Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2019

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	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(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)

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

Title of each class	Trading Symbol (s)	Name of each exchange on which registered
Ordinary Shares, nominal value $0.01 per share	NBRV	The Nasdaq Global Market

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☒
	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 13(a) of the Exchange Act. ☒

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

As of October 31, 2019, the registrant had 78,350,487 ordinary shares outstanding.

NABRIVA THERAPEUTICS plc
INDEX TO REPORT ON FORM 10-Q

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 ability to successfully launch and commercialize XENLETA (lefamulin) for the treatment of community-acquired bacterial pneumonia, or CABP, including the availability of and ease of access to XENLETA through major U.S. specialty distributors;
- our ability to build and maintain a sales force for the commercial launch of XENLETA;
- our expectations regarding how far into the future our cash on hand will fund our ongoing operations and the continued availability and cost of capital to sustain our operations on a longer term basis.
- the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or studies in different disease indications will be indicative of the results of ongoing or future trials;
- our ability to resolve the matters set forth in the Complete Response Letter we received from the U.S. Food and Drug Administration, or FDA, in connection with our New Drug Application, or NDA, for CONTEPO for the treatment of complicated urinary tract infections, or cUTIs, including acute pyelonephritis;
- our ability to satisfy interest and principal payments under our debt facility with Hercules Capital, Inc., or Hercules;
- our ability to comply with the restrictive covenants under our debt facility with Hercules;
- the potential extent of revenues from future sales of XENLETA and/or CONTEPO if approved;
- our plans and the related cost expectations to pursue development of XENLETA for additional indications other than CABP, and of CONTEPO for additional indications other than cUTI;
- our plans to pursue development of other product candidates;
- 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 timing of and our ability to submit applications to obtain and, if approved, maintain marketing approval of CONTEPO and other product candidates, including the completion of any post-marketing requirements with respect to any marketing approval we may obtain, including XENLETA;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- our sales, marketing and distribution capabilities and strategy;
- the potential advantages of XENLETA, CONTEPO and our other product candidates;
- our estimates regarding the market opportunities for XENLETA, CONTEPO and our other product candidates;
- the rate and degree of market acceptance and clinical benefit of XENLETA for CABP, CONTEPO for cUTI and our other product candidates;
- our ability to establish and maintain collaborations;
- the future development or commercialization of XENLETA in the greater China region and Canada;
- the potential benefits under our license agreements with Sinovant Sciences, Ltd., or the Sinovant License Agreement, and with Sunovion Pharmaceuticals Canada Inc., or the Sunovion License Agreement;
- our ability to acquire or in-license additional products, product candidates and technologies;
- our future intellectual property position;
- 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;
- risks of relying on external parties such as contract manufacturing organizations;
- 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.

Throughout this Form 10-Q, unless the context requires otherwise, all references to "Nabriva," "the Company," we," "our," "us" or similar terms refer to Nabriva Therapeutics plc, together with its consolidated subsidiaries.

PART I

ITEM 1. FINANCIAL STATEMENTS

NABRIVA THERAPEUTICS plc
Consolidated Balance Sheets (unaudited)

(in thousands, except share data)	As of December 31, 2018	As of September 30, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 102,003	$ 78,101
Restricted cash	—	228
Short-term investments	225	175
Accounts receivable, net and other receivables	3,871	6,540
Contract asset	1,500	—
Inventory	—	162
Prepaid expenses	1,154	1,202
Total current assets	108,753	86,408
Property, plant and equipment, net	1,139	2,655
Intangible assets, net	98	343
Long-term receivables	428	716
Total assets	**$ 110,418**	**$ 90,122**
Liabilities and equity		
Current liabilities:		
Accounts payable	$ 3,304	$ 3,221
Accrued expense and other current liabilities	14,502	11,663
Total current liabilities	17,806	14,884
Non-current liabilities		
Long-term debt	23,718	34,241
Other non-current liabilities	264	1,782
Total non-current liabilities	23,982	36,023
Total liabilities	**41,788**	**50,907**
Commitments and contingencies (Note 12)		
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 1,000,000,000 ordinary shares authorized at September 30, 2019; 67,019,094 and 77,994,207 issued and outstanding at December 31, 2018 and September 30, 2019, respectively	670	780
Preferred shares, par value $0.01, 100,000,000 shares authorized at September 30, 2019; None issued and outstanding	—	—
Additional paid in capital	461,911	492,105
Accumulated other comprehensive income	27	27
Accumulated deficit	(393,978)	(453,697)
Total stockholders' equity	**68,630**	**39,215**
Total liabilities and stockholders' equity	**$ 110,418**	**$ 90,122**

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

NABRIVA THERAPEUTICS plc
Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share data)	Three Months Ended September 30, 2018	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2019
Revenues:				
Product revenue, net	$ —	$ 1,445	$ —	$ 1,445
Collaboration revenue	—	5,051	6,500	6,051
Research premium and grant revenue	461	424	2,359	1,652
Total revenue	461	6,920	8,859	9,148
Operating expenses:				
Cost of product sales	—	(15)	—	(15)
Research and development expenses	(40,804)	(5,601)	(60,800)	(21,213)
Selling, general and administrative expenses	(12,582)	(18,503)	(31,555)	(45,339)
Total operating expenses	(53,386)	(24,119)	(92,355)	(66,567)
Loss from operations	**(52,925)**	**(17,199)**	**(83,496)**	**(57,419)**
Other income (expense):				
Other income (expense), net	(54)	(10)	(172)	116
Interest income	11	94	39	176
Interest expense	(8)	(709)	(19)	(2,512)
Loss before income taxes	**(52,976)**	**(17,824)**	**(83,648)**	**(59,639)**
Income tax benefit (expense)	151	29	(307)	(80)
Net loss	**$ (52,825)**	**$ (17,795)**	**$ (83,955)**	**$ (59,719)**
Loss per share				
Basic and Diluted ($ per share)	$ (0.90)	**$** (0.24)	$ (1.85)	$ (0.83)
Weighted average number of shares:				
Basic and Diluted	58,442,987	75,161,192	45,369,040	72,153,405

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

NABRIVA THERAPEUTICS plc
Consolidated Statements of Changes in Stockholders' Equity (unaudited)

(in thousands)	Ordinary Shares Number of shares	Ordinary Shares Amount	Additional paid in capital	Accumulated other comprehensive income	Accumulated deficit	Total Stockholders' Equity
January 1, 2018	36,708	$ 367	$ 360,872	$ 27	$ (279,198)	$ 82,068
Issuance of ordinary shares	3,526	35	19,353	—	—	19,388
Equity transaction costs	—	—	(916)	—	—	(916)
Stock-based compensation expense	—	—	1,244	—	—	1,244
Net loss	—	—	—	—	(13,342)	(13,342)
March 31, 2018	**40,234**	**402**	**380,553**	**27**	**(292,540)**	**88,442**
Issuance of ordinary shares	725	8	3,389	—	—	3,397
Equity transaction costs	—	—	(152)	—	—	(152)
Stock-based compensation expense	—	—	767	—	—	767
Net loss	—	—	—	—	(17,788)	(17,788)
June 30, 2018	**40,959**	**410**	**384,557**	**27**	**(310,328)**	**74,666**
Issuance of ordinary shares	18,188	182	49,817	—	—	49,999
Shares issued in connection with acquisition of Zavante Therapeutics, Inc.	7,337	73	26,829	—	—	26,902
Equity transaction costs	—	—	(3,739)	—	—	(3,739)
Stock-based compensation expense	—	—	1,423	—	—	1,423
Net loss	—	—	—	—	(52,825)	(52,825)
September 30, 2018	**66,484**	**$ 665**	**$ 458,887**	**$ 27**	**$ (363,153)**	**$ 96,426**

(in thousands)	Ordinary Shares Number of shares	Ordinary Shares Amount	Additional paid in capital	Accumulated other comprehensive income	Accumulated deficit	Total Stockholders' Equity
January 1, 2019	67,019	$ 670	$ 461,911	$ 27	$ (393,978)	$ 68,630
Issuance of ordinary shares	4,317	43	10,014	—	—	10,057
Equity transaction costs	—	—	(270)	—	—	(270)
Stock-based compensation expense	—	—	1,907	—	—	1,907
Net loss	—	—	—	—	(20,217)	(20,217)
March 31, 2019	**71,336**	**713**	**473,562**	**27**	**(414,195)**	**60,107**
Issuance of ordinary shares	1,221	12	3,522	—	—	3,534
Shares issued in connection with the employee stock purchase plan	91	1	169	—	—	170
Shares issued in connection with the vesting of restricted stock units	258	3	—	—	—	3
Equity transaction costs	—	—	(523)	—	—	(523)
Stock-based compensation expense	—	—	1,821	—	—	1,821
Net loss	—	—	—	—	(21,707)	(21,707)
June 30, 2019	**72,906**	**729**	**478,551**	**27**	**(435,902)**	**43,405**
Issuance of ordinary shares	4,102	41	9,555	—	—	9,596
Shares issued in connection with the vesting of restricted stock units	171	2	—	—	—	2
Shares issued in connection with acquisition of Zavante Therapeutics, Inc.	815	8	(8)	—	—	—
Equity transaction costs	—	—	(131)	—	—	(131)
Stock-based compensation expense	—	—	4,138	—	—	4,138
Net loss	—	—	—	—	(17,795)	(17,795)
September 30, 2019	**77,994**	**$ 780**	**$ 492,105**	**$ 27**	**$ (453,697)**	**$ 39,215**

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

NABRIVA THERAPEUTICS plc
Consolidated Statements of Cash Flows (unaudited)

(in thousands)	Nine Months Ended September 30, 2018	2019
Cash flows from operating activities		
Net loss	$ (83,955)	$ (59,719)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash other expense, net	167	(49)
Non-cash interest income	(57)	24
Non-cash interest expense	—	379
Depreciation and amortization expense	391	162
Amortization of right-of-use assets	—	291
Stock-based compensation	3,434	7,866
In-process research and development in connection with acquisition	31,930	—
Deferred income taxes	—	(5)
Other, net	12	—
Changes in operating assets and liabilities:		
(Increase)/decrease in long-term receivables	(3)	(288)
(Increase)/decrease in accounts receivable, net and other receivables and prepaid expenses	(2,361)	(1,258)
Increase in inventory	—	(162)
(Decrease)/increase in accounts payable	(1,473)	(39)
Increase/(decrease) in accrued expenses and other liabilities	1,137	(3,553)
Increase/(decrease) in other non-current liabilities	41	(88)
Increase/(decrease) in income tax liabilities	245	34
Net cash used in operating activities	(50,492)	(56,405)
Cash flows from investing activities		
Purchases of plant and equipment and intangible assets	(209)	(97)
Purchases of term deposits	(216)	—
Deposits into employee stock purchase plan restricted cash accounts	—	228
Transaction costs related to Zavante acquisition, net of cash acquired	(3,950)	—
Net cash provided by (used in) investing activities	(4,375)	131
Cash flows from financing activities		
Proceeds from July 2018 public offering	50,000	—
Proceeds from at-the-market facility	22,784	23,189
Proceeds from long-term debt, net of issuance costs	535	9,980
Proceeds from employee share purchase plan	—	170
Equity transaction costs	(4,723)	(659)
Net cash provided by financing activities	68,596	32,680
Effects of foreign currency translation on cash and cash equivalents	(167)	(80)
Net increase/(decrease) in cash, cash equivalents and restricted cash	13,562	(23,674)
Cash, cash equivalents and restricted cash at beginning of period	86,769	102,003
Cash, cash equivalents and restricted cash at end of period	$ 100,331	$ 78,329
Supplemental disclosure of cash flow information:		
Transaction costs related to Zavante acquisition included in accounts payable and accrued expensed	$ 243	$ —
Interest paid	$ 4	$ 1,735
Equity transaction costs incurred in prior periods and paid in current period	$ —	$ 18
Equity transaction costs included in accounts payable and accrued expenses	$ 109	$ 382

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., and Nabriva Therapeutics Ireland DAC, (collectively, "Nabriva", or the "Company") is a biopharmaceutical company engaged in the commercialization and development of novel anti-infective agents to treat serious infections. The Company's headquarters are located at 25-28 North Wall Quay, Dublin, Ireland. Throughout these notes to the consolidated financial statements, unless the context requires otherwise, all references to "Nabriva," "the Company," or similar terms refer to Nabriva Therapeutics plc, together with its consolidated subsidiaries.

On September 9, 2019, the Company announced that the oral and intravenous ("IV") formulations of XENLETA (lefamulin) are available in the United States through major specialty distributors. This followed the approval by the U.S. Food and Drug Administration (FDA) of the Company's New Drug Application (NDA) for XENLETA on August 19, 2019 for the treatment of adults with community-acquired bacterial pneumonia (CABP). XENLETA is the first oral and IV treatment in the pleuromutilin class of antibiotics available for the systematic administration in humans.

On July 23, 2018, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") for the acquisition of Zavante Therapeutics Inc., ("Zavante") a biopharmaceutical company focused on developing CONTEPO (fosfomycin for injection). CONTEPO is potentially a first-in-class epoxide antibiotic for IV administration in the United States. The Company is developing CONTEPO IV for complicated urinary tract infections ("cUTI") and may potentially develop XENLETA and CONTEPO for additional indications. In April 2019, the FDA issued a Complete Response Letter ("CRL") in connection with the Company's NDA for CONTEPO for the treatment of cUTIs, including acute pyelonephritis, stating that it was unable to approve the application in its current form. The CRL requests that issues related to facility inspections and manufacturing deficiencies at Nabriva's active pharmaceutical ingredient contract manufacturer be addressed prior to the FDA approving the NDA. The Company requested a "Type A" meeting with the FDA to discuss its findings and this meeting occurred in July 2019 and the Company anticipates resubmitting its NDA in the weeks ahead. The Company cannot predict the final outcome of any interactions with the FDA or when CONTEPO will receive marketing approval, if at all.

As the FDA did not request any new clinical data and did not raise any other concerns with regard to the safety or efficacy of CONTEPO in the CRL, the purpose of the meeting was to discuss and gain clarity on the issues related to facility inspections and manufacturing deficiencies at one of Nabriva's contract manufacturers that were described in the CRL and other matters pertaining to the steps required for the resubmission of the NDA for CONTEPO.

On June 24, 2019, the Company announced that the European Medicines Agency ("EMA") determined that the Company's Marketing Authorization Application ("MAA") for the IV and oral formulations of lefamulin was valid. Validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process and an opinion of the EMA Committee for Medicinal Products for Human Use ("CHMP") is anticipated in the second half of 2020.

The EMA's review of the application will follow the centralized marketing authorization procedure. If approved by the EMA, XENLETA will receive marketing authorization in all 28 member states of the European Union ("EU"), as well as in Norway, Liechtenstein and Iceland. If approved, Nabriva intends to work with a commercial partner to make XENLETA available to patients in the EU.

Liquidity

Since its inception, the Company has incurred net losses and generated negative cash flows from its operations which has resulted in a significant accumulated deficit to date. The Company has financed its operations through the sale of equity securities, convertible and term debt financings and research and development support from governmental grants and proceeds from its licensing agreements. As of September 30, 2019, the Company had cash and cash equivalents, and short-term investments of $78.3 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 consolidated financial statements are issued.

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, in an effort to enhance the commercial launch of XENLETA and potential launch of CONTEPO. While the Company has raised capital in the past, the ability to raise capital in future periods is not considered probable, as defined under the accounting standards. As such, under the requirements of ASC 205-40, management may not consider the potential for future capital raises in their assessment of the Company's ability to meet its obligations for the next twelve months.

If the Company is not able to secure adequate additional funding in future periods, the Company may make reductions in certain expenditures. This may include liquidating assets and suspending or curtailing planned programs. The Company may also have to delay, reduce the scope of, suspend or eliminate one or more research and development programs or its commercialization efforts.

The Company's expenses will increase if it suffers any regulatory delays or is required to conduct additional clinical trials to satisfy regulatory requirements. The Company has incurred and expects to continue to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing for XENLETA and, if approved, CONTEPO, including the recent hiring of a dedicated sales force. It is uncertain when, if ever, the Company will generate sufficient revenues from product sales to achieve profitability.

As a result, based on the Company's available cash resources, the minimum cash required under the Loan and Security Agreement (the "Loan Agreement") with Hercules Capital, Inc., and in accordance with the requirements of ASC 205-40, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for one year from the date these financial statements are issued. A failure to raise the additional funding or to effectively implement cost reductions could harm the Company's business, results of operations and future prospects.

The Company expects that its existing cash, cash equivalents and short-term investments as of September 30, 2019, proceeds from the sale of ordinary shares under the new Open Market Sales Agreement℠ between the Company and Jefferies LLC ("Jefferies"), described below from September 30, 2019 until the date of this filing of $0.7 million, anticipated net product revenues and research premiums from the Austrian government for its qualified research and development expenditures, will be sufficient to enable the Company to fund its operating expenses, debt service obligations and capital expenditure requirements into the third quarter of 2020. The interim consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

In December 2018, the Company entered into a Loan Agreement with Hercules Capital, Inc., pursuant to which a term loan of up to an aggregate principal amount of $75.0 million is available to the Company. The Loan Agreement provides for an initial term loan advance of $25.0 million which was funded in connection with the closing of the Loan Agreement. Additionally, in connection with the approval of XENLETA, an additional advance of $10.0 million was drawn upon by the Company in the third quarter of 2019. The remaining $40.0 million under the Loan Agreement is available to the Company from time to time subject to conditions further described in Note 6 below.

In March 2018, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Cantor ATM Agreement"), with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which, from time to time, the Company could previously offer and sell its ordinary shares having aggregate gross proceeds of up to $50.0 million through Cantor. The Company terminated the Cantor ATM Agreement effective as of June 24, 2019. The Company did not incur any penalties as a result of the termination of the Cantor ATM Agreement. As of the effective date of the termination of the Cantor ATM Agreement, the Company had sold and issued an aggregate of 10,316,190 of its ordinary shares pursuant to the Cantor ATM Agreement for aggregate gross proceeds of $37.8 million and net proceeds to the Company of $36.9 million, after deducting commissions and offering expenses payable by the Company. The $12.2 million of ordinary shares that had been available for sale pursuant to the Cantor ATM Agreement remained unsold at the time of its termination.

On June 25, 2019, the Company entered into an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies, pursuant to which, from time to time, the Company may offer and sell ordinary shares, for aggregate gross sale proceeds of up to $50.0 million through Jefferies by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Company also filed a prospectus supplement with the Securities and Exchange Commission in connection with the Offering under the Company's shelf Registration Statement on Form S-3 (File No. 333-219567), which became effective on August 10, 2017.

As of September 30, 2019, the Company has issued and sold an aggregate of 4,101,282 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $9.6 million and net proceeds of $9.0 million, after deducting commissions to Jefferies and other offerring expenses. From September 30, 2019 through the date of this filing, the Company issued and sold an aggregate of 356,280 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $0.7 million and net proceeds of $0.7 million, after deducting commissions to Jefferies and other offering expenses.

In March 2019, the Company entered into a license and commercialization agreement (the "Sunovion License Agreement"), with Sunovion. As part of the Sunovion License Agreement, Nabriva Therapeutics Ireland DAC, the Company's wholly owned subsidiary, granted Sunovion an exclusive license under certain patent rights, trademark rights and know-how to commercialize certain products containing XENLETA in the forms clinically developed by the Company or any of its affiliates ("Sunovian Licensed Products") in Canada in all uses in humans in community-acquired bacterial pneumonia and in any other indication for which the Licensed Products have received regulatory approval in Canada.

The Company has also entered into a license agreement with Sinovant Services, Ltd., an affiliate of Roviant Sciences, Ltd. To develop and commercialize Lefamulin in the greater China region (the "Sinovant License Agreement"). See Note 11 for a description of the Sinovant License Agreement including the realization of certain milestone payments received through September 30, 2019 as well as the potential for additional milestone and royalty payments in future periods.

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 September 30, 2019 and for the three months and nine months ended September 30, 2018 and 2019 are unaudited. The December 31, 2018 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 September 30, 2019 and for the three and nine months ended September 30, 2018 and 2019. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2018 and 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019, 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, 2018 contained in the Company's Annual Report on Form 10-K, as filed with the SEC on March 12, 2019.

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, 2018. Since the date of those financial statements, the Company has added the following significant accounting policy with respect to revenue recognition due to the commercial launch of XENLETA in September 2019.

Revenue Recognition—The Company recognizes revenue from sales of its commercial products in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606").

Product Revenue

Beginning in September 2019, the Company began selling its XENLETA product principally to a limited number of specialty distributors in the United States. The distributors place orders with the Company for sufficient quantities of its products to maintain an appropriate level of inventory based on its customers' anticipated purchase volumes and demand. The Company recognizes revenue once it has transferred physical possession of the goods and the distributor obtains legal title to the product. Payment terms between Nabriva and its customers are generally approximately 60 days from the invoice date. In addition to distribution agreements with customers, the Company enters into arrangements with health care providers and payers that provide for government mandated and/or privately negotiated rebates, chargebacks and discounts with respect to the purchase of its product.

The transaction price that the Company recognizes as revenue reflects the amount it expects to be entitled to in connection with the sale and transfer of control of product to its customers. At the time that the Company's customers take control of the product, which is when the Company's performance obligation under the sales contracts is complete, the Company records product revenues net of applicable reserves for various types of variable consideration. The types of variable consideration are as follows:

- Fees-for-service
- Product returns
- Chargebacks and rebates
- Government rebates
- Commercial payer and other rebates
- Group Purchasing Organizations ("GPO") administration fees
- Voluntary patient assistance programs

In determining the amounts of certain allowances and accruals, the Company must make significant judgments and estimates. For example, in determining these amounts, the Company estimates prescription demand from the specialty pharmacies, hospital demand, buying patterns by hospitals, hospital systems and/or group purchasing

organizations and the levels of inventory held by specialty distributors and customers. The Company also analyzes third party end usage product consumption patterns to gauge demand for its products. Making these determinations involves analyzing third party industry data to determine whether trends in historical channel distribution patterns will predict future product sales. The Company receives data periodically from its specialty distributors and customers on inventory levels and historical channel sales mix, and the Company considers this data when determining the amount of the allowances and accruals for variable consideration, however given the recent launch of its XENLETA product this data is limited.

In assessing the amount of net revenue to record, the Company considers both the likelihood and the magnitude of the revenue reversal. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known. The specific considerations the Company uses in estimating these amounts related to variable consideration associated with the Company's products are as follows:

Fees-for-service – The Company offers discounts and pays certain distributor service fees for sales order management, data, and distribution services which are explicitly stated at contractually determined rates in the customer's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In assessing if the consideration paid to the customer should be recorded as a reduction of the transaction price, the Company determines whether the payment is for a distinct good or service or a combination of both. Since the Company's distributor fees are not specifically identifiable, it does not consider the fees separate from the distributors' purchase of the product. Additionally, distributor services generally cannot be provided by a third party. Because of these factors, the consideration paid is considered a reduction of revenue. The Company records its fee-for-service accruals based on distributors' purchases and the applicable discount rate.

Product returns – Generally, the Company's customers have the right to return product during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Since the Company currently does not have history of XENLETA returns, the Company estimated returns based on industry data for comparable products in the market. As the Company distributes its product and establishes historical sales over a longer period of time (i.e., two to three years), the Company will be able to place more reliance on historical purchasing, demand and return patterns of its customers when evaluating its reserves for product returns. The Company's XENLETA product has a thirty-six-month shelf life.

At the end of each reporting period for any of our products, the Company may decide to constrain revenue for product returns based on information from various sources, including channel inventory levels and dating and sell-through data, the expiration dates of product currently being shipped, price changes of competitive products and introductions of generic products.

Chargebacks and rebates – Although the Company primarily sells products to specialty distributors in the United States, the Company also enters into agreements with hospitals and retail pharmacies, either directly or through group purchasing organizations acting on behalf of their members, in connection with the purchase of product. Based on these agreements, certain of the Company's customers have the right to receive a discounted price on product purchases. The Company typically provides a credit to its specialty distributors customers (i.e., chargeback), representing the difference between the customer's acquisition list price and the discounted price. The calculation of the accrual for chargebacks and rebates is based on estimates of claims and their associated cost that the Company expects to receive associated with product sales that have been recognized as revenue but remain in the distribution channel as inventory at the end of each reporting period.

Government rebates –The Company is subject to discount obligations primarily under state Medicaid and Medicare programs. The Company estimates its Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payer mix. These reserves are recorded in the same period the related product revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses on the consolidated balance sheet. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional

liability under the Medicare Part D program. The calculation of the accrual for government rebates is based on estimates of claims and their associated cost that the Company expects to receive associated with product sales that have been recognized as revenue but remain in the distribution channel as inventory at the end of each reporting period.

Commercial payer and other rebates – The Company contracts with certain private payer organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of XENLETA and contracted formulary status. The Company estimates these rebates and records reserves for such estimates in the same period the related revenue is recognized. Currently, the reserve for customer payer rebates considers future utilization based on third party studies of payer prescription data; the utilization is applied to product that remains in the distribution and retail pharmacy channel inventories at the end of each reporting period. As the Company distributes its product and establishes historical sales over a longer period of time (i.e., two years), the Company will be able to place more reliance on historical data related to commercial payer rebates (i.e., actual utilization units) while continuing to rely on third party data related to payer prescriptions and utilization. The calculation of the accrual for commercial payer and other rebates is based on estimates of claims and their associated cost that the Company expects to receive associated with product sales that have been recognized as revenue but remain in the distribution channel as inventory at the end of each reporting period.

GPO administration fees – The Company contracts with GPOs and pays administration fees related to contacting and membership management services provided. In assessing if the consideration paid to the GPO should be recorded as a reduction in the transaction price, the Company determines whether the payment is for a distinct good or service or a combination of both. Since GPO fees are not specifically identifiable, the Company does not consider the fees separate from the purchase of the product. Additionally, the GPO services generally cannot be provided by a third party. Because of these factors, the consideration paid is considered a reduction of revenue.

Patient assistance – The Company offers certain voluntary patient assistance programs for prescriptions, such as co-pay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product sales that have been recognized as revenue but remains in the distribution channel as inventory at the end of each reporting period.

At the end of each reporting period, the Company will adjust its variable consideration estimates for product returns, chargebacks, and rebates when the Company believes actual experience may differ from current estimates.

The following table summarizes balances and activity of product revenue allowances and reserves:

	Total
Balance at December 31, 2018	$ —
Provision related to current period sales	575
Adjustment related to prior period sales	—
Credit or payments made during the period	—
Balance at September 30, 2019	$ 575

The variable consideration for fee for service and estimates for chargebacks are recorded as contra-assets in accounts receivable, net, and other receivables whereas the other variable consideration estimates are recorded in accrued expenses as these payments are not made directly to the Company's customers.

Cost of product sales

Cost of product sales consists primarily of the direct and indirect manufacturing costs for XENLETA. All manufacturing costs incurred prior to XENLETA's approval in the United States on August 19, 2019 were expensed in research and development expense. Costs incurred after the approval date were capitalized as inventory.

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 February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. On January 1, 2019, the Company adopted the new lease standard using the optional transition method under which comparative financial information has not been restated and will continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. In addition, the new lease standard provides a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company did not have to reassess whether expired or existing contracts are or contain a lease; and did not have to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases.

The new lease standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption under which the Company will not recognize right of use ("ROU") assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases. The Company elected the practical expedient to not separate lease and non-lease components for certain classes of assets (office buildings).

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease ROU assets, other current liabilities, and operating lease liabilities on the Company's consolidated balance sheet as of September 30, 2019. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the remaining lease term as of January 1, 2019. Since none of the Company's lease agreements provide an implicit rate, the Company estimated an incremental borrowing rate over the lease term based on the information available at January 1, 2019 in determining the present value of lease payments. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Variable lease costs such as operating costs and property taxes are expensed as incurred.

On January 1, 2019, the Company recognized ROU assets and lease liabilities of approximately $2.0 million on its consolidated balance sheet using an estimated incremental borrowing rate of 9.8%. This ROU asset is recorded in property, plant and equipment, net and the ROU liability is recorded in other non-current liabilities.

3. Inventory

Inventory is stated at the lower of cost or estimated net realizable value. Inventory is valued on a first-in, first-out basis and consists primarily of material costs, third-party manufacturing costs, and related transportation costs along the Company's supply chain. The Company capitalizes inventory upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are recorded as research and development expense. Costs of drug product to be consumed in any current or future clinical trials will continue to be recognized as research and development expense and costs of sample inventory is recorded as selling, general and administrative expense. The Company reviews inventories for realization on a quarterly basis and would record provisions for estimated excess, slow-moving and obsolete

inventory, as well as inventory with a carrying value in excess of net realizable value when necessary. Inventory at September 30, 2019 consisted of the following:

(in thousands)	
Raw materials	$ —
Work in process	12
Finished Goods	150
Total Inventory	**$ 162**

4. 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, 2018				
Assets:				
Cash equivalent:				
Money market funds	**$ 50**	$ —	$ —	$ 50
Short term investments:				
Term deposits	175	—	—	175
Total Assets	**$ 225**	**$ —**	**$ —**	**$ 225**

(in thousands)	Level 1	Level 2	Level 3	Total
September 30, 2019				
Assets:				
Cash equivalent:				
Money market funds	**$ 15,050**	$ —	$ —	$ 15,050
Short term investments:				
Term deposits	175	—	—	175
Total Assets	**$ 15,225**	**$ —**	**$ —**	**$ 15,225**

There were no transfers between Level 1 and 2 in the nine months ended September 30, 2019 or the year ended December 31, 2018. There were no changes in valuation techniques during the nine months ended September 30, 2019.

As of September 30, 2019, and December 31, 2018, 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.

5. Accrued Expenses and Other Liabilities

(in thousands)	As of December 31, 2018	As of September 30, 2019
Research and development related costs	$ 5,032	$ 1,718
Payroll and related costs	7,427	5,719
Accounting, tax and audit services	398	340
Other	1,645	3,886
Total other current liabilities	**$ 14,502**	**$ 11,663**

6. Debt

In December 2018, the Company entered into the Loan Agreement by and among the Company, Nabriva Therapeutics Ireland DAC, and certain other subsidiaries of the Company and Hercules Capital, Inc. (the "Lender"), pursuant to which a term loan of up to an aggregate principal amount of $75.0 million is available to the Company. The Loan Agreement provides for an initial term loan advance of $25.0 million, which was funded in December 2018, and, at the Company's option and subject to the occurrence of the funding conditions described below and other customary funding conditions, five additional term loan advances comprised of the following; 1) $10.0 million ("Tranche 2 Advance"), 2) $5.0 million ("Tranche 3 Advance"), 3) $10.0 million ("Tranche 4 Advance"), 4) $15.0 million ("Tranche 5 Advance") and 5) $5.0 million ("Tranche 6 Advance"). On September 20, 2019, the Company borrowed the Tranche 2 Advance, which became available upon the approval by the FDA of its NDA for XENLETA. On September 26, 2019, the Company entered into an amendment to extend the Tranche 3 Advance which was previously available to the Company through September 30, 2019 upon the approval by the FDA of a NDA for CONTEPO, to June 15, 2020, subject to the Company obtaining a specified amount of net cash proceeds from equity financings and/or upfront proceeds from business development, corporate collaborations or similar arrangements received on or after September 12, 2019 and on or before a specified date and other customary funding conditions.

The Tranche 4 Advance will be available to the Company from January 1, 2020 through December 31, 2020 upon the approval by the FDA of the NDA for CONTEPO and upon the achievement of specified product revenue milestones. The Tranche 5 Advance will be available to the Company from July 1, 2020 through June 30, 2021 upon the approval by the FDA of the NDA for CONTEPO and upon the achievement of specified product revenue milestones. The Tranche 6 Advance will be available to the Company from January 1, 2021 through December 15, 2021 upon the approval by the FDA of the NDA for CONTEPO and upon the achievement of specified product revenue milestones. The Company may request a seventh term loan advance of $5.0 million prior to December 31, 2021 subject to the Lender's sole discretion.

The term loan bears interest at an annual rate equal to the greater of 9.80% or 9.80% plus the prime rate of interest minus 5.50%. The Loan Agreement provides for interest-only payments through July 1, 2021, which may be incrementally extended from time to time upon the occurrence of certain conditions through January 1, 2022, and repayment of the outstanding principal balance of the term loan thereafter in monthly installments through June 1, 2023 (the "Maturity Date"). In addition, the Company is required to pay a fee of 6.95% of the aggregate amount of advances under the Loan Agreement at the Maturity Date (the "End of Term Fee"). At the Company's option, the Company may elect to prepay any portion of the outstanding term loan that is greater than or equal to $5.0 million by paying such portion of the principal balance and all accrued and unpaid interest thereon plus a prepayment charge equal to the following percentage of the principal amount being prepaid: (i) 3.0% if the term loan is prepaid during the first 12 months following the initial closing, (ii) 2.0% if the term loan is prepaid after 12 months following the initial closing but before 24 months following the initial closing and (iii) 1.0% if the term loan is prepaid any time thereafter but prior to the Maturity Date. The Company is also required to satisfy certain financial covenants, including an obligation to maintain specified minimum amounts of cash and cash equivalents in accounts pledged to Hercules. The Company is also required to satisfy certain performance covenants, including a stipulation that actual net product sales must exceed a specified percentage of the forecasted net product sales over certain specified time periods or the Company will become subject to a financial covenant requiring it to maintain cash balances equal to the greater of the amount outstanding under the term loan or a specified minimum. The Company was in compliance with all of its Loan Agreement covenants at September 30, 2019.

The Company's obligations under the Loan Agreement are guaranteed by all current and future subsidiaries of the Company, and each of the Company and its subsidiaries has granted the Lender a security interest in all of their respective personal property, intellectual property and other assets owned or later acquired. The Loan Agreement also contains certain events of default, representations, warranties and covenants of the Company and its subsidiaries. For example, the Loan Agreement contains representations and covenants that, subject to exceptions, restrict the Company's and its subsidiaries' ability to do the following, among other things: declare dividends or redeem or repurchase equity interests; incur additional indebtedness and liens; make loans and investments; engage in mergers, acquisitions and asset sales; certain transactions with affiliates; undergo a change in control; and add or change business locations or settle in cash potential milestone payment obligations that may become payable by the Company in the future to former security holders of Zavante.

The Loan Agreement also grants Lender or its nominee an option to purchase up to an aggregate of $2.0 million of the Company's equity securities, or instruments exercisable for or convertible into equity securities, sold to investors in any private financing upon the same terms and conditions afforded to such other investors for as long as there are amounts outstanding under the Loan Agreement.

The Company incurred $2.1 million of costs in connection with the Loan Agreement which along with the initial fee of $0.7 million paid to the Lender, were recorded as debt issuance cost and will be amortized as interest expense using the effective interest method over the term of the loan. The End of Term Fee will also be accrued as additional interest expense using the effective interest method over the term of the loan.

Long-term debt as December 31, 2018 and September 30, 2019 consisted of the following:

(in thousands)	As of December 31 2018	As of September 30 2019
Term loan payable	$ 25,000	$ 35,000
End of term fee	—	305
Unamortized debt issuance costs	(1,990)	(1,845)
Carrying value of term loan	23,010	33,460
Other long-term debt	708	781
Total long-term debt	**$ 23,718**	**$ 34,241**

Maturities of long-term debt as of September 30, 2019 were as follows:

(in thousands)	
2019	$ —
2020	—
2021	8,875
2022	17,450
2023	11,889

7. Revenue

(in thousands)	Three Months Ended September 30, 2018	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2019
Product revenue, net	$ —	$ 1,445	$ —	$ 1,445
Collaboration revenues	—	5,051	6,500	6,051
Research premium	427	424	1,907	1,168
Government grants	34	—	452	484
Total	**$ 461**	**$ 6,920**	**$ 8,859**	**$ 9,148**

The three and nine month period ended September 30, 2019 includes $5.0 million of collaboration revenues recorded from the Sinovant License Agreement (See Note 11) related to a milestone payment that became due upon

receipt of FDA approval for XENLETA. The nine month period ended September 30, 2019, includes an upfront payment of $1.0 million under the Sunovion License Agreement that was received in April 2019. Product revenue, net, relate to sales of XENLETA. The collaboration revenues for the nine months ended September 30, 2018 reflect the income recorded from the Sinovant License Agreement and included a $5.0 million non-refundable upfront payment received in the first quarter of 2018 as consideration for entering into the Sinovant License Agreement (see Note 11) as well as $1.5 million of variable consideration related a future milestone payment that the Company believed was probable to be met which was received in February 2019.

8. Share-Based Payments

Stock Option Plan 2015

On April 2, 2015, the Company's shareholders, management board and supervisory board adopted the Stock Option Plan 2015 (the "SOP 2015") and the shareholders approved an amended and restated version of the SOP 2015 on June 30, 2015. An amendment to the amended and restated SOP 2015 was approved by the shareholders on July 22, 2015. The 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 the Company's stock option awards under the SOP 2015 for the nine months ended September 30, 2019:

Stock Option Plan 2015	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1, 2019	2,842,913	8.34	
Granted	—	—	
Exercised	—	—	
Forfeited	(447,634)	8.46	
Outstanding as of September 30, 2019	**2,395,279**	**8.32**	**$ —**
Vested and exercisable as of September 30, 2019	**2,005,152**	**8.17**	**$ —**

Stock-based compensation expense under the SOP 2015 was $2.0 million and $3.6 million for the three and nine months ended September 30, 2019, respectively, and $0.9 million and $2.2 million for the three and nine months ended September 30, 2018, respectively.

The weighted average remaining contractual life of the options as of September 30, 2019 is 6.7 years.

As of September 30, 2019, there was $2.0 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 0.7 years.

2017 Share Incentive Plan

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

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

At September 30, 2019, 7,512,012 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 the Company's stock option awards under the 2017 Plan for the nine months ended September 30, 2019:

2017 Plan	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1, 2019	2,398,425	5.41	
Granted	2,463,300	1.95	
Exercised	—	—	
Forfeited	(351,456)	5.10	
Outstanding as of September 30, 2019	**4,510,269**	**3.55**	**$ 224**
Vested and exercisable as of September 30, 2019	**1,002,665**	**5.70**	**$ 1**

Stock-based compensation expense under the 2017 Plan was $0.6 million and $1.9 million for the three and nine months ended September 30, 2019, respectively. The weighted average fair value of the options granted during the nine months ended September 30, 2019 was $1.14 per share. The options granted in the nine months ended September

30, 2019 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	61.4% - 63.1%
Expected term of options (in years)	6.1
Range of risk-free interest rate	1.9% - 2.6%
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 September 30, 2019 is 8.9 years.

As of September 30, 2019, there was $5.7 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 1.4 years.

Restricted Stock Units

During the nine months ended September 30, 2019, the Company granted 479,000 RSUs with a grant date fair value of $1.90 per share, which was the closing price of the Company's shares on the grant date. These RSUs vest over a period of four years with 25% vesting upon the first anniversary of the grant date and on a monthly pro rata basis thereafter over the remaining three years. As of September 30, 2019, there were 479,000 of such RSUs outstanding. For the three and nine months ended September 30, 2019, $57 thousand and $152 thousand, respectively, of stock-based compensation expense was recognized for these RSUs.

During 2018, the Company granted 371,550 RSUs with a grant date fair value of $6.13 per share. Vesting of the RSUs was subject to FDA approval of an NDA for XENLETA. Fifty percent (50%) of each RSU award vested upon FDA approval, and the remaining fifty percent (50%) will vest on the one- year anniversary of such approval. In connection with the FDA approval that was received in August 2019, the Company recognized compensation expense of $1.0 million for the three and nine month period ended September 30, 2019. No compensation expense was recognized on these awards prior to this date as it was determined that approval was not probable since it was outside of the Company's control.

The Company has also granted a total of 834,300 RSUs to certain employees with a grant date fair value of $2.16 per share. These RSUs vest in three six-month increments beginning in May 2019 and ending in May 2020. As of September 30, 2019, a total of 256,709 RSUs have vested and were issued and there were 461,586 of such RSUs outstanding. For the three and nine months ended September 30, 2019, $0.2 million and $0.7 million, respectively, of compensation expense was recognized for these RSUs.

2019 Inducement Share Incentive Plan

On March 12, 2019, the Company's board of directors adopted the 2019 Inducement Share Incentive Plan (the "2019 Inducement Plan") and, subject to the adjustment provisions of the 2019 Inducement Plan, reserved 2,000,000 ordinary shares for issuance pursuant to equity awards granted under the 2019 Inducement Plan. In accordance with Nasdaq Listing Rule 5635(c)(4), awards under the 2019 Inducement Plan may only be made to individuals who were not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company.

At September 30, 2019, 1,414,850 ordinary shares were available for issuance under the 2019 Inducement 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 the Company's stock option awards under the 2019 Inducement Plan for the nine months ended September 30, 2019:

2019 Inducement Plan	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1, 2019	—	—	
Granted	595,150	2.27	
Exercised	—	—	
Forfeited	(10,000)	2.02	
Outstanding as of September 30, 2019	585,150	2.27	**$** —
Vested and exercisable as of September 30, 2019	—	—	—

Stock-based compensation expense under the 2019 Inducement Plan was $30 thousand and $44 thousand for the three and nine months ended September 30, 2019, respectively. The weighted average fair value of the options granted during the nine months ended September 30, 2019 was $1.40 per share. The options granted in the nine months ended September 30, 2019 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	
Expected volatility	61.6% – 63.7%
Expected term of options (in years)	6.1
Risk-free interest rate	1.42% – 2.34%
Dividend yield	—

The weighted average remaining contractual life of the options as of September 30, 2019 is 9.8 years.

As of September 30, 2019, there was $0.7 million of total unrecognized compensation expense, related to unvested options granted under the 2019 Inducement Plan, which will be recognized over the weighted-average remaining vesting period of 3.8 years.

Inducement Awards Outside of the 2019 Inducement Plan

On July 25, 2018, the Company granted a non-statutory option to purchase 850,000 of its ordinary shares and 150,000 performance-based RSUs to the Company's newly appointed Chief Executive Officer (the "CEO"). These equity awards were granted outside of the 2017 Plan and the 2019 Inducement Plan, were approved by the Company's compensation committee and board of directors and were made as an inducement material to the CEO entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The exercise price per share for the share option is $3.53 per share, and the option award has a ten-year term and will vest over a four-year period, with 25% of the shares underlying the award vesting on the first anniversary of the grant date and the remaining 75% of the shares underlying the option award to vest monthly over the subsequent 36-month period. The performance-based restricted share units are subject to vesting as follows: 50% will vest upon certification by the board of directors of the receipt of approval by the FDA of an NDA for each of lefamulin and CONTEPO for any indication, and 50% will vest on the first anniversary of such certification by the board of directors, provided, in each case, the CEO is performing services to the Company on the applicable vesting dates. If the FDA does not approve an NDA for both XENLETA and CONTEPO by January 31, 2020, the performance-based restricted share units will terminate in full.

Stock-based compensation expense for the inducement awards granted outside of the 2019 Inducement Plan was $0.3 million and $0.5 million for the three and nine months ended September 30, 2019, respectively, compared to $0.1 million for each of the three and nine months ended September 30, 2018. The performance-based RSUs had a grant date fair value of $3.53 per share and the options had a grant date fair value of $2.05 per share based on a Black Scholes option pricing model using the following assumptions. No expense has been recognized to date on the performance based RSUs as it was determined that approval of CONTEPO is not probable since it is outside of the Company's control. The significant inputs into the model were as follows:

Input parameters	
Expected volatility	59.8 %
Expected term of options (in years)	6.1
Range of risk-free interest rate	2.9 %
Dividend yield	—

The weighted average remaining contractual life of the options as of September 30, 2019 is 8.8 years.

As of September 30, 2019, there was $1.2 million of total unrecognized compensation expense, related to unvested inducement award options granted, which will be recognized over the weighted-average remaining vesting period of 1.5 years.

Employee Stock Purchase Plan

The Company's board of directors adopted, and in August 2018 Company's stockholders approved, the 2018 employee stock purchase plan (the "2018 ESPP"). The maximum aggregate number of shares of ordinary shares that may be purchased under the 2018 ESPP is 500,000 shares, (the "ESPP Share Pool"), subject to adjustment as provided for in the 2018 ESPP. The ESPP Share Pool represented 0.6% of the total number of shares of ordinary shares outstanding as of September 30, 2019. The 2018 ESPP allows eligible employees to purchase shares at a 15% discount to the lower of the closing share price at the beginning and end of the six-month offering periods commencing November 1 and ending April 30 and commencing May1 and ending October 31 of each year. Compensation expense recognized for ESPP awards was $0.1 million for the nine month period ended September 30, 2019.

9. Income Tax (Expense) Benefit

For the three and nine months ended September 30, 2019 the Company recorded a tax benefit of $29 thousand and a tax provision of $80 thousand respectively, compared to an income tax benefit of $151 thousand and an income tax expense of $307 thousand for the corresponding period in the prior year.

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 the Company has recorded a valuation allowance against all of its deferred tax assets at September 30, 2019 and December 31, 2018.

10. Earnings (Loss) per Share

Basic and diluted loss per share

For the three and nine months ended September 30, 2018 and 2019, 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 since the Company had net losses for each period presented below.

(in thousands, except per share data)	Three Months Ended September 30, 2018	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2019
Net loss for the period	$ (52,825)	$ (17,795)	$ (83,955)	$ (59,719)
Weighted average number of shares outstanding	58,442,987	75,161,192	45,369,040	72,153,405
Basic and diluted loss per share	**$ (0.90)**	**$ (0.24)**	**$ (1.85)**	**$ (0.83)**

The following ordinary share equivalents were excluded from the calculations of diluted earnings per share as their effect would be anti-dilutive since the Company had net losses for each period presented below:

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2019
Stock option awards	5,936,724	8,340,698	5,936,724	8,340,698
Restricted stock units	508,100	1,289,111	508,100	1,289,111

11. Sinovant and Sunovion License Agreements

Sinovant License Agreement

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

Under the Sinovant 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 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 Sinovant Licensed Product receives a second or any subsequent regulatory approval in the People's Republic of China. The first milestone was a $1.5 million payment for the submission of a clinical trial application ("CTA"), by Sinovant to the Chinese Food and Drug Administration, which was received in the first quarter of 2019. Additionally, in connection with the FDA approval for lefamulin the Company received a $5.0 million milestone payment in the third quarter of 2019. The remaining milestone payments are tied to additional regulatory approvals and annual sales targets. The Company will also be eligible to receive low double-digit royalties on sales, if any, of Sinovant Licensed Products in the Territory. The Company has recorded the payments received to date as collaboration revenue in the consolidated statement of operations. The future regulatory and commercial milestone payments will be recorded during the period the milestones become probable of achievement.

Sinovant will be solely responsible for all costs related to developing, obtaining regulatory approval of and commercializing Sinovant Licensed Products in the Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Sinovant Licensed Products 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 a sufficient supply of lefamulin for Sinovant to manufacture finished drug products for development and commercialization of the Sinovant 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 Sinovant 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 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 Sinvant License Agreement under specified circumstances relating to the other party's insolvency. The Company has 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 Company will enter into ancillary agreements with Sinovant, including clinical and commercial supply agreements and a pharmacovigilance agreement.

Sunovion License Agreement

In March 2019, the Company entered into the Sunovion License Agreement with Sunovion. As part of the Sunovion License Agreement, Nabriva Therapeutics Ireland DAC, the Company's wholly owned subsidiary, granted Sunovion an exclusive license under certain patent rights, trademark rights and know-how to commercialize the Licensed Products in Canada in all uses in humans in community-acquired bacterial pneumonia and in any other indication for which the Licensed Products have received regulatory approval in Canada. Under the Sunovion License Agreement, Sunovion and DAC will establish a joint development committee (the "Sunovian JDC"), to review and oversee regulatory approval and commercialization plans in the Territory. Sunovion will be solely responsible for all costs related to 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 has identified two performance obligations at inception: (1) the delivery of the exclusive license to Sunovion, which the Company has determined is a distinct license of functional intellectual property that Sunovion has obtained control of; and, (2) the participation in the Sunovian JDC. The $1.0 million non-refundable upfront payment was allocated entirely to the delivery of the license as the Sunovian JDC deliverable was deemed to be de minimis. Any future regulatory and commercial milestone payments under the Sunovion License Agreement will be recorded during the period the milestones become probable of achievement.

12. Commitments and Contingencies

Leases

The Company leases office spaces in King of Prussia, Pennsylvania, San Diego, California, Dublin, Ireland and laboratory and office space in Vienna, Austria under agreements previously classified as operating leases.

The lease agreement in King of Prussia, Pennsylvania expires on December 15, 2023 and does not include any renewal options. The agreement provides for an initial monthly base amount plus annual escalations through the term of the lease.

The lease agreement in San Diego, California expired on June 30, 2019 and was not renewed by the Company. In May 2019, the Company entered into a month-to-month sublease agreement for office space for two employees in San Diego, California.

For the lease agreement in Vienna Austria, the Company can terminate the lease without the landlord's consent and without paying a termination penalty by giving six months' notice to the landlord. The agreement provides for a monthly base fixed amount. The Company is in the process of determining the appropriate space needed in the building based on its needs. As a result, the Company may negotiate a new lease or evaluate additional or alternate spaces. As such, the Company has classified the agreement as a short-term lease. During the third quarter of 2019, the Company subleased certain space at its leased cost.

In March 2019, the Company entered into a lease agreement for office space in Dublin, Ireland which expires on April 30, 2021. The agreement can be automatically renewed by both parties equal to the current lease term but for

no less than three months. The agreement provides for a monthly based fixed amount of 7,000 euros beginning on the commencement date which was in May 2019.

In addition to the monthly base amounts under the lease agreements, the Company is required to pay its proportionate share of real estate taxes and operating expenses during the lease term for the King of Prussia lease.

For the three and nine months ended September 30, 2019, the Company's operating lease expense was $0.4 million and $1.1 million, respectively.

As of September 30, 2019, the lease term of the King of Prussia operating leases was 4.2 years and the discount rate was 9.8%.

As of September 30, 2019, other information related to the operating leases were as follows:

Operating Cash Flow Supplemental Information:

(in thousands)	September 30, 2019
Cash paid for amounts included in the measurement of the operating lease liabilities	$ 389
Right-of-use assets obtained in exchange for operating lease obligations	$ 1,730

The following table sets forth by year the required future payments of operating lease liabilities:

(in thousands)	September 30, 2019
Remainder of 2019	$ 126
2020	507
2021	515
2022	522
2023	533
Total lease payments	2,203
Less imputed interest	(412)
Present value of operating lease liabilities	1,792

The following table sets forth by year the minimum expected lease payments under non-cancelable operating leases as of December 31, 2018:

(in thousands)	December 31, 2018
2019	$ 515
2020	507
2021	515
Total lease payments	$ 1,537

Legal Proceedings

On May 8, 2019, a putative class action lawsuit was filed against the Company and its Chief Executive Officer in the United States District Court for the Southern District of New York, captioned Larry Enriquez v. Nabriva Therapeutics PLC, and Ted Schroeder, No. 19-cv-04183. The complaint purported to be brought on behalf of shareholders who purchased the Company's securities between November 1, 2018 and April 30, 2019. The complaint generally alleged that the Company and its Chief Executive Officer violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements and omitting to disclose material facts concerning the Company's submission of an NDA to the FDA for marketing approval of CONTEPO for the treatment of cUTI in the United States and the likelihood of such approval. The complaint sought unspecified damages, attorneys' fees, and other costs.

On May 22, 2019, a second putative class action lawsuit was filed against the Company and its Chief Executive Officer in the United States District Court for the Southern District of New York, captioned Anthony Manna v. Nabriva Therapeutics PLC, and Ted Schroeder, No. 19-cv-04713. The complaint purported to be brought on behalf of shareholders who purchased the Company's securities between November 1, 2018 and April 30, 2019. The allegations made in the Manna complaint were similar to those made in the Enriquez complaint, and the Manna complaint sought similar relief. On May 24, 2019, these two lawsuits were consolidated by the court. The court appointed a lead plaintiff and approved plaintiff's selection of lead counsel on July 22, 2019.

On September 23, 2019, plaintiff filed an amended complaint, adding the Company's Chief Financial Officer and Chief Medical Officer as defendants; the amended complaint purports to be brought on behalf of shareholders who purchased the Company's securities between January 4, 2019 through April 30, 2019, and otherwise includes allegations similar to those made in the original complaints and seeks similar relief. The Company's pre-motion letter to dismiss the amended complaint was due to plaintiff on October 21, 2019, and plaintiff responded to the Company via a letter on November 4, 2019. The Company intends to file a pre-motion letter to dismiss with the court by the November 18, 2019 deadline, setting forth why a motion to dismiss is warranted.

The Company denies any and all allegations of wrongdoing and intends to vigorously defend against this lawsuit. The Company is unable, however, to predict the outcome of this matter at this time. Moreover, any conclusion of this matter in a manner adverse to the Company and for which it incurs substantial costs or damages not covered by the Company's directors' and officers' liability insurance would have a material adverse effect on its financial condition and business. In addition, the litigation could adversely impact the Company's reputation and divert management's attention and resources from other priorities, including the execution of its business plan and strategies that are important to the Company's ability to grow its business, any of which could have a material adverse effect on the Company's business.

Other Commitments and Contingencies

The Company has other contractual commitments related primarily to contracts entered into with contract research organizations and contract manufacturing organizations in connection with the conduct of clinical trials and other research and development activities. During the nine months ended September 30, 2019, 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, 2018, relating to contract research organizations and contract manufacturing organizations.

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

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, 2018, filed with the Securities and Exchange Commission on March 12, 2019. 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 biopharmaceutical company engaged in the commercialization and research and development of novel anti-infective agents to treat serious infections. In August 2019, our first product was approved by the FDA and we made it available in the United States in September 2019 under the brand name XENLETA. XENLETA (lefamulin) is a first-in-class semi-synthetic pleuromutilin antibiotic for systematic administration in humans discovered and developed by our team. It inhibits the synthesis of bacterial protein, which is required for bacteria to grow by binding with high affinity, high specificity and at molecular targets that are different than other antibiotic classes. Based on results from two global, Phase 3 clinical trials, we believe that XENLETA is well-positioned for use as a first-line monotherapy for the treatment of CABP due to its novel mechanism of action, targeted spectrum of activity, resistance profile, achievement of substantial drug concentration in lung tissue and fluid, availability of oral and intravenous, or IV, formulations and a generally well-tolerated safety profile. We believe XENLETA represents a potentially important new treatment option for the five million adults in the United States diagnosed with CABP each year.

We currently have a team of regional business directors and medical science liaisons in the field performing educational and market development activities. In connection with our commercial launch of XENLETA, we hired a targeted hospital-based sales force to promote XENLETA which we also intend to utilize to market CONTEPO, if approved.

We also submitted a marketing authorization application for XENLETA for the treatment of CABP in adults in Europe in May 2019. On June 24, 2019, we announced that the European Medicines Agency, or the EMA determined that our MAA for XENLETA is valid. Validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process and an opinion of the EMA Committee for Medicinal Products for Human Use (CHMP) is anticipated in the second half of 2020.

We submitted a new drug application ("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 October 2018. The FDA has granted fast track designation to CONTEPO under the Generating Antibiotics Incentives Now Act, or the GAIN Act. In April 2019, the FDA issued a Complete Response Letter ("CRL") in connection with our NDA for CONTEPO for the treatment of cUTI, including AP, stating that is was unable to approve the application in its current form. Specifically, the CRL requested that we address issues related to facility inspections and manufacturing deficiencies at our API contract manufacturer. We held a "Type A" meeting with the FDA in July 2019 to discuss its findings and we anticipate resubmitting our NDA seeking marketing approval for CONTEPO in the coming weeks. However, we cannot predict when CONTEPO will receive marketing approval, if at all.

Since inception, we have incurred significant operating losses. As of September 30, 2019, we had an accumulated deficit of $453.7 million. To date, we have financed our operations primarily through equity offerings, convertible and term debt financings and research and development support from governmental grants and proceeds from our licensing agreements. We have devoted substantially all of our efforts to research and development, including clinical trials as well as preparing for the commercial launch of XENLETA. 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 have negative cash flows for at least the next several years. 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 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.

Although we have a debt facility with Hercules Capital, Inc. (See Note 6 to the unaudited consolidated financial statements included elsewhere in this Form 10-Q for additional details) that may potentially enable us to borrow additional funds, based on our current plans, 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.

Acquisition of Zavante

On July 24, 2018, we acquired Zavante, or the Acquisition, a biopharmaceutical company focused on developing CONTEPO (fosfomycin for injection) to improve the outcomes of hospitalized patients pursuant to the Agreement and Plan of Merger dated July 23, 2018, or the Merger Agreement.

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 cUTIs, 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 AP.

Upon the closing 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 were issued in July 2019 upon release of the Holdback Shares (as defined below) constituted 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 an NDA from 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 with the first commercial milestone becoming payable when CONTEPO exceeds $125 million in net sales in a calendar year.

At our Extraordinary General Meeting of Shareholders held in October 2018, our shareholders approved the issuance of ordinary shares in settlement of potential milestone payment obligations that may become payable in the future to former Zavante stockholders, including the Approval Milestone Payment which will be settled in our ordinary shares. We also now have the right to settle the Net Sales Milestone Payments in our ordinary shares, except as otherwise provided in the Merger Agreement.

In addition, upon the Closing, we assumed certain liabilities and obligations, including contractual liabilities and obligations. Prior to the Acquisition, Zavante was obligated to make milestone payments to the former 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. Zavante will also 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 had 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 States. In addition, Zavante had 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 had 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 research and development office lease, a collaboration agreement governing the supply and manufacturing agreements described above and a commercial packaging agreement.

We accounted for the Acquisition as an asset acquisition as the arrangement did not meet the definition of a business pursuant to the guidance prescribed in Accounting Standards Codification Topic 805, *Business Combinations.* We concluded the Acquisition did not meet the definition of a business because the transaction principally resulted in the acquisition of the exclusive rights to IV fosfomycin in the U.S. which is a single identifiable asset and represents substantially all the fair value of the assets acquired.

We expensed the acquired intellectual property as of the acquisition date as in-process research and development with no alternative future uses. We recorded an in-process research and development expense of $31.9 million which represents $26.9 million for the fair value of the Upfront Shares, $4.8 million of transaction costs and $0.2 million of net liabilities assumed.

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, which we refer to as 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, that was received in February 2019. An additional $5.0 million milestone payment was received in the third quarter of 2019 due to the approval of XENLETA from the FDA in August 2019. 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.

License Agreement with Sunovion Pharmaceutics Canada Inc.

In March 2019, we entered into a license and commercialization agreement, or the Sunovion License Agreement, with Sunovion Pharmaceuticals Canada Inc., or Sunovion. As part of the Sunovion License Agreement, Nabriva Therapeutics Ireland DAC, our wholly owned subsidiary, granted Sunovion an exclusive license under certain patent rights, trademark rights and know-how to commercialize certain products containing lefamulin in the forms clinically developed by us or any of our affiliates, or the Licensed Products, in Canada in all uses in humans in community-acquired bacterial pneumonia and in any other indication for which the Licensed Products have received regulatory approval in Canada.

We have identified the delivery of the exclusive license to Sunovion as the one material performance obligation at inception. We have determined that the Sunovion License Agreement provides for a distinct license of functional intellectual property that Sunovion has obtained control of. The non-refundable upfront payment of $1.0 million that we received in connection with the Sunovion License Agreement was allocated entirely to the delivery of the license.

Any future regulatory and commercial milestone payments under the Sunovion License Agreement will be recorded during the period the milestone is probable of achievement.

Financial Operations Overview

Revenue

In September 2019, in connection with our commercial launch of XENLETA we recorded $1.4 million of product revenues net as XENLETA was purchased by our wholesale customers. Future product revenues will be generated by the amount and frequency of reorders from our wholesale customers based on the ultimate consumption patterns from the end users of XENLETA.

In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. We held a "Type A" meeting with the FDA to discuss its findings in July 2019 and anticipate resubmitting our NDA in the weeks ahead. We cannot predict when CONTEPO will receive marketing approval, if at all. We may also enter into collaboration agreements with third parties and we may generate revenue from those agreements.

Our revenue during the three and nine months ended September 30, 2019, included $5.0 million of collaboration revenues from the Sinovant License Agreement related to the approval of XENLETA. The corresponding prior year periods included 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 believed was probable to be met and was ultimately received in February 2019. 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, 2018.

Research and Development Expenses

Research and development expenses represented 65.8% and 31.9% of our total operating expenses for the nine months ended September 30, 2018 and 2019, 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.

	Nine Months Ended September 30,	
(in thousands)	**2018**	**2019**
Direct Costs		
XENLETA	**$** 13,986	**$** 7,737
CONTEPO	491	3,781
FDA filing fee refund	—	(2,589)
Other programs and initiatives	53	994
Indirect Costs	14,340	11,290
In-process research and development	31,930	—
Total	**$ 60,800**	**$ 21,213**

We expect to continue to incur research and development expenses in connection with our activities related to our planned MAA filings for marketing approval of lefamulin for the treatment of CABP, 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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses represented 34.2% and 68.1% of our total operating expenses for the nine months ended September 30, 2018 and 2019, respectively.

Selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation not related to research and development activities for personnel in our finance, information technology, commercial, medical affairs and administrative functions. Selling, 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 selling, general and administrative expenses to increase with the expansion of our staff primarily related to our commercial sales force for the commercialization of XENLETA.

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, 2018. During the nine months ended September 30, 2019, there were no material changes to our critical accounting policies, other than as described in Note 2 to our unaudited consolidated financial statements included elsewhere in this Form 10-Q.

Results of Operations

Comparison of Three Months Ended September 30, 2018 and 2019

(in thousands)	Three Months Ended September 30, 2018	2019	Change
Consolidated Operations Data:			
Revenues	$ 461	$ 6,920	$ 6,459
Costs and Expenses:			
Cost of product sales	—	(15)	(15)
Research and development expenses	(40,804)	(5,601)	35,203
Selling, general and administrative expenses	(12,582)	(18,503)	(5,921)
Total operating expenses	(53,386)	(24,119)	29,267
Loss from operations	**(52,925)**	**(17,199)**	**35,726**
Other income (expense):			
Other income (expense), net	(54)	(10)	44
Interest income (expense), net	3	(615)	(618)
Loss before income taxes	**(52,976)**	**(17,824)**	**35,152**
Income tax benefit	151	29	(122)
Net loss	**$ (52,825)**	**$ (17,795)**	**$ 35,030**

Revenues

Revenues increased by $6.5 million from $0.5 million for the three months ended September 30, 2018 to $6.9 million for the three months ended September 30, 2019, primarily due a $5.1 million increase in collaboration revenue and a $1.4 million increase in net product sales associated with the launch of XENLETA.

Cost of Product Sales

Cost of product sales primarily represents direct and indirect manufacturing costs of our XENLETA product. Prior to the FDA approval of XENLETA on August 19, 2019, the inventory costs for the product were expensed as research and development expenses since the approval was outside of the Company's control and therefore not considered probable. As such, the majority of the expenses incurred for our initial inventories of XENLETA has been previously expensed. As a result, we anticipate that our cost of product sales will remain at relatively low levels for a period of time until our initial pre-launch inventory stock will be distributed by our customers based on end user consumption demand.

Research and Development Expenses

Research and development expenses decreased by $35.2 million from $40.8 million for the three months ended September 30, 2018 to $5.6 million for the three months ended September 30, 2019. The decrease was primarily due to $31.9 million of in-process research and development expenses associated with the acquisition of Zavante assets recognized in 2018, a $2.7 million decrease in research materials and purchased services related to the development of XENLETA, a $2.6 million decrease in research consulting fees, and a $0.3 million decrease in staff costs, partly offset by a $2.0 million increase in stock-based compensation expense.

Selling, General and Administrative Expenses

Selling, general and administrative expense increased by $5.9 million from $12.6 million for the three months ended September 30, 2018 to $18.5 million for the three months ended September 30, 2019. The increase was primarily due to a $3.2 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a $1.4 million increase in staff costs due to the addition of employees, a $0.7 million increase in stock-based compensation expense, a $0.7 million increase in legal fees, a $0.3 million increase in infrastructure costs and a $0.2 million increase in travel and other corporate costs.

Other Income (Expense), net

Other income (expense), net, decreased by $44 thousand for the three months ended September 30, 2019, that was primarily due to remeasurements of our foreign currency account balances.

Interest Income (Expense), net

Interest income (expense), net increased by $0.6 million due the incurrence of indebtedness under our term loan, or the Loan Agreement, with Hercules in December 2018. See Note 6 to the unaudited consolidated financial statements included elsewhere in this Form 10-Q for further information.

Income Tax Benefit

Our income tax benefit was $0.2 million for the three months ended September 30, 2018 compared to an income tax benefit of $29 thousand for the three months ended September 30, 2019.

Comparison of Nine Months Ended September 30, 2018 and 2019

(in thousands)	Nine Months Ended September 30, 2018	2019	Change
Consolidated Operations Data:			
Revenues	$ 8,859	$ 9,148	$ 289
Costs and Expenses:			
Cost of product sales	—	(15)	(15)
Research and development expenses	(60,800)	(21,213)	39,587
Selling, general and administrative expenses	(31,555)	(45,339)	(13,784)
Total operating expenses	(92,355)	(66,567)	25,788
Loss from operations	**(83,496)**	**(57,419)**	**26,077**
Other income (expense):			
Other income (expense), net	(172)	116	288
Interest income (expense), net	20	(2,336)	(2,356)
Loss before income taxes	**(83,648)**	**(59,639)**	**24,009**
Income tax expense	(307)	(80)	227
Net loss	**$ (83,955)**	**$ (59,719)**	**$ 24,236**

Revenues

Revenues increased by $0.3 million from $8.9 million for the nine months ended September 30, 2018 to $9.1 million for the nine months ended September 30, 2019, primarily due to a $1.4 million increase in product revenues associated with the launch of our product, XENLETA, partially offset by a decrease in research premium provided to us by the Austrian government as a result of a decrease in our research and development expenses for which we can receive grant revenue.

Cost of product sales

Cost of product sales primarily represents the direct and indirect manufacturing costs of our XENLETA product. Prior to the FDA approval of XENLETA, the inventory costs for the product were expensed as research and development expenses since the approval was outside of the Company's control and therefore not considered probable. As such, the majority of the expenses incurred for our initial inventories of XENLETA has been previously expensed. As a result, we anticipate that our cost of product revenue will remain at relatively low levels for a period of time until our initial pre-launch inventory stock is sold.

Research and Development Expenses

Research and development expenses decreased by $39.6 million from $60.8 million for the nine months ended September 30, 2018 to $21.2 million for the nine months ended September 30, 2019. The decrease was primarily due to $31.9 million for in-process research and development expenses associated with the acquisition of Zavante assets in 2018, a $5.7 million decrease in research materials and purchased services related to the development of lefamulin, and a $2.4 million decrease in research consulting fees.

Selling, General and Administrative Expenses

Selling, general and administrative expense increased by $13.8 million from $31.6 million for the nine months ended September 30, 2018 to $45.3 million for the nine months ended September 30, 2019. The increase was primarily due to a $5.0 million increase in staff costs due to the addition of employees, a $4.6 million increase of advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees, a $2.6 million increase in stock-based compensation expense, a $0.7 million increase in infrastructure costs and a $0.8 million increase in legal fees.

Other Income (Expense), net

Other income (expense), net decreased by $0.3 million from $0.2 million of expense for the nine months ended September 30, 2018 to $0.1 million of income for the nine months ended September 30, 2019. The change was due to remeasurements of our foreign currency cash balances.

Interest Income (Expense), net

Interest income (expense), net increased by $2.4 million due the incurrence of indebtedness under our Loan Agreement with Hercules in December 2018. See Note 6 to the unaudited consolidated financial statements included elsewhere in this Form 10-Q for further information.

Income Tax Expense

Our income tax expense was $0.3 million for the nine months ended September 30, 2018 compared to $0.1 million for the nine months ended September 30, 2019. The change to income tax expense was primarily due to the recognition of a valuation allowance on deferred tax assets in 2018.

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, convertible and term debt financings and research, development support from governmental grants and loans and proceeds from licensing agreements.

In December 2018, we announced the closing of up to a $75.0 million term loan with Hercules, or the Loan Agreement, $25.0 million of which was funded on the day of closing. Under the terms of the loan, in addition to the $25.0 million received at closing, we borrowed an additional $10.0 million in connection with the approval by the FDA of the NDA for XENLETA. See Note 6 to the unaudited consolidated financial statements included elsewhere in this Form 10-Q for additional information on the terms associated with the remaining term loans potentially available to the Company and the costs and other conditions associated with this funding source.

In March 2018, we entered into a Controlled Equity Offering℠ Sales Agreement, or the Cantor ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we could previously offer and sell our ordinary shares having aggregate gross proceeds of up to $50.0 million through Cantor. We terminated the Cantor ATM Agreement effective as of June 24, 2019. We did not incur any penalties as a result of the termination of the Cantor ATM Agreement. As of the effective date of the termination of the Cantor ATM Agreement, we had issued and sold an aggregate of 10,316,190 of our ordinary shares pursuant to the Cantor ATM Agreement for aggregate gross

proceeds of $37.8 million and net proceeds of $36.3 million, after deducting commissions and offering expenses. The approximately $12.2 million of ordinary shares that had been available for sale pursuant to the Cantor ATM Agreement remained unsold at the time of its termination. During the second quarter of 2019, under the Cantor ATM Agreement, we issued and sold an aggregate of 1,221,273 ordinary shares and received gross proceeds of $3.5 million and net proceeds of $3.4 million.

On June 25, 2019, we entered into an Open Market Sale Agreement℠, or the Jefferies ATM Agreement, with Jefferies LLC, or Jefferies, as agent, pursuant to which, from time to time, we may offer and sell ordinary shares for aggregate gross sale proceeds of up to $50.0 million through Jefferies by any method permitted that is deemed an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. As of September 30, 2019, we have issued and sold and aggregate of 4,101,282 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $9.6 million and net proceeds of $9.0 million, after deducting commissions to Jefferies and other offering expenses. From September 30, 2019 through the date of this filing, we issued and sold an aggregate of 356,280 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $0.7 million and net proceeds of $0.7 million, after deducting commissions to Jefferies and other offering expenses.

As of September 30, 2019, we had cash and cash equivalents, and short-term investments of $78.3 million.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2018 and 2019:

	Nine Months Ended September 30,	
(in thousands)	**2018**	**2019**
Net cash (used in) provided by:		
Operating activities	$ (50,492)	$ (56,405)
Investing activities	(4,375)	131
Financing activities	68,596	32,680
Effects of foreign currency translation on cash	(167)	(80)
Net increase (decrease) in cash and cash equivalents	**$** 13,562	**$** (23,674)

Operating Activities

Cash flow used in operating activities increased by $5.9 million from $50.5 million for the nine months ended September 30, 2018 to $56.4 million for the nine months ended September 30, 2019 primarily due to a $3.0 million increase in net loss, after removing the impact of non-cash amounts included in net loss in both periods and higher working capital of $2.9 million primarily due to decreases in accrued expenses and other current liabilities.

Investing Activities

Cash flow used in investing activities increased by $4.5 million for the nine months ended September 30, 2019 primarily due to transaction costs related to the acquisition of Zavante assets in 2018.

Financing Activities

Cash flow generated from financing activities decreased by $35.9 million for the nine months ended September 30, 2019 due to higher proceeds generated from equity financing activities in the nine months ended September 30, 2018, partially offset by the $10.0 million of long-term borrowings received through our debt facility in connection with the FDA approval of XENLETA, in the nine months ended September 30, 2019.

Operating and Capital Expenditure Requirements

We anticipate that our expenses will increase as we expect to incur significant additional commercialization expenses related to product sales, marketing, distribution and manufacturing. In addition, our expenses will increase if we suffer any regulatory delays or are required to conduct additional clinical trials to satisfy regulatory requirements.

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

- expand our 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 have or may receive marketing approval;
- establish and expand manufacturing arrangements with third parties;
- 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;
- in-license or acquire other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- draw additional funds under the Loan Agreement with Hercules;
- 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 commercialization efforts.

We expect that our existing cash, cash equivalents and short-term investments as of September 30, 2019, proceeds from the sale of ordinary shares under the Jefferies ATM Agreement from September 30, 2019 until the date of this filing of $0.7 million and anticipated net product sales and research premiums from the Austrian government for our qualified research and development expenditures will be sufficient to enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the third quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings, including additional advances under the Loan Agreement with Hercules. We may be eligible to borrow up an additional $40.0 million under our Loan Agreement with Hercules as discussed in Note 6 to the unaudited consolidated financial statements included elsewhere in this Form 10-Q.

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 commercial launch of XENLETA and the potential launch of 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 XENLETA and CONTEPO;

- the costs, timing and outcome of regulatory review of lefamulin in Europe and for any other indications and CONTEPO;
- the costs of commercialization activities for XENLETA and potentially CONTEPO if we 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 CONTEPO, if approved;
- the commercial success of XENLETA and the amount and frequency of reorders by our wholesale customers;
- subject to receipt of marketing approval, revenue received from commercial sales of CONTEPO;
- the costs of developing XENLETA 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 XENLETA, CONTEPO or any other products that we successfully develop, in-license or acquire. In addition, XENLETA and, if approved, 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. Additional 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.

Capital Expenditures

Capital expenditures were $0.2 million for each of the nine months ended September 30, 2018 and 2019. We made no significant investments in intangible assets during the nine months ended September 30, 2018 and 2019.

Currently, there are no material capital projects planned in 2019.

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 September 30, 2019, we had no debt that exposed us to interest rate risk. As of September 30, 2019, 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 expect that our existing cash, cash equivalents and short-term investments as of September 30, 2019, as well as net proceeds from the sale of ordinary shares under its “at the market” offering facility with Jefferies LLC from October 1, 2019 through the date of this filing of $0.7 million, anticipated net product revenues and research premiums from the Austrian government for our qualified research and development expenditures will be sufficient to enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into

the third quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements or equity or debt financings, including additional advances under the Loan Agreement.

We expect to continue to invest in critical commercialization activities and 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 commercial launch of XENLETA and potential launch of CONTEPO.

If we obtain marketing approval for CONTEPO or any other product candidate that we develop, in-license or acquire, we expect to incur significant additional commercialization expenses related to distribution and manufacturing. Our expenses will increase if we suffer any delays in our clinical programs, 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 Securities Exchange Act of 1934, as amended, or 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 Exchange Act, 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 Exchange Act 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 Exchange Act 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 September 30, 2019, 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

During the three months ended September 30, 2019, we recognized revenues from the sales of commercial products and implemented new controls and processes to report this new revenue stream, including controls around accruals for variable consideration estimates and monthly reviews of journal entries related to product sales.

There were no other changes in our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) that occurred during the three months ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

ITEM 1. LEGAL PROCEEDINGS

On May 8, 2019, a putative class action lawsuit was filed against the Company and its Chief Executive Officer in the United States District Court for the Southern District of New York, captioned Larry Enriquez v. Nabriva Therapeutics PLC, and Ted Schroeder, No. 19-cv-04183. The complaint purported to be brought on behalf of shareholders who purchased the Company's securities between November 1, 2018 and April 30, 2019. The complaint generally alleged that the Company and its Chief Executive Officer violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements and omitting to disclose material facts concerning the Company's submission of an NDA to the FDA for marketing approval of CONTEPO for the treatment of cUTI in the United States and the likelihood of such approval. The complaint sought unspecified damages, attorneys' fees, and other costs.

On May 22, 2019, a second putative class action lawsuit was filed against the Company and its Chief Executive Officer in the United States District Court for the Southern District of New York, captioned Anthony Manna v. Nabriva Therapeutics PLC, and Ted Schroeder, No. 19-cv-04713. The complaint purported to be brought on behalf of shareholders who purchased the Company's securities between November 1, 2018 and April 30, 2019. The allegations made in the Manna complaint were similar to those made in the Enriquez complaint, and the Manna complaint sought similar relief. On May 24, 2019, these two lawsuits were consolidated by the court. The court appointed a lead plaintiff and approved plaintiff's selection of lead counsel on July 22, 2019.

On September 23, 2019, plaintiff filed an amended complaint, adding the Company's Chief Financial Officer and Chief Medical Officer as defendants; the amended complaint purports to be brought on behalf of shareholders who purchased the Company's securities between January 4, 2019 through April 30, 2019, and otherwise includes allegations similar to those made in the original complaints and seeks similar relief. The Company's pre-motion letter to dismiss the amended complaint was due to plaintiff on October 21, 2019, and plaintiff responded to the Company via a letter on November 4, 2019. The Company intends to file a pre-motion letter to dismiss with the court by the November 18, 2019 deadline, setting forth why a motion to dismiss is warranted.

The Company denies any and all allegations of wrongdoing and intends to vigorously defend against this lawsuit. The Company is unable, however, to predict the outcome of this matter at this time. Moreover, any conclusion of this matter in a manner adverse to the Company and for which it incurs substantial costs or damages not covered by the Company's directors' and officers' liability insurance would have a material adverse effect on its financial condition and business. In addition, the litigation could adversely impact the Company's reputation and divert management's attention and resources from other priorities, including the execution of its business plan and strategies that are important to the Company's ability to grow its business, any of which could have a material adverse effect on the Company's business.

ITEM 1A. RISK FACTORS

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Form 10-Q. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.

Risks Related to Our Financial Position and Need for Additional Capital

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

Since inception, we have incurred significant operating losses. Our net losses were $59.7 million for the nine months ended September 30, 2019, $114.8 million for the year ended December 31, 2018 and $74.4 million for the year ended December 31, 2017. As of September 30, 2019, we had an accumulated deficit of $453.7 million. To date, we have financed our operations primarily through the sale of our equity securities, convertible and term debt financings and research and development support from governmental grants and loans and proceeds from our licensing agreements. We have devoted most of our efforts to research and development, including clinical trials and preparation for the commercial sale of our products. We have only recently completed development of and begun to commercialize our first product, XENLETA (lefamulin), and have not developed any other drugs that have received regulatory approval. XENLETA is approved in the United States for the treatment of community-acquired bacterial pneumonia, or CABP, in adults. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years, including in connection with our regulatory approval efforts, supply chain investments and commercialization of XENLETA and, if it receives marketing approval, CONTEPO. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year.

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

In September 2017, we announced positive topline results from our first Phase 3 global, pivotal clinical trial of XENLETA, which we refer to as Lefamulin Evaluation Against Pneumonia 1, or LEAP 1. In May 2018, we announced positive topline results from our second Phase 3 global, pivotal clinical trial of XENLETA, which we refer to as Lefamulin Evaluation Against Pneumonia 2, or LEAP 2. LEAP 2 evaluated the safety and efficacy of five days of oral XENLETA compared to seven days of oral moxifloxacin in adult patients with moderate community-acquired bacterial pneumonia, or CABP. We submitted two NDAs for marketing approval of XENLETA for the treatment of CABP in adults in the United States in December 2018 and received approval in August 2019. On September 9, 2019, the oral and intravenous formulations of XENLETA became commercially available in the United States through major specialty distributors. We also submitted a marketing authorization application, or MAA, for XENLETA for the treatment of community-acquired pneumonia, or CAP, in adults in Europe in May 2019, which the MAA determined was valid in June 2019. We also continue to characterize the clinical pharmacology of XENLETA. We expect to incur significant additional sales, marketing, distribution and manufacturing expenses related to XENLETA and if approved, CONTEPO.

In June 2016, the first patient was enrolled by Zavante Therapeutics, Inc., or 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 fourteen days of treatment for patients with concurrent bacteremia, with CONTEPO compared to piperacillin-tazobactam, or PIP-TAZ, in the treatment of hospitalized adults with complicated urinary tract infections, or cUTIs or acute pyelonephritis, or AP. We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, utilizing the FDA's 505(b)(2) pathway, in October 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. In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including acute pyelonephritis, stating that it was unable to approve the application in its current form. The Complete Response Letter requested that issues related to facility inspections and manufacturing deficiencies at our active pharmaceutical ingredient contract manufacturer be addressed prior to the FDA approving the NDA. In response, we requested a "Type A" meeting with the FDA to discuss its findings, which occurred in July 2019. We anticipate resubmitting an NDA for marketing approval of CONTEPO for injection for the treatment of cUTI, including AP, in the weeks ahead. We cannot predict the outcome of any interactions with the FDA or when CONTEPO will receive marketing approval, if at all. 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, or the Acquisition of Zavante. Upfront consideration in connection with the Acquisition was 8,152,092 of our ordinary shares, including the 815,186 ordinary shares that were initially held back but which were issued in July 2019 upon release of the Holdback Shares pursuant to the terms of the Agreement and Plan of Merger, dated July 23, 2018, or 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 (each as defined below), 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 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 XENLETA and CONTEPO for additional indications and of our other product candidates;
- seek to 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 XENLETA and any other 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;
- incur additional debt;
- 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 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 CONTEPO, and successfully commercialize XENLETA and CONTEPO. In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. We cannot predict the outcome of any interactions with the FDA or when CONTEPO will receive marketing approval, if at all. This will require us to be successful in a range of challenging activities, including:

- obtaining marketing approval for CONTEPO;
- expanding medical affairs, sales, marketing and distribution capabilities to effectively market and sell XENLETA and CONTEPO, if approved, in the United States;
- establishing and maintaining collaboration, distribution or other marketing arrangements with third parties to commercialize XENLETA in markets outside the United States;
- protecting our rights to our intellectual property portfolio related to XENLETA and CONTEPO;
- establishing and maintaining arrangements for the manufacture of and obtaining commercial quantities of XENLETA and CONTEPO; and
- negotiating and securing adequate reimbursement from third-party payors for XENLETA and CONTEPO , if approved.

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 commercialization efforts.

We expect to continue to incur substantial costs in connection with our ongoing activities, particularly as we commercially launch XENLETA and seek marketing approval for 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.

Furthermore, we expect to continue to incur additional costs to service our current debt and any potential future draws on the Loan Agreement (as defined below) and costs associated with operating as a public company and as a company with a commercial rather than a research and development focus. 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 our commercialization efforts.

We expect that our cash, cash equivalents and short-term investments as of September 30, 2019 and proceeds from the sale of ordinary shares under the Jefferies ATM Agreement (as defined below) from September 30, 2019 until the date of this filing of $0.7 million, and anticipated revenues, will be sufficient to enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the third quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate assumes, among other things, that we do not obtain any additional funding through grants and clinical trial support, collaboration agreements, equity or debt financings, including additional advances under the Loan Agreement. We may be eligible to borrow up to an additional $40.0 million under the Loan Agreement if we achieve specified regulatory and product revenue milestones and other financing conditions.

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 commercialization of XENLETA and the potential commercial launch of 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 XENLETA and CONTEPO;
- the costs, timing and outcome of regulatory review of CONTEPO;
- the costs of commercialization activities for XENLETA and CONTEPO if we receive marketing approval for CONTEPO, 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 CONTEPO;
- revenue received from commercial sales of XENLETA and, subject to receipt of marketing approval, CONTEPO;
- the costs of developing XENLETA 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;
- interest expense on our debt and the eventual repayment of our debt obligations;
- the costs of operating as a company with a commercial rather than a research and development focus; and
- the costs of operating as a public company in the United States;

Our commercial revenues will be derived from sales of XENLETA, and from CONTEPO, if approved, or any other products that we successfully develop, in-license or acquire. XENLETA is our only product that is commercially available. XENLETA or, if approved, CONTEPO or any other product candidate that we develop, in-license or acquire may not achieve commercial success. If we fail to generate sufficient revenues from the sale of XENLETA or the commercialization of CONTEPO or any other product candidate that we successfully develop, in-license or acquire, 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, products 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 products or 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, our security holders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our security holders. Additional 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 June 25, 2019, we entered into an Open Market Sale Agreement℠, or the Jefferies ATM Agreement, with Jefferies LLC, or Jefferies, 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 million from time to time through Jefferies under an "at-the-market" offering program. As of the date of this filing, we have issued and sold an aggregate of 4,457,562 ordinary shares under the Jefferies ATM Agreement, for gross proceeds of $10.3 million, and net proceeds of $9.7 million, after deducting commissions and offering costs. We previously entered into a Controlled Equity Offering SM Sales Agreement, or the Cantor ATM Agreement, with Cantor Fitzgerald & Co. that we terminated effective as of June 24, 2019. The approximately $12.2 million of ordinary shares that had been available for sale pursuant to the Cantor ATM Agreement remained unsold at the time of its termination. 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 and following the one year anniversary of the closing of the Acquisition on July 25, 2019, we issued an additional 815,186 ordinary shares to the former Zavante stockholders that had been subject to reduction in respect of certain indemnification and other obligations pursuant to the Merger Agreement. Such shares are 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 will cause dilution to our security 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 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, undertaking preclinical studies and clinical trials of our product candidates, preparing and filing NDAs for our product candidates, and the initial commercial launch of XENLETA. We have not yet demonstrated our ability to 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, 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.

Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

On December 20, 2018, we entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., as administrative agent, collateral agent and lender, pursuant to which an aggregate principal amount of up to $75.0 million is available to us. As of September 30, 2019, we have drawn down on the initial term loan advance under the Loan Agreement of $25.0 million and an additional $10.0 million advance that we became eligible to borrow following the approval by the FDA of the NDA for XENLETA.

All obligations under the Loan Agreement are secured by substantially all of our personal property, intellectual property and other assets owned or later acquired. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- the need to repay our indebtedness by making payment of interest only initially and then interest and principal, which will reduce the amount of funds available to finance our operations, our research and development efforts and our general corporate activities; and

- our failure to comply with the restrictive covenants in the Loan Agreement or the occurrence of an event that has a material adverse effect on our business, operations, properties, assets, condition, our ability to pay any amounts due, the collateral securing our obligations under the Loan Agreement or the ability of Hercules to enforce any of its rights under the Loan Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and the lender could seek to enforce its security interest in the assets securing such indebtedness.

To the extent additional debt is added to our current debt levels, the risks described above could increase.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

Failure to satisfy our current and future debt obligations under the Loan Agreement could result in an event of default and, as a result, the lender under the Loan Agreement could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Loan Agreement as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, the lender could seek to enforce their security interests in the assets securing such indebtedness.

We are subject to certain restrictive covenants which, if breached, could have a material adverse effect on our business and prospects.

The Loan Agreement imposes operating and other restrictions on us. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things:

- declare dividends or redeem or repurchase equity interests;

- incur additional indebtedness and liens;

- make loans and investments;

- engage in mergers, acquisitions and asset sales;
- undertake certain transactions with affiliates
- undergo a change in control;
- add or change business locations; and
- settle in cash potential milestone payment obligations that may become payable by us in the future to former security holders of Zavante.

We are also required to satisfy certain financial covenants, including an obligation to maintain specified minimum amounts of cash and cash equivalents in accounts pledged to Hercules. The Loan Agreement contains a performance covenant that stipulates if actual net product sales do not exceed a specified percentage of the forecasted net product sales over certain specified time periods, we will become subject to a financial covenant requiring us to maintain cash balances equal to the greater of the amount outstanding under the term loan and a specified minimum.

These restrictive covenants may prevent us from undertaking an action that we feel is in the best interests of our business. In addition, if we were to breach any of these restrictive covenants, Hercules could accelerate our indebtedness under the Loan Agreement or enforce its security interest against our assets, either of which would materially adversely affect our ability to continue to operate our business.

We and our Chief Executive Officer, Chief Medical Officer and Chief Financial Officer have been named as defendants in a lawsuit that could result in substantial costs and divert management's attention.

On May 8, 2019, a putative class action lawsuit was filed against us and our Chief Executive Officer. The complaint generally alleged that we and our Chief Executive Officer violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements and omitting to disclose material facts concerning our submission of an NDA to the FDA for marketing approval of CONTEPO for the treatment of cUTI in the United States and the likelihood of such approval. The complaint sought unspecified damages, attorneys' fees, and other costs. On May 22, 2019, a second putative class action lawsuit was filed against us and our Chief Executive Officer. The allegations made in that complaint were similar to those made in the May 8 complaint, and the complaint sought similar relief. On May 24, 2019, the two actions were consolidated by the court. The court appointed a lead plaintiff and approved plaintiff's selection of lead counsel on July 22, 2019. On September 23, 2019, the plaintiff filed an amended complaint, adding our Chief Financial Officer and Chief Medical Officer as defendants. The amended compliant includes allegations similar to those made in the original complaints and seeks similar relief. The Company's pre-motion letter to dismiss the amended compliant was due to plaintiff on October 21, 2019, and plaintiff responded to the Company via letter on November 4, 2019. The Company intends to file a pre-motion letter to dismiss with the court by the November 18, 2019 deadline, setting forth why a motion to dismiss is warranted.

We and our Chief Executive Officer, Chief Financial Officer and Chief Medical Officer deny any and all allegations of wrongdoing and intend to vigorously defend against this lawsuit. We are unable, however, to predict the outcome of this matter at this time. Moreover, any conclusion of this matter in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business. In addition, the litigation could adversely impact our reputation and divert management and our board of directors' attention and resources from other priorities, including the execution of our business plan and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business. Additional lawsuits may be filed.

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 carried out extensive research and development activities, we have benefited from the Austrian research and development support regime, under which we were 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 comprised research and development activities conducted in Austria, however, the research premium was also available for certain related third-party expenses with additional limitations. We received research premiums of $4.7 million for the year ended December 31, 2017 and $5.9 million for the year ended December 31, 2016. We have not received any research premium for our qualified 2018 expenditures as of September 30, 2019. As we increase our personnel and expand our business outside of Austria, we may not be able to continue to claim research premiums to the same extent as we have in previous years or at all, 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 XENLETA, which the FDA has approved for oral and intravenous use for the treatment of CABP, and CONTEPO, which we are developing for cUTI, including AP. If we are unable to obtain marketing approval for CONTEPO, or if we fail in our commercialization efforts for XENLETA 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 XENLETA and, more recently, in CONTEPO. There remains a significant risk that we will fail to successfully develop CONTEPO for cUTI or any other indication and that we may fail to successfully commercialize XENLETA for CABP.

In September 2017, we announced positive topline results for LEAP 1. In May 2018, we announced positive topline results from LEAP 2. On August 19, 2019, the FDA approved the oral and intravenous formulations of XENLETA. We also submitted a marketing authorization application, or MAA, for XENLETA for the treatment of CAP in adults in Europe in May 2019. In mid-2018, we initiated a Phase 1, non-comparative, open-label study of the pharmacokinetics and safety of a single dose of IV XENLETA in pediatric subjects from birth to 18 years of age.

In June 2016, Zavante initiated the ZEUS Study. In April 2017, Zavante announced positive topline results of the ZEUS Study. We submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States, utilizing the FDA's 505(b)(2) pathway, in October 2018. In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. In July 2019, we had a "Type A" meeting with the FDA to discuss its findings, but we cannot predict the outcome of any interactions with the FDA that we may have or when CONTEPO will receive marketing approval, if at all.

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.

We expect to incur significant additional sales, marketing, distribution and manufacturing expenses for the commercialization of XENLETA and, if approved, CONTEPO.

Our ability to generate meaningful product revenues will depend heavily on the successful commercialization of XENLETA and our obtaining marketing approval for CONTEPO. The success of XENLETA and, if approved, 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 CONTEPO for the treatment of cUTI, including AP;
- launching commercial sales of XENLETA and, if and when approved, CONTEPO in collaboration with third parties;
- acceptance of XENLETA and, if and when approved, CONTEPO by patients, the medical community and third-party payors;
- achieving approval of favorable prescribing information;
- effectively competing with other therapies;
- maintaining a continued acceptable safety profile of XENLETA and CONTEPO following approval;
- securing contracts to allow XENLETA and, if approved, CONTEPO to be paid for by private and public health insurance plans;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our rights in our intellectual property portfolio.

Successful development of XENLETA and CONTEPO for the treatment of additional indications, if any, or for use in other patient populations and our ability to broaden the labels for XENLETA and, if approved, 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 XENLETA for CABP or for any other indication or CONTEPO for cUTI, including AP or for any other indication, which would materially harm our business.

If clinical trials of XENLETA, CONTEPO or any of our other product candidates fail to demonstrate safety and efficacy to the satisfaction of the 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 XENLETA, 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.

If we are required to conduct additional clinical trials or other testing or studies of XENLETA, 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;
- 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;
- have the product removed from the market after obtaining marketing approval;
- be unable to obtain reimbursement for use of the product; or
- need to raise capital before we otherwise would or on terms less favorable to us.

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 XENLETA, 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 XENLETA and CONTEPO or other product candidates that could delay or prevent our ability to receive marketing approval or commercialize XENLETA, 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 XENLETA, 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 XENLETA 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 in XENLETA or during the development of CONTEPO or any other product candidate that we develop or following their approval and commercialization, we may need to modify, abandon or limit our development or marketing of that product or product candidate.

It is impossible to predict when or if the FDA, EMA or other regulators will view any of our product candidates as effective and safe in humans or if we will receive marking approval for any of product candidates and it is impossible to ensure that safety or efficacy issues will not arise following the marketing approval. If our products or product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to modify or abandon their marketing or development or limit marketing or 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. Similarly, if we are not able to comply with post-approval regulatory requirements, including safety requirements, with respect to XENLETA or any other approved product that we may develop, we could have the marketing approvals for such products withdrawn by regulatory authorities. 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 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 XENLETA, CONTEPO or any other product candidates that we are developing, the commercial prospects of XENLETA, CONTEPO or such other product candidates will be harmed and our ability to generate product revenues from XENLETA, CONTEPO or any of these other product candidates will be delayed or eliminated. In addition, a higher rate of adverse events in XENLETA or CONTEPO as compared to the standard of care, even if slight, could negatively impact commercial adoption of XENLETA or CONTEPO by physicians. Any of these occurrences could materially harm our business, financial condition, results of operations and prospects.

XENLETA and any other product candidate that receives marketing approval 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 such products and product candidates, if approved, may be smaller than we estimate.

XENLETA and any other product candidate that receives marketing approval 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 CABP, including generic options, are well established in the medical community, and doctors may continue to rely on these treatments without XENLETA, CONTEPO or any of our other product candidates. In addition, our efforts to effectively communicate the differentiating characteristics and key attributes of XENLETA, CONTEPO or any of our other product candidates to clinicians and hospital pharmacies with the goal of establishing favorable formulary status for XENLETA, CONTEPO or any of our other product candidates may fail or may be less successful than we expect. If XENLETA, 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 products and 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 XENLETA, 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 sales, marketing, patient access and distribution capabilities;
- the availability of third-party coverage and adequate reimbursement; and
- the timing of any marketing approval in relation to other approvals of competitive products.

Bacteria might develop resistance to XENLETA, CONTEPO or any future product candidates more rapidly or to a greater degree than we anticipate. If bacteria develop resistance or if XENLETA, CONTEPO or any future product candidates 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 XENLETA, 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 XENLETA, 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 XENLETA, CONTEPO or any other product candidate if and when they are approved.

We have a limited sales, marketing, patient access and distribution infrastructure, and as a company we have limited experience in the sale, marketing or distribution of pharmaceutical products and XENLETA is the first product that we are attempting to commercialize. To achieve commercial success for XENLETA and any other approved product, we must either establish an adequate sales, marketing, commercial operations, patient access and distribution organization or outsource these functions to third parties. We are currently commercializing XENLETA in the United States with our own targeted sales and marketing organization. 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 XENLETA in markets outside the United States. We plan to commercialize CONTEPO, if approved, on our own in the United States with the same commercial organization and targeted sales force, but we do not have the right to commercialize CONTEPO in any markets outside the United States.

There are risks involved with establishing our own sales, marketing, commercial operations, patient access and distribution capabilities and entering into arrangements with third parties to perform these services. If we do not establish adequate sales, marketing, commercial operations, 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, commercial operations and marketing personnel;
- our inability to recruit, train and retain adequate numbers of effective headquarter and field personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe XENLETA or 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, commercial operations, patient access and distribution organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial operations, 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 XENLETA, 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, medical association guidelines and third-party payors for the treatment of CABP. We also are aware of various drugs under development or recently approved by the FDA for the treatment of CABP, including omadacycline (approved by the FDA on behalf of Paratek Pharmaceuticals Inc.), delafloxacin (approved by the FDA for CABP in October 2019 on behalf of 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 recently approved for the treatment of cUTI, including AP, such as imipenem-relebactam (Recarbrio approved in July 2019 on behalf of Merck & Co., Inc.) or other products in development such as cefiderocol (positive FDA advisory committee vote in October 2019 and under development by Shionogi Inc.), ETX0282-cefpodoxime proxetil (under Phase 1 clinical development by Entasis Therapeutics), and LYS228 (under development by Novartis), as well as generically available agents including piperacillin-tazobactam, 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 XENLETA and if approved for cUTI, including AP, CONTEPO will be priced at a significant premium over competitive generic products. This pricing difference may make it difficult for us to replace existing therapies with XENLETA and CONTEPO. The key competitive factors affecting the success of our products and 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 successfully commercialize XENLETA, 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, including XENLETA, 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 XENLETA, 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 XENLETA, 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 XENLETA 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 XENLETA and CONTEPO. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize XENLETA, 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 XENLETA and any other products that we may develop or in-license.

We face an inherent risk of product liability exposure related to the testing of XENLETA, CONTEPO and any other product candidate that we develop in human clinical trials and an even greater risk related to the commercial sale of XENLETA and any other products that we may develop or in-license. If we cannot successfully defend ourselves against claims that XENLETA or our other product candidates 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 XENLETA or any other product candidates 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 may need to increase our product liability insurance coverage due to the FDA approval of XENLETA. 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.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate Program and a number of other federal and state government pricing programs in the United States in order to obtain coverage for XENLETA by certain government healthcare programs. These programs generally require us to pay rebates or provide discounts to certain private purchasers or government payers in connection with our products when dispensed to beneficiaries of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing and rebate calculations that we report on a monthly and quarterly basis to the government agencies that administer the programs. The terms, scope and complexity of these government pricing programs change frequently. We may also have reimbursement obligations or be subject to penalties if we fail to provide timely and accurate information to the government, pay the correct rebates or offer the correct discounted pricing. Changes to the price reporting or rebate requirements of these programs would affect our obligations to pay rebates or offer discounts. Responding to current and future changes may increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

Risks Related to Our Dependence on Third Parties

Use of third parties to manufacture our product candidates or products 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 XENLETA 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 and facilities to manufacture any of our product candidates or products on a clinical or commercial scale. We currently rely on third parties for supply of XENLETA 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 XENLETA and CONTEPO. We obtained the pleuromutilin starting material for the clinical trial supply of XENLETA 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 and entered into a commercial supply agreement with an alternative supplier that we believe will be able to provide pleuromutilin starting material for the commercial supply of XENLETA.

Another third-party manufacturer synthesizes XENLETA starting from pleuromutilin and a readily accessible chiral building block and provides our supply of the active pharmaceutical ingredient. We may engage a secondary supplier to synthesize XENLETA. However, our current operating plans do not include a secondary supplier unless we obtain additional funding. We engage separate manufacturers to provide tablets, sterile vials, and sterile diluent that we are using in our clinical trials of XENLETA. We have entered into commercial supply agreements with these same manufacturers to support the commercialization of XENLETA in the United States and, if approved outside of the United States, future demand outside of the United States. We also entered into a long-term commercial supply agreement with Arran Chemical Company Limited, or Arran, for the supply of the chiral acid starting material required in the synthesis of XENLETA API and a commercial packaging and supply agreement with Sharp Corporation for the secondary packaging of XENLETA for distribution in the United States.

In addition, we have entered into a manufacturing and supply agreement with Ercros, S.A., pursuant to which Ercros, S.A. supplies to us, on an exclusive basis, the API mixture for CONTEPO in support of our NDA filing and, if CONTEPO is approved, will supply the commercial API mixture for CONTEPO in the United States. We have 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 us with certain technical documentation and data as required for our NDA filing for CONTEPO and certain regulatory support in connection with the commercial sale and use of CONTEPO in the United States, if approved. We entered into a commercial packaging agreement with AndersonBrecon, Inc. for the commercial packaging and serialization of CONTEPO in addition to a manufacturing and supply agreement with Fisiopharma S.r.l., or Fisiopharma, for the supply, on a minimum commitment basis, of a percentage of our 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. Such failure could also result in the delay of our obtaining regulatory approval of our product candidates.

If we or any of our third-party manufacturers or suppliers are the subject of any open or unresolved inspection reports or FDA Form 483s identifying noncompliance with applicable regulations, we could be delayed in obtaining or fail to obtain regulatory approval of our product candidates, including CONTEPO.

Our product candidates and any products that we have developed or 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 XENLETA. In early 2015, Novartis completed the sale of its animal health division, including its veterinary products, to a third party. As a result, we were required to identify an alternative supplier for pleuromutilin starting material for XENLETA. 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 and products may adversely affect our 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 XENLETA 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 XENLETA, 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.

We plan to commercialize XENLETA and, if approved, CONTEPO in the United States with our own targeted 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 XENLETA. For example, we have entered into a license agreement with Sinovant pursuant to which we granted Sinovant certain rights to manufacture and commercialize XENLETA in the People's Republic of China, Hong Kong, Macau and Taiwan and with Sunovion pursuant to which we granted Sunovion certain rights to commercialize XENLETA in Canada. We also may seek third-party collaborators for development and commercialization of other product candidates or for XENLETA 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 need to conduct clinical trials, and these clinical trials may not be successful;
- 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 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 commercialization of XENLETA, potential commercialization of CONTEPO, if approved, 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 XENLETA through a variety of types of additional collaboration arrangements outside the United States. These collaborations may help fund the potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for additional collaborations outside greater China and Canada 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. Mergers and acquisitions in the pharmaceutical and biotechnology industries may also reduce the number of potential collaborators with whom we could partner. 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 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.

We enter into various contracts in the normal course of our business in which weagree to indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically agree to indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sub licensees' exercise of rights under the agreement. With respect to our commercial agreements, we have agreed to indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we typically agree to indemnify them from claims arising from the good faith performance of their services.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator or other third party to indemnify us and the collaborator or other third party is denied insurance coverage or otherwise does not have assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology, products and product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize technology, products and product candidates similar or identical to ours, and our ability to successfully commercialize our technology, products and product candidates 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, products and product candidates. 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, products 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, products or product candidates 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, products and product candidates, or limit the duration of the patent protection of our technology, products and product candidates. 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 with commercial products. 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 XENLETA or CONTEPO. Thus, we do not know with certainty whether XENLETA, 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 pleuromutilin 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.

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, products and product candidates, 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 has 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.

XENLETA, CONTEPO, and any other product candidates that we develop, 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 XENLETA, by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. On August 19, 2019, we received approval from the FDA to market the oral and intravenous formulations of XENLETA to treat CABP in the United States. We have not received approval to market XENLETA in any jurisdiction other than the United States or for any other indication, and we have not received approval to market 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. In April 2019, the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. Specifically, the Complete Response Letter requested us to address issues related to facility inspections and manufacturing deficiencies at our API contract manufacturer prior to the FDA approving the NDA. We held a "Type A" meeting with the FDA in July 2019 to discuss its findings, but we cannot predict when CONTEPO will receive marketing approval, if at all.

Even after obtaining marketing approval for XENLETA, we have limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates and we have and expect to continue 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 XENLETA, 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. 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 United Kingdom has a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the European Union. If no formal withdrawal agreement is reached between the United Kingdom and the European Union, then it is expected the United Kingdom's membership of the European Union will automatically terminate on the deadline, which was initially March 29, 2019. On October 28, 2019, that deadline was extended from October 31, 2019 to January 31, 2020 to allow the parties to continue to negotiate a withdrawal agreement. The United Kingdom could leave the European Union earlier if the Parliament approves the withdraw but that has proven to be extremely difficult to date. Discussions between the United Kingdom and the European Union will continue to focus on withdrawal issues and transition agreements. However, limited progress to date in these negotiations and ongoing uncertainty within the UK Government and Parliament sustains the possibility of the United Kingdom leaving the European Union without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

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 XENLETA 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, such as in the case of XENLETA, 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, with respect to XENLETA and any other product candidates for which we receive marketing approval, 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, including XENLETA, 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.

XENLETA and any other 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. Accordingly, we may not promote XENLETA in the United States for use in any indications other than the treatment of CABP, and all promotional claims must be consistent with the FDA-approved labeling of XENLETA.

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;
- exclusion from participation in federal healthcare reimbursement programs or debarment or the imposition of Corporate Integrity Agreements; 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.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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.

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 the IV formulation of CONTEPO as a qualified infectious disease product, or QIDP, and granted a fast track designation for this formulation of CONTEPO. However, neither the QIDP nor the fast track designation ensures that CONTEPO will receive marketing approval or that approval will be granted within any particular timeframe. We may, however, 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. CONTEPO was granted priority review by the FDA, and 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 CONTEPO as a Qualified Infectious Disease Product does not assure FDA approval of this product candidate.

A QIDP is an antibacterial or antifungal drug intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or certain "qualifying pathogens." Upon the approval of an NDA for a drug product designated by the FDA as a QIDP, the product is granted an additional period of five years of regulatory exclusivity. Even though we have received a QIDP designation for CONTEPO, there is no assurance that CONTEPO 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 submitted an NDA for marketing approval of CONTEPO for the treatment of cUTI in adults in the United States in October 2018 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. We have not 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 also may 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, the 21st Century Cures Act, or the 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. 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 of our products, including XENLETA, and product candidates, including 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 XENLETA and any other products for which we obtain marketing approval. Restrictions under applicable federal, state, and foreign 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, and foreign anti-corruption laws, 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 have developed and implemented a corporate compliance

program designed to ensure that we will market and sell any approved products 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 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 products and 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 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 products, including XENLETA, or product candidates, including 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 70% point-of-sale discounts 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.

Congress has repeatedly tried to repeal, replace and amend the ACA in recent years. 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” for the ACA. The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became 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. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs 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. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys Generals filed suit to stop the administration from terminating the subsidies, but their request for

a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

In addition, the Centers for Medicare & Medicaid Services, or CMS, has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization, or PA, and step therapy, or ST, for six protected classes of drugs, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" in the regulations. It is unclear whether these proposed changes will be accepted, and if so, what effect such changes will have on our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act of 2017, or the Tax Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. The Trump Administration has recently represented to the Court of Appeals considering this judgment that it does not oppose the lower court's ruling. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

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. More recently, on January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations.

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, the Irish Criminal Justice (Corruption Offenses) Act, 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 and other anti-corruption laws 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 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 computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect the service reliability and threaten the confidentially, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

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 Our 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 the Acquisition, of Zavante pursuant to the Merger Agreement. 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. The integration process has been, and we expect will continue to be complex, costly and time-consuming. As a result, we

have been, and in the future 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 XENLETA 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 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;
- 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 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 was comprised of 8,152,092 of our ordinary shares, including the 815,186 ordinary shares that were initially held back but which were issued in July 2019 upon release of the Holdback Shares pursuant 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 $25.0 million would become payable upon the first approval of a new drug application from the FDA, for CONTEPO 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, with the first commercial milestone becoming payable when CONTEPO exceeds $125.0 million in net sales in a calendar year. At our Extraordinary General Meeting of Shareholders held in October 2018, our shareholders approved the issuance of ordinary shares in settlement of potential milestone payment obligations that may

become payable in the future to former Zavante stockholders, including the Approval Milestone Payment which will be settled in our ordinary shares. We also now have the right to settle the Net Sales Milestone Payments in ordinary shares, except as otherwise provided in the Merger Agreement. 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.

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 $26.0 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 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 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, 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. Zavante has also 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 and, if CONTEPO is approved, will supply the commercial API Mixture for CONTEPO in the United States.

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 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 commercial 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. 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 companies 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 have expanded and expect to continue to expand, the number of our employees and the scope of our operations in certain areas, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We have significantly increased the number of our employees and the scope of our operations, particularly in the areas of technical operations, supply chain, medical affairs and sales and marketing and we may continue to add staff to these areas. 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 in connection with the Acquisition, has imposed 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, and with such anticipated growth, we may not be able to 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.

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 successfully commercialize the oral and intravenous formulations of XENLETA for the treatment of CABP;
- our ability to successfully implement our proposed business strategy;
- the success of competitive products or technologies;

- results of clinical trials of our product candidates or those of our competitors;
- regulatory delays and greater government regulation of potential products due to adverse events;
- regulatory or legal developments in the United States, the European Union and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- one of our manufacturers or suppliers could have an event which causes an unforeseen disruption of the manufacture or supply of our product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- perception and market performance 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;
- activism by any single large shareholder or combination of shareholders;
- 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 successfully commercialize XENLETA, CONTEPO if approved, 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. For example, we and our Chief Executive Officer, Chief Medical Officer and Chief Financial Officer have been named as defendants in a purported class action lawsuit following our announcement in April 2019 that the FDA issued a Complete Response Letter in connection with our NDA for CONTEPO for injection for the treatment of cUTIs, including AP, stating that it was unable to approve the application in its current form. See *“—Risks Related to Our Financial Position and Need for Additional Capital— We and our Chief Executive Officer, Chief Medical Officer and Chief Financial Officer have been named as defendants in a lawsuit that could result in substantial costs and divert management’s attention.* ”.

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 September 30, 2019 in the aggregate, beneficially owned approximately 20.6% of our share capital. 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 77,994,207 ordinary shares outstanding as of September 30, 2019. 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 September 30, 2019, an aggregate of 3,255,734 options to purchase our ordinary shares had vested and become exercisable although these options are not in the money at this time.

In addition, on June 25, 2019 we entered into the Jefferies ATM Agreement with Jefferies, as agent, pursuant to which we may offer and sell ordinary shares for aggregate gross sale proceeds of up to $50.0 million from time to time through Jefferies under an "at-the-market" offering program. As of the date of this filing, we have issued and sold an aggregate of 4,457,562 ordinary shares under the Jefferies ATM Agreement, for gross proceeds of $10.3 million, and net proceeds of $9.7 million, after deducting commissions and offering costs. We previously entered into the Cantor ATM Agreement with Cantor Fitzgerald & Co. that we terminated effective as of June 24, 2019. As of the effective date of the termination of the Cantor ATM Agreement, we had issued and sold an aggregate of 10,316,190 of our ordinary shares pursuant to the Cantor ATM Agreement for aggregate gross proceeds of $37.8 million and net proceeds to us of $36.3 million, after deducting commissions and offering expenses payable by us.

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 was comprised of 8,152,092 of our ordinary shares, including 815,186 ordinary shares that were initially held back but which were issued in July 2019 upon release of the Holdback Shares pursuant to the terms of the Merger Agreement. Such shares are 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 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 $1.07 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.

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 growing company, 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. As a result, it may not be possible to effect service of process on such persons or us in the United States or to enforce judgments obtained in courts in the United States against such persons 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." In addition, the terms of the Loan Agreement with Hercules currently, and the terms of any future debt agreements may in the future, preclude us from paying dividends. Subject to the foregoing, 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. As a result, capital appreciation, if any, of our ordinary shares will be the sole source of gain for holders of our ordinary shares for the foreseeable future.

We are exposed to risks related to currency exchange rates

A portion of our expenses are denominated in currencies other than the U.S. dollar. Because our consolidated 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; and
- the exchange rates on non-U.S. dollar transactions and cash deposits can distort our financial results.

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. Our employees are also entitled, subject to certain conditions, to purchase our ordinary shares at a discount pursuant to our Employee Share Purchase Plan.

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 Jefferies 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, 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 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.

Certain separate concert parties will also be presumed to be acting in concert. Our board of directors and their relevant family members, related trusts and "controlled companies" are presumed to be acting in concert with any corporate shareholder who holds 20% or more of the company. The application of these presumptions may result in restrictions upon the ability of any of the concert parties and members of our board of directors to acquire more of our securities, including under the terms of any executive incentive arrangements. We may consult with the Irish Takeover Panel with respect to the application of this presumption and the restrictions on the ability to acquire further securities if necessary, although we are unable to provide any assurance as to whether the Irish Takeover Panel would overrule this presumption.

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 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 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.

The IRS may not agree with the conclusion that we should be treated as a foreign corporation for U.S. federal tax purposes.

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are an Irish incorporated entity, we would be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes. New statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have prospective or retroactive application to us and our shareholders.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity by certain significant shareholders over a rolling three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future and/or subsequent shifts in our stock ownership, some of which would be outside our control. If our ability to use our net

operating losses and other tax attributes is limited by ownership changes, we may be unable to utilize a material portion of our net operating losses and other tax attributes.

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.

United States shareholders must also 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 €335,000 in respect of taxable gifts or inheritances received from their parents.

Our business and operations could be negatively affected if we become subject to shareholder activism, which could cause us to incur significant expense, hinder execution of our business strategy and impact our stock price.

Shareholder activism, which takes many forms and arises in a variety of situations, has been increasingly prevalent. If we become the subject of certain forms of shareholder activism, such as proxy contests, the attention of our management and our board of directors may be diverted from execution of our business strategy. Such shareholder activism could give rise to perceived uncertainties as to our future strategy, adversely affect our relationships with business partners and make it more difficult to attract and retain qualified personnel. Also, we may incur substantial costs, including significant legal fees and other expenses, related to activist shareholder matters. Our stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any shareholder activism.

We may be classified as a passive foreign investment company for our tax year ending December 31, 2019, which may result in adverse U.S. federal income tax consequence to U.S. holders.

We may be classified as a passive foreign investment company for one or more of our taxable years, which may result in adverse U.S. federal income tax consequence to U.S. holders.

A corporation organized outside the United States generally will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes (1) in any taxable year in which (A) at least 75% of its gross income is passive income or (B) 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 allow the holder to discontinue that classification as to that holder, generally at a substantial tax cost to that holder. Passive income for this purpose generally includes dividends, interest, royalties, rents and gains from commodities and securities transactions.

Based on our gross income and average value of our gross assets for the year, and given 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 any taxable year from our initial public offering through the year ended December 31, 2018. Our status in any taxable year (determined without regard to our status in any prior taxable year) will depend on our assets and activities in that year, and because this is a factual determination made annually after the end of the year, there can be no assurance that we will not be considered a PFIC for the current taxable year or any other taxable year. In particular, in many cases the gross value of our assets may be inferred from the market price of our ordinary shares, which may fluctuate considerably given that market prices of biotechnology companies can be especially volatile. In other cases, factors external to our specific circumstances may make the presumptive relationship between the gross value of our assets and our market capitalization unreliable, in which case the gross value of our individual assets, based upon valuation methods suitable for use in U.S. federal tax matters (the choice of which may vary from taxable year to taxable year), will govern the determination of our status.

If we were to be treated as a PFIC for the taxable year ending December 31, 2019, or any other taxable year during which a U.S. holder held our ordinary shares, 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 qualified electing fund, or 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 if it is determined that we are a PFIC for a given taxable year. 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

Other than as reported in a Current Report on Form 8-K, 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 September 30, 2019 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	
10.1**	First Amendment to Loan and Security Agreement, dated as of September 26, 2019, by and among Nabriva Therapeutics Public Limited Company, Nabriva Therapeutics Ireland Designated Activity Company, Nabriva Therapeutics GmbH, Nabriva Therapeutics US, Inc., Zavante Therapeutics, Inc., and Hercules Capital, Inc.					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
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 September 30, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2018 and September 30, 2019, (ii) Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and 2019, (iii) Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2019, (iv) Consolidated Statement of Changes in Stockholders' Equity for the three and nine months ended September 30, 2018 and 2019 and (v) Notes to Unaudited Consolidated Financial Statements.					X

** *Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.*

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: November 12, 2019

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

Date: November 12, 2019

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

Exhibit 10.1

Execution Version

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of September 26, 2019 (the "**Amendment Effective Date**"), is made among Nabriva Therapeutics Public Limited Company, a public limited company incorporated in Ireland under registration number 599588 and having its registered office at 25-28 North Wall Quay, Dublin 1, Ireland ("**Parent**"), Nabriva Therapeutics Ireland Designated Activity Company, a designated activity company incorporated in Ireland under registration number 612454 and having its registered office at Suite 510, Regus Dublin Airport, Skybridge House, Dublin Airport, Swords, County Dublin, Ireland ("**Nabriva Ireland**"; together with Parent, individually and collectively, jointly and severally, the "**Borrower**"), Nabriva Therapeutics GmbH, a limited liability company (Gesellschaft mit beschränkter Haftung) incorporated under the laws of the Republic of Austria, having its seat in Vienna and its registered address at Leberstraße 20, 1110 Vienna, and registered with the companies' register (Firmenbuch) of the commercial court of Vienna (Handelsgericht Wien) under registration number 269261 y ("**Nabriva Austria**"), Nabriva Therapeutics US, Inc., a Delaware corporation ("**Nabriva US**"), Zavante Therapeutics, Inc., a Delaware corporation ("**Zavante**"; together with Nabriva Austria and Nabriva US, collectively referred to as the "Guarantors" and each, a "**Guarantor**"), Hercules Capital, Inc. , a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, together with its successors and assigns in such capacity, "**Agent**").

The Loan Parties, the Lenders and Agent are parties to a Loan and Security Agreement dated as of December 20, 2018 (as amended, restated or modified from time to time, the "**Loan and Security Agreement**"). Loan Parties have requested that the Lenders agree to certain consents and amendments to the Loan and Security Agreement. The Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in the last paragraph of Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement.

(a) The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:

(i) New Definitions. The following definitions are added to Section 1.1 in their proper alphabetical order:

"**First Amendment**" means that certain First Amendment to Loan and Security Agreement, dated

as of the First Amendment Effective Date, by and among Borrower, the Guarantors, Agent and the lenders party thereto.

"**First Amendment Effective Date**" means September 26, 2019.

(ii) Amended and Restated Definitions. The following definitions are hereby amended and restated as follows:

"**Performance Milestone 2**" means satisfaction of each of the following events: (a) no Event of Default shall have occurred and be continuing (b) Borrower or any other Loan Party shall have received the approval from the FDA of the NDA for CONTEPO for the treatment of complicated urinary tract infections, with a label generally consistent with the target label included in Borrower's NDA filing and (c) receipt by Borrower on or after September 12, 2019 and on or before [**], of at least $[**] of Net Financing Proceeds (provided however, underwriting fees, sales commissions and transaction expenses for equity financings shall not be net out of Net Financing Proceeds for purposes of this requirement).

"**Performance Milestone 5**" means satisfaction of each of the following events: (a) no Event of Default shall have occurred and be continuing, (b) achievement of Performance Milestone 1, (c) achievement of Performance Milestone 2 and (d) Borrower shall have recognized no less than $[**] in trailing six month Net Product Revenue from commercial sales of CONTEPO and lefamulin as of the last day of any month as of or prior to December 2021.

"**Unrestricted Cash**" means Cash held by the Loan Parties in account(s) subject to an Account Control Agreement or a Foreign Account Pledge Agreement in favor of Agent.

(iii) Section 2.2(a). Section 2.2(a) is hereby amended and restated as follows:

(a) Advances. Subject to the terms and conditions of this Agreement, Lender will severally (and not jointly) make in an amount not to exceed its respective Term Commitment, and Borrower agrees to draw, a Term Loan Advance of $25,000,000 on the Closing Date (the "Tranche 1 Advance"). Subject to the terms and conditions of this Agreement, beginning on the date Borrower achieves Performance Milestone 1 and continuing through September 30, 2019, Borrower may request and Lender shall make an additional Term Loan Advance in a principal amount of $10,000,000 (the "Tranche 2 Advance"). Subject to the terms and conditions of this Agreement, beginning on the date Borrower achieves Performance Milestone 2 and continuing through June 15, 2020, Borrower may request and Lender shall make an additional Term Loan Advance in an aggregate principal amount of $5,000,000 (the "Tranche 3 Advance"). Subject to the terms and conditions of this Agreement, beginning on the later of January 1, 2020 and the date Borrower achieves Performance Milestone 3 and continuing through December 31, 2020, Borrower may request and Lender shall make an additional Term Loan Advance in a principal amount of $10,000,000 (the "Tranche 4 Advance"). Subject to the terms and conditions of this Agreement, beginning on the later of July 1, 2020 and the date Borrower achieves Performance Milestone 4 and continuing through June 30, 2021, Borrower may request and Lender shall make an additional Term Loan Advance in a principal amount of $15,000,000 (the "Tranche 5 Advance"). Subject to the terms and conditions of this Agreement, beginning on the later of January 1, 2021 and the date Borrower achieves Performance Milestone 5 and continuing through December 15, 2021, Borrower may request and Lender shall make an additional Term Loan Advance in a principal amount of $5,000,000 (the "Tranche 6 Advance"). Subject to the terms and conditions of this Agreement and conditioned on approval by Lender's investment committee in its sole discretion, beginning on the date determined by Lender's investment committee and continuing through December 31, 2021, Borrower may request an additional Term Loan Advance in an aggregate principal amount of $5,000,000 (the "Tranche 7 Advance"). The aggregate outstanding Term Loan Advances may be up to the Maximum Term Loan Amount. For the avoidance of doubt, each Advance will be available on the terms stated herein, without regard to the drawdown of any of the Tranche 2 Advance, Tranche 3 Advance, Tranche 4 Advance, Tranche 5 Advance and Tranche 6 Advance.

(iv) Section 11.2(c). Section 11.2(c) is hereby amended and restated as follows:

"(c) If to Loan Parties:

Nabriva Therapeutics Public Limited Company
Attention: General Counsel
1000 Continental Drive, Suite 600
King of Prussia, PA 19406
Email: [**]
Telephone: [**]

With a copy (which shall not constitute notice) to:
Foley & Lardner LLP
111 Huntington Avenue
Boston, MA 02199-7610
Attn: Jamie N. Class
jclass@foley.com
Tel: (617) 225-3111"

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. The Loan Parties shall have paid (i) all invoiced costs and expenses then due under the Loan Documents, and (ii) all other invoiced fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Agent shall have received this Amendment, executed by Agent, the Lenders and the Loan Parties.

(c) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4 Representations and Warranties. To induce the Lenders to enter into this Amendment, Each Loan Party hereby confirm, as of the date hereof, (a) that the representations and warranties made by it in Section 6 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects, except to the extent such representations and warranties expressly relate to an earlier date; (b) that there has not been and there does not exist a Material Adverse Change; (c) that the information included in the Perfection Certificate delivered to Agent on the Closing Date remains true and correct; (d) Lender has and shall continue to have valid, enforceable and perfected first-priority liens, on and security interests in the Collateral and all other collateral heretofore granted by such Loan Party to Lender, pursuant to the Loan Documents or otherwise granted to or held by Lender; (e) the agreements and obligations of such Loan Party contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of such Loan Party, enforceable against such Loan Party in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (f) the execution, delivery and performance of this Amendment by such Loan Party will not violate any law, rule, regulation, order, contractual obligation or organizational document of such Loan Party and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or

revenues. For the purposes of this Section 4, each reference in Section 6 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 5 Post-Closing. Notwithstanding any provision herein or in the Loan Documents to the contrary, to the extent not actually delivered on or prior to the Amendment Effective Date, Borrower shall deliver to Agent (or its designated agent):

(a) By October 4, 2019, a Foreign Account Pledge Agreement with respect to Deposit Account or investment account number [**] maintained [**] or an affiliate of the foregoing (the "[**]"), in form and substance reasonably satisfactory to Agent; provided that if such Foreign Account Pledge Agreement is not delivered by October 4, 2019, Borrower shall hold no more than $[**] in such account at any time thereafter, unless and until such a Foreign Account Pledge Agreement is delivered to the Agent.

SECTION 6 Miscellaneous.

(a) **Consent**.

(i) Agent hereby consents to the updated projections delivered by Borrower to Agent on August 26, 2019 qualifying as the "Forecast" as defined in the Loan Agreement.

(ii) Each of the Agent and Lenders hereby confirm their respective consent, effective as of May 2, 2019, to the relocation of certain of the Borrower's assets to the [**] prior to the date here, notwithstanding any other provision of the Loan Documents, subject only to the requirement set forth in Section 5 hereof.

(b) **Performance Milestone 1**. Each of the undersigned hereby agrees that Performance Milestone 1 was satisfied as of August 19, 2019.

(c) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Each Loan Party hereby expressly (1) reaffirms, ratifies and confirms its Obligations under the Loan Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3.1 of the Loan and Security Agreement, (3) reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, and with effect from (and including) the Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan Agreement and (5) agrees that the Loan Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of any Loan Party's Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Obligations.

(d) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(e) **Release**. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Loan Party, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

(f) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and the Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(g) **Costs and Expenses**. Borrower agrees to pay to Agent within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced on or prior to the Amendment Effective Date), the out-of-pocket costs and expenses of Agent and the Lenders party hereto, including the reasonable fees and disbursements of counsel to Agent and the Lenders party hereto, in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(h) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(i) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF NEW YORK), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(j) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(k) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(l) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(m) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

Nabriva Therapeutics Public Limited Company

GIVEN under the **COMMON SEAL** of

NABRIVA THERAPEUTICS PUBLIC LIMITED COMPANY

and **DELIVERED** as a **DEED**:

/s/ Gary Sender
Gary Sender
Authorised Signatory

Nabriva Therapeutics Ireland Designated Activity Company

SIGNED AND DELIVERED as a Deed

for and on behalf of

NABRIVA THERAPEUTICS IRELAND DESIGNATED ACTIVITY COMPANY

by its lawfully appointed attorney

GARY SENDER

/s/ Gary Sender
Signature of Attorney

in the presence of:

/s/ illegible
Signature of Witness

Attorney
Occupation of Witness

1000 Continental Drive, King of Prussia, PA
Address of Witness

GUARANTORS:

NABRIVA THERAPEUTICS GMBH

By: /s/ Gary Sender
Name: Gary Sender
Title: Authorized Signatory

NABRIVA THERAPEUTICS US, INC.

By: /s/ Gary Sender
Name: Gary Sender
Title: Treasurer

ZAVANTE THERAPEUTICS, INC.

By: /s/ Gary Sender
Name: Gary Sender
Title: Treasurer

AGENT:

HERCULES CAPITAL, INC.,
as Agent

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Assistant General Counsel

LENDER:

HERCULES CAPITAL, INC.,
as Lender

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Assistant General Counsel

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: November 12, 2019

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: November 12, 2019

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 September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Theodore Schroeder, 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: November 12, 2019

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 September 30, 2019 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: November 12, 2019
