Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark one)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2017

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-37558

Nabriva Therapeutics AG
(Exact name of registrant as specified in its charter)

Republic of Austria (State or jurisdiction of organization)	**Not applicable** (I.R.S. Employer Identification No.)
Leberstrasse 20 **1110 Vienna, Austria** (Address of principal executive offices)	**Not applicable** (Zip Code)

43 (0)1 740 930
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒ (Do not check if a smaller reporting company)	Smaller reporting company ☐
	Emergining growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes ☐ No ☒

As of April 30, 2017, the registrant had 2,721,086 common shares outstanding, of which 2,260,443 are represented by 22,604,430 ADS.

Table of Contents

NABRIVA THERAPEUTICS AG
INDEX TO REPORT ON FORM 10-Q

		Page
	PART I — FINANCIAL INFORMATION	
Item 1:	Financial Statements	4
	Consolidated balance sheets as of December 31, 2016 and March 31, 2017 (unaudited)	5
	Consolidated statements of operations and comprehensive loss for the three months ended March 31, 2016 and 2017 (unaudited)	6
	Consolidated statements of cash flows for the three months ended March 31, 2016 and 2017 (unaudited)	7
	Notes to the unaudited consolidated financial statements (unaudited)	8
Item 2:	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3:	Quantitative and Qualitative Disclosures About Market Risk	30
Item 4:	Controls and Procedures	31
	PART II — OTHER INFORMATION	
Item 1:	Legal Proceedings	32
Item 1A:	Risk Factors	32
Item 2:	Unregistered Sales of Equity Securities and Use of Proceeds(1)	67
Item 3:	Defaults Upon Senior Securities	67
Item 4:	Mine Safety Disclosures	67
Item 5:	Other Information	67
Item 6:	Exhibits	68
SIGNATURES		69

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Quarterly Report, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate, "around" "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the timing and conduct of our clinical trials of our lead product candidate, lefamulin, including statements regarding the timing and completion of the trials, and the period during which the results of the trials will become available;
- our expectations regarding how far into the future our cash on hand will fund our ongoing operations;
- the timing of and our ability to submit applications for, obtain and maintain marketing approval of lefamulin;
- the potential receipt of revenues from future sales of lefamulin;
- our plans to pursue development of lefamulin for additional indications other than community-acquired bacterial pnemonia (CABP);
- our plans to pursue research and development of other product candidates;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- our sales, marketing and distribution capabilities and strategy;
- our ability to successfully commercialize lefamulin and our other product candidates;
- the potential advantages of lefamulin and our other product candidates;
- our estimates regarding the market opportunities for lefamulin and our other product candidates;
- the rate and degree of market acceptance and clinical benefit of lefamulin and our other product candidates;
- our ability to establish and maintain collaborations;
- our ability to acquire or in-license additional products, product candidates and technologies;
- our future intellectual property position;
- our estimates regarding future expense, capital requirements and needs for additional financing;
- our ability to effectively manage our anticipated growth;
- our plans for the redomiciliation of our ultimate parent company from Austria to Ireland;

- our ability to attract and retain qualified employees and key personnel; and,
- other risks and uncertainties, including those described in the ‘‘Risk Factors’’ section of this Form 10-Q.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make.

You should refer to the “Risk Factors” section of this Form 10-Q for a discussion of important factors that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements, except as required by applicable law.

PART I

ITEM 1. FINANCIAL STATEMENTS

NABRIVA THERAPEUTICS AG

Consolidated Balance Sheets (unaudited)

(in thousands, except per share data)	As of December 31, 2016	As of March 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 32,778	$ 27,166
Short-term investments	51,106	41,061
Other receivables	5,561	7,448
Prepaid expenses	1,176	903
Total current assets	90,621	76,578
Property, plant and equipment, net	519	490
Intangible assets, net	270	224
Long-term receivables	420	424
Deferred tax assets	1,410	1,232
Total assets	**$ 93,240**	**$ 78,948**
Liabilities and equity		
Current liabilities:		
Accounts payable	$ 2,551	$ 4,337
Accrued expense and other current liabilities	13,326	11,553
Total current liabilities	15,877	15,890
Non-current liabilities		
Long-term debt	—	203
Other non-current liabilities	107	134
Total non-current liabilities	107	337
Total liabilities	**$ 15,984**	**$ 16,227**
Commitments and contingencies (Note 17)		
Stockholders' Equity:		
Common stock — no par value; 1,389,786 and 1,388,395 shares authorized at December 31, 2016 and March 31, 2017, respectively; 2,719,695 and 2,721,086 shares issued and outstanding at December 31, 2016 and March 31, 2017, respectively	$ 2,939	$ 2,946
Treasury shares — at cost; 0 shares at December 31, 2016 and 0 shares at March 31, 2017, respectively	—	—
Additional paid in capital	279,149	279,848
Accumulated other comprehensive income (loss)	10	(7)
Accumulated deficit	(204,842)	(220,066)
Total stockholders' equity	77,256	62,721
Total liabilities and stockholders' equity	**$ 93,240**	**$ 78,948**

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

NABRIVA THERAPEUTICS AG

Consolidated Statements of Operations and Comprehensive Income (Loss) (unaudited)

(in thousands, except per share data)	Three Months Ended March 31, 2016	2017
Revenues:		
Research premium and grant revenue	$ 1,419	$ 1,678
Operating expenses:		
Research and development	$ (13,036)	$ (12,660)
General and administrative	(3,085)	(4,218)
Total operating expenses	$ (16,121)	$ (16,878)
Loss from operations	**$ (14,702)**	**$ (15,200)**
Other income (expense):		
Other income (expense), net	998	206
Interest income	88	121
Interest expense	—	(1)
Loss before income taxes	**$ (13,616)**	**$ (14,874)**
Income tax benefit (expense)	17	(349)
Net loss	**$ (13,599)**	**$ (15,223)**
Other comprehensive income (loss), net of tax		
Unrealized gains (losses) on available-for-sale financial assets	41	(16)
Reclassification to net income	—	—
Other comprehensive income (loss), net of tax	$ 41	$ (16)
Comprehensive loss	**$ (13,558)**	**$ (15,239)**

Loss per share	Three Months Ended March 31, 2016	2017
Basic ($ per share)	$ (6.42)	**$** (5.60)
Diluted ($ per share)	$ (6.42)	**$** (5.60)
Weighted average number of shares:		
Basic	2,117,895	2,720,423
Diluted	2,117,895	2,720,423

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

NABRIVA THERAPEUTICS AG

Consolidated Statements of Cash Flows (unaudited)

(in thousands)	Three Months Ended March 31, 2016	2017
Cash flows from operating activities		
Net loss	$ (13,599)	$ (15,223)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash other expense, net	(924)	(266)
Non-cash interest income	(44)	(30)
Non-cash interest expense	—	—
Depreciation and amortisation expense	45	76
Stock-based compensation	580	684
Deferred income taxes	(18)	178
Other, net	1	86
Changes in operating assets and liabilities:		
Changes in long-term receivables	(15)	(5)
Changes in other receivables	(1,638)	(1,586)
Changes in accounts payable	2,235	1,789
Changes in accrued expenses and other liabilities	2,491	(383)
Changes in other non-current liabilities	8	6
Changes in income tax liabilities	(1)	(10)
Net cash used in operating activities	(10,879)	(14,684)
Cash flows from investing activities		
Purchases of plant and equipment and intangible assets	(67)	(25)
Purchases of available-for-sale securities	—	—
Purchases of term deposits	—	—
Proceeds from sales of property, plant and equipment	—	2
Proceeds from maturities of term deposits	—	—
Proceeds from sales of available-for-sale securities	3,000	10,000
Net cash provided by investing activities	2,933	9,977
Cash flows from financing activities		
Proceeds from December 2016 financing	—	—
Proceeds from long-term debt	—	229
Proceeds from exercise of stock options	29	10
Equity transaction costs	—	(1,410)
Net cash provided by (used in) financing activities	29	(1,171)
Effects of foreign currency translation on cash and cash equivalents	924	266
Net decrease in cash and cash equivalents	(6,993)	(5,612)
Cash and cash equivalents at beginning of period	36,446	32,778
Cash and cash equivalents at end of period	$ 29,453	$ 27,166

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

NABRIVA THERAPEUTICS AG

Notes to the Unaudited Consolidated Financial Statements

(in thousands, except per share data)

1. Organization and Business Activities

Nabriva Therapeutics AG, together with its 100% owned and consolidated U.S. subsidiary Nabriva Therapeutics US, Inc. and 100% owned and consolidated Irish subsidiary Nabriva Therapeutics Ireland DAC, ("Nabriva", "the Group" or the "Company") is 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. Nabriva was incorporated in Austria as a spin-off from Sandoz GmbH in October 2005 and commenced operations in February 2006. The Company's headquarters are at Leberstrasse 20, 1110 Vienna Austria. Nabriva Therapeutics US, Inc. was founded and began operations in the United States in August 2014. In February 2017, the Company purchased all shares issued in the capital of Hyacintho DAC, a designated activity company incorporated by a nominee company in December 2016 and renamed the company to Nabriva Therapeutics Ireland DAC on April 10, 2017.

Liquidity

Since its inception, the Company 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 ADSs and private placements of its common shares, convertible debt financings and research and development support from governmental grants and loans. As of March 31, 2017, the Company had cash and cash equivalents and short term investments of $68.2 million.

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 approximately $24.8 million and net proceeds to the Company of approximately $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 approximately $106.1 million and net proceeds to the Company of approximately $92.4 million, after deducting underwriting discounts and offering expenses.

The Company believes that its existing cash, cash equivalents and short-term investments will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the second quarter of 2018.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. While the Company has raised capital in the past, the ability to raise capital in future periods is not considered probable, as defined under the accounting standards. As such, under the requirements of ASC 205-40, management may not consider the potential for future capital raises in their assessment of the Company's ability to meet its obligations for the next twelve months.

This estimate assumes, among other things, that the Company does not obtain any additional funding through grants and clinical trial support, collaboration agreements or debt financings.

As such, in the event necessary, the Company believes it has the ability to elect to forego certain discretionary costs in order to reduce its requirement for cash and to maintain its operations for more than twelve months following the issuance of this report.

If the Company is unable to raise capital when needed or on attractive terms, it could be forced to delay, reduce or eliminate its research and development programs or any future commercialization effort.

Based on current projections, the company anticipates availability of top-line clinical data from LEAP 1, its first Phase 3 clinical trial of lefamulin for community-acquired bacterial pneumonia ("CABP"), in the third quarter of 2017. In addition, the Company expects to complete patient enrollment for LEAP 2, its second Phase 3 clinical trial of lefamulin for CABP, in the fourth quarter of 2017 and anticipates availability of top-line data for LEAP 2 in the first quarter of 2018.

2. Summary of Significant Accounting Policies

Basis of Preparation

The unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP") for interim financial information and U.S. Securities and Exchange Commission ("SEC") regulations for quarterly reporting.

The accompanying consolidated financial information as of March 31, 2017 and for the three months ended March 31, 2016 and 2017 is unaudited. The year-end condensed balance sheet data was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America. The interim unaudited financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2017 and for the three months ended March 31, 2016 and 2017. The financial data and other information disclosed in these notes related to the three months ended March 31, 2016 and 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017, any other interim periods or any future year or period. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2016 contained in the Company's Annual Report on Form 10-K, as filed with the SEC on March 24, 2017.

The Company's significant accounting policies are described in Note 2 of the notes to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies.

Recent Accounting Pronouncements

At the time of authorization of these consolidated financial statements for publication, a number of revisions, amendments and interpretations had already been published by the Financial Accounting Standards Board (FASB). None of these are expected to have a significant effect on the consolidated financial statements of the Company, except the following set out below:

- In May 2014, the FASB issued Accounting Standards Update ("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 disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. In July 2015, the FASB voted to approve a one-year deferral of the effective date of ASU 2014-09, which will be effective for the Company in the first quarter of fiscal year 2018 and may be applied on a full retrospective or modified retrospective approach. ASU 2014-09 will have no impact on the Company until it begins to generate product revenue.

- In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-16 explicitly requires management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management will assess if there is substantial doubt about an entity's ability to continue as a going concern within one year after the issuance date. Management will consider relevant conditions that are known, and reasonably knowable, at the issuance date. Substantial doubt exists if it is probable that the entity will be unable to meet its obligations within one year after the issuance date. Disclosures will be required if conditions give rise to substantial doubt. The new standard will be effective for all entities in the first annual period ending after December 15, 2016. Early adoption is permitted. 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 November 2015, the FASB issued 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 is effective for fiscal years beginning after December 15, 2016 with early adoption permitted. 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 January 2016, FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact that ASU 2016-01 will have on its financial statements and related disclosures.

- In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842). The new standard 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, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for 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 statements and related disclosures.

- In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which 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 will be effective for the Company in the first quarter of 2017 and will be applied either prospectively, retrospectively or using a modified retrospective transition approach depending on the area covered in this update. 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 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)* ("ASU 2016-08"), in April 2016 issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing* ("ASU 2016-10"), and in May 2016, issued ASU 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting* ("ASU 2016-11"). ASU 2016-08 clarifies principal versus agent considerations relating to when another party, along with the entity, is involved in providing a good or service to a customer. ASU 2016-08 requires an entity to determine whether the nature of its promise is to provide a good or service to a customer, or to arrange for the good or service to be provided to the customer by the other party. This determination is based upon whether the entity controls the good or service before it is transferred to the customer. When the entity that satisfies a performance obligation is the principal, the entity recognizes the gross amount of consideration as revenue. When the entity that satisfies the performance obligation is the agent, it recognizes the amount of any fee or commission as revenue. ASU 2016-10 clarifies the guidance in Topic 606 for identifying performance obligations in a contract as well as the implementation guidance pertaining to revenue recognition related to licensing arrangements. ASU 2016-11 rescinds several SEC Staff Announcements that are codified in Topic 605, including, among other items, guidance relating to accounting for consideration given by a vendor to a customer, as well as accounting for shipping and handling fees and freight services. The Company is currently evaluating the impacts of this standard on its financial statements and anticipates no significant effects when the standard is adoped as of the effective date.

- In May 2016, the FASB also issued ASU 2016-12, *Revenue from Contracts with Customers - Narrow-Scope Improvements and Practical Expedients* ("ASU 2016-12"), which provides clarification on certain topics within ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*("ASU 2014-09"), including assessing collectability, presentation of sales taxes, the measurement date for non-cash consideration and completed contracts at transition, as well as providing a practical expedient for contract modifications at transition. The effective date and transition requirements for the amendments in ASU 2016-08, ASU 2016-10 and ASU 2016-12 are the same as the effective date and transition requirements of ASU 2014-09, which is effective for fiscal years, and for interim periods within those years, beginning after December 15, 2017. The Company is currently evaluating the impacts of this standard on its financial statements and anticipates no significant effects when the standard is adoped as of the effective date.

- In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. The amendments in this ASU introduce clarifications to the presentation of certain cash receipts and cash payments in the statement of cash flows. The primary updates include additions and clarifications of the classification of cash flows related to certain debt repayment activities, contingent consideration payments related to business combinations, proceeds from insurance policies, distributions from equity method investees and cash flows related to securitized receivables. This update is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption of this ASU is permitted, including in interim periods. The ASU requires retrospective application to all prior periods presented upon adoption. The Company is currently evaluating the impact, if any, that the adoption of this guidance will have on its cash flows and/or disclosures, however, the Company does not anticipate that the new guidance will have a significant impact on its financial statements and related disclosures.

- In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments in this ASU are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company does not expect the adoption of the amendments to have a material effect on its financial statements and related disclosures.

3. Research Premium and Grant Revenue

Research premium and grant revenue consists of the following items:

	Three Months Ended March 31,	
(in thousands)	**2016**	**2017**
Research premium	$ 1,392	$ 1,505
Government grants	—	147
Grants from WWFF	27	26
Total	**$ 1,419**	**$ 1,678**

Research premium and grant revenue comprises (1) the research premium from the Austrian government, (2) grants received from the Austrian Research Promotion Agency (*Österreichische Forschungsförderungsgesellschaft, or FFG*) and the Vienna Business

Promotion Fund (*Wiener Wirtschaftsförderungsfonds, or WWFF*) and (3) the benefit of government loans at below-market interest rates.

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 we have incurred research and development expenses. 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. The Company is and has been in full compliance with the conditions of the grants and all related regulations.

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 and the proceeds received. This benefit is deferred, and recognized through profit and loss over the term of the corresponding liabilities.

4. Research and Development Expenses

Research and development expenses include the following items:

(in thousands)	Three Months Ended March 31, 2016	2017
Research materials and purchased services	$ 10,184	$ 9,608
Staff costs	1,985	2,320
Other research and development expenses	838	699
Depreciation and amortization	29	33
Total	**$ 13,036**	**$ 12,660**

Research materials and purchased services include all expenses for materials and services in respect of research activities.

For the three months ended March 31, 2017, other research and development expenses consisted of $0.3 million in infrastructure expenses, $0.3 million in advisory and external consultancy expenses and $0.1 million in intellectual property and trademark related expenses and travel expenses.

For the three months ended March 31, 2016, other research and development expenses consisted of $0.3 million in infrastructure expenses, $0.3 million in advisory and external consultancy expenses, $0.1 million in intellectual property and trademark related expenses and $0.1 million in travel expenses.

5. General and Administrative Expenses

General and administrative expenses include the following items:

(in thousands)	Three Months Ended March 31, 2016	2017
Other general and administrative expenses	$ 1,649	$ 2,797
Staff costs	1,420	1,378
Depreciation and amortization	16	43
Total	**$ 3,085**	**$ 4,218**

For the three months ended March 31, 2017, other general and administrative expenses included the following: $0.7 million of advisory and external consultancy expenses, $0.2 million of tax consulting, payroll accounting, accounting and auditing expenses, $0.4 million in infrastructure expenses, $1.0 million of legal expenses, $0.1 million of travel expenses, $0.1 million in supervisory board fees and expenses and $0.3 million of other expenses.

For the three months ended March 31, 2016, other general and administrative expenses included the following: $0.4 million of advisory and external consultancy expenses, $0.1 million of tax consulting, payroll accounting, accounting and auditing expenses, $0.3 million in infrastructure expenses, $0.3 million of legal expenses, $0.1 million of travel expenses, $0.1 million in supervisory board fees and expenses and $0.3 million of other expenses.

6. 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 three months ended March 31, 2017 and 2016, contribution costs amounted to $11,000 and $11,000, 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 three months ended March 31, 2017 and 2016 contribution expenses were approximately $51,000 and $32,000, respectively.

7. Other income (expense), net

	Three Months Ended March 31,	
(in thousands)	**2016**	**2017**
Foreign exchange gain	$ 1,439	$ 993
Foreign exchange losses	(459)	(809)
Other	18	22
Total	**$ 998**	**$ 206**

8. Income tax (expense) benefit

In accordance with the FASB Accounting Standard Codification (ASC) Topic No. 270 "Interim Reporting" and ASC Topic No. 740 "Income Taxes" (Topic No. 740) at the end of each interim period, the Company is required to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three months ended March 31, 2017, the Company recorded tax expense of $349,000 and for the three months ended March 31, 2016, the Company recorded a tax benefit of $17,000.

As of March 31, 2017 and December 31, 2016, the Company had a non-current deferred tax assets of $1.2 million and $1.4 million, respectively. The deferred tax asset relates to tax attributes of the Company's U.S. subsidiary, Nabriva Therapeutics US, Inc. The Company maintains a valuation allowance against certain deferred tax assets as management has determined that it is not more likely than not that the Company will realize these future tax benefits.

On the basis of this evaluation, as of March 31, 2017 and December 31, 2016, the Company has recorded a valuation allowance of $58,085 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 the Company's projections for growth.

9. Earnings (Loss) per Share

Basic earnings/losses per share

Basic earnings/losses per share is calculated by dividing the net earnings/loss attributable to shareholders by the weighted average number of shares outstanding during the year.

	Three Months Ended March 31,	
(in thousands, except per share data)	**2016**	**2017**
Net loss for the period	$ (13,599)	$ (15,223)
Weighted average number of shares outstanding	2,117,895	2,720,423
Excluded treasury shares on March 31	2,819	—
Basic loss per share	**$ (6.42)**	**$ (5.60)**

Diluted earnings/losses per share

Diluted earnings/losses per share is calculated by adjusting the weighted average number of shares outstanding to assume conversion of all dilutive potential shares. The effect of 278,579 and 191,496 potentially dilutive share options has been excluded from the diluted loss per share calculations as of March 31, 2017 and 2016, respectively because it would result in a decrease in the loss per share for the period and is therefore not to be treated as dilutive.

10. 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**
As of December 31, 2016				
Assets:				
Short-term investments:				
Available-for-sale investments	**$** 15,017	**$** 36,059	**$** —	**$** 51,076
Term Deposits	30	—	—	30
Total Assets	**$ 15,047**	**$ 36,059**	**$** —	**$ 51,106**

(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
As of March 31, 2017				
Assets:				
Short-term investments:				
Available-for-sale investments	**$** 15,001	**$** 26,030	**$** —	**$** 41,031
Term Deposits	30	—	—	30
Total Assets	**$ 15,031**	**$ 26,030**	**$** —	**$ 41,061**

As of March 31, 2017 and December 31, 2016, the Company held short term investments (see Note 12) 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 three months ended March 31, 2017 or the year ended December 31, 2016. There were no changes in valuation techniques during the three months ended March 31, 2017.

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

Other receivables, prepaid expenses, accounts payable and accrued expenses and other current liabilities are carried at their historical cost which approximates fair value due to their short term nature.

11. Long-term and current receivables

(in thousands)	As of December 31, 2016	As of March 31, 2017
Deposits	$ 420	$ 424
Total long-term receivables	**$ 420**	**$ 424**
Research premium	5,346	6,910
VAT and other taxes	46	316
Receivables from grant revenue	144	—
Other receivables	25	222
Total current receivables	**$ 5,561**	**$ 7,448**
Total	**$ 5,981**	**$ 7,872**

Long-term receivables relate to rent deposits made on the office building in Vienna, Austria and King of Prussia, Pennsylvania, United States.

Current receivables are all due within one year. No receivables are past due or impaired.

As of March 31, 2017 and December 31, 2016, no receivables were pledged.

12. Short-term investments

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

	As of December 31, 2016			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments:	$ —	$ —	$ —	$ —
Available-for-sale investments	$ 51,094	$ —	$ (18)	$ 51,076
Term deposits	$ 30	$ —	$ —	$ 30
Total	**$ 51,124**	**$ —**	**$ (18)**	**$ 51,106**

	As of March 31, 2017			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments:	$ —	$ —	$ —	$ —
Available-for-sale investments	$ 41,047	$ —	$ (16)	$ 41,031
Term deposits	$ 30	$ —	$ —	$ 30
Total	**$ 41,077**	**$ —**	**$ (16)**	**$ 41,061**

As of March 31, 2017 and December 31, 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 U.S. dollar-denominated debt securities, and (ii) a U.S. treasury note.

13. Cash and Cash Equivalents

Cash and cash equivalents were as follows:

(in thousands)	As of December 31, 2016	As of March 31, 2017
Cash on hand	$ —	$ —
Cash at bank	32,778	27,166
Total cash and cash equivalents	**$ 32,778**	**$ 27,166**

14. 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 and the shareholders of the Company resolved to amend the SOP 2007 on September 17, 2009, May 7, 2010 and June 30, 2015. The total number of options that were eligible to be granted and vested in the beneficiaries under the SOP 2007 did not exceed 29,889 (the overall number of options under the SOP 2007).

The options grant the beneficiaries the right to acquire shares 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. On the last day of the last calendar month of the second year of the vesting period, a further 25% of the options are vested. During the third and fourth years of the vesting period, the remaining 50% of the options vest on a monthly pro rata basis (i.e. 2.083% per month).

Notwithstanding any of the above, the exercise of vested options was only permissible in case of a liquidation event (e.g. sale of 50% or more of the shares or assets of the Company or merger of the Company) or a qualified public offering. 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 end of the exercise period on September 27, 2017.

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 exercise shareholder rights if and to the extent such beneficiary otherwise holds shares.

As of March 31, 2017, the vested option rights outstanding under the SOP 2007 amount to $1,087 and are recorded under additional paid in capital.

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

	2017		
Stock Option Plan 2007	Weighted average exercise price in $ per share	Options	Aggregate intrinsic value
Outstanding as of January 1, 2017	7.32	10,996	
Granted	—	—	
Exercised	7.32	(5,156)	
Forfeited	—	—	
Outstanding as of March 31, 2017	**7.32**	**5,840**	**$ 1,112**
Vested and exercisable as of March 31, 2017	**7.32**	**5,712**	**$ 1,086**

The total intrinsic value of options exercised during the three months ended March 31, 2017 was $943,000.

The weighted average remaining contractual life of all options granted under the SOP 2007 is 0.2 years. Stock-based compensation expense under the Stock Option Plan 2007 was $15,000, for the three months ended March 31, 2017. We did not accrue any income tax benefit under the Stock Option Plan 2007 for the three months ended March 31, 2017.

The weighted average share price at the date of exercise of options exercised during the three months ended March 31, 2017 was $97.67.

Stock Option Plan 2015

On April 2, 2015, the Company's shareholders, management board and supervisory board adopted the Stock Option Plan 2015 and the shareholders approved an amended and restated version of the Stock Option Plan 2015 on June 30, 2015. An amendment to the amended and restated Stock Option Plan 2015 was approved by the shareholders on July 22, 2015. The Stock Option Plan 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 Stock Option Plan 2015 initially provided for the grant of options for up to 95,000 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 shares. Following approval by the Company's shareholders at its 2016 annual general meeting, the number of shares available for issuance under the Stock Option Plan 2015 was increased to 346,235 common shares.

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 Stock Option Plan 2015 have a term of no more than ten years from the beneficiary's date of 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 such beneficiary otherwise holds shares.

As at March 31, 2017, the vested option rights outstanding under the SOP 2015 amounted to $4,214 and is recorded under additional paid in capital.

Movements in the number of share options outstanding and their related weighted average exercise prices under the Stock Option Plan 2015 are as follows:

	2017		
Stock Option Plan 2015	**Weighted average exercise price in $ per share**	**Options**	**Aggregate intrinsic value**
Outstanding as of January 1, 2017	78.25	179,436	
Granted	85.51	102,560	
Exercised	—	—	
Forfeited	88.00	(9,257)	
Outstanding as of March 31, 2017	**80.65**	**272,739**	**$ 12,255**
Vested and exercisable as of March 31, 2017	**77.12**	**62,805**	**$ 3,926**

Stock-based compensation expense under the Stock Option Plan 2015 was approximately $1.8 million for the three months ended March 31, 2017. The total income tax benefit under the Stock Option Plan 2015 recognized in the statement of operations and comprehensive income (loss) for the three months ended March 31, 2017 was $200,000. The weighted average fair value of the options granted during the three months ended March 31, 2017 was $32.47 per share. The 102,560 options granted in the three months ended March 31, 2017 were valued based on a Black Scholes option pricing model. The significant inputs into the model were as follows:

Input parameters	Granted on February 7, 2017	Granted on March 21, 2017
Grant date share price in $	85.00	110.00
Exercise price in $	85.00	110.00
Expected volatility	68%	66%
Expected term of options	2.2 years	2.2 years
Risk-free interest rate	-0.777%	-0.718%
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 weighted average remaining contractual life of the options granted in the three months ended March 31, 2017 is 9.9 years.

As of March 31, 2017, there was $8.0 million of total unrecognized compensation expense, related to unvested options granted under the Stock Option Plan 2015, which will be recognized over the weighted —average remaining vesting period of 2.2 years.

Founders' Program 2007

The Founders' Program 2007 was an additional share-based payment scheme, the beneficiaries of which were Dr. Gerd Ascher and Dr. Rodger Novak. There remain 623 shares available in form of stock options at an exercise price of €1.00 per share granted under the Founders' Program and otherwise on the same terms and conditions as set out in the Company's Stock Option Plan 2007. The 623 options vested as follows: 25% of the options (156 shares) vested in November 2007. A further 25% (155 shares) vested in February 2008. The remaining 50% vested during the period from March 2008 to February 2010 on a monthly pro rata basis (i.e., 2.083% per month, or 13 shares per month). The fair value of each of these options at grant date is $144.23 per share. The options are fully vested and have been exercised.

15. December 2016 Financing

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 approximately $24.8 million and net proceeds to the Company of approximately $20.6 million, after deducting underwriting fees and offering expenses.

In the rights offering, holders of American Depositary Shares, or ADSs, received 0.276 ADS rights for each ADS owned of record on November 29, 2016. One ADS right entitled an ADS holder to subscribe for and purchase one new ADS at the subscription price of $4.32 per ADS, the U.S. dollar equivalent of €4.014 per ADS. An aggregate of 1,592,750 ADSs, representing 159,275 common shares, were subscribed for by holders of ADSs. Each ADS represents one tenth of a common share.

In the rights offering, holders of common shares received the common share right to subscribe for and purchase 0.276 new common shares, at a subscription price of €40.14 per new common share for each common share owned of record on November 29, 2016. An aggregate of 102,077 new common shares were subscribed for by holders of common shares.

Pursuant to an underwriting agreement that the Company entered into with Cantor Fitzgerald & Co., dated December 14, 2016, Cantor Fitzgerald & Co. agreed to purchase 326,775 common shares, representing all of the unsubscribed common shares in the rights offering, at a purchase price of €40.14 per common share for purposes of resale of ADSs representing such unsubscribed common shares.

16. Accrued Expenses and Other Liabilities

Other non-current liabilities include an obligation to pay jubilee benefits arising under the collective bargaining agreement for the chemical industry, by which employees in Austria are entitled to receive jubilee payments after being employed for a certain number of years. For this obligation a provision of $113,000 and $107,000 has been made as of March 31, 2017 and December 31, 2016, respectively.

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 rate of 1.3% and retirement at the age of 61.5-65 for men and 56.5-65 for women, future annual salary increases of 3%.

Accrued expenses and other current liabilities include the following:

(in thousands)	As of December 31, 2016	As of March 31, 2017
Research and development related costs	$ 8,716	$ 8,739
Payroll and related costs	2,150	1,461
Accounting, tax and audit services	484	471
Other	1,976	882
Total other current liabilities	**$ 13,326**	**$ 11,553**

17. Commitments and Contingencies

Commitments

Lease Agreements

In March 2007, the Company entered into a lease agreement for an unlimited period starting in December 2007 with CONTRA Liegenschaftsverwaltung GMBH for the use of business and research premises at Leberstrasse 20, 1110 Vienna. Within the first 10 years the contract can only be terminated under certain conditions. The monthly rental fee for the premises and laboratory furniture was $84,000 and $85,000, as of March 31, 2017 and December 31, 2016, respectively, and includes all operating costs. Additional monthly costs for facility management and security services amounted to $9,000 and $9,000 as of March 31, 2017 and December 31, 2016, respectively.

In July 2015, the Company entered into a lease agreement with CardConnect, LLC, for the use of office premises at 1000 Continental Drive, Suite 600, King of Prussia, PA 19406, USA with the lease term continuing until December 2023. The monthly base rental fee was $40,000 and $40,000 as of March 31, 2017 and December 31, 2016, respectively.

Rent expense was $304,000 and $272,000 for the three months ended March 31, 2017 and 2016, respectively.

The obligations under the lease agreements are payable as follows:

(in thousands)	As of December 31, 2016	As of March 31, 2017
No later than 1 year	$ 1,484	$ 1,252
Later than 1 year and no later than 5 years	2,536	2,572
Later than 5 years	507	515
Total	**$ 4,527**	**$ 4,339**

Other contractual commitments

In addition to the agreements described above, the Company has entered into a number of other agreements also entailing financial commitments for the future and relating mainly to services provided by third parties in connection with the conduct of clinical trials and other research and development activities. Some of these commitments are also subject to early termination clauses exercisable at the option of the Company. The remaining payments to be made under these agreements, if all milestones and other conditions are met, are estimated to be as follows:

(in thousands)	As of December 31, 2016	As of March 31, 2017
No later than 1 year	$ 51,685	$ 45,575
Later than 1 year and no later than 5 years	6,241	5,290
Later than 5 years	—	—
Total	**$ 57,926**	**$ 50,865**

Contingencies

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

18. Subsequent Events

The Company evaluated all events or transactions that occurred subsequent to March 31, 2017 through the date the unaudited consolidated financial statements were issued, and have not identified any such events material to an understanding of the unaudited consolidated financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our historical consolidated financial statements and the related notes thereto appearing in our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on March 24, 2017. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

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 intend to develop lefamulin for additional indications other than pneumonia. We have initiated two pivotal, international Phase 3 clinical trials of lefamulin for the treatment of moderate to severe CABP. These are the first clinical trials we have conducted with lefamulin for the treatment of CABP. We initiated the first of these 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. Based on our estimates regarding patient enrollment, we expect to have top-line data available from LEAP1 in the third quarter of 2017 and top-line data available from LEAP 2 in the first quarter of 2018. If the results of these trials are favorable, including achievement of the primary efficacy endpoints of the trials, we expect to submit applications for marketing approval for lefamulin for the treatment of CABP in both the United States and Europe in 2018.

We have completed a Phase 2 clinical trial of lefamulin for acute bacterial skin and skin structure infections, or ABSSSI, and seventeen Phase 1 clinical trials of lefamulin in which we exposed healthy subjects to single or multiple doses of IV or oral lefamulin. We plan to pursue additional opportunities for lefamulin, including a development program for use in pediatric patients and potentially for the treatment of ABSSSI. In addition, as an antibiotic with potent activity against a wide variety of multi-drug resistant pathogens, including methicillin-resistant *S. aureus*, we may explore development of lefamulin in further indications, including ventilator-associated bacterial pneumonia, or VABP, hospital-acquired bacterial pneumonia, or HABP, sexually transmitted infections, or STIs, osteomyelitis and prosthetic joint infections. Through our research and development efforts, we have also identified a topical pleuromutilin product candidate, BC-7013, which has completed a Phase 1 clinical trial.

We were incorporated in October 2005 in Austria under the name Nabriva Therapeutics Forschungs GmbH, a limited liability company organized under Austrian law, as a spin-off from Sandoz GmbH and commenced operations in February 2006. In 2007, we transformed into a stock corporation (*Aktiengesellschaft*) under the name Nabriva Therapeutics AG. In 2014, we established our wholly owned U.S. subsidiary, which began operations in August 2014. Since inception, we have incurred significant operating losses. As of March 31, 2017, we had an accumulated deficit of $220.1 million. To date, we have financed our operations primarily through our 2016 rights offering, our 2015 initial public offering, private placements of our common shares, 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. Our ability to generate profits from operations and remain profitable depends on our ability to successfully develop and commercialize drugs that generate significant revenue.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue the development of and 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 delays in enrollment of patients. If we obtain marketing approval for lefamulin or any other product candidate that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, we expect to incur additional costs associated with operating as a public company.

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. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. 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 effort.

Redomiciliation Transaction

On April 17, 2017, we announced that our supervisory board and management board approved the relocation of Nabriva Therapeutics AG, or Nabriva AG, and its subsidiaries, or the Nabriva Group, from Austria to Ireland, which we refer to as the Redomiciliation Transaction. The Redomiciliation Transaction will be effected by the exchange of American Depositary Shares and common shares of Nabriva Therapeutics AG for shares of Nabriva Therapeutics Plc, a newly-formed Irish public limited company, or Nabriva Ireland, with Nabriva Ireland becoming the publicly-traded parent entity of Nabriva Therapeutics AG, which we refer to as the Exchange Offer. Once the Exchange Offer is completed, Nabriva Therapeutics AG, the current Austrian publicly-traded parent company, will become a subsidiary of Nabriva Ireland, and it is expected that Nabriva Ireland will then become the publicly-traded parent company of the Nabriva Group with its tax residency in Ireland.

December 2016 Financing

On December 19, 2016, we 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 approximately $24.8 million and net proceeds to us of approximately $20.6 million, after deducting underwriting fees and offering expenses.

In the rights offering, holders of American Depositary Shares, or ADSs, received 0.276 ADS rights for each ADS owned of record on November 29, 2016. One ADS right entitled an ADS holder to subscribe for and purchase one new ADS at the subscription price of $4.32 per ADS, the U.S. dollar equivalent of €4.014 per ADS. An aggregate of 1,592,750 ADSs, representing 159,275 common shares, were subscribed for by holders of ADSs. Each ADS represents one tenth of a common share.

In the rights offering, holders of common shares received the common share right to subscribe for and purchase 0.276 new common shares, at a subscription price of €40.14 per new common share for each common share owned of record on November 29, 2016. An aggregate of 102,077 new common shares were subscribed for by holders of common shares.

Pursuant to an underwriting agreement that we entered into with Cantor Fitzgerald & Co., dated December 14, 2016, Cantor Fitzgerald & Co. agreed to purchase 326,775 common shares, representing all of the unsubscribed common shares in the rights offering, at a purchase price of €40.14 per common share for purposes of resale of ADSs representing such unsubscribed common shares.

2015 Initial Public Offering

On September 23, 2015 we completed our 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 our common shares. On September 30, 2015 the underwriters of our 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 we sold an aggregate of 10,350,000 ADSs representing 1,035,000 common shares, in our initial public offering, which resulted in gross proceeds of approximately $106.1 million and net proceeds to us of approximately $92.4 million, after deducting underwriting discounts and offering expenses.

Critical Accounting Policies

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 24, 2017 and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the three months ended March 31, 2017, there were no material changes to our critical accounting policies, except as described below.

Share-based Payments

We measure the options under our equity incentive plans at fair value at their grant date in accordance with ASC 718, *Compensation — Stock Compensation*," using the Black-Scholes model. The fair value of such share-based compensation is recognized as an expense over the respective vesting period. No options were granted under the Stock Option Plan 2007 during the three months ended March 31, 2017. Options granted during the three months ended March 31, 2017 under the Stock Option Plan

2015 have a weighted-average exercise price of €80.08 ($85.51) and a weighted average fair value of €30.40 ($32.47).The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model were as follows for the three months ended March 31, 2017:

Input parameters	Granted on February 7, 2017	Granted on March 21, 2017
Expected volatility	68%	66%
Expected term of options	2.2 years	2.2 years
Risk-free interest rate	-0.777%	-0.718%
Dividend yield	—	—

We recognized stock-based compensation expense of approximately $1.8 million during the three months ended March 31, 2017 related to the options granted under the Stock Option Plan 2015.

Results of Operations

Comparison of Three Months Ended March 31, 2016 and 2017

(in thousands)	Three Months Ended March 31, 2016	2017	Change
Consolidated Operations Data:			
Revenues	$ 1,419	$ 1,678	$ 259
Costs and Expenses:			
Research and development	(13,036)	(12,660)	376
General and administrative	(3,085)	(4,218)	(1,133)
Total operating expenses	(16,121)	(16,878)	(757)
Loss from operations	**(14,702)**	**(15,200)**	**(498)**
Other income (expense):			
Other income (expense), net	998	206	(792)
Interest income (expense), net	88	120	32
Loss before income taxes	**(13,616)**	**(14,874)**	**(1,258)**
Income tax benefit (expense)	17	(349)	(366)
Net loss	**$ (13,599)**	**$ (15,223)**	**(1,624)**

Revenues

Revenues, consisting primarily of research premium and grant revenue, increased by $0.3 million from $1.4 million for the three months ended March 31, 2016 to $1.7 million for the three months ended March 31, 2017. The change was primarily due to a $0.2 million increase in grant income, as well as a $0.1 million increase in anticipated grant revenue from research premiums provided to us by the Austrian government as a result of increases in our applicable research and development expenses.

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. Our success depends primarily on the successful development and regulatory approval of our product candidates and our ability to finance operations. If our development efforts result in clinical success and regulatory approval or we enter into collaboration agreements with third parties for our product candidates, we may generate revenue from those product candidates.

Research and Development Expenses

Research and development expenses decreased by $0.4 million from $13.0 million for the three months ended March 31, 2016 to $12.6 million for the three months ended March 31, 2017. The change was primarily due to costs related to the initiation and continuation of patient enrollment for our Phase 3 clinical trials of lefamulin during the three months ended March 31, 2016. Research materials and purchased services for our other programs and initiatives were relatively limited during both periods.

We expect to have significant research and development expenses in connection with our ongoing activities, particularly with our ongoing Phase 3 clinical trials of lefamulin for the treatment of CABP, and as we pursue the clinical development of lefamulin for additional indications and engage in earlier stage research and development activities. We expect our total future direct research and development costs to remain consistent as we continue the clinical development of lefamulin for CABP and other indications. We do not expect to incur significant expenses in the near future for our other programs and initiatives. It is difficult to estimate the duration and completion costs of our other research and development programs.

General and Administrative Expenses

General and administrative expense increased by $1.1 million from $3.1 million for the three months ended March 31, 2016 to $4.2 million for the three months ended March 31, 2017. The increase was primarily due to a $0.7 million increase in legal fees related to the redomiciliation of our ultimate parent company from Austria to Ireland and a $0.4 million increase in pre-commercialization activites and increased professional service fees.

We expect general and administrative expenses to increase with the expansion of our staff and management team to include new personnel responsible for finance, legal, information technology and later, sales and business development functions. We also expect increased infrastructure, consulting, legal, accounting, auditing and investor relations expenses, associated with being a public company in the United States after the loss of our foreign private issuer status and planned redomiciliation to Ireland.

Other Income (Expense), net

Other income (expense), net decreased by $0.8 million from $1.0 million income for the three months ended March 31, 2016, to $0.2 million income for the three months ended March 31, 2017. The decrease was primarily due to re-measurements of our foreign currency account balances.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and generated negative cash flows from our operations. To date, we have financed our operations through the sale of equity securities, including our initial public offering of ADSs and private placements of our common shares, convertible debt financings and research and development support from governmental grants and loans. As of March 31, 2017, we had cash and cash equivalents and short term investments of $68.2 million.

On December 19, 2016, we 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 approximately $24.8 million and net proceeds to us of approximately $20.6 million, after deducting underwriting fees and offering expenses.

On September 23, 2015 we completed our 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 our common shares. Each ADS represents one tenth of a common share. On September 30, 2015 the underwriters of our 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, we sold an aggregate of 10,350,000 ADSs representing 1,035,000 common shares, in our initial public offering, which resulted in gross proceeds of approximately $106.1 million and net proceeds to us of approximately $92.4 million, after deducting underwriting discounts and offering expenses.

Cash Flows

Comparison of Three Months Ended March 31, 2016 and 2017

The following table summarizes our cash flows for the three months ended March 31, 2016 and 2017:

	Three Months Ended March 31,	
(in thousands)	**2016**	**2017**
Net cash (used in) provided by:		
Operating activities	$ (10,879)	$ (14,684)
Investing activities	2,933	9,977
Financing activities	29	(1,171)
Effects of foreign currency translation on cash	924	266
Net decrease in cash	**(6,993)**	**(5,612)**

Operating Activities

Cash flow used in operating activities increased by $3.8 million from $10.9 million for the three months ended March 31, 2016 to $14.7 million for the three months ended March 31, 2017 primarily due to a $0.5 million increase in net loss, after adjustments for non-cash amounts included in net income and lower working capital of $3.3 million primarily due to changes in accrued expenses and other current liabilities.

Investing Activities

Cash flow from investing activities increased by $7.1 million from $2.9 million for the three months ended March 31, 2016 to $10.0 million for the three months ended March 31, 2017 primarily due to proceeds from sale of available-for-sale financial assets to fund operational cash out flows. Other investing activities were relatively insignificant in both periods and related primarily to the acquisition of equipment in support of our research and development activities.

Financing Activities

Cash flow generated from financing activities decreased by $1.2 million from $0.0 million for the three months ended March 31, 2016 to $1.2 million for the three months ended March 31, 2017 due to $1.4 million increase in equity transaction costs related to our rights offering and related underwritten offering in December 2016. The period over period decrease in financing cash inflows was partially offset by proceeds of $0.2 million from long-term debt related to a government loan received from the Austrian Research Promotion Agency (*Österreichische Forschungsförderungsgesellschaft, or FFG*).

Operating and Capital Expenditure Requirements

We anticipate that our expenses will increase substantially as we continue the development of and 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 the treatment of CABP, including delays in enrollment of patients. If we obtain marketing approval for lefamulin or any other product candidate that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Furthermore, we expect to incur additional costs associated with operating as a public company.

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;
- ultimately establish a medical affairs, sales, marketing and distribution infrastructure and build up inventory of finished product and its components 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
- 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.

We expect 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 second quarter of 2018 . 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 assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements or equity or debt financings.

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

- the progress, costs and results of our Phase 3 clinical trials for lefamulin;
- 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
- 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, none of which we expect to be commercially available for several years, 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.

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, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. 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.

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.

Contractual Obligations and Commitments

The table below sets forth our contractual obligations and commercial commitments as of March 31, 2017 that are expected to have an impact on liquidity and cash flow in future periods. The amounts disclosed are the contractual undiscounted cash flow values.

	Payments Due by Period				
(in thousands)	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	More than 5 years	Total
Operating lease obligations	$ 1,252	1,520	1,052	515	4,339

	Payments Due by Period				
(in thousands)	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	More than 5 years	Total
Other contractual commitments	45,575	5,290	—	—	50,865
Total	$ **46,827**	**6,810**	**1,052**	**515**	**55,204**

Operating lease obligations include rental agreements for our facilities in Austria and the United States.

Other contractual commitments relate 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. Some of these commitments include early termination clauses exercisable at our discretion. The amounts shown above are estimated based on the assumptions that all remaining services will be performed as agreed and all milestones and other conditions of the respective contracts are met.

Capital Expenditures

Our total purchases related to capital expenditures were $25,000 and $67,000 for the three months ended March 31, 2017 and 2016, respectively. We made no significant investments in intangible assets during the three months ended March 31, 2017 and 2016. Currently, there are no material capital projects planned in 2017. However, we expect our capital expenditures may increase over the next 12 to 18 months due to the expansion of our U.S. presence and the continued enhancements of our information technology infrastructure.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, other than our operating lease obligations for our facilities in Austria and the United States.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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.

Market 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.

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 research and development support from governmental grants and loans, and acquire materials, in 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.

Interest rate risk may arise from short-term or long-term debt. As of March 31, 2017, we had no debt that exposed us to interest rate risk. As of March 31, 2017, we had neither significant long-term interest-bearing assets nor significant long-term interest-bearing liabilities, other than a 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

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 second quarter of 2018. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

ITEM 4. CONTROLS AND PROCEDURES

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We have carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) under the supervision and the participation of the company's management, which is responsible for the management of the internal controls, and which includes our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation of our disclosure controls and procedures as of March 31, 2017, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) that occurred during the three months ended March 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Form 10-Q. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. 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 $15.2 million for the three months ended March 31, 2017, $54.9 million for the year ended December 31, 2016, $47.0 million for the year ended December 31, 2015 and $14.2 million for the year ended December 31, 2014. As of March 31, 2017, we had accumulated losses of $220.1 million. To date, we have financed our operations primarily through the sale of our equity securities, including our American Depositary Shares, or ADSs, and private placements of our common shares, 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 anticipate that our expenses will increase substantially as we progress our two international Phase 3 clinical trials of our lead product candidate, lefamulin, for the treatment of community-acquired bacterial pneumonia, or CABP. We initiated the first of these 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. If the results of these two trials are favorable, including achievement of the primary efficacy endpoints of the trials, we expect to submit applications for marketing approval for lefamulin for the treatment of CABP in both the United States and Europe in 2018. 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 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;
- ultimately establish a 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
- 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.

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:

- completing enrollment for our Phase 3 clinical trials of lefamulin for the treatment of CABP and completing both trials as and when we expect;
- obtaining favorable results from our Phase 3 clinical trials of lefamulin for the treatment of CABP;
- subject to obtaining favorable results from our Phase 3 clinical trials, applying for and obtaining marketing approval for lefamulin;
- establishing sales, marketing and distribution capabilities to effectively market and sell lefamulin in the United States;
- establishing 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 our research and development, commercialization and other expenses to increase substantially in connection with our ongoing activities, particularly as we continue development of and 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 delays in enrollment of patients. If we obtain marketing approval for lefamulin or any other product candidate that we develop, 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 enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2018 and to obtain top-line data for both our Phase 3 clinical trials of lefamulin. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. These estimates assume, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings.

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

- the progress, costs and results of our ongoing Phase 3 clinical trials of lefamulin;
- 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;

- 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 BC-7013 and 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
- 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, none of which we expect to be commercially available for several years, 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.

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 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 $4.3 million for the year ended December 31, 2015 and $1.4 million for the year ended December 31, 2014. We also expect to receive a research premium for our qualified 2016 expenditures. However, 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.

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. Based on our estimates regarding patient enrollment, we expect to have top-line data from LEAP 1 in the third quarter of 2017. With respect to LEAP 2, based on current projections, we expect to complete patient enrollment in the fourth quarter of 2017, and we anticipate receiving top-line data for LEAP 2 in the first quarter of 2018. Our ability to meet our target timing will depend on our enrollment rates. A significant delay in enrollment would result in delays to our development timeline and additional development costs beyond what we have budgeted. If we ultimately obtain favorable results from our Phase 3 clinical program for lefamulin for CABP, we do not expect to submit applications for marketing approval for lefamulin for this indication until 2018.

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:

- completing our ongoing Phase 3 clinical trials as and when expected;
- obtaining favorable results from clinical trials;
- 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, whether alone or 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.

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.

We have not completed any clinical trials of lefamulin specifically for CABP. Our completed Phase 2 clinical trial evaluated lefamulin in patients with acute bacterial skin and skin structure infections, or ABSSSI. Our Phase 1 clinical trials evaluated lefamulin in healthy subjects to obtain tolerance data and to understand the absorption and distribution of lefamulin in the blood and target tissues, evaluate the metabolism and elimination route of lefamulin and obtain safety and tolerability data to help predict safe and effective doses of lefamulin for the treatment of patients. In addition, we are using a different intravenous, or IV, formulation of lefamulin for our Phase 3 clinical trials for CABP than we used in our Phase 2 clinical trial for ABSSSI. We have only evaluated this new IV formulation of lefamulin, a sterile saline solution buffered by a citrate salt, in Phase 1 clinical trials. Because of these and other factors, the results of our completed clinical trials may not predict success in our Phase 3 clinical trials of lefamulin for CABP. 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 Phase 3 clinical trials of lefamulin for CABP. If the results of our Phase 3 clinical trials are not favorable, including failure to achieve the primary efficacy endpoints of the trials, we may need to conduct additional clinical trials at significant cost or altogether abandon development of lefamulin for CABP and potentially other indications.

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.

If we experience any of a number of possible unforeseen events in connection with our Phase 3 clinical trials 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 Phase 3 clinical trials 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 clinical trials of lefamulin for CABP, 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;
- we may be unable to enroll a sufficient number of patients in our Phase 3 clinical trials of lefamulin for CABP or other clinical trials we conduct to ensure adequate statistical power to detect any statistically significant treatment effects;
- 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 our Phase 3 clinical trials of lefamulin for CABP or other clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health 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. In particular, we may experience enrollment challenges at trial sites in the United States, where it is a common practice to place patients with potential moderate to severe CABP on antibiotics very shortly after examination. This practice could prevent potential trial patients in the United States from being enrolled in our clinical trials based on our eligibility criteria. In addition, 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.

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.

For example, in each of our Phase 3 clinical trials of lefamulin, patients who have previously taken no more than one dose of a short acting, potentially effective antibiotic for the treatment of the current CABP episode within 24 hours of receiving the first dose of study medication will be allowed to participate in the trial but will comprise only up to 25% of the total intent to treat populations. Depending upon a region's or a clinical trial site's standard of care for the administration of antibiotics, this could affect our ability to enroll patients in these clinical trials in a timely fashion. Also, enrollment for our Phase 3 clinical trials may be negatively impacted by delays in opening clinical trial sites or the duration and/or severity of the influenza season. Moreover, our estimates regarding patient enrollment for our Phase 3 clinical trials of lefamulin depend on increasing enrollment rates as each such trial progresses, making it more difficult to precisely estimate the time of completion of such trials during its earlier stages. 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 our Phase 3 clinical trials of lefamulin for CABP or any of our other 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.

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.

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, with a lengthened QT interval representing a marker for potential ventricular arrhythmia. We are continuing to evaluate the effect of lefamulin on the QT interval in our Phase 3 clinical trials of lefamulin for CABP.

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 therapeutic doses, 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. None of the ECG stopping criteria defined in the trial protocols was reached in any clinical trial. However, 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, 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;
- 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.

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 do not have a sales, marketing or 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 develop a 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 establish. 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. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and 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.

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 solithromycin, (New Drug Application, or NDA, filed by Cempra Inc. and a complete response letter issued by the FDA in December 2016), 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.

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.

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 product 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 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 of our product candidates and products to third parties.

We do not currently have any agreements with third-party manufacturers for the long-term commercial supply of any of our product candidates. 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. We have identified an alternative supplier that we believe will be able to provide pleuromutilin starting material for the commercial supply of lefamulin. 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 fill and finish services for the finished product that we are using in our clinical trials of lefamulin. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms.

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

- reliance on the third party for regulatory compliance and quality assurance;
- 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.

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 announced 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. 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.

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 a marketing authorization application, or 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 may enter into 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. 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 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. We are not currently party to any such arrangement. However, if we do enter into any such arrangements 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.

Collaborations involving our product candidates would pose numerous risks to us, including the following:

- 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;
- 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, in 2012, we entered into a stock purchase agreement with Forest pursuant to which Forest reimbursed us for certain external research and development costs and provided us with a $25.0 million loan in exchange for an exclusive right to acquire 100% of our outstanding shares for a one-year period. However, in 2013, Forest decided not to exercise its right to acquire us and terminated the stock purchase agreement. In connection with this termination, we repurchased the $25.0 million loan for €1.00. We no longer have a commercial relationship with Forest, and no rights or obligations remain outstanding under the stock purchase agreement.

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.

If we are not able to establish 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 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 collaboration arrangements outside the United States.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration 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 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.

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 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.

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.

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 the ADSs. 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.

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, 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-party contract research organizations 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’’. 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, since the European Medicines Agency, or EMA, is located in the United Kingdom, the implications for the regulatory review process in the European Union has not been clarified and could result in relocation of the EMA or a disruption in 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.

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.

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.

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. In addition, any significant change to the protocols for our clinical trial subject to the SPA would require prior FDA approval, which could delay implementation of such a change and the conduct of the trial.

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.

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.

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;

- HIPPA, 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;

- 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 collaborators to obtain marketing approval of our product candidates and affect the prices we, or they, may obtain.

In the United States and a number of foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of lefamulin or any of our other product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates, including lefamulin, for which we 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 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 Affordability 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;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- 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 off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- 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;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

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 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 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 bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

We expect that the ACA, 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.

In addition, with the new Administration and Congress, there will likely be additional legislative changes, including repeal and replacement of certain provisions of the ACA. It remains to be seen, however, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. Such reforms 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 or commercialize product candidates. For example, the President and congressional leaders have expressed interest in repealing certain ACA provisions and replacing them with alternatives that may be less costly and provide state Medicaid programs and private health plans more flexibility. It is possible that these 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. The scope of potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, and it is 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.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. 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 product 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 product 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.

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.

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 clinical 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.

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 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.

We expect to expand our development, regulatory and sales and marketing capabilities, and 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 and 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 American Depositary Shares

An active trading market for the ADSs may not be sustained.

Our ADSs began trading on the NASDAQ Global Market on September 18, 2015. Given the limited trading history of the ADSs, there is a risk that an active trading market for the ADSs will not be sustained, which could put downward pressure on the market price of the ADSs and thereby affect the ability of our security holders to sell their ADSs.

The price of the ADSs may be volatile and fluctuate substantially.

The trading price of the ADSs 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 the ADSs 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;
- 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.

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. 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 senior managers, supervisory board members and principal shareholders, if they choose to act together, have the ability to control most matters submitted to shareholders for approval.

Our senior managers and supervisory board members, combined with our shareholders, and their respective affiliates who owned more than 5% of our outstanding common shares as of March 31, 2017 in the aggregate, beneficially owned approximately 76.9% 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 control the election of supervisory board members and approval of any merger, consolidation or sale of all or substantially all of our assets.

ADSs representing only a relatively small percentage of our common shares are publicly traded, which may limit the liquidity of the ADS and may have a material adverse effect on the price of the ADSs.

As of March 31, 2017, only 23.1% of our common shares were beneficially owned by parties other than our supervisory board members, senior management, shareholders holding 5% or more of our common shares, and their respective affiliates. As a result,

ADSs representing only a relatively small number of our common shares are actively traded in the public market. Limited liquidity may increase the volatility of the price of the ADSs.

The ADSs and our common shares do not trade on any exchange outside of the United States.

Our ADSs are listed only in the United States on The NASDAQ Global Market, and we have no plans to list the ADSs or our common shares in any other jurisdiction. As a result, a holder of ADSs or common shares outside of the United States may not be able to effect transactions in the ADSs as readily as the holder may if the ADSs were listed on an exchange in that holder's home jurisdiction. Additionally, a holder of common shares may not be able to effect transactions in our common shares without depositing such common shares with our depositary in exchange for the issuance of ADSs representing such common shares.

The sale of a substantial number of ADSs may cause the market price of the ADSs to decline.

Sales of a substantial number of our common shares or ADS, or the perception in the market that these sales could occur, could reduce the market price of the ADSs. Each ADS represents one tenth (1/10) of a common share and we had 2,721,086 common shares outstanding as of March 31, 2017, of which 2,260,443 shares are represented by 22,604.430 American Depositary Shares. Moreover, holders of an aggregate of 636,153 common shares have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. To the extent any of these shares are sold into the market, particularly in substantial quantities, the market price of the ADSs could decline.

Future issuances of common shares pursuant to our equity incentive plans could also result in additional dilution of the percentage ownership of our shareholders. We filed a registration statement on Form S-8 on November 18, 2015 that covers an aggregate of 201,632 common shares reserved for issuance pursuant to our equity incentive plans. Additionally, the majority of common shares that may be issued under our equity compensation plans also remain subject to vesting in tranches over a four-year period. As of March 31, 2017, an aggregate of 68,517 options to purchase our common shares had vested and become exercisable.

If a large number of the ADSs are sold in the public market after they become eligible for sale, the sales could reduce the trading price of the ADSs 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 the ADSs 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 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 the ADSs or common shares less attractive if we rely on such exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the market price of the ADSs 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 lost our foreign private issuer status on January 1, 2017, which requires us to comply with the Exchange Act's domestic reporting regime, as well as NASDAQ's domestic company corporate governance requirements, which we expect will cause us to incur significant legal, accounting and other expenses.

We determined that, as of June 30, 2016, we no longer qualified as a ''foreign private issuer'' under the rules and regulations of the SEC. As a result, beginning January 1, 2017, our annual filings with the SEC were made on Form 10-K (including our annual report for the year ending December 31, 2016) rather than on Form 20-F. In addition, commencing on January 1, 2017, we also expanded our reporting to be consistent with that of a domestic filer in the United States, including filing quarterly reports on Form 10-Q and current reports on Form 8-K. In addition, we are required to prepare our financial statements in accordance with U.S. GAAP, rather than IFRS, and we will adopt new or revised U.S. GAAP 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 also are now subject to SEC rules governing the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; the provisions of Regulation Fair Disclosure, which regulate the selective disclosure of material information; and the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and establishing insider liability for profits realized from any ''short-swing'' transactions in our equity securities. In addition, we are now subject to the NASDAQ Stock Market listing requirements applicable to domestic issuers.

We expect the regulatory and compliance costs to comply with the reporting and corporate governance requirements applicable to a domestic issuer will be significantly higher than the costs we have historically incurred as a foreign private issuer. As a result, we expect that the loss of our foreign private issuer status will continue to increase our legal and financial compliance costs and may make some activities highly time consuming and costly. We also expect that our loss of foreign private issuer status may make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our supervisory board.

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

Our management has 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 the ADSs. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of the ADSs 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.

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, which in turn could make it more difficult for us to attract and retain qualified members of our supervisory 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, 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 the ADSs.

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 the ADSs.

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.

United States investors may have difficulty enforcing civil liabilities against us, our supervisory board members or senior management and the experts named in our filings with the SEC.

We are incorporated under the laws of Austria, and our registered offices and a substantial portion of our assets are located outside of the United States. In addition, a member of our supervisory board 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. In addition, it is questionable whether a court in Austria would accept jurisdiction and impose civil liability if proceedings were commenced in such court predicated solely upon U.S. federal securities laws. As the United States and Austria do not currently have a treaty providing for reciprocal recognition and enforcement of judgments in civil and commercial matters (other than arbitration awards in such matters), a final judgment for payment of money rendered by a federal or state court in the United States based on civil liability, whether or not predicated solely upon U.S. federal securities laws, will not be enforceable, either in whole or in part, in Austria. However, if the party in whose favor such final judgment is rendered brings a new suit in a competent court in Austria, such party may submit to the Austrian court the final judgment rendered in the United States. Under such circumstances, a judgment by a federal or state court of the United States against the company will be regarded by an Austrian court only as evidence of the outcome of the dispute to which such judgment relates, and an Austrian court may choose to re-hear the dispute. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Austria. An award for monetary damages under the securities laws of the United States would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant.

Holders of ADSs may not have the same voting rights as the holders of our common shares and may not receive voting materials in time to be able to exercise their right to vote.

Holders of the ADSs may not be able to exercise voting rights attaching to the common shares evidenced by the ADSs. Holders of the ADSs will have the right to instruct the depositary with respect to the voting of the common shares represented by the ADSs. If we tell the depositary to solicit your voting instructions, the depositary is required to endeavor to carry out your instructions. If we do not tell the depositary to solicit your voting instructions (and we are not required to do so), you can still send instructions, and, in that case, the depositary may, but is not required to, carry out those instructions. You may not receive voting materials in time to instruct

the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Holders of ADSs may not have the same rights to participate in subscription rights offering as holders of our common shares.

Under Austrian law, whenever we issue new common shares, we are required by law, subject to certain limited exceptions, to grant subscription rights to all holders of our common shares, giving them the right to purchase a sufficient number of new common shares to maintain their existing ownership percentage. Although we may take steps to offer common shares (in the form of ADSs) to holders of ADSs in connection with any future rights offering, we are not required to do so. We also are not required to ensure that holders of ADSs have an opportunity to participate in any rights offering on the same terms as holders of our common shares.

Holders of ADSs may not receive distributions on our common shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to such holders.

The depositary for the ADSs has agreed to pay to holders of ADSs or distribute the cash dividends or other distributions it or the custodian receives on our common shares or other deposited securities after deducting its fees and expenses. Holders of ADSs will receive these distributions in proportion to the number of our common shares their ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, common shares, rights or anything else to holders of the ADSs. This means that holders of ADSs may not receive the distributions we make on our common shares or any value from them if it is unlawful or impractical to make them available to such holders. These restrictions may have a material adverse effect on the value of the ADSs.

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

We have not paid any dividends on our common 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. Payment of future dividends to security holders will be at the discretion of the management board, subject to the approval of the supervisory board after taking into account various factors including our business prospects, cash requirements, financial performance, debt covenant limitations and new product development. In addition, Austrian law imposes limitations on our ability to pay dividends. Under Austrian law, a company may only pay dividends if the distribution of dividends is proposed by the management board and the supervisory board and resolved by the company's shareholders at a general meeting. Our ability to pay dividends is assessed by our management board based primarily on our unconsolidated financial statements prepared in accordance with the Austrian Commercial Code (Unternehmensgesetzbuch). Dividends may be paid only after the relevant balance sheet date from the net profit (Bilanzgewinn) recorded in our unconsolidated annual financial statements as approved by our supervisory board or by our shareholders at a general meeting. In determining the amount available for distribution, the annual net income must be adjusted to account for any accumulated undistributed net profit or loss from previous years as well as for withdrawals from or allocations to reserves. Certain reserves must be established by law, and allocation to such reserves must therefore be deducted from the annual net income to calculate the annual net profit.

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.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation. We are organized as a stock corporation (Aktiengesellschaft) and incorporated under Austrian law.

The rights of holders of our common shares and, therefore, certain of the rights of holders of the ADSs, are governed by Austrian law, including the provisions of the Austrian Stock Corporation Act, and by our articles of association. These rights differ in important respects from the rights of shareholders in typical U.S. corporations. These differences include, in particular:

- Under Austrian law, certain important resolutions, including, for example, capital decreases, mergers, conversions and spin-offs, the issuance of convertible bonds or bonds with warrants attached and the dissolution of the stock corporation (apart from insolvency and certain other proceedings), require the vote of a 75% majority (and, in some cases, as high as a 90% majority) of the capital present or represented at the relevant general meeting of shareholders. Therefore, the holder or holders of a blocking minority of 25% or, depending on the attendance level at the general meeting, the holder or holders of a smaller percentage of the shares in an Austrian stock corporation may be able to block any such votes, possibly to our detriment or the detriment of our other shareholders.

- As a general rule under Austrian law, a shareholder has no direct recourse against the members of the management board or supervisory board of an Austrian stock corporation in the event that it is alleged that any of them have breached their duty of loyalty or duty of care to the Austrian stock corporation. Apart from insolvency or other special circumstances, only the Austrian stock corporation itself has the right to claim damages from members of the management or supervisory board. An Austrian stock corporation may waive or settle these damages claims only after five years, if the shareholders approve the waiver or settlement at the general meeting with a simple majority of the votes cast and no group of shareholders holding, in the aggregate, at least 20% (and in some cases, 5%) of the Austrian stock corporation's share capital objects to such waiver or settlement and has its opposition formally noted in the minutes of the general meeting. However, Austrian courts acknowledge a waiver or settlement of claims for damages earlier if all shareholders consent to such waiver.

We may be classified as a passive foreign investment company for our tax year ending December 31, 2017, 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, 2014, 2015 or 2016, although for our tax year ended December 31, 2016, our calculations indicate that we were close to being so classified, and to the extent of any differences in its own calculations, the U.S. taxing authority might conclude that we were in fact a PFIC for that year. 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, as to that holder, certain elections are made that can entail 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 the ADSs, 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, 2017, or any other future taxable year during which a U.S. holder held the ADSs, 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 ADSs.

RISK FACTORS RELATED TO THE REDOMICILIATION TRANSACTION

We may not realize all of the anticipated benefits of the Redomiciliation Transaction or those benefits may take longer to realize than expected. We may also encounter significant unexpected difficulties in carrying out the Redomiciliation Transaction and after its completion.

The Redomiciliation Transaction of a parent company is a complex, costly and time-consuming process. As a result, we will be required to devote significant management attention and resources to the Exchange Offer and the Redomiciliation Transaction. The Redomiciliation Transaction process may disrupt the business of the Nabriva Group and, if implemented ineffectively, would preclude realization of the full benefits expected by us. Our failure to meet the challenges involved in the Redomiciliation Transaction and to realize the anticipated benefits of the Redomiciliation Transaction could cause an interruption of or a loss of momentum in, the activities of the Nabriva Group and could adversely affect the Nabriva Group's results of operations. In addition, the overall

Redomiciliation Transaction may result in material unanticipated problems, expenses, liabilities, competitive responses and diversion of management's attention. The difficulties of the Redomiciliation Transaction include, among others:

- the diversion of management's attention to Redomiciliation Transaction matters;
- difficulties in achieving anticipated cost savings, business opportunities and growth prospects from the Redomiciliation Transaction; and
- difficulties in managing a newly redomiciled company.

Many of these factors will be outside of our control and any one of them could result in increased costs and diversion of management's time and energy, which could materially impact the business, financial condition and results of operations of the Nabriva Group. In addition, even if the Redomiciliation Transaction is carried out successfully, we may not realize the full benefits of the transactions, including the corporate benefits, cost savings or growth opportunities that we expect.

The benefits we anticipate from the Redomiciliation Transaction may not be achieved within the anticipated time frame, or at all. Additional unanticipated costs may also be incurred in the Redomiciliation Transaction. All of these factors could decrease or delay the expected accretive effect of the Redomiciliation Transaction. As a result, we cannot assure you that the Redomiciliation Transaction will result in the realization of the full benefits anticipated from it.

Failure to successfully complete the Redomiciliation Transaction could negatively impact the share price and the future business and financial results of Nabriva Ireland and/or Nabriva AG.

If the Exchange Offer is not completed, the ongoing businesses of the Nabriva Group may be adversely affected and, without realizing any of the benefits of the Redomiciliation Transaction, the Nabriva Group will be subject to a number of risks, including the following:

- the Nabriva Group will be required to pay costs and expenses relating to the proposed Redomiciliation Transaction; and
- matters relating to the Redomiciliation Transaction (including integration planning) may require substantial commitments of time and resources by the management team of the Nabriva Group, which could otherwise have been devoted to other opportunities that may have been beneficial to the Nabriva Group.

If the Exchange Offer is not completed, these risks may materialize and may adversely affect the Nabriva Group's business, financial results and share price.

While the Redomiciliation Transaction is pending, the Nabriva Group will be subject to business uncertainties that could adversely affect its business.

Uncertainty about the effect of the Redomiciliation Transaction on employees, investors and suppliers may have an adverse effect on the Nabriva Group. These uncertainties may impair the Nabriva Group's ability to attract, retain and motivate key personnel until the Redomiciliation Transaction is complete and for a period of time thereafter, and could cause those who deal with the Nabriva Group to seek to change existing business relationships with the Nabriva Group. Employee retention may be particularly challenging during the pendency of the transactions because employees may experience uncertainty about their future roles within the Nabriva Group. If, despite the Nabriva Group's retention efforts, key employees depart because of issues relating to the uncertainty and difficulty of integration or a desire not to remain with the Nabriva Group, the Nabriva Group's business could be seriously harmed.

Nabriva Ireland Shares will have rights different from Nabriva AG Common Shares and Nabriva AG ADSs. Therefore, your rights as a shareholder will change as a result of the Redomiciliation Transaction.

The consummation of the Redomiciliation Transaction will change the governing law that applies to our shareholders from Austrian Law (which applies to our common shares) and from U.S. law (which applies to our ADSs) to Irish law (which applies to Nabriva Ireland Shares). Many of the principal attributes of our common shares and our ADSs and Nabriva Ireland Shares will be similar. However, once the Redomiciliation Transaction is consummated, your future rights as a shareholder under Irish law will differ from your current rights as a shareholder under Austrian Law. In addition, Nabriva Ireland's proposed constitution will differ from our articles of association.

Nabriva Ireland will be exposed to the risk of future changes in law, which could materially adversely affect us, including by reducing or eliminating the anticipated benefits of the Redomiciliation Transaction.

Nabriva Ireland is subject to Irish law. As a result, Nabriva Ireland would be subject to the risk of future adverse changes in Irish law (including Irish corporate and tax law). In addition, Nabriva Ireland and the Nabriva Group will also be 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 Nabriva Ireland and its subsidiaries operate.

Future adverse changes in law after the Redomiciliation Transaction could result in Nabriva Ireland not being able to maintain a worldwide effective corporate tax rate that is competitive in our industry.

While we believe that the Redomiciliation Transaction 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 after the Redomiciliation Transaction. The tax laws of Ireland, Austria, the U.S., 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 U.S. 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.

We expect to incur transaction costs in connection with the Redomiciliation Transaction.

We expect to incur transaction costs in connection with the Redomiciliation Transaction, which have been and will continue to be expensed as incurred. A significant portion of these costs will be incurred regardless of whether the Redomiciliation Transaction is completed and prior to holders of our common shares and our ADSs tendering into the Exchange Offer. We expect to incur costs and expenses, including professional fees, to comply with U.S., Austrian and Irish corporate and other laws. In addition, we expect to incur attorneys' fees, corporate service provider fees, accountants' fees, filing fees, mailing expenses, solicitation fees, transfer agent fees, and financial printing expenses in connection with the Redomiciliation Transaction.

We may choose not to proceed with the Redomiciliation Transaction.

We may decide not to proceed with the Redomiciliation Transaction and terminate the Exchange Offer at any time prior to its completion.

If the Nabriva Ireland Shares are not eligible for deposit and clearing within the facilities of DTC, then transactions in the Nabriva Ireland Shares may be disrupted.

The facilities of DTC are a widely-used mechanism that allow for rapid electronic transfers of securities between the participants in the DTC system, which include many large banks and brokerage firms. DTC is not obligated to accept the Nabriva Ireland Shares for deposit and clearing within its facilities at the completion of the Exchange Offer and, even if DTC does initially accept the Nabriva Ireland Shares, it will generally have discretion to cease to act as a depository and clearing agency for the ordinary shares. If DTC determined prior to the consummation of the Exchange Offer that the Nabriva Ireland Shares are not eligible for clearance within the DTC system, then we would not expect to complete the Redomicilation Transaction. However, if DTC determined at any time after the consummation of the Exchange Offer that the Nabriva Ireland Shares were not eligible for continued deposit and clearance within its facilities, then we believe the Nabriva Ireland Shares would not be eligible for continued listing on a U.S. securities exchange and trading in the Nabriva Ireland Shares would be disrupted. While we would pursue alternative arrangements to list Nabriva Ireland Shares and maintain trading, any such disruption could have a material adverse effect on the trading price of the Nabriva Ireland Shares.

The Nabriva Ireland Shares issued to holders of registered Nabriva AG ADSs and holders of Nabriva AG Common Shares pursuant to the Exchange Offer will not be issued into the DTC system.

As noted above, the facilities of DTC are a widely-used mechanism that allow for rapid electronic transfers of securities between the participants in the DTC system. The Nabriva Ireland Shares issued to holders of registered Nabriva AG ADSs and holders of Nabriva AG Common Shares (i.e., *not* Nabriva AG ADSs held within DTC) pursuant to the Exchange Offer will be issued in certificated form and not into the DTC system, and will accordingly be less liquid than Nabriva Ireland Shares that are held within the DTC system.

It will be the responsibility of holders of registered Nabriva AG ADSs and holders of Nabriva AG Common Shares who receive Nabriva Ireland Shares pursuant to the Exchange Offer, should they so wish, to seek to have those shares accepted by DTC for deposit and clearing within the DTC system.

As we will be a holding company, our operating results, financial condition and ability to pay dividends or other distributions will be entirely dependent on funding, dividends and other distributions received from our subsidiaries, including Nabriva AG, 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, including Nabriva AG and its subsidiaries and any new subsidiaries we establish in the future. The ability of our companies 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, if the Redomiciliation Transaction is successful and the Irish holding company structure is put in place, our subsidiaries, including Nabriva AG and any new subsidiaries established by us or Nabriva AG following completion of the Exchange Offer, 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 transactions with affiliates. Restrictions and regulatory action of this kind could impede access to funds that we may need to make dividend payments.

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

We do not expect to undertake the Squeeze-Out Process and holders of Nabriva AG Common Shares and holders of Nabriva AG ADSs who do not tender into the Exchange Offer may have very limited liquidity options after the Exchange Offer.

Provided that we acquire 90% or more of the total issued share capital of Nabriva AG (including Nabriva AG Common Shares represented by Nabriva AG ADSs) pursuant to the Exchange Offer, Austrian law permits us to acquire the remaining share capital of Nabriva AG (including Nabriva AG Common Shares represented by Nabriva AG ADSs) for cash pursuant to a process we refer to as the Squeeze-Out Process. The actual cash consideration payable to holders of any untendered Nabriva AG Common Shares or Nabriva AG ADSs, if any, acquired by us pursuant to the Squeeze-Out Process will be based on a report prepared by us and the Nabriva AG Management Board, which must be verified by an Austrian court-appointed expert. Generally, such a process takes about 3 to 4 months or more from initiation of the Squeeze-Out Process until non-tendering holders of Nabriva AG Common Shares or Nabriva AG ADSs receive the cash consideration. Under Austrian law, such price will have to be paid in cash, which will have an impact on our liquidity and cash reserves and therefore may have an adverse effect on our financial and operational flexibility.

We do not expect to undertake the Squeeze-Out Process and cannot give you any assurance that we will undertake the Squeeze-Out Process sometime in the future or that we will have the cash to pay the amounts necessary to effectuate that Squeeze-Out Process. Holders of any untendered Nabriva AG Common Shares or Nabriva AG ADSs are advised that if they do not tender their respective securities in the Exchange Offer, they may be forced to hold their respective security for an indefinite period of time. Consequently, such holders may have to hold their investment indefinitely and may not be able to liquidate their investments or pledge them as collateral for a loan.

The market for any non-tendered Nabriva AG Common Shares or Nabriva AG ADSs will be less liquid following completion of the Exchange Offer, and the value of any non-tendered Nabriva AG Common Shares or Nabriva AG ADSs may decline significantly.

The market for Nabriva AG Common Shares or Nabriva AG ADSs will be significantly less liquid following completion of the Exchange Offer, and the value of any Nabriva AG Common Shares or Nabriva AG ADSs not tendered into the Exchange Offer may be lower or fluctuate more widely following completion of the Exchange Offer. The exchange of Nabriva AG Common Shares or Nabriva AG ADSs for Nabriva Ireland Shares pursuant to the Exchange Offer will reduce the number of holders of Nabriva AG Common Shares and Nabriva AG ADSs as well as the number of Nabriva AG Common Shares and Nabriva AG ADSs that might otherwise trade publicly and, depending upon the number of Nabriva AG Common Shares and Nabriva AG ADSs so exchanged, will adversely affect the liquidity and market value of the remaining Nabriva AG Common Shares and Nabriva AG ADSs held by the public.

We may also take steps following the Exchange Offer to change the corporate structure or assets of Nabriva AG and these steps could affect the liquidity and trading value of Nabriva AG Common Shares and Nabriva AG ADSs. Moreover, if permitted by

applicable laws and rules of U.S. authorities and the stock exchanges, and depending on the level of acceptance of the Exchange Offer, upon consummation of the Exchange Offer, Nabriva Ireland and its affiliates will cause Nabriva AG to effect one or more of the following: (a) delist the Nabriva AG ADSs from the NASDAQ, (b) suspend Nabriva AG's obligation to file reports under the Exchange Act, until termination of registration thereunder, (c) terminate the registration of the Nabriva AG ADSs under the Exchange Act or (d) terminate the ADS facility.

We may restructure Nabriva AG after the completion of the Exchange Offer or take other steps to acquire Nabriva AG Common Shares and Nabriva AG ADSs.

If holders of Nabriva AG Common Shares and Nabriva AG ADSs do not tender their Nabriva AG Common Shares and Nabriva AG ADSs into the Exchange Offer, any of these actions may negatively affect the value and liquidity of their remaining interest in Nabriva AG. We reserve the right to use any legally permitted method to acquire any nontendered Nabriva AG Common Shares and Nabriva AG ADSs following the expiration of the Exchange Offer period. We may undertake any means available to us including, but not limited to, by way of purchases or subsequent exchange or tender offers or to engage in one or more corporate restructuring transactions, such as a redomiciliation, deredomiciliation, liquidation, transfer of assets or conversion of Nabriva AG into another form or corporate entity, or to change the Nabriva AG articles of association to alter the corporate or capital structure in a manner beneficial to us and our shareholders. Conversely, if we decide not to, or are not able to, implement any post-closing transactions or restructuring measures, holders of Nabriva AG Common Shares and Nabriva AG ADSs will remain shareholders of Nabriva AG rather than Nabriva Ireland and be subject to the risks that may affect their remaining minority investment in Nabriva.

Holders of Nabriva AG Common Shares and Nabriva AG ADSs may hold a proportionately higher percentage interest in the Nabriva Group following completion of the Exchange Offer.

If holders of Nabriva AG Common Shares and holders of Nabriva AG ADSs participate fully in the Exchange Offer and 100% of Nabriva AG Common Shares and Nabriva AG ADSs in issue are tendered into the Exchange Offer, each holder of Nabriva AG Common Shares and holder of Nabriva AG ADSs shall hold the same proportion of the total number of Nabriva Ireland Shares as it currently does of the total number of Nabriva AG Common Shares and Nabriva AG ADSs on completion of the Exchange Offer.

If less than 100% of the Nabriva AG Common Shares and Nabriva AG ADSs in issue are tendered into the Exchange Offer and the Squeeze-Out Process is undertaken, tendering holders of Nabriva AG Common Share and Nabriva AG ADSs will receive a higher proportionate percentage interest in the Nabriva Group than they currently hold on completion of the Exchange Offer and the Squeeze-out Process, due to the fact that nontendering holders of Nabriva AG Common Shares or holders of Nabriva AG ADSs will not receive Nabriva Ireland Shares.

We do not expect to undertake the Squeeze-Out Process and cannot give you any assurance that we will undertake the Squeeze-Out Process sometime in the future or that we will have the cash to pay the amounts necessary to effectuate that Squeeze-Out Process. Holders of any untendered Nabriva AG Common Shares or Nabriva AG ADSs are advised that if they do not tender their respective securities in the Exchange Offer, they may be forced to hold their respective security for an indefinite period of time. Consequently, such holders may have to hold their investment indefinitely and may not be able to liquidate their investments or pledge them as collateral for a loan.

The Nabriva AG ADSs will be delisted from the NASDAQ Global Select Market following completion of the Exchange Offer.

If permitted by applicable laws and rules of U.S. authorities and the stock exchanges, upon completion of the Exchange Offer, we intend to cause Nabriva AG to delist the Nabriva AG ADSs from the NASDAQ Global Select Market. Nabriva Ireland has applied for all of the Nabriva Ireland Shares to trade on the NASDAQ Global Select Market, which is expected to be the only listing of the Nabriva Ireland Shares. The NASDAQ Global Select Market will make the final decision as to whether such listing will be permitted or not and consequently, whether the Nabriva AG ADSs will be delisted from the NASDAQ Global Select Market. We expect that such delisting will result in a decrease in the liquidity of the Nabriva AG ADSs, which will make it difficult for holders of Nabriva AG ADSs to divest of their holdings. Non-tendering investors in Nabriva AG may accordingly be forced to hold their Nabriva AG Common Shares and Nabriva AG ADSs for an indefinite period of time.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

We did not sell any of our equity securities or any options, warrants, or rights to purchase our equity securities during the three months ended March 31, 2017 that were not registered under the Securities Act of 1933, as amended, or the Securities Act.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

Use of Proceeds from Registered Securities

We effected the initial public offering of our American Depositary Shares, or ADSs, each representing one tenth (1/10) of a common share, through a Registration Statement on Form F-1 (File No. 333-205073) that was declared effective by the Securities and Exchange Commission on September 17, 2015. On September 23, 2015, we completed the sale of 9,000,000 ADSs, representing 900,000 of our common shares, at a public offering price of $10.25 per ADS, before underwriting discounts. In addition, we granted the underwriters a 30-day option to purchase up to 1,350,000 additional ADSs to cover over allotments, if any. On September 30, 2015, we completed the additional sale of 1,350,000 ADSs under this option at a price to the public of $10.25 per ADS, resulting in aggregate net proceeds to us of approximately $92.4 million after deducting underwriting discounts and commissions of $7.4 million and offering expenses of $6.3 million. None of the underwriting discounts and commissions or other offering expenses were paid to directors or officers of ours or their associates or to persons owning 10% or more of any class of our equity securities or to any affiliates of ours. Leerink Partner LLC, RBC Capital Markets, LLC, Needham & Company, LLC and Wedbush PacGrow Inc. were the underwriters for our initial public offering.

There has been no material change in our planned use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on September 21, 2015.

Our management board retains broad discretion in the allocation and use of the net proceeds of our initial public offering.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

Table of Contents

ITEM 6. EXHIBITS

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NABRIVA THERAPEUTICS AG

Date: May 10, 2017

By: /s/ Colin Broom
Colin Broom
Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2017

By: /s/ Gary Sender
Gary Sender
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101	The following materials from the Company's Quarterly Report on Form10-Q for the quarter ended March 31, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2016 and March 31, 2017, (ii) Consolidated Statements of Operations for the three months ended March 31, 2016 and 2017, (iii) Consolidated Statements of Cash Flows for the three months ended March 31, 2016 and 2017 and (v) Notes to Unaudited Consolidated Financial Statements.					X

EXHIBIT 31.1

CERTIFICATIONS

I, Colin Broom, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nabriva Therapeutics AG;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's supervisory board (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Colin Broom

Colin Broom
Chief Executive Officer
(Principal Executive Officer)

Dated: May 10, 2017

EXHIBIT 31.2

CERTIFICATIONS

I, Gary Sender, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nabriva Therapeutics AG;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's supervisory board (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Gary Sender

Gary Sender
Chief Financial Officer
(Principal Financial Officer)

Dated: May 10, 2017

EXHIBIT 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Nabriva Therapeutics AG (the "Company") for the period ended March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Colin Broom, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Colin Broom

Colin Broom
Chief Executive Officer
(Principal Executive Officer)

Dated: May 10, 2017

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Nabriva Therapeutics AG (the "Company") for the period ended March 31, 2017 as filed with as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Gary Sender, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Gary Sender

Gary Sender
Chief Financial Officer
(Principal Financial Officer)

Dated: May 10, 2017