corporate governance statement); and
- explaining its remuneration report at the annual shareholders' meeting.

The committee's tasks are further described in the nomination and remuneration committee charter as set out in our corporate governance charter and Article 526 *quater* of the Belgian Company Code.

14.3 Executive Management Team

The board of directors has established an executive management team which does not constitute an executive committee ("directiecomité / comité de direction") under Article 524bis of the Belgian Company Code. The terms of service of the executive management team have been determined by the board of directors and are set out in our corporate governance charter. The executive management team is chaired by our Chief Executive Officer. The following table set forth certain information with respect to the current members of our executive management team as of 15 March 2015:

Name	Age	Position(s)
LSS Consulting SPRL, represented by its representative, Christian Homsy	56	Chief Executive Officer
PaJe SPRL, represented by its representative Patrick Jeanmart	42	Chief Financial Officer
Advanced Therapies Consulting Ltd., represented by its representative Peter De Waele.	58	Vice President Research & Development
Georges Rawadi	47	Vice President Business Development
Warren Sherman	63	Chief Medical Officer
ViaNova SPRL, represented by its representatives, Vincent Brichard	49	Vice President Immuno-oncology

The members of the executive management team are appointed and may be dismissed by the board of directors. The board of directors appoints them on the basis of the recommendations of the nomination and remuneration committee, which shall also assist the board of directors on the remuneration policy of the members of the executive management team, and their individual remunerations.

The remuneration, duration and conditions of dismissal of executive management team members are governed by the agreement entered into between us and each member of the executive management team in respect of their function within the company.

Unless otherwise stated, the address for members of the executive management team is Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

There is no potential conflict of interest between the private interests or other duties of the members of the executive management team listed above or the members of the board of directors and their duties to us.

Below are the biographies of those members of our executive management team or of the representatives of the management committee who do not also serve on our board of directors:

Patrick Jeanmart (representative of PaJe SPRL has served as our Chief Financial Officer since September 2007. Prior to joining us, Mr. Jeanmart worked for IBA Group (Ion Beam Applications, Belgium) for six years where he held a number of senior financial management positions within the corporate organization and several IBA subsidiaries located in Belgium, Italy, UK and the U.S. Between January 2004 and 2007, he acted as Vice President of Finance of IBA Molecular. He also holds the position of Chief Financial Officer at Medpole SA and at Biological Manufacturing Services SA. Mr. Jeanmart obtained a Master in Economics from the University of Namur, Belgium.

Peter De Waele (representative of Advanced Therapies Consulting Ltd.) has been our Vice President Research and Development since November 2010. He is the author and co-author of several peer reviewed scientific publications, and the inventor of several patents and patent applications. He has been a consultant to the pharmaceutical and biotech industry since 2006, with a particular focus on adult stem cell product development for different therapeutic indications. Until 2006, Dr. De Waele worked as Chief Operating Officer at XCELLentis NV, a biotech company developing stem cell based therapies and medical devices for wound healing. Before founding XCELLentis in 2001, he held several senior management positions at Innogenetics NV. As Chief Therapeutics Officer of Innogenetics and as Chief Operating Officer of XCELLentis he was responsible for several multicenter international clinical trials with recombinant vaccines and cell derived advanced medical products. Moreover, Dr. De Waele serves as the Managing Director at Advanced Therapies Consulting Limited. He is also consultant for regulatory affairs, quality assurance and quality control and research & development for Esperite N.V. (formerly Cryo-Save Group N.V.) as well as acting as Responsible Person for the Dutch tissue bank Stichting Cryo-Save. He obtained his Master of Science in Biochemistry and Physiology at Ghent University, Belgium and holds a doctoral degree in Molecular Biology at the department of Molecular Biology headed by Professor Walter Fiers at the same university, where he was assistant professor until 1986.

Georges Rawadi has served as Vice President Business Development since June 2014. Prior to joining us, Dr. Rawadi served as Vice President Business Development with Cellectis. He previously held business development management positions at Galapagos, ProStrakan France and Sanofi-Aventis France, and conducted consultancy assignments in Business Development and Alliance Management. His work included all aspects and stages of business development, driving several projects from target identification and negotiation to closing deals. He holds a Ph.D. in Microbiology from the Pierre et Marie Curie University (France), and a Masters in Management and Strategy in the Health Industry from the ESSEC Business School.

Warren Sherman has served as our Chief Marketing Officer since October 2014. He is an American interventional cardiologist with more than 30 years' experience in the field of cardiology, with a focus in cell-based therapies for treating patients post myocardial infarction and with heart failure. Before joining us, Dr. Sherman was at the Columbia University Medical Center in New York, where he served in a number of capacities, including Interventional Cardiologist at Columbia University Medical Center/NewYork-Presbyterian Hospital, Director of Stem Cell Research and Regenerative Medicine at the Center for Interventional Vascular Therapy, and Associate Professor of Medicine at Columbia University College of Physicians and Surgeons. Dr. Sherman is also the founder of the Cardiovascular Research Foundation's International Conference on Cell Therapy for Cardiovascular Disease (IC3D), which is the foremost meeting for healthcare experts dedicated to the evolving field of cell-based therapies for the repair and regeneration of cardiac and vascular disease. He received his Bachelor degree from the Massachusetts Institute of Technology, medical degree from the State University of New York Upstate Medical School in Syracuse, and his fellowship training at Oregon Health Sciences University, in Portland, Oregon. He is certified by the American Board of Internal Medicine in Cardiology and Interventional Cardiology, and serves as an advisor to a multitude of government organizations, societies and industries.

Vincent Brichard (representative of ViaNova SPRL) is a physician by training, specialized in oncology. He started his academic career at the Ludwig Institute for Cancer Research, Brussels Branch, followed by positions at the Institut Curie Cancer Center, Paris, and at the University of Louvain, Brussels. In 2002, he joined GlaxoSmithKline Biologicals, where he led the Cancer Vaccines Business Unit. Until recently, Dr. Brichard was the Senior Vice President of the Immunotherapeutics Business Unit, and member of the Vaccines Executive team at GSK Biologicals. He will continue to hold other non-executive positions with other companies. Dr. Brichard holds a Ph.D. in tumor immunology.

The executive management team discusses and consults with the board of directors and advises the board of directors on the day-to-day management of the company in accordance with our values, strategy, general policy and budget, as determined by the board of directors.

The further tasks for which the executive management team is responsible are described in greater detail in the terms of service of the executive management team as set out in our corporate governance charter.

$14.4\quad$ General Information About Our Directors and Members of Executive Management Team

As of the date of this prospectus and except as set out below, none of the directors or members of our executive management team for at least the previous five years:

- holds any convictions in relation to fraudulent offenses;
- holds an executive function in the form of a senior manager or a member of the administrative, management or supervisory bodies of any company at the time of or preceding any bankruptcy, receivership or liquidation;
- has been subject to any official public incrimination and/or sanction by any statutory or regulatory authority (including any designated professional body); or
- has ever been disqualified by a court from acting as member of the administrative, management or supervisory bodies of any company or from acting in the management or conduct of affairs of any company.

14.5 Family Relationships

There are no family relationships among any of the members of our executive management team or directors.

Serge Goblet is the managing director and controlling shareholder of TOLEFI SA. Mr. Goblet has two voting rights at our board of directors, one in his own name and one on behalf of TOLEFI SA, as its permanent representative.

14.6 Corporate Governance Practices

Along with our articles of association, we adopted a corporate governance charter in accordance with the recommendations set out in the Belgian Corporate Governance Code issued on 12 March 2009 by the Belgian Corporate

Governance Committee. The Belgian Corporate Governance Code is based on a "comply or explain" system: Belgian listed companies are expected to follow the Belgian Corporate Governance Code, but can deviate from specific provisions and guidelines (though not the principles) provided they disclose the justification for such deviations.

Our board of directors complies with the Belgian Corporate Governance Code, but believes that certain deviations from its provisions are justified in view of our particular situation.

These deviations include the grant of options or warrants to non-executive directors. In this way, we have additional possibilities to attract or retain competent non-executive directors and to offer them an attractive additional remuneration without the consequence that this additional remuneration weighs on our financial results. Furthermore, the grant of warrants is a commonly used method in the sector in which we operate. Without this possibility, we would be subject to a considerable disadvantage compared to competitors who do offer warrants to their non-executive directors. Our board of directors is of the opinion that the grant of options or warrants has no negative impact on the functioning of the non-executive directors.

Additionally, Jean-Marc Heynderickx was appointed as a director on 31 January 2013 for a duration of six years, which is in excess of the maximum duration of four years for a director's mandate provided by the Belgian Corporate Governance Code. This appointment was done at a time when the Corporate Governance Code was not applicable to us. In the future, we will ensure that no director's mandate will exceed the maximum duration of four years as provided by the Corporate Governance Code.

Our board of directors reviews its corporate governance charter from time to time and makes such changes as it deems necessary and appropriate. Additionally, our board of directors adopted written terms of reference for each of the executive management team, the audit committee and the nomination and remuneration committee, which are part of the corporate governance charter.

14.7 Code of Business Conduct and Ethics

Prior to the completion of the U.S. initial public offering, we expect to adopt a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees, members of our executive management team and directors. Following the completion of the U.S. initial public offering, the Code of Conduct will be available on our website at www.celyad.com. The audit committee of our board of directors will be responsible for overseeing the Code of Conduct and will be required to approve any waivers of the Code of Conduct for employees, members of our executive management team and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

14.8 Compensation of Directors and Executive Management Team

The aggregate compensation paid and benefits in kind granted by us to the current members of our executive management team and directors, including share-based compensation, for the year ended 31 December 2014, was €2.6 million. For the year ended 31 December 2014, €3,000 of the amounts set aside or accrued to provide pension, retirement or similar benefits to our employees was attributable to members of our executive management team.

For a discussion of our employment arrangements with members of our executive management team and consulting arrangement with our directors, see the remuneration report in our 2014 annual report, which is incorporated by reference in this prospectus. For more information regarding warrant grants, see the section of this prospectus titled "Warrant Plans."

Compensation of Our board of directors

The remuneration of our directors and the grant of warrants to our directors is submitted by our board of directors (following advice from the nomination and remuneration committee) for approval to the general shareholders' meeting and is only implemented after such approval. The aggregate compensation paid and benefits in kind granted by us to our current directors, including share-based compensation, for the year ended 31 December 2014, was €0.2 million.

The procedure for establishing the remuneration policy and setting remuneration for members of our board of directors is determined by our board of directors on the basis of proposals from the nomination and remuneration committee, taking into account relevant benchmarks from the biotechnology industry.

The independent directors receive fixed remuneration in consideration for their membership of the board of directors and their attendance at the committee meetings of which they are members. The remuneration package for the independent directors approved by the shareholders' meeting of 11 June 2013 is made up of a fixed annual fee of ξ ,000. The fee is supplemented with a fixed annual fee of ξ ,000 for membership of each committee of the board of directors, to be increased by ξ ,000 in case the relevant director chairs a committee.

All directors are entitled to a reimbursement of out-of-pocket expenses actually incurred as a result of participation in meetings of the board of directors.

On the advice of the nomination and remuneration committee, the board of directors may propose to the shareholders' meeting to grant options or warrants in order to attract or retain non-executive directors with the most relevant skills, knowledge and expertise. Insofar as this grant of options or warrants comprises variable remuneration under Article 554 of the Belgian Company Code, this remuneration shall be submitted for approval to the next annual general shareholders meeting.

The directors' mandate may be terminated ad nutum (at any time) without any form of compensation.

No loans or guarantees were given to members of the board of directors during the year ended 31 December 2014.

There are no employment or service agreements that provide for notice periods or indemnities between us and members of the board of directors who are not a member of the executive management team. In respect of the members of the board of directors who are a member of the executive management team, reference is made to the section "Executive Management Team" here above.

The chairman of our board of directors, Michel Lussier, does not receive remuneration.

The following table sets forth the fees received by our non-executive directors for the performance of their mandate as a board member, during the year ended 31 December 2014:

Name	Fees Earned (€)
Michel Lussier	_
William Wijns	_
Serge Goblet	_
Pienter-Jan BVBA, represented by its permanent representative, Chris Buyse	18,000
R.A.D. Sciences BVBA, represented by its permanent representative Rudy Dekeyser	11,000
Jean-Marc Heynderickx	_
Chris De Jonghe	_
Hanspeter Spek	25,000
Danny Wong	_
Tolefi SA, represented by its permanent representative, Serge Goblet	_
Total	54,000

Our executive director (i.e., LSS Consulting SPRL, represented by Christian Homsy) does not receive any specific or additional remuneration for his service on our board of directors, as this is included in his total remuneration package in his capacity as Chief Executive Officer. For more information regarding Mr. Homsy's compensation, see the section of this prospectus titled "Compensation of Directors and Executive Management Team".

The table below provides an overview as of 31 December 2014 of the warrants held by the non-executive directors.

	Warrant Awards					
Name	Number of Ordinary Shares Underlying Warrants	Warrant Exercise Price in euros	Warrant Expiration Date			
Michel Lussier	400	35.36	5 May 2016			
William Wijns	_	_	_			
Serge Goblet	_	_	_			
Chris Buyse ^[1]	5,000	35.36	29 Oct 2015			
Rudy Dekeyser	· <u> </u>	_	_			
Jean-Marc Heynderickx	_	_	_			
Chris De Jonghe	_	_	_			
Hanspeter Spek	5,000	35.79	5 May 2019			
Danny Wong	· <u> </u>	_	_			
TOLEFI SA	2,504	35.36	5 May 2016			

Chris Buyse holds these warrants and shares in person, whereby he is the permanent representative of Pienter-Jan BVBA, his management company, which has been appointed as independent director.

Compensation of Members of the Executive Management Team

The compensation of the members of our executive management team is determined by our board of directors based on the recommendations by our nomination and remuneration committee.

The remuneration of the members of our executive management team consists of different components:

- Fixed remuneration: a basic fixed fee designed to fit responsibilities, relevant experience and competences, in line with market rates for equivalent positions. The amount of fixed remuneration is evaluated and determined by the board of directors every year.
- Short term variable remuneration: members of the executive management team may be entitled to a yearly bonus, given the level of achievement of the criteria set out in the corporate objective for that year.
- Incentive plan: warrants have been granted and may be granted in the future, to the members of the executive management team. For a description of the main characteristics of our warrant plans, see the section of this prospectus titled "Warrant Plans."
- Other: Members of the executive management team with an employee contract with us entitle them to our pension, company car and payments for invalidity and healthcare cover and other fringe benefits of nonmaterial value.

No loans, quasi-loans or other guarantees were granted to members of our executive management team during the year ended on 31 December 2014.

The following table sets forth information regarding compensation earned by LSS Consulting SPRL, represented by Christian Homsy, our Chief Executive Officer, during the year ended 31 December 2014.

Compensation (in euros)

Fixed fee	369,000
Variable fee	110,700
Total	479,700

Mr. Homsy was not granted warrants in 2014. Mr. Homsy did exercise 80,000 warrants to acquire 80,000 of our ordinary shares in 2014.

The following table sets forth information concerning the aggregate compensation earned during the year ended 31 December 2014 by the other members of our executive management team.

Compensation (in euros)

Fixed remuneration (gross)	208,278
Variable remuneration (short term)	60,668
Fixed fee	647,276
Variable fee	112,464
Pension/Life	3,269
Other benefits	2,927
Total	1,034,882

In addition, the other members of the executive management team were granted and accepted 17,500 warrants under the 5 May 2014 warrant plan. The exercise price of the warrants is €33.18 and €39.22. The following table sets forth the number of warrants granted under such plans to the other members of the executive management team:

Name	Number of Warrants under the 5 May 2014 plan
Georges Rawadi	7,500
Vincent Brichard	10,000

The table below provides an overview as of 31 December 2014 of the warrants held by the members of our executive management team.

	Warrant Awards					
Name	Number of Ordinary Shares Underlying Warrants	Warrant Exercise Price in euros	Warrant Expiration Date			
Christian Homsy ^[1]	112,000	2.64	6 May 2018			
	200	35.36	5 May 2016			
Patrick Jeanmart ^[2]	56,000	2.64	6 May 2018			
	25	35.36	5 May 2016			
Peter De Waele	6,500	2.64	6 May 2018			
George Rawadi	7,500	39.22	5 May 2024			
Vincent Brichard	10,000	33.18	5 May 2019			

Christian Homsy holds these warrants in person, whereby he is the representative of LSS Consulting SPRL, his management company, which has been appointed as Chief Executive Officer.

14.9 Warrant Plans

We have created various incentive plans under which warrants were granted to our employees, consultants or directors. Additionally, we entered into certain loan agreements loan E, loan F, loan G and loan H further to which anti-dilution warrants were granted to the lenders of the relevant loans. Finally, we have granted warrants to certain of our shareholders and to certain investors in the BMS project (all warrants are together referred to as "Warrants"). This section provides an overview of the outstanding Warrants on the date hereof.

Upon proposal of the board of directors, the extraordinary shareholders' meeting approved the issuance of, in the aggregate, Warrants giving right to subscribe to shares as follows:

- On 26 September 2008, (Warrants giving right to 90,000 shares). Of these 90,000 Warrants, 50,000 were offered and accepted. None are outstanding on the date hereof;
- on 5 May 2010 (Warrants giving right to 50,000 shares). Of these 50,000 Warrants (15,000 Warrants A, 5,000 Warrants B and 30,000 Warrants C), 12,710 Warrants A were accepted but none are outstanding on the date hereof, 5,000 Warrants B were accepted and are still outstanding on the date hereof, and 21,700 Warrants C were accepted and 2,298 Warrants C are still outstanding on the date hereof;
- on 29 October 2010 (Warrants giving right to 79,500 shares). Out of the 79,500 Warrants offered, 61,050 Warrants were accepted by the beneficiaries and 6,882 Warrants are outstanding on the date hereof;
- on 31 January 2013 (Warrants giving right to 140,000 shares). Out of the 140,000 Warrants, 120,000 were granted to certain members of the executive management team and a pool of 20,000 Warrants was created. The Warrants attributed to certain members of the executive management team were fully vested at 31 December 2013 and were all exercised in January 2014 and therefore converted into ordinary shares. The remaining 20,000 Warrants were not granted and therefore lapsed;
- on 6 May 2013 (11 investor Warrants are attached to each Class B Share subscribed in the capital increase in cash which was decided on the same date, with each investor Warrant giving right to subscribe to one ordinary share as a result, these Warrants give right to a maximum 2,433,618 ordinary shares); subject to the Warrants being offered and accepted by the beneficiaries. On 31 May 2013, Warrants giving right to 2,409,176 ordinary shares were issued and accepted, which have all been exercised on the date hereof.
- on 6 May 2013 (Warrants giving right to 266,241 ordinary shares). Out of the 266,241 Warrants offered, 253,150 Warrants were accepted by the beneficiaries and 233,750 warrants are outstanding on the date hereof.
- on 11 June 2013 (Over allotment Warrant giving right to a maximum number of shares equal to 15% of the new shares issued in the context of the U.S. initial public offering, i.e. 207,225 shares). The over allotment Warrant was exercised on 17 July 2013;
- on 5 May 2014 (Warrants giving right to 100,000 shares), a plan of 100,000 Warrants was approved. Warrants were offered to Company's new comers (employees, non-employees and directors) in several tranches. Out of the Warrants offered, 49,000 warrants were accepted by the beneficiaries and 100,000 Warrants are outstanding on the date hereof.

Patrick Jeanmart holds these warrants in person, whereby he is the representative of PaJe SPRL, his management company, which has been appointed as Chief Financial Officer.

As a result, on 31 December 2014, there are 296,930 Warrants outstanding which represent approximately 4.71% of the total number of all our issued and outstanding voting financial instruments.

lssue Date	Term	Number of Warrants Issued [1]	Number of Warrants Granted in number of shares [2]	Exercise Price (in Euros)	Number of Warrants No Longer Exercisable	Warrants exercised	Number of Warrants Outstanding	Exercise periods vested warrants [3]
26 September 2008	From 26 December 2008 to 31 December 2014	90,000	50,000	22.44	32,501	17,499	-	1 January 2012 - 31 December 2014
5 May 2010	From 5 May 2010 to the day of the contribution in kind of Company's debt under the Loan C Agreement	15,000	12,710	22.44	410	12,300	_	The day of the contribution in kind of Company's debt under the Loan C Agreement
5 May 2010	From 5 May 2010 to 5 May 2016	5,000	5,000	35.36	-	_	5,000	5 May 2013 - 5 May 2016
5 May 2010	From 5 May 2010 to 31 December 2016	30,000	21,700	22.44	18,236	1,166	2,298	1 January 2012 - 31 December 2016
29 October 2010	From 29 October 2010 to 28 October 2020	79,500	61,050	35.36	53,418	750	6,882	1 January 2014 - 28 October 2020
31 January 2013	From 31 January 2013 to 31 January 2023	140,000	120,000	4.52	-	120,000	-	From 1 January 2014 to 31 January 2023
6 May 2013	From 6 May 2013 to 4 June 2013	2,409,176	2,409,176	0.01	-	2,409,176	-	From 6 May 2013 to 4 June 2013
6 May 2013	From 6 May 2013 to 6 May 2023	266,241	253,150	2.64	19,400	-	233,750	From 1 January 2017 to 6 May 2018 for non-employees and to 6 May 2023 for employees
5 May 2014	From 16 May 2014 to 15 May 2024	100,000	49,000	35.79	-	="	100,000	From 1 January 2018 to 15 May 2019 for non-employees and to 15 May 2024 for employees

^[1] Issued under the condition precedent of the Warrant effectively being offered and accepted.

Apart from the warrants plans described above, there are currently no other stock options, options to purchase securities, convertible securities or other rights to subscribe for or purchase securities outstanding.

14.10 Statutory auditor

PricewaterhouseCoopers Reviseurs d'Entreprises scrl, organised and existing under the laws of Belgium, with registered office at Woluwe Garden, Woluwedal 18, 1932 Sint-Stevens-Woluwé, Belgium, represented by Patrick Mortroux, has been appointed as our statutory auditor on 5 May 2014 for a term of three years. Patrick Mortroux is a member of the Belgian Institute of Certified Auditors ("Institut des Réviseurs d'Entreprises") (membership number A01995).

The annual remuneration of the auditor for the performance of its three year mandate for the audit of our financial statements (including the statutory financial statements) amounts to 35,000€ for the year 2014 and 35,000€ for the year 2015 (excluding VAT).

The numbers reflect the number of shares for which the holder of Warrants can subscribe upon exercise of all relevant Warrants.

The Warrants (i) can only be exercised by the holder of Warrants if they have effectively vested, and (ii) can only be exercised during the exercise periods as set out in the respective issue and exercise conditions.

15 RELATED PARTY TRANSACTIONS

Since the end of the last financial period for which audited financial information has been published (31 December 2014), we have not entered into any related party transactions.

16 MATERIAL CONTRACTS

Medisun Agreement

On 16 June 2014, we entered into an investment agreement, or Medisun Agreement, with Medisun International Limited, or Medisun, pursuant to which Medisun purchased 568,180 of our ordinary shares for an aggregate purchase price of €25.0 million. In connection with entry into the Medisun Agreement, we and Medisun also entered into a subscription and joint venture agreement, or JV Agreement. Pursuant to the JV Agreement, we and Medisun agreed to form Cardio3 Biosciences Asia Holdings Limited, or Cardio3 Asia, to conduct clinical trials of C-Cure in the Peoples Republic of China, Hong Kong, Macau and Taiwan, and other territories mutually agreed upon by us and Medisun, with the goal of obtaining marketing authorization for C-Cure in the applicable territories. We obtained a 40.0% initial ownership interest in Cardio3 Asia in exchange for our entry into a license agreement with Cardio3 Asia, or License Agreement, pursuant to which we granted an exclusive, royalty-free and non-transferable license to Cardio3 Asia for C-Cure and certain know-how for conducting clinical trials in the applicable territories, and Medisun obtained an initial 60.0% ownership interest in Cardio3 Asia for an aggregate payment of €500,000. Pursuant to the JV Agreement, Medisun agreed to provide additional funding as necessary for clinical trials to be conducted by Cardio3 Asia by purchasing additional shares of Cardio3 Asia. In the event that Cardio3 Asia receives marketing authorization in any of the applicable territories, we have agreed to grant to Cardio3 Asia, at Cardio3 Asia's election, a commercialization license on the terms specified by the parties in the JV Agreement. Either party to the JV Agreement must also offer its shares to the other party before transferring or otherwise disposing of them. Under the JV Agreement, any minority shareholder of Cardio3 Asia must be offered the same pricing for its shares as is being received by a majority shareholder. The JV Agreement can be terminated by the mutual agreement of us and Medisun, by us if the first patient in clinical trials in the applicable territories has not been recruited by 16 June 2015, or the last patient for any of the clinical trials in the applicable territories has not been recruited within two years from the time that the first patient is recruited, and by Medisun if we cease to comply with certain warranties in the JV Agreement and License Agreement, or for reasons related to our failure to secure or maintain certain intellectual property protections. In those cases, the party who terminates is entitled to purchase the shares held by the other party at its fair price, defined in the JV Agreement by reference to their market value. A similar right to purchase the other party's shares is also provided in a number of cases of default by such other party. Medisun is also entitled under the JV Agreement to subscribe for non-cash consideration to a number of additional shares, depending on the achievement of a number of business milestones, allowing it to obtain in total up to 70% of the share capital of Cardio 3 Biosciences Asia, with the remaining 30% held by us.

Licensing and Collaboration Agreements

In the two years preceding the date of this prospectus we have entered into several material contracts in the context of our core relationships and collaborations with the Mayo Foundation for Medical Education and Research, or the Mayo Clinic, and the Trustees of Dartmouth College, or Dartmouth. Reference is made to section 13.6 of this prospectus for a description of these contracts.

Acquisitions

On 5 January 2015, we (as purchaser) entered into a stock purchase agreement with Celdara Medical, LLC, a limited liability company organized under the laws of Delaware (as seller) for the acquisition of all the issued and outstanding membership interest of OnCyte, LLC, a limited liability company under the laws of Delaware. We acquired OnCyte for an upfront payment of \$10 million, of which, \$6 million was paid in cash and \$4 million was paid in the form of 93,087 of our ordinary shares. Concurrently with closing of the acquisition, Celdara Medical, LLC and OnCyte, LLC entered into an asset purchase agreement effecting the transfer of certain assets and governing the milestone, royalty and opt-out payments related thereto and a research and development service agreement outlining each of the party's responsibilities with regard to the development of the products. For the successful development of the most advanced product CM-CS1, Celdara could receive up to \$50 million in development and regulatory milestones until market approval. Celdara will be eligible to additional payments on the other products upon achievement of development and regulatory milestones totalling up to \$21 million per product. In addition, Celdara will receive up to \$80 million in sales milestones when net sales will exceed \$1 billion and royalties ranging from 5 to 8%.

On 5 November 2014, we entered into a share purchase agreement with Mr Didier de Canniere and Mr Serge Elkiner for the acquisition of a 100% interest in CorQuest Medical, Inc. ('CorQuest'), a US private company based in Miami (Florida), through a single cash payment of 1.5MEUR. With this acquisition, the Group intends to strengthen its Medical Device division. The CorQuest technology platform is fully complementary with Celyad C-Cathez® and C-Cure® programs. The acquisition of CorQuest and the development of these technologies will not significantly affect the Company's burn rate over the two coming years. However, the acquisition of an extra medical device with a potential

to market by 2016, as well as other therapeutic value creation milestones for its shareholders.	applications,	will enable	the Company	to create	multiple s	hort	term

17 DESCRIPTION OF THE SHARE CAPITAL AND CORPORATE STRUCTURE

17.1 General

We were incorporated on 24 July 2007 under the name Cardio3 BioSciences. Our name was changed in Celyad on 5 May 2015. We are a public limited liability company ("société anonyme" or "SA") organised and existing under the laws of Belgium with registered office at Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium (enterprise number 0891.118.115 (RPM Nivelles)). Pursuant to the Belgian Company Code, the liability of shareholders of a public limited liability company is limited to the amount of their respective committed capital contribution to our capital. We may be reached by telephone at the number +32 10 394 100.

Our share capital and corporate structure and the material rights of its shareholders under Belgian law and our articles of association are summarised below.

The description hereafter is a summary only and does not purport to give a complete overview of the articles of association, nor of all relevant provisions of Belgian law. Neither should it be considered as legal advice regarding these matters.

17.2 Corporate purpose

For our corporate purpose, reference is made to our articles of association available on our website (http://www.celyad.com/en/corporate-governance).

17.3 Group structure

Our main business is conducted through the Company itself. In 2011, we incorporated Cardio3 Inc, a fully owned subsidiary, in the U.S. for the purposes of regulatory filings. Cardio3 Inc became Celyad Inc on 12 May 2015. Celyad Inc is currently a dormant company without activities.

On 5 November 2014, we acquired CorQuest Medical, Inc., a private U.S. company, or CorQuest, for a single cash payment of €1.5 million and on-going earn-out royalty payments based on sales milestones.

On 21 January 2015, we purchased OnCyte, LLC, or OnCyte, a wholly-owned subsidiary of Celdara Medical, LLC, a privately-held U.S. biotechnology company for an upfront payment of \$10.0 million, of which, \$6.0 million was paid in cash and \$4.0 million was paid in the form of 93,087 of our ordinary shares. Additional contingent payments with an estimated fair value of \$42.0 million are payable upon the attainment of various clinical and sales milestones. As a result of this transaction we acquired our CAR T-cell drug product candidates and related technology, including technology licensed from the Trustees of Dartmouth College.

17.4 Share capital and shares

On the date of this prospectus, our registered capital amounts to $\{27,440,130.63\}$ represented by 7,847,687 shares without nominal value. The par value is $\{3.50\}$ per share. As of the date of this prospectus, the capital is fully paid up.

Development of capital

The table below provides an overview of the history of our share capital since our incorporation in 2007. The overview should be read together with the notes set out below the table.

Category	Transaction date	Description	# of shares	Issue price (in €)
Class A shares	24 July 2007	Company incorporation	409,375	0.15
Class A shares	31 August 2007	Contribution in kind (upfront fee Mayo Licence)	261,732	36.30
Class B shares	23 December 2008	Capital increase in cash (Round B)	137,150	35.36
Class B shares	23 December 2008	Contribution in kind (Loan B)	67,502	35.36
Class B shares	29 October 2010	Contribution in cash	21,000	22.44

Category	Transaction date Description		# of shares	Issue price (in €)	
Class B shares	29 October 2010	Contribution in kind (Loan C)	92,068	35.36	
Class B shares	29 October 2010	Contribution in kind (Loan D)	57,095	35.36	
Class B shares	29 October 2010	Contribution in cash	73,793	35.36	
Class B shares	29 October 2010	Exercise of warrants	12,300	22.44	
Class B shares	29 October 2010	Contribution in kind (Mayo receivable)	69,455	44.20	
Class B shares	29 October 2010	Contribution in cash	9,048	44.20	
Class B shares	6 May 2013	Contribution in kind (Loan E)	118,365	38.39	
Class B shares	6 May 2013	Contribution in kind (Loan F)	56,936	38.39	
Class B shares	6 May 2013	Contribution in kind (Loan G)	654,301	4.52	
Class B shares	6 May 2013	Contribution in kind (Loan H)	75,755	30.71	
Class B shares	31 May 2013	Contribution in cash	219,016	31.96	
Class B shares	4 June 2013	Conversion of warrants	2,409,176	0.01	
Ordinary shares	11 June 2013	Conversion of Class A and Class B shares in ordinary shares	4,744,067	_	
Ordinary shares	9 July 2013	Initial Public Offering	1,381,500	16.65	
Ordinary shares	17 July 2013	Exercise of over-allotment option	207,225	16.65	
Ordinary shares	31 January 2014	Exercise of warrants issued in September 2008	5,966	22.44	
Ordinary shares	31 January 2014	Exercise of warrants issued in May 2010	333	22.44	
Ordinary shares	31 January 2014	Exercise of warrants issued in January 2013	120,000	4.52	
Ordinary shares	5 May 2014	Exercise of warrants issued in September 2008	2,366	22.44	
Ordinary shares	16 June 2014	Capital increase in cash	284,090	44.00	
Ordinary shares	30 June 2014	Capital increase in cash	284,090	44.00	
Ordinary shares	4 August 2014	Exercise of warrants issued in September 2008	5,000	22.44	
Ordinary shares	4 August 2014	Exercise of warrants issued in October 2010	750	35.36	
Ordinary shares	3 November 2014	Exercise of warrants issued in September 2008	5,000	22.44	
Ordinary shares	21 January 2015	Capital increase in kind	93,087	37.08	
Ordinary shares	7 February 2015	Exercise of warrants issued in October 2010	333	22.44	
Ordinary shares	3 March 2015	Capital increase in cash	713,380	44.50	
Ordinary shares	11 May 2015	Exercise of warrants issued in May 2010	500	22.44	

17.5 Warrants

On 31 December 2014, there are 296,930 warrants outstanding which represent approximately 4.05% of the total number of all our issued and outstanding voting financial instruments.

Issue Date	Number of Warrants Issued ^[1]	Number of Warrants Granted in number of shares ^[2]	Exercise Price (in Euros)	Number of Warrants No Longer Exercisable	Warrants exercised	Number of Warrants Outstanding	Exercise periods vested warrants ^[3]
5 May 2010	5,000	5,000	35.36	_	_	5,000	5 May 2013 - 5 May 2016
5 May 2010	30,000	21,700	22.44	18,236	1,166	2,298	1 January 2012 - 31 December 2016
29 October 2010	79,500	61,050	35.36	53,418	750	6,882	1 January 2014 - 28 October 2020
6 May 2013	266,241	253,150	2.64	19,400	-	233,750	From 1 January 2017 to May 2018 for non-employees and to 6 May 2023 for employees
5 May 2014	100,000	49,000	35.79	_	-	100,000	From 1 January 2018 to 15 May 2019 for non- employees and to 15 May 2024 for employees

^[1] Issued under the condition precedent of the warrant effectively being offered and accepted.

Apart from the warrants plans described above, there are currently no other stock options, options to purchase securities, convertible securities or other rights to subscribe for or purchase securities outstanding.

17.6 Major shareholders

The information in the table below is based on information known to us or ascertained by us from public filings made by the shareholders as of the date of this Prospectus, updated, as the case may be, on the basis of the written answers provided by these shareholders to our questionnaires in view of the Nasdaq listing. Except as otherwise indicated in the table below, addresses of the directors, members of the executive management team and named beneficial owners are in care of Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium.

Name of Beneficial Owner	Number	Percentage
5% Shareholders:		
TOLEFI SA(1)	2,267,844	28.90%
PMV-TINA	428,071	5.45%
MEDISUN INTal Ltd	568,180	7.24%
SRIW SA(2)	400,000	5.10%

Name of Beneficial Owner		Percentage	
Directors and Members of Executive Management Team			
Michel Lussier	162,370	2.07%	
Jean-Marc Heynderickx(3)	125,753	1.06%	
Christian Homsy(4)	67,454	0,86%	
Patrick Jeanmart	13,924	0,18%	
William Wijns	4,079	0,05%	

The numbers reflect the number of shares for which the holder of warrants can subscribe upon exercise of all relevant warrants.

The warrants (i) can only be exercised by the holder of warrants if they have effectively vested, and (ii) can only be exercised during the exercise periods as set out in the respective issue and exercise conditions.

All directors and members of the executive management team as a group (six			
persons)	373,580	4.76%	

- (1) TOLEFI SA is represented by its permanent representative, Serge Goblet.
- (2) Includes shares held by Sofipôle SA, a fully owned subsidiary of SRIW SA.
- (3) Includes 125,753 shares held by BELGENEXT SA, which is controlled by Mr. Jean-Marc Heynderickx.
- (4) Includes 8,000 shares held by Karim Homsy, Mr. Homsy's son, 6,000 shares held by Bastian Homsy, Mr. Homsy's son, and 8,000 shares held by Benjamin Homsy, Mr. Homsy's son.

Each of our shareholders is entitled to one vote per share. None of the holders of our shares have different voting rights from other holders of shares. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

17.7 Description of rights and benefits attached to shares

Voting rights

Each shareholder is entitled to one vote per share.

Voting rights may be suspended in relation to shares, in the following events, without limitation and without this list being exhaustive:

- which are not fully paid up, notwithstanding the request thereto by our board of directors;
- to which more than one person is entitled, except in the event that a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 5%, or any multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant shareholders meeting, except in case the relevant shareholder has notified the Company and the FSMA at least 20 days prior to the date of the shareholders meeting (see also "17.12 Notification of important participations".) of its shareholding reaching or exceeding the thresholds above; and
- of which the voting right was suspended by a competent court or the FSMA.

Generally, the shareholders' meeting has sole authority with respect to:

- the approval of our statutory financial statements (statutory financial statements under Belgian GAAP);
- the appointment and dismissal of our directors and the statutory auditor;
- the granting of discharge of liability to the directors and the statutory auditor;
- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate;
- the distribution of profits;
- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other reorganisations; and
- the approval of amendments to the articles of association.

Nomination right with respect to members of the board of directors

Under our articles of association, each of PMV-TINA Comm. V and Sofipôle SA is entitled to nominate a candidate for appointment to our board of directors as long as such entity (or any of its affiliates) continues to hold a minimum number of shares. As of 31 December 2014, the number of shares was 427,929 shares for PMV-TINA and 495,879 shares for Sofipôle.

17.8 Right to attend and vote at shareholders meetings

Annual shareholders meeting

The annual shareholders' meeting is held at our registered office or at the place determined in the notice convening the shareholders meeting. The meeting is held every year on 5 May, at 9.00 a.m. If this date is a Saturday, Sunday or legal holiday, the meeting is held on the next business day.

At the annual shareholders' meeting, the board of directors submits the audited statutory financial statements under Belgian GAAP and the reports of the board of directors and of the statutory auditor with respect thereto to the shareholders. The shareholders meeting then decides on the approval of the statutory financial statements under Belgian GAAP, the proposed allocation of our profit or loss, the discharge of liability of the directors and the statutory auditor, and, as the case may be, the (re-)appointment or dismissal of the statutory auditor and/or of all or certain directors and the matters described in Article 554 of the Belgian Company Code.

Special and Extraordinary shareholders meetings

The board of directors or the statutory auditor may, at any given time when the interest of the Company so requires, convene a Special or extraordinary shareholders meeting. A shareholders meeting must also be convened each time at the request of one or more shareholders holding at least 20% of our share capital.

Notices convening the shareholders meeting

The convening notice to the shareholders meeting must at least state the place, date and hour of the meeting, and must include an agenda indicating the items to be discussed, as well as any motions for resolutions. In addition, it must give a clear description of the formalities to be fulfilled by the shareholders to be allowed entry to the shareholders meeting and to exercise their voting right.

The notice must be published at least 30 days prior to the shareholders meeting in the Belgian Official Gazette ("Le Moniteur belge") and in media of which it reasonably can be expected that it will ensure an effective distribution of the information among the public in the European Economic Area and which is quickly and in a non-discriminatory manner accessible.

The notice must also be published in a national newspaper 30 days prior to the date of the shareholders meeting, except if the relevant meeting is an annual shareholders meeting held at the municipality, place, date and hour mentioned in our articles of association and its agenda is limited to the review of the statutory financial statements, the annual report of the board of directors on the statutory financial statements, the annual report of the statutory auditor, the vote on the discharge of the directors and the statutory auditor, and, as the case may be, matters described in Article 554 of the Belgian Company Code (i.e., approval of the remuneration report and, under certain circumstances, the severance pay of leading persons). The statutory financial statements, the annual report of the board of directors and the annual report of the statutory auditor on the statutory financial statements must be made available to the public as of the date of the publication of the convening notice.

Convening notices must be sent 30 days prior to the shareholders meeting to the holders of registered shares, registered bonds, registered warrants, registered certificates issued with our co-operation (if any) and to our directors and the statutory auditor. This communication is made by way of ordinary letter unless the addressees have individually and expressly accepted in writing to receive the notice by another form of communication in accordance with Article 533 of the Belgian Company Code, without having to give evidence of the fulfilment of such formality.

Formalities to attend the shareholders meeting

The fourteenth day prior to the shareholders meeting, at 24:00 (CET) shall constitute the registration date.

A shareholder can only participate to a shareholders meeting and exercise its voting right provided that its shares are registered in its name, on the registration date (and irrespective of the number of shares the shareholder holds at the date of the shareholders meeting). For registered shares, this is the registration of the shares in our shareholders register, and for dematerialized shares, this is the registration of the shares in the accounts of an authorised account holder or a clearing institution in accordance with Article 536 of the Belgian Company Code.

In the convening notice to the shareholders meeting, the registration date is explicitly mentioned. The shareholder must provide us (or any person so appointed by us) with its intention to participate to the meeting, at the latest on the sixth day before the date of such meeting.

Our board of directors must maintain a register in which, for each shareholder who has duly expressed its intention to participate to the shareholders meeting, it shall record the name and address (or registered offices) of such shareholder, the number of shares it held on the registration date and for which it has expressed its intention to participate to the meeting, as well as a description of the documents evidencing that such shareholder held the relevant shares at the registration date.

Prior to participating to the shareholders meeting, the holders of securities or their proxy holders must sign the attendance list, thereby mentioning: (i) the identity of the holder of securities, (ii) if applicable, the identity of the proxy holder, and (iii) the number of securities they represent. The representatives of shareholders-legal entities must present the documents evidencing their quality as legal body or special proxy holder of such legal entity. In addition, the proxy holders must present the original of their proxy evidencing their powers, unless the convening notice

required the prior deposit of such proxies. The physical persons taking part in the shareholders meeting must be able to prove their identity.

The holders of profit certificates (if any), shares without voting rights (if any), bonds (if any), warrants or other securities issued by us (if any), as well as the holders of certificates issued with our co-operation and representative securities issued by us (if any), may attend the shareholders meeting insofar as the law grants them such right with an advisory vote, or, as the case may be, the right to participate in the vote. If they wish to attend, they must abide by the same formalities, requirements to be admitted, form and deposit of proxies, as those imposed on the shareholders.

Power of attorney

Any shareholder may grant a proxy to any other person, in accordance with Article 547*bis* of the Belgian Company Code, and this for one or more specific shareholders' meetings, or for meetings which shall be held during a specific period. Any person may, as a proxy holder, represent multiple shareholders. Any proxy must be received by us at the latest on the sixth day before the Shareholders meeting, in writing or electronically, in accordance with Article 547*bis* of the Belgian Company Code. We shall only accept such proxies which were provided by shareholders that comply with the formalities to be admitted at the shareholders' meeting.

Quorum and majorities

In general, there is no quorum requirement for a shareholders' meeting and decisions are generally passed with a simple majority of the votes of the shares present and represented.

Capital increases (unless decided by the board of directors within the framework of the authorised capital), decisions with respect to our dissolution, mergers, de-mergers and certain other reorganisations, amendments to the articles of association (other than an amendment of the corporate purpose) and certain other matters referred to in the Belgian Company Code not only require the presence or representation of at least 50% of our share capital but also the approval of at least 75% of the votes cast. An amendment of our corporate purpose or, subject to certain exceptions, the purchase and sale of own shares, requires the approval of at least 80% of the votes cast at a shareholders meeting, which in principle can only validly pass such resolution if at least 50% of our share capital and at least 50% of the profit certificates, if any, are present or represented. On the date of this prospectus, we have not issued any profit certificates. In the event that the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new convening notice. The second shareholders' meeting can validly deliberate and resolve regardless of the number of shares present or represented.

Right of Shareholders to add items to the agenda

In accordance with Article 533ter of the Belgian Company Code, one or more shareholders holding at least 3% of our share capital have the right to add new items on the agenda of a shareholders' meeting and to file proposals of decision concerning items that were or will be written on the agenda of a shareholders' meeting. Any shareholder(s) who exercise(s) this right must comply with the following two conditions for the proposal(s) to be eligible for consideration at the shareholders meeting: (i) they must prove that they hold the above mentioned percentage of shares on the date of their request (either by producing a certificate of registration of those shares in our shareholder register, or by producing a certificate from a recognized account holder or by a clearing institution evidencing that the relevant number of dematerialised shares are registered in the shareholder's name in the accounts of such authorised account holder or clearing institution); and (ii) they must demonstrate that they still hold 3% of our share capital on the registration date. We must receive requests to add new items on the agenda of shareholders meetings and to file new proposals of decision at the latest 22 days prior to the date of the shareholders' meeting. The revised agenda will be published by us at the latest 15 days prior to the date of the shareholders' meeting.

17.9 Dividends

All shares participate in the same manner in our profits (if any). The New Shares carry the right to receive dividends (if any) payable with respect to the entire financial year started on 1 January 2015 and each subsequent year. Pursuant to the Belgian Company Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual shareholders meeting, based on the most recent audited statutory financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of our board of directors. Our articles of association also authorise the board of directors to declare interim dividends subject to the terms and conditions of the Belgian Company Code.

Pursuant to Article 617 of the Belgian Company Code, dividends can only be distributed if, following the declaration and payment of such dividends, the amount of our net assets on the date of the closing of the last financial year as set out in the financial statements of the Company prepared in accordance with Belgian GAAP (i.e., the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities), decreased with the non-amortised

activated costs of incorporation and extension and the non-amortised activated costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the called capital), increased with the amount of non-distributable reserves. In addition, prior to distributing dividends, 5% of the net profits of each financial year must be allocated to a legal reserve, until this legal reserve amounts to 10% of the share capital.

The right to payment of dividends expires five years after the board of directors has declared the dividend payable.

17.10 Rights regarding liquidation

We can only be dissolved by a shareholders' resolution passed with a majority of at least 75% of the votes cast at an extraordinary shareholders meeting where at least 50% of the share capital is present or represented.

If, as a result of losses incurred, the ratio of our net assets (determined in accordance with Belgian GAAP) to share capital is less than 50%, the board of directors must convene a shareholders meeting within two months from the date the board of directors discovered or should have discovered this undercapitalisation. At such shareholders meeting, the board of directors must propose either our dissolution, or the continuation of our activities, in which case the board of directors must propose measures to redress our financial situation. Shareholders representing at least 75% of the votes validly cast at this meeting can decide to dissolve us, provided that at least 50% of our share capital is present or represented at the meeting.

If, as a result of losses incurred, the ratio of our net assets (determined in accordance with Belgian GAAP) to share capital is less than 25%, the same procedure must be followed, it being understood, however, that in such event shareholders representing 25% of the votes validly cast at the meeting can decide to dissolve us.

If the amount of our net assets has fallen below €61,500 (the minimum amount of share capital of a Belgian public limited liability company), each interested party is entitled to request the competent court to dissolve us. The court may order our dissolution or grant a grace period within which we are allowed to remedy the situation.

In the event we are dissolved, the assets or the proceeds of the sale of the remaining assets, after payment of all debts, costs of liquidation and taxes, must be distributed on an equal basis to the holders of the shares.

17.11 Changes to the share capital

17.11.1 Changes to the share capital decided by the shareholders

The shareholders meeting can at any given time decide to increase or decrease our share capital. Such resolution must satisfy the quorum and majority requirements that apply to an amendment of the articles of association, as described above under section 17.8 "Right to attend and vote at shareholders meetings".

17.11.2 Capital increases by the board of directors

Subject to the same quorum and majority requirements as for a capital increase decided by the shareholders' meeting, the latter can authorise the board of directors, within certain limits, to increase our share capital without any further approval of the shareholders being required. This authorisation needs to be limited in time (i.e., it can only be granted for a renewable period of maximum five years as from the date of the publication of the authorisation in the Annexes to the Belgian Official Gazette), and in scope (i.e., the authorised capital may not exceed the amount of the share capital at the time of the authorisation).

On 11 June 2013, the extraordinary shareholders' meeting authorised the board of directors to increase our share capital in one or more transactions with a maximum amount € 21,412,720.43. The board of directors has already used € 5,161,264.50 of the authorized capital. Therefore, the remaining authorized capital, prior to the U.S. initial public offering, amounts to € 16,251,455.93.

If the capital is increased within the limits of the authorised capital, the board of directors will be authorised to request payment of an issuance premium. This issuance premium will be booked on a non-available reserve account, which may only be decreased or disposed of by a resolution of a shareholders meeting taken in accordance with the provisions relating to amendments of the articles of association.

This board of directors' authorisation will be valid for capital increases subscribed for in cash or in kind, or made by capitalisation of reserves and issuance premiums, with or without issue of new shares. The board of directors is authorised to issue convertible bonds, warrants or a combination thereof within the limits of the authorised capital.

The board of directors is authorised, within the limits of the authorised capital, to limit or cancel the preferential subscription rights granted by law to the holders of shares if in doing so it is acting in our interests and in accordance

with Article 596 and following of the Belgian Company Code. The board of directors is authorised to limit or cancel the preferential subscription rights in favour of one or more specified persons, even if such persons are not members of our personnel.

17.11.3 Preferential subscription right

In the event of a capital increase in cash with issue of new shares, or in the event of an issue of convertible bonds or warrants exercisable in cash, the shareholders have a preferential right to subscribe for the new shares, convertible bonds or warrants, *pro rata* to the part of the share capital represented by the shares that they already hold. The shareholders meeting may decide to limit or cancel such preferential subscription right, subject to special substantive and reporting requirements. Such decision must satisfy the same quorum and majority requirements as the decision to increase our share capital (see above under section 17.8 "Right to attend and vote at shareholders meetings - *Quorum and majorities*").

The shareholders can also decide to authorise the board of directors to limit or cancel the preferential subscription right within the framework of the authorised capital, subject to the terms and conditions set forth in the Belgian Company Code. In principle, the authorisation of the board of directors to increase our share capital through contributions in cash with cancellation or limitation of the preferential right of the existing shareholders is suspended as of the notification to us by the FSMA of a public tender offer on our shares. The shareholders meeting can, however, authorise the board of directors to increase the share capital by issuing further shares, not representing more than 10% of our shares at the time of such a public tender offer. On 11 June 2013, our extraordinary shareholders' meeting decided to authorise the board of directors to increase our share capital, including with limitation or cancellation of the shareholders' preferential subscription rights, in one or more times and including the authorisation to make use of such authorised capital in the framework of a public tender offer.

17.11.4 Form and transferability of the shares

Our shares can take the form of registered shares or dematerialised shares.

Belgian company law and our articles of association entitle shareholders to request, in writing and at their expense, the conversion of their dematerialised shares into registered shares and *vice versa*. Any costs incurred as a result of the conversion of shares into another form will be borne by the shareholder.

For shareholders who opt for registered shares, the shares will be recorded in our shareholder register.

All of our shares, including the New Shares upon delivery, are fully paid up and freely transferable, subject, however, to the lock-up arrangements described in section 6.4 "Lock-up and standstill arrangements".

17.11.5 Purchase and sale of own shares

In accordance with our articles of association and the Belgian Company Code, we can only purchase and sell our own shares by virtue of a special shareholders' resolution approved by at least 80% of the votes validly cast at a shareholders meeting where at least 50% of the share capital (and at least 50% of the profit certificates, if any) are present or represented. The prior shareholders' approval is not required if we purchase our own shares to offer them to its personnel.

In accordance with the Belgian Company Code, an offer to purchase its own shares must be made to all shareholders under the same conditions. This does not apply to (i) the acquisition of shares by companies listed on a regulated market and companies whose shares are admitted to trading on a multilateral trading facility (an "MTF"), provided that the company ensures equal treatment of shareholders finding themselves in the same circumstances by offering an equivalent price (which is assumed to be the case: (a) if the transaction is executed in the central order book of a regulated market or MTF; or (b) if it is not so executed in the central order book of a regulated market or dependent bid price in the central order book of a regulated market or (if not listed on a regulated market) of the MTF offering the highest liquidity in the share); or (ii) the acquisition of shares that has been unanimously decided by the shareholders at a meeting where all shareholders were present or represented.

A company can only acquire its own shares with funds that would otherwise be available for distribution to our shareholders pursuant to Article 617 of the Belgian Company Code (see section 17.9 "Dividends").

The total amount of own shares held by a company can at no time be higher than 20% of its share capital.

At the date of this prospectus, our board of directors was not authorised by the shareholders meeting to purchase its own shares and neither do the articles of association authorise the board of directors to purchase own shares in case of imminent serious harm to us in accordance with Article 620, §1, paragraph 3 of the Belgian Company Code.

17.12 Notification of important participations

Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC has been implemented in Belgian law by, *inter alia*, the Belgian law of 2 May 2007 on the disclosure of major shareholdings in issuers whose securities are admitted to trading on a regulated market ("Loi du 2 mai 2007 relative à la publicité des participations importantes dans des émetteurs dont les actions sont admises à la négociation sur un marché réglementé et portant des dispositions diverses") and the Royal Decree of 14 February 2008 on the disclosure of major shareholdings ("Arrêté royal du 14 février 2008 relatif à la publicité des participations importantes").

Pursuant to this legislation, Belgian law, in conjunction with Article 15 of our articles of association, imposes disclosure requirements on any natural person or legal entity acquiring or disposing of, directly or indirectly, securities granting voting rights or securities which give a right to acquire existing securities granting voting rights, when, as a result of such acquisition or disposal, the total number of voting rights directly or indirectly held by such natural person or legal entity, alone or in concert with others, increases above or falls below a (legal) threshold of 5%, or any multiple of 5%, of the total number of voting rights attached to our securities. Any future amendment to these statutory disclosure thresholds must be made public and simultaneously notified to the FSMA. All legal provisions applicable to the legal thresholds of 5% or any multiple of 5% also fully apply to the statutory thresholds.

Pursuant to Article 6 of the Act of 2 May 2007, the above disclosure obligations will be triggered any time the above thresholds are crossed (downwards or upwards) as a result of, *inter alia*: (i) the acquisition or the disposal of securities granting voting rights, regardless of the way in which this acquisition or disposal takes place, e.g. through purchase, sale, exchange, contribution, merger, de-merger, or succession; (ii) the possession of securities granting voting rights at the time of the admission to trading of our shares; (iii) the passive crossing of these thresholds (as a result of events that have changed the breakdown of voting rights even if no acquisition or disposal took place); or (iv) the execution, amendment or termination of an agreement of concerted action.

Pursuant to Article 6 of the Act of 2 May 2007, the disclosure obligations apply to each natural person or legal entity that "directly" or "indirectly" acquires, disposes of or holds (at the time of the admission to trading, at the time of passive crossing the threshold or at the time of execution, amendment or termination of an agreement of concerted action) voting securities or voting rights. In this respect, a natural person or legal entity is deemed to "indirectly" acquire, dispose of or hold voting securities of us: (i) when voting securities are acquired, disposed of or held by a third party that, regardless in whose name it is acting, acts on behalf of such natural person or legal entity (e.g., in case of an agreement of agency, commission, carrying ("portage"), name lending ("prête-nom"), trust or an agreement with similar effect which leaves the principal elements of the ownership rights on the securities with the other contracting party); (ii) when voting securities are acquired, disposed of or held by an undertaking controlled (within the meaning of Articles 5 and 7 of the Belgian Company Code) by such natural person or legal entity (the notion "control" implies that possibly several persons will be deemed to be a controlling person (e.g., the parent company, the parent company of such parent company, as well as the natural person controlling the latter) and therefore subject to the notification duty); or (iii) when such natural person or legal entity acquires or transfers the control over an entity holding voting rights in us in which case there is no acquisition or disposal of a shareholding in us, but an acquisition or transfer of control over an entity holding voting rights in us (e.g., if the entity over which control is acquired or transferred itself holds a holding in Company which must be notified, or if the securities held by the entity over which control is acquired or transferred together with the securities the person acquiring or transferring control holds in a different manner, reaches, exceeds or falls below one of the thresholds).

In addition, persons subject to notification obligations must include in their notification the total number of potential voting rights (provided they (meet the requirements of Article 6, § 1 of the Royal Decree of 14 February 2008) (whether or not incorporated in securities) they own, as well as the percentage that it represents of the total of existing voting shares.

If a transparency notification is legally required, such notification must be made to the FSMA and us as soon as possible and at the latest within a period of four trading days as from the trading day following the day on which the event triggering the disclosure obligation took place.

The notification can be electronically transmitted to us and the FSMA. The forms required to make such notifications, as well as further explanations may be found on the website of the FSMA (www.fsma.be).

Violation of the disclosure requirements may result in the suspension of voting rights, a court order to sell the securities to a third party and/or criminal liability. The FSMA may also impose administrative sanctions.

We must publish all information contained in such notifications no later than three trading days after receipt of such notification. In addition, we must mention in the notes to its annual accounts, its shareholders structure (as it appears from the notifications received). Moreover, we must publish the total share capital, the total number of voting securities and voting rights (for each class of securities (if any)), at the end of each calendar month during which one of these numbers has changed, as well as on the day on which our shares will for the first time be admitted to trading on Euronext Brussels and Euronext Paris. Furthermore, we must disclose, as the case may be, the total number of bonds convertible in voting securities (if any), whether or not incorporated in securities, to subscribe to voting securities not yet issued (if any), the total number of voting rights that can be obtained upon the exercise of these conversion or subscription rights and the total number of shares without voting rights (if any).

17.13 Disclosure of Net Short Positions

Pursuant to the Regulation (EU) No. 236/2012 of the European Parliament and the Council on short selling and certain aspects of credit default swaps, any person that acquires or disposes of a net short position relating to our issued share capital, whether by a transaction in shares or by a transaction creating or relating to any financial instrument where the effect or one of the effects of the transaction is to confer a financial advantage on the person entering into that transaction in the event of a decrease in the price of such shares is required to notify the FSMA if, as a result of which acquisition or disposal his net short position reaches, exceeds or falls below 0.2% of our issued share capital and each 0.1% above that. If the net short position reaches 0.5%, and also at every 0.1% above that, the FSMA will disclose the net short position to the public.

17.14 Public tender offers

The Directive 2004/25/EC of the European Parliament and the Council dated 21 April 2004 on takeover bids (the "Takeover Directive") sets forth the principles governing the choice of laws applicable to the Company in the context of a takeover bid for our shares.

Article 4-2(c) of the Takeover Directive provides that if the securities of the company subject to the offer were first admitted to trading on regulated markets in more than one Member State simultaneously, the offeree company shall determine which of the supervisory authorities of those Member States shall be the authority competent to supervise the bid by notifying those regulated markets and their supervisory authorities on the first day of trading.

Article 4-2 (e) of the Takeover Directive also provides that matters relating to the consideration offered in the case of an offer, in particular the price and matters relating to the offer procedure, in particular the information on the offeror's decision to make an offer, the contents of the offer document and the disclosure of the offer, shall be dealt with in accordance with the rules of the Member State of the competent authority. As to matters relating to the information to be provided to the employees of the offered company and matters relating to corporate law, in particular the percentage of voting rights which confers control and any exemption from the obligation to launch an offer, as well as the conditions under which the supervisory board of the offeree company may undertake any action which might result in the frustration of an offer, the applicable rules and the competent authority shall be those of the Member State in which the offeree company has its registered office.

These provisions have been implemented in Belgium by the Law of 1 April 2007 on public tender offers ("Loi du ^{1er} avril 2007 relative aux offres publiques d'acquisition"), as implemented by the Royal Decree of 27 April 2007 on public tender offers ("Arrêté royal du 27 avril 2007 relatif aux offres publiques d'acquisition") and the Royal Decree of 27 April 2007 on public squeeze-outs ("Arrêté royal du 27 avril 2007 relatif aux offres publiques de reprise") (for the latter, see below under section 17.15 "Squeeze-out and sell-out" of this chapter).

We have chosen the FSMA as competent authority. As a consequence, Belgian laws and regulations will fully apply and public tender offers on our shares and other securities granting access to voting rights (such as warrants or convertible bonds, if any) will be subject to supervision by the FSMA. In accordance with article 6.2 of the Takeover Directive, the tender offer documents approved by the FSMA will be recognized in full in France, subject to any translation required, without the need to obtain the approval of the AMF. The AMF may however require the inclusion of additional information regarding the formalities to be complied with to accept the tender offer and to receive the consideration due at the close of the tender offer as well as to the tax arrangements to which the consideration offered to the holders of the securities will be subject.

Public tender offers must be made for all of our voting securities, as well as for all other securities issued by us that entitle the holders thereof to the subscription for, or the conversion in, voting securities. Prior to making an offer, an offeror must issue and disseminate an offer document, which must be approved by the FSMA. The offeror must also

obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of the shares of the target.

All shareholders and warrantholders (and holders of other securities granting access to voting rights issued by the target company) must have equal rights to contribute their securities in any public tender offer. Furthermore, whenever a person (as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting for their account, directly or indirectly) acquires more than 30% of the voting securities of a company that are (at least in part) admitted to trading on a regulated market, such person must, regardless of the price paid, launch a mandatory tender offer for all the shares, warrants and convertible securities issued by the target company. In general and except for certain exceptions, the mere fact of exceeding the relevant threshold as a result of an acquisition will give rise to the obligation to launch a mandatory tender offer, irrespective of whether or not the price paid in the relevant transaction exceeds the then current market price.

In such an event, the tender offer must be launched at a price equal to the higher of the two following amounts: (i) the highest price paid by the offeror or the persons acting in concert with it for the acquisition of shares during the last 12 calendar months; and (ii) the average trading price during the last 30 days before the obligation to launch a tender offer arose. No mandatory tender offer is required, amongst other things, when the acquisition is the result of a subscription for a capital increase with application of the preferential subscription rights of the shareholders.

The price for the acquisition of the shares can be in cash or in securities. In the event of a mandatory tender offer or a voluntary tender offer launched by an offeror who controls the target, if a price composed of securities is offered, a cash alternative must also be offered in the event that: (i) the price does not consist of liquid securities admitted to trading on a regulated market; or (ii) the offeror, or a person acting in concert with it, acquired shares for cash during a period of 12 calendar months preceding the publication of the tender offer or during the tender offer period (whereby these shares, in the event of a voluntary tender offer by a controlling shareholder, represent more than 1% of the outstanding voting securities).

Where the voluntary tender offer is launched by a controlling shareholder, the price must be supported by a fairness opinion issued by an independent expert. In addition, in any cases, the board of directors of the target company is required to publish its opinion concerning the tender offer, as well as its comments on the offer document.

The acceptance period for the tender offer must be at least two weeks and not more than ten weeks.

In principle, the authorisation granted to the board of directors of a company to increase the share capital through contributions in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the company by the FSMA of a public tender offer on the securities of such company. The shareholders meeting can, however, authorise the board of directors to increase the share capital by issuing shares representing not more than 10% of the existing our shares at the time of such a public tender offer. Such authorisation was granted to our board of directors on date 11 June 2013. Those powers remain in effect for a period of three years from the date of this authorisation.

We can acquire, dispose of, or pledge our own shares, profit certificates or any certificates relating thereto subject to compliance with the relevant legal provisions. In particular, the shareholders meeting can authorise the board of directors to, without any resolution of the shareholders meeting, purchase and keep our own shares when such is necessary to prevent an imminent serious harm to the Company. If granted, such authorisation is valid for a period of three years as of the publication thereof in the Annexes to the Belgian Official Gazette. Such authorisation has not been granted to our board of directors.

Our articles of association do not provide for any other specific protective mechanisms against public tender offers.

17.15 Squeeze-out and sell-out

Pursuant to Article 513 of the Belgian Company Code, a person or legal entity, acting alone or in concert, who owns 95% of the voting securities in a publicly held company, can acquire all of the outstanding voting securities or securities granting access to the voting rights in that company by way of a squeeze-out offer. The above threshold is reduced to 90% if the squeeze-out offer takes place in view of a merger by absorption of the company by the legal entity holding 90% of the voting securities of the company.

The securities that are not voluntarily tendered in response to such offer are deemed to be automatically transferred to the offeror at the end of the bidding process and the consideration due from the offeror for such securities is deposited in an escrow account. The consideration paid for the securities must be in cash and must represent the fair value of the securities with a view to safeguarding the interests of the transferring shareholders.

At the end of the squeeze-out offer, the company is no longer deemed to be a publicly held company, unless bonds issued by us, if any, are still publicly held.

In addition, as from the entry into force on 1 September 2007 of the Belgian Law of 1 April 2007 on public tender offers ("Loi du ^{1er} avril 2007 relative aux offres publiques d'acquisition") and its implementing Royal Decrees, certain new rules on the squeeze-out by majority shareholders of the minority shareholders and on the selling-out right of the minority shareholders are applicable.

If, as a result of a (re-opened) voluntary or mandatory tender offer, a bidder (or any person acting in concert with the bidder) holds 95% or more of the shares of the target company, and provided, in respect of a voluntary tender offer only, that the bidder has acquired at least 90% of the target's shares subject to the tender offer as a result of such offer, then the bidder can proceed with a simplified squeeze-out in accordance with Article 42 of the Royal Decree of 27 April 2007 on public squeeze-outs ("Arrêté royal du 27 avril 2007 relatif aux offres publiques de reprise") to acquire the shares not yet acquired by the bidder (or any other person then deemed to act in concert with the bidder).

Also, if, as a result of such a (re-opened) voluntary or mandatory tender offer, a bidder (or any person acting in concert with the bidder) holds 95% or more of the shares of the target company, and provided, in respect of a voluntary tender offer only, that the bidder acquired at least 90% of the target's shares subject to the tender offer as a result of such offer, each security holder has the right to force the bidder to take over its securities against the offer price in accordance with Article 44 of the aforementioned Royal Decree (the so-called "sell-out").

17.16 American Depositary Shares

Citibank, N.A. as depositary, registers and delivers American Depositary Shares, also referred to as ADSs. Each ADS represents the right to receive one ordinary share deposited with the principal office of Citibank International Limited, located at EGSP 186, 1 North Wall Quay, Dublin 1 Ireland or any successor, as custodian for the depositary.

An ADS holder will not be treated as one of our shareholders and will not have shareholder rights. The depositary will be the holder of the ordinary shares underlying ADSs. A holder of ADSs will have ADS holder rights. A deposit agreement among us, the depositary and all persons directly and indirectly holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADRs.

The depositary has agreed to pay ADS holders the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after deducting its fees and expenses.

An ADS holder may surrender his ADSs at the depositary's corporate trust office. Upon payment of the depository's fees and expenses and of any taxes or charges, such as stamp taxes or share transfer taxes or fees, the depositary will deliver the ordinary shares and any other deposited securities underlying the ADSs to the ADS holder or a person designated by him at the office of the custodian or through a book-entry delivery.

The ADS holder may instruct the depositary to vote the number of whole deposited ordinary shares his ADSs represent. The depositary will notify the ADS holder of shareholders' meetings or other solicitations of consents and arrange to deliver our voting materials to ADS holders if we ask it to. Those materials will describe the matters to be voted on and explain how the ADS holder may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary.

The depositary will try, as far as practical, and subject to the laws of Belgium and to our articles of association, to vote or to have its agents vote the ordinary shares or other deposited securities as instructed by ADS holders. If we requested the depositary to act at least 30 days prior to the meeting date and the depositary does not receive voting instructions from the ADS holder by the specified date, it will consider the ADS holder to have authorized and directed it to vote or cause to be voted the number of deposited securities represented by his ADSs in favor of all resolutions set out in the notice of meeting that are endorsed by the Company's board of directors and against all resolutions of that kind that are not so endorsed. The depositary will vote or cause to be voted the deposited securities in accordance with the above unless we notify the depositary that we do not wish the deposited securities to be so voted. The depositary will only vote or attempt to vote as the ADS holder instructs or as described above.

18 TAXATION IN BELGIUM AND IN FRANCE

The following is a summary of the principal Belgian and French tax consequences for investors relating to the acquisition, the ownership and disposal of our shares. This summary is based on our understanding of the applicable laws, treaties and regulatory interpretations as in effect in Belgium and France on the date of this prospectus, all of which are subject to change, including changes that could have a retroactive effect.

This summary does not purport to address all tax consequences associated with the acquisition, ownership and disposal of the shares, and does not take into account the specific circumstances of any particular investor or the tax laws of any country other than Belgium and France. In particular, this summary deals only with investors who hold the shares as capital assets and does not address the tax treatment of investors who are subject to special rules, such as financial institutions, insurance companies, collective investment undertakings, dealers in securities or currencies or persons who hold the shares as a position in a straddle, share-repurchase transactions, conversion transactions, a synthetic security or other integrated financial transaction. This summary does not address the local taxes that may be due in connection with an investment in shares, other than the additional local taxes which generally vary from 0% to 10% of the investor's income tax liability in Belgium.

Investors should consult their own advisers regarding the tax consequences of an investment in the shares in light of their particular situation, including the effect of any state, local or other national laws, treaties and regulatory interpretations thereof.

18.1 Taxation in Belgium

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (that is, an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (that is, a corporate entity that has its statutory seat, its principal establishment, its administrative seat or seat of management in Belgium), an Organisation for Financing Pensions subject to Belgian corporate income tax (*i.e.*, a Belgian pension fund incorporated under the form of an Organisation for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (that is, a legal entity other than a company subject to Belgian corporate income tax, that has its statutory seat, its main establishment, its administrative seat or seat of management in Belgium). A Belgian non-resident is any person that is not a Belgian resident.

Investors should consult their own advisors regarding the tax consequences of an investment in our shares in the light of their particular circumstances, including the effect of any state, local or other national laws.

18.1.1 Dividends

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to our shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the Belgian Companies Code is not treated as a dividend distribution to the extent such repayment is imputed to fiscal capital. This fiscal capital includes, in principle, the actual paid-up statutory share capital and, subject to certain conditions, the paid-up issuance premiums and the cash amounts subscribed to at the time of the issuance of profit sharing certificates.

Belgian dividend withholding tax of 25% is normally levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions.

In the event of a redemption of our shares, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed shares) will be treated as a dividend subject to Belgian withholding tax of 25%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if this redemption is carried out on Euronext Brussels or another stock exchange and meets certain conditions.

Belgian resident individuals

For Belgian resident individuals who acquire and hold our shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless elect to report the dividends in their personal income tax return. Where the beneficiary opts to report them, dividends will normally be taxable at the lower of the generally applicable 25% tax rate on dividends or at the progressive personal income tax rates applicable to the taxpayer's overall declared income. If the beneficiary reports the dividends, the income tax due on such dividends is not increased by local surcharges. In addition, if the dividends are reported, the dividend withholding

tax levied at source can, in both cases, be credited against the personal income tax due and is reimbursable to the extent it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or capital loss on our shares. The latter condition is not applicable if the individual can demonstrate that he has held our shares in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends.

For Belgian resident individual investors who acquire and hold our shares for professional purposes, the Belgian withholding tax does not fully discharge their income tax liability. Dividends received must be reported by the investor and are, in such an event, taxable at the investor's personal income tax rate increased with local surcharges. Belgian withholding tax levied at source can be credited against the personal income tax due and is reimbursable to the extent it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the shares in full legal ownership at the time the dividends are paid or attributed, and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the shares. The latter condition is not applicable if the investor can demonstrate that he has held the full legal ownership of the shares for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends.

Belgian resident companies

Corporate income tax

For Belgian resident companies, the gross dividend income (including any Belgian withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 33.99% (lower corporate income tax rates apply for Small and Medium Sized Enterprises ("SMEs")).

Belgian resident companies can generally (although subject to certain limitations) deduct up to 95% of the gross dividend received from their taxable income ("dividend received deduction"), provided that at the time of a dividend payment or attribution: (i) the Belgian resident company holds shares representing at least 10% of our share capital or a participation in us with an acquisition value of at least €2,500,000 (it being understood that only one out of the two tests must be satisfied); (ii) our shares have been or will be held in full ownership for an uninterrupted period of at least one year immediately prior to the payment or attribution of the dividend; and (iii) the conditions relating to the taxation of the underlying distributed income, as described in Article 203 of the Belgian Income Tax Code (the "Article 203 ITC Taxation Condition") are met (together, the "Conditions for the application of the dividend received deduction regime").

The Conditions for the application of the dividend received deduction regime depend on a factual analysis and for this reason the availability of this regime should be verified upon each dividend distribution.

Any Belgian dividend withholding tax levied at source can in principle be credited against the corporate income tax due and is reimbursable to the extent it exceeds such corporate income tax, subject to two conditions: (i) the taxpayer must own our shares in full legal ownership at the time the dividends are paid or attributed and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on our shares. The latter condition is not applicable: (i) if the taxpayer can demonstrate that it has held the shares in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) if, during that period, the shares never belonged to a taxpayer other than a Belgian resident company or a non-resident company that has, in an uninterrupted manner, invested the shares in a Belgian establishment.

Withholding tax

Dividends distributed to a Belgian resident company will be exempt from Belgian withholding tax provided that the Belgian resident company holds, upon payment or attribution of the dividends, at least 10% of our share capital and such minimum participation is or will be held for an uninterrupted period of at least one year.

In order to benefit from this exemption, the investor must provide the Company or its paying agent with a certificate confirming its qualifying status and the fact that it satisfies the two conditions. If the investor holds a qualifying participation for less than one uninterrupted year, at the time the dividends are paid or attributed, the Company will levy the withholding tax but not transfer it to the Belgian Treasury provided the investor certifies its qualifying status, the date from which it has held such minimum participation, and its commitment to hold the qualifying participation for an uninterrupted period of at least one year. The investor must also inform the Company or its paying agent when the one-year period expires or if its shareholding will drop below 10% of our share capital before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the levied dividend withholding tax will be passed on to the investor.

Organisations for financing pensions

For organisations for financing pensions ("OFPs"), i.e., Belgian pension funds incorporated under the form of an OFP (organismes de financement de pensions) within the meaning of Article 8 of the Belgian Law of 27 October 2006, the dividend income is generally tax-exempt. Although there is no specific exemption from dividend withholding tax at source for dividends paid or attributed to OFPs, subject to certain limitations, the Belgian dividend withholding tax can be credited against the OFPs' corporate income tax and is reimbursable to the extent it exceeds the corporate income tax due.

Other taxable legal entities

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

Belgian non-resident individuals and companies

For non-resident individuals and companies, the dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds our shares in connection with a business conducted in Belgium through a Belgian establishment.

If our shares are acquired by a non-resident investor in connection with a business in Belgium through a Belgian establishment, the investor must report any dividends received, which are taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Any Belgian withholding tax levied at source can be credited against the non-resident individual or corporate income tax and is reimbursable to the extent it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own our shares in full legal ownership at the time the dividends are paid or attributed and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the shares. The latter condition is not applicable if (i) the non-resident individual or the non-resident company can demonstrate that the shares were held in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the shares in a Belgian establishment.

Non-resident companies that have invested their shares in the Company in a Belgian establishment can deduct up to 95% of the gross dividends included in their taxable profits if, at the date dividends are paid or attributed, the Conditions for the application of the dividend received deduction regime are satisfied. Application of the dividend received deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Belgian dividend withholding tax relief for non-residents

Under Belgian tax law, dividend withholding tax is not due on dividends paid to a foreign pension fund which satisfies the following conditions: (i) to be a legal entity with tax residence outside of Belgium; (ii) whose corporate purpose consists solely of managing and investing funds collected in order to pay statutory or complementary pensions; (iii) whose activity is restricted to the investment of funds collected in the exercise of its statutory mission, without any profit making aim; (iv) which is exempt from income tax in its country of residence; and (v) provided it is neither contractually obligated to redistribute the dividends to any ultimate beneficiary of such dividends for whom it would manage our shares, nor obligated to pay a manufactured dividend with respect to our shares under a securities lending transaction. The exemption will only apply if the foreign pension fund provides a certificate confirming that it is the full legal owner or usufruct holder of the shares and that the above conditions are satisfied. The foreign pension fund must then forward that certificate to the Company or its paying agent.

Dividends distributed to non-resident parent companies established in a Member State of the EU or in a (non-EU) country with which Belgium has concluded a bilateral tax treaty that includes a qualifying exchange of information clause, are exempt from Belgian dividend withholding tax provided our shares held by the non-resident parent company, upon payment or attribution of the dividends, amount to at least 10% of our share capital and such minimum participation is or will be held for an uninterrupted period of at least one year. A company qualifies as a parent company provided that (i) for companies established in a Member State of the EU, it has a legal form as listed in the annex to the EU Parent-Subsidiary Directive of 23 July 1990 (90/435/EC), as amended by Directive 2003/123/EC of 22 December 2003, or, for companies established in a (non-EU) country with which Belgium has concluded a qualifying bilateral tax treaty it has a legal form similar to the ones listed in such annex; and (ii) it is considered to be a tax resident of the country where it is established according to the tax laws of and the bilateral tax treaties concluded by such country; and (iii) it is subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime.

In order to benefit from this exemption, the investor must provide the Company or its paying agent with a certificate confirming its qualifying status and the fact that it meets the three abovementioned conditions. If the investor holds a qualifying participation for less than one year, at the time the dividends are paid or attributed, the Company will levy the withholding tax but not transfer it to the Belgian Treasury provided that the investor certifies its qualifying status, the date from which it has held such qualifying participation, and commits itself to hold the qualifying participation for an uninterrupted period of at least one year. The investor must also inform the Company or its paying agent when the one-year holding period expires or if its shareholding will drop below 10% of our share capital before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the levied dividend withholding tax will be passed on to the investor.

If there is no exemption available under Belgian domestic law, the Belgian withholding tax can potentially be reduced for non-resident investors pursuant to the bilateral tax treaty concluded between Belgium and the state of residence of the investor. Belgium has concluded bilateral tax treaties with over 95 countries, reducing the dividend withholding tax rate to 20%, 15%, 10%, 5% or 0% for residents of those countries, depending on conditions, among others, related to the size of the shareholding and certain identification formalities. Such reduction may be obtained either directly at source or through a refund of taxes withheld in excess of the applicable tax treaty rate.

Prospective holders should consult with their own tax advisors as to whether or not they qualify for any treaty-based reduction of Belgian dividend withholding tax upon payment or attribution of dividends, and as to the procedural requirements for obtaining a reduced withholding tax upon the payment of dividends or for making claims for reimbursement.

18.1.2 Capital gains and losses

Belgian resident individuals

In principle, Belgian resident individuals acquiring our shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the shares; capital losses are not tax deductible.

However, capital gains realised by a private individual are taxable at 33% (plus local surcharges) if the capital gain is deemed to be realised outside the scope of the normal management of the individual's private estate. Moreover, capital gains realised by Belgian resident individuals on the disposal of the Company's shares for consideration, outside the exercise of a professional activity, to a legal person that has its registered office, its principal establishment, or place of management outside the European Economic Area, are in principle taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned directly or indirectly, alone or with his/her spouse or with certain relatives, a substantial shareholding in the Issuer (i.e., a shareholding of more than 25% in the Company). Capital losses are, however, not tax deductible.

Gains realised by Belgian resident individuals upon the redemption of our shares or upon our liquidation are generally taxable as a dividend.

Belgian resident individuals who hold our shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realised upon the disposal of the shares, except for shares held for more than five years, which are taxable at a flat rate of 16.5% (plus local surcharges). Capital losses on the shares incurred by Belgian resident individuals who hold the shares for professional purposes are in principle tax deductible.

Belgian resident companies

Belgian resident companies (not being SMEs) are subject to Belgian capital gains taxation at a flat rate of 0.412% on gains realised upon the disposal of our shares provided that: (i) the Article 203 ITC Taxation Condition is satisfied and (ii) the shares have been held in full legal ownership for an uninterrupted period of at least one year. The 0.412% flat capital gains tax rate cannot be off-set by any tax assets (such as tax losses) or tax credits.

Belgian resident companies qualifying as SMEs (within the meaning of Article 15 of the Belgian Companies Code) are normally not subject to Belgian capital gains taxation on gains realised upon the disposal of our shares provided that (i) the Article 203 ITC Taxation Condition is satisfied and (ii) the shares have been held in full legal ownership for an uninterrupted period of at least one year immediately preceding the disposal.

If the one-year minimum holding condition would not be satisfied (but the Article 203 ITC Taxation Condition is) the capital gains realised upon the disposal of our shares by a Belgian resident company (non-SME or SME) are taxable at a flat corporate income tax rate of 25.75%.

Capital losses on our shares incurred by resident companies (both non-SMEs and SMEs) are as a general rule not tax deductible.

Our shares held in the trading portfolios (portefeuille commercial/handelsportefeuille) of qualifying credit institutions, investment enterprises and management companies of collective investment undertakings which are subject to the Royal Decree of 23 September 1992 on the annual accounts of credit institutions, investment firms and management companies of collective investment undertakings (comptes annuels des établissements de crédit, des entreprises d'investissement et des sociétés de gestion d'organismes de placement collectif/jaarrekening van de kredietinstellingen, de beleggingsondernemingen en de beheervennootschappen van instellingen voor collectieve belegging) are subject to a different regime. The capital gains on such shares are taxable at the ordinary corporate income tax rate of 33.99% and the capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realisation.

Capital gains realised by Belgian resident companies (both non-SMEs and SMEs and both ordinary Belgian resident companies and qualifying credit institutions, investment enterprises and management companies of collective investment undertakings) upon the redemption of shares by us or upon our liquidation are, in principle, subject to the same taxation regime as dividends.

Organisations for financing pensions

OFPs are, in principle, not subject to Belgian capital gains taxation realised upon the disposal of our shares, and capital losses are not tax deductible.

Other taxable legal entities

Belgian resident legal entities subject to the legal entities income tax are, in principle, not subject to Belgian capital gains taxation on the disposal of shares of the Company, safe in case of a sale of the Company's shares which are directly or indirectly part of a stake representing more than 25% of the share capital in the Company which may, under certain conditions, give rise to a 16.5% tax (plus local surcharges).

Capital gains realised by Belgian resident legal entities upon the redemption of our shares or upon our liquidation are in principle taxed as dividends.

Capital losses on our shares incurred by Belgian resident legal entities are not tax deductible.

Belgian non-resident individuals

Capital gains realised on our shares by a non-resident individual who has not acquired the shares in connection with a business conducted in Belgium through a Belgian establishment are in principle not subject to any Belgian taxation, unless the gain is deemed to be realised outside the scope of the normal management of the individual's private estate and the capital gain is obtained or received in Belgium. However, Belgium has concluded tax treaties with more than 95 countries which generally provide for a full exemption from Belgian capital gains taxation on such gains realised by residents of those countries. Capital losses are generally not tax deductible.

Capital gains realised by Belgian non-resident individuals upon the redemption of our shares or upon our liquidation are generally taxable as dividends.

Capital gains are taxable at the ordinary progressive income tax rates and capital losses are tax deductible, if those gains or losses are realised on our shares by a non-resident individual holding the shares in connection with a business conducted in Belgium through a Belgian establishment.

Belgian non-resident companies or entities

Capital gains realised on our shares by non-resident companies or non-resident entities that have not acquired the shares in connection with a business conducted in Belgium through a Belgian establishment are in principle not subject to any Belgian taxation and losses are not tax deductible.

Capital gains realised by non-resident companies or other non-resident entities holding our shares in connection with a business conducted in Belgium through a Belgian establishment are generally subject to the same regime as Belgian resident companies.

Capital gains realised by non-resident companies or other non-resident entities upon redemption of shares of the Company or upon the liquidation of the Company are generally taxable as dividends.

18.1.3 Tax on stock exchange transactions

The purchase and the sale as well as any other acquisition or transfer for consideration of our shares (secondary market) in Belgium through a professional intermediary is subject to the tax on stock exchange transactions (*taxe sur les opérations de bourse/taks op de beursverrichtingen*) of 0.27% of the purchase price, capped at €800 per

transaction and per party. A separate tax is due by each party to the transaction, and both taxes are collected by the professional intermediary.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in Article 2, 9° and 10° of the Belgian Law of 2 August 2002; (ii) insurance companies described in Article 2, \$1 of the Belgian Law of 9 July 1975; (iii) professional retirement institutions referred to in Article 2, 1° of the Belgian Law of 27 October 2006 concerning the supervision on institutions for occupational pension; (iv) collective investment institutions; and (v) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

As stated under paragraph "Any sale, purchase or exchange of the shares may become subject to the Financial Transaction Tax" (see section 1 "RISK FACTORS"), the EU Commission adopted on 14 February 2013 the Draft Directive on a Financial Transaction Tax ("FTT"). The Draft Directive currently stipulates that once the FTT enters into effect, the Participating Member States shall not maintain or introduce any taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into effect. The Draft Directive is still subject to negotiation between the Participating Member States and may, therefore, be further amended at any time.

18.2 Taxation in France

18.2.1 Dividends

Individuals who are fiscally domiciled in France, who hold the shares in their personal portfolio and who do not carry on a trading activity in conditions which are similar to those of a professional trading activity

Income tax

Dividends received by individuals who are fiscally domiciled in France are taken into account for the computation of their taxable income. They are subject to personal income tax at the progressive rates and, subject to certain conditions, to the exceptional tax on high income (contribution exceptionnelle sur les hauts revenus). For taxpayers who are married or have entered into a civil partnership (PACS) and who are filing a joint tax return, the exceptional tax on high income applies at a rate of 3% on fiscal income (revenu fiscal de référence) of the fiscal household between \$500,000 and \$1,000,000and at a rate of 4% on fiscal income above \$1,000,000. For other taxpayers, the tax applies at a rate of 3% on fiscal income between \$250,000 and \$500,000 and at a rate of 4% on fiscal income above \$500,000.

Furthermore, dividends are generally subject to the 21% withholding tax set out under article 117 *quater* of the French Code général des impôts (the "French Tax Code") if paid by a paying agent located in France. The 21% withholding tax is applicable to the gross amount of the dividend paid and is deductible from their personal income tax liability in respect of the year in which the payment has been made. If the 21% withholding tax exceeds the amount of personal income tax due by the taxpayer, it may be reimbursed.

Pursuant to article 158 of the French Tax Code, a rebate of 40% (*abattement de 40%*) is applicable when the personal income tax liability is computed and certain costs and expenses may also be deducted.

Furthermore, in application of the tax treaty entered into between France and Belgium on 10 March 1964 (the "Treaty"), a French shareholder is entitled to claim a tax credit for the Belgian withholding tax applicable to the dividends. This foreign tax credit may be offset against his/her personal income tax, to the extent that the foreign tax credit does not exceed the amount of French tax attributable to the dividend payments (*règle du butoir*) and that the Belgian withholding tax has been levied in accordance with the Treaty.

Social levies

The following social levies are applicable to the gross amount of the dividends:

contribution sociale généralisée (CSG) at the rate of 8.2% (5.1% being deductible from the taxable income subject to personal income tax);

- contribution au remboursement de la dette sociale (CRDS), at the rate of 0.5% (not deductible from the taxable income subject to personal income tax);
- prélèvement social at the rate of 4.5% (not deductible from the taxable income subject to personal income tax);
- contribution additionnelle au prélèvement social at the rate of 0.3% (not deductible from the taxable income subject to personal income tax); and
- prélèvement de solidarité at the rate of 2% (not deductible from the taxable income subject to personal income tax).

The aggregate rate of the social levies equals 15.5%

Legal entities subject to French corporation tax

Shareholders not qualifying for the participation exemption (régime des sociétés mères et filiales)

Dividends received by shareholders who do not qualify for the participation exemption are subject to corporation tax at a rate of 33.33% to which is added a social surtax at a rate of 3.3% calculated on the amount of corporation tax due after a deduction of €763,000. Besides, an additional contribution of 10.7% applies to companies having a turnover in excess of €250,000,000 during the fiscal years ending on or before 30 December 2016.

Small and medium sized enterprises (i.e. enterprises whose turnover is lower than €7,630,000) may benefit, if the conditions specified under articles 219 l b) and 235 ter ZC of the French Tax Code respectively, are met, from a 15% reduced rate of corporation tax up to €38,120 and from an exemption of the 3.3% social surtax.

By application of the Treaty, a French shareholder is entitled to claim a tax credit for the Belgian withholding tax applicable to the dividends. This foreign tax credit may be offset against the corporation tax due, to the extent that the foreign tax credit does not exceed the amount of French tax attributable to the dividend payments (*règle du butoir*) and that the Belgian withholding tax has been levied in accordance with the Treaty.

Shareholders qualifying for the participation exemption

Pursuant to articles 145 and 216 of the French Tax Code, legal entities (i) subject to corporation tax and (ii) holding at least 5% of our share capital and voting rights (iii) for a continuing period of at least two years may benefit, upon election, from the participation exemption.

Under the participating exemption, dividends are exempt from corporation tax, except that 5% of the dividends received (including any foreign tax credit) must be added back to the shareholder's taxable income (quote-part de frais et charges). Foreign tax credits attached to the dividends cannot be set off against such 5% taxable "quote-part de frais et charges".

18.2.2 Capital gains and losses

Individuals who are fiscally domiciled in France, who hold the shares in their personal portfolio and who do not carry on a trading activity in conditions which are similar to those of a professional trading activity

Pursuant to the Treaty, any capital gains realised by a French resident shareholder upon the disposal of our shares will be taxable in France.

In accordance with article 150-0A of the French Tax Code, capital gains on the disposal of shares are subject to personal income tax at the progressive rates and to social levies at the aggregate rate of 15.5%, as mentioned under paragraph "Social levies", under "Individuals who are fiscally domiciled in France, who hold the shares in their personal portfolio and who do not carry on a trading activity in conditions which are similar to those of a professional trading activity" (see section 18.2.1 "Dividends").

Pursuant to article 150-0 D-1 ter of the French Tax Code, capital gains realised upon the disposal of the shares are reduced by a rebate equal to (i) 50% if the shares have been held between two and less than eight years, (ii) 65% if the shares have been held for eight years or more. The rebate does not apply for the computation of the 15.5% social levies.

According to article 150-0 D of the French Tax Code, capital losses incurred in a given year may be offset against capital gains of the same kind realised during that year and during the ten following years. However, the 50% / 65% rebates apply to capital losses too. Accordingly, the amount of capital losses which is deductible from capital gains of the same kind may be reduced by the application of such rebate.

The capital gains on the disposal of shares may also be subject to the exceptional tax on high income (contribution exceptionnelle sur les hauts revenus), as mentioned under paragraph "Income tax", under "Individuals who are fiscally domiciled in France, who hold the shares in their personal portfolio and who do not carry on a trading activity in conditions which are similar to those of a professional trading activity" (see section 18.2.1 "Dividends").

Legal entities subject to French corporation tax

Pursuant to the Treaty, any capital gains realised by a French resident shareholder upon the disposal of our shares will be taxable in France.

General regime

Capital gains realised upon the disposal of the shares are subject to corporation tax, to the social surtax and to the additional contribution at the rates mentioned under paragraph "Shareholders not qualifying for the participation exemption", under "Legal entities subject to French corporation tax" (see section 18.2.1 "Dividends").

Capital losses are deductible from the taxable income.

Special rules applicable to long-term capital gains and losses

Pursuant to article 219 I a) *quinquies* of the French Tax Code, long-term capital gains realised upon the disposal of shares qualifying as non-portfolio shares (*titres de participation*) and which have been held for at least two years, are exempt from corporation tax, except that 12% of the gross capital gains must be added back to the shareholder's taxable income (*quote-part de frais et charges*). Such exemption does not apply to shares of real estate companies as defined under article 219 I a sexies-0 bis of the French Tax Code.

Long-term capital losses are not deductible for corporation tax purposes and may not be imputed against long-term capital gains for the purposes of computation of the *quote-part de frais et charges*.

Prospective investors should consult their own tax advisor as to the qualification and eligibility of our shares as non-portfolio shares (titres de participation).

18.2.3 Special rules applicable to a plan d'épargne en actions, PEA (personal equity plans)

Under certain conditions set out under article 163 quinquies D of the French Tax Code, our shares may be eligible to the PEA (personal equity plan, plan d'épargne actions).

Holders of a PEA are, subject to certain conditions, entitled to an exemption from personal income tax on net income and net capital gains derived from investments held in the PEA provided that no withdrawal occurs during the five-year period following the opening of the PEA. Special rates of personal income tax apply to closing and withdrawals occurring before two years and between two and five years following the opening of the PEA. Social levies are due upon withdrawal from the PEA.

Capital losses incurred on shares held in a PEA may in principle only be offset against capital gains realised on other shares held in the plan.

In accordance with article L.221-32-1 et seq. of the French Code monétaire et financier, our shares should be eligible to the PEA PME-ETI, a new category of PEA which benefits from the same aforementioned favourable regime.

18.2.4 French wealth tax (impôt de solidarité sur la fortune)

Our shares held by individuals fiscally domiciled in France in their personal portfolio are included in the taxable basis for wealth tax purposes (however wealth tax and similar tax paid outside France on these shares may be deducted, to a certain extent, from the French wealth tax). French wealth tax is applicable at progressive rates to individuals whose net wealth exceeds €1,300,000 on 1 January of the taxation year.

Certain exemptions may be available depending on the specific situation of each holder of our shares. Prospective investors in the shares should therefore consult their own tax advisor in this respect.

18.2.5 Stamp duties

The subscription of the shares does not give rise to stamp duties or other transfer taxes in France. The sale of the shares (from their listing onwards) is not subject to stamp duties or other transfer taxes in France provided that the transfer is not evidenced by a written deed or agreement executed in France, unless a purchase agreement is voluntarily registered before the French tax authorities (in which case the 0.1% rate would apply).

18.2.6 Other situations

Prospective investors who are subject to taxation regimes other than those described above should consult their own tax advisor in respect of their specific situation.

19 INDEX TO FINANCIAL STATEMENTS PREPARED IN ACCORDANCE WITH IFRS AND BELGIAN GAAP

1 STATUTORY AUDITOR'S REPORT ON THE CONSOLIDATED ACCOUNTS FOR THE YEAR ENDED 31 DECEMBER 2014

Reference is made to the auditor's report set out in our Annual Report 2014 and available on our website (http://www.celyad.com/en/financial-reports).

2 CONSOLIDATED FINANCIAL STATEMENTS AS OF 31 DECEMBER 2014 AND 2013

Reference is made to our Annual Report 2014, as approved by the annual shareholders meeting of 5 May 2015 and available on our website (http://www.celyad.com/en/financial-reports).

3 NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Reference is made to our Annual Report 2014, as approved by the annual shareholders meeting of 5 May 2015 and available on our website (http://www.celyad.com/en/financial-reports).

A	-	1

Annex A : Glossary

Allogeneic cells	Cells of a type that is from the same specicies but genetically distinct – from a different donor as the recipient.
Acute Myocardial Infarction (AMI)	Commonly known as a heart attack, is the interruption of blood supply to part of the heart, causing some heart cells to die. This is most commonly due to occlusion (blockage) of a coronary artery following the rupture of an atherosclerotic plaque, which is an unstable collection of lipids (like cholesterol) and white blood cells (especially macrophages) in the wall of an artery. The resulting ischemia (restriction in blood supply) and oxygen shortage, if left untreated for a sufficient period of time, can cause damage or death (infarction) of heart muscle tissue (myocardium).
Autologous cells	Cells that are from the same donor as the recipient.
BLA	<i>Biologics Licence Application</i> . A BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2). The BLA is regulated under 21 CFR 600 – 680.
Cardiac Progenitor Cells (CPCs)	A cardioprogenitor cell is a cellular phenotype with the capacity to yield myocardial tissue and blood vessels upon differentiation.
Cardiac Resynchronisation Therapy (CRT)	A CRT is a type of pacemaker (a medical device which uses electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart) that can pace both the septal and lateral walls of the left ventricle.
Cardiac Stem Cells (CSCs)	Cells that can give rise to all of the major cell types in the human heart.
Cardiogenic cocktail	A mixture of growth factors, cytokines and small molecules that have the capacity to drive Cardiopoiesis.
Cardiogenesis	Development of the heart in the embryo.
Cardiopoiesis	Process to drives stem cells towards the cardiac lineage
Cardiopoietic Cells (CPCs)	Cells that are precursors of fully differentiated cardiac muscle cells. In the lab, CPCs can be generated from stem cells by culture in the presence of a specific cocktail of cardiotrophic factors discovered at the Mayo Clinic.
Cardiovascular Disease (CVD)	A group of disorders of the heart and blood vessels which includes: - Coronary heart disease - Cerebrovascular disease - Peripheral arterial disease - Rheumatic heart disease - Congenital heart disease - Deep vein thrombosis and pulmonary embolism
Consistency lots	Lots produced to document evidence that the process, operated within established parameters, can perform effectively and reproducibly to manufacture a product meeting its predetermined specifications and quality attributes.
Coronary Artery	A condition in which atherosclerotic plaque builds up inside the coronary

Disease (CAD) - also known as Coronary Heart Disease (CHD)	arteries. Plaque is made up of fat, cholesterol, calcium and other substances found in the blood. This can cause angina (chest pain or discomfort) or a heart attack (when the blood flow to an area of the heart muscle is completely blocked, preventing oxygen-rich blood from reaching that area and causing it to die).
Cryopreservation	Cryopreservation is a process where cells or whole tissues are preserved by cooling to low sub-zero temperatures. At these low temperatures, any biological activity, including the biochemical reactions that would lead to cell death, is effectively stopped.
Embryonic Stem Cells (ESCs)	Stem cells derived from the undifferentiated inner mass cells of a human embryo. Embryonic stem cells are pluripotent, meaning they are able to grow (i.e. differentiate) into all derivatives of the three primary germ layers: ectoderm, endoderm and mesoderm.
Ex vivo (experiments)	Experimentation done in or on tissue outside the organism with minimal alteration of natural conditions;
Formulation	Formulation is the vehicle and the form in which an active compound is delivered in the body.
Good Manufacturing Practices (GMP)	GMP is part of a quality system covering the manufacture and testing of active pharmaceutical products. GMPs are guidelines that outline the aspects of production and testing that can impact the quality of a product.
Heart Failure (HF)	Heart Failure is a condition in which the heart has been damaged and cannot pump enough blood to meet the body's metabolic needs. HF can be of ischemic or non-ischemic origin:
	 Ischemic Origin (Coronary Artery Disease) Non-ischemic Origin Hypertension: high blood pressure; Other conditions such as heart valve disease, congenital heart defect, endocarditis (infection of the heart valves) and/or myocarditis (infection of the heart muscle).
	The failing heart keeps working but not as efficiently as it should. HF patients cannot exercise because they become short of breath and tired. In the most severe forms, even slight exercises like walking a short distance are impossible.
Human MSCs	MSCs (see definition below) of human origin.
Immunodeficient rodents	A lineage of rodents (like rats or mice) that are genetically modified to omit some components of the immune system (the system that defends against disease and foreign agents).
Implantable Cardioverter Defibrillator (ICD)	Small battery-powered electrical impulse generator which is implanted in patients who are at risk of sudden cardiac death due to ventricular fibrillation and ventricular tachycardia.
Induced Pluripotent Stems Cells (IPS)	IPSs are pluripotent cells derived from differentiated cells by forcing the expression of key pluripotency genes.
Left Ventricular Assist Device (LVAD)	A LVAD is a mechanical circulatory device that is used to partially or completely replace the function of a failing heart.
Left Ventricular Ejection Fraction	The fraction of blood pumped out of the left ventricle with each heart beat.

(LVEF)	
In vivo (experiments)	Experiments done in animal living systems.
In vitro (experiment)	Experiments done outside animal living systems.
Mesenchymal Stem Cells (MSCs)	Cells located in many tissues serving to repair the organs and tissues. These cells are found in organs like bone marrow, adipose tissue, liver, and pancreas.
Multipotent Stem Cells	Cells that have the potential to give rise to cells from multiple, but a limited number of lineages; i.e. multipotent stem cells can differentiate into a number of cells, but only those of a closely related family of cells.
Neovasculogenesis	Development of new blood vessels.
New York Heart Association (NYHA) Class	The NYHA Functional Classification provides a simple way of classifying the extent of heart failure. Divides patients in one of four categories based on the extend of the disease during physical activity; the limitations/symptoms are related to normal breathing and varying degrees in shortness of breath and/or angina pain.
Paracrine	Paracrine signalling is a form of cell signalling in which the target cell is near ("para" = near) the signal-releasing cell.
Proteomics analysis	Proteomics is the large-scale study of proteins, particularly their structures and functions
RVOT	Right ventricular outflow tract
Secretome	The set of proteins secreted by a cell, a tissue or an organism.
Stem cells	Stem cells are primal cells. Stem cells retain the ability to renew themselves by division and can differentiate into a diverse range of specialised cell types. Stem cells can be found in adult tissues (adult stem cells), embryos (embryonic stem cells or ESCs) or umbilical cord blood.
Supra-Ventricular Tachycardia	A supra-ventricular tachycardia is a tachycardia, or fast heart rhythm, that originates above the ventricles of the heart (mostly in the atriums).
Systolic dysfunction	Impairment of the contractile function of the heart.
Ventricular Tachycardia (VT)	A ventricular tachycardia is a tachycardia, or fast heart rhythm, that originates in one of the ventricles of the heart.
Ventricular fibrillation (VF)	Ventricular fibrillation is a condition in which there is uncoordinated contraction of the cardiac muscle of the ventricles in the heart.

$\label{lem:annexB} \textbf{Annex B: OnCyte LLC Pro-Forma Financial Statements as of 31 December 2014}$

P&L	2014
GRANT REVENUES	
Cost reimbursement	\$954.791,00
Fixed fees	\$50.823,00
Total	\$1.005.614,00
COSTS OF OPERATIONS	
Direct costs	\$903.707,00
Indirect costs	\$330.178,00
Total	\$1.233.885,00
NET EARNINGS (LOSS)	-\$228.271,00
ADDITIONAL CAPITAL CONTRIBUTIONS (WITHDRAWALS) DURING THE YEAR, NET	\$170.470,00
(WITHDRAWALS) DURING THE YEAR, NET	\$170.470,00
NET PARENT COMPANY INVESTMENT, beginning of the year	\$82.754,00
NET PARENT COMPANY INVESTMENT, end of the year	\$24.953,00
•	\$24.953,00 2014
year	
year Balance Sheet CURRENT ASSETS	2014
Balance Sheet CURRENT ASSETS Accounts receivable	2014 \$171.765,00
year Balance Sheet CURRENT ASSETS Accounts receivable Prepaid expenses	2014 \$171.765,00 \$4.182,00
Balance Sheet CURRENT ASSETS Accounts receivable	2014 \$171.765,00
Balance Sheet CURRENT ASSETS Accounts receivable Prepaid expenses Total current assets EQUIPMENT, at cost, net of accumulated	2014 \$171.765,00 \$4.182,00
Balance Sheet CURRENT ASSETS Accounts receivable Prepaid expenses Total current assets	2014 \$171.765,00 \$4.182,00
Balance Sheet CURRENT ASSETS Accounts receivable Prepaid expenses Total current assets EQUIPMENT, at cost, net of accumulated depreciation	2014 \$171.765,00 \$4.182,00 \$175.947,00
Balance Sheet CURRENT ASSETS Accounts receivable Prepaid expenses Total current assets EQUIPMENT, at cost, net of accumulated depreciation of \$27,899 in 2014 and \$9,701 in 2013	2014 \$171.765,00 \$4.182,00 \$175.947,00

Total other assets	\$74.487,00	
TOTAL	\$277.730,00	
CURRENT LIABILITIES		
Accrued expenses	\$212.314,00	
Deferred revenues, current portion	\$10.919,00	
Total current liabilities	\$223.233,00	
DEFERRED REVENUES, less current portion	\$29.544,00	
NET PARENT COMPANY INVESTMENT	\$24.953,00	
TOTAL	\$277.730,00	

Annex C: Independent auditor report on UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

ISAE 3420 Report Independent Auditor's Assurance Report on the compilation of Pro Forma Financial Information included in a Prospectus

In accordance with the terms of our engagement contract dated 28 May 2015 (the "Contract"), we have completed our assurance engagement to report on the compilation of pro forma financial information of Celyad (the "Company") by the Company's Directors.

We report on the pro forma condensed combined financial information (the "Pro Forma Financial Information") that consists of the pro forma statement of financial position as at December 31 2014, the pro forma statement of operations for the period ended December 31 2014, and related notes as set out on pages 116, 117 and 118 of the prospectus to be issued by the Company dated 12 June 2015 (hereafter the "Prospectus"). The applicable criteria on the basis of which the Directors have compiled the pro forma financial information (the "Criteria") are specified in Annex 2 of the EC Regulation N° 809/2004 of 29 April 2004 and in the IBR/IRE "Guidelines to the auditor in prospectus and other related engagements" (2009).

The pro forma financial information has been compiled by the Company's Directors to illustrate the impact of the transaction on the Company's financial position as at December 31 2014 and its financial performance for the period ended December 31 2014 as if the transaction had taken place at December 31 2014 and January 1 2014 respectively. As part of this process, information about the Company's financial position and financial performance has been extracted by the Directors from the Company's financial statements for the period ended December 31 2014, on which an audit report has been published.

The Directors' Responsibility

The Company's Directors are responsible for compiling the Pro Forma Financial Information on the basis of the Criteria.

Auditor's Responsibility

Our responsibility is to express an opinion, as required by EC Regulation N° 809/2004 of 29 April 2004, about whether the Pro Forma Financial Information has been compiled, in all material respects, by the Company's Directors on the basis of the Criteria, and whether that basis is consistent with the Company's accounting policies.

We conducted our engagement in accordance with International Standard on Assurance Engagements (ISAE) 3420, Assurance Engagements to Report on the Compilation of Pro Forma Financial Information Included in a Prospectus, issued by the International Auditing and Assurance Standards Board (IAASB). This standard requires that the auditor complies with ethical requirements and plans and performs procedures to obtain reasonable assurance about

whether the Directors have compiled, in all material respects, the Pro Forma Financial Information on the basis of the Criteria.

For purposes of this engagement, we are not responsible for updating or reissuing any reports or opinions on any historical financial information used in compiling the Pro Forma Financial Information, nor have we, in the course of this engagement, performed an audit or review of the financial information used in compiling the Pro Forma Financial Information.

The purpose of Pro Forma Financial Information included in a prospectus is solely to illustrate the impact of a significant event or transaction on unadjusted financial information of the Company as if the event had occurred or the transaction had been undertaken at an earlier date selected for purposes of the illustration. Accordingly, we do not provide any assurance that the actual outcome of the event or transaction at December 31 2014 would have been as presented.

A reasonable assurance engagement to report on whether the Pro Forma Financial Information has been compiled, in all material respects, on the basis of the applicable criteria involves performing procedures to assess whether the Criteria used by the Directors in the compilation of the Pro Forma Financial Information provide a reasonable basis for presenting the significant effects directly attributable to the event or transaction, and to obtain sufficient appropriate evidence about whether:

- · The related pro forma adjustments give appropriate effect to those criteria;
- The Pro Forma Financial Information reflects the proper application of those adjustments to the unadjusted financial information.

The procedures selected depend on the auditor's judgment, having regard to the auditor's understanding of the nature of the Company, the event or transaction in respect of which the Pro Forma Financial Information has been compiled, and other relevant engagement circumstances.

The engagement also involves evaluating the overall presentation of the Company's Pro Forma Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our Independence and Quality Control

We have complied with the independence and other ethical requirements of the *Code of Ethics for Professional Accountants* issued by the International Ethics Standards Board for Accountants, which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

Our firm applies International Standard on Quality Control 1 and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

Opinion

In our opinion,

- the Pro Forma Financial Information has been properly compiled on the basis stated;
- that basis of consistent with the Company's accounting policies.

Other matter - Restriction on Use and Distribution of our Report

The accompanying Pro Forma Financial Information has only been prepared for the purpose of the prospectus issued by the Company for the admission to trading of new shares to Euronext Brussels and Euronext Paris and may not be suitable for another purpose.

This letter is intended for use outside the United States of America in connection with the Prof Forma Financial information included in the Prospectus dated 12 June 2015. It is not to be used in the United States of America.

Liège, 1 June 2015

PwC Reviseurs d'Entreprises SCCRL Represented by

Patrick Mortroux Partner