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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 June 30, 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 ☐ (Do not check if a smaller reporting company)	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 Rule12b-2 of the Act). Yes ☐ No ☒

As of July 31, 2018, the registrant had 66,484,159 ordinary shares outstanding.

NABRIVA THERAPEUTICS plc
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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:

- our expectations with respect to the potential financial impact, synergies, growth prospects and benefits of our acquisition of Zavante Therapeutics, Inc., or Zavante, which was completed on July 24, 2018, or the Acquisition, pursuant to the Agreement and Plan of Merger dated July 23, 2018, or the Merger Agreement, by and among Nabriva, Zuperbug Merger Sub I, Inc., or Merger Sub I, Zuperbug Merger Sub II, Inc., or Merger Sub II, Zavante and the Zavante stockholder representative, including the potential realization of the expected benefits from the Acquisition;
- our expectations with respect to milestone payments pursuant to the Merger Agreement and expectations with respect to potential advantages of CONTEPO or any other product candidate that we acquired in connection with the Acquisition;
- the anticipated and unanticipated costs, fees, expenses and liabilities related to the Acquisition;
- our ability to successfully integrate Zavante's business into our business;
- our expectations regarding how far into the future our cash on hand will fund our ongoing operations;
- whether results of Zavante's pivotal ZTI-01 Efficacy and Safety Study, or ZEUS Study, will be indicative of results for any ongoing or future clinical trials and studies of CONTEPO;
- the timing of and our ability to submit applications for and obtain and maintain marketing approval of lefamulin, CONTEPO and other product candidates, including the completion of any post-marketing requirements with respect to any marketing approval we may obtain;
- the potential receipt of revenues from future sales of lefamulin or CONTEPO;
- our plans to pursue development of lefamulin for additional indications other than community-acquired bacterial pneumonia, or CABP, and of CONTEPO for additional indications other than in complicated urinary tract infections, or cUTIs;
- 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, CONTEPO and our other product candidates;
- the potential advantages of lefamulin, CONTEPO and our other product candidates;
- our estimates regarding the market opportunities for lefamulin, CONTEPO and our other product candidates;
- the rate and degree of market acceptance and clinical benefit of lefamulin for CABP, CONTEPO for cUTI 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., or the Sinovant License Agreement;
- 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;
- our business and business relationships, including with employees and suppliers, following the Acquisition;
- our ability to satisfy milestone, royalty and transaction revenue payments pursuant to the Stock Purchase Agreement between Zavante and SG Pharmaceuticals, Inc.; and
- other risks and uncertainties, including those described in the ‘‘Risk Factors’’ section of this Form 10-Q.

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

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

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 June 30, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 86,769	$ 75,253
Short-term investments	110	225
Other receivables	5,402	6,820
Contract asset	—	1,500
Prepaid expenses	1,558	1,150
Total current assets	93,839	84,948
Property, plant and equipment, net	1,327	1,285
Intangible assets, net	172	127
Long-term receivables	425	428
Total assets	**$ 95,763**	**$ 86,788**
Liabilities and equity		
Current liabilities:		
Accounts payable	$ 5,136	$ 2,928
Accrued expense and other current liabilities	8,124	8,364
Total current liabilities	13,260	11,292
Non-current liabilities		
Long-term debt	232	592
Other non-current liabilities	203	236
Total non-current liabilities	435	828
Total liabilities	**13,695**	**12,120**
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 1,000,000,000 ordinary shares authorized at June 30, 2018; 36,707,685 and 40,959,452 issued and outstanding at December 31, 2017 and June 30, 2018, respectively	367	410
Preferred shares, par value $0.01, 100,000,000 shares authorized at June 30, 2018; None issued and outstanding	—	—
Additional paid in capital	360,872	384,557
Accumulated other comprehensive income	27	27
Accumulated deficit	(279,198)	(310,326)
Total stockholders' equity	82,068	74,668
Total liabilities and stockholders' equity	**$ 95,763**	**$ 86,788**

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 share and per share data)	Three Months Ended June 30, 2017	Three Months Ended June 30, 2018	Six Months Ended June 30, 2017	Six Months Ended June 30, 2018
Revenues:				
Collaboration revenue	$ —	$ —	$ —	$ 6,500
Research premium and grant revenue	1,051	847	2,729	1,898
Total revenue	1,051	847	2,729	8,398
Operating expenses:				
Research and development	(11,043)	(9,717)	(23,703)	(19,996)
General and administrative	(5,570)	(8,837)	(9,788)	(18,973)
Total operating expenses	(16,613)	(18,554)	(33,491)	(38,969)
Loss from operations	**(15,562)**	**(17,707)**	**(30,762)**	**(30,571)**
Other income (expense):				
Other income (expense), net	(116)	(141)	90	(118)
Interest income	112	19	233	28
Interest expense	(3)	(7)	(4)	(11)
Loss before income taxes	**(15,569)**	**(17,836)**	**(30,443)**	**(30,672)**
Income tax benefit (expense)	967	48	618	(458)
Net loss	**(14,602)**	**(17,788)**	**(29,825)**	**(31,130)**
Other comprehensive income (loss), net of tax				
Unrealized losses on available-for-sale financial assets	(10)	—	(26)	—
Reclassification to net income	—	—	—	—
Other comprehensive income (loss), net of tax	(10)	—	(26)	—
Comprehensive loss	**$ (14,612)**	**$ (17,788)**	**$ (29,851)**	**$ (31,130)**
Loss per share				
Basic and Diluted ($ per share)	$ (0.54)	$ (0.44)	$ (1.10)	$ (0.80)
Weighted average number of shares:				
Basic and Diluted	27,186,560	40,515,920	27,197,070	38,723,718

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

NABRIVA THERAPEUTICS plc
Consolidated Statements of Cash Flows (unaudited)

(in thousands)	Six Months Ended June 30, 2017	2018
Cash flows from operating activities		
Net loss	$ (29,825)	$ (31,130)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash other expense, net	(1,008)	91
Non-cash interest income	(63)	(50)
Depreciation and amortization expense	149	262
Stock-based compensation	2,876	2,011
Deferred income taxes	(683)	—
Other, net	105	(5)
Changes in operating assets and liabilities:		
Changes in long-term receivables	12	(3)
Changes in other receivables and prepaid expenses	(3,315)	(2,510)
Changes in accounts payable	4,975	(2,241)
Changes in accrued expenses and other liabilities	(3,456)	(142)
Changes in other non-current liabilities	18	33
Changes in income tax liabilities	(4)	324
Net cash used in operating activities	(30,219)	(33,360)
Cash flows from investing activities		
Purchases of plant and equipment and intangible assets	(236)	(168)
Purchases of term deposits	—	(115)
Proceeds from sales of property, plant and equipment	2	—
Proceeds from sales of available-for-sale securities	18,000	—
Net cash provided by (used in) investing activities	17,766	(283)
Cash flows from financing activities		
Proceeds from sale of ordinary shares	—	22,784
Proceeds from long-term debt	228	410
Proceeds from exercise of stock options	11	—
Equity transaction costs	(1,483)	(976)
Net cash provided by (used in) financing activities	(1,244)	22,218
Effects of foreign currency translation on cash and cash equivalents	1,008	(91)
Net decrease in cash and cash equivalents	(12,689)	(11,516)
Cash and cash equivalents at beginning of period	32,778	86,769
Cash and cash equivalents at end of period	$ 20,089	$ 75,253

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 share and 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 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.

On July 23, 2018, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement"),with Zavante, a biopharmaceutical company focused on developing CONTEPO (fosfomycin for injection) to improve the outcomes of hospitalized patients (the "Acquisition"). The Acquisition is discussed in further detail in Note 11 – "*Subsequent Events*" below.

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, convertible debt financings and research and development support from governmental grants and loans. As of June 30, 2018, the Company had cash, cash equivalents and short-term investments of $75.5 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 the date of this filing , management assessed the Company's ability to continue as a going concern and determined that it expects that its existing cash, cash equivalents and short-term investments, together with the net proceeds from the Company's July 2018 Public Offering (as defined below), as well as anticipated near-term milestone payments under its license agreement with Sinovant Sciences, Ltd. and anticipated research premiums from the Austrian government for its qualified 2017 research and development expenditures, will be sufficient to enable the Company to fund its operating expenses and capital expenditure requirements into the first quarter of 2020, subject to a successful commercial launch in the United States of lefamulin for CABP and CONTEPO for cUTI in 2019. 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 regulatory delays or is required to conduct additional clinical trials to satisfy regulatory requirements. If the Company obtains marketing approval for lefamulin, CONTEPO or any other product candidate that it develops, it expects to incur significant commercialization expenses related to product sales, marketing, distribution and

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

manufacturing. The Company will continue to invest in critical pre-commercialization and supply chain activities prior to potentially receiving marketing approval and making lefamulin and CONTEPO available to patients.

The Company expects to seek additional funding in future periods for purposes of investment in its commercial and medical affairs organization as well as investing in its supply chain, including building active pharmaceutical ingredient safety stock for the commercial supply of lefamulin and CONTEPO, in an effort to enhance the potential commercial launch of lefamulin and CONTEPO.

In March 2018, the Company entered into a Controlled Equity Offering[SM] Sales Agreement (the "ATM Agreement"), with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which, from time to time, the Company may offer and sell its ordinary shares having aggregate gross proceeds of up to $50.0 million through Cantor. As of June 30, 2018, the Company has issued and sold an aggregate of 4,243,096 ordinary shares under the ATM Agreement, for gross proceeds of $22.8 million, and net proceeds of $22.2 million, after deducting commissions. No ordinary shares have been issued and sold under the ATM agreement since June 30, 2018.

On July 31, 2018, the Company completed the underwritten public offering of 18,181,818 ordinary shares at a public offering price of $2.75 per share, resulting in gross proceeds of $50.0 million and net proceeds to the Company of $46.1 million, after deducting underwriting discounts and commissions and offering expenses (the "Public Offering").

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 June 30, 2018 and for the three months and six months ended June 30, 2017 and 2018 are 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 June 30, 2018 and for the three and six months ended June 30, 2017 and 2018. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 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.

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 results in enhanced revenue disclosures,

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 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 Company adopted ASU 2017-09 in the first quarter of fiscal year 2018. 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.

- In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): "*Improvements to Nonemployee Share-Based Payment Accounting*," which largely aligns the accounting for share-based payment awards issued to nonemployees with the accounting for share-based payment awards issued to employees. Under previous GAAP, the accounting for nonemployee share-based payments differed from that applied to employee awards, particularly with regard to the measurement date and the impact of performance conditions. Under the new guidance, (i) equity-classified share-based payment awards issued to nonemployees will be measured at the grant date, instead of the previous requirement to remeasure the awards through the performance completion date, (ii) for performance conditions, compensation cost associated with the award will be recognized when the achievement of the performance condition is probable, rather than upon achievement of the performance condition, and (iii) the current requirement to reassess the classification (equity or liability) for nonemployee awards upon vesting will be eliminated, except for awards in the form of convertible instruments. This new guidance will be effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company does not expect the adoption of the new guidance to have a material effect on its financial statements.

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:

(in thousands)	Level 1	Level 2	Level 3	Total
December 31, 2017				
Assets:				
Short-term investments:				
Available-for-sale securities	$ —	$ 50	$ —	$ 50
Term deposits	60	—	—	60
Total Assets	**$ 60**	**$ 50**	**$ —**	**$ 110**

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

(in thousands)	Level 1	Level 2	Level 3	Total
June 30, 2018				
Assets:				
Short-term investments:				
Available-for-sale securities	$ —	$ 50	$ —	$ 50
Term deposits	175	—	—	175
Total Assets	**$ 175**	$ 50	$ —	$ 225

As of June 30, 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 six months ended June 30, 2018 or the year ended December 31, 2017. There were no changes in valuation techniques during the six months ended June 30, 2018.

As of June 30, 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 June 30, 2018
Research and development related costs	$ 2,308	$ 2,695
Payroll and related costs	4,426	3,760
Accounting, tax and audit services	231	182
Other	1,159	1,727
Total other current liabilities	**$ 8,124**	**$ 8,364**

5. Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2017	2018	2017	2018
Collaboration revenues	$ —	$ —	$ —	$ 6,500
Research premium	871	709	2,376	1,479
Government grants	154	138	301	419
Grants from WWFF	26	—	52	—
Total	**$ 1,051**	**$ 847**	**$ 2,729**	**$ 8,398**

The collaboration revenues for the six months ended June 30, 2018 reflect the income recorded from the Sinovant License Agreement (see Note 9) and includes the $5.0 million non-refundable upfront payment received in the first quarter of 2018 as consideration for entering into the Sinovant License Agreement 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

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

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

Each vested option grants the beneficiary the right to acquire one share in the Company. The vesting period for the options is four years following the grant date. On the last day of the last calendar month of the first year of the vesting period, 25% of the options attributable to each beneficiary are automatically vested. During the second, third and fourth years of the vesting period, the remaining 75% of the options vest on a monthly pro rata basis (i.e. 2.083% per month). Options granted under the SOP 2015 have a term of no more than ten years from the beneficiary's date of participation.

The following table summarizes information regarding our stock option awards under the SOP 2015 for the six months ended June 30, 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	(117,879)	8.05	
Outstanding as of June 30, 2018	2,927,020	8.36	$ —
Vested and exercisable as of June 30, 2018	1,485,557	7.98	$ —

Stock-based compensation expense under the SOP 2015 was $0.4 million and $1.3 million for the three and six months ended June 30, 2018, respectively, and $1.1 million and $2.9 million for the three and six months ended June 30, 2017, respectively.

The weighted average remaining contractual life of the options as of June 30, 2018 is 7.9 years.

As of June 30, 2018, there was $7.6 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 1.1 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.

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

At June 30, 2018, 4,980,271 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 six months ended June 30, 2018:

2017 Plan	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1, 2018	294,100	6.92	
Granted	1,717,400	6.04	
Exercised	—	—	
Forfeited	(42,000)	6.92	
Outstanding as of June 30, 2018	1,969,500	6.16	$ —
Vested and exercisable as of June 30, 2018	—	—	—

Stock-based compensation expense under the 2017 Plan was $0.3 million and $0.7 million for the three and six months ended June 30, 2018, respectively. The weighted average fair value of the options granted during the six months ended June 30, 2018 was $3.51 per share. The options granted in the six months ended June 30, 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	60.0% - 61.0%
Expected term of options (in years)	6.0
Range of risk-free interest rate	2.6% - 2.9%
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 June 30, 2018 is 9.6 years.

As of June 30, 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 1.6 years.

Restricted Stock Units

During the six months ended June 30, 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. As of June 30, 2018, there were 328,300 RSUs outstanding. 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 June 30, 2018.

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(in thousands, except share and per share data)

7. Income Tax (Expense) Benefit

For the three months ended June 30, 2018, the Company recorded a tax benefit of $48,000 and for the three months ended June 30, 2017, the Company recorded a tax benefit of $967,000. For the six months ended June 30, 2018, the Company recorded a tax expense of $458,000 and for the six months ended June 30, 2017, the Company recorded a tax benefit of $618,000.

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 June 30, 2018 and December 31, 2017, the Company has recorded a valuation allowance of $83.6 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.

8. Earnings (Loss) per Share

Basic and diluted loss per share

For the three and six months ended June 30, 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.

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except per share data)	**2017**	**2018**	**2017**	**2018**
Net loss for the period	$ (14,602)	$ (17,788)	$ (29,825)	$ (31,130)
Weighted average number of shares outstanding	27,186,560	40,515,920	27,197,070	38,723,718
Basic and diluted loss per share	**$ (0.54)**	**$ (0.44)**	**$ (1.10)**	**$ (0.80)**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2018**	**2017**	**2018**
Stock option awards	2,930,110	4,896,520	2,930,110	4,896,520
Restricted stock units	—	328,300	—	328,300

9. Sinovant License Agreement

In March 2018, the Company entered into a license agreement (the "License Agreement"), with Sinovant Sciences, Ltd. ("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 have established 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.

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

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.

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 six months ended June 30, 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 June 30, 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, except as described below.

Acquisition of Zavante

On July 23, 2018, the Company entered into the Merger Agreement for the acquisition of Zavante. The Acquisition was completed on July 24, 2018 (the "Closing"). In connection with the Closing, the Company issued 7,336,906 Company ordinary shares to former Zavante stockholders, which together with the 815,186 ordinary shares that are issuable upon release of the Holdback Shares (as defined below) constitute approximately 19.9% of the Company ordinary shares outstanding as of immediately prior to the Closing (the "Upfront Shares").

Pursuant to the Merger Agreement, former Zavante stockholders and other equity holders, in the aggregate and subject to the terms and conditions of the Merger Agreement, will also be entitled to receive from the Company up to $97.5 million in contingent consideration, of which $25.0 million would become payable upon the first approval of a new drug application from the U.S. Food and Drug Administration (the "FDA") for fosfomycin for injection for any indication (the "Approval Milestone Payment") and an aggregate of up to $72.5 million would become payable upon the achievement of specified sales milestones (the "Net Sales Milestone Payments").

Subject to approval of the Company's shareholders of the issuance of Company ordinary shares in satisfaction of the Company's milestone payment obligations in accordance with Nasdaq listing rules and Irish law (the "Milestone Share Approval") in excess of 19.9% of the issued and outstanding ordinary shares of the Company outstanding as of immediately prior to the Closing, the Approval

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Milestone Payment will be settled in Company ordinary shares and the Company will have the right to settle the Net Sales Milestone Payments in Company ordinary shares, except as otherwise provided in the Merger Agreement. In the absence of obtaining the Milestone Share Approval, all milestone payments will be settled in cash. The Company has agreed to use commercially reasonable efforts after the Closing to obtain the Milestone Share Approval and to call a meeting of Company shareholders no later than December 31, 2018 to seek the Milestone Share Approval.

In connection with the Acquisition, former Zavante stockholders agreed to cause any Upfront Shares received by them to abstain from voting on the Milestone Share Approval and to vote any other Company ordinary shares held by them in favor of the Milestone Share Approval.

Subject to the terms of the Merger Agreement, 10% of the Upfront Shares (the "Holdback Shares") will serve as a source for the satisfaction of indemnification and other obligations of the former Zavante stockholders and, subject to reduction in respect of these obligations, will be issued to the former Zavante stockholders following the first anniversary of the Closing.

Former Zavante stockholders who do not comply with specified procedural requirements set forth in the Merger Agreement, and former holders of Zavante options and warrants, will receive cash in lieu of any Company ordinary shares that otherwise would be issuable to them pursuant to the Merger Agreement.

In addition, the Company now possesses certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by the Company upon closing of the Acquisition. See "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations — Corporate Updates — Acquisition of Zavante" for further information regarding the agreements that were assumed by the Company.

Public Offering

On July 31, 2018, the Company completed the Public Offering of 18,181,818 ordinary shares at a public offering price of $2.75 per share, resulting in gross proceeds of $50.0 million and net proceeds to the Company of $46.1 million, after deducting underwriting discounts and commissions and offering expenses.

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. We have two product candidates that are in late stage development: lefamulin, under development to potentially be the first pleuromutilin antibiotic available for systemic administration in humans, and CONTEPO, a potentially first-in-class epoxide intravenous, or IV, antibiotic in the United States. We are developing both IV and oral formulations of lefamulin for the treatment of community-acquired bacterial pneumonia, or CABP. We are developing CONTEPO IV for complicated urinary tract infections, or cUTI. We may potentially develop lefamulin and CONTEPO for additional indications.

On July 24, 2018, we completed the acquisition, or the Acquisition, of Zavante Therapeutics, Inc., or Zavante, a privately-held late clinical-stage biopharmaceutical company focused on developing novel therapies to improve the outcomes of hospitalized patients. Zavante's lead product candidate is CONTEPO (fosfomycin for injection).

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. In addition, we expect to submit an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, utilizing the U.S. Food and Drug Administration, or the FDA's, 505(b)(2) pathway, 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. Both lefamulin and CONTEPO have been granted qualified infectious disease product designation by the FDA. The FDA has granted fast track designation to CONTEPO under the Generating Antibiotics Incentives Now Act, or the GAIN Act, and we plan to apply for fast track designation for lefamulin, which would allow for potential approval of both lefamulin and CONTEPO in 2019. We currently have a team of regional business directors and medical science liaisons in the field performing educational and market development activities. We plan to use a targeted hospital-based sales force to promote both lefamulin and CONTEPO, if approved.

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 topline 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 FDA and European Medicines Agency, or EMA. On May 21, 2018, we announced positive topline results for LEAP 2. In LEAP 2, which enrolled 738 patients, lefamulin met all of the primary endpoints of non-inferiority compared to moxifloxacin as required by the FDA and EMA. In both LEAP 1 and LEAP 2, lefamulin was generally well tolerated.

In June 2016, the first patient was enrolled by Zavante in its pivotal ZTI-01 Efficacy and Safety Study, which we refer to as the ZEUS Study. In April 2017, Zavante announced positive topline results of the ZEUS Study. The ZEUS Study was a multicenter, randomized, parallel-group, double-blind Phase 2/3 clinical trial designed to evaluate safety, tolerability, efficacy and pharmacokinetics of seven days of treatment, or up to 14 days of treatment for patients with concurrent bacteremia, with CONTEPO compared to piperacillin-tazobactam, or PIP-TAZ, in the treatment of hospitalized adults with cUTI or acute pyelonephritis, or AP. In June 2018, Zavante initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age receiving standard-of-care antibiotic therapy for proven or suspected infection or peri-operative prophylaxis. We anticipate completing enrollment in this study in late 2020.

Since inception, we have incurred significant operating losses. As of June 30, 2018, we had an accumulated deficit of $310.2 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 equity securities, convertible loans and research and development support from governmental grants and loans and, most recently, our underwritten public offering completed in July 2018. We have devoted substantially all of our efforts to research and development, including clinical trials. Our ability to

generate profits from operations and remain profitable depends on our ability to successfully develop and commercialize drugs that generate significant revenue.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect to continue to invest in critical pre-commercialization and supply chain activities prior to potentially receiving marketing approval and making lefamulin and CONTEPO available to patients.

Our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for lefamulin, CONTEPO 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 and CONTEPO. 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.

Corporate Updates

Acquisition of Zavante

On July 23, 2018, we entered into an Agreement and Plan of Merger, or the Merger Agreement,with Zavante, a biopharmaceutical company focused on developing CONTEPO (fosfomycin for injection) to improve the outcomes of hospitalized patients.

CONTEPO is a potentially first-in-class epoxide IV antibiotic in the United States with a broad spectrum of bactericidal Gram-negative and Gram-positive activity, including activity against many contemporary multi-drug resistant, or MDR, strains that threaten hospitalized patients. IV fosfomycin has an extensive commercial history in markets outside the United States, where it has been used broadly for over 45 years to treat a variety of indications, including complicated urinary tract infections, bacteremia, pneumonia and skin infections. CONTEPO inhibits the bacteria's ability to form a cell wall, which is critical for the cell's survival and growth. It works at an earlier and different stage of cell wall synthesis than other injectable antibiotics, differentiating its mechanism of action from approved injectable antibiotics. CONTEPO utilizes a dosing approach developed by Zavante for the United States that is designed to optimize the product candidate's pharmacokinetics and pharmacodynamics in order to improve treatment outcomes. The CONTEPO development program has focused on obtaining marketing approval in the United States for the treatment of cUTIs, including acute pyelonephritis, or AP.

The Acquisition was completed on July 24, 2018. Upon completion of the Acquisition, or the Closing, we issued 7,336,906 of our ordinary shares to former Zavante stockholders, which together with the 815,186 ordinary shares that are issuable upon release of the Holdback Shares (as defined below) constitute approximately 19.9% of our ordinary shares outstanding as of immediately prior to the Closing, or the Upfront Shares.

Pursuant to the Merger Agreement, former Zavante stockholders and other equity holders, in the aggregate and subject to the terms and conditions of the Merger Agreement, will also be entitled to receive from us up to $97.5 million in contingent consideration, of which $25.0 million would become payable upon the first approval of a new drug application from the U.S. Food and Drug Administration, or the FDA, for fosfomycin for injection for any indication, or the Approval Milestone Payment, and an aggregate of up to $72.5 million would become payable upon the achievement of specified sales milestones, or the Net Sales Milestone Payments.

Subject to approval of our shareholders of the issuance of our ordinary shares in satisfaction of our milestone payment obligations in accordance with Nasdaq listing rules and Irish law, or the Milestone Share Approval, in excess of 19.9% of the issued and outstanding ordinary shares of Nabriva outstanding as of immediately prior to the Closing, the Approval Milestone Payment will be settled in our ordinary shares and we will have the right to settle the Net Sales Milestone Payments in our ordinary shares, except as otherwise provided in the Merger Agreement. In the absence of obtaining the Milestone Share Approval, all milestone payments will be settled in cash. We have agreed to use commercially reasonable efforts after the Closing to obtain the Milestone Share Approval and to call a meeting of our shareholders no later than December 31, 2018 to seek the Milestone Share Approval.

In connection with the Acquisition, former Zavante stockholders agreed to cause any Upfront Shares received by them to abstain from voting on the Milestone Share Approval and to vote any other of our ordinary shares held by them in favor of the Milestone Share Approval.

Subject to the terms of the Merger Agreement, 10% of the Upfront Shares, or the Holdback Shares, will serve as a source for the satisfaction of indemnification and other obligations of the former Zavante stockholders and, subject to reduction in respect of these obligations, will be issued to the former Zavante stockholders following the first anniversary of the Closing.

In addition, we now possess certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by us upon closing of the Acquisition. Prior to the Acquisition, former Zavante stockholders entered into a stock purchase agreement, dated as of May 5, 2015, or the Stock Purchase Agreement, pursuant to which Zavante is obligated to make milestone payments to the selling stockholders of $3.0 million upon marketing approval by the FDA with respect to any oral, intravenous or other form of fosfomycin, or the Zavante Products, and milestone payments of up to $26.0 million in the aggregate upon the occurrence of various specified levels of net sales with respect to the Zavante Products. In addition, Zavante is obligated to make annual royalty payments of a mid-single-digit percentage of net sales of Zavante Products, subject to adjustment based on net sales thresholds and with such percentage reduced to low single-digits if generic fosfomycin products account for half of the applicable market on a product-by-product and country-by-country basis. The Stock Purchase Agreement also provides that Zavante will pay a mid-single-digit percentage of transaction revenue in connection with the consummation of the grant, sale, license or transfer of market exclusivity rights for a qualified infectious disease product (within the meaning of the 21st Century Cures Act, or the Cures Act) related to a Zavante Product.

Zavante has entered into a manufacturing and supply agreement with Ercros, S.A., pursuant to which Ercros, S.A. supplies to Zavante, on an exclusive basis, a blend of fosfomycin disodium and succinic acid, or API Mixture, for CONTEPO in support of filing an NDA and, if CONTEPO is approved, will supply the commercial API Mixture for CONTEPO in the United State. In addition, Zavante has entered into a manufacturing and supply agreement with Fisiopharma, S.r.l. pursuant to which Zavante has an obligation to purchase a minimum percentage of its commercial requirements of CONTEPO in the United States. Zavante has also entered into a manufacturing and exclusive supply agreement with Laboratorios ERN, S.A., pursuant to which Laboratorios ERN, S.A. has agreed to supply Zavante with certain technical documentation and data as required for submission of an NDA or an abbreviated new drug application for CONTEPO and certain regulatory support in connection with the commercial sale and use of CONTEPO in the United States, and which provides for payments by Zavante to Laboratorios ERN, S.A. of a one-time cash payment upon the first commercial sale of CONTEPO and subsequent quarterly payments thereafter based on the number of vials of CONTEPO sold in the United States during each quarter.

In connection with the closing of the Acquisition, we have assumed other agreements entered into by Zavante, including, among others, an R&D office lease, a collaboration agreement governing the supply and manufacturing agreements described above and a commercial packaging agreement.

License Agreement with Sinovant Sciences, Ltd.

In March 2018, we entered into a license agreement, or the Sinovant 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 Sinovant 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 Sinovant License Agreement, Sinovant and our subsidiaries have established 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 Sinovant 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 Sinovant 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 Sinovant 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 Sinovant License Agreement in the event of the other party's uncured material breach. Either party may also

terminate the Sinovant License Agreement under specified circumstances relating to the other party's insolvency. We have the right to terminate the Sinovant License Agreement immediately if Sinovant does not reach certain development milestones by certain specified dates (subject to specified cure periods). The Sinovant License Agreement contemplates that the 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.

Financial Operations Overview

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 and CONTEPO. 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 we entered into in March 2018, and includes a $5.0 million non-refundable upfront payment received as consideration for entering into the Sinovant License Agreement as well as $1.5 million of variable consideration related to 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 70.8% and 51.3% of our total operating expenses for the six months ended June 30, 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.

	Six Months Ended June 30,	
(in thousands)	2017	2018
Direct Costs		
Lefamulin	$ 15,921	$ 10,543
Other programs and initiatives	60	33
Indirect Costs	7,722	9,420
Total	$ 23,703	$ 19,996

We expect to continue to incur research and development expenses in connection with our activities related to our planned NDA and MAA filings for marketing approval of lefamulin for the treatment of CABP and our planned NDA filing for the marketing approval of CONTEPO for the treatment of cUTI, our ongoing pediatric studies of lefamulin for the treatment of CABP and of

CONTEPO for the treatment of cUTI, the pursuit of the clinical development of lefamulin and CONTEPO for additional indications and engagement 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, 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 29.2% and 48.7% of our total operating expenses for the six months ended June 30, 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 we obtain marketing approval of lefamulin for the treatment of CABP and of CONTEPO for the treatment of cUTI.

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 six months ended June 30, 2018, there were no material changes to our critical accounting policies.

Results of Operations

Comparison of Three Months Ended June 30, 2017 and 2018

	Three Months Ended June 30,		
(in thousands)	2017	2018	Change
Consolidated Operations Data:			
Revenues	$ 1,051	$ 847	$ (204)
Costs and Expenses:			
Research and development	(11,043)	(9,717)	1,326
General and administrative	(5,570)	(8,837)	(3,267)
Total operating expenses	(16,613)	(18,554)	(1,941)
Loss from operations	**(15,562)**	**(17,707)**	**(2,145)**
Other income (expense):			
Other income (expense), net	(116)	(141)	(25)
Interest income (expense), net	109	12	(97)
Loss before income taxes	**(15,569)**	**(17,836)**	**(2,267)**
Income tax benefit	967	48	(919)
Net loss	**$ (14,602)**	**$ (17,788)**	**$ (3,186)**

Revenues

Revenues decreased by $0.2 million from $1.1 million for the three months ended June 30, 2017 to $0.9 million for the three months ended June 30, 2018, primarily due a decrease of grant revenue from research premiums provided to us by the Austrian government by $0.2 million as a result of a decrease in our research and development expenses for which we can receive grant revenue.

Research and Development Expenses

Research and development expenses decreased by $1.3 million from $11.0 million for the three months ended June 30, 2017 to $9.7 million for the three months ended June 30, 2018. The decrease was primarily due to a $1.5 million decrease in research materials and purchased services related to the development of lefamulin and a $0.5 million decrease in stock-based compensation expense, partly offset by a $0.3 million increase in research consulting fees, a $0.3 million increase in staff costs due to the addition of employees and a $0.1 million increase in travel and infrastructure costs.

General and Administrative Expenses

General and administrative expense increased by $3.3 million from $5.6 million for the three months ended June 30, 2017 to $8.8 million for the three months ended June 30, 2018. The increase was primarily due to a $1.1 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a $2.4 million increase in staff costs due to the addition of employees, a $0.2 million increase in infrastructure costs and a $0.4 million increase in travel and other corporate costs, partly offset by a $0.9 million decrease in stock-based compensation expense.

Other Income (Expense), net

Other income (expense), remained constant for the three months ended June 30, 2018 compared to the three months ended June 30, 2017.

Income Tax Expense

Our income tax benefit was $48,000 for the three months ended June 30, 2018 compared to an income tax benefit of $1.0 million for the three months ended June 30, 2017. The change in the income tax benefit is primarily due to the recognition of a full valuation allowance on deferred tax assets and an increase in taxes payable in several of the jurisdictions in which the we operate.

Comparison of Six Months Ended June 30, 2017 and 2018

	Six Months Ended June 30,		
(in thousands)	**2017**	**2018**	**Change**
Consolidated Operations Data:			
Revenues	$ 2,729	$ 8,398	$ 5,669
Costs and Expenses:			
Research and development	(23,703)	(19,996)	3,707
General and administrative	(9,788)	(18,973)	(9,185)
Total operating expenses	(33,491)	(38,969)	(5,478)
Loss from operations	**(30,762)**	**(30,571)**	**191**
Other income (expense):			
Other income (expense), net	90	(118)	(208)
Interest income (expense), net	229	17	(212)
Loss before income taxes	**(30,443)**	**(30,672)**	**(229)**
Income tax benefit (expense)	618	(458)	(1,076)
Net loss	**$ (29,825)**	**$ (31,130)**	**$ (1,305)**

Revenues

Revenues increased by $5.7 million from $2.7 million for the six months ended June 30, 2017 to $8.4 million for the six months ended June 30, 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 to a future milestone payment that we believe is probable to be met and received. Grant revenue from research premiums provided to us by the Austrian government decreased by $0.9 million as a result of a decrease in our research and development expenses for which we can receive grant revenue.

Research and Development Expenses

Research and development expenses decreased by $3.7 million from $23.7 million for the six months ended June 30, 2017 to $20.0 million for the six months ended June 30, 2018. The decrease was primarily due to a $5.3 million decrease in research materials and purchased services related to the development of lefamulin, and a $0.3 million decrease in stock-based compensation expense, partly offset by a $0.8 million increase in research consulting fees, a $0.7 million increase in staff costs due to the addition of employees and a $0.4 million increase in travel and infrastructure costs.

General and Administrative Expenses

General and administrative expense increased by $9.2 million from $9.8 million for the six months ended June 30, 2017 to $19.0 million for the six months ended June 30, 2018. The increase was primarily due to a $3.9 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a $4.7 million increase in staff costs due to the addition of employees, a $0.5 million increase in infrastructure costs and a $0.7 million increase in travel and other corporate costs, partly offset by a $0.6 million decrease in stock-based compensation expense.

Other Income (Expense), net

Other income (expense), net decreased by $0.2 million from $0.1 million income for the six months ended June 30, 2017, to $0.1 million expense for the six months ended June 30, 2018 due to the effects of re-measurements of our foreign currency account balances.

Income Tax Expense

Our income tax expense was $0.5 million for the six months ended June 30, 2018 compared to an income tax benefit of $0.6 million for the six months ended June 30, 2017. The change from an income tax benefit to an income tax expense is primarily due to the recognition of a full valuation allowance on deferred tax assets and an increase in taxes payable in several of the jurisdictions in which the we operate.

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 June 30, 2018, we had cash and cash equivalents and short-term investments of $75.5 million.

In March 2018, we entered into a Controlled Equity Offering^{SM} Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we may offer and sell our ordinary shares having aggregate gross proceeds of up to $50.0 million through Cantor. As of June 30, 2018, we issued and sold an aggregate of 4,243,096 ordinary shares under the ATM Agreement, for gross proceeds of $22.8 million, and net proceeds of $22.2 million, after deducting commissions. From June 30, 2018 to the date of this filing, we have not issued and sold any ordinary shares under the ATM Agreement.

On July 31, 2018, we completed an underwritten public offering of 18,181,818 ordinary shares at a public offering price of $2.75 per share, resulting in gross proceeds of $50.0 million and net proceeds to us of $46.1 million, after deducting underwriting discounts and commissions and offering expenses.

Cash Flows

Comparison of Six Months Ended June 30, 2017 and 2018

The following table summarizes our cash flows for the six months ended June 30, 2017 and 2018:

	Six Months Ended June 30,	
(in thousands)	**2017**	**2018**
Net cash (used in) provided by:		
Operating activities	$ (30,219)	$ (33,360)
Investing activities	17,766	(283)
Financing activities	(1,244)	22,218
Effects of foreign currency translation on cash	1,008	(91)
Net decrease in cash	**$ (12,689)**	$ (11,516)

Operating Activities

Cash flow used in operating activities increased by $3.2 million from $30.2 million for the six months ended June 30, 2017 to $33.4 million for the six months ended June 30, 2018 primarily due to a $0.4 million increase in net loss, after adjustments for non-cash amounts included in net loss and higher working capital of $2.8 million primarily due to changes in accrued expenses and other current liabilities.

Investing Activities

Cash flow from investing activities decreased by $18.0 million from $17.8 million cash provided for the six months ended June 30, 2017 to a use of $0.3 million for the six months ended June 30, 2018 primarily due to proceeds from sale of available-for-sale financial assets to fund operational cash out flows. Other investing activities were relatively insignificant in both periods and related primarily to the acquisition of equipment in support of our research and development activities.

Financing Activities

Cash flow generated from financing activities increased by $23.4 million from $1.2 million cash outflow for the six months ended June 30, 2017 to $22.2 million cash inflow for the six months ended June 30, 2018 due to $22.2 million of proceeds, net of commissions, related to our ATM Agreement.

Operating and Capital Expenditure Requirements

As of the date of this filing, we assessed our ability to continue as a going concern and determined that we expect that our existing cash, cash equivalents and short-term investments, together with the proceeds from our July 2018 public offering (as described above), as well as anticipated near-term milestone payments under our license agreement with Sinovant Sciences, Ltd. and anticipated research premiums from the Austrian government for our qualified 2017 research and development expenditures, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2020, subject to a successful commercial launch in the United States of lefamulin for CABP and CONTEPO for cUTI in 2019. 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 continue to invest in critical pre-commercialization activities prior to receiving marketing approval and making lefamulin and CONTEPO available to patients.

Our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for lefamulin, CONTEPO 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.

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

- initiate or continue the research and development of lefamulin and CONTEPO 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, together with the proceeds our recent underwritten public offering in July 2018, as well as anticipated near-term milestone payments under the Sinovant License Agreement and anticipated research premiums from the Austrian government for our qualified 2017 research and development expenditures, will be sufficient to enable us to fund its operating expenses and capital expenditure requirements into the first quarter of 2020, subject to a successful commercial launch in the United States of lefamulin for CABP and CONTEPO for cUTI in 2019. 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, as well as investing in our supply chain, in an effort to enhance the potential commercial launch of lefamulin and CONTEPO.

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

- the costs and timing of process development and manufacturing scale-up activities associated with lefamulin and CONTEPO;
- the costs, timing and outcome of regulatory review of lefamulin and CONTEPO;
- the costs of commercialization activities for lefamulin and CONTEPO 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 and CONTEPO;
- subject to receipt of marketing approval, revenue received from commercial sales of lefamulin and CONTEPO;
- the costs of developing lefamulin and CONTEPO 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, CONTEPO 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, CONTEPO 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 have generally provided for termination on notice and therefore we believe that our non-cancelable obligations as of June 30, 2018 under these agreements are not material.

During the six months ended June 30, 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. Since June 30, 2018, we have assumed certain contractual liabilities and obligations upon closing of the Acquisition. See "— Corporate Updates — Acquisition of Zavante" for further information regarding certain agreements that we assumed in connection with the Acquisition and our obligations thereunder.

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

Capital Expenditures

Capital expenditures were $236,000 and $168,000 for the six months ended June 30, 2017 and 2018, respectively. We made no significant investments in intangible assets during the six months ended June 30, 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 June 30, 2018, we had no debt that exposed us to interest rate risk. As of June 30, 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, together with the proceeds our recent underwritten public offering in July 2018, as well as anticipated near-term milestone payments under the Sinovant License Agreement and anticipated research premiums from the Austrian government for our qualified 2017 research and development expenditures, will be sufficient to enable us to fund its operating expenses and capital expenditure requirements into the first quarter of 2020, subject to a successful commercial launch in the United States of lefamulin for CABP and CONTEPO for cUTI in 2019. 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 continue to invest in critical pre-commercialization activities prior to potentially receiving marketing approval and making lefamulin a and CONTEPO available to patients. We expect to seek additional funding in future periods for purposes of investment in our commercial and medical affairs organization, as well as investing in our supply chain in an effort to enhance the potential commercial launch of lefamulin and CONTEPO.

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

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

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 June 30, 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 six months ended June 30, 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 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 Recent Acquisition of Zavante

We may fail to realize the anticipated benefits of our Acquisition of Zavante, those benefits may take longer to realize than expected, and we may encounter significant integration difficulties.

On July 24, 2018, we completed our acquisition, or the Acquisition, of Zavante Therapeutics, Inc., or Zavante, pursuant to an Agreement and Plan of Merger, or the Merger Agreement, dated July 23, 2018. Our ability to realize the anticipated benefits of the Acquisition will depend, to a large extent, on our ability to integrate Zavante and CONTEPO into our business and business strategy and realize anticipated growth opportunities and synergies. We expect that the integration process will be complex, costly and time-consuming. As a result, we will be required to devote significant management attention and resources to integrating Zavante into our business and CONTEPO into our business strategy. The integration process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of the Acquisition could cause an interruption of, or a loss of momentum in, our development and commercialization efforts, including with respect to lefamulin and CONTEPO, and could adversely affect our business, financial condition and results of operations.

Our ability to realize the anticipated benefits of the Acquisition is expected to entail numerous additional material potential difficulties, including, among others:

- any delay or failure in obtaining marketing approvals for CONTEPO, or any delay or failure to commercialize CONTEPO in the United States thereafter;
- increased scrutiny from third parties, including regulators, legislative bodies and enforcement agencies, including with respect to product pricing and commercialization matters;
- changes in laws or regulations that adversely impact the anticipated benefits of the Acquisition;

- challenges related to the perception by patients, the medical community and third-party payors of CONTEPO for the treatment of complicated urinary tract infections, or cUTIs;
- disruptions to our manufacturing arrangements with third-party manufacturers, including our manufacturing and supply arrangements with respect to CONTEPO and disruptions to our third-party distribution channel;
- difficulties in managing the expanded operations of a larger and more complex company following the Acquisition;
- the diversion of management attention to integration matters;
- any challenges associated with our chief executive officer transition in connection with the Acquisition;
- difficulties in achieving the anticipated business opportunities and growth prospects from the Acquisition;
- the size of the treatable patient population for CONTEPO may be smaller than we believe it is;
- difficulties in assimilating Zavante employees and in attracting and retaining key personnel; and
- potential unknown liabilities, adverse consequences, unforeseen increased expenses or other unanticipated problems associated with the Acquisition.

Many of these factors are outside of our control, and any one of them could result in increased costs, decreased expected revenues and further diversion of management time and energy, which could materially adversely impact our business, financial condition and results of operations.

Upfront consideration for the Acquisition is comprised of 8,152,092 of our ordinary shares, including the 815,186 ordinary shares that are issuable upon release of the Holdback Shares subject to the terms of the Merger Agreement. Pursuant to the Merger Agreement, former Zavante stockholders are also entitled to receive from us, subject to the terms and conditions of the Merger Agreement, up to $97.5 million in contingent consideration, of which $25 million would become payable upon the first approval of a new drug application from the U.S. Food and Drug Administration, or the FDA, for CONTEPO for injection for any indication, or the Approval Milestone Payment, and an aggregate of up to $72.5 million would become payable upon the achievement of specified net sales milestones, or the Net Sales Milestone Payments. Subject to approval of our shareholders of the issuance of our ordinary shares in satisfaction of the milestone payments, the Approval Milestone Payment will be settled in our ordinary shares and we will have the right to settle the Net Sales Milestone Payments in ordinary shares. In the absence of obtaining such shareholder approval, all milestone payments will be settled in cash. The issuance of our ordinary shares in connection with the closing of the Acquisition was dilutive to our existing shareholders, and the future issuance of our ordinary shares to satisfy our milestone payment obligations would be further dilutive to our then existing shareholders. If we are unable to obtain shareholder approval in connection with the Approval Milestone Payment, the need to satisfy this obligation in cash may have an adverse effect on our liquidity.

Also, following the Acquisition, we now possess certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by us upon closing of the Acquisition. Prior to the Acquisition, former Zavante stockholders and SG Pharmaceuticals, Inc. entered into a stock purchase agreement, dated as of May 5, 2015, or the Stock Purchase Agreement, pursuant to which SG Pharmaceuticals, Inc. acquired all of the outstanding capital stock of Zavante from the Zavante selling stockholders and SG Pharmaceuticals, Inc., subsequently merged with and into Zavante, with Zavante as the surviving entity. Pursuant to the Stock Purchase Agreement, Zavante (as successor to SG Pharmaceuticals, Inc.) is obligated to make milestone payments to the selling stockholders of $3.0 million upon marketing approval by the FDA with respect to any oral, intravenous or other form of fosfomycin, or the Zavante Products, and milestone payments of up to $26 million in the aggregate upon the occurrence of various specified levels of net sales with respect to the Zavante Products. In addition, Zavante is obligated to make annual royalty payments to the Selling Stockholders of a mid single-digit percentage of net sales of Zavante Products, subject to adjustment based on net sales thresholds and with such percentage reduced to low single-digits if generic fosfomycin products account for half of the applicable market on a product-by-product and country-by-country basis. The Stock Purchase Agreement also provides that Zavante will pay to the Selling Stockholders a mid single-digit percentage of transaction revenue in connection with the consummation of the grant, sale, license or transfer of market exclusivity rights for a qualified infectious disease product (within the meaning of the 21st Century Cures Act, or the Cures Act) related to a Zavante Product.

In addition, we expect to incur expenses related to the continued development, regulatory approval process and commercialization with respect to CONTEPO. Zavante has entered into a manufacturing and supply agreement with Fisiopharma, S.r.l. pursuant to which Zavante has an obligation to purchase a minimum percentage of its commercial requirements of CONTEPO in the United

States. Zavante has also entered into a manufacturing and exclusive supply agreement with Laboratorios ERN, S.A., pursuant to which Laboratorios ERN, S.A. has agreed to supply Zavante with certain technical documentation and data as required for submission of an NDA or an abbreviated new drug application for CONTEPO and certain regulatory support in connection with the commercial sale and use of CONTEPO in the United States, and which provides for payments to Laboratorios ERN, S.A. of a one-time cash payment upon the first commercial sale of CONTEPO and subsequent quarterly payments thereafter based on the number of vials of CONTEPO sold in the United States during each quarter.

Because we have limited financial resources, by investing in the Acquisition, we may forgo or delay pursuit of other opportunities that may have proven to have greater commercial potential. Further, it is possible that undisclosed, contingent, or other liabilities or problems may arise in the future of which we were previously unaware. These undisclosed liabilities could have an adverse effect on our business, financial condition and results of operations.

All of these factors could decrease or delay the expected accretive effect of the Acquisition and negatively impact our stock price. As a result, it cannot be assured that the Acquisition will result in the full realization of the benefits anticipated from the Acquisition or in the anticipated time frames or at all.

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 $31.1 million for the six months ended June 30, 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 June 30, 2018, we had an accumulated deficit of $310.3 million. Zavante has also incurred net operating losses since its inception. Zavante's net losses were $12.4 million for the year ended December 31, 2017 and $23.5 million for the year ended December 31, 2016. 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, including in connection with our continued development, regulatory approval efforts and commercialization of lefamulin and CONTEPO. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year.

We expect to continue to invest in critical pre-commercialization activities prior to potentially receiving marketing approval and making lefamulin and CONTEPO available to patients.

We initiated our first Phase 3 global, pivotal clinical trial of lefamulin, which we refer to as Lefamulin Evaluation Against Pneumonia 1, or LEAP 1, in September 2015, and we initiated our second Phase 3 global, pivotal clinical trial of lefamulin, which we refer to as Lefamulin Evaluation Against Pneumonia 2, or LEAP 2, in April 2016. In September 2017, we announced positive topline results for LEAP 1. In December 2017, we announced completion of enrollment for LEAP 2. In May 2018, we announced positive topline results from LEAP 2. LEAP 2 evaluated the safety and efficacy of 5 days of oral lefamulin compared to 7 days of oral moxifloxacin in adult patients with moderate community-acquired bacterial pneumonia, or CABP. 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 June 2016, the first patient was enrolled by Zavante in its pivotal ZTI-01 Efficacy and Safety Study of CONTEPO, which we refer to as the ZEUS Study. In April 2017, Zavante announced positive topline results of the ZEUS Study. The ZEUS Study was a multicenter, randomized, parallel-group, double-blind Phase 2/3, pivotal clinical trial designed to evaluate safety, tolerability, efficacy and pharmacokinetics of seven days of treatment, or up to 14 days of treatment for patients with concurrent bacteremia, with CONTEPO compared to piperacillin-tazobactam, or PIP-TAZ, in the treatment of hospitalized adults with cUTI or acute pyelonephritis, or AP. We expect to submit an NDA for marketing approval of CONTEPO for the treatment of cUTI, including AP, in the United States in the fourth quarter of 2018. In June 2018, Zavante initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age receiving standard-of-care antibiotic therapy for proven or suspected infection or peri-operative prophylaxis. We anticipate completing enrollment in this study in late 2020. We also intend to continue to characterize the clinical pharmacology of CONTEPO. If we obtain marketing approval of CONTEPO for cUTI, including AP, or another indication, we also expect to incur significant additional sales, marketing, distribution and manufacturing expenses.

On July 24, 2018, we completed our Acquisition of Zavante. Upfront consideration in connection with the Acquisition is 8,152,092 of our ordinary shares, including the 815,186 ordinary shares that are issuable upon release of the Holdback Shares subject to the terms of the Merger Agreement. Pursuant to the Merger Agreement, former Zavante stockholders are also entitled to receive from us up to $97.5 million in contingent consideration, consisting of the Approval Milestone Payment and the Net Sales Milestone Payment, subject to the terms and conditions of the Merger Agreement. In connection with the Acquisition, we assumed certain payment obligations under the Stock Purchase Agreement and Zavante manufacturing agreements acquired in the Acquisition. See "*—Risks Related to Our Recent Acquisition of Zavante—We may fail to realize the anticipated benefits of our Acquisition of Zavante, those benefits may take longer to realize than expected, and we may encounter significant integration difficulties.*"

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

- initiate or continue the research and development of lefamulin and CONTEPO 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;
- are required by the FDA, EMA or other regulators to conduct additional clinical trials prior to or after approval;
- continue to build a medical affairs, sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any product candidates for which we receive marketing approval;
- in-license or acquire other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- expand our physical presence in the United States and Ireland;
- establish and expand manufacturing arrangements with third parties; and
- add operational, financial and management information systems and personnel, including personnel to support our product development, our operations as a larger company following the Acquisition and our operations as a public company in addition to our planned future commercialization efforts.

Our ability to generate profits from operations, and to become 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 and CONTEPO. 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:

- applying for and obtaining marketing approval for lefamulin and CONTEPO;
- expanding medical affairs, sales, marketing and distribution capabilities to effectively market and sell lefamulin and CONTEPO 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 and CONTEPO;
- establishing and maintaining arrangements for the manufacture of and obtaining commercial quantities of lefamulin and CONTEPO; and
- negotiating and securing adequate reimbursement from third-party payors for lefamulin and CONTEPO.

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 to become 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, CONTEPO and, possibly, other product candidates and continue our research activities. Our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements. If we obtain marketing approval for lefamulin, CONTEPO 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 and as a larger company with a commercial rather than a research and development focus following the Acquisition. 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, together with the proceeds our recent underwritten public offering in July 2018, as well as anticipated near-term milestone payments under the Sinovant License Agreement and anticipated research premiums from the Austrian government for our qualified 2017 research and development expenditures, will be sufficient to enable us to fund its operating expenses and capital expenditure requirements into the first quarter of 2020, subject to a successful commercial launch in the United States of lefamulin for CABP and CONTEPO for cUTI in 2019. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings.

We expect to seek additional funding in future periods for purposes of investment in our commercial and medical affairs organization, as well as investing in our supply chain in an effort to enhance the potential commercial launch of lefamulin and CONTEPO.

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

- the costs and timing of process development and manufacturing scale-up activities associated with lefamulin and CONTEPO;
- the costs, timing and outcome of regulatory review of lefamulin and CONTEPO;
- the costs of commercialization activities for lefamulin and CONTEPO 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 and CONTEPO;
- subject to receipt of marketing approval, revenue received from commercial sales of lefamulin and CONTEPO;
- the costs of developing lefamulin and CONTEPO 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;
- the costs of operating as a larger company with a commercial rather than a research and development focus following the Acquisition; and
- the costs of operating as a public company in the United States.

Our commercial revenues, if any, will be derived from sales of lefamulin, CONTEPO 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, CONTEPO 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 certain rights to our technologies or product candidates.

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

On March 16, 2018, we entered into a Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co., or Cantor Fitzgerald, as agent, pursuant to which we may offer and sell ordinary shares, nominal value $0.01 per share, for aggregate gross sale proceeds of up to $50,000,000 from time to time through Cantor Fitzgerald under an “at-the-market” offering program. As of June 30, 2018, $27.2 million of ordinary shares remained available for sale under our “at-the-market” offering. If a large number of our ordinary shares is sold in the public market after they become eligible for sale or if we make additional sales under our “at-the-market” offering program, the sales could cause dilution to our security holders, reduce the trading price of our ordinary shares and impede our ability to raise future capital.

In addition, in connection with the closing of the Acquisition, we issued 7,336,906 of our ordinary shares to former Zavante stockholders as initial upfront consideration. An additional 815,186 of ordinary shares will be issued to former Zavante Stockholders upon release of the Holdback Shares, subject to reduction in respect of certain indemnification and other obligations pursuant to the Merger Agreement. While these shares are currently and, with respect to the Holdback Shares will be, restricted as a result of securities laws, following expiration of applicable holding periods, these shares will be able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. In addition, the Merger Agreement provides that we may issue up to an additional $97.5 million in our ordinary shares to former Zavante stockholders upon the achievement of specified regulatory and commercial milestones in the future and obligates us to provide registration rights with respect to the registration for resale of such additional ordinary shares that may become issuable upon the achievement of such milestones. The issuance of our ordinary shares to satisfy the milestone payments could cause dilution to our equity holders, and the sale or resale of these shares in the public market, or the market’s expectation of such sales, may result in an immediate and substantial decline in our stock price. Such a decline would adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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. Also, we may encounter delays or difficulties in our efforts to, or fail to, successfully integrate the operations of Zavante into our business and CONTEPO into our business strategy. Moreover, 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 June 30, 2018. As we increase our personnel and expand our business outside of Austria, including as a result of the Acquisition, 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.

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, lefamulin, which we are developing for CABP and other indications, and CONTEPO, which we are developing for cUTI, including AP. If we are unable to obtain marketing approvals for lefamulin or CONTEPO, or if thereafter we fail to commercialize lefamulin or CONTEPO 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 and, most recently, in CONTEPO in connection with the Acquisition. There remains a significant risk that we will fail to successfully develop lefamulin for CABP or any other indication or CONTEPO for cUTI.

In September 2017, we announced positive topline results for LEAP 1. Patient enrollment for LEAP 2 was completed in December 2017. In May 2018, we announced positive topline results from LEAP 2. 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.

In July 2016, Zavante initiated the ZEUS Study. In April 2017, Zavante announced positive topline results of the ZEUS Study. We expect to submit an NDA for marketing approval of CONTEPO for the treatment of cUTI, including AP, in the United States in the fourth quarter of 2018. In June 2018, Zavante initiated a phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of CONTEPO in pediatric subjects less than 12 years of age receiving standard-of-care antibiotic therapy for proven or suspected infection or peri-operative prophylaxis. We anticipate completing enrollment in this study in late 2020. We also intend to continue to characterize the clinical pharmacology of CONTEPO.

If we obtain marketing approval of lefamulin for CABP, or any other indication, and CONTEPO for cUTI, including AP, we also expect to incur significant additional sales, marketing, distribution and manufacturing expenses.

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 and CONTEPO when and as we expect and our ability to successfully integrate Zavante into our business and CONTEPO into our business strategy. The success of lefamulin and CONTEPO will depend on a number of factors, including the following:

- establishing and maintaining 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 and CONTEPO for the treatment of cUTI, including AP;
- launching commercial sales of lefamulin and CONTEPO, if and when approved, in collaboration with third parties;
- acceptance of lefamulin and CONTEPO, 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 and CONTEPO 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 and CONTEPO 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 labels for lefamulin and CONTEPO 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 other indications or CONTEPO for cUTI, including AP, which would materially harm our business.

If clinical trials of lefamulin, CONTEPO 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, CONTEPO or any other product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and early clinical trials, including Phase 1 clinical trials, in addition to extensive later-stage Phase 3 clinical trials, to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In connection with the ZEUS Study in which CONTEPO met the primary endpoint of statistical non-inferiority versus piperacillin/tazobactam, Zavante conducted a post-hoc primary efficacy analysis of CONTEPO using results of blinded pulsed-field gel electrophoresis molecular typing of urinary tract pathogens. Regulatory authorities typically give greater weight to results from pre-specified analyses and less weight to results from post-hoc, retrospective analyses. While we believe this post-hoc analysis is illustrative information, the FDA may ultimately have a different interpretation of any of our data that may be based on such post-hoc analysis. Also, in advance of our NDA submission for CONTEPO, we are required to complete a four-week Good Laboratory Practice toxicology study.

If we are required to conduct additional clinical trials or other testing or studies of lefamulin, CONTEPO 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 or studies, if the results of these trials, tests or studies are not positive or are only modestly positive, if there are safety concerns or if they are otherwise not acceptable to the FDA, we may:

- be delayed in obtaining marketing approval for our product candidates;
- need to raise capital before we otherwise would or on terms less favorable to us;
- 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 clinical trials, the potential marketing approval or commercialization of lefamulin, CONTEPO or other product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, our clinical trials of lefamulin and CONTEPO or other product candidates that could delay or prevent our ability to receive marketing approval or commercialize lefamulin, CONTEPO or our other product candidates, including:

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials 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 for our product candidates, including with respect to lefamulin, CONTEPO 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 CONTEPO, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- severity of the disease under investigation;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- approval of other therapies to treat the disease under investigation;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the time of year in which the trial is initiated or conducted;
- the geographic distribution of global trial sites, given the timing of pneumonia season globally, and the seasonal variation in the number of patients suffering from pneumonia, including a decline in the number of patients with CABP during the summer months;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;

- delays in the receipt of required regulatory approvals, or the failure to receive required regulatory approvals, in the jurisdictions in which clinical trials are expected to be conducted; and

- delays in the receipt of approvals, or the failure to receive approvals, from the relevant institutional review board or ethics committee at clinical trial sites.

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, CONTEPO 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 of lefamulin, we have continued to assess this potential in all human clinical trials of lefamulin 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 each of LEAP 1 and LEAP 2, 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.

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

In the ZEUS Study, the incidence of premature discontinuation from study drug was low and similar between treatment groups (6.0% in the CONTEPO treatment group compared to 3.9% in the PIP-TAZ treatment group), and the incidence of not completing the study through the last follow-up visit, which occurred on the 24th through 28th day after completion of seven days of treatment with the

study drug, or after up to 14 days of treatment for patients with concurrent bacteremia, was 5.2% in the CONTEPO group compared to 0.9% in the PIP-TAZ group. A total of 42.1% CONTEPO patients and 32.0% PIP-TAZ patients experienced at least one treatment-emergent adverse event. Most treatment-emergent adverse events were mild or moderate in severity, and severe treatment-emergent adverse events were uncommon (2.1% of CONTEPO patients and 1.7% of PIP-TAZ patients). The most common treatment-emergent adverse events in both treatment groups were transient, asymptomatic laboratory abnormalities and gastrointestinal events. Treatment-emergent serious adverse events were uncommon in both treatment groups (2.1% of CONTEPO patients and 2.6% of PIP-TAZ patients). There were no deaths in the study and one treatment-emergent serious adverse event in each treatment group was deemed related to study drug (hypokalemia in a CONTEPO patient and renal impairment in a PIP-TAZ patient), leading to study drug discontinuation in the PIP-TAZ patient. Study drug discontinuations due to the treatment-emergent adverse events were infrequent and similar between treatment groups (3.0% of CONTEPO patients and 2.6% of PIP-TAZ patients).

The most common laboratory abnormality treatment-emergent adverse events in the ZEUS Study were increases in the levels of alanine aminotransferase, or ALT, (8.6% of CONTEPO patients and 2.6% of PIP-TAZ patients) and aspartate transaminase, or AST, (7.3% of CONTEPO patients and 2.6% of PIP-TAZ patients). None of the ALT or AST elevations were symptomatic or treatment-limiting, and none of the patients met the criteria for Hy's Law. Outside the United States, elevated liver aminotransferases are listed among undesirable effects in the labeling for IV fosfomycin.

In the ZEUS Study, hypokalemia occurred in 71 of 232 (30.6%) CONTEPO patients and 29 of 230 (12.6%) PIP-TAZ patients. Most decreases in potassium levels were mild to moderate in severity. Shifts in potassium levels from normal at baseline to hypokalemia, as determined by worst post-baseline hypokalemia values, were more frequent in the CONTEPO group than the PIP-TAZ group for mild (17.7% compared to 11.3%), moderate (11.2% compared to 0.9%), and severe (1.7% compared to 0.4%) categories of hypokalemia. Hypokalemia was deemed a treatment-emergent adverse event in 6.4% of patients receiving CONTEPO and 1.3% of patients receiving PIP-TAZ, and all cases were transient and asymptomatic.

While no significant cardiac adverse events were observed in the ZEUS Study, post-baseline QT intervals calculated using Fridericia's formula, or QTcF, of greater than 450 to less than or equal to 480 msec (baseline QTcF of less than or equal to 450 msec) occurred at a higher frequency in CONTEPO patients (7.3%) compared to PIP-TAZ patients (2.5%). In the CONTEPO arm, these results appeared to be associated with the hypokalemia associated with the salt load of the IV formulation. Only one patient in the PIP-TAZ arm had a baseline QTcF of less than or equal to 500 msec and a post-baseline QTcF of greater than 500 msec.

If we elect or are forced to suspend or terminate any clinical trial of lefamulin, CONTEPO or any other product candidates that we are developing, the commercial prospects of lefamulin, CONTEPO or such other product candidates will be harmed and our ability to generate product revenues, if at all, from lefamulin, CONTEPO or any of these other product candidates will be delayed or eliminated. In addition, a higher rate of adverse events in lefamulin or CONTEPO as compared to the standard of care, even if slight, could negatively impact commercial adoption of lefamulin or CONTEPO by physicians. Any of these occurrences could materially harm our business, financial condition, results of operations and prospects.

Even if lefamulin, CONTEPO 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, CONTEPO or any other product candidate may be smaller than we estimate.

If lefamulin, CONTEPO 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, CONTEPO or any of our other product candidates. In addition, our efforts to effectively communicate the differentiating characteristics and key attributes of lefamulin, CONTEPO or any of our other product candidates to clinicians and hospital pharmacies with the goal of establishing favorable formulary status for lefamulin, CONTEPO or any of our other product candidates may fail or may be less successful than we expect. If lefamulin, CONTEPO or any of our other product candidates 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;
- the ability of lefamulin, CONTEPO or any other anti-infective product candidate 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, patient access 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. Likewise, we believe that because CONTEPO works differently than other IV antibiotics approved in the United States by inhibiting an early step in bacterial cell wall synthesis, it may have a low potential for developing bacterial resistance. If bacteria develop resistance or if lefamulin or CONTEPO is not effective against drug-resistant bacteria, the efficacy of these product candidates would decline, which would negatively affect our potential to generate revenues from these product candidates.

Our ability to negotiate, secure and maintain third-party coverage and reimbursement may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. If the level of reimbursement is below our expectations, our revenue and gross margins would be adversely affected. Obtaining formulary approval from third-party payors can be an expensive and time-consuming process. We cannot be certain if and when we will obtain formulary approval to allow us to sell lefamulin, CONTEPO 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, CONTEPO or any of our other product candidates that receive marketing approval.

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

We have only a very limited sales, marketing, patient access 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, patient access and distribution organization or outsource these functions to third parties. If lefamulin or CONTEPO 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. We do not intend to seek approval to commercialize CONTEPO in any markets outside the United States.

There are risks involved with establishing our own sales, marketing, patient access and distribution capabilities and entering into arrangements with third parties to perform these services. If we do not establish adequate sales, marketing, patient access 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, patient access 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, patient access and distribution organization.

If we enter into arrangements with third parties to perform sales, marketing, patient access 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, CONTEPO and any other products we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are a variety of available therapies marketed for the treatment of CABP and cUTI. Currently the treatment of CABP and cUTI is dominated by generic products. For hospitalized patients, combination therapy is frequently used in both CABP and cUTI. Many currently approved drugs are well-established therapies and are widely accepted by physicians, patients and third-party payors for the treatment of CABP. 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.). If approved, we expect CONTEPO will face competition from commercially available branded antibiotics such as ceftazidime-avibactam, meropenem-vaborbactam, tigecycline and plazomicin, from other products currently in development for the treatment of cUTI, including AP, such as imipenem-relebactam (under Phase 3 clinical development by Merck), cefiderocol (under Phase 3 clinical development by Shionogi), eravacycline (under development by Tetraphase), sulbactam-ETX2514 (under development by Entasis), and LYS228 (under development by Novartis), as well as generically available agents including carbapenems, aminoglycosides, and polymyxins.

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 and CONTEPO is approved for cUTI, including AP, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to replace existing therapies with lefamulin and CONTEPO. 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, CONTEPO 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, CONTEPO 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, CONTEPO 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 and CONTEPO may be particularly difficult because of the number of generic drugs, which are typically available at lower prices, that are available to treat CABP and cUTI. In addition, third-party payors are likely to impose strict requirements for reimbursement of a higher priced drug, such as lefamulin and CONTEPO. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize lefamulin, CONTEPO 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, CONTEPO 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, CONTEPO 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 or CONTEPO that could be used in product candidate development, including clinical trial supply, or for commercial supply, or for the supply of any other compound that we are developing or evaluating in our research program. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of lefamulin and CONTEPO, 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 and CONTEPO. 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.

In addition, Zavante has entered into a manufacturing and supply agreement with Ercros, S.A., pursuant to which Ercros, S.A. supplies to Zavante, on an exclusive basis, the API mixture for CONTEPO in support of filing an NDA and, if CONTEPO is approved, will supply the commercial API Mixture for CONTEPO in the United State. Zavante has also entered into a manufacturing and exclusive supply agreement with Laboratorios ERN, S.A., pursuant to which Laboratorios ERN, S.A. has agreed to supply Zavante with certain technical documentation and data as required for submission of an NDA for CONTEPO and certain regulatory support in connection with the commercial sale and use of CONTEPO in the United States. Zavante entered into a commercial packaging agreement with AndersonBrecon, Inc. for the commercial packaging of CONTEPO in addition to a manufacturing and supply agreement with Fisiopharma S.r.l. for the supply, on a minimum commitment basis, of a percentage of Zavante's commercial requirements of CONTEPO in bulk drug vials for the United States as well as the supply of bulk drug vials of CONTEPO in connection with the submission of an NDA.

We may be unable to maintain our current arrangements for commercial supply, or conclude agreements for commercial supply with additional third-party manufacturers, or we 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. If we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

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

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

We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. We expect to continue to rely on such third parties in conducting our clinical trials of lefamulin and CONTEPO, 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, CONTEPO 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 and CONTEPO receive marketing approval, we plan to commercialize them 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;
- 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 CONTEPO and the development and potential commercialization of other product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to further collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, we intend to seek to commercialize lefamulin through a variety of types of additional collaboration arrangements outside the United States.

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory

review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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 or CONTEPO. Thus, we do not know with certainty whether lefamulin, CONTEPO or any other product candidate, or our commercialization thereof, does not and will not infringe any third party's intellectual property.

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

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

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

In addition, while we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our business was founded as a spin-off from Sandoz. Although all patent applications are fully owned by us and were either filed by Sandoz with all rights fully transferred to us, or filed in our sole name, because we acquired certain of our patents from Sandoz, we must rely on their prior practices, with regard to the assignment of such intellectual property. Similarly, for any patent applications we acquired from Zavante in connection with the Acquisition, we must rely on Zavante's prior practices with regard to the assignment of 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. For example, US patent 9,345,717 claims priority to a provisional patent application. We are in the process of perfecting ownership of that provisional

application and the applications claiming priority to the provisional application in the name of Zavante. If we are not able to effect a complete transfer of right, title and interest in such applications to Zavante, ownership of the invention claimed in the '717 patent and any other patent claiming priority to the provisional application may be subject to dispute.

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 CONTEPO, 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, in the case of lefamulin, 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, CONTEPO or any of our other product candidates from regulatory authorities in any jurisdiction and we do not intend to seek approval to market CONTEPO outside the United States.

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, CONTEPO 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.

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

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

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

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

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

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

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

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

The FDA and other federal and state agencies, including the U.S. Department of Justice, or DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws.

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

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;

- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

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 and the IV formulation of CONTEPO as a qualified infectious disease product, or QIDP, and granted fast track designations to each of these formulations of lefamulin and CONTEPO. However, neither the QIDP nor the fast track designation ensures that lefamulin or CONTEPO will receive marketing approval or that approval will be granted within any particular timeframe. We may also seek fast track designation for our other product candidates. We may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

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

If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the FDA's goal to review an application is six months, rather than the standard review period of ten months. Because the FDA designated each of the IV and oral formulations of lefamulin and IV formulation of CONTEPO as a QIDP, lefamulin and CONTEPO 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 each of lefamulin and CONTEPO as a Qualified Infectious Disease Product does not assure FDA approval of these product candidates.

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 and IV formulation of CONTEPO, there is no assurance that these product candidates will be approved by the FDA.

If the FDA does not conclude that our product candidates satisfy the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetics Act, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates may take longer, cost more and entail greater complications and risks than anticipated, and may not be successful.

We intend to submit an NDA for CONTEPO utilizing Section 505(b)(2) of the Food, Drug and Cosmetic Act, or the FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as Paragraph IV certifications, that certify any patents listed in the Orange Book publication in respect to any product referenced in the 505(b)(2) application are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Under the Hatch-Waxman Act, the holder of the NDA which the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit

triggers a one-time automatic 30-month stay of the FDA's ability to approve the 505(b)(2) application. Neither we nor Zavante have conducted a comprehensive freedom-to-operate review with regard to CONTEPO.

Accordingly, we may invest a significant amount of time and expense in the development of CONTEPO or any other product candidate we may develop and experience significant delays and patent litigation before such products may be commercialized, if at all. A Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or only some of the indications sought by us. The FDA may also reject our future Section 505(b)(2) submissions and may require us to file such submissions under Section 501(b)(1) of the FDCA, which could be considerably more expensive and time consuming.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. Thus, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

If the FDA does not conclude that CONTEPO, or any of our other product candidates for which we may utilize the 505(b)(2) pathway, satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates, including CONTEPO, under Section 505(b)(2) are not as we expect, the approval pathway for CONTEPO and any of our other product candidates for which we may utilize the 505(b)(2) pathway will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

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, 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.

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 and CONTEPO, 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 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, CONTEPO 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 and CONTEPO, 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 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, or 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. Further, in July 2018 following a federal district court decision from New Mexico, the Administration announced that it would be freezing payments to insurers under the ACA to cover sicker patients until it or Congress can address the appropriate methodology for calculating and making such payments. It remains to be seen how this action will affect the implementation of the ACA.

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 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.

In addition, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services, or HHS, will take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' advertisements to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases.

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 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 member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations.

For example, the European Union General Data Protection Regulation, or the GDPR, which came into force on May 25, 2018, introduced new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. The GDPR imposes strict obligations and restrictions on controllers and processors of personal data including, for example, expanded disclosures about how personal data is to be used, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data, mandatory data breach notification requirements and expanded rights for individuals over their personal data. This could affect our ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, and harm our business and financial condition.

While the GDPR, as a directly effective regulation, was designed to harmonize data protection law across the European Union, it does permit member states to legislate in many areas (particularly with regard to the processing of genetic, biometric or health data), meaning that inconsistencies between different member states will still arise. European Union member states have their own regimes on medical confidentiality and national and European Union-level guidance on implementation and compliance practices is often updated or otherwise revised, which adds to the complexity of processing personal data in the European Union.

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the 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 and CONTEPO, 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 and CONTEPO, 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. In addition, our growth in connection with the Acquisition, including expansion of our business operations and employees who joined us in connection with the Acquisition, will impose added responsibilities on members of our management, including the need to recruit, hire, retain, motivate and integrate additional employees and business operations.

Due to our limited financial resources and the limited experience of our management team in managing a company of our current size following the Acquisition, and with such anticipated growth, we may not be able to effectively integrate Zavante into our business and CONTEPO into our business strategy, manage the future expansion of our operations or recruit and train additional qualified

personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Ownership of Our Ordinary Shares

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

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

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

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

- our ability to achieve the anticipated benefits of the Acquisition and to successfully implement our proposed business strategy following the Acquisition;
- market reception to the Acquisition and the transition of our chief executive officer in connection with the Acquisition;
- 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, including any personnel changes or integration issues in connection with the Acquisition;
- 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, CONTEPO 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 significantly influence 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 June 30, 2018 in the aggregate, beneficially owned approximately 51.7% of our share capital. As of July 31, 2018, following the closing of the Acquisition and the completion of our underwritten public offering, our executive officers and directors, and principal shareholders and their respective affiliates who owned more than 5% of our outstanding ordinary shares, held 44.6% of our share capital, assuming the issuance of all Holdback Shares under the Merger Agreement. As a result, if these shareholders were to choose to act together, they would be able to significantly influence 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 significantly influence the election of directors and could, depending on the structure of the particular transaction, significantly influence the approval of a 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.

Substantial future sales of our ordinary shares in the public market, or the perception that these sales could occur, could cause the price of our ordinary shares to decline significantly, even if our business is doing well.

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 40,959,452 ordinary shares outstanding as of June 30, 2018. Following our completion of the Acquisition and our underwritten public offering in July 2018, we had 66,484,159 ordinary shares outstanding as of July 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 June 30, 2018, and July 31, 2018, an aggregate of 1,485,557 and 1,583,335, respectively, 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 June 30, 2018, we had issued and sold an aggregate of 4,243,096 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.

Upfront consideration for the Acquisition is comprised of 8,152,092 of our ordinary shares, including 815,186 ordinary shares that are issuable upon release of the Holdback Shares subject to the terms of the Merger Agreement. While these shares are currently, and in the case of the Holdback Shares will be, restricted as a result of securities laws, following expiration of applicable holding periods, these shares will be able to be freely sold in the public market, subject to any requirements and restrictions, including any applicable volume limitations, imposed by Rule 144 under the Securities Act. In addition, the Merger Agreement provides that we may issue up to an additional $97.5 million in our ordinary shares to former Zavante stockholders upon the achievement of specified regulatory and commercial milestones in the future and obligates us to provide registration rights with respect to the registration for resale of such additional ordinary shares that may become issuable upon the achievement of such milestones.

In addition, on July 31, 2018, we completed an underwritten public offering of 18,181,818 ordinary shares and the underwriters have an option to purchase up to an additional 2,727,272 of our ordinary shares until August 25, 2018.

The sale or resale of these shares in the public market, or the market's expectation of such sales, may result in an immediate and substantial decline in our stock price. Such a decline will adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

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

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

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

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

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

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

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

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

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

As a public company we incur, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable

securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations have made it more expensive for us to obtain director and officer liability insurance, and if such insurance becomes prohibitively expensive, this could make it more difficult for us to attract and retain qualified members of our board.

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

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

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. As a larger company following the Acquisition, implementing and maintaining effective controls may require more resources, and we may encounter internal control integration difficulties. 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 judgments obtained in the other jurisdiction and Irish common law rules govern the process by which a U.S. judgment may be enforced in Ireland. The following requirements must be met as a precondition before a U.S. judgment will be eligible for enforcement in Ireland:

- the judgment must be for a definite sum;
- the judgment must be final and conclusive, and the decree must be final and enforceable in the court which pronounces it;
- the judgment must be provided by a court of competent jurisdiction, and the procedural rules of the court giving the foreign judgment must have been observed;

- the U.S. court must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules; and
- jurisdiction must be obtained by the Irish courts over judgment debtors in enforcement proceedings by service in Ireland or outside Ireland in accordance with the applicable court rules in Ireland.

Even if the above requirements have been met, an Irish court may exercise its right to refuse to enforce the U.S. judgment if the Irish court is satisfied that the judgment (1) was obtained by fraud; (2) is in contravention of Irish public policy; (3) is in breach of natural justice; or (4) is irreconcilable with an earlier judgment. By way of example, a judgment of a U.S. court of liabilities predicated upon U.S. federal securities laws may not be enforced by Irish courts on the grounds of public policy if that U.S. judgment includes an award of punitive damages. Further, an Irish court may stay proceedings if concurrent proceedings are being brought elsewhere.

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

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

We are exposed to risks related to currency exchange rates.

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

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

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

Our ability to pay dividends or other distributions and to pay our obligations in the future will depend on the level of funding, dividends and other distributions, if any, received from our subsidiaries and any new subsidiaries we establish in the future. The ability of our subsidiaries to make loans or distributions (directly or indirectly) to us may be restricted as a result of several factors, including restrictions in financing agreements and the requirements of applicable law and regulatory and fiscal or other restrictions. In particular, our subsidiaries and any new subsidiaries may be subject to laws that restrict dividend payments, authorize regulatory bodies to block or reduce the flow of funds from those subsidiaries to us, or limit or prohibit 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. Additionally, we may issue and sell our ordinary shares under our ATM Agreement from time to time, and we may issue additional ordinary shares as contingent consideration upon the achievement of certain regulatory and commercialization milestones, subject to the terms and conditions of the Merger Agreement. See *"—Risks Related to Ownership of our Ordinary Shares—Substantial future sales of our ordinary shares in the public market, or the perception that these sales could occur, could cause the price of our ordinary shares to decline significantly, even if our business is doing well.*".

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 on shares / bonus issues, the election of directors, the removal of directors, the fiduciary and statutory duties of directors, conflicts of interests of directors, the indemnification of directors and officers, limitations on director liability, the convening of annual meetings of shareholders and special shareholder meetings, notice provisions for meetings, the quorum for shareholder meetings, the adjournment of shareholder meetings, the exercise of voting rights, shareholder suits, rights of dissenting shareholders, anti-takeover measures and provisions relating to the ability to amend the articles of association.

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

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

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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

The Tax Cuts and Jobs Act of 2017, or the Tax Act, introduced significant changes to the United States Internal Revenue Code of 1986, as amended, or Code.

The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense, limitation of the deduction for net operating losses, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, and modifying or repealing many business deductions and credits.

We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the federal corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected.

After tax reform, U.S. persons who own 10 percent or more of our shares may be subject to U.S. federal income taxation on certain of our foreign subsidiaries' income even if such income is not distributed to such U.S. persons.

A foreign corporation is treated as a "controlled foreign corporation", or CFC, for U.S. federal income tax purposes if, on any day during a taxable year, "United States shareholders" (as defined below) own (directly, indirectly or constructively within the meaning of Section 958 of the Code) more than 50% of the total combined voting power of all classes of our voting shares or more than 50% of the total value of all of our shares. A "United States shareholder" of a foreign corporation is a U.S. person who owns (directly, indirectly or constructively within the meaning of Section 958 of the Code) at least 10% of the total combined voting power of voting shares of such non-U.S. corporation or at least 10% of the total value of shares of all classes of stock of such non-U.S. corporation.

As a result of the Tax Act, all of our non-U.S. subsidiaries will be treated as CFCs. The legislative history under the Tax Act indicates that this change was not intended to cause these non-U.S. subsidiaries to be treated as CFCs with respect to a United States shareholder that is not related to the U.S. subsidiary of the Company. However, it is not clear whether the IRS or a court would interpret the change made by the Tax Act in a manner consistent with such indicated intent.

Any United States shareholder who owns our shares (directly or indirectly within the meaning of Section 958(a) of the Code) on the last day in such taxable year must include in its gross income for U.S. federal income tax purposes its pro rata share (based on direct or indirect ownership of value) of the non-U.S. subsidiaries' "subpart F income," regardless of whether that income was actually distributed to such U.S. person (with certain adjustments). "Subpart F income" of a CFC generally includes among other items passive income, such as dividends, interest, annuities, net gains from sales of property that do not generate active income, net commodities gains, net foreign currency gains, passive rents and royalties.

For tax years beginning after December 31, 2017, the Tax Act also requires such United States shareholders to include in their gross income for U.S. federal income tax purposes their pro rata share of a CFC's "global intangible low tax income", or GILTI." In general terms, GILTI is the net income of the CFCs (other than income already included in United States shareholders' taxable income) that exceeds 10% of the CFCs' bases in depreciable tangible assets. GILTI is treated in a manner similar to subpart F income.

In addition, if a U.S. person disposes of shares in a non-U.S. corporation and the U.S. person was a United States shareholder at any time when the corporation was a CFC during the five-year period ending on the date of disposition, any gain from the disposition will generally be treated as a dividend to the extent of the U.S. person's share of the corporation's undistributed earnings and profits that were accumulated during the period or periods that the U.S. person owned the shares while the corporation was a CFC (with certain adjustments). Also, a U.S. person may be required to comply with specified reporting requirements, regardless of the number of shares owned.

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

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. We have also not determined the extent to which the income and assets of Zavante, which will be included in the PFIC calculation following the Acquisition, may adversely affect this determination. 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 June 30, 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.

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	Exhibit Number	
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101	The following materials from the Company's Quarterly Report on Form10-Q for the quarter ended June 30, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2017 and June 30, 2018, (ii) Consolidated Statements of Operations for the six months ended June 30, 2017 and 2018, (iii) Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2018 and (v) Notes to Unaudited Consolidated Financial Statements.					X

SIGNATURES

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

NABRIVA THERAPEUTICS plc

Date: August 9, 2018

By: /s/ Theodore Schroeder
Theodore Schroeder
Chief Executive Officer
(Principal Executive Officer)

Date: August 9, 2018

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

EXHIBIT 31.1

CERTIFICATIONS

I, Theodore Schroeder, 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/ Theodore Schroeder

Theodore Schroeder
Chief Executive Officer
(Principal Executive Officer)

Dated: August 9, 2018

EXHIBIT 31.2

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: August 9, 2018

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Nabriva Therapeutics plc (the "Company") for the period ended June 30, 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/ Theodore Schroeder

Theodore Schroeder
Chief Executive Officer
(Principal Executive Officer)

Dated: August 9, 2018

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Nabriva Therapeutics plc (the "Company") for the period ended June 30, 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: August 9, 2018