
**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, 2018

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 plc

(Exact name of registrant as specified in its charter)

Ireland

(State or jurisdiction of organization)

Not applicable

(I.R.S. Employer Identification No.)

25-28 North Wall Quay

IFSC, Dublin 1, Ireland

(Address of principal executive offices)

Not applicable

(Zip Code)

+353 1 649 2000

(Registrant's telephone number, including area code)

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Emerging 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 Rule 12b-2 of the Act). Yes No

As of April 30, 2018, the registrant had 40,306,924 ordinary shares outstanding.

NABRIVA THERAPEUTICS plc
INDEX TO REPORT ON FORM 10-Q

	<u>Page</u>
<u>PART I — FINANCIAL INFORMATION</u>	
<u>Item 1:</u>	<u>Financial Statements</u> 5
	<u>Consolidated balance sheets as of December 31, 2017 and March 31, 2018 (unaudited)</u> 5
	<u>Consolidated statements of operations and comprehensive income (loss) for the three months ended March 31, 2017 and 2018 (unaudited)</u> 6
	<u>Consolidated statements of cash flows for the three months ended March 31, 2017 and 2018 (unaudited)</u> 7
	<u>Notes to the unaudited consolidated financial statements</u> 8
<u>Item 2:</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> 16
<u>Item 3:</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 24
<u>Item 4:</u>	<u>Controls and Procedures</u> 25
<u>PART II — OTHER INFORMATION</u>	
<u>Item 1:</u>	<u>Legal Proceedings</u> 26
<u>Item 1A:</u>	<u>Risk Factors</u> 26
<u>Item 2:</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 61
<u>Item 3:</u>	<u>Defaults Upon Senior Securities</u> 62
<u>Item 4:</u>	<u>Mine Safety Disclosures</u> 62
<u>Item 5:</u>	<u>Other Information</u> 62
<u>Item 6:</u>	<u>Exhibits</u> 62
<u>SIGNATURES</u>	64

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 report 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 pneumonia, or 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;
- the future development or commercialization of lefamulin in the greater China region;
- the potential benefits under our license agreement with Sinovant Sciences, Ltd.;
- 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 ability to maintain the level of our expenses consistent with our internal budgets and forecasts;
- the demand for securities of pharmaceutical and biotechnology companies in general and our ordinary shares in particular;
- competitive factors;
- compliance with current or prospective governmental regulation;
- general economic and market conditions;
- our ability to attract and retain qualified employees and key personnel; and,

[Table of Contents](#)

- 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.

SPECIAL NOTE REGARDING THE REDOMICILIATION

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

Throughout this Quarterly Report on Form 10-Q, unless the context requires otherwise, all references to “Nabriva,” “the Nabriva Group,” “the Company,” “we,” “ours,” “us,” or similar terms on or prior to June 23, 2017 (the effective date of the Redomiciliation Transaction), refer to our predecessor, Nabriva Therapeutics AG, together with its subsidiaries.

PART I

ITEM 1. FINANCIAL STATEMENTS

NABRIVA THERAPEUTICS plc
Consolidated Balance Sheets (unaudited)

(in thousands, except share data)	As of December 31, 2017	As of March 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 86,769	\$ 89,441
Short-term investments	110	110
Other receivables	5,402	6,436
Contract asset	—	1,500
Prepaid expenses	1,558	1,016
Total current assets	93,839	98,503
Property, plant and equipment, net	1,327	1,376
Intangible assets, net	172	155
Long-term receivables	425	428
Total assets	\$ 95,763	\$ 100,462
Liabilities and equity		
Current liabilities:		
Accounts payable	\$ 5,136	\$ 3,807
Accrued expense and other current liabilities	8,124	7,577
Total current liabilities	13,260	11,384
Non-current liabilities		
Long-term debt	232	411
Other non-current liabilities	203	225
Total non-current liabilities	435	636
Total liabilities	13,695	12,020
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Ordinary shares, nominal value \$0.01, 1,000,000,000 ordinary shares authorized at March 31, 2018; 36,707,685 and 40,233,867 issued and outstanding at December 31, 2017 and March 31, 2018, respectively	367	402
Preferred shares, par value \$0.01, 100,000,000 shares authorized at March 31, 2018; None issued and outstanding	—	—
Additional paid in capital	360,872	380,553
Accumulated other comprehensive income	27	27
Accumulated deficit	(279,198)	(292,540)
Total stockholders' equity	82,068	88,442
Total liabilities and stockholders' equity	\$ 95,763	\$ 100,462

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

NABRIVA THERAPEUTICS plc
Consolidated Statements of Operations and Comprehensive Income (Loss) (unaudited)

(in thousands, except per share data)	Three Months Ended	
	March 31,	
	2017	2018
Revenues:		
Collaboration revenue	\$ —	\$ 6,500
Research premium and grant revenue	1,678	1,051
Total Revenue	<u>1,678</u>	<u>7,551</u>
Operating expenses:		
Research and development	(12,660)	(10,279)
General and administrative	(4,218)	(10,136)
Total operating expenses	<u>(16,878)</u>	<u>(20,415)</u>
Loss from operations	(15,200)	(12,864)
Other income (expense):		
Other income, net	206	23
Interest income	121	9
Interest expense	(1)	(4)
Loss before income taxes	(14,874)	(12,836)
Income tax expense	(349)	(506)
Net loss	(15,223)	(13,342)
Other comprehensive income (loss), net of tax		
Unrealized losses on available-for-sale securities	(16)	—
Reclassification to net income	—	—
Other comprehensive income (loss), net of tax	<u>(16)</u>	<u>—</u>
Comprehensive loss	\$ (15,239)	\$ (13,342)
Loss per share		
Basic and Diluted	<u>\$ (0.56)</u>	<u>\$ (0.36)</u>
Weighted average number of shares:		
Basic and Diluted	<u>27,204,230</u>	<u>36,911,604</u>

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

NABRIVA THERAPEUTICS plc
Consolidated Statements of Cash Flows (unaudited)

(in thousands)	Three Months Ended March 31,	
	2017	2018
Cash flows from operating activities		
Net loss	\$ (15,223)	\$ (13,342)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash other expense, net	(266)	(112)
Non-cash interest income	(30)	(10)
Depreciation and amortization expense	76	133
Stock-based compensation	684	1,244
Deferred income taxes	178	—
Other, net	86	(6)
Changes in operating assets and liabilities:		
Changes in long-term receivables	(5)	(3)
Changes in other receivables and prepaid expenses	(1,586)	(1,992)
Changes in accounts payable	1,789	(1,413)
Changes in accrued expenses and other liabilities	(383)	(1,311)
Changes in other non-current liabilities	6	22
Changes in income tax liabilities	(10)	451
Net cash used in operating activities	(14,684)	(16,339)
Cash flows from investing activities		
Purchases of plant and equipment and intangible assets	(25)	(160)
Proceeds from sales of property, plant and equipment	2	—
Proceeds from sales of available-for-sale securities	10,000	—
Net cash provided by (used in) investing activities	9,977	(160)
Cash flows from financing activities		
Proceeds from sale of ordinary shares	—	19,388
Proceeds from long-term debt	229	189
Proceeds from exercise of stock options	10	—
Equity transaction costs	(1,410)	(518)
Net cash provided by (used in) financing activities	(1,171)	19,059
Effects of foreign currency translation on cash and cash equivalents	266	112
Net (decrease) increase in cash and cash equivalents	(5,612)	2,672
Cash and cash equivalents at beginning of period	32,778	86,769
Cash and cash equivalents at end of period	\$ 27,166	\$ 89,441

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

NABRIVA THERAPEUTICS plc
Notes to the Unaudited Consolidated Financial Statements
(in thousands, except per share data)

1. Organization and Business Activities

Nabriva Therapeutics plc (“Nabriva Ireland”), together with its wholly owned and consolidated subsidiaries, Nabriva Therapeutics GmbH (“Nabriva Austria”), Nabriva Therapeutics US, Inc., Nabriva Therapeutics Ireland DAC, and Nabriva Therapeutics One DAC (In Voluntary Liquidation) (collectively, “Nabriva”, the “Nabriva Group” or the “Company”) is a 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. The Company’s headquarters are located at 25-28 North Wall Quay, Dublin, Ireland.

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

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

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

Liquidity

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

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

NABRIVA THERAPEUTICS plc
Notes to the Unaudited Consolidated Financial Statements (continued)
(in thousands, except per share data)

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

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

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

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

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

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 unaudited consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The accompanying consolidated financial information as of March 31, 2018 and for the three months ended March 31, 2017 and 2018 is unaudited. The December 31, 2017 balance sheet was derived from audited consolidated financial statements but does not include all disclosures required by US GAAP. The interim unaudited consolidated 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, 2018 and for the three months ended March 31, 2017 and 2018. The financial data and other information disclosed in these notes related to the three months ended March 31, 2017 and 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018, 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, 2017 contained in the Company’s Annual Report on Form 10-K, as filed with the SEC on March 16, 2018.

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, 2017. Since the date of those financial statements, there have been no changes to the Company’s significant accounting policies.

Recent Accounting Pronouncements

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

NABRIVA THERAPEUTICS plc
Notes to the Unaudited Consolidated Financial Statements (continued)
(in thousands, except per share data)

Adopted as of the current period:

- 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 revenue disclosures, provide guidance for transactions that were not previously addressed comprehensively and improve guidance for multiple-element arrangements. The effective date of ASU 2014-09 for the Company is the first quarter of fiscal year 2018. The adoption of ASU 2014-09 did not have an impact on the consolidated financial statements of the Company.
- In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation: Scope of Modification Accounting*. ASU 2017-09 clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718, *Compensation—Stock Compensation*. ASU 2017-09 is effective for annual periods beginning after December 15, 2017. An entity should apply the amendments prospectively to a modification that occurs on or after the adoption date. The impact of adopting this standard did not have a material effect on the Company’s financial position, results of operation or cash flow and related disclosures.

To be adopted in future periods:

- In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842). ASU 2016-02 establishes a right-of-use (“ROU”) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. A modified retrospective transition approach is required for lessees of capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact that the standard will have on its financial position, results of operation or cash flow and related disclosures.

3. 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:

<u>(in thousands)</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
December 31, 2017				
Assets:				
Short-term investments:				
Available-for-sale securities	\$ —	\$ 50	\$ —	\$ 50
Term deposits	60	—	—	60
Total Assets	\$ 60	\$ 50	\$ —	\$ 110
<hr/>				
<u>(in thousands)</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
March 31, 2018				
Assets:				
Short-term investments:				
Available-for-sale securities	\$ —	\$ 50	\$ —	\$ 50
Term deposits	60	—	—	60
Total Assets	\$ 60	\$ 50	\$ —	\$ 110

NABRIVA THERAPEUTICS plc
Notes to the Unaudited Consolidated Financial Statements (continued)
(in thousands, except per share data)

As of March 31, 2018 and December 31, 2017, the Company held short-term investments classified as both Level 1 and Level 2, and the Company did not hold any Level 3 financial instruments measured at fair value. There were no transfers between Level 1 and 2 in the three months ended March 31, 2018 or the year ended December 31, 2017. There were no changes in valuation techniques during the three months ended March 31, 2018.

As of March 31, 2018 and December 31, 2017, the Company did not hold any financial instruments as liabilities that were held at fair value. Other receivables and accounts payable are carried at their historical cost which approximates fair value due to their short-term nature.

4. Accrued Expenses and Other Liabilities

(in thousands)	As of December 31, 2017	As of March 31, 2018
Research and development related costs	\$ 2,308	\$ 2,479
Payroll and related costs	4,426	2,651
Accounting, tax and audit services	231	586
Other	1,159	1,861
Total other current liabilities	\$ 8,124	\$ 7,577

5. Revenue

(in thousands)	Three Months Ended March 31,	
	2017	2018
Collaboration revenue	\$ —	\$ 6,500
Research premium	1,505	770
Government grants	147	281
Grants from WWFF	26	—
Total	\$ 1,678	\$ 7,551

The collaboration revenue for the three months ended March 31, 2018 reflects the amounts recorded from the Sinovant License Agreement (see Note 9) and includes the \$5.0 million non-refundable upfront payment received as consideration for entering into the license agreement with Sinovant as well as \$1.5 million of variable consideration related a future milestone payment that the Company believes is probable to be met and received.

6. Share-Based Payments

Stock Option Plan 2015

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

Each vested option grants the beneficiary the right to acquire one share in the Company. The vesting period for the options is four years following the grant date. On the last day of the last calendar month of the first year of the vesting period, 25% of the options attributable to each beneficiary are automatically vested. During the second, third and fourth years of the vesting period, the remaining

NABRIVA THERAPEUTICS plc
Notes to the Unaudited Consolidated Financial Statements (continued)
(in thousands, except per share data)

75% of the options vest on a monthly pro rata basis (i.e. 2.083% per month). Options granted under the SOP 2015 have a term of no more than ten years from the beneficiary's date of participation.

The following table summarizes information regarding our stock option awards under the SOP 2015 for the three months ended March 31, 2018:

Stock Option Plan 2015	Options	Weighted average exercise price in \$ per share	Aggregate intrinsic value
Outstanding as of January 1, 2018	3,044,899	8.35	
Granted	—	—	
Exercised	—	—	
Forfeited	(29,050)	7.49	
Outstanding as of March 31, 2018	3,015,849	8.35	\$ 3
Vested and exercisable as of March 31, 2018	1,337,202	7.88	\$ 1

Stock-based compensation expense under the SOP 2015 was \$0.7 million and \$0.9 million for the three months ended March 31, 2017 and 2018, respectively.

The weighted average remaining contractual life of the options as of March 31, 2018 is 8.2 years.

As of March 31, 2018, there was \$8.9 million of total unrecognized compensation expense, related to unvested options granted under the SOP 2015, which will be recognized over the weighted-average remaining vesting period of 1.2 years.

2017 Share Incentive Plan

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

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

At March 31, 2018, 4,891,442 ordinary shares were available for issuance under the 2017 Plan.

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

The following table summarizes information regarding our stock option awards under the 2017 Plan for the three months ended March 31, 2018:

NABRIVA THERAPEUTICS plc
Notes to the Unaudited Consolidated Financial Statements (continued)
(in thousands, except per share data)

2017 Plan	Options	Weighted average exercise price in \$ per share	Aggregate intrinsic value
Outstanding as of January 1, 2018	294,100	6.92	
Granted	1,543,400	6.18	
Exercised	—	—	
Forfeited	—	—	
Outstanding as of March 31, 2018	1,837,500	6.29	\$ —
Vested and exercisable as of March 31, 2018	—	—	—

Stock-based compensation expense under the 2017 Plan was \$0.4 million for the three months ended March 31, 2018. The weighted average fair value of the options granted during the three months ended March 31, 2018 was \$3.60 per share. The options granted in the three months ended March 31, 2018 were valued based on a Black Scholes option pricing model using the following assumptions. The significant inputs into the model were as follows:

Input parameters

Range of expected volatility	60.9% - 61.0%
Expected term of options (in years)	6.1
Range of risk-free interest rate	2.6% - 2.7%
Dividend yield	—

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

The weighted average remaining contractual life of the options as of March 31, 2018 is 9.8 years.

As of March 31, 2018, there was \$6.3 million of total unrecognized compensation expense, related to unvested options granted under the 2017 Plan, which will be recognized over the weighted-average remaining vesting period of 1.9 years.

Restricted Stock Units

During the three months ended March 31, 2018, the Company granted 339,550 RSUs with a grant date fair value of \$6.47 per share, which was the closing price of the Company's shares on the grant date. Vesting of the RSUs is subject to U.S. Food and Drug Administration ("FDA"), approval of a new drug application ("NDA"), for lefamulin. Fifty percent (50%) of each RSU award will vest upon FDA approval of an NDA for lefamulin, and the remaining fifty percent (50%) will vest on the one-year anniversary of such approval. If the FDA does not approve an NDA for lefamulin within two years of the grant date, the RSU award will terminate in full. The award of 67,500 RSUs to our chief executive officer is contingent upon shareholder approval of an amendment to the 2017 Plan. No compensation expense was recognized for the RSUs as vesting is not probable at March 31, 2018.

7. 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 and 2018, the Company recorded income tax expense of \$349,000 and \$506,000, respectively.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax bases of assets and liabilities using statutory rates. Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, including the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of its deferred tax assets. On the basis of this evaluation, as of March 31, 2018 and December 31, 2017, the Company has recorded a valuation allowance of \$81.3 million and \$80.1 million, respectively. The amount of the deferred tax assets 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.

NABRIVA THERAPEUTICS plc
Notes to the Unaudited Consolidated Financial Statements (continued)
(in thousands, except per share data)

8. Earnings (Loss) per Share**Basic and diluted loss per share**

For the three months ended March 31, 2017 and 2018, basic and diluted net loss per share was determined by dividing net loss attributable to shareholders by the weighted average number of shares outstanding during the period. Diluted net loss per share is the same as basic net loss per share during the periods presented as the effects of the Company's potential common stock equivalents are antidilutive and thus not included in the calculation.

(in thousands, except per share data)	Three Months Ended March 31,	
	2017	2018
Net loss for the period	\$ (15,223)	\$ (13,342)
Weighted average number of shares outstanding	27,204,230	36,911,604
Basic and diluted loss per share	\$ (0.56)	\$ (0.36)

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

(in thousands)	Three Months Ended March 31,	
	2017	2018
Stock options	278,579	4,853,349
Restricted stock units	—	339,550

9. License Agreement

In March 2018, the Company entered into a license agreement (the "License Agreement"), with Sinovant Sciences, Ltd. or Sinovant, an affiliate of Roivant Sciences, Ltd., to develop and commercialize lefamulin in the greater China region. As part of the License Agreement, Nabriva Therapeutics Ireland DAC and Nabriva Therapeutics GmbH, our wholly owned subsidiaries, granted Sinovant an exclusive license to develop and commercialize, and a non-exclusive license to manufacture, certain products containing lefamulin (the "Licensed Products"), in the People's Republic of China, Hong Kong, Macau, and Taiwan (together the "Territory").

Under the License Agreement, Sinovant and the Company's subsidiaries will establish a joint development committee (the "JDC"), to review and oversee development and commercialization plans in the Territory. The Company received a non-refundable \$5.0 million upfront payment pursuant to the terms of the License Agreement and will be eligible for up to an additional \$91.5 million in milestone payments upon the achievement of certain regulatory and commercial milestone events related to lefamulin for CABP, plus an additional \$4.0 million in milestone payments if any Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The first milestone is a \$1.5 million payment for the submission of a clinical trial application ("CTA"), by Sinovant to the Chinese Food and Drug Administration, which is planned for the third quarter of 2018. The remaining milestone payments are tied to additional regulatory approvals and annual sales targets. In addition, the Company will be eligible to receive low double-digit royalties on sales, if any, of Licensed Products in the Territory.

Sinovant will be solely responsible for all costs related to developing, obtaining regulatory approval of and commercializing Licensed Products in the Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Licensed Product in the Territory. The Company is obligated to use commercially reasonable efforts to supply, pursuant to supply agreements to be negotiated by the parties, to Sinovant sufficient supply of lefamulin for Sinovant to manufacture finished drug products for development and commercialization of the Licensed Products in the Territory.

Unless earlier terminated, the License Agreement will expire upon the expiration of the last royalty term for the last Licensed Product in the Territory, which the Company expects will occur in 2033. Following the expiration of the last royalty term, the license granted to Sinovant will become non-exclusive, fully-paid, royalty-free and irrevocable. The License Agreement may be terminated in its entirety by Sinovant upon 180 days' prior written notice at any time. Either party may, subject to specified cure periods, terminate the License Agreement in the event of the other party's uncured material breach. Either party may also terminate the License Agreement under specified circumstances relating to the other party's insolvency. The Company has the right to terminate the License Agreement immediately if Sinovant does not reach certain development milestones by certain specified dates (subject to specified cure periods). The License Agreement contemplates that the Company will enter into ancillary agreements with Sinovant, including clinical and commercial supply agreements and a pharmacovigilance agreement.

NABRIVA THERAPEUTICS plc
Notes to the Unaudited Consolidated Financial Statements (continued)
(in thousands, except per share data)

The Company has identified two performance obligations at inception: (1) the delivery of the licenses to Sinovant; and, (2) the participation in the JDC. The \$5.0 million non-refundable upfront payment was allocated to the delivery of the licenses as the JDC deliverable was deemed to be de minimis. In addition, since the first \$1.5 million milestone payment related to the submission of the CTA is within the control of the parties and is scheduled for submission in the third quarter of this year, the Company recorded such milestone as variable consideration allocated to the licenses at the inception of the arrangement as the Company believes it is probable to be met and received. The future regulatory and commercial milestone payments will be accounted for on an “as incurred basis” and recorded during the period the milestones are achieved.

10. Commitments and Contingencies

During the three months ended March 31, 2018, there were no material changes outside the ordinary course of the Company’s business to its contractual obligations as disclosed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017.

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

11. Subsequent Events

The Company evaluated all events or transactions that occurred subsequent to March 31, 2018 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, 2017, filed with the Securities and Exchange Commission on March 16, 2018. 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 may potentially develop lefamulin for additional indications other than CABP.

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

On March 1, 2017, Nabriva Therapeutics plc, or Nabriva Ireland, was incorporated in Ireland under the name Hyacintho 2 plc, and was renamed to Nabriva Therapeutics plc on April 10, 2017, in order to effectuate the change of the jurisdiction of incorporation of the ultimate company of the group from Austria to Ireland. Nabriva Ireland replaced Nabriva Therapeutics AG, or Nabriva Austria, as the ultimate parent company on June 23, 2017, following the conclusion of a tender offer, or the Exchange Offer, in which holders of 98.6% of the outstanding share capital of Nabriva Austria exchanged their holdings for ordinary shares, \$0.01 nominal value per share, of Nabriva Ireland, which we refer to as the Redomiciliation Transaction. The ordinary shares of Nabriva Ireland were issued on a one-for-ten basis to the holders of the Nabriva Austria common shares and on a one-for-one basis to the holders of the Nabriva Austria American Depositary Shares, or Nabriva Austria ADSs, participating in the Exchange Offer. On June 26, 2017, the ordinary shares of Nabriva Ireland began trading on the Nasdaq Global Market under the symbol "NBRV," the same symbol under which the Nabriva Austria ADSs were previously traded. This transaction was accounted for as a merger between entities under common control; accordingly, the historical financial statements of Nabriva Austria for periods prior to this transaction are considered to be the historical financial statements of Nabriva Ireland. As of August 18, 2017, 100% of Nabriva Austria share capital had been exchanged for ordinary shares of Nabriva Ireland.

Nabriva Austria was incorporated in 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, Nabriva Austria transformed into a stock corporation (*Aktiengesellschaft*) under the name Nabriva Therapeutics AG. On October 19, 2017, Nabriva Austria was converted into a limited liability company under Austrian law and renamed Nabriva Therapeutics GmbH. 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, 2018, we had an accumulated deficit of \$292.5 million. To date, we have financed our operations primarily through our 2018 "at-the-market" equity offering, our 2017 equity offering, our 2016 rights offering, our 2015 initial public offering, private placements of our

[Table of Contents](#)

equity securities, convertible loans and research and development support from governmental grants and loans. We have devoted substantially all of our efforts to research and development, including clinical trials. 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. However, we have re-evaluated the need for the previously planned expansion of our commercial organization, medical education, and supply chain activities and we now anticipate that our expenses for 2018 will decrease as compared to our expenses for 2017 as we wind down our Phase 3 clinical trial program for lefamulin for the treatment of CABP. We expect to continue to invest in critical pre-commercialization activities prior to receiving marketing approval and making lefamulin available to patients.

Our expenses will increase if we suffer any delays in our Phase 3 clinical program, including regulatory delays, or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for lefamulin or any other product candidate that we develop, in-license or acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing.

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.

Financial Operations Overview

Revenue

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

Our revenue consists principally of the collaboration revenues recorded from the Sinovant License Agreement entered into in March 2018, discussed more fully below, and includes a \$5.0 million non-refundable upfront payment received as consideration for entering into the license agreement with Sinovant as well as \$1.5 million of variable consideration related a future milestone payment that we believe is probable to be met and received. Revenue also includes governmental research premiums, non-refundable government grants and the benefit of government loans at below-market interest rates, which are more fully described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies” in our Annual Report on Form 10-K for the year ended December 31, 2017.

Research and Development Expenses

Research and development expenses represented 75.0% and 50.4% of our total operating expenses for the three months ended March 31, 2017 and 2018, respectively.

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

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

[Table of Contents](#)

(in thousands)	Three Months Ended	
	March 31,	
	2017	2018
Direct Costs		
Lefamulin	\$ 9,491	\$ 6,507
Other programs and initiatives	13	29
Indirect Costs	3,156	3,743
Total	\$ 12,660	\$ 10,279

We expect to continue to incur research and development expenses in connection with our activities related to our ongoing LEAP 2 clinical trial of lefamulin for the treatment of CABP which is winding down as we expect top-line date in the spring of 2018, our subsequent NDA and MAA filings and the pursuit of the clinical development of lefamulin for additional indications and engage in earlier stage research and development activities. It is difficult to estimate the duration and completion costs of our research and development programs.

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

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

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

General and Administrative Expenses

General and administrative expenses represented 25.0% and 49.6% of our total operating expenses for the three months ended March 31, 2017 and 2018, respectively.

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

We expect to incur significant marketing, commercial and manufacturing supply chain costs if LEAP 2 data is positive and we obtain marketing approval of lefamulin for the treatment of CABP.

[Table of Contents](#)

License Agreement with Sinovant Sciences

In March 2018, we entered into a license agreement, or the License Agreement, with Sinovant Sciences, Ltd. or Sinovant, an affiliate of Roivant Sciences, Ltd., to develop and commercialize lefamulin in the greater China region. As part of the License Agreement, Nabriva Therapeutics Ireland DAC and Nabriva Therapeutics GmbH, our wholly owned subsidiaries, granted Sinovant an exclusive license to develop and commercialize, and a non-exclusive license to manufacture, certain products containing lefamulin, or the Licensed Products, in the People's Republic of China, Hong Kong, Macau, and Taiwan (together the "Territory"). We retain development and commercialization rights in the rest of the world.

Under the License Agreement, Sinovant and our subsidiaries will establish a joint development committee, or the JDC, to review and oversee development and commercialization plans in the Territory. We received a \$5.0 million upfront payment pursuant to the terms of the License Agreement and will be eligible for up to an additional \$91.5 million in milestone payments upon the achievement of certain regulatory and commercial milestone events related to lefamulin for CABP, plus an additional \$4.0 million in milestone payments if any Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The first milestone is a \$1.5 million payment for the submission of a clinical trial application by Sinovant to the Chinese Food and Drug Administration, which is planned for the third quarter of 2018. The remaining milestone payments are tied to additional regulatory approvals and annual sales targets. In addition, we will be eligible to receive low double-digit royalties on sales, if any, of Licensed Products in the Territory.

Sinovant will be solely responsible for all costs related to developing, obtaining regulatory approval of and commercializing Licensed Products in the Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Licensed Product in the Territory. We are obligated to use commercially reasonable efforts to supply, pursuant to supply agreements to be negotiated by the parties, to Sinovant sufficient supply of lefamulin for Sinovant to manufacture finished drug products for development and commercialization of the Licensed Products in the Territory.

Unless earlier terminated, the License Agreement will expire upon the expiration of the last royalty term for the last Licensed Product in the Territory, which we expect will occur in 2033. Following the expiration of the last royalty term, the license granted to Sinovant will become non-exclusive, fully-paid, royalty-free and irrevocable. The License Agreement may be terminated in its entirety by Sinovant upon 180 days' prior written notice at any time. Either party may, subject to specified cure periods, terminate the License Agreement in the event of the other party's uncured material breach. Either party may also terminate the License Agreement under specified circumstances relating to the other party's insolvency. We have the right to terminate the License Agreement immediately if Sinovant does not reach certain development milestones by certain specified dates (subject to specified cure periods). The License Agreement contemplates that we will enter into ancillary agreements with Sinovant, including clinical and commercial supply agreements and a pharmacovigilance agreement.

We have identified two performance obligations at inception: (1) the delivery of the licenses to Sinovant; and, (2) the participation in the JDC. The \$5.0 million non-refundable upfront payment was allocated entirely to the of the licenses as the JDC deliverable was deemed to be de minimis. In addition, since the first \$1.5 million milestone payment related to the as the submission of the CTA is in the control of the parties and is scheduled for submission in the third quarter of this year, we recorded such milestone as variable consideration allocated to the licenses at the inception of the arrangement as we believe it is probable to be met and received. The future regulatory and commercial milestone payments will be accounted for on an "as incurred basis" and recorded during the period the milestone is achieved.

Critical Accounting Policies

Our consolidated 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 for the year ended December 31, 2017. During the three months ended March 31, 2018, there were no material changes to our critical accounting policies.

Results of Operations**Comparison of Three Months Ended March 31, 2017 and 2018**

(in thousands)	Three Months Ended March 31,		Change
	2017	2018	
Consolidated Operations Data:			
Revenues	\$ 1,678	\$ 7,551	\$ 5,873
Costs and Expenses:			
Research and development	(12,660)	(10,279)	(2,381)
General and administrative	(4,218)	(10,136)	5,918
Total operating expenses	(16,878)	(20,415)	3,537
Loss from operations	(15,200)	(12,864)	2,336
Other income (expense):			
Other income (expense), net	206	23	(183)
Interest income (expense), net	120	5	(115)
Loss before income taxes	(14,874)	(12,836)	2,038
Income tax expense	(349)	(506)	(157)
Net loss	\$ (15,223)	\$ (13,342)	\$ 1,881

Revenues

Revenues increased by \$5.9 million from \$1.7 million for the three months ended March 31, 2017 to \$7.6 million for the three months ended March 31, 2018, primarily due to the \$5.0 million upfront payment received from our Sinovant License Agreement as well as \$1.5 million of variable consideration related a future milestone payment that we believe is probable to be met and received and a \$0.1 million increase in grant income. The increase was partially offset by a \$0.7 million decrease in grant revenue from research premiums provided to us by the Austrian government as a result of lower applicable research and development expenses.

Research and Development Expenses

Research and development expenses decreased by \$2.4 million from \$12.7 million for the three months ended March 31, 2017 to \$10.3 million for the three months ended March 31, 2018. The decrease was primarily due to a \$3.8 million decrease in research materials and purchased services related to the development of lefamulin, offset by a \$0.5 million increase in research consulting fees, a \$0.4 million increase in staff costs due to the addition of employees, a \$0.2 million increase in stock-based compensation expense and a \$0.2 million increase in travel and infrastructure costs.

General and Administrative Expenses

General and administrative expense increased by \$5.9 million from \$4.2 million for the three months ended March 31, 2017 to \$10.1 million for the three months ended March 31, 2018. The increase was primarily due to a \$2.7 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a \$2.3 million increase in staff costs due to the addition of employees, a \$0.3 million increase in share-based compensation expense due to the inclusion of additional employees in our share-based compensation plan, a \$0.3 million increase in infrastructure costs and a \$0.3 million increase in travel and other corporate costs.

Other Income (Expense), net

Other income (expense), net decreased by \$0.2 million from \$0.2 million income for the three months ended March 31, 2017, to nil for the three months ended March 31, 2018 due to the effects of re-measurements of our foreign currency account balances.

Income Tax Expense

Our income tax expense was \$0.3 million for the three months ended March 31, 2017 compared to income tax expense of \$0.5 million for the three months ended March 31, 2017. The income tax expense in both periods represents the current tax expense of our foreign subsidiaries.

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, public offering of our ordinary shares and private placements of our equity securities, convertible debt financings and research and development support from governmental grants and loans.

As of March 31, 2018, we had cash and cash equivalents and short-term investments of \$89.6 million.

In March 2018, we entered into a Controlled Equity OfferingSM Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we may offer and sell our ordinary shares having aggregate gross proceeds of up to \$50.0 million through Cantor. As of March 31, 2018, we issued and sold an aggregate of 3,517,511 ordinary shares under the ATM Agreement, for gross proceeds of \$19.4 million, and net proceeds of \$18.9 million, after deducting commissions. From March 31, 2018 to the date of this filing, we issued and sold on aggregate of 3,590,568 ordinary shares under the ATM agreement.

Cash Flows

Comparison of Three Months Ended March 31, 2017 and 2018

(in thousands)	Three Months Ended March 31,	
	2017	2018
Net cash provided by (used in):		
Operating activities	\$ (14,684)	\$ (16,339)
Investing activities	9,977	(160)
Financing activities	(1,171)	19,059
Effects of foreign currency translation on cash	266	112
Net (decrease) increase in cash	\$ (5,612)	\$ 2,672

Operating Activities

Cash flow used in operating activities increased by \$1.7 million from \$14.7 million for the three months ended March 31, 2017 to \$16.4 million for the three months ended March 31, 2018 primarily due to a \$2.4 million decrease in net loss, after adjustments for non-cash amounts included in net income, offset by higher working capital of \$4.1 million primarily due to changes in accrued expenses and other current liabilities.

Investing Activities

Cash flow generated from investing activities decreased by \$10.1 million from cash provided of \$10.0 million for the three months ended March 31, 2017 to cash used of \$0.1 million for the three months ended March 31, 2018 primarily due to changes in proceeds from sale of available-for-sale financial assets to fund operational cash out flows.

Financing Activities

Cash flow generated from financing activities increased by \$20.2 million from a use of \$1.2 million for the three months ended March 31, 2017 to cash provided of \$19.1 million for the three months ended March 31, 2017 consisting of proceeds, net of commissions, related to our ATM Agreement.

Operating and Capital Expenditure Requirements

We have re-evaluated the need for the previously planned expansion of our commercial organization, medical education, and supply chain activities and we now anticipate that our expenses for 2018 will decrease as compared to our expenses for 2017 as we wind down our Phase 3 clinical trial program for lefamulin for the treatment of CABP. We expect to continue to invest in critical pre-commercialization activities prior to receiving marketing approval and making lefamulin available to patients.

Our expenses will increase if we suffer any delays in our Phase 3 clinical program, including regulatory delays, or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for lefamulin or any other product candidate that we develop, in-license or acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing.

[Table of Contents](#)

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

- initiate or continue the research and development of lefamulin for additional indications and of our other product candidates;
- seek to discover and develop additional product candidates;
- seek marketing approval for any product candidates that successfully complete clinical development;
- continue to establish a medical affairs, sales, marketing and distribution infrastructure and 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;
- establish and expand manufacturing arrangements with third parties;
- expand our physical presence in the United States and Ireland; 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 first quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

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

- the progress, costs and results of our clinical trials for lefamulin, including our LEAP 2 trial;
- the costs and timing of process development and manufacturing scale-up activities associated with lefamulin;
- the costs, timing and outcome of regulatory review of lefamulin;
- the costs of commercialization activities for lefamulin if we receive, or expect to receive, marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities, including the costs of building finished product inventory and its components in preparation of initial marketing of lefamulin;
- subject to receipt of marketing approval, revenue received from commercial sales of lefamulin;
- the costs of developing lefamulin for the treatment of additional indications;
- our ability to establish collaborations on favorable terms, if at all;
- the scope, progress, results and costs of product development of any other product candidates that we may develop;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;

[Table of Contents](#)

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property-related claims;
- the continued availability of Austrian governmental grants;
- the rate of the expansion of our physical presence in the United States and Ireland; and
- the costs of operating as a public company in the United States.

Conducting clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of lefamulin or any other products that we successfully develop, in-license or acquire, none of which we expect to be commercially available for more than a year, if at all. In addition, if approved, lefamulin or any other product candidate that we develop, in-license or acquire may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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

We enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies, research supplies and other services and products for operating purposes. We also lease our office and laboratory facilities. These contracts generally provide for termination on notice and therefore we believe that our non-cancelable obligations under these agreements are not material.

During the three months ended March 31, 2018, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those specified in our 2017 Annual Report on Form 10-K.

We have no contingent liabilities in respect of legal claims arising in the ordinary course of business.

Capital Expenditures

Capital expenditures were \$25,000 and \$160,000 for the three months ended March 31, 2017 and 2018, respectively. We made no significant investments in intangible assets during the three months ended March 31, 2017 and 2018. Currently, there are no material capital projects planned in 2018.

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 payments and acquire materials, in each of these other currencies. We have not established any formal practice to manage the foreign exchange risk against our functional currency. However, we attempt to minimize our net exposure by buying or selling foreign currencies at spot rates upon receipt of new funds to facilitate committed or anticipated foreign currency transactions.

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

Liquidity Risk

Since our inception, we have incurred net losses and generated negative cash flows from our operations. Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

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

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

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, 2018, 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, 2018 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 \$13.3 million for the three months ended March 31, 2018, \$74.4 million for the year ended December 31, 2017, \$54.9 million for the year ended December 31, 2016 and \$47.0 million for the year ended December 31, 2015. As of March 31, 2018, we had an accumulated deficit of \$292.5 million. To date, we have financed our operations primarily through the sale of our equity securities, convertible loans and research and development support from governmental grants and loans. We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed development of any drugs. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year.

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

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

- initiate or continue the research and development of lefamulin for additional indications and of our other product candidates;
- seek to discover and develop additional product candidates;
- seek marketing approval for any product candidates that successfully complete clinical development;
- continue to establish a medical affairs, sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any product candidates for which we receive marketing approval;
- in-license or acquire other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;

[Table of Contents](#)

- expand our physical presence in the United States and Ireland;
- establish and expand manufacturing arrangements with third parties; and
- add operational, financial and management information systems and personnel, including personnel to support our product development, our operations as a public company and our planned future commercialization efforts.

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

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

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

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

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

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

We expect that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditures into the first quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assume, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings.

[Table of Contents](#)

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

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

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

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

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and funding from local and international government entities and non-government organizations in the disease areas addressed by our product candidates and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a security holder. Debt financing, if

[Table of Contents](#)

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 14% (12% for the fiscal years 2016 and 2017 and 10%, in the case of fiscal years prior to 2016) of a specified research and development cost base. Qualifying expenditures largely comprise research and development activities conducted in Austria, however, the research premium is also available for certain related third-party expenses with additional limitations. We received research premiums of \$5.9 million for the year ended December 31, 2016 and \$4.3 million for the year ended December 31, 2015. We have not received any research premium for our qualified 2017 expenditures as of March 31, 2018. As we increase our personnel and expand our business outside of Austria, we may not be able to continue to claim research premiums to the same extent as we have in previous years, as some research and development activities may no longer be considered to occur in Austria. As research premiums that have been paid out already may be audited by the tax authorities, there is a risk that parts of the submitted cost base may not be considered as eligible and therefore repayments may have to be made.

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

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

[Table of Contents](#)

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

Risks Related to Product Development and Commercialization

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

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

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

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

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

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

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.

[Table of Contents](#)

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

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

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements or restrictions; or
- have the product removed from the market after obtaining marketing approval.

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

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

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

- clinical trials of lefamulin or our other product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

[Table of Contents](#)

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

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

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

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

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;

[Table of Contents](#)

- the time of year in which the trial is initiated or conducted;
- the geographic distribution of global trial sites, given the timing of pneumonia season globally, and the seasonal variation in the number of patients suffering from pneumonia, including a decline in the number of patients with CABP during the summer months;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- delays in the receipt of required regulatory approvals, or the failure to receive required regulatory approvals, in the jurisdictions in which clinical trials are expected to be conducted; and
- delays in the receipt of approvals, or the failure to receive approvals, from the relevant institutional review board or ethics committee at clinical trial sites.

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

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

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

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

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

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

There were no systemic adverse events of clinical concern and no drug-related serious adverse events observed in any of our completed Phase 1 clinical trials of lefamulin. In these trials, the most commonly observed adverse effects with oral administration of lefamulin were related to the gastrointestinal tract, including nausea and abdominal

[Table of Contents](#)

discomfort, while the most commonly observed adverse effects related to IV administration were related to irritation at the infusion site. In addition, lefamulin produced a transient, predictable and reproducible prolongation of the QT interval based on the maximum concentration of the drug in the blood plasma. At the doses administered in the Phase 3 clinical trials for lefamulin for CABP, we expect that the drug will not produce large effects on the QT interval that would be of clinical relevance. We did not observe any drug-related cardiac adverse events, such as increase in ectopic ventricular activity or other cardiac arrhythmia, or clinically relevant ECG findings during the conduct of any of our completed Phase 1 clinical trials. If we observe clinically relevant effects on the QT interval in our Phase 3 clinical trials of lefamulin for CABP or in any other clinical trial of lefamulin, our ability to successfully develop lefamulin for CABP or any other indication may be significantly delayed or prevented.

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

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

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

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

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

[Table of Contents](#)

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

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

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

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

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

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

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

[Table of Contents](#)

that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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

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

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

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

[Table of Contents](#)

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

Risks Related to Our Dependence on Third Parties

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

We do not own or operate manufacturing facilities for the production of lefamulin that could be used in product candidate development, including clinical trial supply, or for commercial supply, or for the supply of any other

[Table of Contents](#)

compound that we are developing or evaluating in our research program. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of lefamulin, and our strategy is to outsource all manufacturing, packaging, testing, serialization and distribution of our product candidates and products to third parties.

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

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

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

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

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

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

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

[Table of Contents](#)

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 an MAA.

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

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

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

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

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

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

- 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;

[Table of Contents](#)

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

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

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

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

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

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

[Table of Contents](#)

into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

Risks Related to Our Intellectual Property

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

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

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

[Table of Contents](#)

provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

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

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

[Table of Contents](#)

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 our ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

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

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

Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Other Legal Compliance Matters

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

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

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

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

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

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

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.

[Table of Contents](#)

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

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

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

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

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

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

[Table of Contents](#)

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

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

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

[Table of Contents](#)

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

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

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

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

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

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

[Table of Contents](#)

more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

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

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

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

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

Further, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in

[Table of Contents](#)

other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

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

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

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

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

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

[Table of Contents](#)

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 drug development programs and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

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

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

[Table of Contents](#)

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

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

Risks Related to Employee Matters and Managing Growth

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

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

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

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

[Table of Contents](#)

Risks Related to Ownership of Our Ordinary Shares

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[Table of Contents](#)

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

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

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

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

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

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

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

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

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

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting

[Table of Contents](#)

firm, as and when required, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

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

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

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

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

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

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

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

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

We are exposed to risks related to currency exchange rates.

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

- weakening of the U.S. dollar may increase the U.S. dollar cost of overseas research and development expenses;
- strengthening of the U.S. dollar may decrease the value of our revenues denominated in other currencies;

[Table of Contents](#)

- the exchange rates on non-U.S. dollar transactions and cash deposits can distort our financial results; and
- commercial pricing and profit margins are affected by currency fluctuations.

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

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

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

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

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

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

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

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

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

Under Irish law, our board of directors may increase our authorized share capital and issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital, without shareholder approval, once authorized to do so by our articles of association or by an ordinary resolution of our shareholders. Additionally, subject to specified exceptions, Irish law grants statutory preemption rights to existing shareholders where shares are being issued for cash consideration but allows shareholders to disapply such statutory

[Table of Contents](#)

preemption rights either in our articles of association or by way of special resolution. Such disapplication can either be generally applicable or be in respect of a particular allotment of shares. Accordingly, our articles of association contain, as permitted by Irish company law, provisions authorizing our board of directors to issue new shares, and to disapply statutory preemption rights. The authorization of our board of directors to issue shares and the disapplication of statutory preemption rights must both be renewed by the shareholders at least every five years, and we cannot provide any assurance that these authorizations will always be approved, which could limit our ability to issue equity and thereby adversely affect the holders of our ordinary shares.

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

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

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

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

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

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

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

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

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

Transfers of our ordinary shares effected by means of the transfer of book entry interests in the Depository Trust Company, or "DTC", will not be subject to Irish stamp duty. However, if you hold our ordinary shares directly rather than beneficially through DTC, any transfer of your shares could be subject to Irish stamp duty (currently at the rate of

[Table of Contents](#)

1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty could adversely affect the price of our ordinary shares.

Our ordinary shares received by means of a gift or inheritance could be subject to Irish capital acquisitions tax.

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

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

Based on our estimated gross income and average value of our gross assets and the nature of our business, we do not believe that we were a “passive foreign investment company,” or PFIC, for U.S. federal income tax purposes for our tax years ended December 31, 2015, 2016 or 2017. A corporation organized outside the United States generally will be classified as a PFIC for U.S. federal income tax purposes (1) in any taxable year in which at least 75% of its gross income is passive income or on average at least 50% of the gross value of its assets is attributable to assets that produce passive income or are held for the production of passive income and (2) as to a given holder who was a holder in such year and regardless of such corporation’s income or asset composition, in any subsequent taxable year, unless certain elections are made by that holder that can discontinue that classification as to that holder, at the risk of imposing substantial tax costs to that holder. Passive income for this purpose generally includes dividends, interest, royalties, rents and gains from commodities and securities transactions. Our status in any taxable year will depend on our assets and activities in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC for the current taxable year or any future taxable year. The market value of our assets may be determined in large part by reference to the market price of our ordinary shares, which may fluctuate considerably given that market prices of biotechnology companies have been especially volatile. If we were to be treated as a PFIC for the tax year ending December 31, 2018, or any other future taxable year during which a U.S. holder held our ordinary shares, however, certain adverse U.S. federal income tax consequences could apply to the U.S. holder. We currently intend to make available the information necessary to permit a U.S. holder to make a valid QEF election, which may mitigate some of the adverse U.S. federal income tax consequences that could apply to a U.S. holder of ordinary shares. However, we may choose not to provide such information at a future date.

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, 2018 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 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. Leerink Partner LLC, RBC Capital Markets, LLC, Needham & Company, LLC and Wedbush PacGrow Inc. were the underwriters for our initial public offering.

As of March 31, 2018, we have used all of the approximately \$92.4 million of net proceeds from the offering in our operating activities in a manner consistent with the planned use of proceeds described in the prospectus for our initial public offering. We have not used any of the net proceeds from the offering to make payments, directly or

[Table of Contents](#)

indirectly, to any director or officer of ours or any of their associates, to any person owning 10% or more of any class of our equity securities, or to any affiliate of ours.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit	Incorporated by Reference			Filed Herewith
		Form	File Number	Date of Filing	
10.1	Controlled Equity Offering Sales Agreement dated March 16, 2018, by and between the registrant and cantor Fitzgerald & Co.	8-K	001-37558	3/16/2018	1.1
10.2*	License Agreement, dated March 26, 2018, by and among Nabriva Therapeutics Ireland DAC, Sinovant Sciences, Ltd., Nabriva Therapeutics GmbH and Roivant Sciences, Ltd.				X
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 Form 10-Q for the quarter ended March 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2017 and March 31, 2018, (ii) Consolidated Statements of Operations for the three months ended March 31, 2017 and 2018, (iii) Consolidated Statements of Cash Flows for the three months ended March 31, 2017 and 2018 and (v) Notes to Unaudited Consolidated Financial Statements.				X

[Table of Contents](#)

* Confidential treatment has been requested as to certain portions, which portions have been omitted and separately filed with the Securities and Exchange Commission.

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.

Date: May 8, 2018

NABRIVA THERAPEUTICS plc

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

Date: May 8, 2018

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

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.

LICENSE AGREEMENT

DATED

MARCH 26, 2018

Among

NABRIVA THERAPEUTICS IRELAND DESIGNATED ACTIVITY COMPANY,

SINOVANT SCIENCES LTD.,

solely for purposes of Clauses 2.1 (Grants to Licensee), 5 (PAYMENTS AND RECORDS), 8.4 (Additional Covenant of Nabriva), 11.3 (Assignment), 11.6 (Notices), 11.11 (No Benefit to Third Parties), 11.13 (Relationship of the Parties) and 11.17 (Guaranty), NABRIVA THERAPEUTICS GMBH (formerly Nabriva Therapeutics AG),

and

solely for purposes of Clauses 11.17 (Guaranty) and 11.18 (Parent Representation and Warranty), ROIVANT SCIENCES, LTD.

CONTENTS

	<u>Page</u>
Clause	
1. Definitions	1
2. Grant of Rights	16
3. Regulatory and Commercialization Activities	21
4. Development Committee	27
5. Payments and Records	29
6. Intellectual Property	35
7. Confidentiality and Non-Disclosure	43
8. Representations and Warranties	48
9. Indemnity	52
10. Term and Termination	55
11. Miscellaneous	58
Schedules	
Schedule 1 – Corporate Names	
Schedule 2 – Existing Patents	
Schedule 3 – Licensed Compound	
Schedule 4 – Press Release	
Signatories	67

This License Agreement (the **Agreement**) is made and entered into effective as of March 26, 2018 (the **Effective Date**)

BY and BETWEEN:

- (1) **Nabriva Therapeutics Ireland Designated Activity Company**, a private limited company incorporated under the laws of Ireland (registered number 612454), with its registered office at Suite 510, Regus Dublin Airport, Skybridge House Dublin, Airport, Swords, Co. Dublin, K67 P6K2, Republic of Ireland (**Nabriva**); and
- (2) **Sinovant Sciences Ltd.**, an exempted limited company incorporated under the laws of Bermuda, having its registered office at 2 Church Street, Hamilton, Bermuda and a wholly-owned subsidiary of Parent (**Licensee**);
- (3) Solely for purposes of Clauses 2.1 (Grants to Licensee), 5 (PAYMENTS AND RECORDS), 8.4 (Additional Covenant of Nabriva), 11.3 (Assignment), 11.6 (Notices), 11.11 (No Benefit to Third Parties), 11.13 (Relationship of the Parties) and 11.17 (Guaranty), **Nabriva Therapeutics GmbH** (formerly **Nabriva Therapeutics AG**), a private limited company incorporated and registered in Austria (registered number FN 269261y), with its registered office at Leberstrasse 20, 1110 Vienna, Austria (**NTGmbH**); and
- (4) Solely for purposes of Clauses 11.17 (Guaranty) and 11.18 (Parent Representation and Warranty), **Roivant Sciences, Ltd.**, an exempted limited company incorporated under the laws of Bermuda, having its registered office at 2 Church Street, Hamilton, Bermuda (**Parent**).

Nabriva and Licensee are referred to herein individually as a **Party** and collectively as the **Parties**. Nabriva and NTGmbH are referred to herein individually as a **Nabriva Party** and collectively as the **Nabriva Parties**.

RECITALS:

- (A) **WHEREAS**, Nabriva and NTGmbH own and control certain intellectual property rights with respect to the Licensed Compound (as defined herein) and Licensed Products (as defined herein) in the Territory (as defined herein); and
- (B) **WHEREAS**, Nabriva and NTGmbH wish to grant a license to Licensee and Licensee wishes to take a license under such intellectual property rights to develop and commercialize Licensed Products in the Territory, in each case in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

1. DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

AAA has the meaning set forth in Clause 11.5(d) (Governing Law and Dispute Resolution - subclause (d)).

ABSSSI means acute bacterial skin and skin structure infections.

Active Pharmaceutical Ingredient means any substance intended to be used in a pharmaceutical product that, when used, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions in man or animal or to make a medical diagnosis; but excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants or controlled release technologies.

Affiliate means, with respect to a Party or NTGmbH, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party (or NTGmbH, if applicable), but for only so long as such control exists. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means:

- (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise;
- (b) the right to elect a majority of the members of the Board of Directors, or to appoint the chief executive officer, general manager or other senior management officials; or
- (c) the ownership, directly or indirectly, of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

Agreement has the meaning set forth in the preamble hereto.

Alliance Manager has the meaning set forth in Clause 4.2(e) (Alliance Managers).

Anti-Corruption Laws has the meaning set forth in Clause 8.6 (Anti-Bribery and Anti-Corruption Compliance).

Applicable Law means applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time and applicable to a particular activity hereunder, including the FFDA, DAL, the Provisions for Drug Registration of the CFDA and the Anti-Corruption Laws.

Arbitration Notice has the meaning set forth in Clause 11.5(d) (Governing Law and Dispute Resolution - subclause (d)).

Arbitrators has the meaning set forth in Clause 11.5(d) (Governing Law and Dispute Resolution - subclause (d)).

Auditor has the meaning set forth in Clause 5.10 (Audit Dispute).

Authorized Representatives has the meaning set forth in Clause 8.6 (Anti-Bribery and Anti-Corruption Compliance).

Board of Directors has the meaning set forth in the definition of **Change of Control**.

Breaching Party has the meaning set forth in Clause 10.2(a) (Material Breach).

Business Day means a day other than a Saturday or Sunday or a day on which banking institutions in New York, NY or Bermuda are permitted or required to be closed.

CABP means Community-Acquired Bacterial Pneumonia.

Calendar Half-Year means each successive period of six (6) calendar months commencing on 1 January and 1 July and except that the first Calendar Half-Year of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of 1 January or 1 July after the Effective Date.

Calendar Quarter means each successive period of three (3) calendar months commencing on 1 January, 1 April, 1 July and 1 October, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to 1 April, 2018.

Calendar Year means each successive period of twelve (12) calendar months commencing on 1 January and ending on 31 December except that the first Calendar Year of the Term shall commence on the Effective Date and end on 31 December of the year in which the Effective Date occurs.

CFDA means the China Food and Drug Administration, or its predecessor State Food and Drug Administration, and any successor agency thereto.

Change of Control means with respect to a Party, the occurrence of any of the following after the Effective Date:

- (a) any Third Party “person” or “group” (as such terms are defined below) (i) is or becomes the “beneficial owner” (as defined below, except that a “person” or “group” shall be deemed to have “beneficial ownership” of all shares of capital stock or other equity interests if such person or group has the right to acquire such shares of capital stock or other equity interests, whether such right is exercisable immediately or only after the passage of time), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party (or, solely with respect to Nabriva and if applicable, a parent of such Party) then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (**Voting Stock**) of such Party (or, solely with respect to Nabriva and if applicable, such parent) representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party (or, solely with respect to Nabriva and if applicable, such parent) or (ii) has the power, directly or indirectly, to elect a majority of the members of the Party’s (or, solely with respect to Nabriva and if applicable, such parent’s) board of directors or similar governing body (**Board of Directors**);
- (b) such Party (or, solely with respect to Nabriva and if applicable, a parent of such Party) enters into a merger, consolidation or similar transaction with a Third Party (whether or not such Party (or, solely with respect to Nabriva and if applicable, such parent) is the surviving entity) and as a result of such merger, consolidation or similar transaction (i) the members of the Board of Directors of such Party (or, solely with respect to Nabriva and if applicable, such parent) immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Party (or, solely with respect to Nabriva and if applicable, such parent) or such surviving Person immediately following such transaction or (ii) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party (or, solely with respect to Nabriva and if applicable, such parent) immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party (or, solely with respect to Nabriva and if applicable, such parent) representing at

least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party (or, solely with respect to Nabriva and if applicable, such parent) immediately prior to such transaction;

- (c) such Party sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of such Party's consolidated total assets to which this Agreement relates; or
- (d) the holders of capital stock of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this definition of Change of Control:

- (i) **person** and **group** have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the aforesaid Act;
- (ii) a **beneficial owner** shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and
- (iii) the terms **beneficially owned** and **beneficially own** shall have meanings correlative to that of "beneficial owner".

For clarity, any investment transaction by venture capital or other financial investors not engaged directly in the pharmaceutical or biotechnology business and not otherwise affiliated with a pharmaceutical or biotechnology company, the purpose of which is to raise capital for a Party, shall not be deemed to be a Change of Control of that Party.

Clinical Supply Agreement has the meaning set forth in Clause 3.5(b)

Combination Product means a Licensed Product that is comprised of or contains the Licensed Compound as an Active Pharmaceutical Ingredient together with one (1) or more other Active Pharmaceutical Ingredients and is sold either as a fixed dose or as separate doses in a single package.

Commercial Supply Agreement has the meaning set forth in Clause 3.5(b).

Commercialization means any and all activities undertaken before and after Regulatory Approval directed to the preparation for sale, offering for sale, or sale of a product, including activities related to marketing, advertising, promoting, detailing, medical education, sales force training, scientific and medical affairs, distributing (including without limitation importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering the product to customers), selling such product, booking sales, and interacting with Regulatory Authorities regarding any of the foregoing; provided, however, that Commercialization does not include research, Development or Manufacturing. When used as a verb, to **Commercialize** and Commercializing means to engage in Commercialization and **Commercialized** has a corresponding meaning.

Commercially Reasonable Efforts means, with respect to the performance of Development or Commercialization activities with respect to the Licensed Compound or a Licensed Product by Licensee, the carrying out of such activities using efforts and resources comparable to the efforts and resources commonly used in the biopharmaceutical industry by companies of a similar stage and size

as Licensee with resources and expertise similar to those of Licensee for compounds or products of similar market potential at a similar stage in development or product life, taking into account, as applicable, relative safety and efficacy, product profile, the regulatory environment, payors' policies and regulations, competitiveness of the marketplace and the market potential of such products, the nature and extent of market exclusivity, including patent coverage and regulatory data protection, and price and reimbursement status, but not taking into account any payment obligations under this Agreement.

Commercialization Plan means the strategic commercialization plan for the Commercialization of Licensed Products in the Field in the Territory, as such plan may be amended or updated from time to time in accordance with this Agreement, which plan Licensee shall ensure is at all times consistent with the terms and conditions of this Agreement and all In-License Agreements. The Commercialization Plan will include in reasonable detail (a) marketing principal strategies with respect to marketing and promoting the Licensed Products during the applicable time period, (b) the material activities to be conducted by Licensee in connection with the Commercialization of the Licensed Products during such time period, and (c) an estimate of all expenses associated with the activities set forth in such Commercialization Plan.

Confidential Information has the meaning set forth in Clause 7.1 (Confidentiality Obligations).

Control means, subject to Clause 2.5(b) (In-License Agreements) and Clause 11.3(b) (Assignment - subclause (b)), with respect to any item of Information, Regulatory Documentation, material, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in Clause 2.1 (Grants to Licensee), 2.2 (Grants to Nabriva) or 10.3 (Consequences of Termination)), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.

Controlling Party has the meaning set forth in Clause 6.5 (Invalidity or Unenforceability Defenses or Actions).

Corporate Names means (a) the Trademarks, names and logos identified on Schedule 1, (b) the Trademarks (in their native language or any translation thereof) with respect to any Licensed Product outside the Territory (the **Nabriva Product Trademarks**) and (c) such other Trademarks, names and logos as Nabriva may designate in writing from time to time.

Cost of Goods Sold or **COGS** means, with respect to particular Lefamulin Materials, the aggregate of internal and external costs of Nabriva and any of its Affiliates to Manufacture such Lefamulin Materials, calculated as follows: (a) to the extent that Nabriva or any of its Affiliates performs any part of the Manufacturing of such Lefamulin Materials, the actual direct material costs and direct labor costs for, plus manufacturing overhead directly allocable to, such Manufacturing of such Lefamulin Materials, all calculated in accordance with GAAP; and (b) to the extent that Manufacturing of such Lefamulin Materials is performed by a Third Party, the costs paid to such Third Party for such activities that are directly allocable to such Manufacturing of such Lefamulin Materials and, directly allocated labor costs actually incurred by Nabriva or any of its Affiliates in managing and overseeing the relationship with such Third Party manufacturer, determined in accordance with GAAP. Cost of Goods Sold shall also include royalties or license fees paid by Nabriva or any of its Affiliates to any Third Party to license Information or Patents for the Manufacture of such Licensed Product. To the extent that any of the foregoing costs are attributable both to such Licensed Product and to one or more other products of Nabriva or any of its Affiliates, such costs shall be equitably allocated across all such products.

CTA means Clinical Trial Application that is required to initiate a clinical trial for registering a drug product under the Drug Administration Law of the People's Republic of China and the Provisions for Drug Registration (SFDA Order. 28) or equivalents thereof under future Chinese laws and regulations, as the same may be amended from time to time.

DAL means the Drug Administration Law of the People's Republic of China.

Development means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, in vitro microbiology, clinical studies, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval; provided, however, that Development excludes Manufacturing or Commercialization. When used as a verb, **Develop** and **Developing** means to engage in Development and **Developed** has a corresponding meaning.

Development Plan means the plan for the Development of the Licensed Products, including for Regulatory Approval and Post-Approval Research, in the Field in the Territory, including in reasonable detail (a) all material Development activities reasonably anticipated to be undertaken by Licensee to obtain Regulatory Approval of Licensed Products in the Field in the Territory (b) estimated dates on which Licensee expects to achieve each Milestone Event, (c) an estimate of costs and expenses associated with the activities set forth therein as such plan may be amended or updated from time to time in accordance with this Agreement and (d) such other information set forth in Clause 3.1(a) (Development Plan), which plan Licensee shall ensure is at all times consistent with the terms and conditions of this Agreement and all In-License Agreements.

Dispute has the meaning set forth in Clause 11.5(b)(ii) (Governing Law and Dispute Resolution - subclause (b)(ii)).

Dollars or \$ means United States Dollars.

Drug Approval Application means with respect to any pharmaceutical product in any Jurisdiction, an application for Regulatory Approval for such pharmaceutical product in such Jurisdiction, including, as applicable: (a) a **New Drug Application** or **NDA** as defined in the FFDCAs, (b) a **Drug Registration Application** or any future equivalents thereof as defined in the DAL and the Provisions for Drug Registration, (c) any corresponding foreign application in a Jurisdiction; and (d) all renewals, supplements and amendments to any of the foregoing.

Effective Date has the meaning set forth in the preamble hereto.

Enforcing Party has the meaning set forth in Clause 6.3(b) (Enforcement of Patents).

Existing Patents means the Patents listed on Schedule 2.

Exploit means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. **Exploitation** means the act of Exploiting a compound, product or process.

FDA means the United States Food and Drug Administration and any successor agency thereto.

FDCA means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

Field means all uses in humans in those indications for which the Licensed Products may be Developed and Commercialized in the Territory, as specified by Nabriva in writing.

First Commercial Sale means, with respect to a Licensed Product and a Jurisdiction in the Territory, the first arm's length sale for monetary value for use or consumption by the end user of such Licensed Product in such Jurisdiction after Regulatory Approval for such Licensed Product has been obtained in such Jurisdiction (whether or not Reimbursement Approval has been received). Sales, for no charge, of reasonable amounts of such Licensed Product in such Jurisdiction prior to receipt of Regulatory Approval for such Licensed Product as so-called "treatment IND sales," "named patient sales," or "compassionate use sales" shall not be construed as a First Commercial Sale.

PFV means the first patient's first screening visit in a clinical trial at or prior to which such subject signs an informed consent to participate in such clinical trial (if required under Applicable Law).

GAAP means, with respect to a Party or any of its Affiliates or Sublicensees, as applicable, United States generally accepted accounting principles, International Financial Reporting Standards or such other similar national standards as such Party, Affiliate or Sublicensee, as applicable, adopts, in each case, consistently applied.

Generic Product means, with respect to a particular mode of administration of a Licensed Product in a Jurisdiction, any other prescription pharmaceutical product (a) that is not produced, licensed or owned by Licensee, any of its Affiliates or any Sublicensee, (b) that contains the Licensed Compound and the same other Active Pharmaceutical Ingredient(s), if any, of such Licensed Product, (c) uses the same mode of administration as such Licensed Product, and (d) with respect to which a Third Party (other than a Sublicensee) has received Regulatory Approval for a Drug Approval Application for such other product in such Jurisdiction through an abbreviated regulatory pathway in reliance on the approved Drug Approval Application for such Licensed Product in such mode of administration in such Jurisdiction received by Licensee, any of its Affiliates or any Sublicensee (such as Class 4 drugs under the current CFDA regulations); provided, however, that, if, with respect to a particular mode of administration of a Licensed Product in a Jurisdiction, (y) a product otherwise meets the criteria in clauses (a), (b) and (d) but uses a different mode of administration and (z) the relevant Regulatory Authority in such jurisdiction determines in accordance with Applicable Law that such product is substitutable for such Licensed Product, then such product shall also be considered a Generic Product of such Licensed Product.

Government Official means (a) any Person employed by or acting on behalf of a government, government-controlled agency or entity or public international organization, (b) any political party, party official or candidate, (c) any Person who holds or performs the duties of an appointment, office or position created by custom or convention or (d) any Person who holds himself out to be the authorized intermediary of or has a close relationship with any of the foregoing who can reasonably influence foregoing's decision making, including, but not limited to, the direct relatives of foregoing.

Governmental Authority means any federal, national, multinational, state, provincial, city, county or local government or any court, arbitral tribunal, administrative agency or commission or government authority acting under the authority of any federal, national, multinational, state, provincial, city, county or local government.

Hatch-Waxman Act has the meaning set forth in the definition of Hatch Waxman Act Certification.

Hatch-Waxman Act Certification means a certification under the U.S. “Drug Price Competition and Patent Term Restoration Act” of 1984 (**Hatch-Waxman Act**), as set forth at 21 U.S.C. §355(b)(2)(A)(iv) or 21 U.S.C. §355(j)(2)(A)(vii)(IV).

IDL means an imported drug license under the DAL and its relevant regulation and rules.

Improvement means any invention, discovery, development or modification with respect to the Licensed Compound or a Licensed Product or relating to the Exploitation thereof, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture, ingredients, preparation, presentation, formulation, means of delivery (including the development of any delivery system or enhancement thereto) or dosage of such Licensed Compound or Licensed Product, any discovery or development of any new or expanded indications for such Licensed Compound or Licensed Product, or any discovery or development that improves the stability, safety or efficacy of such Licensed Compound or Licensed Product.

IND means (a) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other Jurisdictions and (b) all supplements and amendments that may be filed with respect to the foregoing.

Indemnification Claim Notice has the meaning set forth in Clause 9.3(a) (Notice of Claim).

Indemnified Party has the meaning set forth in Clause 9.3(a) (Notice of Claim).

Information means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed; provided, however, that Information excludes Patents.

Infringement has the meaning set forth in Clause 6.3(a) (Notice).

In-License Agreement means any license or other agreement entered into after the Effective Date by and between Nabriva or any of its Affiliates, on the one hand, and one or more Third Parties, on the other hand, pursuant to which Nabriva or, subject to Clause 11.3(b), such Affiliate acquires Control of any Patents or Information that, subject to Clause 2.5(b) (In-License Agreements), would be Nabriva Patents or Nabriva Know-How, as such license or other agreement may be amended from time to time during the Term.

Invoiced Sales has the meaning set forth in the definition of **Net Sales**.

Joint Intellectual Property Rights has the meaning set forth in Clause 6.1(b) (Ownership of Joint Patents and Joint Know-How).

Joint Know-How has the meaning set forth in Clause 6.1(b) (Ownership of Joint Patents and Joint Know-How).

Joint Patents has the meaning set forth in Clause 6.1(b) (Ownership of Joint Patents and Joint Know-How).

Joint Development Committee or **JDC** has the meaning set forth in Clause 4.1 (Joint Development Committee).

JDC Dispute has the meaning set forth in Clause 11.5 (Governing Law and Dispute Resolution).

Jurisdiction means, as applicable, a country, region or jurisdiction.

Knowledge means the actual knowledge, without any duty to conduct any investigation with respect to such facts and information, of (a) with respect to Nabriva and its Affiliates, the Chief Executive Officer, Chief Scientific Officer, Chief Financial Officer, Chief Commercial Officer and General Counsel of Nabriva and (b) with respect to Licensee, the Chief Executive Officer and Chief Medical Officer of Licensee or, as set forth herein, its relevant Affiliate, or any personnel holding positions equivalent to such job title (but only to the extent such positions exist at Licensee or such Affiliate).

Lefamulin Materials means, as applicable, the Licensed Compound in bulk form manufactured for use as an Active Pharmaceutical Ingredient, intermediates required to Manufacture the finished product formulation of a Licensed Product, the finished product formulation of a Licensed Product, and any other components required to Manufacture any Licensed Product.

Licensed Compound means Lefamulin as shown in Schedule 3 and, to the extent included in any Licensed Product, any metabolite, salt, ester, hydrate, solvate, isomer, enantiomer, free acid form, free base form, crystalline form, co-crystalline form, amorphous form, pro-drug (including ester pro-drug) form, racemate, polymorph, chelate, stereoisomer, tautomer or optically active form of any of the foregoing.

Licensed Product means any product that is comprised of or contains a Licensed Compound alone or in combination with one or more other Active Pharmaceutical Ingredients, in each case only in the specific form(s) (i.e., the specific Active Pharmaceutical Ingredients, mode of administration, formulation, etc. (but not dosage) for each such product) clinically Developed by Nabriva or any of its Affiliates.

Licensed Product Agreement means, with respect to a Licensed Product, any agreement entered into by and between Licensee or any of its Affiliates or its or their Sublicensees, on the one hand, and one or more Third Parties, on the other hand, that is necessary or reasonably useful for the Exploitation of such Licensed Product in the Field in the Territory, including (a) any agreement pursuant to which Licensee, its Affiliates or its or their Sublicensees receives any license or other rights to Exploit such Licensed Product, (b) supply agreements pursuant to which Licensee, its Affiliates or its or their Sublicensees obtain or will obtain quantities of such Licensed Product or applicable Lefamulin Materials (*provided, however, that this clause (b) shall not be interpreted to grant Licensee, its Affiliates or Sublicensees the right to Manufacture or have Manufactured, or otherwise obtain, any quantity of any Active Pharmaceutical Ingredient (or other Lefamulin Materials) of a Licensed Product other than from Nabriva, except in accordance with the applicable Supply Agreement*), (c) clinical trial agreements, (d) contract research organization agreements and (e) service agreements.

Licensee has the meaning set forth in the preamble hereto.

Licensee Development Data means any (a) pharmacology, toxicology and other biological data included in or in support of the Regulatory Documentation in the Territory that was created or Controlled by Licensee, any of its Affiliates or any Sublicensee, or on behalf of Licensee or any of its Affiliates or any Sublicensee (**Licensee Regulatory Documentation**), and (b) clinical data included in or in support of Licensee Regulatory Documentation.

Licensee Know-How means all Information Controlled by Licensee or any of its Affiliates or its or their Sublicensees as of the Effective Date or during the Term that is necessary or reasonably useful for the Exploitation of the Licensed Compound or a Licensed Product or any Improvement thereto. For clarity, Licensee Know-How includes any Licensee Development Data and Licensee Regulatory Documentation to the extent consistent with this definition.

Licensee Patents means all of the Patents Controlled by Licensee or any of its Affiliates or its or their Sublicensees as of the Effective Date or at any time during the Term that claim or cover the Licensed Compound or a Licensed Product or any Improvement thereto, or the Exploitation of any of the foregoing, but excluding any Joint Patents.

Losses has the meaning set forth in Clause 9.1 (Indemnification of Nabriva).

Manufacture and Manufacturing means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, in-process and finished testing, shipping, storing, or release of a product or any ingredient or intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, test method development and stability testing, formulation, quality assurance and quality control of the any compound, product or intermediate, and regulatory affairs with respect to the foregoing.

Milestone Event has the meaning set out in Clause 5.2 (Milestones).

Nabriva has the meaning set forth in the preamble hereto.

Nabriva Know-How means all Information Controlled by Nabriva or, subject to Clause 11.3(b) (Assignment - subclause (b)), any of its Affiliates as of the Effective Date or during the Term that is necessary or reasonably useful for the Development or Commercialization of the Licensed Compound or a Licensed Product in the Field in the Territory. For clarity, Nabriva Know-How includes any Nabriva Development Data and Nabriva Regulatory Documentation to the extent consistent with this definition.

Nabriva Development Data means any of the following related to the Licensed Compound or a Licensed Product that is Controlled by Nabriva and necessary or reasonably useful for the Development or Commercialization of the Licensed Compound or a Licensed Product in the Field in the Territory: (a) pharmacology, toxicology and other biological data included in or in support of the Regulatory Documentation outside of the Territory that was created by Nabriva or on behalf of Nabriva and (b) clinical data included in or in support of the Regulatory Documentation outside of the Territory.

Nabriva Entity has the meaning set out in Clause 2.6(b) (Territorial Restrictions - subclause(b)).

Nabriva Patents means all of the Patents in the Territory Controlled by Nabriva or, subject to Clause 11.3(b) (Assignment - subclause (b)), any of its Affiliates as of the Effective Date or during the Term, that are necessary or reasonably useful (or, with respect to a Patent application, would be necessary or reasonably useful if such Patent application were to issue as a Patent) for the Development, Manufacture or Commercialization of the Licensed Compound or a Licensed Product in the Field in the Territory, but excluding any Joint Patents; *provided, however*, that, solely with respect to Clauses 6.2 (Maintenance and Prosecution of Patents), 6.3 (Enforcement of Patents) and 6.5 (Invalidity or Unenforceability Defenses or Actions), Nabriva Patents means all of the Patents in the Territory Controlled by Nabriva or, subject to Clause 11.3(b) (Assignment - subclause (b)), any of its Affiliates as of the Effective Date or during the Term, that are necessary or reasonably useful (or, with respect to a Patent application, would be necessary or reasonably useful if such Patent application were to

issue as a Patent) for the Development or Commercialization of the Licensed Compound or a Licensed Product in the Field in the Territory, but excluding any Joint Patents. The Nabriva Patents include the Existing Patents.

Nabriva Regulatory Documentation means (a) Regulatory Documentation Controlled by Nabriva or any of its Affiliates as of the Effective Date relating to the Licensed Compound and (b) Regulatory Documentation Controlled by Nabriva during the Term relating to the Licensed Compound that a Regulatory Authority in the Territory requires from Licensee in order for Licensee to submit a CTA or Drug Approval Application for a Licensed Product in the Territory.

Net Sales means, with respect to a Licensed Product for any period, the gross amount billed or invoiced by Licensee, its Affiliates or its or their Sublicensees to Third Parties for the sale of a Licensed Product (the **Invoiced Sales**), less deductions with respect to such Licensed Product for:

- (a) normal and customary trade, quantity, cash and prompt settlement discounts (including chargebacks and allowances) actually taken or accrued;
- (b) amounts repaid or credited by reason of rejection, return or recall of goods, allowances for sales, rebates, bona fide price reductions, retroactive price reductions, or billing errors;
- (c) transportation, importation, freight, postage, shipping, insurance and other handling expenses to the extent that such items are included in the gross amount invoiced;
- (d) taxes imposed on production, sale, or delivery, including sales, use, customs and excise duties, turnover, inventory, value added taxes (but excluding taxes imposed on net income), and other taxes or duties related to a Licensed Product, in each case described in this clause (d) to the extent that such items are included in the gross amount invoiced;
- (e) discounts, rebates, reimbursements, chargeback payments, and similar payments granted to managed health care organizations or other health care institutions (including hospitals), health care administrators, patient assistance or similar programs, pharmacy benefit managers (or equivalents thereof), wholesalers and other distributors, pharmacies and other retailers, group purchasing organizations or other buying groups, health maintenance organizations, national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, any other providers of health insurance coverage, or to trade customers including, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program;
- (f) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such Licensed Product; and
- (g) amounts invoiced for sales of Licensed Product that are written off as uncollectible after reasonable collection efforts, in accordance with GAAP; *provided* that the amounts deducted under this subsection (g) shall not exceed [**] percent ([**]%) of Net Sales of the relevant Licensed Product in the relevant Calendar Quarter;

in each case to the extent consistent with Applicable Law.

All deductions shall only be allowable to the extent they are commercially reasonable and shall be determined, on a Jurisdiction-by-Jurisdiction basis, as incurred in the ordinary course of business in type and amount consistent with Licensee's, its Affiliate's, or a Sublicensee's (as the case may be) business practices consistently applied across its product lines and accounting standards. Any of the

deductions listed above that involves a payment by Licensee, its Affiliates or its or their Sublicensees shall be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity; *provided, however*, that, if the accrued amount with respect to such deduction is determined in a subsequent Calendar Quarter to have been greater than the actual amount of such deduction, the amount over-accrued shall be included in Net Sales in such subsequent Calendar Quarter. For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when billed or invoiced and a sale shall not include transfers or dispositions of such Licensed Product for pre-clinical or clinical purposes or provided in good faith as samples or through patient assistance programs, in each case, without charge. Licensee's, its Affiliates' or its or their Sublicensees' transfer of any Licensed Product to an Affiliate or Sublicensee shall not result in any Net Sales, unless such Licensed Product is consumed or administered by such Affiliate or Sublicensee in the course of its commercial activities, provided that the first sale to a Third Party thereafter is included in Net Sales. With respect to any unit of Licensed Product that is consumed or administered by Licensee or its Affiliates or its or their Sublicensees, Net Sales shall include the greater of (A) any amount billed or invoiced with respect to such consumption or administration, including any services provided directly in connection therewith or (B) the average per-unit Net Sales of such Licensed Product in the relevant Jurisdiction in the relevant Calendar Quarter.

In the event that a Licensed Product is sold in the form of a Combination Product, the Parties will discuss in good faith a proper methodology for adjusting Net Sales of such Combination Product.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among the relevant products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Licensee's, its Affiliates' or its or their Sublicensees' existing allocation method; *provided* that any such allocation to a Licensed Product shall be: (i) done in accordance with Applicable Law, including any price reporting laws, rules and regulations and (ii) subject to clause (i), in no event no greater than a pro rata allocation, such that the portion of each of the foregoing rebates, discounts and other forms of reimbursements shall not be included as deductions from Invoiced Sales hereunder in any amount greater than the proportion of the number of units of such Licensed Product sold by Licensee, its Affiliates or its or their Sublicensees to Third Parties hereunder compared to the number of units of all the products sold by Licensee, such Affiliates and such Sublicensees to Third Parties to which such foregoing rebate, discount or other form of reimbursement, as applicable, are granted.

If a Licensed Product is sold or otherwise commercially disposed of for consideration other than cash or in a transaction that is not at arm's length between the buyer and the seller, then the gross amount to be included in the calculation of Net Sales shall be the amount that would have been invoiced had the transaction been conducted at arm's length and for cash. Such amount that would have been invoiced shall be determined, wherever possible, by reference to the average selling price of the relevant Licensed Product in arm's length transactions in the relevant Jurisdiction in the relevant Calendar Quarter.

Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Licensee, its Affiliates or its or their Sublicensees, which must be in accordance with GAAP.

Non-Breaching Party has the meaning set forth in Clause 10.2(a) (Material Breach).

Notice Period has the meaning set forth in Clause 10.2(a) (Material Breach).

Party and Parties has the meaning set forth in the preamble hereto.

Patents means:

- (a) all national, regional and international patents and patent applications, including provisional patent applications;
- (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications;
- (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, invention patents and design patents and certificates of invention;
- (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)); and
- (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

Payment has the meaning set forth in Clause 5.6(a) (General).

Person means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a Governmental Authority.

Phase 3 Clinical Trial means a controlled clinical trial, or a portion of a controlled clinical trial, in humans of the efficacy and safety of a pharmaceutical product, which study (in its entirety or such portion, as applicable) is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a manner sufficient to file a Drug Approval Application, as described in Federal Regulation 21 C.F.R. §312.21(c) and its foreign equivalents. For the sake of clarity, with respect to what is commonly called a phase 2/3 trial, the Phase 3 Clinical Trial definition is met upon the FPFV in the portion of such study that is prospectively designed to demonstrate statistically whether such pharmaceutical product is effective and safe for use in a manner sufficient to file a Drug Approval Application, as described in Federal Regulation 21 C.F.R. §312.21(c) and its foreign equivalents. If a clinical trial does not constitute a Phase 3 Clinical Trial at the time of FPFV, but is later determined by the applicable Regulatory Authority to be sufficient to form the primary basis of an efficacy claim in a Drug Approval Application, then, such clinical trial shall be deemed to constitute a Phase 3 Clinical Trial, and the FPFV of such Phase 3 Clinical Trial shall be deemed to occur, on the date of such determination by the applicable Regulatory Authority.

Post-Approval Research means ongoing research and development of a Licensed Product after such Licensed Product has received Regulatory Approval in the Territory, including phase IV clinical studies and clinical studies in support of indications within the Field or labeling changes for such Licensed Product within the Field in the Territory during the Term.

Prior CDA has the meaning set forth in Clause 7.1 (Confidentiality Obligations).

Product Trademarks means the Trademark(s) used or to be used by Licensee or its Affiliates or its or their Sublicensees for the Commercialization of Licensed Products in the Field in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any Corporate Names and any Trademarks that consist of or include any corporate name or corporate logo of the Parties or their Affiliates or its or their (sub)licensees (or Sublicensees)).

Prohibited Payment has the meaning set forth in Clause 8.6 (Anti-Bribery and Anti-Corruption Compliance).

Prosecuting Party has the meaning set forth in Clause 6.2(a) (In General).

Quality Assurance Agreement has meaning set forth in Clause 3.5(c) (Quality Assurance Agreement).

Regulatory Approval means, with respect to a Jurisdiction in the Territory, any and all approvals (including Drug Approval Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a pharmaceutical product in such Jurisdiction, including, where applicable, (a) pricing or reimbursement approval (**Reimbursement Approval**) in such Jurisdiction, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) labeling approval.

Regulatory Authority means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other Governmental Authority regulating or otherwise exercising authority with respect to the Exploitation of any compound or pharmaceutical product, including the CFDA.

Regulatory Documentation means: all (a) applications (including all INDs, CTAs, Drug Registration Application and Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (c) clinical and other data contained or relied upon in any of the foregoing; in each case ((a), (b) and (c)) relating to the Licensed Compound or a Licensed Product.

Regulatory Exclusivity Period means, with respect to each Licensed Product in any Jurisdiction in the Territory, any period of data, market or other regulatory exclusivity (other than Patent exclusivity) granted or afforded by Applicable Law or by a Regulatory Authority in such Jurisdiction that confers exclusive marketing rights with respect to such Licensed Product in such Jurisdiction or prevents another Person from using or otherwise relying on any data supporting the approval of the Drug Approval Application with respect to such Licensed Product in such Jurisdiction without the prior written consent of the Drug Approval Application-holder, as applicable.

Representatives has the meaning set forth in Clause 7.1 (Confidentiality Obligations).

Retained Rights means, with respect to the Licensed Compound and Licensed Products, the rights of Nabriva, its Affiliates and its and their licensors, (sub)licensees and contractors to:

- (a) perform its and their obligations and exercise its and their rights under this Agreement;

- (b) Manufacture and research the Licensed Compound or any Licensed Product anywhere in the world solely for Exploitation outside the Territory; and
- (c) Develop and otherwise use the Licensed Compound or Licensed Products for Exploitation outside the Territory.

Royalty Term means, with respect to each Licensed Product and each Jurisdiction in the Territory, the period beginning on the date of the first sale of such Licensed Product in such Jurisdiction (other than sales, for no charge, of Licensed Products as “treatment IND sales,” “named patient sales,” or “compassionate use sales”) and ending on the latest to occur of:

- (a) the expiration of the last-to-expire Valid Claim in any Nabriva Patent or Joint Patent in such Jurisdiction that that claims or covers (i) such Licensed Product, or its composition of matter, (ii) the Licensed Compound included in such Licensed Product as a composition of matter, or a method of treatment or other use of such Licensed Compound for any indication in the Field, or (iii) a method of use of or a method of Manufacturing such Licensed Product;
- (b) the expiration of the Regulatory Exclusivity Period in such Jurisdiction for such Licensed Product; and
- (c) the tenth (10th) anniversary of the First Commercial Sale of such Licensed Product in such Jurisdiction.

Second Notice has the meaning set forth in Clause 3.1(c) (Specific Diligence Breach).

Senior Officer means, with respect to Nabriva, its Chief Executive Officer, and, with respect to Licensee, its Chief Executive Officer.

Sublicensee means a Person, other than an Affiliate, that is granted a sublicense, directly or indirectly, by Licensee or its Affiliate under the grants in Clause 2.1 (Grants to Licensee), as provided in Clause 2.3 (Sublicenses).

Supply Agreement means the Clinical Supply Agreement (and any related Quality Assurance Agreement) or the Commercial Supply Agreement (and any related Quality Assurance Agreement).

Term has the meaning set forth in Clause 10.1 (Term and Expiration).

Termination Notice has the meaning set forth in Clause 10.2(a) (Material Breach).

Territory means any or all (as applicable) of the following: the People’s Republic of China, the Hong Kong Special Administrative Region of the People’s Republic of China, the Macau Special Administrative Region of the People’s Republic of China, and Taiwan, each of which shall be considered a Jurisdiction in the Territory for purposes of this Agreement.

Third Party means any Person other than Nabriva, Licensee and their respective Affiliates.

Third Party Claims has the meaning set forth in Clause 9.1 (Indemnification of Nabriva).

Third Party Infringement Claim has the meaning set forth in Clause 6.4 (Infringement Claims by Third Parties).

Third Party Patent Right has the meaning set forth in Clause 6.6 (Third Party Patent Rights).

Trademark means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration right, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source, origin or quality, whether or not registered, and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

Valid Claim means (a) a claim of any issued and unexpired Patent whose validity, enforceability or patentability has not been affected by (i) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (ii) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, Governmental Authority, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal or (b) a claim of a pending Patent application that was filed and is being prosecuted in good faith, has been pending for no more than five (5) years, and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.

VAT has the meaning set forth in Clause 5.6(b) (Value Added Tax).

Voting Stock has the meaning set forth in the definition of **Change of Control**.

2. GRANT OF RIGHTS

2.1 Grants to Licensee

Subject to Clauses 2.3 (Sublicenses) and 2.5 (Retention of Rights; Limitations Applicable to License Grants) and the other terms and conditions of this Agreement, Nabriva and NTGmbH hereby grant to Licensee (a) an exclusive (including with regard to Nabriva and its Affiliates) license, with the right to grant multiple tiers of sublicenses in accordance with Clause 2.3 (Sublicenses), under the Nabriva Patents, the Nabriva Know-How, and Nabriva's interests in the Joint Intellectual Property, to Develop and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory; *provided, however*, that Licensee may not co-formulate or co-package the Licensed Compound with any other Active Pharmaceutical Ingredient without Nabriva's prior written consent; and (b) a non-exclusive license, with the right to grant multiple tiers of sublicenses in accordance with Clause 2.3 (Sublicenses), under the Nabriva Patents, the Nabriva Know-How, and Nabriva's interests in the Joint Intellectual Property to Manufacture Lefamulin Materials (other than (i) the Active Pharmaceutical Ingredient of the Licensed Compound or (ii) except as set forth in the relevant Supply Agreement, any other Lefamulin Materials supplied by Nabriva to Licensee) in the Territory, solely for the Development and Commercialization of the Licensed Compound and Licensed Products in the Field in the Territory.

2.2 Grants to Nabriva

Licensee hereby grants to Nabriva an exclusive (including with regard to Licensee and its Affiliates), royalty-free, perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under the Licensee Patents, the Licensee Know-How, and Licensee's interests in the Joint Intellectual Property, to Exploit the Licensed Compound, Licensed Product(s) or any product containing the Licensed Compound, and any Improvements thereto, *mutatis mutandis*, (a) outside the Territory, or (b) for purposes of performing or exercising the Retained Rights.

Licensee hereby grants to Nabriva a non-exclusive (subject to Clause 10.3(d)), royalty-free, perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under the Licensee Patents, the Licensee Know-How and Licensee's interests in the Joint Intellectual Property to Exploit any products, systems, or methods claimed in the Licensee Patents or the Joint Intellectual Property other than the Licensed Product or Licensed Compound.

Licensee hereby grants to Nabriva (a) an exclusive, royalty-free, perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under the Licensee Patents, the Licensee Know-How, and Licensee's interests in the Joint Intellectual Property to Manufacture the Active Pharmaceutical Ingredient of the Licensed Compound in the Territory and (b) a non-exclusive, royalty-free, perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under the Licensee Patents, the Licensee Know-How, and Licensee's interests in the Joint Intellectual Property to Manufacture the Licensed Product or Lefamulin Materials (other than the Active Pharmaceutical Ingredient of the Licensed Compound) in the Territory.

2.3 Sublicenses

Licensee shall have the right to grant sublicenses, through multiple tiers of sublicensees, under the licenses granted in Clause 2.1 (Grants to Licensee), to its Affiliates and other Persons; *provided* that any such sublicenses shall be: (a) subject to the prior written consent of Nabriva if granted to a Person other than an Affiliate of the Licensee, which consent shall not be unreasonably withheld, conditioned or delayed; (b) subject to the prior written consent of any applicable Third Party licensor as required under any In-License Agreement; and (c) consistent with, and expressly made subject to, the terms and conditions of this Agreement and the In-License Agreements. Licensee shall cause each Affiliate and Sublicensee to comply with the applicable terms and conditions of this Agreement and the In-License Agreements, as if such Affiliate or Sublicensee were a Party to this Agreement.

2.4 Rights of Reference

Solely to the extent Regulatory Authorities in the Territory are permitted, under Applicable Law, to utilize Regulatory Documentation submitted to Regulatory Authorities outside of the Territory:

- (a) Nabriva hereby grants to Licensee and its Sublicensees a Right of Reference and Use, as that term is defined in 21 C.F.R. § 314.3(b) and any foreign counterpart to such regulation, to all Nabriva Regulatory Documentation and the Nabriva Development Data to the extent necessary or reasonably useful to Develop, obtain Regulatory Approval of, or Commercialize the Licensed Compound or Licensed Products in the Field in the Territory, in each case, pursuant to the Development Plan or Commercialization Plan and otherwise subject to the terms and conditions of this Agreement.
- (b) Without any additional consideration to Licensee, Licensee hereby grants to Nabriva and its Affiliates, and any current or future direct or indirect (sub)licensee of Nabriva with respect to the Licensed Compound or a Licensed Product, a Right of Reference and Use to the Licensee Development Data to the extent (i) necessary or useful to Exploit the Licensed Compound, Licensed Product(s) or any product containing the Licensed Compound, and any Improvements thereto, outside of the Territory, or (ii) in support of Development, Manufacturing, Regulatory Approval, or Commercialization of the Licensed Compound, Licensed Product(s) or any product containing the Licensed Compound, and any Improvements thereto, outside of the Territory.

- (c) Each Party will provide a signed statement to this effect, if requested by the other Party, 21 C.F.R. § 314.50(g)(3) or any foreign counterpart to such regulation, in the case of a request by either Party, for the limited purpose described in this Clause 2.4 (Rights of Reference).
- (d) In the event that Licensee discontinues Development of any Licensed Product in the Territory, then Licensee shall return all Nabriva Development Data and Nabriva Regulatory Documentation to Nabriva as well as transfer to Nabriva any Licensee Development Data related to the discontinued Licensed Product.
- (e) Other than as expressly set forth in Clauses 2.4(c) and (d), nothing in this Clause 2.4 shall require either Party to take, or forbear to take, any action.
- (f) Any information of a Party to which the other Party obtains access pursuant to this Clause 2.4 shall, subject to Clauses 7.1(a)-(e) (Confidentiality Obligations - subclauses (a)-(e)), be deemed the Confidential Information of such first Party. For avoidance of doubt, Licensee's submission of useful or necessary information to CFDA shall be governed by and subject to the terms of Clause 7 (CONFIDENTIALITY AND NON-DISCLOSURE).

2.5 Retention of Rights; Limitations Applicable to License Grants

(a) Retained Rights of Nabriva

Notwithstanding anything to the contrary in this Agreement and without limitation of any rights granted or reserved to Nabriva pursuant to any other term or condition of this Agreement, Nabriva hereby expressly retains, on behalf of itself and its Affiliates (and on behalf of its and their direct and indirect Third Party licensors under any In-License Agreement, (sub)licensees and contractors) all right, title and interest in and to the Nabriva Patents, the Nabriva Know-How, Nabriva Development Data, Nabriva's interests in and to Joint Patents and Joint Know-How, Nabriva Regulatory Documentation and Nabriva's Corporate Names, in each case, for purposes of performing or exercising the Retained Rights.

(b) In-License Agreements

- (i) If Nabriva or any of its Affiliates enters into an In-License Agreement, then Nabriva shall promptly notify Licensee, identifying the relevant Third Party's Patents or Information. The applicable Third Party's Patents or Information shall be included in the license granted to Licensee under Clause 2.1 (Grants to Licensee) and considered Nabriva Patents or Nabriva Know-How hereunder only if Nabriva discloses the substantive terms of the applicable license agreement to Licensee, which Nabriva hereby agrees to do, and Licensee agrees in writing to (A) comply with all the relevant obligations of such In-License Agreement, and (B) pay all milestones, royalties and other payments applicable to the Development, Manufacture or Commercialization of the Licensed Compound or any Licensed Product in the Field in the Territory; *provided, however*, that, solely with respect to the Manufacture of the Licensed Compound or any Licensed Product in the Field in the Territory, Licensee will only be responsible for milestones, royalties and other payments directly attributable to the Manufacture of the Licensed Compound or any Licensed Product in the Field in the Territory by Licensee or any of its Affiliates or any Sublicensees.
- (ii) Subject to this Clause 2.5(b) (In-License Agreements), the licenses granted by Nabriva in Clause 2.1 (Grants to Licensee) include sublicenses solely under the applicable license rights granted to Nabriva or, subject to Clause 11.3(b) (Assignment - subclause (b)), any of its Affiliates by Third Parties under the In-License Agreements. Any sublicense with respect to

Information or Patents of a Third Party hereunder and any right of Licensee (if any) to grant a further sublicense thereunder, shall be subject and subordinate to the terms and conditions of the In-License Agreement under which such sublicense is granted and shall be effective solely to the extent permitted under the terms of such agreement. Without limitation of the foregoing, in the event and to the extent that any In-License Agreement requires that particular terms or conditions of such In-License Agreement be contained or incorporated in any agreement granting a sublicense thereunder, such terms and conditions are hereby deemed to be incorporated herein by reference and made applicable to the sublicense granted herein under such In-License Agreement.

- (iii) The Parties shall cooperate with each other in good faith to support each other in complying with Nabriva's and its Affiliate's obligations under each In-License Agreement. Without limitation to the foregoing, (A) the Parties shall, from time to time, upon the reasonable request of either Party, discuss the terms of an In-License Agreement and agree upon, to the extent reasonably possible, a consistent interpretation of the terms of such In-License Agreement in order to, as fully as possible, allow Nabriva and its Affiliates to comply with the terms of such In-License Agreement; (B) to the extent there is a conflict between any terms of this Agreement and any terms of any In-License Agreement (including with respect to sublicensing rights, diligence obligations, prosecution, maintenance, enforcement, defense, any obligations for a counterparty to such In-License Agreement to maintain a Party's information as confidential and any obligations for a Party to maintain as confidential the information of a counterparty to such In-License Agreement), the terms of such In-License Agreement shall control with respect to the relevant Information, Patents or other rights granted to Licensee hereunder; and (C) Licensee and its Affiliates and Sublicensees shall comply with any applicable reporting and other requirements under the In-License Agreements, and the provisions regarding currency conversion, international payments and late payments, and any other relevant definitions and provisions, of the relevant In-License Agreements shall apply to the calculation of the payments due under the relevant In-License Agreements.
- (iv) On an In-License Agreement-by-In-License Agreement basis, from and after the date on which Licensee agrees in writing to (A) comply with all the relevant obligations of such In-License Agreement, and (B) pay all milestones, royalties and other payments applicable to the Development or Commercialization of the Licensed Compound or any Licensed Product in the Field in the Territory under such In-License Agreement (if any), Nabriva shall not enter into any subsequent agreement with any other party to such In-License Agreement that modifies or amends such In-License Agreement in any way that would materially adversely affect Licensee's rights or interest under this Agreement without Licensee's prior written consent, which shall not be unreasonably withheld, and shall provide Licensee with a copy of all modifications to or amendments of such In-License Agreement, regardless of whether Licensee's consent was required with respect thereto.

(c) No Other Rights Granted by Nabriva

Except as expressly provided herein and without limiting the foregoing, Nabriva grants no other right or license, including any rights or licenses to the Nabriva Patents, the Nabriva Know-How, Nabriva Development Data, Nabriva's interest in the Joint Patents and the Joint Know-How, the Nabriva Regulatory Documentation, the Nabriva Corporate Names or any other Patent, Trademark or other intellectual property right not otherwise expressly granted herein. For clarity, no rights are granted to Licensee, or anyone acting with or through Licensee, to Manufacture the Active Pharmaceutical Ingredient of the Licensed Compound or any Licensed Product (or any other Lefamulin Materials supplied by Nabriva to Licensee), or to Develop or Commercialize the Licensed Compound or any Licensed Product for any use in or for animals.

(d) No Other Rights Granted by Licensee

Except as expressly provided herein, Licensee grants no other right or license, including any rights or licenses to the Licensee Patents, the Licensee Know-How, the Licensee Development Data Controlled by Licensee, Licensee's interest in the Joint Patents and the Joint Know-How, or any other Patent, Trademark or other intellectual property rights not otherwise expressly granted herein.

2.6 Territorial Restrictions

- (a) Licensee shall not, and shall not permit any of its Affiliates or any of its or their licensees, Sublicensees or distributors to, knowingly distribute, market, promote, offer for sale or sell the Licensed Products directly or indirectly (i) to any Person outside the Territory or (ii) to any Person in the Territory that Licensee or any of its Affiliates or any of its or their licensees, Sublicensees or distributors knows (A) is likely to distribute, market, promote, offer for sale or sell any Licensed Product for use outside the Territory or to assist another Person to do so, or (B) has directly or indirectly distributed, marketed, promoted, offered for sale or sold any Licensed Product for use outside the Territory or assisted another Person to do so. If Licensee or any of its Affiliates receives or becomes aware of the receipt by a licensee, Sublicensee or distributor of any orders for any Licensed Product for use outside the Territory, such Person shall refer such orders to Nabriva. Licensee shall cause its Affiliates and its and their licensees, Sublicensees and distributors to notify Nabriva of any receipt of any orders for any Licensed Product for use outside the Territory.
- (b) Solely to the extent inconsistent with the rights exclusively licensed to Licensee in accordance with Clause 2.1 (Grants to Licensee), and subject to Nabriva's right to perform or exercise the Retained Rights, (1) Nabriva shall not, and shall not permit any of its Affiliates or any of its or their licensees, sublicensees or distributors (each, a "**Nabriva Entity**") to, distribute, market, promote, offer for sale or sell the Licensed Products directly or indirectly (i) to any Person for use in the Field in the Territory, or (ii) to any Person outside the Territory that the applicable Nabriva Entity knows (A) is likely to distribute, market, promote, offer for sale or sell any Licensed Product for commercial use in the Field in the Territory or to assist another Person to do so, or (B) has directly or indirectly distributed, marketed, promoted, offered for sale or sold any Licensed Product for commercial use in the Field in the Territory or assisted another Person to do so; (2) if Nabriva or any of its Affiliates receives any orders for any Licensed Product for commercial use in the Field in the Territory, such Person shall refer such orders to Licensee and if Nabriva or any of its Affiliates becomes aware of the receipt by its (sub)licensee or distributor of any orders for any Licensed Product for commercial use in the Territory, Nabriva shall use reasonable efforts to have such Person refer such orders to Licensee; and (3) Nabriva shall cause its Affiliates to notify Licensee of any receipt of any orders for any Licensed Product for use in the Field in the Territory other than orders relating solely to the exercise by Nabriva of its Retained Rights in the Territory..

2.7 Non-Compete

During the Term of this Agreement, Licensee and its Sublicensees, shall not, and shall not enable or assist any Person that is not a Party to this Agreement to, Develop, Manufacture or Commercialize any product that is indicated or being Developed for CABP, ABSSSI or any other indication in the Field, other than the Licensed Compound and Licensed Products in accordance with this Agreement. Notwithstanding the foregoing, in the event that any of Licensee's Affiliates independently Develops, Manufactures, or Commercializes such product, any royalties, dividends, or other payments paid by Licensee to such an Affiliate shall not be construed as enabling or assisting such activities under this clause as long as Licensee otherwise complies with this Clause 2.7 (Non-Compete).

2.8 Section 365(n)

All rights and licenses granted under or pursuant to this Agreement by Licensee or Nabriva are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, and any similar law in the Territory, licenses of rights to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code or any similar law in the Territory. The Parties agree that the Parties, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any similar law in the Territory. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any similar law in the Territory, the Party that is not a party to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in their possession, will be promptly delivered to them (a) upon any such commencement of a bankruptcy proceeding upon their written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject party.

3. REGULATORY AND COMMERCIALIZATION ACTIVITIES

3.1 Development

(a) Development Plan

Promptly after the Effective Date, the Parties will agree on a Development Plan for each Licensed Product in the Field in the Territory through the JDC. The Licensee will conduct the Development of the Licensed Products according to the Development Plan. The Development Plan will include, among other things, the indications in the Field for which the Licensed Products are to be Developed and other exploratory indications in the Field for which the Licensed Products may be Developed, critical activities to be undertaken, certain timelines, go/no go decision points and relevant decision criteria and, only to the extent expressly agreed by Nabriva with respect to any responsibilities allocated to Nabriva, certain allocations of responsibilities between the Parties for the various activities to be undertaken under the Development Plan. The Development Plan will be focused on efficiently obtaining Regulatory Approval for Licensed Products in the Field in the Territory, while taking into consideration potential impacts on Development, Regulatory Approval or Commercialization of the Licensed Products other than in the Field in the Territory. During the Term, the Parties will review the Development Plan from time to time and will amend such Development Plan on an ongoing basis as necessary. The then-current Development Plan will at all times contain at least that level of detail and cover at least the same matters (to the extent applicable) as the original Development Plan for the Licensed Products. If Licensee or any of its Affiliates or any Sublicensee, intends to conduct any research, pre-clinical and other non-clinical testing, toxicology, formulation, or regulatory affairs with respect to the Licensed Compound or Licensed Products, it will first obtain approval for such activities from the JDC.

(b) Diligence

After the Effective Date, as between the Parties, Licensee shall be solely responsible for all aspects of the Development of the Licensed Products in the Field in the Territory. Without limitation of Clause 3.1(d) (Development Costs), Licensee shall use Commercially Reasonable Efforts to Develop, and obtain and maintain Regulatory Approvals for, Licensed Products for use in the Field in the Territory. Licensee will be solely responsible for all clinical development activities for the Licensed Products in the Field in the Territory in accordance with the Development Plan(s). Licensee will not have the right

to engage contract research organizations to handle any clinical development activities without the prior written consent from Nabriva (which consent shall not be unreasonably withheld).

As a part of diligence, Licensee agrees to use Commercially Reasonable Efforts to (i) [**], and (ii) [**]; *provided, however*, that if a [**], Licensee shall use Commercially Reasonable Efforts to [**].

(c) Specific Diligence Breach

Without limitation of Clause 3.1(b) (Diligence), if Licensee fails to (A) [**] or (B) [**], then Nabriva may provide written notice of its intent to terminate this Agreement, and Licensee will have [**] to provide to Nabriva any information reasonably demonstrating that Licensee is exercising Commercially Reasonable Efforts to Develop the Licensed Products in the Field in the Territory. If Nabriva notifies Licensee within [**] after receipt of such information that Nabriva in good faith believes that Licensee is not exercising such Commercially Reasonable Efforts (a **Second Notice**), then (i) if requested by Licensee within [**] after receipt of such Second Notice from Nabriva, the Senior Officers will meet within [**] to discuss each Party's views with respect thereto, and (ii) unless Licensee has, as applicable, [**] or [**] by the end of [**] after receipt of such Second Notice from Nabriva, then, in addition to any other rights or remedies available to Nabriva, Nabriva may terminate this Agreement immediately upon written notice to Licensee, and Licensee may not dispute such termination under Clause 11.5 (Governing Law and Dispute Resolution) or in any other manner. Licensee's agreement not to dispute termination will not prohibit Licensee from instituting arbitration in accordance with Clause 11.5 (Governing Law and Dispute Resolution) and will not alter any other rights or remedies to which Licensee may be entitled based on such termination other than the right to seek injunctive relief to prevent such termination. For clarity, the request for, and the meeting of, the Senior Officers described in clause (i) shall not extend the cure period set forth in clause (ii).

(d) Development Costs

Licensee shall be solely responsible for all costs and expenses in connection with the Development of, and obtaining and maintaining Regulatory Approvals for, the Licensed Products in the Field in the Territory. If multi-region clinical trials are conducted, Licensee shall be responsible for all direct clinical trial costs in the Territory and a pro rata portion of the indirect multi-region costs for such clinical trials outside of the Territory that are conducted by Nabriva, its Affiliates or any of its other (sub)licensees based on the number of patients enrolled in each region, not exceeding [**] percent ([**]%) of such total indirect costs.

(e) Development Records

Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, maintain, in good scientific manner, complete and accurate books and records pertaining to Development of Licensed Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall (i) be appropriate for patent and regulatory purposes, (ii) be in compliance with Applicable Law, (iii) properly reflect all work done and results achieved in the performance of its Development activities hereunder, (iv) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement and (v) be retained by Licensee for at least [**] years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. Nabriva shall have the right, during normal business hours and upon [**] prior written notice, to inspect and copy all such books and records maintained pursuant to this Clause 3.1(e) (Development Records); *provided* that Nabriva shall maintain such records and information disclosed therein in confidence to the extent set forth in Clause 7 (CONFIDENTIALITY AND NON-DISCLOSURE).

(f) Development Reports

Without limiting Clause 3.1(e) (Development Records), within [**] following the end of each Calendar Half-Year, Licensee shall provide the JDC with a detailed written report of such Development activities it has performed, or caused to be performed, since the preceding report, its Development activities in process and the future activities it expects to initiate during the following Calendar Half-Year period. Each such report shall contain sufficient detail to enable the JDC to assess Licensee's compliance with its obligations set forth in Clause 3.1(a) (Development Plan) and Clause 3.1(b) (Diligence), including:

- (i) Licensee's, or its Affiliates' or its or their Sublicensees' activities with respect to achieving Regulatory Approvals of Licensed Products in the Territory; and
- (ii) clinical study results and results of other Development activities.

3.2 Regulatory Activities

(a) Regulatory Approvals

Licensee shall have the responsibility, at its cost, and subject to the Retained Rights, except as otherwise expressly set forth in this Clause 3.2 (Regulatory Activities), and in accordance with this Agreement, to prepare, obtain and maintain Drug Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals and other submissions (including INDs and CTAs) and to conduct communications with the Regulatory Authorities, for Licensed Products in the Field in the Territory in its name.

(b) Regulatory Cooperation

Each Party shall use commercially reasonable efforts to timely communicate to the other Party all Nabriva Development Data and Nabriva Regulatory Documentation (with respect to Nabriva as the obligor) or Licensee Development Data and Licensee Regulatory Documentation (with respect to Licensee as the obligor). If the other Party reasonably requests additional information related to these material submissions, filings, notices or communications, the Party shall use commercially reasonable efforts to provide relevant documents. Following the Effective Date, Nabriva shall use commercially reasonable efforts to promptly provide Licensee with all currently existing Nabriva Development Data and Nabriva Regulatory Documentation obtained in connection with the Development of the Licensed Products outside the Territory. Licensee would bear the reasonable costs related to Nabriva's transferring the Nabriva Development Data and Nabriva Regulatory Documentation under the immediately preceding sentence, which shall not exceed [**] US dollars (\$[**]) in aggregation. For clarity, this Clause 3.2(b) (Regulatory Cooperation) does not apply to any transfer of Manufacturing information, which shall be required of Nabriva only as set forth in any relevant Supply Agreement.

(c) Recalls, Suspensions or Withdrawals

Licensee shall notify Nabriva promptly following its determination that any event, incident or circumstance has occurred that would reasonably be expected to result in the need for a recall, market suspension or market withdrawal of a Licensed Product in the Field in the Territory and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, Licensee shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal of a Licensed Product in the Field in the Territory; *provided* that prior to any implementation of such a recall, market suspension or market withdrawal, Licensee shall consult with Nabriva and shall consider Nabriva's comments in good faith.

If a recall, market suspension or market withdrawal of a Licensed Product in the Field in the Territory is mandated by a Regulatory Authority in the Territory, as between the Parties, Licensee shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law. For all recalls, market suspensions or market withdrawals undertaken pursuant to this Clause 3.2(c) (Recalls, Suspensions or Withdrawals), as between the Parties, Licensee shall be solely responsible for the execution thereof. Subject to Clause 9 (INDEMNITY), Licensee shall be responsible for all costs of any such recall, market suspension or market withdrawal.

(d) Pharmacovigilance Agreement; Global Safety Database

The Parties shall enter into a pharmacovigilance agreement promptly following the Effective Date providing for the terms pursuant to which (i) Nabriva shall establish, hold and maintain (at Nabriva's sole cost and expense) the global safety database for Licensed Products; (ii) Licensee shall timely, and shall ensure that its Affiliates and Sublicensees, provide Nabriva with information in the Control of Licensee, its Affiliates or Sublicensees as necessary for Nabriva to comply with its pharmacovigilance responsibilities outside the Territory, including, as applicable, any adverse drug experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. Sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States) with respect to any Licensed Product, including from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies and commercial experiences with a Licensed Product, in each case, in the form reasonably requested by Nabriva; (iii) Nabriva shall provide Licensee with access to data in such global safety database as necessary for Licensee to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any adverse drug experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States), from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies and commercial experiences with a Licensed Product.

(e) Regulatory Inspections

If any Regulatory Authority (i) contacts Licensee or any of its Affiliates or any Sublicensee with respect to the alleged improper Development, Manufacture or Commercialization of any Licensed Product, (ii) conducts, or gives notice of its intent to conduct, an inspection at Licensee's or its Affiliate's or a Sublicensee's facilities used in the Development or Manufacturing of Licensed Products, or (iii) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of Licensee or its Affiliates or a Sublicensee that could reasonably be expected to adversely affect any Development, Manufacture or Commercialization activities with respect to the Licensed Product in or outside of the Territory, then Licensee will promptly notify Nabriva of such contact, inspection or notice.

If any Regulatory Authority (I) contacts Nabriva or any of its Affiliates with respect to the alleged improper Manufacture of any Licensed Product that is provided by or on behalf of Nabriva to Licensee under this Agreement or any Supply Agreement, (II) conducts, or gives notice of its intent to conduct, an inspection at Nabriva's or its Affiliate's facilities used in the Manufacturing of Licensed Products provided by or on behalf of Nabriva to Licensee under this Agreement or any Supply Agreement, (III) contacts Nabriva or any of its Affiliates with respect to a material issue concerning the alleged improper Development or Commercialization of any Licensed Product that could reasonably be expected to materially adversely affect any Development or Commercialization activities with respect to the Licensed Product in the Field in the Territory, or (IV) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of Nabriva or its Affiliates that could reasonably be expected to materially adversely affect any Development or Commercialization activities with respect to the Licensed

Product in the Field in the Territory, then Nabriva will promptly notify Licensee of such contact, inspection or notice.

3.3 Commercialization

(a) Commercialization Plan

Licensee will prepare and provide to the JDC a Commercialization Plan for each Licensed Product in the Field in the Territory at least [**] in advance of the last JDC meeting occurring prior to Licensee's, any of its Affiliates' or any Sublicensee's, first filing for Drug Approval Application of a Licensed Product in the Territory, which Commercialization Plan shall be subject to the approval of the Parties through the JDC. Licensee will be solely responsible for and pay for all Commercialization activities with respect to the Licensed Products in the Field in the Territory, which activities shall be conducted in accordance with the Commercialization Plan.

(b) Diligence

As between the Parties, Licensee shall be solely responsible for Commercialization of the Licensed Products in the Field throughout the Territory at Licensee's own cost and expense. Licensee, upon Regulatory Approval with respect to a Licensed Product in a Jurisdiction in the Territory, shall use Commercially Reasonable Efforts to Commercialize such Licensed Product in such Jurisdiction.

(c) Commercialization Costs; Booking of Sales; Distribution

Licensee shall invoice and book sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute the Licensed Products in the Field in the Territory and perform or cause to be performed all related Commercialization services. Subject to Clause 3.2(c) (Recalls, Suspensions or Withdrawals), Licensee shall handle all returns, recalls or withdrawals, order processing, invoicing, collection, distribution and inventory management with respect to the Licensed Products in the Field in the Territory.

(d) Commercialization Records

Without limitation of Clause 5.9 (Audit), Licensee shall, and shall require its Affiliates and the Sublicensees to, maintain complete and accurate books and records pertaining to Commercialization of Licensed Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement and which shall be in compliance with Applicable Law and properly reflect all work done and results achieved in the performance of its Commercialization activities. Such records shall be retained by Licensee for at least [**] years after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. Nabriva shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such books and records maintained pursuant to this Clause 3.3(d) (Commercialization Records); *provided* that Nabriva shall maintain such records and information disclosed therein in confidence to the extent set forth in Clause 7 (CONFIDENTIALITY AND NON-DISCLOSURE).

(e) Commercialization Reports

Without limiting Clause 3.3(d) (Commercialization Records), within [**] following the end of each Calendar Half-Year, commencing upon Licensee's, any of its Affiliates' or any Sublicensee's first filing for Drug Approval Application of a Licensed Product in the Territory and thereafter, Licensee shall provide to the JDC with detailed written reports of such Commercialization activities it, any of its Affiliates or any Sublicensee has performed, or caused to be performed, since the preceding report

and the future activities it expects to initiate during the following twelve (12)-month period. Each such report shall contain sufficient detail to enable the JDC to assess Licensee's compliance with its obligations set forth in Clauses 3.3(a) (Commercialization Plan), 3.3(b) (Diligence) and 3.3(c) (Commercialization Costs; Booking of Sales; Distribution), including, in each case, Net Sales for such Licensed Product in the Territory.

3.4 Statements and Compliance with Applicable Law

Licensee shall and shall cause its Affiliates and Sublicensees to, comply with all Applicable Law with respect to the Exploitation of Licensed Products. Licensee shall avoid, and shall require and use commercially reasonable efforts to cause its Affiliates and Sublicensees, and its Affiliates' and its and their Sublicensees', employees, representatives, agents, and distributors, to avoid, taking or failing to take, any actions that Licensee, such Affiliates or Sublicensees know or reasonably should know would jeopardize the goodwill or reputation of Nabriva, any of its Affiliates, or the Licensed Products or any Trademark associated therewith. Without limitation to the foregoing, Licensee shall, and shall ensure that its Affiliates and Sublicensees shall, in all material respects conform their practices and procedures relating to the Commercialization of the Licensed Products and educating the medical community in the Territory with respect to the Licensed Products to any applicable industry association regulations, policies and guidelines, as the same may be amended from time to time, and Applicable Law.

3.5 Supply of Licensed Products

- (a) Nabriva will use commercially reasonable efforts to supply, pursuant to the Clinical Supply Agreement, Active Pharmaceutical Ingredient (or other Lefamulin Materials agreed by the Parties) for Licensed Products to Licensee for Manufacturing of Licensed Products for Development of Licensed Products in the Field in the Territory at a price of [**] percent ([**]%) of the Cost of Goods Sold. Nabriva will use commercially reasonable efforts to supply, pursuant to the Commercial Supply Agreement, Active Pharmaceutical Ingredient (or other Lefamulin Materials agreed by the Parties) for Licensed Products to Licensee for Manufacturing of Licensed Products for Commercialization of Licensed Products in the Field in the Territory at a price of [**] percent ([**]%) of the Cost of Goods Sold.
- (b) Starting within [**] after the Effective Date, the Parties will negotiate in good faith a clinical supply agreement based on the principles illustrated in this Agreement (the **Clinical Supply Agreement**), which agreement the Parties anticipate executing as soon as reasonably practicable after the start of such negotiations. Starting with the [**], the Parties will negotiate in good faith a commercial supply agreement based on the principles illustrated in this Agreement (the **Commercial Supply Agreement**), which agreement the Parties anticipate executing as soon as reasonably practicable after the start of such negotiations. As between the Parties, Nabriva will have the sole right and responsibility for Manufacturing (or having Manufactured) in or outside the Territory, and supplying to Licensee, the Active Pharmaceutical Ingredient (or other Lefamulin Materials agreed by the Parties) for Licensed Products for Licensee's, its Affiliates' and Sublicensees' Manufacturing, Development and Commercialization activities in the Field in the Territory in accordance with this Agreement; provided, however, that the Clinical Supply Agreement and Commercial Supply Agreement will include provisions to permit Licensee to source the Active Pharmaceutical Ingredient (or other Lefamulin Materials agreed by the Parties) for Licensed Products from a second supplier if Nabriva is unable or unwilling to supply such Active Pharmaceutical Ingredient (or other Lefamulin Materials agreed by the Parties) in the quantities reasonably required by Licensee.

(c) Quality Assurance Agreement

The Parties will use good faith efforts to enter into one or more agreement(s) governing the quality standards for supply under each Supply Agreement (the **Quality Assurance Agreement**) within [**] after execution of such Supply Agreement, or earlier if required by Applicable Law.

3.6 Transfer of Nabriva Know-How

Promptly after the [**] has been made available to Nabriva, Nabriva shall provide (a) the Nabriva Know-How (other than marketing research, strategy documents and any Manufacturing information) that, to Nabriva's Knowledge at such time, would be material or reasonably necessary to the Development of the Licensed Compound in the Territory and (b) the Nabriva Regulatory Documentation, preferably in electronic format, in each case that has not, as of such time, already been made available to Licensee or any of its Affiliates.

3.7 Subcontracting

Subject to Clause 2.3 (Sublicenses) and Clause 3.1(b) (Diligence), Licensee, any of its Affiliates or any Sublicensee may subcontract with a Third Party to perform any or all of its obligations hereunder (including by appointing one or more distributors); *provided* that (a) no such permitted subcontracting shall relieve Licensee, its Affiliates or any Sublicensee of any obligation hereunder (except to the extent satisfactorily performed by such subcontractor) or any liability and Licensee shall be and remain fully responsible and liable therefor and (b) the agreement pursuant to which Licensee, any of its Affiliates or any Sublicensee engages any Third Party subcontractor must (i) be consistent in all material respects with this Agreement, (ii) contain terms obligating such subcontractor to comply with the confidentiality, intellectual property and all other relevant provisions of this Agreement and (iii) contain terms obligating such subcontractor to permit Nabriva rights of inspection, access and audit substantially similar to those provided to Nabriva in this Agreement. Licensee shall ensure that each subcontractor accepts and complies with all of the applicable terms and conditions of this Agreement as if such permitted subcontractor were a Party to this Agreement. Licensee hereby waives any requirement that Nabriva exhaust any right, power or remedy, or proceed against any subcontractor for any obligation or performance under this Agreement prior to proceeding directly against Licensee. For clarity, nothing shall restrict Nabriva's right to exercise any of the Retained Rights or any other rights of Nabriva, or the performance of any obligation by Nabriva, through any of its Affiliates or any Third Party.

4. DEVELOPMENT COMMITTEE

4.1 Joint Development Committee

Within [**] after the Effective Date, the Parties shall establish a joint development committee (the **Joint Development Committee** or **JDC**), which shall consist of [**] representatives from each of the Parties, each with the requisite authority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JDC. From time to time, each Party may substitute one (1) or more of its representatives to the JDC on written notice to the other Party. Licensee shall select from its representatives the chairperson for the JDC, which chairperson may be changed from time to time, on written notice to Nabriva, and which chairperson shall have no greater authority than any other representative on the JDC. The JDC shall:

- (a) serve as a forum for discussing and supervising Development of the Licensed Compound and Licensed Products in the Field in the Territory, including by reviewing and approving Development Plans and any amendments thereto, and overseeing the conduct of the

Development activities as provided in Clause 3.1 (Development) (including as set forth in Development reports as provided in Clause 3.1(f) (Development Reports));

- (b) serve as a forum for discussing and supervising the Commercialization of Licensed Products in the Field in the Territory as provided in Clause 3.3 (Commercialization), including by establishing the Commercialization strategy for the Territory, reviewing and approving the Commercialization Plans and any amendments thereto, and overseeing the conduct of the Commercialization activities; and
- (c) perform such other functions as are expressly set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

4.2 General Provisions Applicable to the JDC

(a) Meetings and Minutes

The JDC shall meet every [**] (of which at least [**] shall be in person) or as otherwise agreed to by the Parties, with the location of any in-person meetings alternating between reasonable locations designated by Licensee and reasonable locations designated by Nabriva. Either Party shall have the right to call meetings on no less than [**] notice unless exigent circumstances require shorter notice. Each Party shall make all proposals for agenda items at least [**] in advance of the applicable meeting and shall provide all appropriate information with respect to such proposed items at least [**] in advance of the applicable meeting; *provided* that under exigent circumstances requiring input by the JDC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (which consent shall not be unreasonably withheld, conditioned or delayed). The chairperson of the JDC (or his or her designee) shall prepare and circulate the meeting agenda at least [**] in advance of the meeting, and shall prepare and circulate for review and approval of the Parties minutes of each meeting as promptly as possible after the meeting. The JDC representatives shall comment on the minutes, and the Parties shall agree on the finalized minutes of each meeting promptly, but in no event later than [**].

(b) Procedural Rules

The JDC shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the JDC shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Representatives of the Parties on the JDC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants; *provided, however*, that at least [**] shall be held in person. Representation by proxy shall be allowed. Subject to Clause 4.2(c) (Decision-Making), the JDC shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance. Alliance Managers or other employees or consultants of a Party who are not representatives of the Parties on the JDC may attend meetings of the JDC; *provided, however*, that such attendees shall not vote or otherwise participate in the decision-making process of the JDC. Each such attendee and each JDC representative shall be bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Clause 7 (CONFIDENTIALITY AND NON-DISCLOSURE).

(c) Decision-Making

Except for matters outside the jurisdiction and authority of the JDC (including as set forth in Clause 4.2(d) (Limitations on Authority)), if the JDC cannot, or does not, reach consensus on an issue, then such issue shall be resolved pursuant to Clause 11.5 (Governing Law and Dispute Resolution).

(d) Limitations on Authority

Without limitation to the foregoing, the Parties hereby agree that matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement or other subsequent agreements between the Parties, are outside the jurisdiction and authority of the JDC, including (i) amendment, modification or waiver of compliance with this Agreement, (which may only be amended or modified as provided in Clause 11.7 (Entire Agreement; Amendments) or compliance with which may only be waived as provided in Clause 11.10 (Waiver and Non-Exclusion of Remedies)) and (ii) such other matters as are reserved to the consent, approval, agreement or other decision-making authority of either or both Parties in this Agreement that are not required by this Agreement to be considered by the JDC prior to the exercise of such consent, approval or other decision-making authority.

(e) Alliance Managers

Each Party shall appoint a person(s) who shall oversee contact between the Parties for all matters between meetings of the JDC and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an **Alliance Manager**), which person(s) may be replaced at any time by notice in writing to the other Party. The Alliance Managers shall work together to manage and facilitate the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

(f) Discontinuation; Disbandment; Annual Reports

The JDC shall continue to exist until the first to occur of:

- (i) the Parties mutually agreeing to disband the JDC; and
- (ii) Nabriva providing to Licensee written notice of its intention to disband the JDC.

Upon the occurrence of any of the foregoing, (A) the JDC shall disband, have no further responsibilities or authority under this Agreement and will be considered dissolved by the Parties, and (B) any requirement of a Party to provide Information or other materials to the JDC shall be deemed a requirement to provide such Information or other materials to the other Party and any matters that are subject to the review or approval by the JDC hereunder shall be discussed by the Parties, with any Disputes to be resolved pursuant to Clause 11.5 (Governing Law and Dispute Resolution).

5. PAYMENTS AND RECORDS

5.1 Upfront Payment

In consideration of the rights granted by NTGmbH to Licensee hereunder, no later than [**] following the Effective Date, Licensee shall pay NTGmbH a non-refundable and non-creditable upfront amount equal to five million Dollars (\$5,000,000).

5.2 Milestones

As partial consideration for the rights granted to Licensee by the Nabriva Parties pursuant to Clause 2.1 (Grants to Licensee), Licensee will notify the Nabriva Parties of the following one-time milestone payments within [**] after the first occurrence of each of the following events (each, a **Milestone Event**). Nabriva or NTGmbH shall promptly invoice Licensee for the corresponding amount below, and Licensee shall pay to the Nabriva Parties (in such proportions as directed under Clause 5.5 (Mode of Payment; Offsets)) the following one-time milestone payments within [**] of receipt of such invoice.

Milestone Event	Milestone Payment
(i) [**]	[**]
(ii) [**]	[**]
(iii) [**]	[**]
(iv) Receipt of each subsequent Regulatory Approval (whether or not Reimbursement Approval is received) from the CFDA in each subsequent indication with respect to any Licensed Product	\$4,000,000 for each such Regulatory Approval
(v) First Calendar Year in which the aggregate annual Net Sales of all Licensed Products in the Territory exceed \$[**]	[**]
(vi) First Calendar Year in which the aggregate annual Net Sales of all Licensed Products in the Territory exceed \$[**]	[**]
(vii) First Calendar Year in which the aggregate annual Net Sales of all Licensed Products in the Territory exceed \$[**]	[**]
(viii) First Calendar Year in which the aggregate annual Net Sales of all Licensed Products in the Territory exceed \$[**]	[**]
(ix) First Calendar Year in which the aggregate annual Net Sales of all Licensed Products in the Territory exceed \$[**]	[**]

Once Licensee has made any particular milestone payment under this Clause 5.2 (Milestones), Licensee will not be obligated to make any payment with respect to the re-occurrence of the same Milestone Event; but, for clarity, the milestone payment in clause (iv) shall be due upon each achievement of such Milestone Event. If any two or more of the Milestone Events above occur in the same Calendar Year, both applicable milestone payments will be due to the Nabriva Parties (in such proportions as directed under Clause 5.5 (Mode of Payment; Offsets)). The above milestone payments shall be non-creditable and non-refundable.

5.3 Royalties

(a) Royalty Rate

As further consideration for the rights granted to Licensee by the Nabriva Parties hereunder, during the Royalty Term with respect to a Licensed Product in a Jurisdiction, on a Licensed Product-by-Licensed Product and Jurisdiction-by-Jurisdiction basis, Licensee shall pay to the Nabriva Parties (in such proportions as directed under Clause 5.5 (Mode of Payment; Offsets)) a royalty on Net Sales of such Licensed Product in such Jurisdiction in the Territory at a royalty rate of [**] percent ([**]%).

(b) Blended Royalty

Licensee acknowledges that (i) the Nabriva Know-How and the Information included in the Nabriva Regulatory Documentation licensed to Licensee are proprietary and valuable and that without the Licensee Know-How and such Information, Licensee would not be able to obtain and maintain Regulatory Approvals with respect to the Licensed Products, (ii) such Regulatory Approvals will allow Licensee to obtain and maintain regulatory exclusivity with respect to the Licensed Products in the Field in the Territory, (iii) access to the Licensee Know-How and the rights with respect to the Nabriva Regulatory Documentation will have provided Licensee with a competitive advantage in the marketplace beyond the exclusivity afforded by the Nabriva Patents and the regulatory exclusivity and (iv) the upfront payment and royalties set forth in Clauses 5.1 (Upfront Payment) and 5.3 (Royalties), respectively, are, in part, intended to compensate the Nabriva Parties for such exclusivity and such competitive advantage. The Parties and NTGmbH agree that the royalty rate set forth in Clause 5.3(a) (Royalty Rate) reflects an efficient and reasonable blended allocation of the value provided by the Nabriva Parties to Licensee.

(c) Royalty Term

Licensee shall have no obligation to pay any royalty with respect to Net Sales of any Licensed Product in any Jurisdiction after the Royalty Term for such Licensed Product in such Jurisdiction has expired. Upon termination of the Royalty Term with respect to a Licensed Product in any Jurisdiction, the license grants to Licensee in Clause 2.1 (Grants to Licensee), as applicable, with respect to such Licensed Product shall convert to non-exclusive and shall become fully paid-up with respect to such Jurisdiction.

(d) Reductions

(A) In the event that in any Jurisdiction in the Territory during the Royalty Term for a Licensed Product in a particular mode of administration, unit sales of all Generic Products of such Licensed Product in such mode of administration in such Jurisdiction in a Calendar Quarter are:

- (i) equal to or greater than [**] percent ([**]%) but less than [**] percent ([**]%) of the sum of unit sales of such Licensed Product and all such Generic Products in such Jurisdiction, then the royalty rate set forth in Clause 5.3(a) (Royalty Rate) with respect to such Licensed Product in such Jurisdiction in such Calendar Quarter shall be reduced by [**] percent ([**]%); or
- (ii) equal to or greater than [**] percent ([**]%) of the sum of unit sales of such Licensed Product and all such Generic Products in such Jurisdiction, then the royalty rate set forth in Clause 5.3(a) (Royalty Rate) with respect to such Licensed Product in such Jurisdiction in such Calendar Quarter shall be reduced by [**] percent ([**]%).

Unit sales shall be measured by IMS Health Data (or, in the absence of such data, an appropriate end user-level database mutually agreed by the Parties and NTGmbH).

(B) In the event that Clause 5.3(d)(A) does not apply, but, under Applicable Law, the royalty rate must be reduced in order to ensure enforceability of the royalty obligation once clause (a) of the Royalty Term ends with respect to a Licensed Product in a Jurisdiction, then the royalty with respect to such Licensed Product in such Jurisdiction shall be reduced by [**] percent ([**]%) from the rate set forth in Clause 5.3(a) (Royalty Rate).

(C) If Licensee, its Affiliates or Sublicensees, in their reasonable judgment, obtain a license from a Third Party under any issued patent of such Third Party that Licensee reasonably believes would be infringed by the making, use, import, offer for sale, or sale of any Licensed Product in the Field in any Jurisdiction in the Territory, then Licensee may deduct, from the royalty payment that would otherwise have been due to Nabriva on the Net Sales of such Licensed Product in the Field in such Jurisdiction in the Territory in any Calendar Quarter, an amount equal to [**] percent ([**]%) of the royalties paid by Licensee, its Affiliate or Sublicensee to such Third Party pursuant to such license for such Licensed Product in such Jurisdiction in such Calendar Quarter. The amounts that may be deducted in this section with respect to a given Licensed Product in a given Jurisdiction in a given Calendar Quarter may also include [**] percent ([**]%) of any royalties paid by Licensee, its Affiliates or Sublicensees under any In-License Agreement pursuant to Clause 2.5(b) (In-License Agreements) for such Licensed Product in such Jurisdiction in such Calendar Quarter.

(D) Notwithstanding anything to the contrary in this Clause 5.3(d) (Reductions), in no event shall any royalty payment payable to the Nabriva Parties for any Licensed Product in a Jurisdiction in a given Calendar Quarter be reduced, as a result of the payment reductions set forth in Clauses 5.3(d)(A), 5.3(d)(B), and 5.3(d)(C) above, in the aggregate, to less than [**] percent ([**]%) of the amount otherwise payable to the Nabriva Parties with respect to such Licensed Product in such Jurisdiction in such Calendar Quarter in accordance with Clause 5.3(a) (Royalty Rate).

5.4 Royalty Payments and Reports

Licensee shall calculate all amounts payable to the Nabriva Parties pursuant to Clause 5.3 (Royalties) at the end of each Calendar Quarter, which amounts shall be converted to Dollars, in accordance with Clause 5.5 (Mode of Payment; Offsets). Licensee shall pay to the Nabriva Parties the royalty amounts due with respect to a given Calendar Quarter within [**] after the end of such Calendar Quarter. Each payment of royalties due to the Nabriva Parties shall be accompanied by a statement specifying, on a Licensed Product-by-Licensed Product and Jurisdiction-by-Jurisdiction basis, the amount of Invoiced Sales, Net Sales and deductions taken to arrive at Net Sales attributable to each Licensed Product in each Jurisdiction in the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter. Without limiting the generality of the foregoing, Licensee shall require its Affiliates and Sublicensees to account for their Net Sales and to provide such reports with respect thereto, either directly to the Nabriva Parties or through Licensee, as if such sales were made by Licensee.

5.5 Mode of Payment; Offsets

All payments to the Nabriva Parties under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account(s) as the Nabriva Parties may from time to time designate by notice to Licensee. At least [**] prior to the date for payment of the first milestone payment under Clause 5.2 (Milestones), the Nabriva Parties shall issue a joint instruction to the Licensee specifying (a) the allocation of the milestone payments (described in Clause 5.2 (Milestones)) and the royalty

payments (described in Clause 5.3 (Royalties)) between the Nabriva Parties; and (b) the bank account(s) into which such amounts shall be deposited. Licensee shall make all payments described in Clause 5.2 (Milestones) and Clause 5.3 (Royalties) in accordance with such joint instruction (unless and until an updated joint instruction is received by the Licensee from the Nabriva Parties). If a joint instruction has not been received by the Licensee [**] prior to the due date for payment of any amount described in Clause 5.2 (Milestones) or Clause 5.3 (Royalties) of this Agreement, the Licensee shall pay such amount to the Nabriva Parties in equal proportions. The Nabriva Parties may issue an updated joint instruction to the Licensee at any time during the Term. Any such updated joint instruction shall take effect in respect of payments due [**] or more following receipt by the Licensee of the instruction. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), Licensee shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or Sublicensee's, as applicable, standard conversion methodology consistent with GAAP, subject to Clause 5.6(a) (General).

The Nabriva Parties may direct that all or any portion of any payments be paid to any of Nabriva's or NTGmbH's Affiliates (other than any Nabriva Party), so long as (a) such instruction does not result in adverse tax consequences to Licensee or (b) Nabriva or NTGmbH agrees in writing to promptly pay such adverse tax consequences, which may be accomplished through an offset or deduction from amounts due to the Nabriva Parties hereunder.

5.6 Taxes

(a) General

The milestones and royalties payable by Licensee to the Nabriva Parties pursuant to this Agreement (each, a **Payment**) shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. The applicable Nabriva Party shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from Payments and remitted by Licensee) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Licensee shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if a Nabriva Party is entitled to a reduction in the rate of, or the elimination of, applicable withholding tax, it may deliver to Licensee or the appropriate governmental authority (with the reasonable assistance of Licensee to the extent that this is reasonably required and is requested in writing) the documentation necessary to reduce or eliminate the withholding tax otherwise due, and Licensee shall apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that Licensee has received evidence of the Nabriva Party's delivery of all supporting documentation (and, if necessary, its receipt of appropriate governmental authorization) at least [**] prior to the time that the Payment to which such documentation and authorization apply is due. If, in accordance with the foregoing, Licensee withholds any amount, it shall pay to the Nabriva Party the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to the Nabriva Party proof of such payment within [**] following such payment. To the extent that amounts are so withheld, such amounts shall be treated for all purposes of this Agreement as having been paid to the Nabriva Party. The Parties and NTGmbH will cooperate with respect to all documentation required by any taxing authority or reasonably required by either Party or NTGmbH to secure a reduction in the rate of applicable withholding taxes. If (i) Licensee (A) had a duty to deduct, withhold and pay over any tax to any governmental authority in connection with any Payment it made to Nabriva or NTGmbH under this Agreement but (B) failed to so deduct, withhold and timely pay over all or any portion of such tax, and (ii) such tax or portion thereof is assessed against Nabriva or NTGmbH, then Licensee will indemnify and hold harmless the Nabriva Parties from and against any penalties imposed as a result thereof; provided, however, that no such indemnification shall be due from Licensee to the extent of

any such penalties imposed solely as a result of or in connection with Licensee's reliance on any Nabriva Party's claim for reduced or no withholding hereunder that has been finally determined to have been incorrect.

(b) Value Added Tax

Notwithstanding anything contained in Clause 5.6(a) (General), this Clause 5.6(b) (Value Added Tax) shall apply with respect to value added tax (VAT) and all applicable local surcharges. All Payments are exclusive of VAT and all local surcharges. No Payments shall be deducted for any VAT or local surcharge. If any VAT or local surcharge is chargeable in respect of any Payments, Licensee shall pay and bear the VAT and the local surcharge at the applicable rate in respect of any such Payments following the receipt of an invoice issued by NTGmbH or Nabriva, as applicable, illustrating the amounts of the Payments and applicable VAT and local surcharge(es) separately. Licensee shall make such VAT and local surcharge payments to the tax bureau timely in order to make the Payments by the due date of the Payments. Parties shall reasonably cooperate in accordance with Applicable Law to minimize indirect Taxes (such as VAT, sales tax, consumption tax and other similar taxes) in connection with this Agreement.

5.7 Interest on Late Payments

Except as expressly set forth herein, if any payment due to either Party or NTGmbH under this Agreement is not paid when due, then, in addition to any other rights and remedies available to such Party or NTGmbH under this Agreement, such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of the lesser of (a) [**] above the prime rate, as published in *The Wall Street Journal*, Eastern Edition, as adjusted from time to time on the first Business Day of each month or (b) the highest rate permitted under Applicable Law, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest. Any such interest payment that is itself such to withholding tax or VAT shall be subject to the provisions of Clause 5.6(a) (Taxes) or 5.6(b) (Value Added Tax), as applicable.

5.8 Financial Records

Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, keep complete and accurate financial books and records pertaining to the Development and Commercialization of Licensed Products hereunder, including books and records of Invoiced Sales and Net Sales of Licensed Products, in sufficient detail to calculate and verify all amounts payable hereunder. Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, retain such books and records until the later of (a) [**] after the end of the period to which such books and records pertain, (b) the expiration of the applicable tax statute of limitations (or any extensions thereof) and (c) for such period as may be required by Applicable Law.

5.9 Audit

At the request of a Nabriva Party, Licensee shall and shall cause its Affiliates and its and their Sublicensees to, permit such Nabriva Party or an independent auditor designated by such Nabriva Party and reasonably acceptable to Licensee, during regular business hours and upon at least [**] written notice, no more than [**] during the term and no more than [**] following termination of this Agreement, to audit the books and records maintained pursuant to Clause 5.8 (Financial Records) for a period dating back no more than [**], to ensure the accuracy of all reports and payments made hereunder. No period shall be audited more than once. The independent public accountant shall disclose to such Nabriva Party only (a) the accuracy of reports and the basis for royalty and other

payments made to the Nabriva Parties under this Agreement and (b) the difference, if any, in such reports or such reported and paid amounts from reports and amounts determined as a result of the audit. Except as provided below, the cost of this audit shall be borne by the applicable Nabriva Party, unless the audit reveals, with respect to a period, a variance of more than [**] percent ([**]%) from the reported amounts for such period, in which case Licensee shall bear the cost of the audit. If such audit concludes that (i) additional amounts were owed by Licensee, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Clause 5.7 (Interest on Late Payments) or (ii) excess payments were made by Licensee to a Nabriva Party, such Nabriva Party shall reimburse such excess payments (without interest), in either case ((i) or (ii)), within [**] after the date on which such audit is completed by a Nabriva Party.

5.10 Audit Dispute

In the event of a dispute with respect to any audit under Clause 5.9 (Audit), the applicable Nabriva Party and Licensee shall work in good faith to resolve the disagreement. If such Persons are unable to reach a mutually acceptable resolution of any such dispute within [**], the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each such Persons' certified public accountants or to such other Person as such Persons shall mutually agree (the **Auditor**). The decision of the Auditor shall be final and the costs of such audit as well as the initial audit shall be borne between such Persons in such manner as the Auditor shall determine. Not later than [**] after such decision and in accordance with such decision, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Clause 5.7 (Interest on Late Payments) or the applicable Nabriva Party shall reimburse the excess payments without interest, as applicable.

6. INTELLECTUAL PROPERTY

6.1 Ownership of Intellectual Property

(a) Ownership of Technology

Subject to Clause 6.1(b) (Ownership of Joint Patents and Joint Know-How), as between the Parties, each Party shall own and retain all right, title and interest in and to any and all:

- (i) Information, Improvements and other inventions that are conceived, discovered, developed, authored or otherwise made by or on behalf of such Party or its Affiliates or its or their (sub)licensees (or Sublicensee(s)), as applicable), under or in connection with this Agreement, whether or not patented or patentable, and any and all Patents and other intellectual property rights with respect thereto, except to the extent that any such Information or invention or any Patent or intellectual property rights with respect thereto, is Joint Know-How or Joint Patents; and
- (ii) other Information, inventions, Patents and other intellectual property rights that are owned by or otherwise licensed to (other than pursuant to the license grants set forth in Clauses 2.1 (Grants to Licensee), 2.2 (Grants to Nabriva), and 10.3 (Consequences of Termination)) such Party or its Affiliates or its or their (sub)licensees (or Sublicensees) (as applicable) outside of this Agreement;

provided, however, that this Clause 6.1(a) (Ownership of Technology) shall not require a Party to obtain ownership or Control of any Information, Improvement or other invention conceived, discovered, developed, authored or otherwise made by or on behalf of such Party or its Affiliates or its or their (sub)licensees (or Sublicensee(s)), as applicable), or any Patent or other intellectual property right with respect thereto.

(b) Ownership of Joint Patents and Joint Know-How

As between the Parties, each Party shall have an equal, undivided interest in any and all:

- (i) Information, Improvements and other inventions that are conceived, discovered, developed, authored or otherwise made jointly by or on behalf of Nabriva or, subject to Clause 11.3(b), its Affiliates, on the one hand, and Licensee or its Affiliates or its or their Sublicensees, on the other hand, in connection with the work conducted under or in connection with this Agreement, whether or not patented or patentable (the **Joint Know-How**); and
- (ii) Patents to the extent they claim the Information, Improvements and other inventions described in paragraph (i) (**Joint Patents**).

With respect to the Joint Patents and other intellectual property rights embedded in the Information, Improvements and other inventions described in paragraph (i) (together with Joint Know-How and Joint Patents, the **Joint Intellectual Property Rights**), each Party shall promptly disclose to the other Party in writing and shall cause its Affiliates, and Licensee shall cause its and their Sublicensees to so disclose, the discovery, development, making, authoring or conception of any Joint Know-How or Joint Patents. Subject to the licenses granted under Clauses 2.1 (Grants to Licensee), 2.2 (Grants to Nabriva), and 10.3 (Consequences of Termination), each Party shall have the right to Exploit, license, assign and otherwise transfer its rights in the Joint Intellectual Property Rights without a duty of seeking consent or accounting to the other Party.

(c) United States Law

The determination of whether Information, Improvements and other inventions are conceived, discovered, developed, authored or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States, irrespective of where or when such conception, discovery, development, authorship or making occurs. Each Party shall, and does hereby, assign, and shall cause its Affiliates and Licensee shall cause its and their Sublicensees to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Information, Improvements and other inventions as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the joint ownership provided for in Clause 6.1(b) (Ownership of Joint Patents and Joint Know-How).

(d) Assignment Obligation

Solely with respect to Patents and Information that would, if Controlled by Licensee or, subject to Clause 11.3(b) (Assignment - subclause (b)), any of its Affiliates, be Licensee Patents or Licensee Know-How, respectively: Licensee shall cause all Persons who perform Development activities, Manufacturing activities or regulatory activities for Licensee under this Agreement or who conceive, discover, develop, author or otherwise make any applicable Information, Improvement or other invention by or on behalf of Licensee or its Affiliates or its or their Sublicensees under or in connection with this Agreement to be under an obligation to assign (or, if Licensee is unable to cause such Person to agree to such assignment obligation despite Licensee's using commercially reasonable efforts to negotiate such assignment obligation, then to grant a license under, with Licensee Controlling) their rights in any applicable Information, Improvement and inventions resulting therefrom, and any Patent or intellectual property rights with respect thereto, to Licensee, except where Applicable Law requires otherwise and except in the case of Governmental Authorities, not-for-profit and public institutions that have standard policies against such an assignment (in which case, a suitable license or right to obtain or negotiate such a license, with Control, shall be obtained).

Solely with respect to Patents and Information that would, if Controlled by Nabriva or, subject to Clause 11.3(b) (Assignment - subclause (b)), any of its Affiliates, be Nabriva Patents or Nabriva Know-How, respectively (in each case subject to Clause 2.5(b) (In-License Agreements)): Nabriva shall use commercially reasonable efforts to cause all Persons who perform Development activities, Manufacturing activities or regulatory activities for Nabriva under this Agreement or who conceive, discover, develop, author or otherwise make any applicable Information, Improvement or other invention by or on behalf of Nabriva or its Affiliates or its or their sublicensees under or in connection with this Agreement to be under an obligation to assign to Nabriva their rights in any applicable Information, Improvement and inventions resulting therefrom, and any applicable Patent or intellectual property rights with respect thereto, or, if Nabriva is unable to cause such Person to agree to such assignment obligation despite Nabriva's using commercially reasonable efforts to negotiate such assignment obligation, then Nabriva shall use commercially reasonable efforts to cause such Persons to grant a royalty-free sublicenseable license under their rights in such applicable Information, Improvement or invention, and such applicable Patent or intellectual property right (which such license shall be an In-License Agreement subject to Clause 2.5(b) (In-License Agreements)), or, if Nabriva is unable to cause such Person to agree to such royalty-free license despite Nabriva's using commercially reasonable efforts to negotiate such licensee, then Nabriva shall use commercially reasonable efforts to cause such Persons to grant a royalty-bearing sublicenseable license under their rights in such applicable Information, Improvement or invention, and such Patent or intellectual property right (which such license shall be an In-License Agreement subject to Clause 2.5(b) (In-License Agreements)); in each case, except where Applicable Law requires otherwise and except in the case of Governmental Authorities, not-for-profit and public institutions that have standard policies against such an assignment (in which case, Nabriva shall use commercially reasonable efforts to obtain a suitable license or right to obtain or negotiate such a license, which such license shall be an In-License Agreement subject to Clause 2.5(b) (In-License Agreements)). Notwithstanding the above, if Nabriva is only able to cause such Persons to grant a royalty-bearing sublicenseable license under such Person's rights in an applicable Patent described in the preceding sentence, and (i) such applicable Patent is necessary for Licensee to exercise its Manufacturing license under Clause 2.1(b) and (ii) Licensee, its Affiliates, or Sublicensees are required to make any payments to such Persons under such license with respect to such Manufacturing in the Territory, Licensee will be entitled to deduct from the royalty payment that would otherwise have been due to Nabriva under Clause 5.3(a) (Royalty Rate), an amount equal to **[**]** percent (**[**]**%) of the amounts paid by Licensee, its Affiliates or Sublicensees to such Persons.

(e) Ownership of Product Trademarks

As between the Parties, Licensee shall own all right, title and interest to the Product Trademarks in the Territory, and all goodwill associated therewith will inure to the benefit of Licensee.

(f) Ownership of Corporate Names

As between the Parties, Nabriva shall retain all right, title and interest in and to its Corporate Names, and all goodwill associated therewith will inure to the benefit of Nabriva.

(g) Ownership of Development Data

Subject to the licenses granted under Clause 2 (GRANT OF RIGHTS) or Clause 10.3 (Consequences of Termination), as between the Parties, Licensee shall own the Licensee Development Data Controlled by Licensee and Nabriva shall own the Nabriva Development Data.

6.2 Maintenance and Prosecution of Patents

(a) In General

As between the Parties, subject to Clauses 6.2(c) (Patent Term Extension and Supplementary Protection Certificate) and 6.5 (Invalidity or Unenforceability Defenses or Actions),

- (i) Nabriva shall have the sole right, but not the obligation, through counsel of its choice at its discretion, to prepare and file the Nabriva Patents (and Nabriva will coordinate any such preparation and filing with Licensee), and the first right, but not the obligation, through counsel of its choice at its discretion, to prepare, file, prosecute and maintain Joint Patents outside the Territory, including any related invalidation, appeals of invalidation, interference, re-issuance, re-examination, patent term extension and opposition proceedings with respect thereto.
- (ii) Licensee shall have the first right, but not the obligation, to prosecute and maintain the Nabriva Patents in the Territory and to prepare, file, prosecute and maintain the Licensee Patents worldwide and the Joint Patents in the Territory, including any related invalidation, interference, re-issuance, re-examination, patent term extension and opposition proceedings with respect thereto, in each case, at its sole cost and expense and through counsel of its choice.
- (iii) For purposes of this Clause 6.2 (Maintenance and Prosecution of Patents), the Party prosecuting, maintaining or undertaking other related activities pursuant to clause (i) or (ii) with respect to a Patent shall be the **Prosecuting Party**. The Prosecuting Party shall periodically inform the other Party of all material steps with regard to the preparation, filing, prosecution and maintenance of the Nabriva Patents in the Territory and the Licensee Patents and Joint Patents worldwide, as applicable, including by providing the non-Prosecuting Party with a copy of material communications to and from any applicable patent authority regarding such Patents and by providing the non-Prosecuting Party drafts of any material filings or responses to be made to such patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for the non-Prosecuting Party to review and comment thereon. The Prosecuting Party shall consider in good faith the requests and suggestions of the non-Prosecuting Party with respect to such drafts and with respect to strategies for filing and prosecuting such Patents, including taking into consideration the commercial strategy of Licensee in the Territory. If the Prosecuting Party decides not to prosecute or maintain a Nabriva Patent in the Territory, or to prepare, file, prosecute or maintain a Licensee Patent or Joint Patent anywhere in the world, the Prosecuting Party shall provide reasonable prior written notice to the non-Prosecuting Party of such intention and the non-Prosecuting Party shall thereupon have the right, in its sole discretion, to assume the control and direction of the prosecution and maintenance of such Nabriva Patent, or the preparation, filing, prosecution and maintenance of such Licensee Patent or Joint Patent, at its sole cost and expense, whereupon the non-Prosecuting Party shall be deemed the Prosecuting Party with respect to such Patent.

(b) Co-operation

The non-Prosecuting Party shall, and shall cause its Affiliates to, assist and co-operate with the Prosecuting Party, as the Prosecuting Party may reasonably request from time to time, in the preparation, filing, prosecution and maintenance of the Nabriva Patents in the Territory and the Licensee Patents and Joint Patents worldwide under this Agreement, including that the non-Prosecuting Party shall, and shall ensure that its Affiliates, (i) offer its comments, if any, promptly, (ii) provide access to relevant documents and other evidence and make its employees available at

reasonable business hours and (iii) provide the Prosecuting Party, upon its request, with copies of any patentability search reports generated by its patent counsel with respect to such Nabriva Patents, Joint Patents or Licensee Patents, including relevant Third Party patents and patent applications located; *provided, however*, that neither Party shall be required to provide legally privileged information with respect to such intellectual property unless and until procedures reasonably acceptable to such Party are in place to protect such privilege; and *provided, further*, that the Prosecuting Party shall reimburse the non-Prosecuting Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Each Party will use reasonable efforts to make available to the other Party its authorized attorneys, agents or representatives, or such of its employees, in each case as are reasonably necessary to assist the other Party in exercising its rights described under this Clause 6.2 (Maintenance and Prosecution of Patents). Each Party will sign, or will use reasonable efforts to have signed, all legal documents as are reasonably necessary to prosecute and maintain Patents in accordance with this Clause 6.2 (Maintenance and Prosecution of Patents).

(c) Patent Term Extension and Supplementary Protection Certificate

The Parties shall jointly make decisions regarding the application for patent term extensions, or any other extensions that are now or become available in the future, in the Territory, for the Nabriva Patents, Joint Patents and any Licensee Patents, in each case with respect to the Licensed Compound and the Licensed Products, and in each case including whether or not to do so. Licensee shall provide prompt and reasonable assistance, as requested by Nabriva, including by taking such action as patent holder as is required under any Applicable Law to obtain such extensions or supplementary protection certificates. If under Applicable Law, Licensee may need to file such a mutually agreed patent term extension or supplementary protection certificate or equivalent thereof under its own name with respect to a Nabriva Patent, Joint Patent or Licensee Patent, then Nabriva shall promptly provide assistance to Licensee to enable such filing.

(d) Common Ownership Under Joint Research Agreements

Notwithstanding anything to the contrary in this Clause 6 (INTELLECTUAL PROPERTY), neither Party shall have the right to make an election under 35 U.S.C. 102(c) when exercising its rights under this Clause 6 (INTELLECTUAL PROPERTY) without the prior written consent of the other Party. With respect to any such permitted election, the Parties shall co-ordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. 100(h).

(e) Patent Listings

As between the Parties, Licensee shall have the sole right to make decisions regarding patent listings under the equivalents of the Hatch-Waxman Act in the Territory with respect to the Licensed Products in the Field and Licensee shall have the right to make all filings with respect thereto with Regulatory Authorities in the Territory with respect to the Nabriva Patents and Joint Patents or other international equivalents; *provided that* Licensee shall consult with Nabriva to determine the course of action with respect to such filings.

6.3 Enforcement of Patents

(a) Notice

Each Party shall promptly notify the other Party in writing of (i) any alleged or threatened infringement of the Nabriva Patents in the Territory or Joint Patents or Licensee Patents worldwide, in each case with respect to a product containing a Licensed Compound, or (ii) any certification, with respect to the

Nabriva Patents in the Territory or Joint Patents or Licensee Patents worldwide, that is similar to a Hatch-Waxman Act Certification in the US, in each case with respect to a product containing a Licensed Compound (each, an **Infringement**), in each case ((i) and (ii)) of which such Party becomes aware.

(b) Enforcement of Patents

As between the Parties, (i) the Parties shall coordinate with each other to prosecute any Infringement in the Territory with respect to the Nabriva Patents that claim the composition of matter of the Licensed Compound or any Licensed Product, including as a defense or counterclaim in connection with any Third Party Infringement Claim, and share the cost and expense; (ii) Nabriva shall have the first right, but not the obligation, to prosecute Infringement with respect to any other Nabriva Patents in the Territory or Joint Patents outside the Territory, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Nabriva's own cost and expenses, using counsel of its choice; (iii) Licensee shall have the first right, but not the obligation, to prosecute Infringement with respect to the Licensee Patents worldwide or Joint Patents in the Territory, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Licensee's sole cost and expense, using counsel of its choice, and any recovery realized as a result of such a prosecution action shall be subject to Clause 6.3(d) (Recovery). For purposes of this Clause 6.3 (Enforcement of Patents), the Party prosecuting any Infringement pursuant to the foregoing sentence with respect to a Patent shall be the **Enforcing Party**. In the event Nabriva prosecutes any such Infringement in the Field in the Territory pursuant to (ii) above, Licensee shall have the right to join as a party to such claim, suit or proceeding and participate with its own counsel at its sole cost and expense; *provided* that Nabriva shall retain control of the prosecution of such claim, suit or proceeding, including the response to any defense or defense of any counterclaim raised in connection therewith. In the event Licensee prosecutes any such Infringement pursuant to (iii) above, Nabriva shall have the right to join as a party to such claim, suit or proceeding and participate with its own counsel at its sole cost and expense; *provided* that Licensee shall retain control of the prosecution of such claim, suit or proceeding, including the response to any defense or defense of any counterclaim raised in connection therewith. If the Enforcing Party does not take commercially reasonable steps to prosecute an Infringement under (ii) or (iii) above (A) within [**] following the first notice provided above with respect to such Infringement or (B) [**] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then (i) the Enforcing Party shall so notify the non-Enforcing Party and (ii) the non-Enforcing Party may prosecute such alleged or threatened infringement at its sole cost and expense, whereupon the non-Enforcing Party shall be deemed the Enforcing Party with respect to such Infringement.

(c) Co-operation

The non-Enforcing Party agrees to co-operate fully in any Infringement action pursuant to this Clause 6.3 (Enforcement of Patents), including by making the inventors, applicable records and documents (including laboratory notebooks) with respect to the relevant Patents available to the Enforcing Party on the Enforcing Party's reasonable request. With respect to an action controlled by the applicable Enforcing Party, the other Party shall, and shall cause its Affiliates to, assist and co-operate with the Enforcing Party, as the Enforcing Party may reasonably request from time to time, in connection with its activities set forth in this Clause 6.3 (Enforcement of Patents), including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; *provided* that the Enforcing Party shall reimburse such other Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. Unless otherwise set forth herein, the Enforcing Party shall have the right to settle such claim; *provided* that neither Party shall have the right to settle any Infringement litigation

under this Clause 6.3 (Enforcement of Patents) in a manner that has a material adverse effect on the rights or interest of the other Party under this Agreement or with respect to any Nabriva Patent, Licensee Patent or Joint Patent, or in a manner that imposes any costs or liability on or involves any admission by the other Party, without the express written consent of such other Party (which consent shall not be unreasonably withheld, conditioned or delayed). In connection with any activities with respect to an Infringement action prosecuted by the applicable Enforcing Party pursuant to this Clause 6.3 (Enforcement of Patents) involving Patents jointly owned by, or licensed under Clause 2 (GRANT OF RIGHTS) to, the other Party, the Enforcing Party shall (i) consult with the other Party as to the strategy for the prosecution of such claim, suit or proceeding, (ii) consider in good faith any comments from the other Party with respect thereto and (iii) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such action.

(d) Recovery

Except as otherwise agreed by the Parties in connection with a cost-sharing arrangement, any recovery realized as a result of such litigation described above in this Clause 6.3 (Enforcement of Patents) (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses incurred with respect to such litigation (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Enforcing Party; *provided, however*, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to a Nabriva Patent or Joint Patent is attributable to loss of sales or profits with respect to a Licensed Product in the Field in the Territory, any amount that may be obtained by Licensee shall be considered Net Sales and subject to the royalty obligations under Clause 5.3 (Royalties).

6.4 Infringement Claims by Third Parties

If the Exploitation of a Licensed Product in the Field in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party against Licensee or any of its Affiliates or Sublicensees alleging infringement by Licensee or any of its Affiliates or its or their Sublicensees, distributors or customers (a **Third Party Infringement Claim**), including any defense or counterclaim in connection with an Infringement action initiated pursuant to Clause 6.3 (Enforcement of Patents), the Party first becoming aware of such alleged infringement shall promptly notify the other Party thereof in writing. As between the Parties, subject to Clause 9 (INDEMNITY), (a) Licensee shall be responsible for defending any such claim, suit or proceeding at its sole cost and expense, using counsel of Licensee's choice, (b) Nabriva may participate in any such claim, suit or proceeding with counsel of its choice at its sole cost and expense; *provided* that Licensee shall retain the right to control such claim, suit or proceeding, (c) Nabriva shall, and shall cause its Affiliates to, assist and co-operate with Licensee, as Licensee may reasonably request from time to time, in connection with its activities set forth in this Clause 6.4 (Infringement Claims by Third Parties), including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; *provided* that Licensee shall reimburse Nabriva for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith, (d) Licensee shall keep Nabriva reasonably informed of all material developments in connection with any such claim, suit or proceeding, (e) Licensee agrees to provide Nabriva with copies of all material pleadings filed in such action and to allow Nabriva reasonable opportunity to participate in the defense of the claims, and (f) any damages, or awards, including royalties, incurred or awarded in connection with any Third Party Infringement Claim defended under this Clause 6.4 (Infringement Claims by Third Parties) shall be borne by Licensee.

6.5 Invalidity or Unenforceability Defenses or Actions

Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Nabriva Patents in the Territory or Joint Patents or Licensee Patents worldwide, by a Third Party and of which such Party becomes aware. As between the Parties, (a) the Parties shall coordinate with each other to defend and control the defense of the validity and enforceability of the Nabriva Patents and the Joint Patents that claim the composition of matter of the Licensed Compound and Licensed Products in the Territory and share the cost and expense thereof, (b) Nabriva shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of any other Nabriva Patents in the Territory or Joint Patents outside the Territory, at its sole cost and expense, using counsel of Nabriva's choice; (c) Licensee shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensee Patents worldwide or Joint Patents in the Territory at its sole cost and expense, using counsel of Licensee's choice, including, in each case ((a), (b) and (c)), when such invalidity or unenforceability is raised as a defense or counterclaim in connection with an Infringement action initiated pursuant to Clause 6.3 (Enforcement of Patents). For purposes of this Clause 6.5 (Invalidity or Unenforceability Defenses or Actions), the Party defending and controlling the defense of the validity and enforceability pursuant to the foregoing sentence with respect to a Patent shall be the **Controlling Party**. With respect to any such claim, suit or proceeding in the Territory under clause (a), (b) or (c), the non-Controlling Party may participate in such claim, suit or proceeding with counsel of its choice at its sole cost and expense; *provided* that the Controlling Party shall retain control of the defense in such claim, suit or proceeding. If the Controlling Party elects not to defend the applicable Patents in a suit, then the Controlling Party shall notify the non-Controlling Party of such election at least [**] before the time limit, if any, set forth in Applicable Law for defending such actions, and the non-Controlling Party may assume control of the defense of any such claim, suit or proceeding at its sole cost and expense. The non-Controlling Party in such an action shall, and shall cause its Affiliates to, assist and co-operate with the Controlling Party, as such Controlling Party may reasonably request from time to time. in connection with its activities set forth in this Clause 6.5 (Invalidity or Unenforceability Defenses or Actions), including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; *provided* that the Controlling Party shall reimburse the non-Controlling Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith. In connection with any activities with respect to a defense, claim or counterclaim relating to the Nabriva Patents, Licensee Patents or Joint Patents jointly owned by, or licensed under Clause 2 (GRANT OF RIGHTS) to, the other Party pursuant to this Clause 6.5 (Invalidity or Unenforceability Defenses or Actions), the Controlling Party shall (i) consult with the non-Controlling Party as to the strategy for such activities, (ii) consider in good faith any comments from the non-Controlling Party and (iii) keep the non-Controlling Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense, claim or counterclaim.

6.6 Third Party Patent Rights

If, in the reasonable opinion of Licensee, the Exploitation of the Licensed Compound or Licensed Products in the Field and in the Territory by Licensee, any of its Affiliates or any of its or their Sublicensees or distributors or customers infringes or is reasonably expected to infringe any Patent of a Third Party in any Jurisdiction in the Territory (such right, a **Third Party Patent Right**), then Licensee shall have a right, but not the obligation, to negotiate and obtain a license from such Third Party to such Third Party Patent Right as necessary or desirable for Licensee or its Affiliates or its or their Sublicensees to Exploit the Licensed Compound and Licensed Products in the Field in such Jurisdiction; *provided* that (a) as between the Parties, Licensee shall bear all expenses incurred in connection therewith, including any royalties, milestones or other payments incurred under any such

license subject to Clause 5.3(d)(C) (Reductions - subsection (C)) and (b) any such license shall be limited to the Development or Commercialization of Licensed Products in the Field in the Territory (and Licensee must coordinate with Nabriva with respect to any such license with respect to Manufacturing of Licensed Products in the Field in the Territory) and provide for the unencumbered right, but not the obligation, to transfer such license to Nabriva or any of its Affiliates upon termination or expiration of this Agreement with respect to the applicable Jurisdiction(s).

6.7 Product Trademarks

(a) Notice

Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party, in each case, of which such Party becomes aware.

(b) Prosecution of Product Trademarks

Licensee shall be responsible for the registration, prosecution and maintenance of the Product Trademarks using counsel of its own choice. All costs and expenses of registering, prosecuting and maintaining the Product Trademarks shall be borne solely by Licensee.

(c) Enforcement of Product Trademarks

Licensee shall have the sole right to take such action as Licensee deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party in the Territory at its sole cost and expense and using counsel of its own choice. Licensee shall retain any damages or other amounts collected in connection therewith.

(d) Nabriva Product Trademarks

If Licensee wishes to obtain a license under Nabriva Product Trademarks to use such Trademarks with respect to the Commercialization of the Licensed Products in the Field in the Territory, Licensee shall notify Nabriva thereof and the Parties shall negotiate a license with respect thereto.

7. CONFIDENTIALITY AND NON-DISCLOSURE

7.1 Confidentiality Obligations

At all times during the Term and for a period of [**] following termination or expiration of this Agreement in its entirety, each Party shall, and shall cause its Affiliates and its and their respective officers, directors, employees and agents (collectively, **Representatives** of such Party) to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. **Confidential Information** means any technical, business or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, on or after the Effective Date, including the terms of this Agreement (subject to Clause 7.2 (Permitted Disclosures), Clause 7.4 (Public Announcements) and Clause 7.5 (Publications)), information relating to the Licensed Compound or any Licensed Product (including any clinical data and Regulatory Documentation), any Information relating to the Development or Commercialization of the Licensed

Compound or any Licensed Product developed by or on behalf of the disclosing Party or its Affiliates (including Licensee Know-How and Nabriwa Know-How, as applicable) or the scientific, regulatory or business affairs or other activities of either Party. In addition, Confidential Information means any information of the disclosing Party that, as of the Effective Date, is considered "Confidential Information" under the Mutual Confidential Disclosure Agreement between Nabriwa and Parent dated as of October 4, 2017 (the **Prior CDA**) and not subject to Section 4 of the Prior CDA. Notwithstanding the foregoing, Joint Know-How and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Clause 7.1 (Confidentiality Obligations), and **Confidential Information**, shall not include any information that:

- (a) is or hereafter becomes part of the public domain or publicly known by public use, publication, general knowledge or the like through no breach of the Prior CDA or this Agreement by the receiving Party or any of its Representatives;
- (b) can be demonstrated by documentation or other competent proof to have been in the receiving Party's or any of its Affiliates' possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information; *provided* that the foregoing exception shall not apply with respect to Joint Know-How or the terms of this Agreement;
- (c) is subsequently received by the receiving Party or any of its Affiliates from a Third Party who is not bound by any obligation of confidentiality with respect to such information;
- (d) has been published by a Third Party or otherwise enters the public domain or becomes publicly known through no fault of the receiving Party or any of its Representatives in breach of the Prior CDA or this Agreement; or
- (e) can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information; *provided* that the foregoing exception shall not apply with respect to Joint Know-How or the terms of this Agreement.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party.

7.2 Permitted Disclosures

Each Party may disclose Confidential Information to the extent that such disclosure is:

- (a) made in response to a valid order of a court of competent jurisdiction or other Governmental Authority or Regulatory Authority of competent jurisdiction or if, based on the reasonable advice of the receiving Party's outside legal counsel, such disclosure is otherwise required by Applicable Law or the rules of a securities exchange on which the securities of the disclosing Party or any of its Affiliates are listed (or to which an application for listing has been submitted), including by reason of filing with securities regulators or any securities exchange; provided, however, that, to the extent permitted under Applicable Law, the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or Governmental Authority or, if disclosed, be used only

for the purposes for which the order was issued; and provided, further, that the Confidential Information disclosed in response to such court or Governmental Authority order or as required by Applicable Law shall be limited to that information which is legally required to be disclosed in response to such court or Governmental Authority order, as advised by outside counsel;

- (b) made by or on behalf of the receiving Party, its Affiliates or (sub)licensees or Sublicensees, as applicable, to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval to the extent consistent with this Agreement; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;
- (c) made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of obtaining, enforcing or defending a Patent in accordance with this Agreement; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available; or
- (d) (i) made by or on behalf of the receiving Party to any of its Representatives or (ii) made by or on behalf of the receiving Party or any of its Affiliates to any of its or their potential or actual investors, acquirers, lenders, licensors, (sub)licensees or contractors as may be necessary in connection with their evaluation of, exercise of rights under or performance under such potential or actual investment, acquisition or applicable transaction; *provided, however*, that, with respect to clauses (i) and (ii), such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information no less protective than the obligations of confidentiality and non-use of the receiving Party pursuant to this Clause 7 (CONFIDENTIALITY AND NON-DISCLOSURE) (*provided, however*, that, solely with respect to the individuals and entities described in clause (ii), the duration of confidentiality and non-use obligations need not exceed [**] from the date of disclosure and may be [**] from the date of disclosure if such shorter duration is consistent with industry norms). Each Party shall be responsible for any breach of this Agreement by any Person to which Confidential Information of the other Party has been disclosed by or on behalf of such Party pursuant to this clause (d).

7.3 Use of Name

Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their (sub)licensees (or Sublicensees) (or any abbreviation or adaptation thereof) in any publication, press release, marketing or promotional material or other form of publicity without the prior written approval of such other Party. The restrictions imposed by this Clause 7.3 (Use of Name) shall not prohibit (a) either Party from making any disclosure identifying the other Party to the extent required in connection with its exercise of its rights or obligations under this Agreement or (b) either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a securities exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). Notwithstanding the above, solely following the issuance of the initial press releases described in Clause 7.4 (Public Announcements), each Party and its Affiliates may disclose on its website and in its promotional materials that the other Party is a development partner of such Party and may utilize the other Party's name and logo in conjunction with such disclosure.

7.4 Public Announcements

The Parties have agreed upon the content of one (1) or more press releases which shall be issued substantially in the form(s) attached hereto as Schedule 4, the release of which the Parties shall co-ordinate in order to accomplish such release promptly upon execution of this Agreement. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned, except for any such disclosure that, based on the advice of the disclosing Party's outside counsel, is required by Applicable Law or the rules of a securities exchange on which the securities of the disclosing Party or any of its Affiliates are listed (or to which an application for listing has been submitted).

In the event a Party is, based on the advice of its outside counsel, required by Applicable Law or the rules of a securities exchange on which its or any of its Affiliates' securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall (i) submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event, unless inconsistent with Applicable Law, less than [**] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon and (ii) except with respect to financial disclosures, (A) consult and coordinate with the other Party with respect to the preparation and submission of a confidential treatment request for this Agreement and (B) in good faith consider incorporating such comments. Subject to the foregoing, such Party will have the right to make such disclosure at the time and in the manner reasonably determined by its counsel to be required by Applicable Laws or such securities exchange.

Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party in accordance with this Clause 7.4 (Public Announcements) or by the other Party; *provided* that such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable.

7.5 Publications

If Licensee, any of its Affiliates or any Sublicensee plans to publish or present the results of any studies regarding the Licensed Compound or Licensed Products conducted by Licensee, any of its Affiliates or any Sublicensee in the Territory, Licensee shall submit the draft of the publication to Nabriva no later than [**] prior to the planned submission for publication for approval. Nabriva shall have the right (a) to require modifications to the publication or presentation for patentability reasons or trade secret reasons, and Licensee will remove all of Nabriva's Confidential Information if requested by Nabriva and (b) to require a reasonable delay in publication or presentation in order to protect patentable information. If Nabriva requests a delay, then Licensee shall, and shall ensure that its Affiliate(s) or the Sublicensee(s) shall, delay submission or presentation for a period of [**] (or such shorter period as may be mutually agreed by the Parties) to enable Nabriva to file patent applications protecting Nabriva's rights in such information. Any other publication or presentation by Licensee, any of its Affiliates, any Sublicensee, or any Person acting on behalf of any of the foregoing shall need Nabriva's prior written consent, which shall not be unreasonably withheld or delayed.

7.6 Return of Confidential Information

Upon the effective date of the expiration or termination of this Agreement for any reason, either Party may request in writing and the non-requesting Party shall either, with respect to Confidential Information of the requesting Party to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement, at the requesting Party's election, (a) promptly destroy all

copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party or (b) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information (i) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes and (ii) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information retained under this Clause 7.6 (Return of Confidential Information) shall continue to be subject to the terms of this Agreement for the period set forth in Clause 7.1 (Confidentiality Obligations).

7.7 Privileged Communications

In furtherance of this Agreement, it is expected that the Parties may, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential in accordance with this Clause 7 (CONFIDENTIALITY AND NON-DISCLOSURE), that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between Nabriva and Licensee, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of the Nabriva Patents, Licensee Patents and Joint Patents. In the event of any litigation (or potential litigation) with a Third Party related to this Agreement or the subject matter hereof, the Parties shall, upon either Party's request, enter into a reasonable and customary joint defense or common interest agreement. In any event, each Party shall consult in a timely manner with the other Party before engaging in any conduct (e.g., producing information or documents) in connection with litigation or other proceedings that could conceivably implicate privileges maintained by the other Party. Notwithstanding anything contained in this Clause 7.7 (Privileged Communications), nothing in this Agreement shall prejudice a Party's ability to take discovery of the other Party in disputes between them relating to the Agreement and no information otherwise admissible or discoverable by a Party shall become inadmissible or immune from discovery solely by this Clause 7.7 (Privileged Communications).

7.8 Reporting of Financial Information.

From and after the Effective Date, upon [**] notice to Nabriva, in the event that Licensee is required to produce "carve out" financial statements (historical or pro forma) for the Licensed Products in the Field in the Territory to be included in any securities filing made by Licensee or any of its Affiliates under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, and the regulations promulgated thereunder, including Regulation S-X, Nabriva shall provide such financial information as is required by Licensee to comply with Rule 3-05 and 11-02 of Regulation S-X or otherwise cooperate with Licensee or its Affiliates and their respective accountants and auditors by providing access to information, books, and records to the extent related to the Licensed Products in the Field in the Territory, in each case as Licensee may reasonably request in connection with the preparation of such "carve out" financial statements. Licensee shall derive such "carve out" financial statements from Nabriva's historical financial statements and accurately present in all material respects the financial position of the Licensed Products in the Field in the Territory as of the dates thereof. Licensee shall (i) submit to Nabriva any proposed filing containing or incorporating by reference any financial statements provided to Licensee under this Clause 7.8 (Reporting of Financial Information)

as far in advance as reasonably practicable (and in no event, unless inconsistent with Applicable Law, less than [**] prior to the anticipated date of filing) so as to provide Nabriva a reasonable opportunity to comment thereon and (ii) in good faith consider incorporating such comments. Subject to the immediately preceding sentence, Nabriva hereby consents to the inclusion or incorporation by reference of any financial statements provided to Licensee under this Clause 7.8 (Reporting of Financial Information), to the extent related to the Licensed Products in the Field in the Territory, in any filing by Licensee or its Affiliates with the U.S. Securities and Exchange Commission and, upon request therefor of Licensee, agrees to request that any auditor of Nabriva that audits any financial statements provided to Licensee or its Affiliates under this Clause 7.8 (Reporting of Financial Information) consent to the inclusion or incorporation by reference of its audit opinion with respect to such financial statements in any filing by Licensee or its Affiliates with the U.S. Securities and Exchange Commission to the extent related to the Licensed Products in the Field in the Territory. Licensee shall reimburse Nabriva for all costs and expenses incurred by or on account of Nabriva in connection with its compliance with this Clause 7.8 (Reporting of Financial Information). All information of Nabriva obtained by or on behalf of Licensee under this Clause 7.8 (Reporting of Financial Information) shall be deemed Confidential Information of Nabriva.

8. REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties

Nabriva and Licensee each represents and warrants to the other, as of the Effective Date, and, as set forth in clause (e), covenants, that:

- (a) It is a corporation or other entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform under this Agreement;
- (b) The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate:
 - (i) such Party's charter documents, bylaws or other organizational documents;
 - (ii) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound;
 - (iii) any requirement of any Applicable Law; or
 - (iv) any order, writ, judgment, injunction, decree, determination or award of any court or Governmental Authority presently in effect applicable to such Party;
- (c) This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);
- (d) It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder; and

- (e) Neither it nor any of its Affiliates has been debarred or is subject to debarment, and neither it nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred, in each case pursuant to Section 306 of the FDCA (or any equivalent provision under Applicable Law) or who is the subject of a conviction described in such section or provision. It will inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the FDCA (or any equivalent provision under Applicable Law) or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.

8.2 Additional Representations and Warranties of Nabriva

Nabriva further represents and warrants to Licensee, as of the Effective Date, that:

- (a) Nabriva and its Affiliates Control the Existing Patents and have the right to grant the licenses and sublicenses specified herein;
- (b) Nabriva has not received any written or, to Nabriva's Knowledge, oral claim or demand alleging that (i) the issued patents within the Existing Patents are invalid or unenforceable or (ii) the Development or Commercialization of the Licensed Products as contemplated herein infringes any Patent owned by any Third Party;
- (c) to Nabriva's Knowledge, no Person is infringing or threatening to infringe the Existing Patents in the Field in the Territory;
- (d) Nabriva is not subject to any agreement with a Third Party that includes a royalty or similar payment obligation to, or other restriction or limitation in favor of, such Third Party (including, for this purpose, to current or former officers, directors, employees, consultants or personnel of Nabriva or any predecessor) with respect to (i) its rights to practice the Nabriva Know-How or Nabriva Patents in the Territory as licensed to Licensee in accordance with Clause 2.1 (Grants to Licensee) or (ii) the Development or Commercialization of the Licensed Compound or any Licensed Product in the Field in the Territory;
- (e) To Nabriva's Knowledge, the conception, development, and reduction to practice of the inventions claimed by the Nabriva Patents, and the Nabriva Know-How, existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person;
- (f) No Nabriva Patents are subject to, or were developed pursuant to, any funding agreement with any Governmental Authority;
- (g) Nabriva is not in material breach of any provisions of any agreements with Third Parties relating to the Nabriva Patents or Nabriva Know-How, in each case, in a manner that is reasonably likely to adversely affect the rights of Licensee hereunder or adversely affect the Development, Manufacturing, Regulatory Approval, or Commercialization of any Licensed Product hereunder;
- (h) Nabriva has not received any written claim of ownership, inventorship or patent infringement from any Third Party (including by current or former officers, directors, employees, consultants, or personnel of Nabriva or any predecessor) with respect to the Nabriva Know-

How or Nabriva Patents that is inconsistent with the rights granted to Licensee hereunder, and Nabriva does not Know of any reasonable basis for any such claim;

- (i) No claim or litigation has been brought or, to Nabriva's Knowledge, threatened on Nabriva by any Person alleging that any of the issued patents in the Nabriva Patents are invalid or unenforceable;
- (j) To Nabriva's Knowledge, the Manufacture, use or sale in the Field in the Territory of the Licensed Product (in the current form being clinically Developed by Nabriva in the United States) will not infringe any issued claim of an issued patent of any Third Party;
- (k) To Nabriva's Knowledge, it has conducted any Development and Commercialization activities in accordance with good laboratory and clinical practice and Applicable Law;
- (l) To Nabriva's Knowledge, neither Nabriva nor any of its Affiliates, nor any of its or their respective officers, employees, or agents has (i) made an untrue statement of material fact or fraudulent statement to any Regulatory Authority with respect to the Development of the Licensed Compound or the Licensed Products, failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the Development of the Licensed Compound or the Licensed Products, or committed an act, made a statement, or failed to make a statement with respect to the Development of the Licensed Compound or the Licensed Products that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) or (ii) made or failed to make any equivalent statement or committed any equivalent act to any Regulatory Authority in the Territory;
- (m) To Nabriva's Knowledge, it and its Affiliates have not violated any material Anti-Corruption Laws with respect to the Territory;
- (n) To Nabriva's Knowledge, Nabriva has made available to Licensee for review in due diligence (i) all those clinical trial reports for completed clinical trials of Licensed Products that are in Nabriva's possession and Control as of the Effective Date, (ii) all those tables and listings of safety and efficacy data for any ongoing Phase 3 Clinical Trial of a Licensed Product that are in Nabriva's or its Affiliates' possession and Control as of the Effective Date, (iii) all Nabriva Know-How that has been specifically requested of Nabriva by Licensee that, to Nabriva's Knowledge, is material to the Development or Commercialization of the Licensed Product(s) in the Field in the Territory hereunder, (iv) all documents that, to Nabriva's, are material to Nabriva Patents contained in the data room and requested by Licensee in writing, and (v) all material adverse information with respect to the safety and efficacy of the Licensed Products Known to Nabriva or its Affiliates as of the Effective Date; and
- (o) Subject to the terms and conditions of this Agreement, including Nabriva's rights under the Retained Rights, (i) the license granted to Licensee in Clause 2.1(a) (Grants to Licensee) is an exclusive grant of all rights under the Nabriva Patents, the Nabriva Know-How, and Nabriva's interests in the Joint Intellectual Property, to Develop and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory and (ii) no other Person (including Nabriva and NTGmbH) has the right under the Nabriva Patents, the Nabriva Know-How, and Nabriva's interests in the Joint Intellectual Property, to Develop and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory or the right to grant any licenses under the Nabriva Patents, the Nabriva Know-How, and Nabriva's interests in the Joint Intellectual Property, to Develop and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory.

8.3 Additional Representations and Warranties of Licensee

Licensee further represents and warrants to Nabriva, as of the Effective Date, that each of Parent and Roivant Sciences, Inc. is an Affiliate of Licensee.

8.4 Additional Covenant of Nabriva

If for any reason any court, tribunal or governmental agency in the Territory determines that the license granted to Licensee in Clause 2.1(a) (Grants to Licensee) is not an exclusive grant of all rights under the Nabriva Patents, the Nabriva Know-How, and Nabriva's interests in the Joint Intellectual Property, to Develop and Commercialize the Licensed Compound and Licensed Products in the Field in the Territory such that Licensee does not have sufficient rights to enforce the Nabriva Patents as provided in Clause 6.3(b) (Enforcement of Patents), then Nabriva and NTGmbH agree to take such commercially reasonable steps as Licensee reasonably requests to grant Licensee such rights.

8.5 DISCLAIMER OF WARRANTIES

EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

8.6 Anti-Bribery and Anti-Corruption Compliance

- (a) Each Party will conduct its business in accordance with Applicable Law. By signing this Agreement, each Party agrees to conduct its activities under this Agreement in a manner that is consistent with Applicable Law, including the U.S. Foreign Corrupt Practices Act, the UK Bribery Act 2010, and the relevant provisions of the Criminal Law of the People's Republic of China and the Anti-Unfair Competition Law of the People's Republic of China, each as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, or money laundering (collectively, **Anti-Corruption Laws**).
- (b) Each Party will not, directly or indirectly, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything of value (collectively, a **Prohibited Payment**) to any Government Official where such Prohibited Payment would constitute a violation of any Anti-Corruption Law. In addition, regardless of legality, each Party will make no Prohibited Payment, directly or indirectly, to any Government Official if such Prohibited Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of the other Party's business. Each Party acknowledges and agrees that none of it, or any of its Affiliates or its or their respective officers, directors, employees, agents and representatives (collectively, **Authorized Representatives**) is authorized to waive compliance with the provisions of this Clause 8.6 (Anti-Bribery and Anti-Corruption Compliance) and that each Party will be solely responsible for its compliance with the provisions of this Clause 8.6 (Anti-Bribery and Anti-Corruption Compliance) and the Anti-Corruption Laws irrespective of any act or omission of the other Party or any of its Affiliates, Sublicensees or its or their respective Authorized Representatives. Each Party's failure to abide by the provisions of this Clause 8.6

(Anti-Bribery and Anti-Corruption Compliance) shall be deemed a material breach of this Agreement.

9. INDEMNITY

9.1 Indemnification of Nabriva

Licensee shall indemnify Nabriva, its Affiliates, its or their (sub)licensees and its and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, **Losses**) in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, **Third Party Claims**) to the extent arising from or occurring as a result of:

- (a) the breach by Licensee of this Agreement;
- (b) the negligence or willful misconduct on the part of Licensee or its Affiliates or its or their Sublicensees or its or their distributors or contractors or its or their respective directors, officers, employees or agents in performing its or their obligations under this Agreement; or
- (c) the Exploitation by Licensee or any of its Affiliates or its or their Sublicensees or its or their distributors or contractors of any Licensed Product or the Licensed Compound in or for the Territory,

except, in each case ((a), (b) and (c)), for those Losses for which Nabriva has an obligation to indemnify Licensee pursuant to Clause 9.2 (Indemnification of Licensee) hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

9.2 Indemnification of Licensee

Nabriva shall indemnify Licensee, its Affiliates and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims to the extent arising from or occurring as a result of:

- (a) the breach by Nabriva of this Agreement;
- (b) the negligence or willful misconduct on the part of Nabriva or its Affiliates or its or their respective directors, officers, employees or agents in performing its obligations under this Agreement; or
- (c) the Exploitation by Nabriva or any of its Affiliates or its or their sublicensees or its or their distributors or contractors of the Licensed Compound or Licensed Products outside the Territory; or
- (d) the Development, Manufacture or Commercialization of the Licensed Compound or any Licensed Product by or on behalf of Nabriva or any of its Affiliates or (sub)licensees in the Territory after the end of the Term;

except, in each case (((a), (b), (c) and (d))), for those Losses for which Licensee has an obligation to indemnify Nabriva pursuant to Clause 9.1 (Indemnification of Nabriva) hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

9.3 Indemnification Procedures

(a) Notice of Claim

All indemnification claims in respect of a Party, its Affiliates or its or their Sublicensees (or (sub)licensees) or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the **Indemnified Party**). The Indemnified Party shall give the indemnifying Party a prompt written notice (an **Indemnification Claim Notice**) of any Losses or discovery of fact upon which such indemnified Party intends to base a request for indemnification under this Clause 9 (INDEMNITY), but in no event shall the indemnifying Party be liable for any Losses to the extent that such Losses result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the Third Party Claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time).

(b) Control of Defense

The indemnifying Party shall have the right to assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [**] after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Clause 9.3(c) (Right to Participate in Defense), the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all reasonable and verifiable out-of-pocket costs and expenses (including attorneys' fees and costs of suit) incurred by the indemnifying Party in accordance with this Clause 9 (INDEMNITY) in its defense of the Third Party Claim.

(c) Right to Participate in Defense

Any Indemnified Party shall be entitled to participate in the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided, however*, that such employment shall be at the Indemnified Party's sole cost and expense unless (i) the employment thereof has been specifically authorized in writing by the indemnifying Party in writing (in which case, the defense shall be controlled as provided in Clause 9.3(b) (Control of Defense), *mutatis mutandis*), (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Clause 9.3(b) (Control of Defense) (in which case the Indemnified Party shall control the defense, with the reasonable out-of-pocket expense with respect thereto borne by the indemnifying Party) or (iii) the interests of the indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules

or equitable principles (in which case, the Indemnified Party shall control its defense, with the reasonable out-of-pocket expense with respect thereto borne by the indemnifying Party).

(d) Settlement

With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim that shall not result in the applicable indemnitee(s) becoming subject to injunctive or other relief or otherwise adversely affect the business or interests of the Indemnified Party in any manner and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the applicable indemnitee hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Clause 9.3(b) (Control of Defense), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided*, it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; *provided*, that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

(e) Co-operation

If the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall and shall cause each indemnitee to, co-operate in the defense or prosecution thereof and furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested by the indemnifying Party in connection therewith. Such co-operation shall include access during normal business hours afforded to the indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim and making the Indemnified Party, the indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the indemnifying Party shall reimburse the Indemnified Party for all of its, its Affiliates' and its and their (sub)licensees' or their respective directors', officers', employees' and agents', as applicable, reasonable and verifiable out-of-pocket expenses in connection therewith.

(f) Expenses

Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party and its Affiliates and its and their Sublicensees (or (sub)licensees) and their respective directors, officers, employees and agents, as applicable, in connection with any Third Party Claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

(g) Indemnification Payments

The Parties agree to treat any indemnification payments applicable to Nabriva pursuant to this Clause 9 (INDEMNITY) as an adjustment to the consideration paid to Nabriva pursuant to Clause 5

(PAYMENTS AND RECORDS) solely for tax purposes, unless otherwise required by Applicable Law

9.4 Special, Indirect and Other Losses

EXCEPT (a) IN THE EVENT OF THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY, (b) IN THE EVENT OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER CLAUSE 2.7 (NON-COMPETE) OR CLAUSE 7 (CONFIDENTIALITY AND NON-DISCLOSURE), OR (c) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS CLAUSE 9 (INDEMNITY), NEITHER PARTY NOR ANY OF ITS AFFILIATES OR (SUB)LICENSEES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, CONSEQUENTIAL, MULTIPLE, INDIRECT, INCIDENTAL OR PUNITIVE DAMAGES OR FOR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

10. TERM AND TERMINATION

10.1 Term and Expiration

This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until the First Commercial Sale of the first Licensed Product in the Field in any Jurisdiction in the Territory and continue thereafter until date of expiration of the last Royalty Term for the last Licensed Product (such period, the **Term**). Following the expiration of the Royalty Term for a Licensed Product in a Jurisdiction, the grants in Clause 2.1 (Grants to Licensee) become non-exclusive, fully-paid, royalty-free, and irrevocable for such Licensed Product in such Jurisdiction. For clarity, upon the expiration (but not the earlier termination) of the Term, the grants in Clause 2.1 (Grants to Licensee) shall become non-exclusive, fully-paid, royalty-free, and irrevocable in their entirety.

10.2 Termination

(a) Material Breach

In the event that either Party (the **Breaching Party**) shall be in material breach in the performance of any of its obligations under this Agreement, in addition to any other right and remedy the other Party (the **Non-Breaching Party**) may have, the Non-Breaching Party may terminate this Agreement by providing [**] (but only [**] with respect to a payment breach) (the **Notice Period**) prior written notice (the **Termination Notice**) to the Breaching Party and specifying the breach and its claim of right to terminate; *provided, however*, that (a) the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Notice Period; (b) for any breach other than a payment breach, if such breach cannot be cured within the Notice Period, then, if the Breaching Party commences actions to cure such breach within the Notice Period and thereafter diligently continues such actions, the Breaching Party shall have an additional [**] after the end of the Notice Period to cure such breach (and, if the Breaching Party does not cure such breach by the end of such additional [**] period, the termination shall become effective at the end of such additional [**] period); and (c) if the Breaching Party disputes in good faith, prior to the end of the Notice Period, the existence of such material breach in accordance with the procedures set forth in Clause 11.5 (Governing Law and Dispute Resolution), then the Notice Period shall be tolled until such dispute is finally resolved in accordance with the procedures set forth in Clause 11.5 (Governing Law and Dispute Resolution). In the event of any conflict between the terms of this

Clause 10.2(a) (Material Breach) and Clause 3.1(c) (Specific Diligence Breach) with respect to the cure period for a breach described in Clause 3.1(c) (Specific Diligence Breach) or the right to terminate this Agreement described in Clause 3.1(c) (Specific Diligence Breach), the cure period for such breach or the right to terminate this Agreement, as applicable, shall be as set forth Clause 3.1(c) (Specific Diligence Breach).

(b) Termination for Convenience by Licensee

Prior to its expiration, this Agreement may be terminated in its entirety at any time by Licensee effective upon at least one hundred eighty (180) days' prior written notice to Nabriva for any reason.

(c) Termination for Insolvency

In the event that either Party: (i) files for protection under bankruptcy or insolvency laws, (ii) makes an assignment for the benefit of creditors, (iii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within ninety (90) days after such filing, (iv) proposes a written agreement of composition or extension of its debts, (v) proposes or is a party to any dissolution or liquidation of such Party, (vi) voluntarily files a petition, or has any petition filed against it, under any bankruptcy or insolvency law that is not discharged within sixty (60) days of the filing thereof, or (vii) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

(d) Automatic Termination for Nonpayment

If Licensee fails to pay Nabriva the upfront payment set forth in Clause 5.1 (Upfront Payment) within five (5) Business Days after the Effective Date, this Agreement will automatically and immediately terminate.

10.3 Consequences of Termination

Upon termination of this Agreement, as applicable,

- (a)** all rights and licenses granted by Nabriva and NTGmbH hereunder shall immediately terminate, including, for clarity, any sublicense granted by Licensee pursuant to Clause 2.3 (Sublicenses);
- (b)** Licensee shall and hereby does, and shall cause its Affiliates and its and their Sublicensees to, when and as requested by Nabriva, assign to Nabriva all of its right, title and interest in and to: all Product Trademarks and all Regulatory Documentation (including any Regulatory Approvals) applicable to any Licensed Compound or Licensed Products then owned or Controlled by Licensee or any of its Affiliates or Sublicensees; provided that if any such Regulatory Documentation or Regulatory Approval is not immediately transferable in a Jurisdiction, Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, provide Nabriva with all benefit of such Regulatory Documentation or Regulatory Approval, as applicable, and such assistance and co-operation as necessary or reasonably requested by Nabriva to timely transfer such Regulatory Documentation or Regulatory Approval, as applicable, to Nabriva or its designee or, at Nabriva's option, to enable Nabriva to obtain a substitute for such Regulatory Documentation or Regulatory Approval, as applicable, without disruption to Nabriva's Exploitation of the Licensed Compound or applicable Licensed Product(s);

- (c) all Confidential Information of Licensee relating to the Licensed Compound or any Licensed Product shall become Confidential Information of Nabriva, with Nabriva considered the disclosing Party and Licensee considered the receiving Party and Licensee may not rely on its or any of its Affiliates' or any Sublicensee's possession or development thereof as an exception under Clause 7.1(b) or 7.1(e);
- (d) Licensee shall and hereby does, and shall cause its Affiliates and its and their Sublicensees to, effective as of the effective date of termination, grant Nabriva, an exclusive, royalty-free license, with the right to grant multiple tiers of sublicenses, in and to the Licensed Know-How, Licensee Patents and Licensee's interest in any Joint Intellectual Property to Exploit any Licensed Compound, Licensed Product or any product containing any Licensed Compound in the Territory (and Nabriva shall have the first right to prepare, file, prosecute, maintain, prosecute Infringement with respect to, defend and control the defense of the validity and enforceability of all Joint Patents worldwide); provided that if the Agreement is terminated by Licensee due to Nabriva's material breach, Nabriva shall pay Licensee a royalty of (i) [**] percent ([**]%) (if terminated before Licensee has obtained Regulatory Approval for a Licensed Product in the Territory) or (ii) [**] percent ([**]%) (if terminated after Licensee has obtained Regulatory Approval for a Licensed Product in the Territory) of Net Sales of Licensed Products in the Territory, mutatis mutandis, with the provisions of Clauses 5.3 (Royalties) through 5.9 (Audit) applying with respect thereto, substituting Licensee Patents for Nabriva Patents and otherwise mutatis mutandis;
- (e) unless expressly prohibited by any Regulatory Authority, at Nabriva's written request, Licensee shall, and shall cause its Affiliates and its and their Sublicensees to: (i) if Nabriva notifies Licensee of its intent to assume control of ongoing clinical studies, transfer control to Nabriva of any or all clinical studies involving Licensed Products being conducted by or on behalf of Licensee, an Affiliate or a Sublicensee as of the effective date of termination and (ii) if Nabriva does not notify Licensee of any intent to assume control of ongoing clinical studies within [**] after the effective date of termination, promptly wind down such studies in accordance with Applicable Law;
- (f) Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, promptly provide a copy to Nabriva of all Licensed Product Agreements, and, to the extent requested by Nabriva in writing, assign to Nabriva any Licensed Product Agreement, unless, with respect to any such Licensed Product Agreement, such Licensed Product Agreement expressly prohibits such assignment, in which case Licensee (or such Affiliate or Sublicensee, as applicable) shall co-operate with Nabriva in all reasonable respects to secure the consent of the applicable Third Party to such assignment, at Licensee's expense, and if any such consent cannot be obtained with respect to a Licensed Product Agreement, Licensee shall, and shall cause its Affiliates and its and their Sublicensees to, to the extent requested by Nabriva in writing, obtain for Nabriva substantially all of the practical benefit and burden under such Licensed Product Agreement, including by: (i) entering into appropriate and reasonable alternative arrangements on terms agreeable to Nabriva, and (ii) subject to the consent and control of Nabriva, enforcing, at Nabriva's cost and expense and for the account of Nabriva, any and all rights of Licensee (or such Affiliate or Sublicensee, as applicable) against the other party thereto arising out of the breach or cancellation thereof by such other party or otherwise;
- (g) Licensee shall inform Nabriva of the units of Licensed Compound and Licensed Product or other Lefamulin Materials held by or on behalf of Licensee, any of its Affiliates or its or their Sublicensees, and the status of each unit of such Licensed Compound or Licensed Product or other Lefamulin Materials (including its remaining shelf-life and its compliance with GMP), and, to the extent requested by Nabriva, Licensee shall, or shall cause, the transfer to Nabriva

of such units at the cost paid for such units by Licensee to Nabriva pursuant to the applicable Supply Agreement or, if not supplied to Licensee by Nabriva pursuant to a Supply Agreement, at [**] percent ([**]%) of Licensee's COGS with respect to such units;

- (h) at Nabriva's written request, to the extent Licensee has the ability to Manufacture Licensed Products, Licensee shall supply to Nabriva such quantities of the Licensed Compound and Licensed Products as Nabriva indicates in written forecasts and orders therefor from time to time at Licensee's COGS (plus [**] percent ([**]%) if for Commercialization by Nabriva in the Territory) until the earlier of: (i) such time as Nabriva has established an alternate, validated source of supply for the Licensed Compound and Licensed Products for Commercialization in the Territory, and Nabriva is receiving supply from such alternative source, and (ii) the [**] of the effective date of termination of this Agreement; and
- (i) To the extent requested by Nabriva in writing, Licensee shall, and shall cause, the transfer to Nabriva of any Product Trademarks.

10.4 Remedies

Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

10.5 Accrued Rights; Surviving Obligations

Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Clauses 1, 2.2, 2.5(a), 2.5(b) (solely upon expiration in accordance with Clause 10.1), 2.5(c), 2.5(d), 2.8, 3.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 6.1, 6.2 (solely with respect to Joint Patents and Licensee Patents to which Nabriva retains a license), 6.3 (solely with respect to Joint Patents and Licensee Patents to which Nabriva retains a license), 6.5 (solely with respect to Joint Patents and Licensee Patents to which Nabriva retains a license), 7.1, 7.2, 7.4, 7.5, 7.6, 7.7, 8.4, 8.5, 9, 10.1 (last two sentences, if applicable as of the date of expiration or termination), 10.3, 10.4, 10.5, and 11 of this Agreement shall survive the termination or expiration of this Agreement for any reason.

11. MISCELLANEOUS

11.1 Force Majeure

Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, which may include fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any Governmental Authority (including expropriation, seizure of works, requisition, nationalization, and exercise of march-in rights or compulsory licensing), except to the extent such delay results from the breach by the non-performing Party of any term or condition of this Agreement. The non-performing Party shall notify the other Party of such force majeure within thirty (30) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being

taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

11.2 Export Control

This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other Jurisdictions that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other Governmental Authority approval, without first obtaining the written consent to do so from the appropriate agency or other Governmental Authority in accordance with Applicable Law.

11.3 Assignment

- (a) Neither Party (nor NTGmbH) may assign its rights or, except as provided in Clause 3.7 (Subcontracting), delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party (and, with respect to assignments by Licensee, NTGmbH), which consent shall not be unreasonably withheld, conditioned or delayed, except that any Party (and NTGmbH) shall have the right, without such consent: (i) to perform any or all of its obligations under this Agreement through any of its Affiliates or its or their (sub)licensees (subject, in the case of Licensee, to Clause 2.3 (Sublicenses), Clause 3.7 (Subcontracting) and Clause 3.1(b) (Diligence)), and (ii) assign all of its rights and delegate all of its obligations hereunder (A) to any of its Affiliates or (B) to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business and assets of such Party (or NTGmbH, as applicable) to which this Agreement relates; provided that, with respect to ((i) or (ii)), such Party (or NTGmbH, as applicable) shall provide written notice to the other Party (and, with respect to assignments by Licensee, NTGmbH) within [**] after such assignment or delegation and such Party (or NTGmbH, as applicable) shall remain liable with respect to such Party's (or NTGmbH's, as applicable) obligations under this Agreement. All validly assigned rights of a Party (or NTGmbH, as applicable) shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party (or NTGmbH, as applicable) shall be binding on and be enforceable against, the permitted successors and assigns of such Party (or NTGmbH, as applicable). Any attempted assignment or delegation in violation of this Clause 11.3(a) shall be void and of no effect.
- (b) The rights to Information, materials and intellectual property owned by, or licensed by a Third Party to, an Affiliate of a Party that becomes an Affiliate of such Party through any Change of Control of such Party shall be automatically excluded from the rights licensed or granted to such other Party under this Agreement.

11.4 Severability

If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Applicable Law: (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal,

invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

11.5 Governing Law and Dispute Resolution

- (a) This Agreement shall be governed by and construed in accordance with the laws of **the State of New York, USA**, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.
- (b) Except as provided in Clause 11.9 (Equitable Relief), if a dispute arises:
 - (i) within the JDC with respect to any decision under the jurisdiction of the JDC (a **JDC Dispute**); or
 - (ii) otherwise between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (collectively, (i) and (ii), a **Dispute**),

then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of [**]. Any final decision mutually agreed to by the Senior Officers shall be conclusive and binding on the Parties.

(c) Final Decision-Making

- (i) If such Senior Officers are unable to resolve any such Dispute that is a JDC Dispute within such [**] period, the Parties shall refer such JDC Dispute to the chief executive officer of Licensee for review and determination, which decision of the chief executive officer of Licensee, if made in good faith and without favoring other products being Exploited by or on behalf of Licensee or any of its Affiliates that are not Licensed Products, shall, subject to Clause 11.5(c)(ii), be final, binding and conclusive. For the avoidance of doubt, any Dispute related to Development strategy or operation of Licensed Products in the Field in the Territory shall be a JDC Dispute and is subject to the final decision of the chief executive officer of Licensee, subject to Clause 11.5(c)(ii).
- (ii) No Party (itself or through its Senior Officer) shall have the deciding vote on, and the JDC and the chief executive officer of Licensee shall not have decision-making authority regarding, any of the following matters:
 - (A) Except with Nabriva's consent, any decision that would reasonably be expected to have a material adverse effect on the Development of, Regulatory Approval process for, or Commercialization of, the Licensed Products or any product containing the Licensed Compound anywhere outside the Territory;
 - (B) the imposition of any requirement on the other Party to undertake any obligation beyond those for which it is responsible, or to forgo any of its rights, under this Agreement;
 - (C) the resolution of any Dispute involving the breach or alleged breach of this Agreement; or
 - (D) any matter that would excuse such Party from any of its obligations under this Agreement.

- (d) If such Senior Officers are unable to resolve any such Dispute that is not a JDC Dispute within such [**] period, either Party shall be free to resolve such Dispute solely by instituting binding arbitration in accordance with this Clause 11.5(d) upon written notice to the other Party (an **Arbitration Notice**) and seek such remedies as may be available. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three (3) experts with relevant industry experience (the **Arbitrators**). Each of Licensee and Nabriva shall promptly select one (1) Arbitrator, which selections shall in no event be made later than [**] after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Licensee and the Arbitrator chosen by Nabriva, but in no event later than [**] after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; provided that the Arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the Dispute. The arbitration shall be administered by the American Arbitration Association (**AAA**) (or its successor entity) in accordance with the then current Commercial Arbitration Rules of the AAA including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in **New York City, New York, USA**, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall hold a hearing within [**] of selection of the third Arbitrator. The Arbitrators shall, within [**] after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final, binding, conclusive and non-appealable, and judgment may be entered upon it in accordance with Applicable Law in the State of New York or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages or, subject to Clause 9.4 (Special, Indirect or Other Losses), any other damages and injunctive relief, but, subject to Clause 11.4 (Severability), shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.
- (e) Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Clause 11.5 (Governing Law and Dispute Resolution), and shall pay an equal share of the fees and costs of the Arbitrators, as applicable, and all other general fees related to any arbitration described in Clause 11.5(d); *provided, however*, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses), or the fees and costs of the Arbitrators, as applicable. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Clause 11.5(d) is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement to the extent possible in light of such pending arbitration proceeding.
- (f) Subject to Clause 3.1(c) (Specific Diligence Breach), nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding or the provisions of Clause 11.5(d). All arbitration proceedings, briefs, awards and decisions of the Arbitrators under Clause 11.5(d) shall, subject to clauses 7.1(a), (c) and (d), be deemed Confidential Information of both Parties under Clause 7 (CONFIDENTIALITY AND NON-DISCLOSURE) and all discovery will, subject to

Clauses 7.1(a)-(e), be treated as the Confidential Information of the Party that produced it; *provided, however*, that either Party may disclose any such award or decision to the extent required to enforce such award or decision.

- (g) Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Clause 11.6(b) (Address for Notice) (or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with Clause 11.6(a) shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

11.6 Notices

(a) Notice Requirements

Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if (i) delivered by hand, (ii) sent by email (with delivery confirmation and read receipt) or (iii) deposited with an internationally recognized overnight delivery service that maintains records of delivery, in each case addressed to the receiving Party (or NTGmbH) at its addresses specified in paragraph (b) or to such other address as the Party (or NTGmbH) to whom notice is to be given may have provided to the other Party (or NTGmbH, as applicable) in accordance with this paragraph (a). Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by email (with delivery confirmation and read receipt) or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by email shall be confirmed by a hard copy delivered in accordance with clause (i) or deposited in accordance with clause (iii), in each case no later than the following Business Day. This Clause 11.6(a) (Notice Requirements) is not intended to govern the day-to-day business communications necessary between the Parties (or NTGmbH) in performing their obligations under the terms of this Agreement.

(b) Address for Notice

If to Licensee, to:

Sinovant Sciences, Ltd.
2 Church Street
Hamilton, Bermuda
Attention: Head, Global Transactions and Risk Management

with a copy (which shall not constitute notice) to:

Roivant Sciences, Inc.
320 West 37th Street
5th Floor
New York, NY 10018
Attention: Legal Department
Email: [**]

If to Nabriva, to:

Nabriva Therapeutics Ireland Designated Activity Company
25-28 North Wall Quay
Dublin 1, Ireland
Attention: Colin Broom, CEO

with a copy (which shall not constitute notice) to:

Nabriva Therapeutics Ireland Designated Activity Company
c/o Nabriva Therapeutics US, Inc.
1000 Continental Drive, Suite 600
King of Prussia, Pennsylvania
USA
Attention: Robert Crotty, General Counsel

If to NTGmbH, to:

Nabriva Therapeutics GmbH
Leberstrasse 20
1110 Vienna, Austria
Attention: Colin Broom, CEO

with a copy (which shall not constitute notice) to:

Nabriva Therapeutics GmbH
c/o Nabriva Therapeutics US, Inc.
1000 Continental Drive, Suite 600
King of Prussia, Pennsylvania
USA
Attention: Robert Crotty, General Counsel

11.7 Entire Agreement; Amendments

This Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto between Nabriva or any of its Affiliates, on the one hand, and Licensee or any of its Affiliates, on the other hand, including the Prior CDA, are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge shall be binding on the Parties unless in writing and duly executed by authorized representatives of both Parties. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

11.8 English Language

This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and in the event of any conflict in interpretation between the English version and such translation, the original English version shall prevail.

11.9 Equitable Relief

Each Party acknowledges and agrees that the restrictions set forth in Clause 2.7 (Non-Compete), Clause 6 (INTELLECTUAL PROPERTY) and Clause 7 (CONFIDENTIALITY AND NON-DISCLOSURE) are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such Clauses may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Clauses, the non-breaching Party shall be authorized and entitled to seek from the Arbitrators or any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity.

11.10 Waiver and Non-Exclusion of Remedies

Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

11.11 No Benefit to Third Parties

Except as provided in Clause 9 (INDEMNITY), covenants and agreements set forth in this Agreement are for the sole benefit of the Parties (or NTGmbH, as applicable) and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.

11.12 Further Assurance

Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

11.13 Relationship of the Parties

It is expressly agreed that Nabriva and NTGmbH, on the one hand, and Licensee, on the other hand, shall be independent contractors and that the relationship among any of these Persons shall not constitute a partnership, joint venture or agency. Neither Nabriva and NTGmbH, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations or commitments of any kind or to take any action that will be binding on the other, without the prior written consent of the other Party (and, as applicable, NTGmbH) to do so. All persons employed by a Party (or NTGmbH) shall be employees of such Party (or NTGmbH, as applicable) and not of the other Party (or NTGmbH, as applicable) and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party (or NTGmbH, as applicable). Neither Nabriva nor NTGmbH shall be liable for any obligation or liability of the other, and any obligation, covenant, warranty, representation, indemnification or undertaking assumed or given by

Nabriva or NTGmbH shall be construed as if expressed to be given severally by such Persons and not jointly or jointly and severally.

11.14 References

Unless otherwise specified: (a) references in this Agreement to any Clause, Section or Schedule shall mean references to such Clause, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto (except to the extent any such amendment, replacement or supplement is not permitted in accordance with the terms thereof).

11.15 Construction

- (a) Except where the context otherwise requires, wherever used, (i) the singular shall include the plural, the plural shall include the singular, (ii) the use of any gender shall be applicable to all genders, (iii) the word “or” is used in the inclusive sense (and/or), (iv) the words “herein”, “hereof” and “hereunder”, and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, and (v) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner.
- (b) Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days.
- (c) The captions and table of contents of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement.
- (d) The term “including,” “include,” “includes” or “e.g.” as used herein shall mean including, without limiting the generality of any description preceding such term.
- (e) References to a “year” or “annual” mean a Calendar Year.
- (f) References to an “indication” means, with respect to a product, any use to which such product is intended to be put for the treatment, prevention, mitigation, cure or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition, in each case for any size patient population, which, if approved in the U.S., would be reflected in the “Indications and Usage” section of labeling pursuant to 21 C.F.R. §201.57(c)(2) or, to the extent applicable, any comparable labeling section outside the U.S., including any such use that is the subject to a clinical trial. References to the “Field” mean any or all of the applicable indications described in the definition of **Field**, in any size patient population. References to CABP or ABSSSI means the treatment of CABP or ABSSSI in any size patient population.
- (g) Any reference to any law shall mean such law as in effect as of the relevant time, including all rules and regulations thereunder and any successor law in effect as of the relevant time, and including the then-current amendments thereto.

- (h) Unless the context otherwise requires, references to “Sublicensees,” “its Sublicensees,” “its or their Sublicensees” and the like shall be interpreted to mean any Sublicensee.
- (i) References to Nabriva’s (or its Affiliates’) (sub)licensees excludes Licensee, its Affiliates and Sublicensees unless such Persons are expressly referenced.
- (j) The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto.

11.16 Counterparts

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

11.17 Guaranty

In consideration of the Nabriva Parties entering into this Agreement, Parent hereby guarantees to the Nabriva Parties the due and punctual payment of all financial obligations of Licensee under this Agreement, in each case after any applicable notice and cure period requirements, until the earlier of the date that (a) Licensee completes an initial public offering of equity raising at least [**] U.S. dollars (\$[**]) in available funds to Licensee, (b) Licensee completes a private financing round raising at least [**] U.S. dollars (\$[**]) in available funds to Licensee, or (c) a Change of Control transaction is consummated in which Licensee is no longer an Affiliate of Parent, only if (i) the Person that acquires Licensee in such Change of Control shall thereafter guarantee to the Nabriva Parties the due and punctual payment of all financial obligations of Licensee under this Agreement, and (ii) if Licensee is acquired by a Person with less than [**] U.S. dollars (\$[**]) in cash or liquid assets, then Parent shall continue to guarantee to the Nabriva Parties the due and punctual payment of all financial obligations of Licensee under this Agreement.

11.18 Parent Representation and Warranty

Parent represents and warrants that, as of the Effective Date, Licensee is an Affiliate of each of Parent and Roivant Sciences, Inc.

[Signature Page Follows]

THIS AGREEMENT is executed by the authorized representatives of the Parties, NTGmbH and Parent as of the date first written above.

SIGNATORIES

Nabriva Therapeutics Ireland Designated Activity Company

Sinovant Sciences Ltd.

By: /s/ Paul Ryan

By: /s/ Marianne L. Romeo

Name: Paul Ryan

Name: Marianne L. Romeo

Title: Director

Title: Head, Global Transactions & Risk Management

And, solely for purposes of Clauses 2.1 (Grants to Licensee), 5 (PAYMENTS AND RECORDS), 8.4 (Additional Covenant of Nabriva), 11.3 (Assignment), 11.11 (No Benefit to Third Parties), 11.6 (Notices), 11.13 (Relationship of the Parties) and 11.17 (Guaranty),

Nabriva Therapeutics GmbH

By: /s/ Mihovil Spoljaric

Name: Mihovil Spoljaric

Title: Managing Director

And, solely for purposes of Clauses 11.17 (Guaranty) and 11.18 (Parent Representation and Warranty),

Roivant Sciences Ltd.

By: /s/ Marianne L. Romeo

Name: Marianne L. Romeo

Title: Head, Global Transactions & Risk Management

SCHEDULE 1
CORPORATE NAMES

1. Nabriva Therapeutics plc
2. Nabriva Therapeutics GmbH
3. Nabriva Therapeutics Ireland Designated Activity Company
4. Nabriva Therapeutics One Designated Activity Company
5. Nabriva Therapeutics US, Inc.

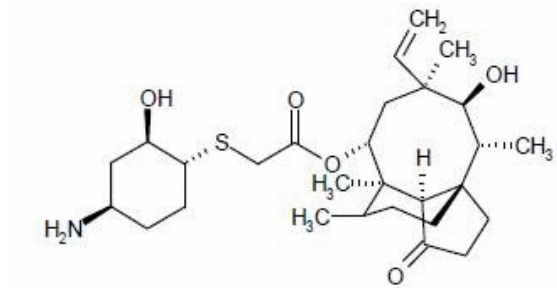


SCHEDULE 2
EXISTING PATENTS

Jurisdiction	Filing Date	Application Number	Grant Date	Patent Number	Status
[**]	[**]	[**]	[**]	[**]	[**]

SCHEDULE 3

LICENSED COMPOUND



SCHEDULE 4
PRESS RELEASE

Nabriva Therapeutics and Roivant Sciences Enter into License Agreement to Develop and Commercialize Lefamulin in Greater China

DUBLIN, Ireland, and HONG KONG, March 27, 2018 -Nabriva Therapeutics plc (NASDAQ:NBRV), 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, and Roivant Sciences today announced the initiation of a collaboration to develop and commercialize lefamulin in greater China. Lefamulin has completed a pivotal, international Phase 3 trial for the treatment of adults with moderate to severe community-acquired bacterial pneumonia (CABP). Topline data from a second pivotal, international Phase 3 clinical trial are expected in the spring of 2018.

As part of the agreement, Nabriva has granted a Roivant subsidiary an exclusive license to develop and commercialize lefamulin for the greater China region, namely the People's Republic of China, Hong Kong, Macau, and Taiwan. The companies will establish a joint steering committee to review and oversee all development and commercialization plans. Nabriva will receive a \$5 million upfront payment and will be eligible for up to approximately \$90 million in additional payments tied to the successful completion of certain regulatory and commercial milestones. In addition, Nabriva will be eligible to receive low double-digit royalties on sales upon approval in the covered territories. Roivant and its affiliates will be solely responsible for all clinical development and regulatory filings necessary to secure approval in the covered territories.

“Our partnership with Roivant underscores our commitment to ensuring rapid access of lefamulin to adults with CABP around the globe,” said Dr. Colin Broom, chief executive officer of Nabriva Therapeutics. “Roivant has a broad therapeutic portfolio and deep development and commercialization expertise, making the company an excellent partner as we pursue bringing an important and much-needed new treatment option for CABP—and potentially other serious bacterial infections—to China and surrounding territories. The funding from this agreement will also contribute to our efforts to prepare for a successful launch in the U.S. should lefamulin be approved.”

“This partnership demonstrates our commitment to build out a robust pipeline of products in China in addition to derazantinib,” said Vivek Ramaswamy, founder and chief executive officer of Roivant Sciences. “It is also indicative of our desire to develop treatments for infectious diseases beyond hepatitis B virus. Increasing resistance to commonly prescribed anti-infectives represents a significant threat to public health, especially in China, but we believe that lefamulin’s novel mechanism of action represents a promising advance. Our partnership with Nabriva is an important step in our contribution to this area of medicine and this region of the world.”

Pneumonia is a leading cause of infectious disease mortality worldwide. In China, pneumonia is the fourth leading cause of death in urban areas and the leading cause of death in rural areas.⁽¹⁾ Mortality is expected to rise

(1) Guan X, Silk B, Li W, et al. Pneumonia incidence and mortality in mainland China: systematic review of Chinese and English literature, 1985-2008

as bacteria become increasingly resistant to currently prescribed treatments. The incidence of multi-drug resistant pneumonia is rising in China and several other Asian countries.(2),(3),(4)

About Lefamulin

Lefamulin is a semi-synthetic derivative of pleuromutilin that inhibits a key process for bacterial growth. In pre-clinical studies, lefamulin has demonstrated a targeted spectrum of activity against the pathogens that most commonly cause CABP, including multi-drug resistant strains. Due to its novel mechanism of action, low incidence of cross-resistance between other antibacterial agents commonly used to treat CABP, and low propensity for bacterial resistance to develop, lefamulin has the potential to be used as a first-line empiric monotherapy for the treatment of CABP. Furthermore, if approved, the availability of both oral and IV formulations and a favorable tolerability profile make it appropriate for potential use across all three CABP treatment settings, including in-hospital, transition of care, and community-initiated.

In the U.S., Nabriva Therapeutics anticipates filing a New Drug Application in the second half of this year contingent on positive results from its second lefamulin evaluation against pneumonia (LEAP 2) Phase 3 clinical trial. Topline data from LEAP 2 is expected in the spring of 2018. LEAP 2 is designed to assess the efficacy and safety of oral lefamulin compared to oral moxifloxacin in adult patients with moderate CABP. In September 2017, Nabriva Therapeutics announced positive topline results from its first Phase 3 clinical trial of lefamulin (LEAP 1), which evaluated the efficacy and safety of intravenous (IV) to oral lefamulin in adult patients with moderate to severe CABP compared to moxifloxacin with or without adjunctive linezolid. In LEAP 1, lefamulin met both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) primary endpoints of non-inferiority compared to moxifloxacin with or without adjunctive linezolid. Lefamulin also showed a favorable tolerability profile in the LEAP 1 trial, with no unexpected safety signals or evidence of off-target activity.

About Roivant Sciences

Roivant is dedicated to transformative innovation in healthcare. Roivant focuses on realizing the full potential of promising biomedical research by developing and commercializing novel therapies across diverse therapeutic areas. Roivant partners with innovative biopharmaceutical companies and academic institutions to ensure that important medicines are rapidly developed and delivered to patients.

Roivant advances its drug pipelines through wholly- or majority-owned subsidiary companies, including Myovant (women's health and endocrine diseases), Axovant (neurology), Urovant (urology), Enzyvant (rare diseases), Dermavant (dermatology) and Metavant (cardiometabolic diseases). Roivant also pursues its mission by incubating and launching innovative healthcare companies operating outside of traditional biopharmaceutical development, including Datavant (healthcare analytics). Roivant's long-range mission is to reduce the time and cost of developing and delivering new medicines for patients.

About Nabriva Therapeutics plc

(2) Liu Y, Chen M, Zhao T, et al. Causative agent distribution and antibiotic therapy assessment among adult patients with community acquired pneumonia in Chinese urban population. *BMC Infect Dis* 2009;9:31.

(3) Cao B, Zhao CJ, Yin YD, et al. High prevalence of macrolide resistance in *Mycoplasma pneumoniae* isolates from adult and adolescent patients with respiratory tract infection in China. *Clin Infect Dis* 2010;51:189-94.

(4) Qiao M, Ying GG, Singer A, et al. Review of antibiotic resistance in China and its environment. *Env Int* 2018;110:160-172

Nabriva Therapeutics is a biopharmaceutical company engaged in the research and development of new medicines to treat serious bacterial infections, with a focus on the pleuromutilin class of antibiotics. Nabriva Therapeutics' medicinal chemistry expertise has enabled targeted discovery of novel pleuromutilins, including both intravenous and oral formulations. Nabriva Therapeutics' lead product candidate, lefamulin, is a novel semi-synthetic pleuromutilin antibiotic with the potential to be the first-in-class available for systemic administration in humans. The company believes that lefamulin is the first antibiotic with a novel mechanism of action to have reached late-stage clinical development in more than a decade. Nabriva has announced positive topline data for lefamulin from the first of its two global, registrational Phase 3 clinical trials evaluating lefamulin in patients with moderate to severe community-acquired bacterial pneumonia (CABP). Nabriva Therapeutics believes lefamulin is well-positioned for use as a first-line empiric monotherapy for the treatment of moderate to severe CABP due to its novel mechanism of action, targeted spectrum of activity, resistance profile, achievement of substantial drug concentration in lung tissue and fluid, oral and IV formulations and a favorable tolerability profile, with the results of the LEAP 1 trial showing a rate of treatment-emergent adverse events comparable to moxifloxacin with or without linezolid. Nabriva Therapeutics is evaluating the continued development of lefamulin for indications in addition to CABP. Pediatric oral formulation development is ongoing and we anticipate initiating clinical studies in pediatric patients in mid-2018. We believe lefamulin has potential to treat ABSSSI, VABP or HABP and STIs. In addition, we may explore longer duration of treatment with lefamulin to support development of a treatment for osteomyelitis and prosthetic joint infections.

Outside of the greater China region, Nabriva Therapeutics owns exclusive rights to lefamulin, which is protected by composition of matter patents issued in the United States, Europe and Japan.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Nabriva, including but not limited to statements about the development of Nabriva's product candidates, such as the future development or commercialization of lefamulin in the greater China region, the potential benefits under its license agreement with Sinovant Sciences, plans for the design, conduct and timelines of Nabriva's ongoing Phase 3 clinical trial of lefamulin for CABP, the clinical utility of lefamulin for CABP and Nabriva's plans for filing of regulatory approvals and efforts to bring lefamulin to market, the market opportunity for and the potential market acceptance of lefamulin for CABP, the development of lefamulin for additional indications, the development of additional formulations of lefamulin, plans to pursue research and development of other product candidates, the sufficiency of Nabriva's existing cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or trials in different disease indications will be indicative of the results of ongoing or future trials, whether results of Nabriva's first Phase 3 clinical trial of lefamulin will be indicative of the results for its second Phase 3 clinical trial of lefamulin, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of product candidates including lefamulin for use as a first-line empiric monotherapy for the treatment of moderate to severe CABP, the sufficiency of cash resources and need for additional financing and such other important factors as are

set forth under the caption “Risk Factors” in Nabriva’s annual and quarterly reports on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Nabriva’s views as of the date of this release. Nabriva anticipates that subsequent events and developments will cause its views to change. However, while Nabriva may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Nabriva’s views as of any date subsequent to the date of this release.

CONTACTS:

Nabriva Therapeutics plc

FOR INVESTORS

Dave Garrett
Nabriva Therapeutics plc
david.garrett@nabriva.com
610-816-6657

FOR MEDIA

Benjamin Navon
W2Opure
bnavon@w2ogroup.com
617-337-4166

CERTIFICATIONS

I, Colin Broom, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nabriva Therapeutics plc;
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 board of directors (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 8, 2018

CERTIFICATIONS

I, Gary Sender, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nabriva Therapeutics plc;
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 board of directors (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 8, 2018

**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 plc (the “Company”) for the period ended March 31, 2018 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 8, 2018

**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 plc (the "Company") for the period ended March 31, 2018 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 8, 2018
