

**Nabriva Therapeutics Public Limited Company**

**Directors' Report and Financial Statements**

**Financial Year Ended December 31, 2017**

**Dated: 02 July 2018**

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## DIRECTORS' REPORT

The directors present their report together with the financial statements of the Company (as defined below) for the financial period ended December 31, 2017.

### Note on redomiciliation

On March 1, 2017, Nabriva Therapeutics plc ("Nabriva Ireland"), was incorporated in Ireland under the name Hyacintho 2 plc, and was renamed to Nabriva Therapeutics plc on April 10, 2017. On June 23, 2017, Nabriva Therapeutics plc, a public limited company organized under the laws of Ireland, or Nabriva Ireland, became the successor issuer to Nabriva Therapeutics AG, a stock corporation (Aktiengesellschaft) organized under the laws of Austria, or Nabriva Austria, for certain purposes under both the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such succession occurred following the conclusion of a tender offer related to the exchange of American Depositary Shares and common shares of Nabriva Austria for ordinary shares of Nabriva Ireland, which resulted in Nabriva Ireland, a new Irish holding company, becoming the ultimate holding company of Nabriva Austria (the predecessor registrant and former ultimate holding company) and its subsidiaries, which we refer to as the Redomiciliation Transaction. On October 19, 2017, Nabriva Austria was converted into a limited liability company under Austrian law and renamed Nabriva Therapeutics GmbH.

Unless the context requires otherwise, all references in this Annual Report to "Nabriva," "the Nabriva Group," "the Company," "we," "ours," "us," or similar terms refer to Nabriva Ireland together with its subsidiaries and on or prior to June 23, 2017 (the effective date of the Redomiciliation Transaction), refer to our predecessor, Nabriva Therapeutics AG, together with its subsidiaries.

### Basis of presentation

The directors have elected to prepare the consolidated financial statements in accordance with Section 279 of the Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position and profit or loss may be given by preparing the financial statements in accordance with United States (U.S.) accounting standards (U.S. GAAP), as defined in that section to the extent that the use of those principles in the preparation of the consolidated financial statements does not contravene any provision of Part 6 of the Companies Act 2014.

### Principal activities

We are a clinical stage biopharmaceutical company engaged in the research and development of novel anti-infective agents to treat serious infections, with a focus on the pleuromutilin class of antibiotics. We are developing our lead product candidate, lefamulin, to be the first pleuromutilin antibiotic available for systemic administration in humans. We are developing both intravenous, or IV, and oral formulations of lefamulin for the treatment of community-acquired bacterial pneumonia, or CABP and may potentially develop lefamulin for additional indications other than CABP.

### Statement of directors' responsibilities in respect of the directors' report and the financial statements

The directors are responsible for preparing the directors' report and the financial statements in accordance with Irish law.

Irish law requires the directors to prepare financial statements for each financial year giving a true and fair view of the consolidated and company's assets, liabilities and financial position as at the end of the financial year and of the profit or loss of the group for the financial year. Under that law, the Directors have prepared the consolidated financial statements in accordance with U.S. accounting standards, as defined in Section 279(1) of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Act or of any regulations made thereunder, and the Parent Company financial statements in accordance with Generally Accepted Accounting Practice in Ireland (accounting standards issued by the Financial Reporting Council of the UK, including Financial Reporting Standard 102, the Financial Reporting Standard applicable in the UK and Republic of Ireland and Irish law).

Under Irish law, the directors shall not approve the financial statements unless they are satisfied that they give a true and fair view of the company's assets, liabilities and financial position as at the end of the financial year and the profit or loss of the company for the financial year.

## **DIRECTORS' REPORT - continued**

### **Statement of directors' responsibilities in respect of financial statements – continued**

In preparing these financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable and prudent;
- state that the consolidated financial statements comply with accounting principles generally accepted in the United States of America (U.S. GAAP) to the extent that it does not contravene Irish Company Law and that the entity financial statements of the Company comply with accounting standards issued by the Financial Reporting Council and Irish law; and
- assess the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and
- use the going concern basis of accounting unless they either intend to liquidate the Company or to cease operations, or have no realistic alternative but to do so.

The directors are responsible for keeping adequate accounting records which disclose with reasonable accuracy at any time the assets, liabilities, financial position and profit or loss of the Company and enable them to ensure that the financial statements comply with the Companies Act 2014. They are responsible for such internal controls as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error, and have general responsibility for taking such steps as are reasonably open to them to safeguard the assets of the Company and to prevent and detect fraud and other irregularities. The directors are also responsible for preparing a directors' report that complies with the requirements of the Companies Act 2014.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the company's website ([www.nabriva.com](http://www.nabriva.com)). Legislation in Ireland governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

### **Accounting records**

The directors believe that they have complied with the requirements of sections 281 to 285 of the Companies Act 2014 with regard to adequate accounting records by employing accounting personnel with appropriate expertise and by providing adequate resources to the financial function. The accounting records of the Company are maintained at Leberstrasse 20, 1110 Vienna, Austria.

### **Directors' compliance statement**

The directors, in accordance with Section 225(2) of the Companies Act 2014, acknowledge that they are responsible for securing the Company's compliance with certain obligations specified in that section arising from the Companies Act 2014, and Tax laws ('relevant obligations'). The directors confirm that:

- a compliance policy statement has been drawn up setting out the Company's policies with regard to such compliance;
- appropriate arrangements and structures that, in their opinion, are designed to secure material compliance with the Company's relevant obligations, have been put in place; and
- a review has been conducted, during the financial year, of the arrangements and structures that have been put in place to secure the Company's compliance with its relevant obligations.

In discharging their responsibilities under Section 225 of the Companies Act 2014, the directors relied on the advice of persons who the directors believe have the requisite knowledge and experience to advise the Company on compliance with its relevant obligations.

### **Audit committee**

In accordance with Section 167 of the Companies Act 2014, the Company has an audit committee, which meets the requirements of the Companies Act.

### **Dividends**

No dividends were paid or proposed during the year.

## DIRECTORS' REPORT - continued

### Events since the end of the financial year

The Company evaluated all events or transactions that occurred subsequent to December 31, 2017 through the date of the approval of the directors' report, and have identified the following events.

In March 2018, the Company entered into a sales agreement with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, the Company may offer and sell its ordinary shares having an aggregate offering price of up to \$50.0 million through Cantor pursuant to an effective universal shelf registration statement. Sales of ordinary shares, if any, under the agreement with Cantor may be made in sales deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. During the first quarter of 2018, the Company issued and sold 3,517,511 ordinary shares for gross proceeds of \$19.4 million, and net proceeds of \$18.5 million, after deducting commissions and other issuance costs.

On March 26, 2018, the Company entered into a license agreement with Sinovant Sciences ("Sinovant") to develop and commercialize lefamulin in greater China. As part of the license agreement, the Company has granted Sinovant, a Roivant Sciences, LTD. subsidiary, an exclusive license to develop and commercialize lefamulin in the greater China region, specifically the People's Republic of China, Hong Kong, Macau, and Taiwan. The companies will establish a joint development committee to review and oversee all development and commercialization plans. Nabriva received a \$5 million upfront payment and will be eligible for up to approximately \$90 million in additional payments tied to the successful completion of certain regulatory and commercial milestones related to lefamulin for CABP. In addition, Nabriva will be eligible to receive low double-digit royalties on sales upon approval in the covered territories. Roivant's affiliate will be solely responsible for all clinical development and regulatory filings necessary to secure approval in the covered territories.

### Research and development

We initiated the first of two pivotal, international Phase 3 clinical trials of lefamulin, which we refer to as Lefamulin Evaluation against Pneumonia 1, or LEAP 1, in September 2015 and initiated the second trial, which we refer to as LEAP 2, in April 2016. On September 18, 2017, we announced positive top-line results for LEAP 1. In LEAP 1, which enrolled 551 patients, lefamulin met all of the primary endpoints of non-inferiority compared to moxifloxacin with or without linezolid as required by the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA. Lefamulin also showed a favorable tolerability profile in the LEAP 1 trial, with no unexpected safety signals or evidence of off-target activity. We completed patient enrollment of 738 adult patients in LEAP 2 in December 2017 and expect to have top-line data available from LEAP 2 in the spring of 2018. If the results of LEAP 2 are also favorable, including achievement of the primary efficacy endpoints of the trial, we expect to submit a new drug application, or NDA, for marketing approval of lefamulin for the treatment of CABP in adults in the United States in the second half of 2018. We also expect to submit a marketing authorization application, or MAA, for lefamulin for the treatment of CABP in adults in Europe a few months after our NDA filing.

We believe that pleuromutilin antibiotics can help address the major public health threat posed by bacterial resistance, which the World Health Organization, or WHO, characterized in 2017 as one of the biggest threats to human health. Increasing resistance to antibiotics used to treat CABP is a growing concern and has become an issue in selecting the appropriate initial antibiotic treatment prior to determining the specific microbiological cause of the infection, referred to as empiric treatment. For example, the U.S. Centers for Disease Control and Prevention, or CDC, has classified *Streptococcus pneumoniae*, the most common respiratory pathogen, as a serious threat to human health as a result of increasing resistance to currently available antibiotics. In addition, the CDC recently reported on the growing evidence of widespread resistance to macrolides, widely used antibiotics that disrupt bacterial protein synthesis, in *Mycoplasma pneumoniae*, a common cause of CABP that is associated with significant morbidity and mortality. Furthermore, *Staphylococcus aureus*, including methicillin-resistant *S. aureus*, or MRSA, which has also been designated as a serious threat to human health by the CDC, has emerged as a more common cause of CABP in some regions of the world, and a possible pathogen to be covered with empiric therapy.

## **DIRECTORS' REPORT - continued**

### **Research and development - continued**

As a result of increasing resistance to antibiotics and the wide array of potential pathogens that cause CABP, the current standard of care for hospitalized patients with CABP whose treatment is initiated in the hospital usually involves first-line empiric treatment with a combination of antibiotics (beta-lactams and macrolides) to address all likely bacterial pathogens or monotherapy with a fluoroquinolone. Combination therapy presents the logistical challenge of administering multiple drugs with different dosing regimens, with some drugs available only as IV, and increases the risk of drug-drug interactions and the potential for serious side effects. Fluoroquinolones are associated with safety and tolerability concerns, including a relatively high risk for developing *Clostridium difficile* infection and increasing rates of resistance for uropathogens. We believe these concerns have resulted in a decreasing use of fluoroquinolones and restriction of their use within a growing number of hospitals. In addition, in May 2016, the FDA announced that an FDA safety review has shown that fluoroquinolones, when used systemically, in the form of tablets, capsules and injectable, are associated with disabling and potentially permanent serious side effects that can occur together. These side effects can involve the tendons, muscles, joints, nerves, and central nervous system. Fluoroquinolones are typically administered in combination with other antibiotics, if community-acquired MRSA is suspected. In addition, many currently available antibiotic therapies are only available for IV administration and are prescribed for seven to fourteen days, meaning continued treatment requires prolonged hospitalization or a switch to a different antibiotic administered orally, with the attendant risk that the patient might respond differently.

Effective January 1, 2017, the Joint Commission & Center for Medicare and Medicaid Services, or CMS, began requiring all U.S. hospitals to have Antibiotic Management guidelines, also known as "Stewardship" Committees, in place to identify antibiotics most appropriate and targeted to each individual patient's infection. Past efforts to "cast the widest net possible" with broad-spectrum antibiotics that affect many types of bacteria have caused problems, such as *C. difficile* infections, by killing good bacteria or increased antibiotic resistance in other bacteria in different areas of the body. Additionally, in 2016, the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America, or IDSA/SHEA, updated their Antibiotic Stewardship guidelines for antibiotic use. We believe that three key goals from these guidelines are applicable to the treatment of CABP:

- Reduce the risk of antibiotics associated with a high risk of *C. difficile* infections;
- Increase use of oral antibiotics as a strategy to improve outcomes or decrease costs; and
- Reduce antibiotic therapy to the shortest effective duration.

Consistent with the Antimicrobial Stewardship principles, we believe that lefamulin could be well suited as either a first-line or second-line empiric monotherapy for the treatment of CABP patients in the hospital setting, outpatient-transition of care or in the community setting, because of its novel mechanism of action, complete spectrum of activity for CABP pathogens, including against multidrug resistant strains, achievement of substantial drug concentrations in lung fluids and lung immune cells, and flexibility as step down oral agent with both the IV and oral formulations and favorable safety and tolerability profile.

In recognition of the growing need for the development of new antibiotics, recent regulatory changes, including priority review and regulatory guidance enabling smaller clinical trials, have led to renewed interest from the pharmaceutical industry in anti-infective development. For example, the Food and Drug Administration Safety and Innovation Act became law in 2012 and included the Generating Antibiotic Incentives Now Act, or the GAIN Act, which provides incentives, including access to expedited FDA review for approval, fast track designation and five years of potential data exclusivity extension for the development of new Qualified Infectious Disease Products ("QIDP").

### **Branches**

The company does not operate any branches outside of the state.

### **Political donations**

No political contributions that require disclosure under Irish law were made during the financial year.

**DIRECTORS' REPORT - continued**

**Business review**

*Revenue*

To date we have not generated any revenues from product sales and we do not expect to generate any revenue from the sale of products in the near future. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, lefamulin. We do not expect to obtain marketing approval before 2019, if at all. If our development efforts result in clinical success and regulatory approval we may also enter into collaboration agreements with third parties and we may generate revenue from those agreements.

Our revenue consists principally of governmental research premiums, non-refundable government grants and the benefit of government loans at below-market interest rates, which are more fully described below under "Critical Accounting Policies."

*Research and development expenses*

Research and development expenses represented 78.0% and 62.7% of our total operating expenses for the years ended December 31, 2016 and 2017, respectively.

For each of our research and development programs, we incur both direct and indirect expenses. Direct expenses include third party expenses related to these programs such as expenses for manufacturing services, non-clinical and clinical studies and other third party development services. Indirect expenses include salaries and related costs, including stock-based compensation, for personnel in research and development functions, infrastructure costs allocated to research and development operations, costs associated with obtaining and maintaining intellectual property associated with our research and development operations, laboratory consumables, consulting fees related to research and development activities and other overhead costs. We utilize our research and development staff and infrastructure resources across multiple programs, and many of our indirect costs historically have not been specifically attributable to a single program. Accordingly, we cannot state precisely our total indirect costs incurred on a program-by-program basis.

The following table summarizes our direct research and development expenses by program and our indirect costs:

(in thousands)	Year ended December 31,	
	2017	2016
	\$	\$
<b>Direct costs</b>		
Lefamulin	34,538	36,003
Other programs and initiatives	223	71
Indirect costs	14,854	11,920
<b>Total</b>	<b>49,615</b>	<b>47,994</b>

We expect to continue to incur research and development expenses in connection with our activities related to our ongoing LEAP 2 clinical trial of lefamulin for the treatment of CABP, our subsequent NDA and MAA filings and the pursuit of the clinical development of lefamulin for additional indications and engage in earlier stage research and development activities. It is difficult to estimate the duration and completion costs of our research and development programs.

## DIRECTORS' REPORT - continued

### Business review – continued

#### *Research and development expenses - continued*

The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, costs and results of clinical trials and other research and development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the efficacy and potential advantages of our product candidates compared to alternative treatments, including any standard of care, and our ability to achieve market acceptance for any of our product candidates that receive marketing approval;
- the costs and timing of commercialization activities, including product sales, marketing, distribution and manufacturing, for any of our product candidates that receive marketing approval; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights and defending against any intellectual property-related claims.

A change in the outcome of any of these variables with respect to the development of our product candidates could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we have completed or currently contemplate will be required for the completion of clinical development of any product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional resources and time on the completion of clinical development of that product candidate.

#### *General and administrative expenses*

General and administrative expenses represented 22.0% and 37.3% of our total operating expenses for the years ended December 31, 2016 and 2017, respectively.

General and administrative expenses consist primarily of salaries and related costs, including share-based compensation not related to research and development activities for personnel in our finance, information technology, commercial, medical affairs and administrative functions. General and administrative expenses also include costs related to professional fees for auditors, lawyers and tax advisors and consulting fees not related to research and development operations, as well as functions that are partly or fully outsourced by us, such as accounting, payroll processing and information technology.

We expect general and administrative expenses to increase with the expansion of our staff and management team in anticipation of the commercialization of lefamulin particularly commercial, medical affairs, technical operations and business development functions.

Additionally, we expect to incur significant marketing, commercial and manufacturing supply chain costs if LEAP 2 data is positive.

### Critical accounting policies

Our management's business review is based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP to the extent that the use of these principles does not contravene any provision of part 6 of the Republic of Ireland's Companies Act 2014. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the end of the reporting period, as well as the reported revenues and expenses during the reporting periods. We base our estimates on our limited historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements. However, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.



**DIRECTORS' REPORT - continued****Research premium and grant revenue**

As a company that carries out extensive research and development activities, we benefit from the Austrian research and development support regime, under which we are eligible to receive a research premium from the Austrian government equal to 12% (10%, in the case of fiscal years prior to 2016) of a specified research and development cost base. Qualifying expenditures largely comprise research and development activities conducted in Austria, however, the research premium is also available for certain related third-party expenses with additional limitations. We received research premiums of \$5.9 million for the year ended December 31, 2016. We have not received any research premium for our qualified 2017 expenditures as of December 31, 2017. We recognize the research premium, as long as we have incurred research and development expenses. Significant judgment is required in determining which expenditures are eligible to be included in the research and development costs base and such costs are subject to review by the Austrian government.

**Research and development expenses**

Research expenses are defined as costs incurred for current or planned investigations undertaken with the prospect of gaining new scientific or technical knowledge and understanding. Development expenses are defined as costs incurred for the application of research findings or specialist knowledge to production, production methods, services or goods prior to the commencement of commercial production or use. We expense all research and development costs as incurred.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- the production of preclinical and clinical trial materials;
- CROs in connection with clinical trials; and,
- investigative sites in connection with clinical trials.

**Results of operations**

*Comparison of Years Ended December 31, 2017 and 2016*

(in thousands)	Year ended December 31,		Change
	2017	2016	\$
	\$	\$	\$
<b>Consolidated operations data:</b>			
Revenues	5,319	6,482	(1,163)
<b>Costs and expenses:</b>			
Research and development	(49,615)	(47,994)	(1,621)
General and administrative	(29,472)	(13,535)	(15,937)
Total operating expenses	<u>(79,087)</u>	<u>(61,529)</u>	<u>(17,558)</u>
<b>Loss from operations</b>	(73,768)	(55,047)	(18,721)
<b>Other income (expense):</b>			
Other income (expense), net	492	(783)	1,275
Interest income (expense), net	<u>275</u>	<u>268</u>	<u>7</u>
<b>Loss before income taxes</b>	(73,001)	(55,562)	(17,439)
Income tax (expense) benefit	<u>(1,355)</u>	<u>672</u>	<u>(2,027)</u>
Net loss	<u>(74,356)</u>	<u>(54,890)</u>	<u>(19,466)</u>

## DIRECTORS' REPORT - continued

### Results of operations - continued

#### *Revenues*

Revenues, consisting primarily of research premium and grant revenue, decreased by \$1.2 million from \$6.5 million for the year ended December 31, 2016 to \$5.3 million for the year ended December 31, 2017. The change was primarily due to a \$1.4 million decrease in grant revenue from research premiums provided to us by the Austrian government as a result of lower applicable research and development expenses, which was offset by a \$0.2 million increase in grant income.

#### *Research and development expenses*

Research and development expenses increased by \$1.6 million from \$48.0 million for the year ended December 31, 2016 to \$49.6 million for the year ended December 31, 2017. The increase was primarily due to a \$2.1 million increase in staff costs due to the addition of employees and a \$1.2 million increase in share-based compensation expense also due to the inclusion of additional employees in our share-based compensation plan, partially offset by a \$1.5 million decrease in direct costs for purchased services related to the development of lefamulin and a \$0.2 million decrease of advisory and external consultancy, travel and other expenses.

#### *General and administrative expenses*

General and administrative expense increased by \$16.0 million from \$13.5 million for the year ended December 31, 2016 to \$29.5 million for the year ended December 31, 2017. The increase was primarily due to a \$4.1 million increase in legal fees mainly related to the redomiciliation of our parent company from Austria to Ireland, a \$6.1 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a \$2.0 million increase in share-based compensation expense due to the inclusion of additional employees in our share-based compensation plan, a \$2.8 million increase in staff costs due to the addition of employees, a \$0.7 million increase in VAT tax expenses, and a \$0.3 million increase in support, infrastructure and other corporate costs.

#### *Other income (expense)*

Other income (expense) decreased by \$1.3 million from a net expense of \$0.8 million for the year ended December 31, 2016 to net income of \$0.5 million for the year ended December 31, 2017. The increase was primarily due to re-measurements of our foreign currency account balances.

#### *Interest income*

During the year ended December 31, 2017, net interest income was relatively flat compared to the same period in 2016.

#### *Income tax (expense) benefit*

Our income tax expense was \$1.4 million for the year ended December 31, 2017 compared to an income tax benefit of \$0.7 million for the year ended December 31, 2016. The year over year change was primarily due to the recognition of a valuation allowance against deferred tax assets in our foreign subsidiaries. Our income tax (expense) benefit includes Irish, Austrian and U.S. income taxes at statutory rates and the effects of various permanent differences.

## DIRECTORS' REPORT - continued

### Principal risks and uncertainties

The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

### Risks related to our financial position and need for additional capital

***We have incurred significant losses since our inception. We expect to incur losses for at least the next several years and may never generate profits from operations or maintain profitability.***

Since inception, we have incurred significant operating losses. Our net losses were \$13.3 million for the three months ended March 31, 2018, \$74.4 million for the year ended December 31, 2017, \$54.9 million for the year ended December 31, 2016. As of March 31, 2018, we had an accumulated deficit of \$292.5 million. To date, we have financed our operations primarily through the sale of our equity securities, convertible loans and research and development support from governmental grants and loans. We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed development of any drugs. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year.

We have re-evaluated the need for the previously planned expansion of our commercial organization, medical education, and supply chain activities and we now anticipate that our expenses for 2018 will decrease as compared to our expenses for 2017 as we wind down our Phase 3 clinical trial program for lefamulin for the treatment of community-acquired bacterial pneumonia, or CABP. We expect to continue to invest in critical pre-commercialization activities prior to receiving marketing approval and making lefamulin available to patients. We initiated the first of our Phase 3 clinical trials, which we refer to as LEAP 1, in September 2015 and initiated the second trial, which we refer to as LEAP 2, in April 2016. In September 2017, we announced positive top-line results for LEAP 1. In December 2017, we announced completion of enrollment for LEAP 2. If the results of LEAP 2 are also favorable, including achievement of the primary efficacy endpoints of the trials, we expect to submit a new drug application, or NDA, for marketing approval of lefamulin for the treatment of CABP in adults in the United States in the fourth quarter of 2018. We also expect to submit a marketing authorization application, or MAA, for lefamulin for the treatment of CABP in adults in Europe a few months after our NDA filing. We also continue to characterize the clinical pharmacology of lefamulin. If we obtain marketing approval of lefamulin for CABP or another indication, we also expect to incur significant additional sales, marketing, distribution and manufacturing expenses.

In addition, our expenses will increase if and as we:

- initiate or continue the research and development of lefamulin for additional indications and of our other product candidates;
- seek to discover and develop additional product candidates;
- seek marketing approval for any product candidates that successfully complete clinical development;
- continue to establish a medical affairs, sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any product candidates for which we receive marketing approval;
- in-license or acquire other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- expand our physical presence in the United States and Ireland;
- establish and expand manufacturing arrangements with third parties; and
- add operational, financial and management information systems and personnel, including personnel to support our product development, our operations as a public company and our planned future commercialization efforts.

## DIRECTORS' REPORT - continued

### Risks related to our financial position and need for additional capital - continued

Our ability to generate profits from operations and remain profitable depends on our ability to successfully develop and commercialize drugs that generate significant revenue. Based on our current plans, we do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, lefamulin. We do not expect to obtain marketing approval before 2019, if at all. This will require us to be successful in a range of challenging activities, including:

- obtaining favorable results from our LEAP 2 clinical trial of lefamulin for the treatment of CABP;
- subject to obtaining favorable results from our LEAP 2 clinical trial, applying for and obtaining marketing approval for lefamulin;
- expanding medical affairs, sales, marketing and distribution capabilities to effectively market and sell lefamulin in the United States;
- establishing and maintaining collaboration, distribution or other marketing arrangements with third parties to commercialize lefamulin in markets outside the United States;
- protecting our rights to our intellectual property portfolio related to lefamulin;
- contracting for the manufacture of and obtaining commercial quantities of lefamulin; and
- negotiating and securing adequate reimbursement from third-party payors for lefamulin.

We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to generate profits from operations. Even if we do generate profits from operations, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to generate profits from operations and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations. A decline in the value of our company could also cause our shareholders to lose all or part of their investment.

***We will need substantial additional funding. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or future commercialization efforts.***

We expect to continue to incur substantial costs in connection with our ongoing activities, particularly as we potentially seek marketing approval for lefamulin and, possibly, other product candidates and continue our research activities. Our expenses will increase if we suffer any delays in our Phase 3 clinical program for lefamulin for CABP, including regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for lefamulin or any other product candidate that we develop, in-license or acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing.

Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We expect that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditures into the first quarter of 2020. 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. This estimate assume, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings.

We expect to seek additional funding in future periods for purposes of investment in our commercial and medical affairs organization, including the expansion of a targeted hospital based sales force and related infrastructure, as well as investing in our supply chain in an effort to enhance the potential commercial launch of lefamulin.

## DIRECTORS' REPORT - continued

### Risks related to our financial position and need for additional capital - continued

Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our clinical trials for lefamulin, including our LEAP 2 trial;
- the costs and timing of process development and manufacturing scale-up activities associated with lefamulin;
- the costs, timing and outcome of regulatory review of lefamulin;
- the costs of commercialization activities for lefamulin if we receive, or expect to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities, including the costs of building finished product inventory and its components in preparation of initial marketing of lefamulin;
- subject to receipt of marketing approval, revenue received from commercial sales of lefamulin;
- the costs of developing lefamulin for the treatment of additional indications;
- our ability to establish collaborations on favorable terms, if at all;
- the scope, progress, results and costs of product development of any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the continued availability of Austrian governmental grants;
- the rate of the expansion of our physical presence in the United States and Ireland; and
- the costs of operating as a public company in the United States.

Conducting clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of lefamulin or any other products that we successfully develop, in-license or acquire, none of which we expect to be commercially available for more than a year, if at all. In addition, if approved, lefamulin or any other product candidate that we develop, in-license or acquire may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives.

Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

***Raising additional capital may cause dilution to our security holders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and funding from local and international government entities and non-government organizations in the disease areas addressed by our product candidates and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a security holder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt service obligations under any debt financings may limit the availability of our cash for other purposes, and we may be unable to make interest payments or repay the principal of such debt financings when due.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

## DIRECTORS' REPORT - continued

### **Risks related to our financial position and need for additional capital - continued**

***Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

Our operations to date have been limited to organizing and staffing our company, developing and securing our technology, raising capital and undertaking preclinical studies and clinical trials of our product candidates. We have not yet demonstrated our ability to successfully complete development of any product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***We have relied on, and expect to continue to rely on, certain government grants and funding from the Austrian government. Should these funds cease to be available, or our eligibility be reduced, or if we are required to repay any of these funds, this could impact our ongoing need for funding and the timeframes within which we currently expect additional funding will be required.***

As a company that carries out extensive research and development activities, we benefit from the Austrian research and development support regime, under which we are eligible to receive a research premium from the Austrian government equal to 14% (12% for the fiscal years 2016 and 2017 and 10%, in the case of fiscal years prior to 2016) of a specified research and development cost base. Qualifying expenditures largely comprise research and development activities conducted in Austria, however, the research premium is also available for certain related third-party expenses with additional limitations. We received research premiums of \$5.9 million for the year ended December 31, 2016. We have not received any research premium for our qualified 2017 expenditures as of March 31, 2018. As we increase our personnel and expand our business outside of Austria, we may not be able to continue to claim research premiums to the same extent as we have in previous years, as some research and development activities may no longer be considered to occur in Austria. As research premiums that have been paid out already may be audited by the tax authorities, there is a risk that parts of the submitted cost base may not be considered as eligible and therefore repayments may have to be made.

***The intended efficiency of our corporate structure depends on the application of the tax laws and regulations in the countries where we operate, and we may have exposure to additional tax liabilities or our effective tax rate could change, which could have a material impact on our results of operations and financial position.***

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the United States and various foreign jurisdictions. We have designed our corporate structure, the manner in which we develop and use our intellectual property, and our intercompany transactions between our subsidiaries in a way that is intended to enhance our operational and financial efficiency. The application of the tax laws and regulations of various countries in which we operate and to our global operations is subject to interpretation. We also must operate our business in a manner consistent with our corporate structure to realize such efficiencies. The tax authorities of the countries in which we operate may challenge our methodologies for valuing developed technology or for transfer pricing. If, for one or more of these reasons, tax authorities determine that the manner in which we operate results in our business not achieving the intended tax consequences, our effective tax rate could increase and harm our financial position and results of operations.

## DIRECTORS' REPORT - continued

### **Risks related to our financial position and need for additional capital - continued**

A change in the tax law in the jurisdictions in which we do business, including an increase in tax rates, an adverse change in the treatment of an item of income or expense, a decrease in tax rates in a jurisdiction in which we have significant deferred tax assets, or a new or different interpretation of applicable tax law, could result in a material increase in tax expense.

### **Risks related to product development and commercialization**

***We depend heavily on the success of our lead product candidate, lefamulin, which we are developing for CABP and other indications. If we are unable to complete our Phase 3 clinical program for lefamulin for CABP as and when expected and obtain marketing approvals for lefamulin, or if thereafter we fail to commercialize lefamulin or experience significant delays in doing so, our business will be materially harmed.***

We have invested a significant portion of our efforts and financial resources in the development of lefamulin. There remains a significant risk that we will fail to successfully develop lefamulin for CABP or any other indication. In September 2017, we announced positive top-line results for LEAP 1, the first of our two pivotal, international Phase 3 clinical trials of lefamulin for the treatment of CABP. Patient enrollment for our second Phase 3 clinical trial of lefamulin for the treatment of CABP was completed in December 2017. We currently expect availability of top-line data for LEAP 2 in the spring of 2018. Our ability to meet our target timing will depend on data analysis for LEAP 2. A significant delay in data analysis would result in delays to our development timelines and additional development costs beyond what we have budgeted. If we ultimately obtain favorable results from LEAP 2, we expect to submit an NDA for marketing approval for lefamulin for the treatment of CABP in adults in the United States in the fourth quarter of 2018. We also expect to submit an MAA for lefamulin for the treatment of CABP in adults in Europe a few months after our NDA filing.

Our ability to generate product revenues, which may not occur for several years, if ever, will depend heavily on our obtaining marketing approval for and commercializing lefamulin. The success of lefamulin will depend on a number of factors, including the following:

- obtaining favorable safety and efficacy results from clinical trials, particularly LEAP 2;
- making arrangements with third-party manufacturers for commercial supply and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities for lefamulin for the treatment of CABP;
- launching commercial sales of lefamulin, if and when approved, in collaboration with third parties;
- acceptance of lefamulin, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- maintaining a continued acceptable safety profile of lefamulin following approval;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our rights in our intellectual property portfolio.

Successful development of lefamulin for the treatment of additional indications, if any, or for use in other patient populations and our ability, if it is approved, to broaden the label for lefamulin will depend on similar factors.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize lefamulin for CABP or for any additional indications, which would materially harm our business.

## DIRECTORS' REPORT - continued

### Risks related to product development and commercialization - continued

***If clinical trials of lefamulin or any of our other product candidates fail to demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration, or FDA, regulatory authorities in the European Union, or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of lefamulin or any other product candidate.***

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and early clinical trials, including Phase 1 clinical trials, in addition to extensive later-stage Phase 3 clinical trials, to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

LEAP 2 and other clinical trials we conduct may not be successful, and the results of our completed clinical trials may not predict success in LEAP 2 or any other clinical trials. Notably, the LEAP 1 and LEAP 2 trial designs are not the same, as the LEAP 2 trial is evaluating a patient population with CABP that is less severe than those patients evaluated in LEAP 1, and LEAP 2 is only investigating oral lefamulin, among other differences. Positive results from LEAP 1 do not guarantee favorable results from LEAP 2. Although we believe that the collective data from prior trials and our preclinical studies provide support for concluding that lefamulin is well suited for treatment of CABP, we may fail to obtain favorable results in our LEAP 2 clinical trial of lefamulin for CABP or regulatory authorities could disagree with our interpretations or analyses of our clinical data. If the results of our LEAP 2 clinical trial are not favorable, including failure to achieve the primary efficacy endpoints of the trial, or regulatory authorities disagree with our interpretations or analyses of our clinical data, we may need to conduct additional clinical trials at significant cost or altogether abandon development of lefamulin for CABP.

If we are required to conduct additional clinical trials or other testing of lefamulin or any other product candidate that we develop beyond those that we contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval 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, including boxed warnings;
- be subject to additional post-marketing testing requirements or restrictions; or
- have the product removed from the market after obtaining marketing approval.

The occurrence of any of the developments listed above could materially harm our business, financial condition, results of operations and prospects.



## DIRECTORS' REPORT - continued

### Risks related to product development and commercialization - continued

***If we experience any of a number of possible unforeseen events in connection with our LEAP 2 clinical trial of lefamulin for CABP or other clinical trials, the potential marketing approval or commercialization of lefamulin or other product candidates could be delayed or prevented.***

We may experience numerous unforeseen events during, or as a result of, our LEAP 2 clinical trial of lefamulin for CABP or other clinical trials we conduct that could delay or prevent our ability to receive marketing approval or commercialize lefamulin or our other product candidates, including:

- clinical trials of lefamulin or our other product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for lefamulin for other indications or our other product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, institutional review boards or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health or safety risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, institutional review boards or independent ethics committees to suspend or terminate the trials.

Our product development costs will increase if we experience delays in enrollment in our clinical development program or our non-clinical development program or in obtaining marketing approvals. We do not know whether any additional non-clinical tests or clinical trials will be required, or if they will begin as planned, or if they will need to be restructured or will be completed on schedule, or at all. Significant non-clinical development program delays, including chemistry, manufacturing and control activities, or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***If we experience delays or difficulties in the enrollment of patients in our clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials of lefamulin or any other product candidate that we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. Some of our competitors have ongoing clinical trials for product candidates that could be competitive with lefamulin, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

## DIRECTORS' REPORT - continued

### Risks related to product development and commercialization - continued

Patient enrollment is affected by other factors including:

- severity of the disease under investigation;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- approval of other therapies to treat the disease under investigation;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the time of year in which the trial is initiated or conducted;
- the geographic distribution of global trial sites, given the timing of pneumonia season globally, and the seasonal variation in the number of patients suffering from pneumonia, including a decline in the number of patients with CABP during the summer months;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- delays in the receipt of required regulatory approvals, or the failure to receive required regulatory approvals, in the jurisdictions in which clinical trials are expected to be conducted; and
- delays in the receipt of approvals, or the failure to receive approvals, from the relevant institutional review board or ethics committee at clinical trial sites.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients in any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

***If serious adverse or undesirable side effects are identified during the development of lefamulin or any other product candidate that we develop, we may need to abandon or limit our development of that product candidate.***

All of our product candidates are in clinical or preclinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development of the compound.

In LEAP 1, lefamulin was generally well tolerated and exhibited a similar rate of treatment-emergent adverse events to the comparator drug. However, 104 patients in the lefamulin arm of the trial reported at least one treatment-emergent adverse event and eight patients withdrew from the trial following an adverse event. Furthermore, at least 2.0% of patients in LEAP 1 who were dosed with lefamulin reported the following adverse events: hypokalemia, nausea, insomnia, infusion site pain and infusion site phlebitis. Fewer than 2.0% of trial patients dosed with lefamulin also experienced hypertension and an increase in alanine aminotransaminase, although no patients met Hy's Law criteria, which is an indicator for severe liver damage.

In addition, lefamulin was well tolerated in our Phase 2 clinical trial for ABSSSI. No patient in the trial suffered any serious adverse events that were found to be related to lefamulin, and no patient in the trial died. Some patients experienced adverse events that were assessed by the investigator as possibly or probably related to study medication. The majority of their symptoms were mild in severity. Four patients discontinued study medication following a drug-related event, three of whom were in a lefamulin treatment group: one patient experienced events of hyperhidrosis, vomiting and headache; one patient experienced infusion site pain; and one patient experienced dyspnea.

## DIRECTORS' REPORT - continued

### Risks related to product development and commercialization - continued

Because the potential for mild effect on electrocardiogram, or ECG, measurements was observed in preclinical studies, we have continued to assess this potential in all human clinical trials we have conducted. In the Phase 2 clinical trial, no change in ECG measurements was considered to be of clinical significance, and no drug-related cardiovascular adverse event was reported. Both lefamulin and vancomycin treatment were associated with a small increase in the QT interval. The QT interval is a measure of the heart's electrical cycle, and a prolonged QT interval is a risk factor for a potential ventricular arrhythmia. In LEAP 1, while changes in QT that were of potential clinical concern were uncommon, one patient treated with lefamulin had an increase in absolute QT interval to greater than 500 msec. We are continuing to evaluate the effect of lefamulin on the QT interval in LEAP 2.

There were no systemic adverse events of clinical concern and no drug-related serious adverse events observed in any of our completed Phase 1 clinical trials of lefamulin. In these trials, the most commonly observed adverse effects with oral administration of lefamulin were related to the gastrointestinal tract, including nausea and abdominal discomfort, while the most commonly observed adverse effects related to IV administration were related to irritation at the infusion site. In addition, lefamulin produced a transient, predictable and reproducible prolongation of the QT interval based on the maximum concentration of the drug in the blood plasma. At the doses administered in the Phase 3 clinical trials for lefamulin for CABP, we expect that the drug will not produce large effects on the QT interval that would be of clinical relevance. We did not observe any drug-related cardiac adverse events, such as increase in ectopic ventricular activity or other cardiac arrhythmia, or clinically relevant ECG findings during the conduct of any of our completed Phase 1 clinical trials. If we observe clinically relevant effects on the QT interval in our Phase 3 clinical trials of lefamulin for CABP or in any other clinical trial of lefamulin, our ability to successfully develop lefamulin for CABP or any other indication may be significantly delayed or prevented.

If we elect or are forced to suspend or terminate any clinical trial of lefamulin or any other product candidates that we are developing, the commercial prospects of lefamulin or such other product candidates will be harmed and our ability to generate product revenues, if at all, from lefamulin or any of these other product candidates will be delayed or eliminated. Any of these occurrences could materially harm our business, financial condition, results of operations and prospects.

***Even if lefamulin or any other product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for lefamulin may be smaller than we estimate.***

If lefamulin or any of our other product candidates receive marketing approval, it or they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current treatments for pneumonia, including generic options, are well established in the medical community, and doctors may continue to rely on these treatments without lefamulin. In addition, our efforts to effectively communicate lefamulin's differentiating characteristics and key attributes to clinicians and hospital pharmacies with the goal of establishing favorable formulary status for lefamulin may fail or may be less successful than we expect. If lefamulin does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- lefamulin's ability to limit the development of bacterial resistance in the pathogens it targets;
- the prevalence and severity of any side effects;
- the ability to offer our product candidates for sale at competitive prices, including in comparison to generic competition;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies, physicians to prescribe these therapies and hospitals to approve the cost and use by their physicians of these therapies;
- our investment in and the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement; and
- the timing of any marketing approval in relation to other product approvals.

## DIRECTORS' REPORT - continued

### **Risks related to product development and commercialization - continued**

Although we believe that the mechanism of action for pleuromutilin antibiotics may result in a low propensity for development of bacterial resistance to lefamulin or our other pleuromutilin product candidates, bacteria might nevertheless develop resistance to lefamulin or our other pleuromutilin product candidates more rapidly or to a greater degree than we anticipate. If bacteria develop such resistance or if lefamulin is not effective against drug-resistant bacteria, the efficacy of these product candidates would decline, which would negatively affect our potential to generate revenues from these product candidates.

Our ability to negotiate, secure and maintain third-party coverage and reimbursement may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. If the level of reimbursement is below our expectations, our revenue and gross margins would be adversely affected. Obtaining formulary approval from third-party payors can be an expensive and time-consuming process. We cannot be certain if and when we will obtain formulary approval to allow us to sell lefamulin or any future product candidates into our target markets. Even if we do obtain formulary approval, third-party payors, such as government or private health care insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drugs. These and other similar developments could significantly limit the degree of market acceptance of lefamulin or any of our other product candidates that receive marketing approval.

***If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing lefamulin or any other product candidate if and when they are approved.***

We have only a very limited sales, marketing and distribution infrastructure, and as a company we have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either establish an adequate sales, marketing and distribution organization or outsource these functions to third parties. If lefamulin receives marketing approval, we plan to commercialize it in the United States with our own targeted hospital sales and marketing organization that we plan to expand, subject to our ability to raise additional capital. In addition, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize lefamulin in markets outside the United States.

There are risks involved with establishing our own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. If we do not establish adequate sales, marketing and distribution capabilities prior to or in connection with the commercial launch of any of our products, such products may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community and may fail commercially or be less successful than we expect. If the commercial launch of a product candidate for which we establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put our sales representatives at a competitive disadvantage relative to sales representatives from companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales, marketing and distribution organization.

## DIRECTORS' REPORT - continued

### **Risks related to product development and commercialization - continued**

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market, sell and distribute ourselves any products that we develop. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to lefamulin and any other products we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are a variety of available therapies marketed for the treatment of CABP. Currently the treatment of CABP is dominated by generic products. For hospitalized patients, combination therapy is frequently used. Many currently approved drugs are well-established therapies and are widely accepted by physicians, patients and third-party payors. We also are aware of various drugs under development for the treatment of CABP, including omadacycline (under Phase 3 clinical development by Paratek Pharmaceuticals Inc.), delafloxacin (under Phase 3 clinical development by Melinta Therapeutics Inc.) and oral nafithromycin (under Phase 2 clinical development by Wockhardt Ltd.).

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 approved for broader indications or patient populations, are more convenient or are less expensive than any products that we may develop. Our competitors may also obtain marketing approvals 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. In addition, our ability to compete may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products. This may have the effect of making branded products less attractive, from a cost perspective, to buyers. We expect that if lefamulin is approved for CABP, it will be priced at a significant premium over competitive generic products. This may make it difficult for us to replace existing therapies with lefamulin. The key competitive factors affecting the success of our product candidates are likely to be their efficacy, safety, convenience, price and the availability of coverage and reimbursement from government and other third-party payors.

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

## DIRECTORS' REPORT - continued

### Risks related to product development and commercialization - continued

***Even if we are able to commercialize lefamulin or any other product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.***

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize lefamulin or any other product candidate successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A major trend in the healthcare industries in the European Union and the United States and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for lefamulin or any other product that we commercialize and, if coverage and reimbursement are available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for lefamulin may be particularly difficult because of the number of generic drugs, which are typically available at lower prices, that are available to treat CABP. In addition, third-party payors are likely to impose strict requirements for reimbursement of a higher priced drug, such as lefamulin. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize lefamulin or other product candidates for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the applicable regulatory authority. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

## DIRECTORS' REPORT - continued

### **Risks related to product development and commercialization - continued**

***Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and to limit commercialization of any products that we may develop or in-license.***

We face an inherent risk of product liability exposure related to the testing of lefamulin and any other product candidate that we develop in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop or in-license. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We maintain clinical trial liability insurance that covers bodily injury to patients participating in our clinical trials up to a \$10.0 million annual aggregate limit and subject to a per event deductible. This amount of insurance may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when and if we begin commercializing lefamulin or any other product candidate that receives marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

### **Risks related to our dependence on third parties**

***Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable quality or cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not own or operate manufacturing facilities for the production of lefamulin that could be used in product candidate development, including clinical trial supply, or for commercial supply, or for the supply of any other compound that we are developing or evaluating in our research program. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of lefamulin, and our strategy is to outsource all manufacturing, packaging, testing, serialization and distribution of our product candidates and products to third parties.

We have entered into agreements, and expect to enter into additional agreements, with third-party manufacturers for the long-term commercial supply of lefamulin. We obtained the pleuromutilin starting material for the clinical trial supply of lefamulin from a single third-party manufacturer, Sandoz GmbH, or Sandoz, a division of Novartis AG, or Novartis. Novartis stopped manufacturing pleuromutilin for us in June 2015 and will not be a commercial supplier of pleuromutilin for us. We have identified an alternative supplier that we believe will be able to provide pleuromutilin starting material for the commercial supply of lefamulin. However, our current operating plans do not include engaging an alternative supplier unless we obtain additional funding. Another third-party manufacturer synthesizes lefamulin from the pleuromutilin starting material and provides our supply of the active pharmaceutical ingredient. We engage separate manufacturers to provide tablets, sterile vials, and sterile diluent that we are using in our clinical trials of lefamulin. We may be unable to conclude agreements for commercial supply with additional third-party manufacturers, or may be unable to do so on acceptable terms.

## DIRECTORS' REPORT - continued

### Risks related to our dependence on third parties - continued

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third-party for regulatory compliance and quality assurance;
- an event at one of our manufacturers or suppliers causing an unforeseen disruption of the manufacture or supply of our product candidates;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and products.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our non-clinical testing and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these trials while we identify and qualify replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us. For example, there are only a limited number of known manufacturers that produce the pleuromutilin starting material used in the synthesis of lefamulin. In early 2015, Novartis completed the sale of its animal health division, including its veterinary products, to a third party. As a result, we have identified an alternative supplier that currently manufactures pleuromutilin starting material for veterinary products, that we believe will be able to provide pleuromutilin starting material for the commercial scale manufacture of lefamulin. However, our current operating plans do not include engaging an alternative supplier unless we obtain additional funding. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

***We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. We expect to continue to rely on such third parties in conducting our clinical trials of lefamulin, and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities.



## DIRECTORS' REPORT - continued

### **Risks related to our dependence on third parties - continued**

Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, or GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a U.S. government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Similar GCP and transparency requirements apply in the European Union. Failure to comply with such requirements, including with respect to clinical trials conducted outside the European Union, can also lead regulatory authorities to refuse to take into account clinical trial data submitted as part of an MAA.

Furthermore, third parties that we rely on for our clinical development activities may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Our product development costs will increase if we experience delays in testing or obtaining marketing approvals.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

***We have entered into and may enter into additional collaborations with third parties for the development or commercialization of lefamulin and our other product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates***

If lefamulin receives marketing approval, we plan to commercialize it in the United States with our own targeted hospital sales and marketing organization. Outside the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize lefamulin. For example, we have entered into a license agreement with Sinovant pursuant to which we granted Sinovant certain rights to manufacture and commercialize lefamulin in the People's Republic of China, Hong Kong, Macau and Taiwan. We also may seek third-party collaborators for development and commercialization of other product candidates or for lefamulin for indications other than CABP.

Our likely future collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Under our license agreement with Sinovant we have, and under any such arrangements we enter into with any third parties in the future we will likely have, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Our current collaborations involving our product candidates pose, and any future collaborations likely will pose, numerous risks to us, including the following:

## DIRECTORS' REPORT - continued

### Risks related to our dependence on third parties - continued

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, product and product candidate priorities, available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborator and us as to the ownership of intellectual property arising during the collaboration;
- we may grant exclusive rights to our collaborators, which would prevent us from collaborating with others;
- collaborators may be unable to enforce our intellectual property rights in territories where we have licensed, or may license, them such rights, which may expose us to material adverse tax and other consequences;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

For example, under our license agreement with Sinovant, if any court, tribunal or governmental agency in the People's Republic of China, Hong Kong, Macau or Taiwan determines that the exclusive license granted to Sinovant pursuant to the license agreement is not sufficiently exclusive such that Sinovant does not have sufficient rights to enforce the licensed patent rights in such territories, we and our subsidiary, Nabriva Therapeutics GmbH, have agreed to take such commercially reasonable steps as Sinovant reasonably requests to grant Sinovant such rights. If a court in such jurisdictions were to determine that our license to Sinovant was not sufficiently exclusive and that Sinovant did not have the rights to enforce the licensed patent rights in the licensed territories, Sinovant may require us to take such actions that it deems reasonable but that we do not and which may have a material adverse effect on our business, including requiring us to make changes to our organizational structure that may result in adverse tax and other consequences, or to conduct other activities that may cause us to incur significant expenses.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

## DIRECTORS' REPORT - continued

### **Risks related to our dependence on third parties - continued**

***If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans.***

The potential commercialization of lefamulin and the development and potential commercialization of other product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to further collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, we intend to seek to commercialize lefamulin through a variety of types of additional collaboration arrangements outside the United States.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for additional collaborations outside greater China will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into additional collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

### **Risks related to our intellectual property**

***If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.***

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States, Europe and in certain additional foreign jurisdictions related to our novel technologies and product candidates that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, if we license technology or product candidates from third parties in the future, these license agreements may not permit us to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering this intellectual property. These agreements could also give our licensors the right to enforce the licensed patents without our involvement, or to decide not to enforce the patents at all. Therefore, in these circumstances, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

## **DIRECTORS' REPORT - continued**

### **Risks related to our intellectual property - continued**

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. We also may not pursue or obtain patent protection in all major markets or may not obtain protection that enables us to prevent the entry of third parties onto the market. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our U.S. patents or pending U.S. patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or any future licensed patents by developing similar or alternative technologies or products in a non-infringing manner. In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity that we obtain under applicable legislation, which may require us to allocate significant resources to preventing such circumvention. Legal and regulatory developments in the European Union and elsewhere may also result in clinical trial data submitted as part of an MAA becoming publicly available. Such developments could enable other companies to circumvent our intellectual property rights and use our clinical trial data to obtain marketing authorizations in the European Union and in other jurisdictions. Such developments may also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights. Our attempts to prevent third parties from circumventing our intellectual property and other rights may ultimately be unsuccessful. We may also fail to take the required actions or pay the necessary fees to maintain our patents.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

## DIRECTORS' REPORT - continued

### Risks related to our intellectual property - continued

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter such infringement or unauthorized use, we may be required to file claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly 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.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.***

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, inter partes review or post-grant review proceedings before the USPTO. The risks of being involved in such litigation and proceedings may increase as our product candidates approach commercialization, and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We may not be aware of all such intellectual property rights potentially relating to our product candidates. Any freedom-to-operate search or analysis previously conducted may not have uncovered all relevant patents and patent applications, and there may be pending or future patent applications that, if issued, would block us from commercializing lefamulin. Thus, we do not know with certainty whether lefamulin, any other product candidate, or our commercialization thereof, does not and will not infringe any third party's intellectual property.

If we are found to infringe a third party's intellectual property rights, or to avoid or settle litigation, we could be required to obtain a license to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to make substantial payments. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

## **DIRECTORS' REPORT - continued**

### **Risks related to our intellectual property - continued**

In addition, while we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our business was founded as a spin-off from Sandoz. Although all patent applications are fully owned by us and were either filed by Sandoz with all rights fully transferred to us, or filed in our sole name, because we acquired certain of our patents from Sandoz, we must rely on their prior practices, with regard to the assignment of such intellectual property. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Intellectual property litigation could cause us to spend substantial resources and could distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be obtained or independently developed by a competitor, our competitive position would be harmed.

## DIRECTORS' REPORT - continued

### Risks related to our intellectual property - continued

***We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.***

Our trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

### Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters

***Even if we complete the necessary non-clinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, in particular in the United States or the European Union, we will not be able to commercialize our product candidates in those markets, and our ability to generate revenue will be materially impaired.***

Our product candidates, including lefamulin, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market lefamulin or any of our other product candidates from regulatory authorities in any jurisdiction.

We have no experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates and expect to rely on third-parties to assist us in this process. Securing marketing approval requires the submission of extensive non-clinical and clinical data and supporting information to various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that lefamulin or any of our other product candidates are not effective or only moderately effective, or have undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval or that prevent or limit commercial use.

The process of obtaining marketing approvals is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, on June 23, 2016, eligible members of the electorate in the United Kingdom decided by referendum to leave the European Union, commonly referred to as "Brexit". On March 29, 2017, the United Kingdom formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Because a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially change the regulatory regime applicable to the approval of any of our product candidates in the United Kingdom. In addition, because the European Medicines Agency, or EMA, is currently located in the United Kingdom but expected to move to the Netherlands as a result of the Brexit, the implications for the regulatory review process in the European Union has not been fully clarified and could result in disruption to the EMA review process.

The FDA and comparable regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from non-clinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

## DIRECTORS' REPORT - continued

### **Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued**

Accordingly, if we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

***Our failure to obtain marketing approval in jurisdictions other than the United States and Europe would prevent our product candidates from being marketed in these other jurisdictions, and any approval we are granted for our product candidates in the United States and Europe would not assure approval of product candidates in other jurisdictions.***

In order to market and sell lefamulin and our other product candidates in jurisdictions other than the United States and Europe, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval process varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval or approvals from regulatory authorities in the European Union. The regulatory approval process outside the United States and Europe generally includes all of the risks associated with obtaining FDA approval or approvals from regulatory authorities in the European Union. In addition, some countries outside the United States and Europe require approval of the sales price of a drug before it can be marketed. In many countries, separate procedures must be followed to obtain reimbursement and a product may not be approved for sale in the country until it is also approved for reimbursement. We may not obtain marketing, pricing or reimbursement approvals outside the United States and Europe on a timely basis, if at all. Approval by the FDA or regulatory authorities in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States and Europe does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA or regulatory authorities in the European Union. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Marketing approvals in countries outside the United States and Europe do not ensure pricing approvals in those countries or in any other countries, and marketing approvals and pricing approvals do not ensure that reimbursement will be obtained.

***Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.***

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the potential requirements to implement a risk evaluation and mitigation strategy or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements including ensuring that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.



## DIRECTORS' REPORT - continued

### Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued

***Any product candidate for which we obtain marketing approval will be subject to strict enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.***

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval.

The FDA and other federal and state agencies, including the U.S. Department of Justice, or DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements.

The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws.

Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

## DIRECTORS' REPORT - continued

### **Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued**

***Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.***

In some countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. Also, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

***The FDA's agreement to a Special Protocol Assessment, or SPA, with respect to the study design of our first Phase 3 clinical trial of lefamulin for CABP does not guarantee any particular outcome from regulatory review, including ultimate approval, and may not lead to a faster development or regulatory review or approval process.***

We reached agreement with the FDA in September 2015 on a SPA, which was later amended in April 2016, regarding the study design of our first Phase 3 clinical trial of lefamulin for the treatment of CABP. The SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a product candidate's efficacy and safety. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to the effectiveness in the indication studied.

Our agreement with the FDA regarding the SPA may not lead to faster development, regulatory review or approval for lefamulin. Once the FDA and an applicant reach an agreement under the special protocol assessment process regarding the design and size of a clinical trial, the agreement generally cannot be changed after the clinical trial begins. Nevertheless, the FDA may revoke or alter a SPA under defined circumstances, such as changes in the relevant data or assumptions provided by the sponsor or the emergence of new public health concerns. A revocation or alteration in our SPA could significantly delay or prevent approval of any marketing applications we submit for lefamulin.

***Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidate.***

If a drug is intended for the treatment of a serious or life threatening condition and the drug demonstrates the potential to address unmet medical need for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has designated each of the IV and oral formulations of lefamulin as a qualified infectious disease product, or QIDP, and granted fast track designations to each of these formulations of lefamulin. However, neither the QIDP nor the fast track designation ensures that lefamulin will receive marketing approval or that approval will be granted within any particular timeframe. We may also seek fast track designation for our other product candidates. We may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

**DIRECTORS' REPORT - continued**

**Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued**

***Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of our product candidate.***

If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the FDA's goal to review an application is six months, rather than the standard review period of ten months. Because the FDA designated each of the IV and oral formulations of lefamulin as a QIDP, lefamulin also will receive priority review. We may also request priority review for other product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

***Designation of our product candidate, lefamulin, as a Qualified Infectious Disease Product does not assure FDA approval of this product candidate.***

A QIDP is an antibacterial or antifungal drug intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or certain "qualifying pathogens." Upon the approval of an NDA for a drug product designated by the FDA as a QIDP, the product is granted an additional period of five years of regulatory exclusivity. Even though we have received QIDP designation for the IV and oral formulations of lefamulin, there is no assurance that this product candidate will be approved by the FDA.

***Under the CURES Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.***

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. 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, which would adversely affect our business, prospects, financial condition and results of operations.

## DIRECTORS' REPORT - continued

### **Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued**

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which in the event of a violation could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates, including lefamulin, for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, 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, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program 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, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at \$5,500 to \$11,000 per false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

## DIRECTORS' REPORT - continued

### Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals, with data collection beginning in August 2013; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any future products that we successfully develop from our product candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations 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 and regulations. 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 civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of lefamulin or any of our other product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any product candidates, including lefamulin, for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA. Among the provisions of the ACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

## DIRECTORS' REPORT - continued

### Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued

- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts (and 70% starting January 1, 2019) off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in April 2013 and, due to subsequent legislative amendments to the statutes, will stay in effect through 2027 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures was passed by the United States Senate.

## **DIRECTORS' REPORT - continued**

### **Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued**

With enactment of the legislation commonly referred to as the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction (CSR) payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain.

We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop commercialize product candidates.

## DIRECTORS' REPORT - continued

### **Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued**

Further, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Moreover, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent drug labeling and post-marketing testing and other requirements.

***We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.***

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in that existing laws might be administered or interpreted.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.



## DIRECTORS' REPORT - continued

### **Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued**

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

There is no assurance that we will be effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, including trade control laws. If we are not in compliance with the FCPA and other anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

***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 currently, and may in the future, involve the use of hazardous and flammable materials, including chemicals and medical and biological materials, and produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and wastes, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or disposal of hazardous wastes, we could be held liable for any resulting damages, and any liability could exceed our resources.

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, this insurance may not provide adequate coverage against potential liabilities. We also maintain a general liability program for some of the risks, but our insurance program includes limited environmental damage coverage, which has an annual aggregate coverage limit of \$2.0 million. Although we maintain an umbrella policy with an annual aggregate coverage limit of \$10.0 million, which may provide some environmental coverage, we do not maintain a separate policy covering environmental damages.

In addition, we may incur substantial costs 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.

***Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.***

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, provide accurate information to the FDA or comparable non-U.S. regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

## DIRECTORS' REPORT - continued

### **Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued**

Employee misconduct could also involve the improper use of information obtained during clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

***We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.***

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our drug development programs and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data 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 our product research, development and commercialization efforts could be delayed.

***We are subject to various laws protecting the confidentiality of certain patient health information, and our failure to comply could result in penalties and reputational damage.***

Certain countries in which we operate have, or are developing, laws protecting the confidentiality of certain patient health information. European Union, or EU, member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations.

## **DIRECTORS' REPORT - continued**

### **Risks related to regulatory approval and marketing of our product candidates and other legal compliance matters - continued**

For example, the EU Data Protection Directive, as implemented into national laws by the EU member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU member states may interpret the EU Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. The EU Data Protection Directive prohibits the transfer of personal data to countries outside of the EU member states that are not considered by the European Commission to provide an adequate level of data protection, and transfers of personal data to such countries can only be made in certain circumstances—for example, where the transfer is required by law or the data subject (i.e. the individual to whom the personal data relates) has given his or her consent to the transfer. Nevertheless, any failure to comply with the rules arising from the EU Data Protection Directive and related national laws of EU member states, as well as privacy laws in other countries in which we operate, could lead to government enforcement actions and significant sanctions or penalties against us, adversely impact our results of operations and subject us to negative publicity.

The EU Data Protection Regulation, which will replace the current EU Data Protection Directive, was adopted in 2016 and will become enforceable on May 25, 2018. The EU Data Protection Regulation will introduce new data protection requirements in the EU and substantial fines for breaches of the data protection rules, may increase our responsibility and liability in relation to personal data that we process and may require us to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

### **Risks related to employee matters and managing growth**

***Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on Dr. Colin Broom, our Chief Executive Officer, and the other principal members of our management and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain "key person" insurance on any of our executive officers. The unplanned loss of the services of any of these persons might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel, including in the United States and Ireland where we plan to expand our physical presence, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we cannot recruit and retain qualified personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

## DIRECTORS' REPORT - continued

### **Risks related to employee matters and managing growth - continued**

***We expect to expand our development, regulatory and sales and marketing capabilities, and, subject to obtaining marketing approval of lefamulin, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs technical operations, supply chain, medical affairs and, subject to obtaining marketing approval of lefamulin, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

### **Risks related to ownership of our ordinary shares**

***An active trading market for our ordinary shares may not be sustained.***

Following the Redomiciliation Transaction, our ordinary shares began trading on the Nasdaq Global Market on June 26, 2017. Given the limited trading history of our ordinary shares, there is a risk that an active trading market for our ordinary shares will not be sustained, which could put downward pressure on the market price of our ordinary shares and thereby affect the ability of our security holders to sell their shares.

***The price of our ordinary shares may be volatile and fluctuate substantially.***

The trading price of our ordinary shares has been and is likely to continue to be volatile. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced significant volatility that has often been unrelated to the operating performance of particular companies. The market price for our ordinary shares may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- regulatory delays and greater government regulation of potential products due to adverse events;
- regulatory or legal developments in the United States, the European Union and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- one of our manufacturers or suppliers could have an event which causes an unforeseen disruption of the manufacture or supply of our product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

## **DIRECTORS' REPORT - continued**

### **Risks related to ownership of our ordinary shares - continued**

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize lefamulin or any of our other product candidates or if our securities experience volatility for any reason. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources.

### **Our executive officers, directors and principal shareholders, if they choose to act together, have the ability to control most matters submitted to shareholders for approval.**

Our executive officers and directors, combined with our shareholders, and their respective affiliates who owned more than 5% of our outstanding ordinary shares as of March 31, 2018 in the aggregate, beneficially owned approximately 52.8% of our share capital. As a result, if these shareholders were to choose to act together, they would be able to control most matters submitted to our shareholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would have significant influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

### **Our ordinary shares do not trade on any exchange outside of the United States.**

Our ordinary shares are listed only in the United States on The Nasdaq Global Market, and we have no plans to list our ordinary shares in any other jurisdiction. As a result, a holder of ordinary shares outside of the United States may not be able to effect transactions in our ordinary shares as readily as the holder may if our ordinary shares were listed on an exchange in that holder's home jurisdiction.

### **The sale of a substantial number of ordinary shares may cause the market price of our ordinary shares to decline.**

Sales of a substantial number of our ordinary shares, or the perception in the market that these sales could occur, could reduce the market price of our ordinary shares. We had 40,233,867 ordinary shares outstanding as of March 31, 2018. To the extent any of these shares are sold into the market, particularly in substantial quantities, the market price of our ordinary shares could decline.

Future issuances of ordinary shares pursuant to our equity incentive plans could also result in a reduction in the market price of our ordinary shares. We have filed registration statements on Form S-8 registering all of the ordinary shares that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance and once vested, subject to volume, notice and manner of sale limitations applicable to affiliates. The majority of ordinary shares that may be issued under our equity compensation plans remain subject to vesting in tranches over a four-year period. As of March 31, 2018, an aggregate of 1,337,202 options to purchase our ordinary shares had vested and become exercisable.

## **DIRECTORS' REPORT - continued**

### **Risks related to ownership of our ordinary shares - continued**

In addition, in March 2018, we entered into a Controlled Equity Offering SM Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we may offer and sell our ordinary shares having an aggregate offering price of up to \$50 million through Cantor. As of March 31, 2018, we issued and sold an aggregate of 3,517,511 ordinary shares under the ATM agreement. From March 31, 2018 to the date of this filing, we issued and sold an aggregate of 3,590,568 ordinary shares under the ATM agreement.

If a large number of our ordinary shares are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our ordinary shares and impede our ability to raise future capital.

### **We are an "emerging growth company", and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.**

We are an "emerging growth company," as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2020 or such earlier time that we are no longer an emerging growth company. For so long as we remain an emerging growth company, we are permitted and may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- an exemption from compliance with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, on the design and effectiveness of our internal controls over financial reporting;
- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board may adopt regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure about the company's executive compensation arrangements; and
- exemptions from the requirements to obtain a non-binding advisory vote on executive compensation or a shareholder approval of any golden parachute arrangements.

We may choose to take advantage of some, but not all, of the available exemptions. We may take advantage of these provisions until December 31, 2020 or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: the last day of the fiscal year in which we have more than \$1 billion (as may be inflation-adjusted by the SEC from time-to-time) in annual revenues; the date we qualify as a "large accelerated filer," with more than \$700 million in market value of our share capital held by non-affiliates; or the issuance by us of more than \$1 billion of non-convertible debt over a three-year period.

We may choose to take advantage of some, but not all, of the available benefits under the JOBS Act. We cannot predict whether investors will find our ordinary shares less attractive if we rely on such exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the market price of our ordinary shares may be more volatile.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

### **We have broad discretion in the use of our funds and may not use them effectively.**

We have broad discretion in the application of our available funds and could spend the funds in ways that do not improve our results of operations or enhance the value of our ordinary shares. Our failure to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our ordinary shares to decline and delay the development of our product candidates. Pending their use, we may invest funds in a manner that does not produce income or that loses value.

**DIRECTORS' REPORT - continued**

**Risks related to ownership of our ordinary shares - continued**

***We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company we incur, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations have made it more expensive for us to obtain director and officer liability insurance, and if such insurance becomes prohibitively expensive, this could make it more difficult for us to attract and retain qualified members of our board.

For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies as described elsewhere in this "Risk Factors" section. We may remain an emerging growth company until December 31, 2020, although if the market value of our share capital that is held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have annual gross revenues of \$1 billion or more in any fiscal year (as may be inflation adjusted by the SEC from time-to-time), we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than \$1 billion of non-convertible debt over a three-year period.

**If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, security holders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.**

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, as an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm until we are no longer an emerging growth company. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

## DIRECTORS' REPORT - continued

### **Risks related to ownership of our ordinary shares - continued**

#### ***United States investors may have difficulty enforcing judgments against us, our directors and executive officers.***

We are incorporated under the laws of Ireland, and our registered offices and a substantial portion of our assets are located outside of the United States. In addition, one of our directors is a resident of a jurisdiction other than the United States. As a result, it may not be possible to effect service of process on such person or us in the United States or to enforce judgments obtained in courts in the United States against such person or us based on civil liability provisions of the securities laws of the United States.

There is no treaty between Ireland and the United States providing for the reciprocal enforcement of foreign judgments. The following requirements must be met before the foreign judgment will be deemed to be enforceable in Ireland:

- the judgment must be for a definite sum;
- the judgment must be final and conclusive; and
- the judgment must be provided by a court of competent jurisdiction.

An Irish court will also exercise its right to refuse judgment if the foreign judgment (1) was obtained by fraud; (2) violates Irish public policy; (3) is in breach of natural justice; or (4) is irreconcilable with an earlier judgment. Further, an Irish court may stay proceedings if concurrent proceedings are being brought elsewhere. Judgments of U.S. courts of liabilities predicated upon U.S. federal securities laws may not be enforced by Irish courts if deemed to be contrary to public policy in Ireland.

#### ***We do not expect to pay dividends in the foreseeable future.***

We have not paid any dividends on our ordinary shares since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that earnings, if any, will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. If we propose to pay dividends in the future, we must do so in accordance with Irish law, which provides that distributions including dividend payments, share repurchases and redemptions be funded from "distributable reserves." Payment of future dividends to security holders will be at the discretion of our board, after taking into account various factors including our business prospects, cash requirements, financial performance, debt covenant limitations and new product development.

#### ***We are exposed to risks related to currency exchange rates.***

A significant portion of our expenses are denominated in currencies other than the U.S. dollar. Because our financial statements are presented in U.S. dollars, changes in currency exchange rates have had and could have a significant effect on our operating results. Exchange rate fluctuations between foreign currencies and the U.S. dollar create risk in several ways, including the following:

- weakening of the U.S. dollar may increase the U.S. dollar cost of overseas research and development expenses;
- strengthening of the U.S. dollar may decrease the value of our revenues denominated in other currencies;
- the exchange rates on non-U.S. dollar transactions and cash deposits can distort our financial results; and
- commercial pricing and profit margins are affected by currency fluctuations.

#### ***As a holding company, our operating results, financial condition and ability to pay dividends or other distributions are entirely dependent on funding, dividends and other distributions received from our subsidiaries, which may be subject to restrictions.***

Our ability to pay dividends or other distributions and to pay our obligations in the future will depend on the level of funding, dividends and other distributions, if any, received from our subsidiaries and any new subsidiaries we establish in the future. The ability of our subsidiaries to make loans or distributions (directly or indirectly) to us may be restricted as a result of several factors, including restrictions in financing agreements and the requirements of applicable law and regulatory and fiscal or other restrictions. In particular, our subsidiaries and any new subsidiaries may be subject to laws that restrict dividend payments, authorize regulatory bodies to block or reduce the flow of funds from those subsidiaries to us, or limit or prohibit



## DIRECTORS' REPORT - continued

### **Risks related to ownership of our ordinary shares - continued**

transactions with affiliates. Restrictions and regulatory action of this kind could impede access to funds that we may need to make dividend payments or to fund our own obligations.

Furthermore, we may guarantee some of the payment obligations of certain of our subsidiaries from time to time. These guarantees may require us to provide substantial funds or assets to our subsidiaries or their creditors or counterparties at a time when we are in need of liquidity to fund our own obligations.

***The ownership percentage of our shareholders may be diluted in the future which could dilute the voting power or reduce the value our outstanding ordinary shares.***

As with any publicly traded company, the ownership percentage of our shareholders may be diluted in the future because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we intend to continue to grant to our directors, officers and employees. From time to time, we may issue additional options or other share awards to our directors, officers and employees under our benefits plans.

In addition, our articles of association authorize us to issue, without the approval of our shareholders, one or more classes or series of preferred shares having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our ordinary shares respecting dividends and distributions, as our board of directors generally may determine. The terms of one or more classes or series of preferred shares could dilute the voting power or reduce the value of our ordinary shares. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred shares could affect the residual value of the ordinary shares.

***The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation. We are incorporated as a public limited company under Irish law.***

The rights of our shareholders are governed by our memorandum and articles of association and Irish law. The rights associated with our ordinary shares are different to the rights generally associated with shares held in a U.S. corporation. Material differences between the rights of shareholders of a U.S. corporation and the rights of our shareholders include differences with respect to, among other things, distributions, dividends, repurchases and redemptions, dividends in shares / bonus issues, the election of directors, the removal of directors, the fiduciary and statutory duties of directors, conflicts of interests of directors, the indemnification of directors and officers, limitations on director liability, the convening of annual meetings of shareholders and special shareholder meetings, notice provisions for meetings, the quorum for shareholder meetings, the adjournment of shareholder meetings, the exercise of voting rights, shareholder suits, rights of dissenting shareholders, anti-takeover measures and provisions relating to the ability to amend the articles of association.

***As an Irish public limited company, certain capital structure decisions require shareholder approval, which may limit our flexibility to manage our capital structure.***

Under Irish law, our board of directors may increase our authorized share capital and issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital, without shareholder approval, once authorized to do so by our articles of association or by an ordinary resolution of our shareholders. Additionally, subject to specified exceptions, Irish law grants statutory preemption rights to existing shareholders where shares are being issued for cash consideration but allows shareholders to disapply such statutory preemption rights either in our articles of association or by way of special resolution. Such disapplication can either be generally applicable or be in respect of a particular allotment of shares. Accordingly, our articles of association contain, as permitted by Irish company law, provisions authorizing our board of directors to issue new shares, and to disapply statutory preemption rights. The authorization of our board of directors to issue shares and the disapplication of statutory preemption rights must both be renewed by the shareholders at least every five years, and we cannot provide any assurance that these authorizations will always be approved, which could limit our ability to issue equity and thereby adversely affect the holders of our ordinary shares.

**DIRECTORS' REPORT - continued**

**Risks related to ownership of our ordinary shares - continued**

***Irish law differs from the laws in effect in the U.S. with respect to defending unwanted takeover proposals and may give our board less ability to control negotiations with hostile offerors.***

We are subject to the Irish Takeover Panel Act, 1997, Takeover Rules, 2013. Under those Irish Takeover Rules, the board is not permitted to take any action that might frustrate an offer for our ordinary shares once the board has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issue of ordinary shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which the board has reason to believe an offer is or may be imminent. These provisions may give the board less ability to control negotiations with hostile offerors and protect the interests of holders of ordinary shares than would be the case for a corporation incorporated in a jurisdiction of the United States.

***The operation of the Irish Takeover Rules may affect the ability of certain parties to acquire our ordinary shares.***

Under the Irish Takeover Rules, if an acquisition of ordinary shares were to increase the aggregate holding of the acquirer and its concert parties to ordinary shares that represent 30% or more of the voting rights of a company, the acquirer and, in certain circumstances, its concert parties would be required (except with the consent of the Irish Takeover Panel) to make an offer for the outstanding ordinary shares at a price not less than the highest price paid for the ordinary shares by the acquirer or its concert parties during the previous 12 months. This requirement would also be triggered by an acquisition of ordinary shares by a person holding (together with its concert parties) ordinary shares that represent between 30% and 50% of the voting rights in the company if the effect of such acquisition were to increase that person's percentage of the voting rights by 0.05% within a 12-month period. The Irish Takeover Rules could therefore discourage an investor from acquiring 30% or more of our outstanding ordinary shares, unless such investor was prepared to make a bid to acquire all outstanding ordinary shares.

***We will be exposed to the risk of future changes in law, which could materially adversely affect us.***

We are subject to Irish law. As a result, we are subject to the risk of future adverse changes in Irish law (including Irish corporate and tax law). In addition, we and our subsidiaries are also subject to the risk of future adverse changes in Austrian and U.S. law, as well as changes of law in other countries in which we and our subsidiaries operate.

***Future adverse changes in law could result in our not being able to maintain a worldwide effective corporate tax rate that is competitive in our industry.***

While we believe that being incorporated in Ireland should not affect our ability to maintain a worldwide effective corporate tax rate that is competitive in our industry, we cannot give any assurance as to what our effective tax rate will be because of, among other things, uncertainty regarding the tax policies of the jurisdictions where we will operate. The tax laws of Ireland, Austria, the United States, and other jurisdictions could change in the future, and such changes could cause a material change in our worldwide effective corporate tax rate. In particular, legislative action could be taken by Ireland, Austria, the United States or other jurisdictions which could override tax treaties upon which we expect to rely and adversely affect our effective tax rate. As a result, our actual effective tax rate may be materially different from our expectation.

***A transfer of our ordinary shares, other than a transfer effected by means of the transfer of book-entry interests in the Depository Trust Company, may be subject to Irish stamp duty.***

Transfers of our ordinary shares effected by means of the transfer of book entry interests in the Depository Trust Company, or "DTC", will not be subject to Irish stamp duty. However, if you hold our ordinary shares directly rather than beneficially through DTC, any transfer of your shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty could adversely affect the price of our ordinary shares.

## DIRECTORS' REPORT - continued

### Risks related to ownership of our ordinary shares - continued

#### ***Our ordinary shares received by means of a gift or inheritance could be subject to Irish Capital Acquisitions Tax.***

Irish Capital Acquisitions Tax, or "CAT" could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares will be regarded as property situated in Ireland. The person who receives the gift or inheritance has primary liability for CAT. Gifts and inheritances passing between spouses are exempt from CAT. Children have a tax-free threshold of €310,000 in respect of taxable gifts or inheritances received from their parents.

#### ***We may be classified as a passive foreign investment company for our tax year ending December 31, 2018, which may result in adverse U.S. federal income tax consequence to U.S. holders.***

Based on our estimated gross income and average value of our gross assets and the nature of our business, we do not believe that we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for our tax years ended December 31, 2016 or 2017. A corporation organized outside the United States generally will be classified as a PFIC for U.S. federal income tax purposes (1) in any taxable year in which at least 75% of its gross income is passive income or on average at least 50% of the gross value of its assets is attributable to assets that produce passive income or are held for the production of passive income and (2) as to a given holder who was a holder in such year and regardless of such corporation's income or asset composition, in any subsequent taxable year, unless certain elections are made by that holder that can discontinue that classification as to that holder, at the risk of imposing substantial tax costs to that holder. Passive income for this purpose generally includes dividends, interest, royalties, rents and gains from commodities and securities transactions. Our status in any taxable year will depend on our assets and activities in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC for the current taxable year or any future taxable year. The market value of our assets may be determined in large part by reference to the market price of our ordinary shares, which may fluctuate considerably given that market prices of biotechnology companies have been especially volatile. If we were to be treated as a PFIC for the tax year ending December 31, 2018, or any other future taxable year during which a U.S. holder held our ordinary shares, however, certain adverse U.S. federal income tax consequences could apply to the U.S. holder. We currently intend to make available the information necessary to permit a U.S. holder to make a valid QEF election, which may mitigate some of the adverse U.S. federal income tax consequences that could apply to a U.S. holder of ordinary shares. However, we may choose not to provide such information at a future date.

### **Financial risk management**

We are exposed to a variety of financial risks in the ordinary course of our business: market risk, credit risk and liquidity risk. Our overall risk management program focuses on preservation of capital given the unpredictability of financial markets. These market risks are principally limited to interest rate and foreign currency fluctuations.

#### **Credit risk**

We do not have any significant credit risk exposure to any single counterparty or any group of counterparties having similar characteristics. The credit risk on liquid funds (bank accounts, cash balances, marketable securities and term deposits) is limited because the counterparties are banks with high credit ratings from international credit rating agencies. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes.

#### **Market risk**

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the euro and the British pound. Our functional currency is the U.S. dollar, but we receive payments and acquire materials, in each of these other currencies. We have not established any formal practice to manage the foreign exchange risk against our functional currency. However, we attempt to minimize our net exposure by buying or selling foreign currencies at spot rates upon receipt of new funds to facilitate committed or anticipated foreign currency transactions.

## **DIRECTORS' REPORT - continued**

### **Market risk - continued**

Interest rate risk may arise from short-term or long-term debt. As of March 31, 2018, we had no debt that exposed us to interest rate risk. As of March 31, 2018, we had neither significant long-term interest-bearing assets nor significant long-term interest-bearing liabilities, other than a de minimis government loan we have received at a below-market rate of interest from the Austrian Research Promotion Agency (Österreichische Forschungsförderungsgesellschaft, or FFG). Due to the short-term nature of our investment portfolio, we do not believe an immediate 10% increase in interest rates would have a material effect on the fair market value of our portfolio, and accordingly we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

### **Liquidity risk**

Since our inception, we have incurred net losses and generated negative cash flows from our operations. Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2020. 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.

We have re-evaluated the need for the previously planned expansion of our commercial organization, medical education, and supply chain activities and we anticipate that our expenses for 2018 will decrease as compared to our expenses for 2017 as we wind down our Phase 3 clinical trial program for lefamulin for the treatment of CABP. We expect to continue to invest in critical pre-commercialization activities prior to receiving marketing approval and making lefamulin available to patients. We expect to seek additional funding in future periods for purposes of investment in our commercial and medical affairs organization, including the expansion of a targeted hospital based sales force and related infrastructure, as well as investing in our supply chain in an effort to enhance the potential commercial launch of lefamulin.

If we obtain marketing approval for lefamulin or any other product candidate that we develop, in-license or acquire, we expect to incur significant additional commercialization expenses related to product sales, marketing, distribution and manufacturing. Our expenses will increase if we suffer any delays in our Phase 3 clinical program, including regulatory delays, or are required to conduct additional clinical trials to satisfy regulatory requirements. We have developed plans to mitigate this risk, which primarily consist of raising additional capital through a combination of equity or debt financings, new collaborations, and reducing cash expenditures.

However, there can be no assurance that we will be successful in acquiring additional capital at level sufficient to fund our operations or on terms favorable to us. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce to eliminate our research and development programs or any future commercialization effort.

### **Acquisition of own shares**

On June 23, 2017, 1 Ordinary share of \$0.01 and 25,000 Euro Deferred shares of €1.00 each in the issued share capital of the Company, which were fully paid and held by Canyon Corporate Secretaries Limited, were fully redeemed for nil consideration and upon redemption such shares were immediately cancelled, in accordance with the Articles of Association of the Company.

**DIRECTORS' REPORT - continued**

**Directors**

The names of the persons who served as directors during the financial year are:

Daniel Burgess  
 Stephen Webster  
 George Talbot  
 Charles Rowland  
 Mark Corrigan  
 Axel Bolte  
 Carrie Bourdow  
 Colin Broom  
 Andrew Ryan (resigned June 23, 2017)  
 Paul Ryan (resigned June 23, 2017)  
 Gary Sender (resigned June 23, 2017)  
 Mihovil Spoliaric (resigned June 23, 2017)  
 Chau Khuong (resigned August 11, 2017)

**Directors' and secretary's interests in shares and debentures**

The interests of the directors and the secretary in office as at December 31, 2017 in shares of the Company were:

	December 31, 2017		Date of appointment	
	Ordinary shares	Share options	Ordinary shares	Share options
<i>Directors:</i>				
Daniel Burgess	-	-	-	-
Stephen Webster	-	-	-	-
George Talbot	33,140	36,767	28,490	32,123
Charles Rowland	-	-	-	-
Mark Corrigan	-	-	-	-
Axel Bolte	-	-	-	-
Carrie Bourdow	-	-	-	-
Colin Broom	<u>160,000</u>	<u>422,385</u>	<u>157,412</u>	<u>277,880</u>
<i>Secretary</i>				
Robert Crotty	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>

The directors and secretary had no other interests in the shares or debentures of the company or any other group company at December 31, 2017 or on their date of appointment.

**DIRECTORS' REPORT - continued**

**Disclosure of information to auditors**

For the purposes of section 330 of the Companies Act, each of the persons who are directors at the date of approval of this report individually confirm that:

- In so far as they are aware, there is no relevant audit information of which the company's statutory auditors are unaware; and
- That they have taken all the steps that they ought to have taken as a director in order to make themselves aware of any relevant audit information and to establish that the company's statutory auditors are aware of that information.

**Statutory auditors**

The statutory auditors, KPMG Ireland, have indicated their willingness to continue in office, and a resolution that they be re-appointed will be proposed at the Annual General Meeting.

**On behalf of the board**



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**Colin Broom**  
Director



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**Charles Rowland**  
Director

Date:



**KPMG**  
**Audit**  
1 Stokes Place  
St. Stephen's Green  
Dublin 2  
D02 DE03  
Ireland

## Independent auditor's report to the members of Nabriva Therapeutics Plc

### 1 Opinion: our opinion is unmodified

We have audited the Group and Parent Company financial statements of Nabriva Therapeutics Plc for the period ended 31 December 2017 which comprise the Consolidated and Parent Company Balance Sheets, the Consolidated Statement of Operations and Comprehensive Loss, the Consolidated and Parent Company Statements of Changes in Shareholders' Equity, the Consolidated Statements of Cash Flows and the related notes, including the accounting policies in note 1. The financial reporting framework that has been applied in the preparation of the Group financial statements is Irish law and US Generally Accepted Accounting Principles ("US GAAP"). The financial reporting framework that has been applied in the preparation of the Parent Company financial statements is Irish law and FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland*.

In our opinion:

- the Group financial statements give a true and fair view, in accordance with US GAAP, of the assets, liabilities and financial position of the Group as at 31 December 2017 and of its loss for the year then ended;
- the Parent Company statement of financial position gives a true and fair view, in accordance with FRS 102, of the assets, liabilities and financial position of the Parent Company as at 31 December 2017;
- the Group financial statements have been properly prepared in accordance with US GAAP, as applied in accordance with the provisions of the Companies Act 2014;
- the Parent Company financial statements have been properly prepared in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland*, as applied in accordance with the provisions of the Companies Act 2014; and
- the Group financial statements and Parent Company financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

### ***Basis for opinion***

We conducted our audit in accordance with International Standards on Auditing (Ireland) ("ISAs (Ireland)") and applicable law. Our responsibilities are further described in the *Auditor's Responsibilities* section of our report. We have fulfilled our ethical responsibilities under, and we remained independent of the Group and Parent Company in accordance with, ethical requirements applicable in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority (IAASA) as applied to listed entities. We believe that the audit evidence we have obtained is a sufficient and appropriate basis for our opinion.

### 2 Key audit matters: our assessment of risks of material misstatement

Key audit matters are those matters that, in our professional judgment, were of most significance in the audit of the financial statements and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by us, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. In addition to the matter described in the *Material uncertainty related to going concern* section, we have determined the matters described below to be the key audit matters to be communicated in our report.

## Independent auditor's report to the members of Nabriva Therapeutics Plc - continued

In arriving at our audit opinion above, there was one key audit matter identified for the Group as follows:

### **Existence & Accuracy of Research Premium Revenue \$5.3million (2016: \$6.5million)**

*Refer to page 69 (accounting policy) and pages 72 (financial disclosures)*

#### **The key audit matter**

The research premium received from the Austrian government is calculated at a 12 percent (2016: 10%) of specified research and development cost base. Qualifying expenditures largely comprise research and development activities conducted in Austria, however, the research premium is also available for certain related third-party expenses with additional limitations.

The Company recognizes the research premium revenue as long as it has incurred research and development expenses.

We identified a risk around the judgements used to determine the research and development expenses that qualify for reimbursement by the Austrian government. Such costs are subject to review by the Austrian government.

#### **How the matter was addressed in our audit**

We obtained an understanding of the process and tested the design and implementation of key controls over the research premium and the related financial statement accounts.

We inspected and critically assessed the underlying supporting documentation of research premium, including the following documents:

- the Group's calculation of related expenditures eligible to be claimed;
- documentation submitted to the relevant government agency/organization;
- a corresponding independent attestation report over the balance claimed,
- other documents as relevant to determine the completeness, existence, accuracy and presentation of the research premium.

We tested a sample of major supplier contracts and evaluated the content in order to find out if the contracts contained agreements that could challenge the Group's role as a researcher in accordance with OECD standard practice.

We tested a sample of clinical trial I and III costs.

We agreed post year end cash receipts to evidence such as bank statement or check copy for balances collected subsequent to 31 December 2017.

We considered the financial statement disclosures for completeness and accuracy.

Based on the procedures performed we found the judgements used to determine the research expenses that qualify for reimbursement by the Austrian government and related disclosures to be reasonable.





## Independent auditor's report to the members of Nabriwa Therapeutics Plc – continued

In arriving at our Parent Company audit opinion, there was one key audit matter as follows:

### ***Parent Company Key Audit Matter – Valuation of Investment in subsidiaries \$289.2 million***

Refer to financial statements page 94 (accounting policy) and note 2 to the Parent Company financial statements

#### **The key audit matter**

We identified a significant risk of error related to the impairment test for the Parent Company's investment in subsidiaries, as the fair values used for the impairment calculation information are dependent on projected financial information.

#### **How the matter was addressed in our audit**

*We obtained* an understanding of the process related to the development of projected financial information, including the preparation of the impairment calculation.

We performed audit procedures to evaluate the appropriateness of the Company's projected financial information, including assessment of significant assumptions against externally derived data and internal source data.

We considered the financial statement disclosures for completeness and accuracy.

Based on the evidence obtained we found that the inputs to the Parent Company investment in subsidiaries impairment calculation and related disclosures to be reasonable.



## **Independent auditor's report to the members of Nabriva Therapeutics Plc – continued**

### **3 Our application of materiality and an overview of the scope of our audit**

We determined materiality for the Group based on total expenses for the year. Due to the nature of the Group, total expenses is the most relevant metric due to the focus of the financial statements users on the Group's R&D activities, technological advances, and cash burn.

We set our measure of Group materiality for the financial statements as a whole at 4.7% of total expenses which is \$3.5 million for the year ended 31 December 2017. We report to the Audit Committee any corrected or uncorrected identified misstatements exceeding \$0.2 million, in addition to other misstatements that warrant reporting on qualitative grounds.

With respect to the Parent Company, we based our calculation of materiality on total assets due to its nature as a holding company. As the calculated materiality was higher than Group materiality, we restricted our materiality to \$3.5 million.

Our Group audit was conducted over the consolidated results of the Group as a whole and involved a component auditor in Austria performing specified procedures, resulting in the entirety of the groups revenues, losses before taxes and total assets being subject to audit. The Group audit team instructed the component auditor as to the significant areas to be covered, including the relevant risks and the information to be reported back. In considering the specific audit procedures to be performed at this component, materiality was set at \$3.2 million, which was below Group materiality but based on the relative size of the component's % of the benchmark of Group total expenses for the year.

Our audit of the rest of the Group and the parent Company was undertaken to the materiality level specified above and was all performed by one engagement team in Dublin.

### **4 Material uncertainty related to going concern**

We draw attention to note 1 to the financial statements which indicates that the Group and Parent Company has incurred recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The Group and Parent Company financial statements do not include any adjustments that might result from the outcome of this uncertainty. These events and conditions, along with the other matters explained in note 1, constitute a material uncertainty that may cast significant doubt on the groups and the parent company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

### **5 We have nothing to report on the other information in the annual report**

The directors are responsible for the other information presented in the annual report together with the financial statements. The other information comprises the information included in the directors' report other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except as explicitly stated below, any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether, based on our financial statements audit work, the information therein is materially misstated or inconsistent with the financial statements or our audit knowledge. Based solely on that work we have not identified material misstatements in the other information.

## **Independent auditor's report to the members of Nabriva Therapeutics Plc – continued**

Based solely on our work on the other information;

- we have not identified material misstatements in the directors' report;
- in our opinion, the information given in the directors' report is consistent with the financial statements; and
- in our opinion, the directors' report has been prepared in accordance with the Companies Act 2014.

### **6 Our opinions on other matters prescribed by the Companies Act 2014 are unmodified**

We have obtained all the information and explanations which we consider necessary for the purpose of our audit.

In our opinion, the accounting records of the Parent Company were sufficient to permit the financial statements to be readily and properly audited and the Parent Company's statement of financial position is in agreement with the accounting records.

### **7 We have nothing to report on other matters on which we are required to report by exception**

The Companies Act 2014 requires us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions required by Sections 305 to 312 of the Act are not made.

### **8 Respective responsibilities**

#### ***Directors' responsibilities***

As explained more fully in their statement set out on pages 2 and 3, the directors are responsible for: the preparation of the financial statements including being satisfied that they give a true and fair view; such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error; assessing the Group and Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and using the going concern basis of accounting unless they either intend to liquidate the Group or the Parent Company or to cease operations, or have no realistic alternative but to do so.

#### ***Auditor's responsibilities***

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue our opinion in an auditor's report. Reasonable assurance is a high level of assurance, but does not guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

A fuller description of our responsibilities is provided on IAASA's website at [https://www.iaasa.ie/getmedia/b2389013-1cf6-458b-9b8f-a98202dc9c3a/Description\\_of\\_auditors\\_responsibilities\\_for\\_audit.pdf](https://www.iaasa.ie/getmedia/b2389013-1cf6-458b-9b8f-a98202dc9c3a/Description_of_auditors_responsibilities_for_audit.pdf)



## **Independent auditor's report to the members of Nabriva Therapeutics Plc – continued**

### **9 The purpose of our audit work and to whom we owe our responsibilities**

Our report is made solely to the Parent Company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the Parent Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Parent Company and the Parent Company's members, as a body, for our audit work, for our report, or for the opinions we have formed.

*John Corrigan*  
for and on behalf of  
**KPMG**  
**Chartered Accountants, Statutory Audit Firm**  
**1 Stokes Place, St. Stephen's Green**  
**Dublin 2, Ireland**

2 July 2018

**CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE INCOME/(LOSS)**  
**Financial Year Ended December 31, 2017**  
(in thousands, except per share data)

	Note	2017 \$	2016 \$
<b>Revenues:</b>			
Research premium and grant revenue	3	5,319	6,482
<b>Operating expenses:</b>			
Research and development		(49,615)	(47,994)
General and administrative		(29,472)	(13,535)
<b>Total operating expenses</b>		<u>(79,087)</u>	<u>(61,529)</u>
Loss from operations		(73,768)	(55,047)
<b>Other income (expense):</b>			
Other income (expense)		492	(783)
Interest income		318	343
Interest expense		(43)	(75)
		<u>          </u>	<u>          </u>
<b>Loss before income taxes</b>		(73,001)	(55,562)
Income tax (expense) benefit	4	(1,355)	672
		<u>          </u>	<u>          </u>
<b>Net loss</b>		(74,356)	(54,890)
<b>Other comprehensive income (loss), net of tax</b>			
Exchange differences on translating foreign operations		-	-
Unrealized losses on available-for-sale securities		(26)	(18)
Reclassification to net income		43	68
		<u>          </u>	<u>          </u>
<b>Other comprehensive income, net of tax</b>		17	50
		<u>          </u>	<u>          </u>
<b>Comprehensive loss</b>		<u>(74,339)</u>	<u>(54,840)</u>
<b>Loss per share</b>			
Basic and diluted	5	<u>(2.49)</u>	<u>(2.56)</u>
<b>Weighted average number of shares:</b>			
Basic and diluted	5	<u>29,830,669</u>	<u>21,478,320</u>

The accompanying notes form an integral part of these consolidated financial statements.

**CONSOLIDATED BALANCE SHEET**  
**As at December 31, 2017**  
(in thousands, except per share data)

	Note	2017 \$	2016 \$
<b>Assets</b>			
Current assets:			
Cash and cash equivalents		86,769	32,778
Short-term investments	6	110	51,106
Receivables			
Other receivables	8	5,402	5,561
Prepaid expenses		<u>1,558</u>	<u>1,176</u>
<b>Total current assets</b>		93,839	90,621
Property, plant and equipment	9	1,327	519
Intangible assets	10	172	270
Long-term other receivables		425	420
Deferred tax assets	4	<u>-</u>	<u>1,410</u>
<b>Total assets</b>		<u>95,763</u>	<u>93,240</u>
<b>Liabilities and equity</b>			
Current liabilities:			
Accounts payable		5,136	2,551
Accrued expenses	11	<u>8,124</u>	<u>13,326</u>
<b>Total current liabilities</b>		13,260	15,877
Non-current liabilities:			
Long-term debt	12	232	-
Other non-current liabilities	13	<u>203</u>	<u>107</u>
<b>Total non-current liabilities</b>		<u>435</u>	<u>107</u>
<b>Total liabilities</b>		<u>13,695</u>	<u>15,984</u>

The accompanying notes form an integral part of these consolidated financial statements.

**CONSOLIDATED BALANCE SHEET - continued**  
**As at December 31, 2017**  
**(in thousands, except per share data)**

	Note	2017 \$	2016 \$
<b>Stockholders' equity:</b>			
Called up share capital presented as equity	14	367	2,939
Share premium account		366,186	-
Other reserve		(5,314)	279,149
Accumulated other comprehensive income		27	10
Accumulated deficit		(279,198)	(204,842)
<b>Total stockholders' equity</b>		<u>82,068</u>	<u>77,256</u>
<b>Total liabilities and stockholders' equity</b>		<u>95,763</u>	<u>93,240</u>

On behalf of the board



**Colin Broom**  
 Director



**Charles Rowland**  
 Director

Date:

**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY/(DEFICIT)**  
**Financial Year Ended December 31, 2017**  
**(in thousands)**

	<u>Common stock/ordinary shares</u>		<u>Treasury shares</u>		Share premium account	Other reserve	Accumulated other comprehensive income/(loss)	Accumulated Deficit	Total stockholders' equity/(deficit)
	Number of shares	Amount	Number of shares	Amount					
		\$		\$	\$	\$	\$	\$	\$
<b>January 1, 2016</b>	2,120	2,308	3	(22)	-	256,412	(40)	(149,952)	108,706
Issuance of common stock	588	618	-	-	-	24,204	-	-	24,822
Exercise of stock options	12	13	(3)	22	-	235	-	-	270
Equity transaction costs	-	-	-	-	-	(4,247)	-	-	(4,247)
Stock based compensation expense	-	-	-	-	-	2,545	-	-	2,545
Other comprehensive income, net of tax	-	-	-	-	-	-	50	-	50
Net loss	-	-	-	-	-	-	-	(54,890)	(54,890)
<b>December 31, 2016</b>	2,720	2,939	-	-	-	279,149	10	(204,842)	77,256
Issuance of common stock	9,412	94	-	-	-	79,906	-	-	80,000
Exercise of stock options	54	3	-	-	-	51	-	-	54
Equity transaction costs	-	-	-	-	-	(6,635)	-	-	(6,635)
Redomiciliation share exchange	24,522	(2,669)	-	-	366,186	(363,517)	-	-	-
Stock based compensation expense	-	-	-	-	-	5,732	-	-	5,732
Other comprehensive income, net of tax	-	-	-	-	-	-	17	-	17
Net loss	-	-	-	-	-	-	-	(74,356)	(74,356)
<b>December 31, 2017</b>	36,708	367	-	-	366,186	(5,314)	27	(279,198)	82,068

The accompanying notes form an integral part of these consolidated financial statements.



**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Financial Year Ended December 31, 2017**  
(in thousands)

	2017	2016
	\$	\$
<b>Cash flows from operating activities</b>		
Net loss	(74,356)	(54,890)
<b>Adjustments to reconcile net loss to net cash used in operating activities</b>		
Non-cash other income, net	(1,371)	996
Non-cash interest income	-	(52)
Non-cash interest expense	-	35
Depreciation and amortisation expense	432	233
Stock-based compensation	5,732	2,545
Deferred income taxes	1,410	(794)
Other, net	131	1
<b>Changes in operating assets and liabilities</b>		
Changes in long-term receivables	(5)	10
Changes in other receivables	(223)	(1,932)
Changes in accounts payable	2,585	(383)
Changes in accrued expenses and other liabilities	(3,778)	6,034
Changes in other non-current liabilities	96	24
Changes in income tax liabilities	(1)	(152)
<b>Net cash used in operating activities</b>	<u>(69,348)</u>	<u>(48,325)</u>
<b>Cash flows from investing activities</b>		
Purchases of plant and equipment and intangible assets	(1,173)	(603)
Purchases of available-for-sale securities	-	(57,035)
Purchases of term deposits	(30)	(10)
Proceeds from sale of property, plant and equipment	2	-
Proceeds from maturities of term deposits	-	45,000
Proceeds from sales of available-for-sale securities	50,950	36,000
<b>Net cash (used in) provided by investing activities</b>	<u>49,749</u>	<u>23,352</u>
<b>Cash flows from financing activities</b>		
Proceeds from December 2016 financing	-	24,822
Proceeds from September 2017 public offering	80,000	-
Proceeds from long-term borrowings	228	-
Proceeds from exercise of stock options	83	269
Equity transaction costs	(8,092)	(2,790)

The accompanying notes form an integral part of these consolidated financial statements.

**CONSOLIDATED STATEMENTS OF CASH FLOWS - continued**  
**Financial Year Ended December 31, 2017**  
(in thousands)

	2017 \$	2016 \$
<b>Net cash provided by financing activities</b>	<u>72,219</u>	<u>22,301</u>
<b>Effects of foreign currency translation on cash and cash equivalents</b>	<u>1,371</u>	<u>(996)</u>
Net increase (decrease) in cash and cash equivalents	53,991	(3,668)
Cash and cash equivalents at beginning of year	<u>32,778</u>	<u>36,446</u>
<b>Cash and cash equivalents at end of year</b>	<u>86,769</u>	<u>32,778</u>
<b>Supplemental disclosures of cash flow information:</b>		
Interest paid	(1)	(41)
Taxes paid	(5)	(867)
Equity transaction costs included in accrued expenses	<u>28</u>	<u>1,451</u>

The accompanying notes form an integral part of these consolidated financial statements.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
(in thousands, except per share data)

**1 Organization and business activities**

Nabriva clinical Therapeutics plc ("Nabriva Ireland"), together with its wholly owned and consolidated subsidiaries, Nabriva Therapeutics GmbH ("Nabriva Austria"), Nabriva Therapeutics US, Inc., Nabriva Therapeutics Ireland DAC, and Nabriva Therapeutics One DAC (In Voluntary Liquidation) (collectively, "Nabriva", the "Nabriva Group" or the "Company") is a stage biopharmaceutical company engaged in the research and development of novel anti-infective agents to treat serious infections, with a focus on the pleuromutilin class of antibiotics. The Company's headquarters are located at 25-28 North Wall Quay, Dublin, Ireland.

On March 1, 2017, Nabriva Ireland was incorporated in Ireland with registration number 599588 under the name Hyacintho 2 plc, and was renamed to Nabriva Therapeutics plc on April 10, 2017, in order to effectuate the change of the jurisdiction of incorporation of the ultimate parent company of the Nabriva Group from Austria to Ireland. Nabriva Ireland replaced Nabriva Austria as the ultimate parent company on June 23, 2017, following the conclusion of a tender offer (the "Exchange Offer") in which holders of 98.5% of the outstanding share capital of Nabriva Austria exchanged their holdings for ordinary shares, \$0.01 nominal value per share, of Nabriva Ireland (the "Redomiciliation Transaction"). The ordinary shares of Nabriva Ireland were issued on a one-for-ten basis to the holders of the Nabriva Austria common shares ("Nabriva Austria common shares") and on a one-for-one basis to the holders of the Nabriva Austria American Depositary Shares ("Nabriva Austria ADSs") participating in the Exchange Offer. On June 26, 2017, the ordinary shares of Nabriva Ireland began trading on the Nasdaq Global Market under the symbol "NBRV," the same symbol under which the American Depositary Shares of Nabriva Austria were previously traded. This transaction was accounted for as a merger between entities under common control; accordingly, the historical financial statements of Nabriva Austria for periods prior to this transaction are considered to be the historical financial statements of Nabriva Ireland. As of August 18, 2017, 100% of Nabriva Austria share capital had been exchanged for ordinary shares of Nabriva Ireland.

Nabriva Austria was incorporated in Austria as a spin-off from Sandoz GmbH in October 2005 and commenced operations in February 2006 as Nabriva Therapeutics AG. On October 19, 2017, Nabriva Austria was converted into a private limited liability company under Austrian law and renamed Nabriva Therapeutics GmbH. Nabriva Therapeutics US, Inc. was founded and began operations in the United States in August 2014. In February 2017, Nabriva Austria purchased all shares issued in the capital of Hyacintho DAC, a designated activity company incorporated by a nominee company in December 2016; it renamed the company to Nabriva Therapeutics Ireland DAC on April 10, 2017 and renamed the company again to Nabriva Therapeutics One DAC on October 13, 2017 ("One DAC"). From April 2017, One DAC held a license of all of the intellectual property rights of the Nabriva Group from Nabriva Austria. In October 2017, the Company purchased all shares issued in the capital of a new Irish designated activity company, Nabriva Therapeutics Ireland DAC ("Nabriva DAC") from a nominee company. On October 19, 2017, Nabriva Austria terminated the intellectual property rights license in place with One DAC and put in place a new intellectual property rights license with Nabriva DAC in respect of all of the intellectual property rights of the Nabriva Group. On February 8, 2018, Nabriva Austria passed a shareholder resolution to approve the voluntary and solvent liquidation of One DAC.

Throughout these Notes to the Consolidated Financial Statements, unless the context requires otherwise, all references to "Nabriva," "the Nabriva Group," "the Company," or similar terms on or prior to June 23, 2017 (the effective date of the Redomiciliation Transaction), refer to our predecessor, Nabriva Austria, together with its subsidiaries.

Certain share and per share amounts have been retrospectively adjusted to reflect the Exchange Offer and the Redomiciliation Transaction.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
**(in thousands, except per share data)**

**1 Organization and business activities - continued**

**Liquidity**

Since its inception, the Company has incurred net losses and generated negative cash flows from its operations. To date, it has financed its operations through the sale of equity securities, including its initial public offering of Nabriva Austria ADSs, public offerings of our ordinary shares and private placements of its Nabriva Austria common shares, convertible debt financings and research and development support from governmental grants and loans. As of March 31, 2018, the Company had cash, cash equivalents and short-term investments of \$89.6 million.

The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, Presentation of Financial Statements - Going Concern ("ASC 205-40"), which requires management to assess the Company's ability to continue as a going concern for one year after the date the financial statements are issued. As of December 31, 2017, in accordance with the requirements of ASC 205-40, the Company's management had concluded that substantial doubt existed about the Company's ability to continue as a going concern for one year from the date the consolidated financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2017, were issued.

In March 2018, the Company entered into a Controlled Equity Offering SM Sales Agreement (the "ATM Agreement"), with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which, from time to time, the Company may offer and sell our ordinary shares having aggregate gross proceeds of up to \$50.0 million through Cantor. As of March 31, 2018, the Company has issued and sold an aggregate of 3,517,511 ordinary shares under the ATM Agreement, for gross proceeds of \$19.4 million, and net proceeds of \$18.9 million, after deducting commissions.

Since the filing of the Company's Annual Report, the Company has re-evaluated the need for the previously planned expansion of its commercial organization, medical education, and supply chain activities and anticipates that the Company's expenses for 2018 will decrease as compared to its expenses for 2017 as the Company winds down its Phase 3 clinical trial program for lefamulin for the treatment of community-acquired bacterial pneumonia ("CABP"). The Company expects to continue to invest in critical pre-commercialization activities prior to receiving marketing approval and making lefamulin available to patients.

As of March 31, 2018, management assessed the Company's ability to continue as a going concern and determined that it now expects that its existing cash, cash equivalents and short-term investments will be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements into the first quarter of 2020. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could use its capital resources sooner than it currently expects.

The Company's expenses will increase if it suffers any delays in its Phase 3 clinical program, including regulatory delays, or is required to conduct additional clinical trials to satisfy regulatory requirements. If the Company obtains marketing approval for lefamulin or any other product candidate that it develops, it expects to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing.

The Company expects to seek additional funding in future periods for purposes of investment in its commercial and medical affairs organization, including the expansion of a targeted hospital based sales force and related infrastructure, as well as investing in its supply chain, in an effort to enhance the potential commercial launch of lefamulin.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**1 Organization and business activities - continued**

**Liquidity - continued**

The directors have concluded that the combination of these circumstances represents a material uncertainty that casts significant doubt upon the Company's and Group's ability to continue as a going concern and that, therefore the Company and Group may be unable to continue realising its assets and discharging its liabilities in the normal course of business. Nevertheless, after making enquiries and considering the uncertainties described above, the directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. For these reasons, they continue to adopt the going concern basis in preparing the annual financial statements.

**2 Summary of significant accounting policies**

**Basis of preparation**

The directors have elected to prepare the consolidated financial statements in accordance with Section 279 of the Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position and profit or loss may be given by preparing the financial statements in accordance with US accounting standards ("US GAAP"), as defined in that section to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of Part 6 of the Republic of Ireland's Companies Act 2014 ("the Companies Act").

These consolidated financial statements were prepared in accordance with Irish Company Law, to present to the shareholders of the Company and file with the Companies Registration Office in Ireland. Accordingly, these financial statements include disclosures required by the Companies Act in addition to those required under accounting principles generally accepted in the US ("US GAAP"). The consolidated financial statements include the accounts of Nabriva Therapeutics plc and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

*Functional and presentation currency*

Effective January 1, 2016, the Company's functional and reporting currency changed to the U.S. dollar ("USD"). Prior to January 1, 2016, the consolidated financial statements were presented in euro ("€"), which was the Company's functional and presentation currency. With the expansion of Nabriva's operations to the United States, the Company's assets, liabilities, revenues and expenses are expected to be predominantly denominated in USD, and accordingly, the use of USD to measure and report the Company's financial performance and financial position was considered to be more appropriate. The impact of the currency translation up to January 1, 2016 is recorded in accumulated other comprehensive income (loss). Upon the change in functional currency on January 1, 2016, all assets and liabilities of the Company's operations were translated from their euro functional currency into USD using the exchange rates in effect on the balance sheet date, equity was translated at the historical rates and revenues, expenses, and cash flows were translated at the average rates during the reporting period presented. The resulting translation adjustments are reported under comprehensive income (loss) as a separate component of stockholders' equity.

*Transactions and balances*

In preparing the consolidated financial statements, transactions in currencies other than the entity's functional currency (foreign currencies) are recognized at the exchange rates prevailing at the dates of the transactions. Foreign currency exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the consolidated statement of comprehensive income (loss).

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**2 Summary of significant accounting policies - continued**

**Basis of preparation - continued**

*Use of estimates*

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

**Cash and cash equivalents**

The company considers highly liquid investments with original maturities of three months or less to be cash equivalents.

**Short-term Investments**

The Company has designated its investments in securities as available-for-sale securities and measures these securities at their respective fair values. Investments that mature in one year or less are classified as short-term available-for-sale securities. Investments that are not considered available for use in current operations are classified as long-term available-for-sale securities. Changes in the fair value of available-for-sale investments are recognized in other comprehensive income (loss).

**Property, plant and equipment**

Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. The estimated useful lives of property, plant and equipment are as follows: 3-5 years for IT equipment, 5-10 years for laboratory equipment and 3-10 years for other plant and office equipment. The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each reporting date. When assets are sold or otherwise disposed of, the difference between the net proceeds, if any, and the net carrying amount of the asset is recognized as a gain or a loss in other operating income or expenses.

**Intangible assets and other long-lived assets**

Intangible assets, such as acquired computer software licenses, are capitalized on the basis of the costs incurred to acquire the software and bring it into use. These costs are amortized on a straight-line basis over their estimated useful lives (3-10 years).

Long-lived assets are assessed for potential impairment when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. An impairment loss would be recognized when undiscounted cash flows expected to be generated by an asset, is less than its carrying amount. The impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value and recognized in these financial statements.

**Research premium and grant revenue**

Grant revenue comprises (a) the research premium from the Austrian government, (b) grants received from the Vienna Center for Innovation and Technology (*Zentrum für Innovation, or ZIT*) and the Vienna Business Promotion Fund (*Wiener Wirtschaftsförderungsfonds, or WWFF*), (c) grants received from the Austrian Research Promotion Agency (*Österreichische Forschungsförderungsgesellschaft, or FFG*), and (d) the benefit of government loans at below-market interest rates. Please refer to Note 3 for further details on all forms of grant revenue.

The research premium the Company receives from the Austrian government is calculated at a specified percent of specified research and development cost base. The Company recognizes the research premium as long as it has incurred research and development expenses. The ZIT grants are provided to support specific research projects and are recognized according to the progress of the respective project. The WWFF grant is paid out through the landlord in the form of a monthly reduction in lease payments and is recognized over the period from grant date in March 2010 until end of the lease termination waiver term in December 2017. All grants are non-refundable as long as the conditions of the grant are met. Nabriva is and has been in full compliance with the conditions of the grants and all related regulations.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**2 Summary of significant accounting policies - continued**

**Research premium and grant revenue - continued**

The benefit of a government loan at a below-market rate of interest is treated as a government grant. The benefit due to the difference between the market rate of interest and the rate of interest charged by the governmental organization is measured as the difference between the initial carrying value of the loan determined and the proceeds received. This benefit is deferred, and recognized through profit and loss over the term of the corresponding liabilities.

**Research and development expenses**

All research and development costs are expensed as incurred. Research and development costs included direct personnel and material costs, related overheads, depreciation of equipment used for research or development purposes; costs for clinical research; costs for the utilization of third parties' patents for research and development purposes and other taxes related to research facilities.

**Share-based payments**

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award in accordance with ASC 718, *Compensation—Stock Compensation*, using the Black-Scholes model. All grants under share-based payment programs are accounted for at fair value and that cost is recognized over the period during which an employee is required to provide service in exchange for the award—the requisite service period (vesting period). The Company accounts for forfeitures as incurred. Compensation expense for options granted to non-employees is determined as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of awards granted to non-employees is re-measured each period until the related service is complete.

**Income taxes**

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

In recognizing the benefit of tax positions, the Company has taken or expects to take, the Company determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Company's policy is to record interest and penalties related to tax matters in income tax expense.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the top U.S. federal corporate tax rate from 35 percent to 21 percent; eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; creating the base erosion anti-abuse tax (BEAT), a new minimum tax; creating a new limitation on deductible interest expense; and, changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**2 Summary of significant accounting policies - continued**

**Income taxes - continued**

The Tax Act reduces the U.S. corporate income tax rate from 35% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under the Tax Act, the Company revalued the ending net deferred tax assets and liabilities of our U.S. subsidiary at December 31, 2017.

**Mezzanine equity**

Silent partnership agreements entered into in 2014 and 2015, which entitled the silent partners to a proportionate share in the fair value of the Company, similar to a shareholder, including a share in profit or loss, according to an agreed participation rate, were classified as mezzanine equity pursuant to ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and ASC 815, *Derivatives and Hedging* ("ASC 815"). The silent partnership interests were evaluated for equity or mezzanine classification based upon the nature of the partnerships settlement provisions which unilaterally provided the Company the option to settle the obligation in cash or a variable number of shares. However, when a settlement in shares cannot always be presumed, irrespective of probability of the event occurring, a classification outside of stockholders' equity is required. Mezzanine equity was initially measured at fair value and subsequently at the redemption value at each reporting period, representing the proceeds resulting from an exit event (trade sale or initial public offering), and such amount recognized in retained earnings.

**Subsequent events**

Material subsequent events are evaluated and disclosed through the report issuance date.

**Recent accounting pronouncements**

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date.

*Adopted as of the current period:*

- In November 2015, the FASB issued Accounting Standards Update ("ASU") 2015-17, *Income Taxes: Balance Sheet Classification of Deferred Taxes*. ASU 2015-17 simplifies the balance sheet classification of deferred taxes and requires that all deferred taxes be presented as noncurrent. ASU 2015-17 was effective for fiscal years beginning after December 15, 2016. The impact of adopting this standard did not have a material effect on the Company's financial position, results of operation or cash flow and related disclosures.
- In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 was effective for the fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The impact of adopting this standard did not have a material effect on the Company's financial position, results of operation or cash flow and related disclosures.

*To be adopted in future periods:*

- In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or US GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced revenue disclosures, provide guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. The effective date of ASU 2014-09 for the Company is the first quarter of fiscal year 2018 and may be applied on a full retrospective or modified retrospective approach. The adoption of ASU 2014-09 will have no impact on the Company until it begins to generate product revenue.



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**2 Summary of significant accounting policies - continued**

**Recent accounting pronouncements - continued**

- In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842). ASU 2016-02 establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. A modified retrospective transition approach is required for lessees of capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact that the standard will have on its financial position, results of operation or cash flow and related disclosures.
- In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation: Scope of Modification Accounting*. ASU 2017-09 clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718, *Compensation—Stock Compensation*. ASU 2017-09 is effective for annual periods beginning after December 15, 2017. An entity should apply the amendments prospectively to a modification that occurs on or after the adoption date. The Company does not anticipate the initial adoption of the provisions of this guidance in the first quarter of fiscal year 2018 to have a material impact on its financial position, results of operation or cash flow and related disclosures.

**3 Research premium and grant revenue**

Research premium and grant revenue consists of the following items:

(in thousands)	Year ended December 31,	
	2017	2016
	\$	\$
Research premium	4,842	6,232
Government grants	369	-
Grants from WWFF and ZIT	108	250
<b>Total</b>	<u>5,319</u>	<u>6,482</u>

**4 Income tax (expense) benefit**

Loss before income taxes attributable to domestic and international operations, consists of the following:

(in thousands)	December 31,	
	2017	2016
	\$	\$
Domestic	(66,109)	(54,509)
Foreign	(6,892)	(1,053)
<b>Loss before income taxes</b>	<u>(73,001)</u>	<u>(55,562)</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**4 Income tax (expense) benefit - continued**

Income tax (expense) benefit consists of the following:

(in thousands)	December 31,	
	2017	2016
	\$	\$
<b>Current tax</b>		
Domestic	-	(4)
Foreign	55	(118)
<b>Deferred tax</b>		
Domestic	-	-
Foreign	(1,410)	794
<b>Total income tax (expense) benefit</b>	<u>(1,355)</u>	<u>672</u>

The reconciliation to our effective tax rate from the Austrian statutory income tax rate of 25% for the year ended December 31, 2016 and from the Irish statutory income tax rate of 12.5% for the year ended December 31, 2017 is as follows:

(% of pre-tax income)	December 31,	
	2017	2016
	%	%
Statutory income tax rate	12.5	25.0
Non-deductible expenses	(0.8)	(0.2)
Income not subject to tax	0.9	2.8
Impairment	1.4	-
Tax credits	0.2	0.4
Foreign rate differential	21.0	(2.5)
Other	(1.4)	0.2
Valuation allowance	(35.6)	(24.5)
<b>Effective income tax rate</b>	<u>(1.8)</u>	<u>1.2</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**4 Income tax (expense) benefit - continued**

The following table summarizes the components of deferred income tax balances:

(in thousands)	2017 \$	2016 \$
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	70,871	54,220
Tax loss on liquidation of subsidiary	7,846	-
Equity compensation	1,450	1,025
Non-deductible reserves	57	409
<b>Total deferred tax assets</b>	<u>80,224</u>	<u>55,654</u>
<b>Valuation allowance</b>	<u>(80,087)</u>	<u>(54,114)</u>
<b>Net deferred tax assets</b>	<u>137</u>	<u>1,540</u>
<b>Deferred tax liabilities:</b>		
Financial liabilities	80	95
Property, plant and equipment	57	35
<b>Total deferred tax liability</b>	<u>137</u>	<u>130</u>
<b>Deferred tax, net</b>	<u>-</u>	<u>1,410</u>

The table below summarizes changes in the deferred tax valuation allowance:

(in thousands)	Year ended December 31,	
	2017 \$	2016 \$
Balance at beginning of year	(54,114)	(40,487)
Tax benefit	(25,973)	(13,627)
<b>Balance at end of year</b>	<u>(80,087)</u>	<u>(54,114)</u>

The following table summarizes carryforwards of net operating losses as of December 31, 2017:

(in thousands)	Amount \$	Expiration
Ireland	27,490	Indefinite
Austria	268,285	Indefinite
United States	200	2037

Due to uncertainty regarding the ability to realize the benefit of deferred tax assets primarily relating to net operating loss carryforwards, valuation allowances have been established to reduce deferred tax assets to an amount that is more likely than not to be realized.

On the basis of this evaluation, as of December 31, 2017 and 2016, the Company has recorded a valuation allowance of \$80,087 and \$54,114, respectively, to recognize only the portion of the deferred tax asset that is more likely than not to be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as our projections for growth.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**4 Income tax (expense) benefit - continued**

The Tax Cuts and Jobs Act (the "TCJA") was enacted on December 22, 2017 and became effective January 1, 2018. The Tax Act had significant changes to U.S. tax law, lowering U.S. corporate income tax rates, implementing a territorial tax system, and modified the taxation of other income and expense items.

The TCJA reduces the U.S. corporate income tax rate from 35% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under the TCJA, the Company revalued the ending net deferred tax assets and liabilities of its U.S. subsidiary as of December 31, 2017. The tax impact of the revaluation of these deferred tax assets, net was \$0.8 million, which was wholly offset by a corresponding reduction in the valuation allowance for these net deferred tax assets resulting in a no net impact to income tax expense.

At December 31, 2017 and 2016, the Company had no uncertain tax positions and does not expect any material increase or decrease in income tax expense related to examinations or changes in uncertain tax positions.

The Company files income tax returns in Ireland. In addition, the Company's foreign subsidiaries file separate income tax returns in Austria and the United States and state jurisdictions in which they are located. Tax years 2012 and forward remain open for examination for Austrian tax purposes and years 2014 and forward remain open for examination for United States tax purposes.

The Company's policy is to record interest and penalties related to tax matters in income tax expense.

**5 Earnings (loss) per share**

**Basic and diluted loss per share**

Basic and diluted loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of shares outstanding during the year. Diluted net loss per share is the same as basic net loss per share during the periods presented as the effects of the Company's common stock equivalents are antidilutive and thus not included in the calculation.

	Year ended December 31,	
	2017	2016
(in thousands, except per share data)	\$	\$
Net loss for the period	(74,356)	(54,890)
Adjustment to redemption value of silent partnerships	-	-
Net loss attributable to shareholders	(74,356)	(54,890)
Weighted average number of shares outstanding	29,830,669	21,478,320
Excluded treasury shares on December 31	-	-
<b>Basic and diluted loss per share</b>	<b>(2.49)</b>	<b>(2.56)</b>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**5 Earnings (loss) per share - continued**

**Basic and diluted loss per share - continued**

The following common stock equivalents were excluded from the calculations of diluted loss per share as their effect would be anti-dilutive:

	Year ended December 31,	
	2017	2016
	\$	\$
<b>Stock options</b>	<u>3,338,999</u>	<u>1,904,320</u>

**6 Short-term investments**

The Company's short-term investments were as follows:

(in thousands)	As at December 31, 2017			
	Amortized cost \$	Unrealized gains \$	Unrealized losses \$	Fair value \$
Short-term investments:				
Available-for-sale securities	76	-	(26)	50
Term deposits	<u>60</u>	<u>-</u>	<u>-</u>	<u>60</u>
<b>Total</b>	<u>136</u>	<u>-</u>	<u>(26)</u>	<u>110</u>
(in thousands)	As at December 31, 2016			
	Amortized cost \$	Unrealized gains \$	Unrealized losses \$	Fair value \$
Short-term investments:				
Available-for-sale securities	51,094	-	(18)	51,076
Term deposits	<u>30</u>	<u>-</u>	<u>-</u>	<u>30</u>
<b>Total</b>	<u>51,124</u>	<u>-</u>	<u>(18)</u>	<u>51,106</u>

As of December 31, 2017 and 2016 the Company's short-term investments were classified as available-for-sale and comprised a (i) money market fund that invests all of its assets, excluding cash and deposits, in short term USD-denominated debt securities, and (ii) a U.S. treasury note.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**7 Fair value measurement**

US GAAP establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (as exchange rates).
- Level 3: Valuation techniques that include inputs for the asset or liability that are not based on observable market data (those are unobservable inputs) and significant to the overall fair value measurement.

The following table presents the financial instruments measured at fair value and classified by level according to the fair value measurement hierarchy:

(in thousands)	Level 1 \$	Level 2 \$	Level 3 \$	Total \$
<b>December 31, 2017</b>				
<b>Assets:</b>				
Short-term investments:				
Available-for-sale securities	-	50	-	50
Term deposits	60	-	-	60
<b>Total assets</b>	<b>60</b>	<b>50</b>	<b>-</b>	<b>110</b>

(in thousands)	Level 1 \$	Level 2 \$	Level 3 \$	Total \$
<b>December 31, 2016</b>				
<b>Assets:</b>				
Short-term investments:				
Available-for-sale securities	15,017	36,059	-	51,076
Term deposits	30	-	-	30
<b>Total assets</b>	<b>15,047</b>	<b>36,059</b>	<b>-</b>	<b>51,106</b>

As of December 31, 2017 and December 31, 2016, the Company held short-term investments classified as both Level 1 and Level 2, and the Company did not hold any Level 3 financial instruments measured at fair value. There were no transfers between Level 1 and 2 in the years ended December 31, 2017 and December 31, 2016. There were no changes in valuation techniques during the year ended December 31, 2017.

As of December 31, 2017 and December 31, 2016, the Company did not hold any financial instruments as liabilities that were held at fair value.

Other receivables and accounts payable are carried at their historical cost which approximates fair value due to their short-term nature.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

8 Other receivables	As of December 31	
	2017	2016
(in thousands)	\$	\$
Research premium	5,124	5,346
VAT and other taxes	28	46
Receivables from grant revenue	231	144
Other receivables	19	25
<b>Total current receivables</b>	<b>5,402</b>	<b>5,561</b>

9 Property, plant and equipment	IT	Laboratory	Other	Total
	Equipment	equipment	equipment	
	\$	\$	\$	\$
(in thousands)				
<b>Cost</b>				
At January 1, 2017				
Cost	1,038	2,217	15	3,270
Additions	22	1,082	-	1,104
At December 31, 2017	1,060	3,299	15	4,374
<b>Accumulated depreciation</b>				
At January 1, 2017	(823)	(1,916)	(12)	(2,751)
Charge for financial year	(85)	(210)	(1)	(296)
At December 31, 2017	(908)	(2,126)	(13)	(3,047)
	IT	Laboratory	Other	Total
	Equipment	equipment	equipment	
	\$	\$	\$	\$
<b>Net book values</b>				
Cost	1,038	2,217	15	3,270
Accumulated depreciation	(823)	(1,916)	(12)	(2,751)
At December 31, 2016	215	301	3	519
Cost	1,060	3,299	15	4,374
Accumulated depreciation	(908)	(2,126)	(13)	(3,047)
At December 31, 2017	152	1,173	2	1,327

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

<b>10 Intangible assets</b>	Computer Software \$	Total \$
(in thousands)		
<b>Cost</b>		
At January 1, 2017	611	611
Additions	<u>23</u>	<u>23</u>
At December 31, 2017	<u>634</u>	<u>634</u>
<b>Accumulated amortisation</b>		
At January 1, 2017	(342)	(342)
Amortisation charge	<u>(120)</u>	<u>(120)</u>
At December 31, 2017	<u>(462)</u>	<u>(462)</u>
<b>Net book values</b>		
Cost	611	611
Accumulated amortisation	<u>(341)</u>	<u>(341)</u>
At December 31, 2016	<u>270</u>	<u>270</u>
Cost	634	634
Accumulated amortisation	<u>(462)</u>	<u>(462)</u>
At December 31, 2017	<u>172</u>	<u>172</u>

**11 Accrued expenses**

Accrued expenses include the following:

(in thousands)	As of December 31	
	2017	2016
	\$	\$
Research and development related costs	2,308	8,716
Payroll and related costs	4,426	2,345
Accounting, tax and audit services	231	484
Other	<u>1,159</u>	<u>1,781</u>
	<u>8,124</u>	<u>13,326</u>



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**12 Long-term debt**

As of December 31, 2017, the Company had a de minimis government loan amounting to \$232 thousand from the Austrian Research Promotion Agency (*Österreichische Forschungsförderungsgesellschaft, or FFG*) which is subject to interest rate of 0.75% per annum paid 6 months retroactively and is repayable on March 31, 2021.

**13 Other non-current liabilities**

Other non-current liabilities include an obligation to pay jubilee benefits to it Austrian employees of \$ 137 and \$107 at December 31, 2017 and 2016, respectively, arising under the collective bargaining agreement for the chemical industry in Austria, by which employees are entitled to receive jubilee payments after being employed for a certain number of years. These amounts qualify as provisions for liabilities under Irish law.

The Company's net obligation in respect of the jubilee payments is calculated annually by an independent actuary in accordance with ASC 710-10-25 using the projected unit credit method. The principle actuarial assumptions used were as follows:

Discount rates of 1.7% and 1.3% used for the 2017 and 2016 calculations, respectively, retirement at the age of 61.5-65 for men and 56.5-65 for women and future annual salary increases of 3%.

The movement in the jubilee payment provisions for the year was as follows:

(in thousands)	Total \$
At January 1, 2017	107
Increase in provisions	30
At December 31, 2017	<u>137</u>

**14 Stockholders' equity**

(in thousands, except per share data)	2017	2016
<b>Authorized</b>	\$	\$
1,389,786 Common Shares with no par value	-	-
1,000,000,000 Ordinary Shares of \$0.01	10,000	-
100,000,000 Preferred Shares of \$0.01	1,000	-
	<u>11,000</u>	<u>-</u>
	€	€
25,000 Euro Deferred Shares of €1 each	25	-
	<u>25</u>	<u>-</u>
<b>Allotted and fully paid</b>	\$	\$
2,719,695 Common Shares with no par value	-	2,939
36,707,685 Ordinary Shares of \$0.01	367	-
	<u>367</u>	<u>2,939</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
**(in thousands, except per share data)**

**14 Stockholders' equity - continued**

On September 22, 2017 the Company completed an underwritten public offering of 9,411,765 ordinary shares at a public offering price of \$8.50 per share, resulting in gross proceeds of \$80.0 million and net proceeds to the Company of \$73.3 million, after deducting underwriting discounts and commissions and offering expenses.

On December 19, 2016, the Company completed a rights offering and a related underwritten offering for the sale of an aggregate of 588,127 common shares resulting in aggregate gross proceeds of \$24.8 million and net proceeds of \$20.6 million, after deducting underwriting fees and offering expenses.

On September 23, 2015 the Company completed its initial public offering on the Nasdaq Global Market issuing 9,000,000 ADSs at a price to the public of \$10.25 per ADS, representing 900,000 of its common shares. Each ADS represents one tenth of a common share. On September 30, 2015 the underwriters of its initial public offering exercised in full their over-allotment option to purchase an additional 1,350,000 ADSs, representing 135,000 common shares, at the initial public offering price of \$10.25 per ADS, less underwriting discounts. Including the over-allotment ADSs, the Company sold an aggregate of 10,350,000 ADSs representing 1,035,000 common shares, in its initial public offering, which resulted in gross proceeds of \$106.1 million and net proceeds to the Company of \$92.4 million, after deducting underwriting discounts and offering expenses.

In connection with the Company's April 2015 financing, it sold 730,162 common shares with contractual preference rights under a shareholders agreement, including the sale of 511,188 common shares at a price per share of €82.35 (\$87.71) for €42.1 million (\$44.8 million) in cash consideration and the sale of 218,974 common shares in exchange for certain contributions in-kind consisting of the conversion of outstanding convertible loans and silent partnership interests. The Company also agreed to sell a second tranche of common shares with contractual preference rights under the shareholders agreement to the investors in its April 2015 financing at their option for an aggregate purchase price of \$70.0 million if the Company did not complete a public offering in the United States within specified parameters or by a specified date. As a result of the preferred dividend rights, which were not legally separable, the Company was deemed to have issued common shares accompanied by preferred dividends that may be settled for cash or shares. Accordingly, the proceeds from the April 2015 financing, including the consideration from conversion of the convertible loan agreements and silent partnership interests, were recorded as mezzanine equity. A mezzanine equity classification arises as a result of the dividend provision in the Shareholders Agreement 2015, which the Company's shareholders have covenanted to vote in favor of the requisite shareholder resolutions to allow it to satisfy the preferred dividend rights. As a result, (i) the Company could not avoid fulfilling the preferred dividend rights if a triggering event occurred that was outside its control, and (ii) could not always presume a settlement in shares. Therefore, when a settlement in shares cannot always be presumed for an event not solely within the control of the issuer, irrespective of probability of the event occurring, a classification outside of stockholders' equity is required. Mezzanine equity was initially measured at fair value and subsequently at the redemption value at each reporting period, representing the proceeds resulting from an exit event (trade sale or initial public offering), and such amount recognized in retained earnings.

Upon the closing of its initial public offering and the issuance of the shares for nominal value in satisfaction of the preferred dividend rights, all contractual preference rights under the shareholders agreement terminated.

In connection with this April 2015 financing, all existing convertible loan agreements and silent partnership interests were converted to common shares with contractual preference rights under the Shareholders Agreement 2015.

On March 31, 2015, the Company, its existing investors and new investors in the April 2015 financing signed the Investment and Subscription Agreement 2015, or ISA 2015.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**14 Stockholders' equity – continued**

The signing of the ISA 2015 resulted in the following effects with respect to the Company's existing financial instruments:

- (a) the lenders under all existing convertible loan agreements, or CLAs, irrevocably waived their claims for payment of interest accrued on the loan amounts,
- (b) all CLA lenders irrevocably waived and acknowledged the termination of their call option rights granted under the CLAs, and
- (c) all silent partners irrevocably agreed to the forfeiture of their claims for payment of interest accrued on their silent partnership investments.

The April 2015 financing and the related conversion of the Company's outstanding convertible loan agreements and silent partnership interests resulted in total consideration of \$77.3 million which was recorded in mezzanine equity. Upon the closing of the Company's initial public offering in September 2015, a triggering event occurred as described above, and the holders of the preferred dividend right received 17,149 additional shares against payment of the nominal amount of €1.00 per share, effectively removing the mezzanine equity classification.

**15 Share-based payments**

***Stock option plan 2007***

On September 12, 2007 the Company's management and supervisory boards resolved to implement a stock option plan ("SOP 2007") for all employees (including members of the management board) with open-ended contracts of employment with the Company and for selected members of the supervisory board of the Company and further participants. The stock option plan became effective on September 28, 2007. In connection with the Redomiciliation Transaction, the SOP 2007 was amended to take account of certain requirements under Irish law and assumed by Nabriva Ireland, with each option to acquire one Nabriva Austria common share becoming an option to acquire ten ordinary shares of Nabriva Ireland on the same terms and conditions. As of September 27, 2017, all outstanding options under the SOP 2007 automatically terminated and were forfeited.

Movements in the number of share options outstanding and their related weighted average exercise prices concerning the SOP 2007 are as follows:

	2017		2016	
	Weighted average exercise price in \$ per share	Options	Weighted average exercise price in \$ per share	Options
Outstanding as of January 1	0.73	109,960	0.73	234,760
Granted	-	-	-	-
Exercised	0.73	(108,440)	0.73	(124,540)
Forfeited	0.73	(1,520)	0.73	(260)
<b>Outstanding as of December 31</b>	-	-	0.73	109,960
<b>Vested and exercisable as of December 31</b>	-	-	0.73	107,900

As a result of the Redomiciliation Transaction, the 2016 movement in the number of share options outstanding and their related weighted average exercise prices have been adjusted on a one-for-ten basis from the Nabriva Austria common shares, to the Nabriva Ireland ordinary shares.

The total intrinsic value of options exercised during the years ended December 31, 2016 and 2017 was \$860 and \$899, respectively.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**15 Share-based payments - continued**

Stock-based compensation expense under the SOP 2007 for the years ended December 31, 2016 and 2017 was \$95 and \$40, respectively.

**Stock option plan 2015**

On April 2, 2015, the Company's shareholders, management board and supervisory board adopted the Stock Option Plan 2015 (the "SOP 2015") and the shareholders approved an amended and restated version of the SOP 2015 on June 30, 2015. An amendment to the amended and restated SOP 2015 was approved by the shareholders on July 22, 2015. SOP 2015 became effective on July 3, 2015 upon the registration with the commercial register in Austria of the conditional capital increase approved by the shareholders on June 30, 2015. The SOP 2015 initially provided for the grant of options for up to 95,000 Nabriva Austria common shares to the Company's employees, including members of the management board, and to members of the supervisory board. Following the closing of the initial public offering of the Company, the overall number of options increased to 177,499 Nabriva Austria common shares. Following approval by the Company's shareholders at its 2016 annual general meeting, the number of shares available for issuance under the SOP 2015 was increased to 346,235 Nabriva Austria common shares. In connection with the Redomiciliation Transaction, the SOP 2015 was amended to take account of certain requirements under Irish law and assumed by Nabriva Ireland, with each option to acquire one Nabriva Austria common share becoming an option to acquire ten ordinary shares of Nabriva Ireland on the same terms and conditions.

Each vested option grants the beneficiary the right to acquire one share in the Company. The vesting period for the options is four years following the grant date. On the last day of the last calendar month of the first year of the vesting period, 25% of the options attributable to each beneficiary are automatically vested. During the second, third and fourth years of the vesting period, the remaining 75% of the options vest on a monthly pro rata basis (i.e. 2.083% per month). Options granted under the SOP 2015 have a term of no more than ten years from the beneficiary's date of participation. Since the closing of the initial public offering of the Company on September 23, 2015 the beneficiaries are entitled to exercise their vested options until the 10th anniversary of the date of their participation. The beneficiaries are not entitled to transfer vested options except to individuals by way of inheritance or bequest. Options do not entitle beneficiaries to exercise any shareholder rights. Beneficiaries may only exercise shareholder rights if and to the extent he holds shares.

Movements in the number of share options outstanding and their related weighted average exercise prices concerning the SOP 2015 are as follows:

	2017			2016	
	Weighted average exercise price in \$ per share	Options	Aggregate Intrinsic Value \$	Weighted average exercise price in \$ per share	Options
Outstanding as of January 1	7.83	1,794,360		7.61	1,092,300
Granted	9.02	1,458,300		8.02	922,130
Exercised	-	-		7.21	(23,360)
Forfeited	8.60	(207,761)		7.64	(196,710)
<b>Outstanding as of December 31</b>	<b>8.35</b>	<b>3,044,899</b>	<b>9</b>	<b>7.83</b>	<b>1,794,360</b>
<b>Vested and exercisable as of December 31</b>	<b>7.68</b>	<b>989,656</b>	<b>3</b>	<b>7.52</b>	<b>425,210</b>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
**(in thousands, except per share data)**

**15 Share-based payments – continued**

***Stock option plan 2015 - continued***

The total intrinsic value of options exercised during the years ended December 31, 2016 and 2017 was \$181 and \$0, respectively. The Company has 3,044,899 option grants outstanding at December 31, 2017 with exercise prices ranging from \$4.06 per share to \$11.00 per share and a weighted average remaining contractual life of 8.4 years.

Stock-based compensation expense under the SOP 2015 was \$2,450 and \$5,610 for the years ended December 31, 2016 and 2017, respectively. The weighted average fair value of the options granted during the years ended December 31, 2016 and 2017 was \$4.76 per share and \$5.05 per share, respectively.

The grant date fair value of each option grant was estimated throughout the year using the Black-Scholes option-pricing model using the following assumptions:

Input parameters	2017	2016
Expected volatility	55.6% - 62.0%	59.8% - 67.2%
Expected term of options	6.1 years	6.0 years
Risk-free interest rate	1.89% - 2.10%	1.15% - 2.09%
Expected dividend yield	-	-

The expected price volatility is based on historical trading volatility for the publicly traded peer companies under consideration of the remaining life of the options. The risk free interest rate for the year 2015, is based on the 6 year euro area market yield for AAA-rated European central government bonds and for the years 2016 and 2017, is based on the average of 5 and 7 year market yield on U.S. treasury securities in effect at the time of grant.

As of December 31, 2017, there was \$10.1 million of unrecognized compensation expense, related to unvested options granted under the SOP 2015 Plan, which will be recognized over the weighted average remaining vesting period of 1.3 years.

***2017 share incentive plan***

On July 26, 2017, the Company's board of directors adopted the 2017 Share Incentive Plan (the "2017 Plan") and the shareholders approved the 2017 Plan at the Company's Extraordinary General Meeting of Shareholders on September 15, 2017. Following shareholder approval of the 2017 Plan, the Company ceased making awards under the SOP 2015, and future awards will be made under the 2017 Plan. However, all outstanding awards under SOP 2015 will remain in effect and continue to be governed by the terms of the SOP 2015. The 2017 Plan permits the award of share options (both incentive and nonstatutory options), share appreciation rights ("SARs"), restricted shares, restricted share units ("RSUs"), and other share-based awards to the Company's employees, officers, directors, consultants and advisers. The 2017 Plan is administered by the Company's board of directors.

Under the 2017 Plan, the number of ordinary shares that will be reserved for issuance will be the sum of (1) 3,000,000 ordinary shares; plus (2) a number of ordinary shares (up to 3,438,990 ordinary shares) which is equal to the sum of the number of the Company's ordinary shares then available for issuance under the SOP 2015 and the number of ordinary shares subject to outstanding awards under the SOP 2015 that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year beginning in the fiscal year ending December 31, 2018 and continuing until, and including, the fiscal year ending December 31, 2027, equal to the least of (i) 2,000,000 ordinary shares, (ii) 4% of the number of outstanding ordinary shares on such date and (iii) an amount determined by the board of directors.

At December 31, 2017, 3,394,091 ordinary shares were available for issuance under the 2017 Plan.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**15 Share-based payments - continued**

***2017 share incentive plan - continued***

Options and SARs granted will be exercisable at such times and subject to such terms and conditions as the board may specify in the applicable option agreement; provided, however, that no option or SAR will be granted with a term in excess of ten years. The board will also determine the terms and conditions of restricted shares and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

The following table summarizes information regarding our stock option awards under the 2017 Plan at December 31, 2017:

	2017		
	Weighted average exercise price in \$ per share	Options	Aggregate intrinsic value
Outstanding as of January 1, 2017	-	-	
Granted	6.92	294,100	
Exercised	-	-	
Forfeited	-	-	
<b>Outstanding as of December 31, 2017</b>	<b>6.92</b>	<b>294,100</b>	<b>-</b>
<b>Vested and exercisable as of December 31, 2017</b>	<b>-</b>	<b>-</b>	<b>-</b>

There were no options exercised during the year ended December 31, 2017.

The Company has 294,100 option grants outstanding at December 31, 2017 with exercise prices ranging from \$5.98 per share to \$8.35 per share and a weighted average remaining contractual life of 9.8 years.

Stock-based compensation expense under the 2017 Plan was \$82 for the year ended December 31, 2017. The weighted average fair value of the options granted during year ended December 31, 2017 was \$3.98 per share based on a Black Scholes option pricing model using

The significant inputs into the model were as follows:

Input parameters	
Range of expected volatility	59.5% - 63.0%
Expected term of options (in years)	6.0
Range of risk-free interest rate	1.93% - 2.27%
Dividend yield	-

The expected price volatility is based on historical trading volatility for the publicly traded peer companies under consideration of the remaining life of the options. The risk free interest rate is based on the average of 5 and 7 year market yield on U.S. treasury securities in effect at the time of grant.

As of December, 2017, there was \$1.1 million of total unrecognized compensation expense, related to unvested options granted under the 2017 Plan, which will be recognized over the weighted-average remaining vesting period of 1.7 years.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**15 Share-based payments - continued**

**2017 share incentive plan - continued**

Our share-based compensation expense has been allocated to research and development and general and administrative expenses in the Consolidated Statement of Operations and Comprehensive Loss as follows:

(in thousands)	December 31,	
	2017	2016
	\$	\$
Research and development	2,128	894
General and administrative	3,604	1,651
<b>Total</b>	<u>5,732</u>	<u>2,545</u>

**16 Post-employment benefit obligations**

As required under Austrian labor law, the Company makes contributions to a state plan classified as defined contribution plan (Mitarbeitervorsorgekasse) for its employees in Austria. Monthly contributions to the plan are 1.53% of salary with respect to each employee and are recognized as expense in the period incurred. In the years ended December 31, 2017 and 2016, contribution costs amounted to \$58 and \$59 respectively.

For employees of Nabriva Therapeutics US, Inc., the Company makes contributions to a defined contribution plan as defined in subsection 401(k) of the Internal Revenue Code. The Company matches 100% of the first 3% of the employee's voluntary contribution to the plan and 50% of the next 2% contributed by the employee. Contributions are recognized as expense in the period incurred. In the years ended December 31, 2017 and 2016 contribution expenses were \$213 and \$152 respectively.

**17 Commitments and contingencies**

In March 2007, a lease agreement for an unlimited period starting in December 2007 was entered into for the use of business and research premises in Vienna. Within the first 10 years the contract can only be terminated under certain conditions.

In July 2015, a lease agreement was entered into for the use of approximately 15,000 square feet of office space in King of Prussia, PA, with the lease term continuing until December 2023 with no renewal options.

We also enter into lease agreements for equipment such as copiers and printers.

Lease expense was \$1,264 and \$1,263 for the years ended December 31, 2017 and 2016 respectively.

Future minimum contractual obligations and commitments at December 31, 2017 are as follows:

(in thousands)	Total	2018	2019	2020	2021	2022	Thereafter
	\$	\$	\$	\$	\$	\$	\$
Operating lease obligations	3,327	776	500	507	515	522	507
Other contractual commitments	10,550	10,550	-	-	-	-	-
<b>Total</b>	<u>13,877</u>	<u>11,326</u>	<u>500</u>	<u>507</u>	<u>515</u>	<u>522</u>	<u>507</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
 (in thousands, except per share data)

**17 Commitments and contingencies – continued**

In addition to the agreements described above, the Company has other contractual commitments related primarily to contracts entered into with contract research organizations and contract manufacturing organizations in connection with the conduct of clinical trials and other research and development activities. The estimated payments to the services providers included in the table above are based solely on the estimated work to be performed by them to complete the trials and other activities along with the anticipated achievement of milestones included within the agreements. Also, some of these contracts are subject to early termination clauses exercisable at the discretion of the Company. The Company is not obligated to make minimum required payments under these service agreements.

The Company has no contingent liabilities in respect of legal claims arising in the ordinary course of business.

**18 Reconciliation of amounts reported in our annual report on Form 10-K filed with the United States securities and exchange**

As discussed in Note 1, these consolidated financial statements are prepared using US GAAP to the extent that the use of such principles does not contravene Irish Company Law. We also prepare consolidated financial statements using US GAAP which are included in our Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission on March 16, 2018. The primary differences between these statutory financial statements and our consolidated financial statements included in our Form 10-K are the presentational format of the profit and loss and balance sheet, terminology used, and the inclusion of certain additional disclosures.

**US GAAP terminology**

**Irish Company Law terminology**

Operating results  
 Risk factors

Key performance indicators  
 Principal risks and uncertainties

Irish company law contains specific requirements for the classification of any liability uncertain as to the amount at which it will be settled or as to the date on which it will be settled.

**19 Employee cost**

The average number of employees for the year was as follows:

	Year ended December 31,	
	2017	2016
	Number	Number
Management	5	5
Other staff	65	51
	<u>        </u>	<u>        </u>



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**19 Employee cost - continued**

The following table represents compensation costs, including restructuring, for the years ended December 31, 2017 and 2016 (in thousands):

	Year ended December 31,	
	2017	2016
	\$	\$
Wages and salaries	12,690	9,051
Stock-based compensation	5,732	2,545
Other retirement benefit costs	58	58
Social welfare	713	680
Other benefits	2,264	1,066
<b>Total</b>	<b>21,457</b>	<b>13,400</b>

The total amount of employee costs capitalized in the year was \$Nil (2016: \$Nil). All other employee costs were charged to profit and loss.

**20 Directors' remuneration**

Although Nabriva Therapeutics Plc was incorporated on March 1, 2017, the disclosure below shows the remuneration of the directors of the Company for the financial year including the period pre-incorporation in Ireland. The remuneration for the comparative period uses the historic financial statements of Nabriva Austria for periods prior to the date of the redomiciliation.

(in thousands)	Year ended December 31,	
	2017	2016
	\$	\$
Emoluments	762	656
Benefits under long-term incentive schemes	184	176
Contributions to retirement benefit schemes (2):		
- Defined benefit scheme	-	-
- Defined contribution scheme	40	43
Gain on the exercise of options by a director	124	-
	<b>1,110</b>	<b>875</b>

(1) Emoluments include salaries, fees and percentages, bonuses, any sums paid by way of expense allowance in so far as those sums are chargeable to income tax, and the estimated money value of any other benefits received otherwise than in cash.

(2) Retirement benefits are accruing to one of the directors.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**21 Auditors' remuneration**

	Year ended December 31,	
	2017	2016
(in thousands)	\$	\$

Auditors' remuneration billed or billable by KPMG Ireland and its affiliates for 2017 and PwC, the predecessor auditor for 2016 was as follows:

Auditors' remuneration	<u>1,701</u>	<u>1,689</u>
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The table below shows remuneration for all work carried out for the Company and its subsidiaries by KPMG Ireland in each of the following categories of work (in thousands):

	Year ended December 31,	
	2017	2016
	\$	\$
Auditors' remuneration - Group:		
Statutory audit of group financial statements	55	-
Other assurance services	-	-
Tax advisory services	-	-
Other non-audit services	-	-
	<u>55</u>	<u>-</u>

All fees paid to the Company's auditors are approved by the Company's audit committee.

**22 Subsidiary undertakings**

As of December 31, 2017 the Company had the following subsidiaries:

<b>Name</b>	<b>Registered office</b>	<b>Principal activities</b>	<b>Portion of equity held</b>
Nabriva Therapeutics Ireland Designated Activity Company	25-28 North Wall Quay, Dublin 1, Ireland	Holding company	100%
Nabriva Therapeutics GmbH	Leberstrasse 20, 1110 Vienna, Austria	Holding company	100%
Nabriva Therapeutics One Designated Activity Company	25-28 North Wall Quay, Dublin 1, Ireland	Holding company	100%
Nabriva Therapeutics US, Inc.	1000 Continental Drive, Suite 600, King of Prussia, PA 19406, USA	Management, commercial clinical research & development support	100%

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - continued**  
(in thousands, except per share data)

**23 Subsequent events**

The Company evaluated all events or transactions that occurred subsequent to December 31, 2017 through the date the consolidated financial statements were issued, and have identified the following events.

In March 2018, the Company entered into a sales agreement with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, the Company may offer and sell its ordinary shares having an aggregate offering price of up to \$50.0 million through Cantor pursuant to an effective universal shelf registration statement. Sales of ordinary shares, if any, under the agreement with Cantor may be made in sales deemed to be an “at-the-market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. During the first quarter of 2018, the Company issued and sold 3,517,511 ordinary shares for gross proceeds of \$19.4 million, and net proceeds of \$18.5 million, after deducting commissions and other issuance costs.

On March 26, 2018, the Company entered into a license agreement with Sinovant Sciences (“Sinovant”) to develop and commercialize lefamulin in greater China. As part of the license agreement, the Company has granted Sinovant, a Roivant Sciences, LTD. subsidiary, an exclusive license to develop and commercialize lefamulin in the greater China region, specifically the People’s Republic of China, Hong Kong, Macau, and Taiwan. The companies will establish a joint development committee to review and oversee all development and commercialization plans. Nabriva received a \$5 million upfront payment and will be eligible for up to approximately \$90 million in additional payments tied to the successful completion of certain regulatory and commercial milestones related to lefamulin for CABP. In addition, Nabriva will be eligible to receive low double-digit royalties on sales upon approval in the covered territories. Roivant’s affiliate will be solely responsible for all clinical development and regulatory filings necessary to secure approval in the covered territories.

**24 Approval**

The financial statements were approved by the directors on 02 July 2018.

**Nabriva Therapeutics Public Limited Company**

**Company Financial Statements**

**Financial Period Ended December 31, 2017**

**Dated: 02 July 2018**

**COMPANY BALANCE SHEET**  
**As at December 31, 2017**  
**(in thousands)**

	Note	2017 \$
<b>Fixed assets</b>		
Financial assets	2	<u>289,236</u>
<b>Current assets</b>		
Debtors: amounts falling due within one year	3	7,018
Cash at bank and in hand		<u>66,889</u>
		73,907
<b>Creditors: amounts falling due within one year</b>	4	<u>(10,758)</u>
<b>Net current assets</b>		<u>63,149</u>
<b>Total assets less current liabilities</b>		<u>352,385</u>
<b>Net assets</b>		<u>352,385</u>
<b>Capital and reserves</b>		
Called up share capital presented as equity	5	367
Share premium account	6	366,186
Share option reserve	6	2,870
Profit and loss account	6	<u>(17,038)</u>
<b>Total equity</b>		<u>352,385</u>

On behalf of the board



**Colin Broom**  
 Director



**Charles Rowland**  
 Director

Date: 02 July 2018

**COMPANY STATEMENT OF CHANGES IN EQUITY**  
**Financial Year Ended December 31, 2017**  
(in thousands)

	Called-up share capital \$	Share premium account \$	Share option reserve \$	Profit and loss account \$	Total equity \$
<b>Balance at incorporation</b>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
Loss for the financial period	-	-	-	(10,400)	(10,400)
Other comprehensive income	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
<b>Total comprehensive loss</b>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(10,400)</u>	<u>(10,400)</u>
Issue of ordinary shares	367	366,186	-	-	366,553
Transaction costs on issue of shares	-	-	-	(6,638)	(6,638)
Share option reserve movement	<u>-</u>	<u>-</u>	<u>2,870</u>	<u>-</u>	<u>2,870</u>
<b>Balance at December 31, 2017</b>	<u>367</u>	<u>366,186</u>	<u>2,870</u>	<u>(17,038)</u>	<u>352,385</u>

## NOTES TO THE COMPANY FINANCIAL STATEMENTS

### 1 Basis of preparation and summary of significant accounting policies

On March 1, 2017, Nabriva Therapeutics plc (“Nabriva Ireland”), was incorporated in Ireland under the name Hyacintho 2 plc, and was renamed to Nabriva Therapeutics plc on April 10, 2017, in order to effectuate the change of the jurisdiction of incorporation of the ultimate parent company of the Nabriva Group from Austria to Ireland. Nabriva Ireland replaced Nabriva Therapeutics AG (“Nabriva Austria”) as the ultimate parent company on June 23, 2017, following the conclusion of a tender offer (the “Exchange Offer”) in which holders of 98.5% of the outstanding share capital of Nabriva Austria exchanged their holdings for ordinary shares, \$0.01 nominal value per share, of Nabriva Ireland (the “Redomiciliation Transaction”). The ordinary shares of Nabriva Ireland were issued on a one-for-ten basis to the holders of the Nabriva Austria common shares (“Nabriva Austria common shares”) and on a one-for-one basis to the holders of the Nabriva Austria American Depositary Shares (“Nabriva Austria ADSs”) participating in the Exchange Offer. On June 26, 2017, the ordinary shares of Nabriva Ireland began trading on the NASDAQ Global Market under the symbol “NBRV,” the same symbol under which the American Depositary Shares of Nabriva Austria were previously traded.

Nabriva Ireland is incorporated as a company limited by shares in the Republic of Ireland with registration number 599588. The address of its registered office is 25 -28 North Wall Quay, Dublin, Ireland.

#### Statement of compliance

The entity financial statements have been prepared on a going concern basis and in accordance with Irish GAAP (accounting standards issued by the Financial Reporting Council of the UK and the Companies Act 2014). The entity financial statements comply with Financial Reporting Standard 102, ‘The Financial Reporting Standard applicable in the UK and Republic of Ireland’ (FRS 102) and the Companies Act 2014.

#### Significant accounting policies

The significant accounting policies used in the preparation of the entity financial statements are set out below. These policies have been consistently applied to all financial years presented.

#### Basis of preparation

The entity financial statements have been prepared under the historical cost convention. The preparation of financial statements in conformity with FRS 102 requires the use of certain key assumptions concerning the future, and other key sources of estimation uncertainty at the reporting date. It also requires the directors to exercise their judgment in the process of applying the Company’s accounting policies. Estimates and judgments made in the process of preparing the entity financial statements are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

#### Exemption for qualifying entities under FRS 102

FRS 102 allows a qualifying entity certain disclosure exemptions to a member of a group where the parent of that group prepares publicly available consolidated financial statements which are intended to give a true and fair view (of the assets, liabilities, financial position and profit or loss) and that member is included in the consolidation. The Company is a qualifying entity and has taken advantage of the below disclosure exemptions:

- (1) Exemption from the requirement to present a statement of cash flows,
- (2) Exemption from the financial instrument disclosure requirement to provide the equivalent disclosures included in the consolidated financial statements of the group in which the entity is consolidated, and
- (3) Exemption from the requirement to disclose key management personnel compensation in total.

#### Critical accounting estimates

The directors make estimates and assumptions concerning the future in the process of preparing the entity financial statements. 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 relate to the carrying value of the investment in subsidiaries.

## NOTES TO THE COMPANY FINANCIAL STATEMENTS - continued

### 1 Basis of presentation and summary of significant accounting policies - continued

#### **Going concern**

The directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Therefore, these entity financial statements have been prepared on a going concern basis. See note 1 to the consolidated financial statements for further details of the directors' assessment of going concern for the group.

#### **Currency translation**

The Company's functional and presentation currency is the U.S. dollar (\$). Transactions denominated in currencies other than the functional currency are translated into U.S. dollars using the spot exchange rates at the dates of the transactions.

Monetary items are translated to the U.S. dollar using the closing exchange rate at each reporting date. Non-monetary items measured at historical cost are translated using the spot rate on the date of the transaction.

Foreign currencies exchange differences are recognized in other expenses in the statement of comprehensive income.

#### **Investment in subsidiaries**

Investment in subsidiaries is recorded at cost less impairment. Cost equalled the fair value on the date of the completion of the Redomiciliation Transaction, based on the market capitalization of Nabriva Therapeutics AG as at that date. This is the Company's cost basis for its investment in its subsidiaries.

#### **Impairments of investment in subsidiaries**

The Company evaluates whether facts or circumstances indicate that the carrying values of its investment in subsidiaries may not be recoverable. If such facts or circumstances are determined to exist, an estimate of the recoverable amount is compared to the carrying value of the asset to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's recoverable amount and its carrying value.

#### **Cash at bank and in-hand**

Cash at bank and in hand includes all cash balances and deposits which are repayable upon demand.

#### **Share-based payments**

The Company operates an equity-settled, share-based compensation plan for employees of some of its subsidiaries. The grant-date fair value, calculated using the Black-Scholes model, of the employee services received in exchange for the equity instruments granted in each of the subsidiaries of the Company is recognized as an addition to the investment with a corresponding increase in equity as a contribution by the Company. The grant-date fair value of the award is recognized over the period during which the employee is required to provide service in exchange for the award (vesting period). The proceeds received by the Company when share options are exercised are credited to share capital (nominal value) and the balance to share premium.

#### **Financial instruments**

The Company has chosen to apply the provisions of Sections 11 and 12 of FRS 102 to account for all of its financial instruments.

#### *Financial assets*

Basic financial assets, including trade and other debtors, cash and cash equivalents and short-term deposits, are initially recognized at transaction price (including transaction costs), unless the arrangement constitutes a financing transaction. Where the arrangement constitutes a financing transaction the resulting financial asset is initially measured at the present value of the future receipts discounted at a market rate of interest for a similar debt instrument.

Trade and other debtors, cash and cash equivalents and financial assets from arrangements which constitute financing transactions are subsequently measured at amortized cost using the effective interest method.



## NOTES TO THE COMPANY FINANCIAL STATEMENTS - continued

### 1 Basis of presentation and summary of significant accounting policies - continued

#### **Financial instruments - continued**

##### *Financial assets - continued*

At the end of each financial year financial assets measured at amortized cost are assessed for impairment. If there is objective evidence that a financial asset measured at amortized cost is impaired an impairment loss is recognized in the statement of comprehensive income. The impairment loss is the difference between the financial asset's carrying amount and the present value of the financial asset's estimated cash inflows discounted at the asset's original effective interest rate.

If, in a subsequent financial year, the amount of an impairment loss decreases, and the decrease can be objectively related to an event occurring after the impairment was recognized, the previously recognized impairment loss is reversed. The reversal is such that the current carrying amount does not exceed what the carrying amount would have been had the impairment loss not previously been recognized. The impairment reversal is recognized in statement of comprehensive income.

Financial assets are derecognized when (a) the contractual rights to the cash flows from the asset expire or are settled, (b) substantially all the risks and rewards of ownership of the financial asset are transferred to another party, or (c) control of the financial asset has been transferred to another party who has the practical ability to unilaterally sell the financial asset to an unrelated third party without imposing additional restrictions.

##### *Financial liabilities*

Basic financial liabilities, including trade and other creditors, bank loans, loans from fellow group companies and preference shares, are initially recognized at transaction price, unless the arrangement constitutes a financing transaction. Where the arrangement constitutes a financing transaction the resulting financial liability is initially measured at the present value of the future payments discounted at a market rate of interest for a similar debt instrument.

Trade and other creditors, bank loans, loans from fellow group companies, and financial liability from arrangements which constitute financing transactions are subsequently carried at amortized cost, using the effective interest method.

Fees paid on the establishment of loan facilities are recognized as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. In this case, the fee is deferred until the draw-down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is treated as a prepayment for liquidity services and amortized over the period of the facility to which it relates.

Trade creditors are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade creditors are classified as due within one year if payment is due within one year or less. If not, they are presented as falling due after more than one year. Trade creditors are recognized initially at transaction price and subsequently measured at amortized cost using the effective interest method.

Financial liabilities are derecognized when the liability is extinguished, that is when the contractual obligation is discharged, canceled or expires.

#### **Contingencies**

Contingent liabilities, arising as a result of past events, are not recognized as a liability if it is not probable that the Company will be required to transfer economic benefits in settlement of the obligation or the amount cannot be reliably measured. Possible but uncertain obligations are not recognized as liabilities but are contingent liabilities. Contingent liabilities are disclosed in the financial statements unless the probability of payment is remote.

#### **Share capital**

Equity shares issued are recognized at the proceeds received. The par value of the shares issued is credited to the called up share capital account with the excess of the proceeds received over the par value of those shares recorded in the share premium account.

## NOTES TO THE COMPANY FINANCIAL STATEMENTS - continued

## 1 Basis of presentation and summary of significant accounting policies - continued

**Dividends**

Dividends may only be declared and paid out of the profits available for distribution in accordance with accounting practice generally accepted in Ireland and applicable Irish company law. Any dividends, if and when declared, will be declared and paid in U.S. dollars. Dividends declared by the directors are recognized when paid.

## 2 Financial assets

(in thousands)

Investment  
in subsidiary  
undertakings  
\$**Cost**

At date of incorporation

-

Additions – share based payments

2,740

Redomiciliation transaction

286,496

At December 31, 2017

289,236

**Net book value**

At date of incorporation

-

At December 31, 2017

289,236

Financial fixed assets comprise equity shares in the following direct subsidiary undertakings:

Name of company	Principal activity	Registered office address	Ownership percentage
Nabriva Therapeutics Ireland Designated Activity Company	Holding company	25-28 North Wall Quay, Dublin 1, Ireland	100%
Nabriva Therapeutics GmbH	Holding company	Leberstrasse 20, 1110 Vienna, Austria	100%

The Company evaluated whether facts or circumstances indicated that the carrying value of the investment in subsidiaries at December 31, 2017 may not be recoverable. The recoverable amount was measured using a discounted cash flow valuation model prepared by the company, and the key assumptions in this model relate to revenue commencement date and subsequent growth rates. The estimated recoverable amount exceeds the carrying value of the asset and so it has been concluded that no impairment existed at December 31, 2017.

NOTES TO THE COMPANY FINANCIAL STATEMENTS - continued

<b>3 Debtors: amounts falling due within one year</b>	2017
	\$
(in thousands)	
Amounts owed by subsidiary undertakings	6,500
Prepayments	518
	<u>7,018</u>

Amounts owed by group undertakings are unsecured, interest free, have no fixed date of repayment and are repayable on demand.

<b>4 Creditors: amounts falling due within one year</b>	2017
	\$
(in thousands)	
Trade creditors	126
Amounts owed to subsidiary undertakings	10,412
Income tax payable on emoluments	20
Accruals	200
	<u>10,758</u>

Trade and other creditors are payable in accordance with the creditors usual and customary credit terms.

Amounts due to group undertakings are unsecured, interest free, have no fixed date of repayment and are repayable on demand.

<b>5 Called up share capital presented as equity</b>	2017
	\$
(in thousands, except per share data)	
<b>Authorised</b>	
1,000,000,000 ordinary shares of \$0.01	10,000
100,000,000 preferred shares of \$0.01	1,000
	<u>11,000</u>
	€
25,000 Euro deferred shares of €1 each	<u>25</u>
	\$
<b>Allotted and fully paid</b>	
36,707,685 ordinary shares of \$0.01	<u>367</u>

## NOTES TO THE COMPANY FINANCIAL STATEMENTS - continued

## 5 Called up share capital presented as equity - continued

## Share capital movements

(in thousands, except per share data)	Ordinary shares		Euro deferred shares	
	Number of shares	Par value \$	Number of shares	Par value €
Shares issued on incorporation of the company	1	-	25,000	25
Shares redeemed and cancelled during the financial period	(1)	-	(25,000)	(25)
Shares issued during the financial period	36,707,685	367	-	-
	<u>36,707,685</u>	<u>367</u>	<u>-</u>	<u>-</u>

For details of the reasons why shares were issued during the period and the consideration received refer to note 14 of the consolidated financial statements.

**Redemption of shares**

Following the redemption and cancellation of the shares above, in line with the Irish law, the par value of the cancelled shares has been transferred to an undenominated capital account.

**Ordinary shares**

The rights and restrictions attaching to the ordinary shares are as follows:

- the right to attend and speak at any general meeting of the company and to exercise one vote per Ordinary Share held at any general meeting of the company
- the right to participate pro rata in all dividends declared by the company with respect to the Ordinary Shares; and
- the right, in the event of the company's winding up, to participate pro rata with all other holders of Ordinary Shares in the total assets of the company.

The rights attaching to the Ordinary Shares shall be subject to the terms of issue of any series or class of preferred shares allotted by the directors from time to time.

**Preferred shares**

The directors are authorised to issue all or any of the authorised but unissued Preferred Shares from time to time in one or more classes or series. The directors may at any time before the allotment of any preferred share by further resolution in any way amend the designations, preferences, rights, qualifications, limitations or restrictions, or vary or revoke the designations of such Preferred Shares.

**Euro deferred shares**

The holders of the Euro Deferred Shares shall not be entitled to receive any dividend or distribution and shall not be entitled to receive notice of, nor to attend, speak or vote at, any general meeting of the Company. On a return of assets, whether on liquidation or otherwise, the Euro Deferred Shares shall entitle the holder thereof only to the repayment of the amounts paid up on such shares after repayment of the capital paid up on the Ordinary Shares plus the payment of \$5,000,000 on each of the Ordinary Shares and the holders of the Euro Deferred Shares (as such) shall not be entitled to any further participation in the assets or profits of the company.

## NOTES TO THE COMPANY FINANCIAL STATEMENTS - continued

### 6 Reserves

#### Share premium account

Share premium represents the excess of proceeds received in relation to the issuance of equity shares over the par value of those shares.

#### Share option reserve

Share option reserves relates to the equity settled share based payments to employees of the group.

#### Profit and loss account

Profit and loss account represents the aggregate of accumulated comprehensive income/(loss) since incorporation.

### 7 Loss attributable to Nabriva Therapeutics plc

In accordance with Section 304 of the Companies Act 2014, the Company is availing of the exemption from presenting and filing its individual profit and loss account. The Company's loss for the financial period (from the date of incorporation to December 31, 2017) as determined in accordance with Irish GAAP (FRS 102) was \$10.4 million.

### 8 Related-party transactions

The Company has not disclosed related party transactions between the Company and its subsidiaries as it has availed of the exemption available under Schedule 3(67), paragraph 3, Companies Act 2014, which exempts disclosure of transactions entered into between two or more members of a group, provided that any subsidiary undertaking which is a party to the transaction is wholly owned by a member of that group.

### 9 Auditors' remuneration

Auditors' remuneration for services provided by KPMG Ireland, the statutory auditor to the Company was \$55 thousand. Disclosure of the auditors' remuneration for the group is included in note 21 to the consolidated financial statements of the company.

### 10 Contingencies and guarantees

The Company has no contingent liabilities in respect of legal claims arising in the ordinary course of the business

**NOTES TO THE COMPANY FINANCIAL STATEMENTS - continued**

**11 Events since the end of the financial year**

The Company evaluated all events or transactions that occurred subsequent to December 31, 2017 through the date of the approval of the directors' report and the company financial statements, and have identified the following events.

In March 2018, the Company entered into a sales agreement with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, the Company may offer and sell its ordinary shares having an aggregate offering price of up to \$50.0 million through Cantor pursuant to an effective universal shelf registration statement. Sales of ordinary shares, if any, under the agreement with Cantor may be made in sales deemed to be an "at-the-market offering" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. During the first quarter of 2018, the Company issued and sold 3,517,511 ordinary shares for gross proceeds of \$19.4 million, and net proceeds of \$18.5 million, after deducting commissions and other issuance costs.

**12 Approval of financial statements**

The directors approved the financial statements on 02 July 2018.