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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2020

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**	**Not applicable**
(Address of principal executive offices)	(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 Select 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, 2020, the registrant had 150,775,676 ordinary shares outstanding.

NABRIVA THERAPEUTICS plc
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FORWARD-LOOKING STATEMENTS

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

- our ability to successfully continue commercial activities for XENLETA (lefamulin) for the treatment of community-acquired bacterial pneumonia, or CABP, including the availability of and ease of access to XENLETA through hospital formularies, managed care plans and major U.S. specialty distributors;
- our ability to successfully commercialize SIVEXTRO and realize value from our agreement with Merck & Co., Inc.;
- our ability to build and maintain a sales force for the commercialization of XENLETA, SIVEXTRO and CONTEPO, if approved;
- the timing of the resubmission of the NDA for CONTEPO and potential marketing approval of CONTEPO and other product candidates, including the completion of any post marketing requirements with respect to XENLETA and any other product candidates we may obtain;
- our expectations regarding how far into the future our cash on hand and anticipated revenues from product sales will fund our ongoing operations and the continued availability and cost of capital to sustain our operations on a longer term basis;
- our expectations regarding our strategy to expand our product pipeline through opportunistically in licensing or acquiring the rights to complementary products, product candidates and technologies for the treatment of a range of infectious diseases or other products, including additional community products;
- our ability to comply with the restrictive covenants under our debt facility with Hercules Capital, Inc., or Hercules, including but not limited to the ability to maintain minimum cash balance requirements;
- our ability to satisfy interest and principal payments under our debt facility with Hercules;
- our sales, marketing and distribution capabilities and strategy;
- the potential extent of revenues from future sales of XENLETA, SIVEXTRO and/or CONTEPO, if approved;
- our expectations about the impact of the COVID-19 pandemic on our business operations, ongoing clinical trials and regulatory matters;
- the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, and 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 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;
- the availability of lefamulin in China and Canada;
- our expectations regarding the ability of our customers to satisfy the demand for XENLETA with their existing inventory;
- 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;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- the potential advantages of XENLETA, SIVEXTRO, CONTEPO, and our other product candidates;
- our estimates regarding the market opportunities for XENLETA, SIVEXTRO, CONTEPO, and our other product candidates;
- the rate and degree of market acceptance and clinical benefit of XENLETA for CABP, SIVEXTRO for acute bacterial skin and skin structure infections, CONTEPO for cUTI and our other product candidates;
- our ability to establish and maintain collaborations including additional licensing agreements for XENLETA outside the United States, Canada and the greater China region;
- 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 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, 2019	As of September 30, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 86,019	$ 41,122
Restricted cash	392	230
Short-term investments	175	16
Accounts receivable, net and other receivables	2,744	3,385
Inventory	682	5,803
Prepaid expenses	1,158	3,754
Total current assets	91,170	54,310
Property, plant and equipment, net	2,474	2,007
Intangible assets, net	91	84
Long-term receivables	378	369
Total assets	**$ 94,113**	**$ 56,770**
Liabilities and equity		
Current liabilities:		
Accounts payable	$ 4,673	$ 2,041
Accrued expense and other current liabilities	11,966	8,934
Total current liabilities	16,639	10,975
Non-current liabilities		
Long-term debt	34,502	7,610
Other non-current liabilities	1,698	1,956
Total non-current liabilities	36,200	9,566
Total liabilities	**52,839**	**20,541**
Commitments and contingencies (Note 12)		
Stockholders' Equity:		
Ordinary shares, nominal value $0.01, 1,000,000,000 ordinary shares authorized at September 30, 2020; 94,545,116 and 150,006,432 issued and outstanding at December 31, 2019 and September 30, 2020, respectively	945	1,500
Preferred shares, par value $0.01, 100,000,000 shares authorized at September 30, 2020; None issued and outstanding	—	—
Additional paid in capital	517,044	563,095
Accumulated other comprehensive income	27	27
Accumulated deficit	(476,742)	(528,393)
Total stockholders' equity	**41,274**	**36,229**
Total liabilities and stockholders' equity	**$ 94,113**	**$ 56,770**

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, 2019	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2020
Revenues:				
Product revenue, net	$ 1,445	(47)	$ 1,445	$ 61
Collaboration revenue	5,051	616	6,051	768
Research premium and grant revenue	424	722	1,652	1,738
Total revenue	6,920	1,291	9,148	2,567
Operating expenses:				
Cost of product sales	(15)	(25)	(15)	(401)
Research and development expenses	(5,601)	(3,486)	(21,213)	(14,930)
Selling, general and administrative expenses	(18,503)	(10,997)	(45,339)	(35,094)
Total operating expenses	(24,119)	(14,508)	(66,567)	(50,425)
Loss from operations	**(17,199)**	**(13,217)**	**(57,419)**	**(47,858)**
Other income (expense):				
Other income (expense), net	(10)	450	116	614
Interest income	94	5	176	85
Interest expense	(709)	(261)	(2,512)	(1,536)
Loss on extinguishment of debt	—	—	—	(2,757)
Loss before income taxes	**(17,824)**	**(13,023)**	**(59,639)**	**(51,452)**
Income tax benefit (expense)	29	72	(80)	(199)
Net loss	**$ (17,795)**	**(12,951)**	**$ (59,719)**	**$ (51,651)**
Loss per share				
Basic and Diluted ($ per share)	$ (0.24)	(0.09)	$ (0.83)	$ (0.44)
Weighted average number of shares:				
Basic and Diluted	75,161,192	144,690,904	72,153,405	117,454,536

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, 2019	**67,019**	**$ 670**	**$ 461,911**	**$ 27**	**$ (393,978)**	**$ 68,630**
Issuance of ordinary shares	4,317	43	10,014	—	—	10,057
Exercise of stock options	—	—	—	—	—	—
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	1,570	16	3,691	—	—	3,707
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	5,088	51	9,547	—	—	9,598
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**

(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, 2020	**94,545**	**$ 945**	**$ 517,044**	**$ 27**	**$ (476,742)**	**$ 41,274**
Issuance of ordinary shares	479	5	181	—	—	186
Equity transaction costs	—	—	(39)	—	—	(39)
Shares issued in connection with the vesting of restricted stock units	85	1	(1)	—	—	—
Stock-based compensation expense	—	—	1,752	—	—	1,752
Net loss	—	—	—	—	(23,259)	(23,259)
March 31, 2020	**95,109**	**951**	**518,937**	**27**	**(500,001)**	**19,914**
Issuance of ordinary shares	47,578	476	40,891	—	—	41,367
Equity transaction costs	—	—	(2,709)	—	—	(2,709)
Shares issued in connection with the employee stock purchase plan	93	1	42	—	—	43
Shares issued in connection with the vesting of restricted stock units	185	2	(2)	—	—	—
Stock-based compensation expense	—	—	1,287	—	—	1,287
Net loss	—	—	—	—	(15,441)	(15,441)
June 30, 2020	**142,965**	**1,430**	**558,446**	**27**	**(515,442)**	**44,461**
Issuance of ordinary shares	6,894	69	4,036	—	—	4,105
Equity transaction costs	—	—	(613)	—	—	(613)
Shares issued in connection with the vesting of restricted stock units	147	1	(1)	—	—	—
Stock-based compensation expense	—	—	1,227	—	—	1,227
Net loss	—	—	—	—	(12,951)	(12,951)
September 30, 2020	**150,006**	**$ 1,500**	**$ 563,095**	**$ 27**	**$ (528,393)**	**$ 36,229**

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, 2019	2020
Cash flows from operating activities		
Net loss	$ (59,719)	$ (51,651)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash other income/expense, net	(49)	(19)
Non-cash interest income	24	1
Non-cash interest expense	379	351
Loss on extinguishment of debt	—	2,757
Depreciation and amortization expense	162	315
Amortization of right-of-use assets	291	260
Stock-based compensation	7,866	4,266
Deferred income taxes	(5)	—
Other, net	—	(66)
Changes in operating assets and liabilities:		
Increase/(decrease) in long-term receivables	(288)	
Increase/(decrease) in accounts receivable, net and other receivables and prepaid expenses	(1,258)	(3,237)
Increase/(decrease) in inventory	(162)	(5,121)
Increase/(decrease) in accounts payable	(39)	(2,529)
Decrease in accrued expenses and other liabilities	(3,553)	(3,103)
Increase/(decrease) in other non-current assets	—	9
Increase/(decrease) in other non-current liabilities	(88)	(156)
Increase/(decrease) in income tax liabilities	34	(44)
Net cash used in operating activities	(56,405)	(57,967)
Cash flows from investing activities		
Purchases of plant and equipment and intangible assets	(97)	(95)
Deposits into employee stock purchase plan restricted cash accounts	228	—
Changes in restricted cash	—	(162)
Net cash used in investing activities	131	(257)
Cash flows from financing activities		
Proceeds from exercise of warrants	—	665
Proceeds from issuance of common stock and warrants associated with May 2020 financing	—	38,414
Proceeds from at-the-market facility	23,189	7,119
Proceeds from long-term debt, net of issuance costs	9,980	—
Proceeds from employee stock purchase plan	170	43
Repayments of long-term borrowings	—	(30,000)
Equity transaction costs	(659)	(3,338)
Net cash provided by financing activities	32,680	12,903
Effects of exchange rate changes on the balance of cash and cash equivalents held in foreign currencies	(80)	262
Net decrease in cash, cash equivalents and restricted cash	(23,674)	(45,059)
Cash, cash equivalents and restricted cash at beginning of period	102,003	86,411
Cash, cash equivalents and restricted cash at end of period	$ 78,329	$ 41,352
Supplemental disclosure of cash flow information:		
Interest paid	$ 1,735	$ 1,273
Equity transaction costs included in accounts payable and accrued expenses	$ 382	$ 564

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

NABRIVA THERAPEUTICS plc
Notes to the Unaudited Consolidated Financial Statements

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., Zavante Therapeutics, 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.

In September 2020, the Centers for Medicare & Medicaid Services ("CMS") granted a new technology add-on payment ("NTAP") for XENLETA® (lefamulin) for injection, when administered in the hospital inpatient setting. Both the intravenous ("IV") and oral formulations of XENLETA were granted Qualified Infectious Disease Product ("QIDP") and Fast Track designation by the U.S. Food and Drug Administration ("FDA"). CONTEPO was granted an NTAP making it the first QIDP antibiotic to be granted conditional NTAP approval prior to receiving FDA approval. CONTEPO was granted QIDP and Fast Track Designation by the FDA for the treatment of complicated urinary tract infections ("cUTIs"), including acute pyelonephritis.

On July 28, 2020, the Company announced that the European Commission ("EC") issued a legally binding decision for approval of the marketing authorization application for XENLETA™ (lefamulin) for the treatment of community-acquired pneumonia ("CAP") in adults following a review by the European Medicines Agency ("EMA"). The EMA approval of XENLETA in CAP patients when it is considered inappropriate to use antibacterial agents that are commonly recommended for initial treatment or when these agents have failed paves the way for the launch of XENLETA across Europe. The Company previously announced that the Committee for Medicinal Products for Human Use ("CHMP") of the EMA adopted a positive opinion recommending approval of XENLETA for the treatment of CAP. The EC approved XENLETA for all 28 countries of the European Union ("E.U."), Norway, Iceland, and Liechtenstein. Nabriva intends to work with a commercial partner to make XENLETA available to patients in the E.U.

On July 16, 2020, the Company announced that Sunovion Pharmaceuticals Canada Inc. ("Sunovion"), received approval from Health Canada to market oral and intravenous ("IV") formulations of XENLETA® (lefamulin) for the treatment of CAP in adults, with the Notice of Compliance from Health Canada dated July 10, 2020. Nabriva entered into a license and commercialization agreement in March 2019 with Sunovion Pharmaceuticals Canada Inc. for XENLETA in Canada.

On July 15, 2020, the Company announced that it entered into a Sales Promotion and Distribution Agreement (the "Distribution Agreement") with MSD International GmbH ("MSD") and Merck Sharp & Dohme Corp. ("Supplier"), each a subsidiary of Merck & Co. Under the Distribution Agreement, MSD appointed the Company as its sole and exclusive distributor of certain products containing tedizolid phosphate as the active ingredient previously marketed and sold by Supplier and MSD under the trademark SIVEXTRO® for injection, intravenous use and oral use in the United States and its territories. SIVEXTRO is an oxazolidinone-class antibacterial indicated in adults and pediatric patients 12 years of age and older for the treatment of acute bacterial skin and skin structure infections caused by certain susceptible Gram-positive microorganisms. Nabriva has also engaged Amplity Health, a leading pharmaceutical contract commercial organization, to provide community-based commercial and sales services for SIVEXTRO and XENLETA® in the United States.

On June 30, 2020 the Company announced that WE Pharma Ltd. ("WEP Clinical"), a specialist pharmaceutical services company, had signed an exclusive agreement with the Company to supply XENLETA® (lefamulin) on a named patient or expanded access basis in certain countries outside of the US, China and Canada. The Named Patient Program ("NPP") is designed to ensure that physicians, contingent on meeting the necessary eligibility criteria and receiving

approval, can request IV or oral XENLETA on behalf of patients who live in certain countries where it is not yet available and have an unmet medical need.

On September 9, 2019, the Company announced that the oral and intravenous ("IV") formulations of XENLETA (lefamulin) are available in the United States for the treatment of community-acquired bacterial pneumonia ("CABP") 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. 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 acquired Zavante Therapeutics Inc. ("Zavante"), a biopharmaceutical company focused on developing CONTEPO (fosfomycin for injection), and entered into an Agreement and Plan of Merger (the "Merger Agreement"). 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. 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. The Company resubmitted its NDA in December 2019 and the FDA acknowledged the resubmission in January 2020. On June 19, 2020, the FDA issued a second CRL on the NDA for CONTEPO. Although the Company's European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cites observations at the Company's manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions caused by the COVID-19 pandemic. In general, previously identified product quality and facility inspection related observations at the Company's contract manufacturing partners are required to be satisfactorily resolved before the NDA may be approved. 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 second CRL. The Company's contract manufacturers continue to interact with FDA to discuss its plans for conducting inspections at their sites. On October 30, 2020, the Company participated in a Type A meeting with the FDA to obtain any new information related to the FDA's pending conduct of inspections of foreign manufacturers during the COVID-19 pandemic that has negatively impacted a number of FDA product reviews, including the CONTEPO NDA. The FDA informed the Company that it has not yet determined how it will conduct international inspections during the COVID-19 pandemic. As a result, next steps and specific timing of the CONTEPO NDA resubmission cannot be finalized until the FDA issues industry guidance. The Company and the industry await future communication from the FDA as it continues to assess the options available under existing regulations and laws to conduct these foreign facility inspections. CONTEPO has been granted Qualified Infectious Disease Product ("QIDP") and Fast Track designations by the FDA for the treatment of serious infections, including cUTI. However, the Company cannot predict when the CONTEPO NDA will be resubmitted or when CONTEPO would receive marketing approval, if at all.

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, 2020, the Company had cash and cash equivalents, restricted cash and short-term investments of $41.4 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 continue to invest in critical commercial and medical affairs activities, its commitments per the agreement with Merck & Co., Inc., as well as investing in its supply chain for the commercialization of XENLETA, SIVEXTRO and the potential launch of CONTEPO. The Company expects to seek additional funding in future periods to support these activities. 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.

In April 2020, the Company announced a restructuring of its hospital-based commercial sales force and transition to a community-based sales effort. The restructuring has reduced costs to align with the capabilities of the Company's sales effort with its strategic re-focus on making sales of XENLETA to community health care professionals. The Company incurred $676,000 of selling, general and administrative expense related to the reduction in personnel, consisting of severance, benefits and related costs, all of which were incurred in the second quarter of 2020. As of September 30, 2020, there were no outstanding liabilities associated with the restructuring. The termination of the sales force was timed, in part, to coincide with operational changes that have been implemented by the Company in response to the outbreak of the novel coronavirus, SARS-CoV-2, causing the disease referred to as "COVID-19". In response to the COVID-19 pandemic, the Company closed its administrative offices and shifted to a remote working business model. The Company implemented a work-from-home policy for all of its employees. The commercial and medical organizations suspended in-person interactions with physicians and customers and were restricted to conducting educational and promotional activities virtually. The Company has secured a new virtual and in-person sales effort with community-based expertise with Amplity Health, which is a Contract Sales Organization, to replace its hospital-based sale force. In September 2020, the Company began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. The Company plans to expand this effort to 60 sales representatives in November 2020.

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 its commitments per the agreement with Merck & Co., Inc., product sales, marketing, distribution and manufacturing for XENLETA, SIVEXTRO and CONTEPO, if approved. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain. It is also 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 consolidated 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. If the Company is not able to secure adequate additional funding in future periods, the Company may make additional 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.

As discussed in Note 6, the Company repaid $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement with Hercules in March 2020. Based on its current operating plans, the Company expects that its existing cash, cash equivalents and short-term investments as of September 30, 2020, will be sufficient to enable the Company to fund its operating expenses, debt service obligations and capital expenditure requirements substantially through the first quarter of 2021. The Company has based this estimate on assumptions that may prove to be wrong, and the Company could use its capital resources sooner than expected. This estimate assumes, among other things, that the Company does not obtain any additional funding through grants and clinical trial support, collaboration agreements or equity or debt financings. This estimate also assumes that the Company remains in compliance with the covenants and no event of default occurs under the Loan Agreement. The consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

On June 25, 2019, the Company entered into an Open Market Sale Agreement℠ (the "Jefferies ATM 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 and filed a new prospectus supplement with the Securities and Exchange Commission in connection with the Offering under the Company's new shelf Registration Statement on Form S-3 (File No. 333-248530), which became effective on September 11, 2020.

As of September 30, 2020, the Company has issued and sold an aggregate of 19,161,452 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $21.5 million and net proceeds of $20.5 million, after deducting commissions to Jefferies and other offering expenses. During the three months ended September 30, 2020, the Company issued and sold an aggregate of 6,044,418 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $3.4 million and net proceeds of $3.3 million, after deducting commissions to Jefferies and other offering expenses. From September 30, 2020 and through the date of this filing, the Company sold and issued 762,452 ordinary shares pursuant to the Jefferies ATM Agreement for net proceeds of approximately $0.4 million. As of the date of this filing, the Company may issue and sell ordinary shares for gross proceeds of up to $28.1 million under the Jefferies ATM Agreement.

In December 2019, the Company sold to certain institutional investors in a registered direct offering an aggregate of 13,793,106 ordinary shares, and accompanying warrants to purchase up to an aggregate of 13,793,106 ordinary shares. Each share was issued and sold together with an accompanying warrant at a combined price of $1.45 per security. The gross proceeds to the Company from the offering, before deducting the placement agent's fees and other offering expenses payable by the Company were $20.1 million. Each warrant has an exercise price of $1.90 per share, is initially exercisable six months following the date of issuance (the "Initial Exercise Date") and will expire on the three-year anniversary of the Initial Exercise Date. As of September 30, 2020, all of the warrants from this offering were outstanding.

In May 2020, the Company sold to certain institutional investors, including Fidelity Management & Research Company, LLC, in a registered direct offering an aggregate of 41,445,373 ordinary shares and accompanying warrants to purchase up to an aggregate of 41,445,373 ordinary shares at a combined price of $0.91686 per security. The gross proceeds to the Company from the offering, before deducting the placement agent's fees and other estimated offering expenses payable by the Company, were $38.0 million. Each warrant has an exercise price of $0.792 per share, is immediately exercisable and will expire on the two-year anniversary of the issuance date. As of September 30, 2020, 40,595,373 warrants from this offering were outstanding.

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, 2020 and for the three and nine months ended September 30, 2019 and 2020 are unaudited. The December 31, 2019 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, 2020 and results of operations for the three and nine months ended September 30, 2019 and 2020. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2019 and 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020, 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, 2019 contained in the Company's Annual Report on Form 10-K, as filed with the SEC on March 12, 2020.

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 fiscal year ended December 31, 2019. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company has not adopted any new accounting pronouncements for the nine months ended September 30, 2020.

3. Inventory

Inventory is stated at the lower of cost or 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. During the nine months ended

September 30, 2020, the Company recorded a $0.4 million non-cash reserve for excess and obsolete inventory due to the uncertainty of commercial activities underlying XENLETA product sales. Inventory reported at December 31, 2019 and September 30, 2020 consisted of the following:

(in thousands)	As of December 31, 2019 2019	As of September 30, 2020 2020
Raw materials	$ —	$ 915
Work in process	498	4,596
Finished goods	184	292
Total Inventory	**$ 682**	**$ 5,803**

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, 2019				
Assets:				
Cash equivalent:				
Money market fund	$ 15,050	$ —	$ —	$ 15,050
Short term investments:				
Term deposits	175	—	—	175
Total Assets	**$ 15,225**	**$ —**	**$ —**	**$ 15,225**

(in thousands)	Level 1	Level 2	Level 3	Total
September 30, 2020				
Assets:				
Cash equivalent:				
Money market fund	$ 8,050	$ —	$ —	$ 8,050
Short term investments:				
Term deposits	16	—	—	16
Total Assets	**$ 8,066**	**$ —**	**$ —**	**$ 8,066**

There were no transfers between Level 1 and 2 in the nine months ended September 30, 2020 or the year ended December 31, 2019. There were no changes in valuation techniques during the nine months ended September 30, 2020.

As of September 30, 2020, and December 31, 2019, 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, 2019	As of September 30, 2020
Research and development related costs	$ 1,347	$ 1,059
Payroll and related costs	6,327	4,151
Accounting, tax and audit services	420	871
Manufacturing and inventory	639	434
Accrued gross to net	493	752
Other	2,740	1,667
Total other current liabilities	**$ 11,966**	**$ 8,934**

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. ("Hercules"), pursuant to which a term loan of up to an aggregate principal amount of $75.0 million was available to the Company. The Loan Agreement initially provided 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 certain funding conditions, several additional tranches of which $5.0 million became available upon the approval by the FDA of the NDA for XENLETA, which was drawn down. The other Tranches are no longer available as their contingencies were not achieved. The Company may request a term loan advance of $5.0 million prior to December 31, 2021 subject to Hercules'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 provided for interest-only payments through July 1, 2021 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.

On March 11, 2020, the Company entered into an amendment (the "Amendment"), to its Loan Agreement with Hercules. Pursuant to the Amendment, the Company repaid $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement (the "Prepayment"). The Company determined to enter into the Amendment following the effectiveness of a performance covenant in February 2020 under which it became obligated to either (1) achieve 80% of its net product revenue sales target over a trailing six-month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or $40.0 million (the "Liquidity Requirement"). Under the Amendment, the Company and Hercules agreed to defer the end of term loan charge payment of $2.1 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered the minimum liquidity requirement to $3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and the Company achieves at least 70% of its revised net product revenue targets under the Loan Agreement. The Company was in compliance with all of its Loan Agreement covenants at September 30, 2020.

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 Hercules 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 Hercules 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 $1.3 million of costs in connection with the Loan Agreement which along with the initial fee of $0.7 million paid to Hercules were recorded as debt issuance cost and are being amortized as interest expense using the effective interest method over the term of the loan. In connection with the Amendment, the Company recognized a non-cash $2.7 million loss on the extinguishment of debt which represents the excess of the reacquisition price of the $30.0 million debt repaid over the net carrying amount of the extinguished debt. The carrying value of the term loan payable at September 30, 2020 includes the present value of the End of Term Fee and the Prepayment Fee. The End of Term Fee on the remaining $5.0 million principal balance is being accrued as additional interest expense using the effective interest method over the term of the loan.

Long-term debt as December 31, 2019 and September 30, 2020 consisted of the following:

(in thousands)	As of December 31, 2019	As of September 30, 2020
Term loan payable	$ 35,000	$ 5,000
End of term fee	443	1,976
Unamortized debt issuance costs	(1,742)	(215)
Carrying value of term loan	33,701	6,761
Other long-term debt	801	849
Total long-term debt	**$ 34,502**	**$ 7,610**

Maturities of long-term debt as of September 30, 2020 were as follows:

(in thousands)	September 30, 2020
2020	$ —
2021	1,156
2022	2,493
2023	1,351

7. Revenue

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2020
Product revenue, net	$ 1,445	$ (47)	$ 1,445	$ 61
Collaboration revenues	5,051	616	6,051	768
Research premium	424	211	1,168	802
Government grants	—	511	484	936
Total	**$ 6,920**	**$ 1,291**	**$ 9,148**	**$ 2,567**

Collaboration revenues for the nine months ended September 30, 2019 reflects a $1.0 million upfront payment under the Sunovion License Agreement received in April 2019, and a $5.0 million milestone payment under the Sinovant License Agreement (see Note 11). Collaboration revenues for the three and nine months ended September 30, 2020 include a $0.5 million regulatory milestone payment from Sunovion, as well as our share of revenues associated with the SIVEXTRO distribution agreement with Merck & Co., Inc.

We sell our products to pharmaceutical wholesalers/distributors (i.e., our customers). Our wholesalers/distributors in turn sell our products directly to clinics, hospitals, and private practices. Revenue from our product sales is recognized as physical delivery of product occurs (when our customer obtains control of the product), in return for agreed-upon consideration.

For the three and nine months ended September 30, 2020 product revenues, gross were $8 thousand and $0.4 million, respectively. Our product revenues, gross (i.e., delivered units multiplied by the contractual price per unit) are reduced by our corresponding gross-to-net ("GTN") estimates, resulting in our reported "product revenues, net" in the accompanying consolidated statements of operations. These GTN estimates are based upon information received from external sources (such as written or oral information obtained from our customers with respect to their period-end inventory levels and sales to end-users during the period), in combination with management's informed judgments. Due to the inherent uncertainty of these estimates, the actual amount incurred may be materially above or below the amount initially estimated when product revenues are originally recorded, then requiring prospective adjustments to our reported product revenues, net.

The following tables summarizes gross-to-net ("GTN") adjustments for the periods presented:

(in thousands)	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
Product revenue, gross	$ 8	$ 406
GTN accruals		
Chargebacks and cash discounts	—	13
Medicaid and Medicare rebates	1	47
Other returns, rebates, discounts and adjustments	2	94
Total GTN accruals	3	154
Product revenue	5	252
Adjustments to prior period accruals		
Returns reserve (1)	(52)	(391)
GTN accrual adjustments	—	200
Product revenue, net	**$ (47)**	**$ 61**

(1) As of September 30, 2020, the Company recorded a returns reserve adjustment for slow-moving inventory, representing 50% of XENLETA IV inventory held at our Specialty Distributors, as well as an adjustment for returns from a single mail order specialty pharmacy.

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, 2020:

Stock Option Plan 2015	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1, 2020	2,290,594	8.33	
Granted	—	—	
Exercised	—	—	
Forfeited	(174,242)	8.90	
Outstanding as of September 30, 2020	**2,116,352**	**8.28**	**$ —**
Vested and exercisable as of September 30, 2020	**2,011,922**	**8.21**	**$ —**

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 $0.3 million and $0.9 million for the three and nine months ended September 30, 2020, respectively.

The weighted average remaining contractual life of the options as of September 30, 2020 is 5.7 years.

As of September 30, 2020, there was $0.6 million of total unrecognized compensation expense, related to unvested options granted under the SOP 2015, which will be recognized over the weighted-average remaining vesting period of 0.4 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. 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 ended 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.

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, 2020:

2017 Plan	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1, 2020	4,422,664	3.55	
Granted	1,290,500	1.35	
Exercised	—	—	
Forfeited	(1,015,723)	2.84	
Outstanding as of September 30, 2020	**4,697,441**	**3.10**	**$ —**
Vested and exercisable as of September 30, 2020	**2,204,830**	**3.94**	**$ —**

Stock-based compensation expense for stock options granted under the 2017 Plan was $0.6 million and $1.9 million for the three and nine months ended September 30, 2019, and $0.5 million and $1.6 million for the three and nine months ended September 30, 2020, respectively. The weighted average fair value of the options granted during the nine months ended September 30, 2020 was $0.80 per share. The options granted in the nine months ended September 30, 2020 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	63.8% - 64.0%
Expected term of options (in years)	6.1
Range of risk-free interest rate	0.8% - 1.5%
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, 2020 is 8.4 years.

As of September 30, 2020, there was $3.3 million of total unrecognized compensation expense, related to unvested options granted under the 2017 Plan, which will be recognized over the weighted-average remaining vesting period of 1.0 years.

Restricted Stock Units ("RSUs")

Under the 2017 Plan, the Company granted RSUs which 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. The Company also granted RSUs to certain employees that 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.

During 2018, the Company granted RSUs to certain employees where 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 started recognizing compensation expense, as there was no compensation expense recognized on these awards prior to the FDA approval as it was determined that approval was not probable since it was outside of the Company's control. Also during 2018, the Company granted RSUs to certain employees that have vested in three six-month increments beginning in May 2019 and ending in May 2020. Lastly, the Company granted RSUs in 2018 to certain employees where vesting of the RSUs is subject to FDA approval of an NDA for CONTEPO. Fifty percent (50%) of each RSU award will vest upon FDA approval, and the remaining fifty percent (50%) will vest on the one- year anniversary of such approval.

The following table summarizes information regarding the Company´s restricted stock unit awards under the 2017 Plan at September 30, 2020:

2017 Plan	RSUs	Weighted average fair value per share
Outstanding as of January 1, 2020	901,686	3.69
Granted	1,557,300	1.35
Vested and issued	(508,772)	3.16
Forfeited	(253,292)	1.82
Outstanding as of September 30, 2020	**1,696,922**	**1.48**

For the three and nine months ended September 30, 2019, $57 thousand and $152 thousand, respectively, of stock-based compensation expense was recognized for RSUs. Stock-based compensation expense for RSUs granted under the 2017 Plan was $0.3 million and $1.3 million for the three and nine months ended September 30, 2020, respectively.

The Company has total unrecognized compensation costs of $2.2 million associated with RSUs which are expected to be recognized over the awards average remaining vesting period of 1.2 years. The fair value of RSU's that vested during the nine months ended September 30, 2020 was $0.9 million.

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.

On April 28, 2020, the board of directors resolved not to make any further awards 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, 2020:

2019 Inducement Plan	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1, 2020	605,650	2.14	
Granted	182,000	1.35	
Exercised	—	—	
Forfeited	(516,558)	1.96	
Outstanding as of September 30, 2020	**271,092**	**1.93**	**$ —**
Vested and exercisable as of September 30, 2020	**50,253**	**2.61**	**—**

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 and $24 thousand and $51 thousand for the three and nine months ended September 30, 2020, respectively. The weighted average fair value of the options granted during the nine months ended September 30, 2020 was $0.79 per share. The options granted in the nine months ended September 30, 2020 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	63.7% - 64.0%
Expected term of options (in years)	6.1
Risk-free interest rate	1.0% - 1.4%
Dividend yield	—

The weighted average remaining contractual life of the options as of September 30, 2020 is 8.9 years.

As of September 30, 2020, there was $0.2 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 1.3 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. Since the FDA did not approve an NDA for both XENLETA and CONTEPO by January 31, 2020, the award was forfeited and the performance-based restricted share units terminated in full. The Company also issues non-statutory options to new employees upon the commencement of their employment

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, and $0.1 million and $0.3 million for the three and nine months ended September 30, 2020, respectively. 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. 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, 2020 is 7.8 years.

As of September 30, 2020, there was $0.8 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 1.0 years.

2020 Share Incentive Plan

On March 4, 2020, the Company´s board of directors adopted the 2020 Share Incentive Plan (the "2020 Plan"), which was approved by the Company´s shareholders at the 2020 Annual General Meeting of Shareholders in July 2020 ("AGM"). As of the date of the 2020 AGM, the total number of ordinary shares reserved for issuance under the 2020 Plan was for the sum of 9,300,000 ordinary shares, plus the number of the Company´s ordinary shares that remained available for grant under the 2017 Plan as of immediately prior to the AGM and the number of ordinary shares subject to awards granted under the 2017 Plan and the Company´s Amended and Restated Stock Option Plan 2015, that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right. Following shareholder approval of the 2020 Plan, no further awards will be made under the 2017 Plan.

The 2020 Plan provides for the grant of incentive share options, non-statutory share options, share appreciation rights, restricted share awards, restricted share units, other share-based and cash-based awards and performance awards.

At September 30, 2020, 7,548,354 ordinary shares were available for future issuance under the 2020 Plan.

The following table summarizes information regarding the Company's stock option awards under the 2020 Plan for the nine months ended September 30, 2020:

2020 Plan	Options	Weighted average exercise price in $ per share	Aggregate intrinsic value
Outstanding as of January 1, 2020	—	—	
Granted	3,090,750	0.71	
Exercised	—	—	
Forfeited	—	—	
Outstanding as of September 30, 2020	**3,090,750**	**0.71**	**$ —**
Vested and exercisable as of September 30, 2020	—	—	**$ —**

Stock-based compensation expense under the 2020 Plan was $8 thousand and $72 thousand for the three and nine months ended September 30, 2020, respectively. The weighted average fair value of the options granted during the nine months ended September 30, 2020 was $0.44 per share. The options granted in the nine months ended September 30, 2020 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	73.3% - 74.4%
Expected term of options (in years)	5.5 - 6.1
Risk-free interest rate	0.3% - 0.4%
Dividend yield	—

The weighted average remaining contractual life of the options as of September 30, 2020 is 9.9 years.

As of September 30, 2020, there was $1.3 million of total unrecognized compensation expense related to unvested options granted under the 2020 Plan, which will be recognized over the weighted-average remaining vesting period of 1.3 years.

Restricted Stock Units ("RSUs")

During 2020, the Company granted 459,869 RSUs to certain employees that vest in three six-month increments beginning in January 2021 and ending in January 2022. Also during 2020, the Company granted 431,250 RSUs to certain employees with a grant date fair value of $0.53 per share, where vesting of the RSUs was subject to individual performance goals. For the three and nine months ended September 30, 2020 stock-based compensation expense of $45 thousand was recognized for these RSUs. As of September 30, 2020, there was $0.5 million of unrecognized compensation expense related to unvested RSUs, which will be recognized over the weighted-average remaining vesting period of 1.2 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 available as of September 30, 2020, represented less than 0.1% of the total number of shares of ordinary shares outstanding as of September 30, 2020. 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 May 1 and ending October 31 of each year. As of the date of this filing, the Company has suspended the 2018 ESPP until further notice.

9. Income Tax Expense

For the three and nine months ended September 30, 2019 the Company recorded a tax benefit of $29 thousand, and a tax expense of $0.1 million, respectively. For the three and nine months ended September 30, 2020 the Company recorded a tax benefit of $0.1 million, and a tax expense of $0.2 million, respectively.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax bases of assets and liabilities using statutory rates. Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, including the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of its deferred tax assets. On the basis of this evaluation the Company has recorded a valuation allowance against all of its deferred tax assets at September 30, 2020 and December 31, 2019.

10. Earnings (Loss) per Share

Basic and diluted loss per share

For the three and nine months ended September 30, 2019 and 2020, 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 ordinary share equivalents are antidilutive since the Company had net losses for each period presented below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share data)	2019	2020	2019	2020
Net loss for the period	$ (17,795)	$ (12,951)	$ (59,719)	$ (51,651)
Weighted average number of shares outstanding	75,161,192	144,690,904	72,153,405	117,454,536
Basic and diluted loss per share	**$ (0.24)**	**$ (0.09)**	**$ (0.83)**	**$ (0.44)**

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,		Nine Months Ended September 30,	
	2019	2020	2019	2020
Stock option awards	8,340,698	11,025,635	8,340,698	11,025,635
Restricted stock units	1,289,111	2,588,041	1,289,111	2,588,041
Warrants	—	54,388,479	—	54,388,479

11. Significant Arrangements and 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 of up to $86.5 million 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 statements 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 XENLETA 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 Sinovant 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 "Sunovion 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. On November 7, 2019, the Company, through Sunovion, submitted a NDS. Health Canada determined there was a screening deficiency in December 2019 and a response from the Company/Sunovion was provided on December 18, 2019 and acknowledged by Health Canada on January 13, 2020. The NDS approval occurred on July 10, 2020.

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 Sunovion JDC. The $1.0 million non-refundable upfront payment was allocated entirely to the delivery of the license as the Sunovion JDC deliverable was deemed to be de minimis. With the NDS approval that occurred on July 10, 2020, the Company has received a regulatory milestone payment of $0.5 million . Any future regulatory and commercial milestone payments under the Sunovion License Agreement will be recorded during the period the milestones become probable of achievement.

Sales Promotion and Distribution Agreement with Merck & Co.

On July 15, 2020, the Company entered into a Sales Promotion and Distribution Agreement (the "Distribution Agreement") with MSD International GmbH ("MSD") and Merck Sharp & Dohme Corp. ("Supplier"), each a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. Under the Distribution Agreement, upon satisfaction of certain specified conditions, MSD appointed the Company as its sole and exclusive distributor of certain products containing tedizolid phosphate as the active ingredient (marketed and sold by Supplier and MSD prior to the effective date of the Distribution Agreement under the trademark SIVEXTRO®) for injection, intravenous use and oral use (the "Products") in final packaged form labeled with the Company's National Drug Code numbers in the United States and its territories (the "Territory"). SIVEXTRO is an oxazolidinone-class antibacterial indicated in adults and pediatric patients 12 years of age and older for the treatment of acute bacterial skin and skin structure infections caused by certain susceptible Gram-positive microorganisms. Under the Distribution Agreement and subject to the fulfillment of certain conditions, including the Company having engaged sufficient sales representatives, restrictions relating to travel and physician

office access in the Territory due to COVID-19 having continued to decrease in a sufficient portion of the Territory so as not to hinder the successful detailing of SIVEXTRO, the Company is granted the right by MSD initially to promote the Products in the Territory and, upon satisfaction of additional conditions, including an increase in sales representatives, the right to exclusively distribute the Products in the Territory, including the sole right and responsibility to fill orders with respect to the Products in the Territory. Subject to applicable law, the Company is entitled to determine the final selling prices of the Products charged by the Company to its customers at its sole discretion, subject to an overall annual limit on price increases, and will be solely responsible for sales contracting and all market access activities, including bidding, hospital listing and reimbursement. The Company is responsible for all costs related to the promotion, sale and distribution of the Products by the Company, as well as all costs required to meet the Company's staffing obligations under the Distribution Agreement. The Company is obligated to use commercially reasonable efforts to promote and distribute the Products and to maximize the sales of the Products throughout the Territory. The Company has agreed to employ a sales force or retain the services of a contract sales organization to fulfill its obligations under the Distribution Agreement.

Named Patient Program Agreement with WE Pharma Ltd.

On June 30, 2020 the Company announced that WE Pharma Ltd. ("WEP Clinical"), a specialist pharmaceutical services company, had signed an exclusive agreement with the Company to supply XENLETA on a named patient or expanded access basis in certain countries outside of the US, China and Canada. The Named Patient Program ("NPP") is designed to ensure that physicians, contingent on meeting the necessary eligibility criteria and receiving approval, can request IV or oral XENLETA on behalf of patients who live in certain countries where it is not yet available and have an unmet medical need.

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 the third quarter of 2020, the Company entered into a month-to-month sublease agreement for office space for one employee in San Diego, California through March 31, 2021.

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. Starting in 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 nine months ended September 30, 2020, the Company's operating lease expense was $1.0 million.

As of September 30, 2020, the lease term of the King of Prussia operating leases was 3.1 years and the discount rate was 9.8%.

As of September 30, 2020, other information related to the operating leases were as follows:

Operating Cash Flow Supplemental Information:

(in thousands)		September 30, 2020
Cash paid for amounts included in the measurement of the operating lease liabilities	$	379
Right-of-use assets obtained in exchange for operating lease obligations	$	1,387

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

(in thousands)		September 30, 2020
2020	$	128
2021		515
2022		522
2023		507
Total lease payments		1,672
Less imputed interest and amortization differences		(225)
Present value of operating lease liabilities	$	1,447

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. On November 18, 2019, the Company filed a pre-motion letter to dismiss with the Court, seeking leave to move to dismiss and setting forth why a motion to dismiss is warranted. On April 28, 2020, the Court dismissed the amended complaint without prejudice and granted plaintiff twenty days to show cause why the lawsuit should not be dismissed with prejudice. On May 8, 2020, the Court granted plaintiff a 21-day extension to show cause. On June 8, 2020, plaintiff filed a letter application to the court seeking leave to file a proposed second amended complaint, and on

June 23, 2020, the court directed plaintiff to file the proposed second amended complaint. Plaintiff did so on June 24, 2020. The Company filed an answer to the second amended complaint on July 8, 2020.

On October 21, 2020, the parties mediated this case and reached a settlement, subject to court approval. The settlement will be covered in full by the Company´s directors' and officers' insurance.

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, 2020, there were no material changes outside the ordinary course of the Company's business to its contractual obligations 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.

13. Subsequent Events

The Company has evaluated all subsequent events through the filing date of this Form 10-Q with the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of September 30, 2020, and events which occurred subsequently but were not recognized in the financial statements. There were no subsequent events which required recognition, adjustment to, or disclosure in the financial statements.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our historical consolidated financial statements and the related notes thereto appearing in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on March 12, 2020. 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. These risks and uncertainties include risks relating to the impact of the COVID-19 pandemic on our business. 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. We have the commercial right to two approved products, XENLETA and SIVEXTRO, as well as one product candidate, CONTEPO. In August 2019, our first product was approved by the U.S. Food and Drug Administration, or 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.

On July 28, 2020, we announced that the European Commission, or EC, issued a legally binding decision for approval of the marketing authorization application for XENLETA™ (lefamulin) for the treatment of community-acquired pneumonia, or CAP, in adults following a review by the European Medicines Agency, or EMA. The EMA approval of XENLETA in CAP patients when it is considered inappropriate to use antibacterial agents that are commonly recommended for initial treatment or when these agents have failed paves the way for the potential launch of XENLETA across Europe. We previously announced that the Committee for Medicinal Products for Human Use, or CHMP, of the EMA adopted a positive opinion recommending approval of XENLETA for the treatment of CAP. The EC approved XENLETA for all 28 countries of the European Union, or E.U., Norway, Iceland, and Liechtenstein. We intend to work with a commercial partner to make XENLETA available to patients in the E.U.

We submitted a new drug application, or 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. 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, or 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 resubmitted our NDA seeking marketing approval for CONTEPO in December 2019. In June 2020, the FDA issued a second CRL. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the second CRL cited observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. In general, previously identified product quality and facility inspection related observations at our contract manufacturing partners are required to be satisfactorily resolved before the NDA may be approved. 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 second CRL. Our contract manufacturers continue to interact with FDA to discuss its

plans for conducting inspections at their sites. On October 30, 2020, we participated in a Type A meeting with the FDA to obtain any new information related to the FDA's pending conduct of inspections of foreign manufacturers during the COVID-19 pandemic that has negatively impacted a number of FDA product reviews, including the CONTEPO NDA. The FDA informed us that it has not yet determined how it will conduct international inspections during the COVID-19 pandemic. As a result, next steps and specific timing of the CONTEPO NDA resubmission cannot be finalized until the FDA issues industry guidance. We and the industry await future communication from the FDA as it continues to assess the options available under existing regulations and laws to conduct these foreign facility inspections. CONTEPO has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA for the treatment of serious infections, including cUTI. However, we cannot predict when the CONTEPO NDA will be resubmitted, or when CONTEPO would receive marketing approval, if at all.

Since inception, we have incurred significant operating losses. As of September 30, 2020 we had an accumulated deficit of $528.4 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. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, the timing and amount of sales of XENLETA, SIVEXTRO or other product candidates are uncertain. Under the Distribution Agreement (defined below), we were required to secure a sales force and the restrictions related to COVID-19 must be eased in a sufficient manner to permit us to promote and distribute SIVEXTRO. Re-securing a sales force for the promotion and distribution of SIVEXTRO will result in significant additional expense and our efforts to secure a sales force may not be successful. Based on our current forecasts and plans, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional capital 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 and commercialization efforts.

Market conditions for antibiotic companies continue to be challenging as evidenced by the bankruptcy of two organizations engaged in the research and development and commercialization of antibiotics in 2019. The cost of capital has risen significantly for others and us. On December 20, 2019, we issued 13,793,106 ordinary shares and 13,793,106 warrants with an exercise price of $1.90 per share that generated gross proceeds of $20.1 million. In addition, on March 11, 2020, we entered into an amendment, or the Amendment, to our Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, as administrative agent, collateral agent and lender. Pursuant to the Amendment, we repaid Hercules in March 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. On May 29, 2020, we issued in a registered direct offering an aggregate of 41,445,373 ordinary shares with 41,445,373 warrants at a combined price of $0.91686 per security. The gross proceeds were $38.0 million. Each warrant has an exercise price of $0.792 per share, is exercisable immediately and will expire on the two-year anniversary of the issuance date. As of September 30, 2020, there were 54,388,479 warrants still outstanding from both offerings.

As part of our corporate strategy, we continue to evaluate business development opportunities and potential collaborations. We may further expand our product pipeline through opportunistically in licensing or acquiring the rights to complementary products, product candidates and technologies for the treatment of a range of infectious diseases or other products that we would market with our commercial infrastructure, including additional community products, which could involve an acquisition of or combination or other strategic transaction with another operating business. In addition, we plan to continue to evaluate the merits of entering into collaboration agreements with other pharmaceutical or biotechnology companies that may contribute to our ability to efficiently advance our product candidates, build our

product pipeline, concurrently advance a range of research and development programs and leverage our commercial infrastructure.

Business Update Regarding COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19, which continues to spread throughout the U.S. and the world, as a pandemic. The outbreak is having an impact on the global economy, resulting in rapidly changing market and economic conditions. National and local governments around the world instituted certain measures, including travel bans, prohibitions on group events and gatherings, shutdowns of certain non-essential businesses, curfews, shelter-in-place orders and recommendations to practice social distancing. The COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. The impact of COVID-19 is unknown and may continue as the rates of infection have increased in many states in the U.S., thus additional restrictive measures may be necessary. Federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, and the adoption of work-from-home policies, all of which have had, and we believe will continue to have, an impact on our consolidated results of operations, financial position, and cash flows.

In response to the COVID-19 pandemic, we closed our administrative offices and shifted to a remote working business model. We have implemented a work-from-home policy for all of our employees, and we may take further actions that alter our operations as may be required by federal, state, or local authorities, or which we determine are in our best interests. The commercial and medical organizations have suspended in-person interactions with physicians and customers and were restricted to conducting educational and promotional activities virtually. The impact of the COVID-19 pandemic could continue to have a material adverse effect on our business, results of operations, financial condition, liquidity and prospects in the near-term and beyond 2020. While we have used all currently available information in our forecasts, the ultimate impact of the COVID-19 pandemic and our product sales for XENLETA and SIVEXTRO, on our results of operations, financial condition and cash flows is highly uncertain, and cannot currently be accurately predicted. Our results of operations, financial condition and cash flows are dependent on future developments, including the duration of the pandemic and the related length of its impact on the global economy, such as a lengthy or severe recession or any other negative trend in the U.S. or global economy and any new information that may emerge concerning the COVID-19 outbreak and the actions to contain it or treat its impact, which at the present time are highly uncertain and cannot be predicted with any accuracy.

COVID-19 has demonstrated the devastating impact that infectious diseases can have on public health and the economy. Similar to other acute respiratory virus infections, including influenza virus, patients infected with SARS-CoV-2 are at increased risk of developing concomitant bacterial pneumonia. In published reports, bacterial pneumonia has been shown to affect nearly 50% of hospitalized patients with COVID-19, with an associated mortality of almost 50%. As a result, the World Health Organization currently recommends empiric antimicrobials to treat all likely pathogens causing severe acute respiratory infections and sepsis as soon as possible in patients with COVID-19.

SIVEXTRO is approved for the treatment of acute bacterial skin and skin structure infections, or ABSSIs, caused by certain susceptible Gram-positive microorganisms. Before we were permitted to sell SIVEXTRO under the Distribution Agreement, we were required to secure a sales force of a certain size and the restrictions related to COVID-19 must be eased in a sufficient manner to permit us to promote and distribute SIVEXTRO. Re-securing a sales force of a certain size for the promotion and distribution of SIVEXTRO will result in significant additional expense and our efforts to secure a sales force may not be successful. In September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020.

XENLETA is approved for the treatment of CABP in adults in the United States. In addition to XENLETA's potential role in treating COVID-19 patients with superimposed bacterial pneumonia, we are assessing the anti-inflammatory activity of XENLETA and what role, if any, these characteristics may play in the management of patients with COVID-19. The National Institute for Allergy and Infectious Diseases, or NIAID, has identified that secondary bacterial pneumonia caused by common upper respiratory tract bacteria plays a predominant role in the cause of death in pandemic influenza. NIAID recommends that the prevention, diagnosis, prophylaxis, and treatment of secondary bacterial pneumonia, as well as the stockpiling of antibiotics and bacterial vaccines, be high priorities for pandemic planning. We believe there is a potential for XENLETA to be considered for U.S. government stockpiling for pandemic influenza.

Two ongoing pediatric Phase 1 clinical trials for lefamulin and IV fosfomycin were temporarily closed for enrollment as hospitals suspended access and non-essential clinical research to focus on health care delivery to COVID-19 patients. As of July 2020, both trials have started to re-open, where allowed by the institution, and initiated screening of potential subjects at sites.

In collaboration with the Global Antibiotic Research & Development Partnership, we are assessing XENLETA for the treatment of sexually transmitted infections, including *N. gonorrhoeae*, *C. trachomatis*, and *M. genitalium*. In preclinical studies, XENLETA has been shown to possess potent in vitro activity against all three of these organisms, which is maintained in the presence of resistance to all standard of care treatment options (aminoglycoside, cephalosporin, fluoroquinolone, macrolide, penicillin, and tetracycline antibiotic classes). Importantly, XENLETA has been shown to be bactericidal *in vitro* against both *N. gonorrhoeae* and *M. genitalium*.

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.

License Agreement with Sinovant Sciences, Ltd.

In March 2018, we entered into a license agreement, or the Sinovant License Agreement, with Sinovant, to develop and commercialize XENLETA 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 XENLETA, or the Sinovant Licensed Products, in the People's Republic of China, Hong Kong, Macau, and Taiwan, which we refer to collectively as the Sinovant 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 Sinovant Territory. We received a $5.0 million upfront payment pursuant to the terms of the Sinovant License Agreement and were initially

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, or CTA, by Sinovant to the Chinese Food and Drug Administration that was received in February 2019. We received an additional $5.0 million milestone payment from Sinovant in the third quarter of 2019 due to the receipt of approval for XENLETA from the FDA in August 2019. The remaining milestone payments of up to $86.5 million are tied to additional regulatory approvals and annual sales targets. In addition, we are eligible to receive low double-digit royalties on sales, if any, of Sinovant Licensed Products in the Sinovant Territory.

Sinovant will be solely responsible for all costs related to developing, obtaining regulatory approval of and commercializing Sinovant Licensed Products in the Sinovant Territory and is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize Sinovant Licensed Product in the Sinovant 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 Sinovant Licensed Products in the Sinovant 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 Sinovant 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.

In recognition of the rising rates of bacterial resistance in China and because CABP is commonly associated with acute respiratory viruses infections, including influenza and coronavirus, and based on XENLETA's robust safety and efficacy data in the treatment of patients with CABP generated globally and in China, Sinovant is in active discussions with China's National Medical Products Administration to expedite development activities and regulatory filings for lefamulin in mainland China. Despite the serious measures taken to control COVID-19, which significantly impacted the treatment of bacterial pneumonia patients, enrollment in a pivotal trial has continued and is expected to be completed in next two to three quarters. The filing by Sinovant for regulatory approval in China is expected in the next 12 to 18 months.

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 XENLETA in the forms clinically developed by us or any of our affiliates, or the Sunovion Licensed Products, in Canada in all uses in humans in CABP and in any other indication for which the Sunovion 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.

On November 7, 2019, through Sunovion, we have submitted a New Drug Submission ("NDS"). Health Canada determined there was a screening deficiency in December 2019 and a response from us/Sunovion was provided on December 18, 2019 and acknowledged by Health Canada on January 13, 2020. Following the NDS approval that occurred on July 10, 2020, we have received a regulatory milestone payment of $0.5 million from Sunovion. Any future regulatory and commercial milestone payments under the Sunovion License Agreement will be recorded during the period the milestone is probable of achievement.

Sales Promotion and Distribution Agreement with Merck & Co., Inc.

In July 2020, we entered into a Sales Promotion and Distribution Agreement, or the Distribution Agreement, with subsidiaries of Merck pursuant to which we licensed the right, subject to specified conditions, to promote, distribute and sell SIVEXTRO for acute bacterial skin and skin structure infections, or ABSSIs, caused by certain susceptible Gram-positive microorganisms in the United States and its territories, or the Territory.

Under the Distribution Agreement and subject to the fulfillment of certain conditions, including our engaging sufficient sales representatives, restrictions relating to travel and physician office access in the Territory due to COVID-19 having continued to decrease in a sufficient portion of the Territory so as not to hinder the successful detailing of SIVEXTRO, we have been granted the right to initially promote SIVEXTRO in the Territory and, upon satisfaction of additional conditions, including an increase in the number of our sales representatives, the right to exclusively distribute SIVEXTRO in the Territory, including the sole right and responsibility to fill orders with respect to SIVEXTRO in the Territory.

Before we were permitted to sell SIVEXTRO under the Distribution Agreement, we were required to secure a sales force and the restrictions related to COVID-19 must be eased in a sufficient manner to permit us to promote and distribute SIVEXTRO. Re-securing a sales force for the promotion and distribution of SIVEXTRO will result in significant additional expense and our efforts to secure a sales force may not be successful. In September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020. To date, we have satisfied our requirements under the Distribution Agreement.

Furthermore, a subsidiary of Merck will sell, and we have agreed to purchase, SIVEXTRO at specified prices in such quantities as we may specify. Although we are entitled, subject to appliable law, to determine the final selling prices of SIVEXTRO in our sole discretion, subject to an overall annual limit on price increases, we may not be able to sell SIVEXTRO at prices high enough to recoup our investment in a sales force and other commercialization activities.

Financial Operations Overview

Revenue

In September 2019 we had our commercial launch of XENLETA. For the nine months ended September 30, 2020, we recorded $0.4 million of product revenue, gross and $61 thousand of product revenues, net of gross-to-net accruals and adjustments for returns. In the second and third quarter of 2020, we recorded $0.4 million returns reserve adjustments for slow moving inventory, representing 50% of XENLETA IV inventory held at our Specialty Distributors, as well as an adjustment for returns from a single mail order specialty pharmacy, partly offset by a $0.2 million reversal of gross-to-net accruals, resulting in $61 thousand product revenue, net for the nine months ended September 30, 2020. Third quarter collaboration revenues include a $0.5 million regulatory milestone payment from Sunovion, as well as $43 thousand of our share of revenues associated with the SIVEXTRO distribution agreement with Merck & Co., Inc. which commenced at the end of September 2020. 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 and eventually SIVEXTRO. Our distribution partners continue to primarily utilize their existing inventory to satisfy product demand for XENLETA which in turn impacted sales in the first nine months of 2020. In response to the COVID-19 pandemic, we closed our administrative offices and shifted to a remote working business model. We have implemented a work-from-home policy for all of our employees, and we may take further actions that alter our operations as may be

required by federal, state, or local authorities, or which we determine are in our best interests. The commercial and medical organizations have suspended in-person interactions with physicians and customers and were restricted to conducting educational and promotional activities virtually. In addition, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort. The restructuring resulted in the termination of 66 employees, consisting of our entire hospital-based sales personnel and certain members of our sales force leadership team. Additional reductions in headcount occurred in the third quarter of 2020 including the restructuring of the commercial organization, which led to the elimination of the role of the Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. In September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain.

Our revenues for the nine months ended September 30, 2020 included governmental research premiums, non-refundable government grants, collaboration revenues 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, 2019.

Research and Development Expenses

Research and development expenses represented 31.9% and 29.6% of our total operating expenses for the nine months ended September 30, 2019 and 2020, 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 (prior to our products receiving FDA approval, after which time these costs are capitalized in inventory until product is sold), 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)	2019	2020
Direct Costs		
XENLETA	$ 7,737	$ 1,715
CONTEPO	3,781	614
FDA filing fee refund	(2,589)	—
Other programs and initiatives	994	774
Indirect Costs	11,290	11,827
Total	**$ 21,213**	**$ 14,930**

We expect to continue to incur research and development expenses in connection with required regulatory activities, our activities related to our ongoing pediatric studies of lefamulin for the treatment of CABP and of CONTEPO for the treatment of cUTI, and may incur costs related to 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 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;
- the costs, timing and outcome of regulatory review of our product candidates;
- the scope, progress, costs and results of clinical trials and other research and development activities; 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 68.1% and 69.6% of our total operating expenses for the nine months ended September 30, 2019 and 2020, respectively.

Selling, general and administrative expenses consist primarily of the cost of our contract sales organization, 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 costs to increase in the fourth quarter of 2020 primarily due to the recent resumption of selling efforts for XENLETA and SIVEXTRO. We recently secured a virtual and in-person community-based sales effort with Amplity Health, and in September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020.

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, 2019. During the nine months ended September 30, 2020, there were no material changes to our critical accounting policies.

Results of Operations

Comparison of Three Months Ended September 30, 2019 and 2020

(in thousands)	Three Months Ended September 30, 2019	2020	Change
Consolidated Operations Data:			
Revenues	$ 6,920	$ 1,291	$ (5,629)
Costs and Expenses:			
Cost of product sales	(15)	(25)	(10)
Research and development expenses	(5,601)	(3,486)	2,115
Selling, general and administrative expenses	(18,503)	(10,997)	7,506
Total operating expenses	(24,119)	(14,508)	9,611
Loss from operations	**(17,199)**	**(13,217)**	**3,982**
Other income (expense):			
Other income (expense), net	(10)	450	460
Interest income (expense), net	(615)	(256)	359
Loss before income taxes	**(17,824)**	**(13,023)**	**4,801**
Income tax benefit	29	72	43
Net loss	**$ (17,795)**	**$ (12,951)**	**$ 4,844**

Revenues

Revenues decreased by $5.6 million from $6.9 million for the three months ended September 30, 2019 to $1.3 million for the three months ended September 30, 2020, primarily due to a $4.4 million decrease in collaboration revenue and a $1.5 million decrease in product revenues, net. Collaboration revenues in 2019 included a $5.0 million milestone payment from Sinovant. For the three months ended September 30, 2020, we recorded $5 thousand of product revenue, net of gross-to-net accruals. In addition, we recorded a $0.1 million adjustments for returns from mail order specialty pharmacies, resulting in $47 thousand of negative product revenue, net for the three months ended September 30, 2020. For the three months ended September 30, 2019, we recorded $1.4 million of product revenue, net upon the initial 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 our 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 has been distributed by our customers based on end user consumption demand.

Research and Development Expenses

Research and development expenses decreased by $2.1 million from $5.6 million for the three months ended September 30, 2019 to $3.5 million for the three months ended September 30, 2020. The decrease was primarily due to a $0.8 million decrease in stock-based compensation expense, a $0.3 million decrease in staff costs, a $0.5 million decrease in research materials and purchased services, a $0.2 million decrease in research consulting fees, and a $0.2 million decrease in travel costs.

Selling, General and Administrative Expenses

Selling, general and administrative expense decreased by $7.5 million from $18.5 million for the three months ended September 30, 2019 to $11.0 million for the three months ended September 30, 2020. The decrease was primarily due to a $3.5 million decrease in advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees in 2019, a $2.3 million decrease in staff costs due to the reduction of headcount, and a $2.2 million decrease in stock-based compensation expense, partly offset by a $0.3 million increase in legal fees, and a $0.1 million increase in tax and audit related fees.

Other Income (Expense), net

Other income (expense), net, decreased by $0.5 million for the three months ended September 30, 2020, primarily due to remeasurements of our foreign currency account balances.

Interest Income (Expense), net

Interest income (expense), net decreased by $0.4 million due the repayment of indebtedness under our Loan Agreement with Hercules in March 2020. See Note 6 to the unaudited consolidated financial statements included elsewhere in this Form 10-Q for further information.

Income Tax Benefit (Expense)

Our income tax benefit was $29 thousand for the three months ended September 30, 2019 and our income tax benefit was $72 thousand for the three months ended September 30, 2020.

Comparison of Nine Months Ended September 30, 2019 and 2020

(in thousands)	Nine Months Ended September 30, 2019	2020	Change
Consolidated Operations Data:			
Revenues	$ 9,148	$ 2,567	$ (6,581)
Costs and Expenses:			
Cost of product sales	(15)	(401)	(386)
Research and development expenses	(21,213)	(14,930)	6,283
Selling, general and administrative expenses	(45,339)	(35,094)	10,245
Total operating expenses	(66,567)	(50,425)	16,142
Loss from operations	**(57,419)**	**(47,858)**	**9,561**
Other income (expense):			
Other income (expense), net	116	614	498
Interest income (expense), net	(2,336)	(1,451)	885
Loss on extinguishment of debt	—	(2,757)	(2,757)
Loss before income taxes	**(59,639)**	**(51,452)**	**8,187**
Income tax expense	(80)	(199)	(119)
Net loss	**$ (59,719)**	**$ (51,651)**	**$ 8,068**

Revenues

Revenues decreased by $6.6 million from $9.1 million for the nine months ended September 30, 2019 to $2.5 million for the nine months ended September 30, 2020, primarily due a $5.3 million decrease in collaboration revenue and a $1.4 million decrease in product revenue, net associated with the launch of XENLETA in 2019, offset by a $0.1 million increase in research premium and grant revenue. Collaboration revenues in 2019 included $6.5 million for two milestone payments from Sinovant. For the nine months ended September 30, 2020 we recorded $0.3 million of product revenue, net of gross-to-net accruals. In addition, we recorded a $0.4 million returns reserve adjustment for slow moving

inventory, representing 50% of XENLETA IV inventory held at our Specialty Distributors and adjustments for returns from mail order specialty pharmacies, partly offset by a favorable $0.2 million gross-to-net adjustment, resulting in $61 thousand product revenue, net for the nine months ended September 30, 2020.

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 our 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 has been distributed by our customers based on end user consumption demand. During the nine months ended September 30, 2020 we recorded a $0.4 million non-cash reserve for excess and obsolete inventory due to the uncertainty of commercial activities underlying XENLETA sales.

Research and Development Expenses

Research and development expenses decreased by $6.3 million from $21.2 million for the nine months ended September 30, 2019 to $14.9 million for the nine months ended September 30, 2020. The decrease was primarily due to a $3.5 million decrease in research materials and purchased services, a $1.9 million decrease in research consulting fees, a $2.2 million decrease in staff costs, a $0.7 million decrease in stock-based compensation expense, and a $0.3 million decrease in travel and infrastructure costs, partly offset by a $2.6 million refund of NDA filing fees for our product candidate, CONTEPO in 2019.

Selling, General and Administrative Expenses

Selling, general and administrative expense decreased by $10.2 million from $45.3 million for the nine months ended September 30, 2019 to $35.1 million for the nine months ended September 30, 2020. The decrease was primarily due to a $6.0 million decrease in advisory and external consultancy expenses primarily related to pre-commercialization activities and professional service fees in 2019, a $2.9 million decrease in stock-based compensation expense, a $0.8 million decrease in travel, a $0.1 million decrease infrastructure costs, and a $0.1 million decrease in other corporate costs.

Other Income (Expense), net

Other income (expense), net, decreased by $0.5 million for the nine months ended September 30, 2020, primarily due to remeasurements of our foreign currency account balances.

Interest Income (Expense), net

Interest income (expense), net decreased by $0.9 million due the repayment of indebtedness under our Loan Agreement with Hercules in March 2020. See Note 6 to the unaudited consolidated financial statements included elsewhere in this Form 10-Q for further information.

Loss on Extinguishment of Debt

In connection with the third amendment to our Loan Agreement with Hercules, we recognized a non-cash $2.8 million loss on the extinguishment of debt during the nine months ended September 30, 2020, which represents the excess of the reacquisition price of the $30.0 million debt repaid over the net carrying amount of the extinguished debt.

Income Tax Expense

Our income tax expense was $0.1 million for the nine months ended September 30, 2019 and $0.2 million for the nine months ended September 30, 2020.

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, research and development support from governmental grants and loans and proceeds from licensing agreements.

In May 2020, we entered into a securities purchase agreement with certain institutional investors, including Fidelity Management & Research Company, LLC, pursuant to which we issued and sold in a registered direct offering an aggregate of 41,445,373 ordinary shares and accompanying warrants to purchase up to an aggregate of 41,445,373 ordinary shares. Each share was issued and sold together with an accompanying warrant at a combined price of $0.91686 per security. The gross proceeds to us from the offering, before deducting the placement agent's fees and other estimated offering expenses payable by us were $38.0 million. Each warrant has an exercise price of $0.792 per share, is immediately exercisable and will expire on the two-year anniversary of the issuance date. As of September 30, 2020, 40,595,373 warrants from this offering were outstanding.

In December 2019, we entered into a securities purchase agreement with certain institutional investors pursuant to which we agreed to issue and sell in a registered direct offering an aggregate of 13,793,106 ordinary shares and accompanying warrants to purchase up to an aggregate of 13,793,106 ordinary shares. Each share in the offering was issued and sold together with an accompanying warrant at a combined price of $1.45 per security. The gross proceeds to us from the offering, before deducting the placement agent's fees and other offering expenses payable by us, was $20.0 million. Each warrant has an exercise price of $1.90 per share, is initially exercisable six months following the date of issuance, which was December 24, 2019, and will expire on the three-year anniversary of the date on which the warrant becomes initially exercisable. As of September 30, 2020, all of the warrants from this offering were outstanding.

On June 25, 2019, we entered into an Open Market Sale Agreement[SM], 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, 2020, we sold and issued an aggregate of 19,161,452 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $21.5 million and net proceeds of $20.5 million, after deducting commissions to Jefferies and other offering expenses. During the three months ended September 30, 2020, we sold and issued an aggregate of 6,044,418 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $3.4 million and net proceeds of $3.3 million, after deducting commissions to Jefferies and other offering expenses. From September 30, 2020 and through the date of this filing we sold and issued an aggregate of 762,452 ordinary shares pursuant to the Jefferies ATM Agreement and received gross proceeds of $0.4 million and net proceeds of $0.4 million, after deducting commissions to Jefferies and other offering expenses.

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. In March 2020, we repaid Hercules $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement. 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 us and the costs and other conditions associated with this funding source.

As of September 30, 2020, we had cash and cash equivalents, restricted cash and short-term investments of $41.4 million.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2019 and 2020:

(in thousands)	Nine Months Ended September 30, 2019	2020
Net cash (used in) provided by:		
Operating activities	$ (56,405)	$ (57,967)
Investing activities	131	(257)
Financing activities	32,680	12,903
Effects of foreign currency translation on cash	(80)	262
Net decrease in cash, cash equivalents and restricted cash	**$ (23,674)**	**$ (45,059)**

Operating Activities

Cash flow used in operating activities increased by $1.6 million from $56.4 million for the nine months ended September 30, 2019 to $58.0 million for the nine months ended September 30, 2020 primarily due to a $7.3 million decrease in net loss, after adjustments for the impact of non-cash amounts included in net loss in both periods, offset by a higher working capital of $8.8 million primarily due to decreases in accrued expenses and other current liabilities.

Investing Activities

Cash flow used in investing activities for the purchase of property and equipment was $0.1 million for the nine months ended September 30, 2020.

Financing Activities

Cash flow generated from financing activities for the nine months ended September 30, 2020 was $12.9 million, primarily from total net proceeds of approximately $42.9 million from the securities purchase agreement entered into in May 2020, as well as our ATM Agreement, partly offset by the repayment of $30.0 million of long-term borrowings on our debt facility in the nine months ended September 30, 2020.

Operating and Capital Expenditure Requirements

We anticipate that our expenses will increase as we expect to incur additional significant 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, including for SIVEXTRO;
- 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, including additional community products;;
- maintain, expand and protect our intellectual property portfolio;
- expand our physical presence in the United States and Ireland; and,
- add operational, financial and management information systems and personnel, including personnel to support our product development, our operations as a public company and our planned commercialization efforts.

As described above, on March 11, 2020, we entered into an Amendment to our Loan Agreement with Hercules. Pursuant to the Amendment, we repaid Hercules in March 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. Under the Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately $2.1 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to $3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain. Based on our current operating plans, we expect that our existing cash resources will be sufficient to enable us to fund our operations, debt service obligations and capital expenditure requirements substantially through the first quarter of 2021. 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. This estimate also assumes that we remain in compliance with the covenants and no event of default occurs under the Loan Agreement.

We expect to continue to invest in critical commercial promotion and distribution, medical affairs and other commercialization activities, as well as investing in our supply chain for the commercialization of XENLETA, SIVEXTRO and the potential launch of CONTEPO. We expect to seek additional funding in future periods to support these activities.

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 to secure supply of SIVEXTRO and costs to sell and market the product in the U.S.;
- 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, SIVEXTRO 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 SIVEXTRO and the amount and frequency of reorders or product returns by our wholesale customers;

- subject to the resubmission of the CONTEPO NDA and potential receipt of marketing approval, revenue received from commercial sales of CONTEPO;
- the costs of developing XENLETA and CONTEPO for the treatment of additional indications;
- the impact of the COVID-19 pandemic;
- 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, including additional community products;
- the costs related to the promotion, sale and distribution of the products under our distribution agreement with Merck & Co., Inc.;
- 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 need to satisfy interest and principal obligations under our Loan Agreement with Hercules as well as the covenants contained in our Loan Agreement;
- 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.

Our commercial revenues, if any, will be derived from sales of XENLETA, SIVEXTRO, and if approved, CONTEPO or any other products that we successfully develop, in-license or acquire. In addition, XENLETA, SIVEXTRO 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, warrants 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.

In addition, as part of our corporate strategy, we continue to evaluate business development opportunities and potential collaborations. We may further expand our product pipeline through opportunistically in licensing or acquiring the rights to complementary products, product candidates and technologies for the treatment of a range of infectious diseases or other products that we would market with our commercial infrastructure, including additional community products, which could involve an acquisition of or combination or other strategic transaction with another operating business. To the extent any additional business development opportunity is consummated, our capital expenditures may increase significantly.

Capital Expenditures

Capital expenditures were $0.1 million and $0.1 million for the nine months ended September 30, 2019 and 2020, respectively. We made no significant investments in intangible assets during the nine months ended September 30, 2019 and 2020.

Currently, there are no material capital projects planned in 2020.

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. Our outstanding indebtedness with Hercules bears interest at the greater of 9.80% and 9.80% plus the prime rate of interest minus 5.50%. Based on the current prime rate, our outstanding indebtedness with Hercules bears interest at 9.80%. If the prime rate increases to over 5.50%, the interest on our loan with Hercules will increase.

Liquidity Risk

Since our inception, we have incurred net losses and generated negative cash flows from our operations. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain. We anticipate based on our current operating plans, that our existing cash, cash equivalents and short-term investments as of the date of this filing will be sufficient to enable us to fund our operating expenses, debt service obligations and capital expenditure requirements substantially through the

first quarter of 2021. 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.

We expect to continue to invest in critical commercial and medical affairs activities, as well as investing in our supply chain for the commercialization of XENLETA, SIVEXTRO and the potential launch of CONTEPO. We expect to seek additional funding in future periods to support these activities.

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.

There can be no assurance that we will be successful in acquiring additional capital at a 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 our commercialization efforts.

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, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable level of assurance.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) that occurred during the three months ended September 30, 2020 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. On November 18, 2019, the Company filed a pre-motion letter to dismiss with the Court, seeking leave to move to dismiss and setting forth why a motion to dismiss is warranted. On April 28, 2020, the Court dismissed the amended complaint without prejudice and granted plaintiff twenty days to show cause why the lawsuit should not be dismissed with prejudice. On May 8, 2020, the Court granted plaintiff a 21-day extension to show cause. On June 8, 2020, plaintiff filed a letter application to the court seeking leave to file a proposed second amended complaint, and on June 23, 2020, the court directed plaintiff to file the proposed second amended complaint. Plaintiff did so on June 24, 2020. The Company filed an answer to the second amended complaint on July 8, 2020.

On October 21, 2020, the parties mediated this case and reached a settlement, subject to court approval. The settlement will be covered in full by our directors’ and officers’ insurance.

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 $51.7 million for the nine months ended September 30, 2020, $82.8 million for the year ended December 31, 2019 and $114.8 million for the year ended December 31, 2018. As of September 30, 2020, we had an accumulated deficit of $528.4 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 the commercial sale of our products. XENLETA is approved in the United States for the treatment of community-acquired bacterial pneumonia, or CABP, in adults. In July 2020, we entered into a Sales Promotion and Distribution Agreement, with subsidiaries of Merck pursuant to which we licensed the right, subject to specified conditions, to promote, distribute and sell SIVEXTRO for acute bacterial skin and skin structure infections, or ABSSIs, caused by certain susceptible Gram-positive microorganisms in the United States and its territories, or the Territory. We recently secured a virtual and in-person community-based sales effort with Amplity Health, and in September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain. 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, the promotion and distribution efforts for SIVEXTRO, and, if it receives marketing approval, CONTEPO. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year.

We expect to continue to invest in critical commercial promotion and distribution, medical affairs and other commercialization activities, as well as investing in our supply chain for the commercialization of XENLETA, SIVEXTRO and the potential launch of CONTEPO. We expect to seek additional funding in future periods to support these activities. In December 2019, we resubmitted the NDA for CONTEPO. On June 19, 2020 we received a second Complete Response Letter from the FDA. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cites observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. On October 30, 2020, we participated in a Type A meeting with the FDA to obtain any new information related to the FDA's pending conduct of inspections of foreign manufacturers during the COVID-19 pandemic that has negatively impacted a number of FDA product reviews, including the CONTEPO NDA. The FDA informed us that it has not yet determined how it will conduct international inspections during the COVID-19 pandemic. As a result, next steps and specific timing of the CONTEPO NDA resubmission cannot be finalized until the FDA issues industry guidance. We and the industry await future communication from the FDA as it continues to assess the options available under existing regulations and laws to conduct these foreign facility inspections. We cannot predict the outcome of any further interactions with the FDA or when CONTEPO will receive marketing approval, if at all. Our contract manufacturers continue to interact with FDA to discuss its plans for conducting inspections at their sites. 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 or re-build a medical affairs, sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize XENLETA, SIVEXTRO and any other product candidates for which we receive marketing approval;
- in-license or acquire other products, product candidates or technologies, including additional community products;
- 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 and actively promote SIVEXTRO. On June 19, 2020 we received a second Complete Response Letter from the FDA in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cites observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. Our contract manufacturers continue to interact with FDA to discuss its plans for conducting inspections at their sites. On October 30, 2020, we participated in a Type A meeting with the FDA to obtain any new information related to the FDA's pending conduct of inspections of foreign manufacturers during the COVID-19 pandemic that has negatively impacted a number of FDA product reviews, including the CONTEPO NDA. The FDA informed us that it has not yet determined how it will conduct international inspections during the COVID-19 pandemic. As a result, next steps and specific timing of the CONTEPO NDA resubmission cannot be finalized until the FDA issues industry guidance. We and the industry await future communication from the FDA as it continues to assess the options available under existing regulations and laws to conduct these foreign facility inspections. We cannot predict the outcome of any further interactions with the FDA or when CONTEPO will receive marketing approval, if at all. In April 2020, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort. This restructuring intended to reduce costs and to align the capabilities of our sales effort with our strategic re-focus on making sales of XENLETA to community health care professionals. This

restructuring resulted in the termination of 66 employees, consisting of our entire hospital-based sales personnel and certain members of our sales force leadership team. Additional reductions in headcount occurred in the third quarter of 2020 including the restructuring of the commercial organization, which led to the elimination of the role of the Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. We recently secured a virtual and in-person community-based sales effort with Amplity Health, and in September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain. Our ability to generate significant revenue will require us to be successful in a range of challenging activities, including:

- maintaining and expanding a community-based sales effort;
- obtaining marketing approval for CONTEPO;
- establishing and maintaining medical affairs, sales, marketing and distribution capabilities to effectively market and sell XENLETA, SIVEXTRO 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, SIVEXTRO and CONTEPO, if approved; and
- negotiating and securing adequate reimbursement from third-party payors for XENLETA, SIVEXTRO 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, conduct commercial activities, maintain our commercial efforts 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. These activities include the commercialization of XENLETA and SIVEXTRO, the process of obtaining marketing approval for CONTEPO and, possibly, other product candidates, and our ongoing 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 further delay, reduce or eliminate our research and development programs or reduce our commercialization efforts.

On March 11, 2020, we entered into an amendment, or the Amendment, to our Loan and Security Agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, as administrative agent, collateral agent and lender. Pursuant to the Amendment, we repaid Hercules in March 2020, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement, which we refer to as the Prepayment. We determined to enter into the Amendment following the effectiveness of a performance covenant in February 2020 under which we became obligated to either (1) achieve 80% of our net product revenue sales target over a trailing six-month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or $40.0 million, which we refer to as the liquidity requirement. Under the Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately $2.1 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to $3.0 million in cash and cash equivalents, in each case, following the Prepayment. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales are uncertain. Based on our current operating plans, we expect that our existing cash resources will be sufficient to enable us to fund our operations, debt service obligations and capital expenditure requirements substantially through the first quarter of 2021. 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. This estimate also assumes that we remain in compliance with the covenants and no event of default occurs under the Loan Agreement.

We expect to continue to invest in critical commercial and medical affairs activities, as well as investing in our supply chain for the commercialization of XENLETA and SIVEXTRO and the potential launch of CONTEPO. We expect to seek additional funding in future periods to support these activities.

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, SIVEXTRO 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, SIVEXTRO and, subject to the resubmission of the CONTEPO NDA and potential receipt of marketing approval, CONTEPO;
- the costs of developing XENLETA and CONTEPO for the treatment of additional indications;
- the impact of the COVID-19 pandemic;
- 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, including additional community products;
- 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 costs of our physical presence in the United States and Ireland;
- interest expense on our debt and the eventual repayment of our debt obligations;
- the requirement to keep minimum cash balances per the terms of our debt obligations as well as our ability to remain in compliance with our debt covenants;
- 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, SIVEXTRO, and from CONTEPO, if approved, or any other products that we successfully develop, in-license or acquire. XENLETA, SIVEXTRO or, if approved, CONTEPO or any other product candidate that we develop, in-license or acquire may not achieve commercial success. Additionally, the termination of our sales force may adversely impact our sales of XENLETA. If we fail to generate sufficient revenues from the sale of XENLETA, SIVEXTRO 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, as part of our corporate strategy, we continue to evaluate business development opportunities and potential collaborations. We may further expand our product pipeline through opportunistically in licensing or acquiring the rights to complementary products, product candidates and technologies for the treatment of a range of infectious diseases or other products that we would market with our commercial infrastructure, including additional community products, which could involve an acquisition of or combination or other strategic transaction with another operating business. To the extent any additional business development opportunity is consummated, our capital expenditures may increase significantly.

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[SM], 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 $50.0 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 19,923,904 ordinary shares under the Jefferies ATM Agreement, for gross proceeds of $21.9 million, and net proceeds of $20.9 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.

On May 29, 2020, we entered into a securities purchase agreement with certain institutional investors, including Fidelity Management & Research Company, LLC pursuant to which we issued and sold in a registered direct offering an aggregate of 41,445,373 ordinary shares and accompanying warrants to purchase up to an aggregate of 41,445,373 ordinary shares. Each share we issued and sold together with an accompanying warrant at a combined price of $0.91686. The gross proceeds to us from the offering, before deducting the placement agent's fees and other offering expenses payable by us were $38.0 million. Each warrant has an exercise price of $0.792 per share, was immediately exercisable and will expire on the two-year anniversary of the exercise date.

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, the commercial launch of XENLETA and the direct selling of SIVEXTRO. 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 are in the process of

transitioning 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.

As of December 31, 2019, under our Loan Agreement with Hercules, we had 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. On March 11, 2020, we entered into the Amendment to the Loan Agreement, pursuant to which we repaid Hercules in March, $30.0 million of the $35.0 million in aggregate principal amount of debt outstanding under the Loan Agreement. As of September 30, 2020, there remains outstanding $5.0 million in principal amount under the Loan Agreement, and we may request to borrow an additional $5.0 million subject to the lender's sole discretion.

All obligations under the Loan Agreement are secured by substantially all of our personal property, intellectual property and other assets owned or later acquired by us and our subsidiaries. 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; and

- the need to maintain minimum cash balances under specified circumstances, which restricts our ability to invest in the business and fund our operations.

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 or to comply with minimum cash balance requirements.

Failure to satisfy our current and future debt obligations under the Loan Agreement, or the occurrence of a material adverse effect as defined in 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 contained a performance covenant that became effective in February 2020 under which we became obligated to either (1) achieve 80% of our net product revenue sales target over the trailing six month period, or (2) maintain an amount of cash and cash equivalents in accounts pledged to Hercules plus a specified amount of eligible accounts receivables equal to the greater of the amount outstanding under the Loan Agreement or $40.0 million. Since we did not achieve our net product sales targets, we became obligated to maintain compliance with the liquidity requirement under the Loan Agreement. As a result, we entered into an Amendment to the Loan Agreement with Hercules. Under the Amendment, we and Hercules agreed to defer the end of term loan charge payment in the amount of approximately $2.1 million that would have otherwise become payable on the date of the Prepayment and to reduce the prepayment charge with respect to the Prepayment from $600,000 to $300,000 and to defer its payment, in each case, until June 1, 2023 or such earlier date on which all loans under the Loan Agreement are repaid or become due and payable. The Amendment also reset the revenue performance covenant to 70% of targeted revenue based on a revised net product revenue forecast and lowered our minimum liquidity requirement to $3.0 million in cash and cash equivalents. The new minimum liquidity requirement will not apply if CONTEPO receives regulatory approval from the U.S. Food and Drug Administration and we achieve at least 70% of our revised net product revenue targets under the Loan Agreement.

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 complaint includes allegations similar to those made in the original complaints and seeks similar relief. Our pre-motion letter to dismiss the amended complaint was due to plaintiff on October 21, 2019, and plaintiff responded to us via letter on November 4, 2019. On November 18, 2019, we filed a pre-motion letter to

dismiss with the Court, seeking leave to move to dismiss and setting forth why a motion to dismiss is warranted. On April 28, 2020, the Court dismissed the amended complaint without prejudice and granted plaintiff twenty days to show cause why the lawsuit should not be dismissed with prejudice. On May 8, 2020, the Court granted plaintiff a 21-day extension to show cause. On June 8, 2020, plaintiff filed a letter application to the court seeking leave to file a proposed second amended complaint, and on June 23, 2020, the court directed plaintiff to file the proposed second amended complaint. Plaintiff did so on June 24, 2020. We filed an answer to the second amended complaint on July 8, 2020. On October 21, 2020, the parties mediated this case and reached a settlement, subject to court approval. The settlement will be covered in full by our directors' and officers' insurance.

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 $2.4 million for the year ended December 31, 2018 and $4.7 million for the year ended December 31, 2017. We have not received any research premium for our qualified 2019 and 2020 expenditures as of September 30, 2020. As we 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

Business interruptions resulting from the SARS-CoV-2 infection causing COVID-19 outbreak or similar public health crises could cause a disruption of the development of our product candidates and adversely impact our business.

Beginning in 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, surfaced in Wuhan, China and has spread to countries across the world, including Ireland, Austria and the United States, where our offices and laboratory space are located. COVID-19 is causing federal, state and local governments to implement measures to slow the spread of the outbreak through quarantines, strict travel restrictions and bans, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen significantly.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, business closures, school closures, travel restrictions and other public health safety measures, as well as reported adverse impacts on healthcare resources, facilities and providers across the United States and in other countries including Ireland and Austria. The extent to which COVID-19 further impacts our operations or those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and the actions to contain COVID-19 or address its impact in the short and long term, among others.

Additionally, timely completion of clinical trials is dependent upon the availability of, for example, clinical trial sites, researchers and investigators, site monitors, screening of study subjects, regulatory agency personnel, and materials, which may be adversely affected by global health matters, such as pandemics. We are conducting a clinical trial that has been delayed by COVID-19.

In particular, shelter-in-place orders and other mandated local travel prohibitions restricted the activities of our sales force and caused us to determine to terminate our entire hospital-based sales force in April 2020. Furthermore, the majority of our day-to-day operations are continuing while our employees are working remotely.

We have implemented a work-from-home policy for all of our U.S. employees, and we may take further actions that alter our operations as may be required by federal, state, or local authorities, or which we determine are in our best interests. While most of our operations can be performed remotely, there is no guarantee that we will be as effective while working remotely because our team is dispersed, many employees may have additional personal needs to attend to (such as looking after children as a result of school closures or family who become sick), and employees may become sick themselves and be unable to work. Decreased effectiveness of our team could adversely affect our results due to our inability to meet in person with customers and physicians, or other decreases in productivity that could seriously harm our business.

The effects of COVID-19 disrupted the FDA's review of our NDA for CONTEPO. On March 10, 2020, the FDA announced that it would restrict travel of its employees to Europe for inspections as a result of the spread of COVID-19. On June 19, 2020 we received a Complete Response Letter for CONTEPO in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cites observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. We do not have a forecasted date for the resubmission of the CONTEPO NDA.

Additionally, certain of the activities of our collaborator, Sinovant, have been delayed in China. If these delays continue and impact Sinovant's efforts to develop and commercialize lefamulin in China, our receipt of future milestone payments or potential royalties on sales of the Sinovant Licensed Products may be delayed. Also, the spread of COVID-19 may affect the ability of our third-party manufacturers to supply XENLETA, CONTEPO or any future product candidates. We recently secured a virtual and in-person community-based sales effort with Amplity Health, and in September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain.

The COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also

impact the volatility of our ordinary share price and trading in our ordinary shares. Moreover, the significant ongoing impact of the pandemic on economies worldwide could result in more extensive adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to significantly and adversely affect our business, financial condition, results of operations and prospects.

In April 2020, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort.

In April 2020, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort. This restructuring reduced costs to align the capabilities of our sales efforts with our strategic re-focus on making sales of XENLETA to community health care professionals, This restructuring resulted in the termination of 66 employees, consisting of our entire hospital-based sales personnel and certain members of our sales force leadership team. Additional reductions in headcount occurred in the third quarter of 2020 including the restructuring of the commercial organization, which led to the elimination of the role of the Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. This restructuring has resulted and may continue to result in less revenue during the time when we have no or limited sales efforts. We recently secured a virtual and in-person community-based sales effort with Amplity Health, and in September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain.

We depend heavily on the success of XENLETA, which the FDA has approved for oral and intravenous use for the treatment of CABP, SIVEXTRO, approved by the FDA for oral and intravenous use of adults and adolescents for the treatment of ABSSSI, 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, SIVEXTRO 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.

On August 19, 2019, the FDA approved the oral and intravenous formulations of XENLETA. On July 28, 2020, the European Commission issued a legally binding decision for approval of the marketing authorization application for XENLETA for the treatment of community-acquired pneumonia in adults following a review by the European Medicines Agency. Sunovion Pharmaceuticals Canada Inc. additionally received approval from Health Canada to market oral and intravenous formulations of XENLETA for the treatment of community-acquired pneumonia in adults, with the Notice of Compliance from Health Canada dated July 10, 2020. We have entered into a license and commercialization agreement in March 2019 with Sunovion Pharmaceuticals Canada Inc. for XENLETA in Canada. 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. Due to the COVID-19 pandemic, sites were closed to enrollment in 1Q2020; starting in July 2020, some sites are re-opening for screening of potential subjects if allowed by their institution.

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 December 2019, we resubmitted the NDA for CONTEPO. On June 19, 2020 we received a second Complete Response Letter from the FDA. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cites observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. We do not have a forecasted date for the resubmission of the CONTEPO NDA. On October 30, 2020, we participated in a Type A meeting with the FDA to obtain any new information related to the FDA´s pending conduct of inspections of foreign manufacturers during the COVID-19 pandemic that has negatively impacted a number of FDA product reviews, including the CONTEPO NDA. The FDA informed us that it has not yet determined how it will

conduct international inspections during the COVID-19 pandemic. As a result, next steps and specific timing of the CONTEPO NDA resubmission cannot be finalized until the FDA issues industry guidance. We and the industry await future communication from the FDA as it continues to assess the options available under existing regulations and laws to conduct these foreign facility inspections. We cannot predict the outcome of any further interactions with the FDA or when CONTEPO will receive marketing approval, if at all.

In June 2018, we 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. Completion remains uncertain due to delays related to the COVID 19 pandemic. We also intend to continue to characterize the clinical pharmacology of CONTEPO.

In July 2020, we entered into a Sales Promotion and Distribution Agreement, or the Distribution Agreement, with subsidiaries of Merck pursuant to which we licensed the right, subject to specified conditions, to promote, distribute and sell SIVEXTRO for acute bacterial skin and skin structure infections, or ABSSIs, caused by certain susceptible Gram-positive microorganisms in the United States and its territories, or the Territory.

We expect to incur significant additional sales, marketing, distribution and manufacturing expenses for the commercialization of XENLETA, SIVEXTRO and CONTEPO, if approved. We expect to continue to invest in critical commercial promotion and distribution, medical affairs and other commercialization activities, as well as investing in our supply chain for the commercialization of XENLETA, SIVEXTRO and the potential launch of CONTEPO. We expect to seek additional funding in future periods to support these activities.

Our ability to generate meaningful product revenues will depend heavily on the successful commercialization of XENLETA and SIVEXTRO and our obtaining marketing approval for CONTEPO. In April 2020, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort. This restructuring was intended to reduce costs and to align the capabilities of our sales efforts with our strategic re-focus on making sales of XENLETA to community health care professionals. This restructuring resulted in the termination of 66 employees, consisting of our entire hospital-based sales personnel and certain members of our sales force leadership team. Additional reductions in headcount occurred in the third quarter of 2020 including the restructuring of the commercial organization, which led to the elimination of the role of the Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. This restructuring may result in less revenue during the time when we have no or limited sales efforts. We recently secured a virtual and in-person community-based sales effort with Amplity Health, and in September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain. The success of XENLETA, SIVEXTRO 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;
- the resubmission of the CONTEPO NDA and potential receipt of marketing approval from the FDA for CONTEPO for the treatment of cUTI, including AP;
- re-establishing an effective sales and marketing organization to successfully generate recurring sales of XENLETA, SIVEXTRO and, if and when approved, CONTEPO;
- acceptance of XENLETA, SIVEXTRO and, if and when approved, CONTEPO by patients, the medical community and third-party payors, including hospital formularies;
- achieving approval of favorable prescribing information;

- effectively competing with other therapies;
- the continued acceptable safety profile of XENLETA, SIVEXTRO and, if approved, CONTEPO;
- securing contracts to allow XENLETA, SIVEXTRO 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;
- protecting our rights in our intellectual property portfolio;
- obtaining and maintaining adequate distribution levels of XENLETA, SIVEXTRO and, if approved, CONTEPO at all appropriate trade channels; and
- resolution of the COVID-19 pandemic.

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.

XENLETA, SIVEXTRO 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, SIVEXTRO 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, ABSSSI and cUTI, including generic options, are well established in the medical community, and doctors may continue to rely on these treatments without XENLETA, SIVEXTRO, CONTEPO or any of our other product candidates. In addition, our efforts to effectively communicate the differentiating characteristics and key attributes of XENLETA, SIVEXTRO, CONTEPO or any of our other product candidates to clinicians and hospital pharmacies with the goal of establishing favorable formulary status for XENLETA, SIVEXTRO, CONTEPO or any of our other product candidates may fail or may be less successful than we expect. If XENLETA, SIVEXTRO, 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, SIVEXTRO, 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;
- the timing of any marketing approval in relation to other approvals of competitive products; and
- obtaining and maintaining adequate distribution of our products to the appropriate trade channels.

Bacteria might develop resistance to XENLETA, SIVEXTRO, CONTEPO or any future product candidates more rapidly or to a greater degree than we anticipate. If bacteria develop resistance or if XENLETA, SIVEXTRO, 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.

Hospital formulary approval of XENLETA, SIVEXTRO, CONTEPO or any future product candidates is an important component of our commercialization strategy. Accordingly, sales of IV formulations of XENLETA, SIVEXTRO, CONTEPO or any future IV product candidates will depend substantially on the extent to which hospital formulary approval is obtained. Hospital formulary approval may depend upon several factors, including the determination that use of a product is:

- safe, effective and medically necessary;
- appropriate for the specific patient population;
- cost-effective; and
- neither experimental nor investigational.

Obtaining formulary approval from third-party payors can be an expensive and time-consuming process that will require us to provide supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to hospital formulary approval. We cannot be certain if and when we will obtain hospital formulary approval to allow us to sell XENLETA, SIVEXTRO, CONTEPO or any future product candidates into our target markets. Even if we do obtain hospital 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. Increasing efforts by hospitals in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit formulary approval. We have experienced and expect to continue to experience pricing pressures in connection with the sale of XENLETA in the hospital setting due to the trend toward reducing hospital costs, managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. These and other similar developments could significantly limit the degree of market acceptance of XENLETA, SIVEXTRO, CONTEPO or any of our other product candidates that receive marketing approval. To address this uncertainty, in early 2020 we began to utilize our hospital based sales force to call upon approximately 6,000 high prescriber community doctors in an effort to potentially increase our penetration rates in the community setting while maintaining sales efforts in the hospital setting before determining to terminate our entire sales force. This effort ceased with the termination of our entire hospital-based sales force in April 2020. Additional reductions in headcount occurred in the third quarter of 2020 including the restructuring of the commercial organization, which led to the elimination of the role of the Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. We recently secured a virtual and in-person community-based sales effort with Amplity Health, and in September 2020,

we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain.

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, SIVEXTRO, 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 commercializing. To achieve commercial success for XENLETA, SIVEXTRO and any other approved product, we must re- establish and maintain an adequate sales, marketing, commercial operations, patient access and distribution organization or outsource these functions to third parties. We recently secured a virtual and in-person community-based sales effort with Amplity Health, and in September 2020, we began a small and focused sales effort for SIVEXTRO and XENLETA, by utilizing 15 sales representatives. We plan to expand this effort to 60 sales representatives in November 2020. In light of the COVID-19 pandemic, the associated disruption to the healthcare delivery and the uncertainty of resuming full direct physician promotion, future sales in 2020 are uncertain. 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 targeted sales efforts, 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, SIVEXTRO 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;
- the COVID-19 pandemic;
- unforeseen costs and expenses associated with creating an independent sales, marketing, commercial operations, patient access and distribution organization; and
- a change in strategy resulting in the decrease or elimination of sales personnel.

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 re-establish and maintain sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing XENLETA, SIVEXTRO, or, if approved, CONTEPO.

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, SIVEXTRO, 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, ABSSSI and cUTI. Currently the treatment of CABP, ABSSSI and cUTI is dominated by generic products. For both hospitalized and community patients, combination therapy is frequently used in CABP, ABSSSI 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 and ABSSSI. We also are aware of various drugs under development or recently approved by the FDA for the treatment of CABP and ABSSSI, including omadacycline (approved by the FDA in October 2018 on behalf of Paratek Pharmaceuticals Inc. for both CABP and ABSSSI), delafloxacin (approved by the FDA for ABSSSI in June 2017 and expanded for CABP in October 2019 on behalf of Melinta Therapeutics Inc.), and oral nafithromycin (under Phase 2 clinical development by Wockhardt Ltd. for CABP). 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 by the FDA in July 2019 on behalf of Merck & Co., Inc.), cefiderocol (Fetroja approved by the FDA in November 2019 on behalf of Shionogi Inc.), cefepime-taniborbactam (under Phase 3 clinical development by Venatorx Pharmaceuticals), Cefepime-enmetazobactam (under Phase 3 clinical development by Allecra Therapeutics), 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, SIVEXTRO and if approved, 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, SIVEXTRO 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, SIVEXTRO, 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, SIVEXTRO, CONTEPO or any other product candidate successfully also will depend in part on its availability on hospital formularies and 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, SIVEXTRO, 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, SIVEXTRO 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, SIVEXTRO and CONTEPO. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize XENLETA, SIVEXTRO, 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 particularly in the hospital, 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.

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, or the FDA may conduct its own analyses and modify analysis populations which could lead to different numerical results or conclusions.

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;
- ongoing or future restrictions resulting from the COVID-19 pandemic and its collateral consequences may result in internal and external operational delays and limitations; 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, including our Phase 1 clinical trial of IV XENLETA in pediatric patients. In addition, the COVID-19 pandemic has resulted in enrollment suspension globally for many 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;
- 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;
- restrictions resulting from the COVID-19 pandemic and its collateral consequences; and
- willingness of potential patients to participate in our trials; 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, SIVEXTRO, or 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 our 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.

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 will be procuring supply of SIVEXTRO from Merck & Co., Inc.

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 is not a commercial supplier of pleuromutilin for us. We have identified and entered into a commercial supply agreement with an alternative supplier that provides 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, or API. We have initiated engagement with a potential secondary supplier to synthesize XENLETA, with a preliminary technology transfer and pilot scale manufacture. However, our current operating plans do not include completing technology transfer, scale-up and validation of this potential secondary supplier until they have demonstrated that they can successful manufacture the API at pilot scale and until 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, to support 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. Alternatively, we may elect to have secondary packaging and serialization of CONTEPO completed under our existing commercial packaging and supply agreement with Sharp Corporation. We also entered into 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. Also, the spread of COVID-19 may affect the ability of our third-party manufacturers to supply XENLETA, CONTEPO or any future product candidates.

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. In December 2019, we resubmitted the NDA for CONTEPO. On June 19, 2020 we received a second Complete Response Letter from the FDA. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cites observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. We do not have a forecasted date for the resubmission of the CONTEPO NDA. On October 30, 2020, we participated in a Type A meeting with the FDA to obtain any new information related to the FDA´s pending conduct of inspections of foreign manufacturers during the COVID-19 pandemic that has negatively impacted a number of FDA product reviews, including the CONTEPO NDA. The FDA informed us that it has not yet determined how it will conduct international inspections during the COVID-19 pandemic. As a result, next steps and specific timing of the CONTEPO NDA resubmission cannot be finalized until the FDA issues industry guidance. We and the industry await future communication from the FDA as it continues to assess the options available under existing regulations and laws to conduct these foreign facility inspections. Our contract manufacturers continue to interact with FDA to discuss its plans for conducting inspections at their sites. If these manufacturing issues are not resolved to the FDA's satisfaction, or if we or any of our third-party manufacturers, or suppliers are the subject of any other open or unresolved regulatory inspections, inspection reports, or FDA Form 483s identifying noncompliance with applicable regulations, we would 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 products, or the drug substances used to manufacture them, it will be more difficult for us to develop or commercialize 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 revenues and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis. In addition, slower than forecasted commercialization of our products in approved territories may adversely affect our profit margins and uninterrupted supply of our product as a result of our potential failure to comply with contractual minimum order commitments with our third party suppliers.

We have entered into a Sales Promotion and Distribution Agreement with Merck & Co. related to the promotion, distribution and sale of SIVEXTRO. If our collaboration with Merck is not successful, we may incur significant expenses related to the distribution of SIVEXTRO without realizing any value from the agreement.

In July 2020, we entered into a Sales Promotion and Distribution Agreement, or the Distribution Agreement, with subsidiaries of Merck pursuant to which we licensed the right, subject to specified conditions, to promote, distribute and sell SIVEXTRO for acute bacterial skin and skin structure infections, or ABSSIs, caused by certain susceptible Gram-positive microorganisms in the United States and its territories, or the Territory.

Under the Distribution Agreement and subject to the fulfillment of certain conditions, including our engaging sufficient sales representatives, restrictions relating to travel and physician office access in the Territory due to COVID-19 having continued to decrease in a sufficient portion of the Territory so as not to hinder the successful detailing of SIVEXTRO, we have been granted the right to initially promote SIVEXTRO in the Territory and, upon satisfaction of additional conditions, including an increase in the number of our sales representatives, the right to exclusively distribute SIVEXTRO in the Territory, including the sole right and responsibility to fill orders with respect to SIVEXTRO in the Territory.

Before we were permitted to sell SIVEXTRO under the Distribution Agreement, we were required to secure a sales force of a certain size and the restrictions related to COVID-19 must be eased in a sufficient manner to permit us to promote and distribute SIVEXTRO. Re-securing a sales force for the promotion and distribution of SIVEXTRO will result in significant additional expense and our efforts to secure a sales force may not be successful.

Furthermore, a subsidiary of Merck will sell, and we have agreed to purchase, SIVEXTRO at specified prices in such quantities as we may specify. Although we are entitled, subject to appliable law, to determine the final selling prices of SIVEXTRO in our sole discretion, subject to an overall annual limit on price increases, we may not be able to sell SIVEXTRO at prices high enough to recoup our investment in a sales force and other commercialization activities. In addition, we will rely on a subsidiary of Merck to supply SIVEXTRO to us, who in turn, relies on third party manufacturers for the production, packaging, and serialization of SIVEXTRO for our distribution. Relying on a third-party manufacturer subjects us to a number of additional risks. See “Risk Factors—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 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 are commercializing XENLETA and expect to commercialize CONTEPO, if approved, in the United States with targeted sales and marketing efforts. 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 we have also entered into a license agreement 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 agreements with Sinovant and Sunovion, 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 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 we agree 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 or not covered by insurance, 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, products or product candidates from third parties, 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, maintained 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, products or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies, products and product candidates. 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, products or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products and product candidates 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 technology, products or 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 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, time consuming and a distraction to management. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging our patents, trademarks, copyrights or other intellectual property are invalid or unenforceable or 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, product candidates 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 products and 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 technology, products and product candidates. 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, products or product candidates. 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 technology, products and 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 patents and 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 patent rights from Sandoz, we must rely on their prior practices, with regard to the assignment of such intellectual property. Similarly, for any patents and 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 our trade secrets, know-how, technology and other proprietary information, 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 and other confidential information 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. Further, on July 28, 2020, the European Commission issued a legally binding decision for approval of the marketing authorization application for XENLETA for the treatment of community-acquired pneumonia in adults following a review by the European Medicines Agency. Sunovion Pharmaceuticals Canada Inc. additionally received approval from Health Canada to market oral and intravenous formulations of XENLETA for the treatment of community-acquired pneumonia in adults, with the Notice of Compliance from Health Canada dated July 10, 2020. We have entered into a license and commercialization agreement in March 2019 with Sunovion Pharmaceuticals Canada Inc. for XENLETA in Canada. We have not received approval to market XENLETA in any jurisdiction other than those mentioned above 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. In December 2019, we resubmitted the NDA for CONTEPO. On June 19, 2020 we received a second Complete Response Letter from the FDA. Although our European contract manufacturing partners were prepared for regulatory authority inspections, the CRL cites observations at our manufacturing partners that could not be resolved due to FDA's inability to conduct onsite inspections because of travel restrictions. We do not have a forecasted date for the resubmission of the CONTEPO NDA.

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, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). The Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. Negotiations between the United Kingdom and EU towards a trade agreement have been progressing, but recently have been subject to late negotiation brinkmanship. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

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 subject to 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 have delayed the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which has adversely affected our business. The FDA announced that in order to bring new therapies to patients sick with COVID-19 as quickly as possible, it has redeployed medical and regulatory staff from other areas to work on COVID-19 therapies. On June 19, 2020 we received a second Complete Response Letter in connection with our NDA for CONTEPO for the treatment of cUTIs, including AP due to issues at our third party manufacturers that could not be inspected by the FDA owing to operational restrictions placed on the FDA by COVID-19. Additionally, 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 an 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 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, and we resubmitted the NDA in December 2019, 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. We cannot predict whether these Executive Orders will be canceled or repealed or whether there will be new government regulations that may arise from future legislation or administrative or executive action, that could prevent, limit or delay regulatory approval of our product candidates.

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, SIVEXTRO, 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, SIVEXTRO, 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 a minimum of $11,181 and a maximum of $22,363 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, SIVEXTRO, 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 2029 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. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended 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." The Congress may consider other legislation to replace elements of the ACA during the next Congressional session.

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. This decision is under review by the U.S. Supreme Court during its current term. The full 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, 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 recently represented to the Court of Appeals considering this judgment that it does not oppose the lower court's ruling. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. On December 18, 2019, that court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. On January 21, 2020, the U.S. Supreme Court declined to review this decision on an expedited basis. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. On November. 10, 2020 the U.S. Supreme Court will hear arguments on whether the ACA is constitutional, in whole or in part. The court is expected to rule on the matter before its term ends in June 2021.

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. In addition, on December 23, 2019, the Trump Administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, FDA issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products). More recently, President Trump issued additional executive orders that are intended to lower the costs of prescription drug products.

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.

We are increasingly dependent upon technology systems and data to operate our business. In particular, the COVID-19 pandemic has caused us to modify our business practices, including the requirement that our office-based employees work from home. As a result, we are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data.

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 payable in cash 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 that may be settled in ordinary shares 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

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 team. 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 personnel, including in the United States and Ireland where we have key business processes, 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. Our functional teams are small and therefore attrition can lead to gaps in institutional knowledge and risks to running the business. 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 recently reduced the size of our organization, and we may encounter difficulties in managing our business as a result of this reduction, or the attrition that may occur following this reduction, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from the reduction.

In April 2020, we announced a plan to restructure our hospital-based commercial sales force and transition to a community-based sales effort. Additional reductions in headcount occurred in the third quarter including the restructuring of the commercial organization, which led to the elimination of the role of the Chief Commercial Officer. Our commercial operations now report directly to our Chief Executive Officer. The restructuring is intended to reduce costs and to align the capabilities of our sales efforts with our strategic re-focus on making sales of XENLETA to community health care professionals, as well as our business development strategy to in-license additional community products, such as SIVEXTRO and additional community products. The restructuring resulted in the termination of long-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity and nature of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel. This will be made more challenging given the restructuring described above and additional measures we may take to reduce costs. As a result, our management may need to divert a disproportionate amount of its attention away from our day-to-day strategic and operational activities and devote a substantial amount of time to managing these organizational changes. Further, the restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended reduction in headcount and reduced employee morale. In addition, the restructuring may result in employees who were not affected by the reduction in headcount seeking alternate employment, which would result in us seeking contract support at unplanned additional expense. In addition, we may not achieve anticipated benefits from the restructuring. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may also determine to take additional measures to reduce costs, which could result in further disruptions to our operations and present additional challenges to the effective management of our company. If our management is unable to effectively manage this transition and restructuring and additional cost containment measures, our expenses may be more than expected, and we may not be able to implement our business strategy.

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 Select 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 and the intravenous formulation of CONTEPO, if approved;
- our ability to promote and distribute SIVEXTRO;
- our ability to obtain FDA approval of CONTEPO;
- 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 or regions;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key 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, including additional community products;
- one or more of our manufacturers or suppliers could have an event which causes an unforeseen disruption of the manufacture or supply of our product candidates;
- our ability to comply with the restrictive covenants under our Loan Agreement and avoid an event of default that may lead to an acceleration of the amounts due under the Loan Agreement;
- 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;
- our need to raise additional funds;
- the societal and economic impact of public health epidemics, such as the ongoing COVID-19 pandemic;

- 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, SIVEXTRO or, if approved, CONTEPO or any of our other product candidates or if our securities experience volatility for any reason. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources. 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.*".

The number of shares of ordinary shares underlying our outstanding warrants is significant in relation to our currently outstanding ordinary shares, which could have a negative effect on the market price of our ordinary shares and make it more difficult for us to raise funds through future equity offerings.

As part of our May 2020 registered direct offering, we issued warrants to purchase an aggregate of up to 41,445,373 ordinary shares at an exercise price of $0.792 per share. As part of our December 2019 registered direct offering, we issued warrants to purchase an aggregate of up to 13,793,106 shares of ordinary shares at an exercise price of $1.90 per share. Substantially all of these warrants remain outstanding and, upon exercise in full of these warrants, the shares issuable upon exercise would represent a significant portion of our outstanding ordinary shares. Each of the December 2019 warrants is initially exercisable six months following the date of issuance, which was December 24, 2019, and will expire on the three-year anniversary of the date on which such warrants became initially exercisable. Each of the May 2020 warrants is initially exercisable and will expire on the two-year anniversary of the date of issuance. We have registered the issuance of shares upon exercise of these warrants under a registration statement under the Securities Act of 1933, as amended, and, accordingly, such shares can be freely sold into the public market upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares could cause the market price of our ordinary shares to decline significantly. Furthermore, if our share price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our ordinary shares and reduce or eliminate any appreciation in our share price that might otherwise occur. As of September 30, 2020, there were 54,388,479 warrants outstanding from both offerings.

We may also find it more difficult to raise additional equity capital while these warrants are outstanding. At any time during which these warrants are likely to be exercised, we may be unable to obtain additional equity capital on more favorable terms from other sources. In addition, the exercise of these warrants would result in a significant increase in the number of our outstanding ordinary shares, which could have the effect of significantly diluting the interest of our current shareholders, and following such exercise the former holders of such warrants could have significant influence over our company as a result of the ordinary shares they acquire upon such exercise.

If we fail to meet the requirements for continued listing on The Nasdaq Global Select Market, our ordinary shares could be delisted from trading, which would decrease the liquidity of our ordinary shares and our ability to raise additional capital.

Our ordinary shares are currently listed for quotation on The Nasdaq Global Select Market. We are required to meet specified requirements in order to maintain our listing on The Nasdaq Global Select Market, including, among other things, a minimum bid price of $1.00 per share.

On April 29, 2020, we received written notice from The Nasdaq Stock Market LLC, or Nasdaq, indicating that, based on the closing bid for the last 30 consecutive business days, we are not in compliance with the $1.00

minimum bid price requirement for continued listing on The Nasdaq Global Select Market, as set forth in Listing Rule 5450(a)(1), or the Bid Price Rule. The notice did not result in the immediate delisting of our ordinary shares from The Nasdaq Global Select Market. In accordance with Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days to regain compliance with the Bid Price Rule. However, due to recent market conditions, Nasdaq has determined to toll the compliance period for the Bid Price Rule through June 30, 2020. As a result, the compliance period for the Bid Price Rule will be reinstated on July 1, 2020 and we will have until December 28, 2020, or the Compliance Date, to regain compliance with the Bid Price Rule. To regain compliance, the closing bid price of our ordinary shares must be at least $1.00 per share for a minimum of ten consecutive business days on or before the Compliance Date. If we do not regain compliance with the Bid Price Rule by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. In addition to continuing to monitor the closing bid price of our ordinary shares, we expect to consider available options to regain compliance with the Bid Price Rule, which could include seeking to effect a reverse stock split. However, there can be no assurance that we will be able to regain compliance with the Bid Price Rule.

If we do not regain compliance with the Bid Price Rule by the Compliance Date or if in the future we fail to satisfy The Nasdaq Global Select Market's other continued listing requirements, we may transfer to The Nasdaq Capital Market, which generally has lower financial requirements for initial listing, to avoid delisting, or, if we fail to meet its listing requirements, the OTC Bulletin Board. A transfer of our listing to The Nasdaq Capital Market or having our ordinary shares trade on the OTC Bulletin Board could adversely affect the liquidity of our ordinary shares. Any such event could make it more difficult to dispose of, or obtain accurate quotations for the price of, our ordinary shares, and there also would likely be a reduction in our coverage by securities analysts and the news media, which could cause the price of our ordinary shares to decline further. We may also face other material adverse consequences in such event, such as negative publicity, a decreased ability to obtain additional financing, diminished investor and/or employee confidence, and the loss of business development opportunities, some or all of which may contribute to a further decline in our share price.

At our Annual Shareholders Meeting on July 29, 2020, our shareholders approved, subject to and conditional upon the board of directors determining, in its sole discretion, that a reverse stock split is necessary for us to comply with the minimum $1.00 per share requirement pursuant to Nasdaq Listing Rule 5450(a)(1), or the Bid Price Rule, a reverse stock split (i.e., a consolidation of share capital under Irish law) whereby every 10 ordinary shares of $0.01 (nominal value) each in the authorized and unissued and authorized and issued share capital of ours be consolidated into 1 ordinary share of $0.10 (nominal value) each, and the subsequent reduction in the nominal value of the ordinary shares in the authorized and unissued and authorized and issued share capital of ours from $0.10 each to $0.01 each.

There are many factors that may adversely affect our minimum bid price, including those described throughout this section titled "Risk Factors". Many of these factors are outside our control. As a result, we may not be able to comply with the Bid Price Rule. Any potential delisting of our ordinary shares from The Nasdaq Global Select Market would likely result in decreased liquidity and increased volatility for our ordinary shares and would adversely affect our ability to raise additional capital or enter into strategic transactions. Any potential delisting of our ordinary shares from The Nasdaq Global Select Market would also make it more difficult for our shareholders to sell their ordinary shares in the public market.

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 Select 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 150,006,432 ordinary shares outstanding as of

September 30, 2020. 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, 2020, an aggregate of 4,727,422 options to purchase our ordinary shares had vested and become exercisable although these options all have an exercise price that is higher than the recent market trading prices of our ordinary shares.

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 19,923,904 ordinary shares under the Jefferies ATM Agreement, for gross proceeds of $21.9 million, and net proceeds of $20.9 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.

Moreover, as part of our May 2020 registered direct offering, we issued warrants to purchase an aggregate of up to 41,445,373 shares of ordinary shares at an exercise price of $0.792 per share. In addition, as part of our December 2019 registered direct offering, we issued warrants to purchase an aggregate of up to 13,793,106 shares of ordinary shares at an exercise price of $1.90 per share. Substantially all of these warrants remain outstanding and, upon exercise in full of these warrants, the shares issuable upon exercise would represent a significant portion of our outstanding ordinary shares. Each of the December 2019 warrants is initially exercisable six months following the date of issuance, which was December 24, 2019, and will expire on the three-year anniversary of the date on which such warrants became initially exercisable. Each of the May 2020 warrants is initially exercisable and will expire on the two-year anniversary of the date of issuance. We have registered the issuance of shares upon exercise of these warrants under a registration statements under the Securities Act of 1933, as amended, and, accordingly, such shares can be freely sold into the public market upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares, or the perception that sales of these shares could occur, could cause the market price of our ordinary shares to decline significantly. Furthermore, if our share price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our ordinary shares and reduce or eliminate any appreciation in our share price that might have otherwise occurred. As of September 30, 2020, there were 54,388,479 warrants outstanding from both offerings.

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 a "smaller reporting company", and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting 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 our 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.

We are also a "smaller reporting company" as defined in Rule 12b-2 promulgated under the Exchange Act. We may remain a smaller reporting company until we have a non-affiliate public float in excess of $250 million and annual revenues in excess of $100 million, or a non-affiliate public float in excess of $700 million, each as determined on an annual basis. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements. 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 or a smaller reporting 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 Select 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 or a smaller reporting 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 or a smaller reporting 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.

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.

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 point 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 as a result of shifts in our share 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 to offset our future taxable income. In addition, there is also a risk that due to changes in laws and regulations, such as suspensions on the use of net operating losses, or other unforeseen reasons, our existing net operating losses could expire or otherwise become unavailable to offset future income tax liabilities.

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 may not have been 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 our U.S. subsidiary. However, particularly since an express provision to that general effect was at one time part of recently introduced tax legislation but was not included in the version signed into law by the President, 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 apparent 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 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 taxable 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 and from sales of property that produced, or was held for the production of, passive income (or no income).

Based on our gross income and average value of our gross assets for each relevant taxable 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 such taxable year from our initial public offering through the year ended December 31, 2019. 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, 2020, or any other taxable year during which a U.S. holder held or holds 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

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, 2020 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	Retention Agreement, dated August 5, 2020, by and between Nabriva Therapeutics US, Inc. and Jennifer Schranz					X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, formatted in inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2019 and September 30, 2020, (ii) Consolidated Statements of Operations for the three months and nine months ended September 30, 2019 and 2020, (iii) Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2020, (iv) Consolidated Statement of Changes in Stockholders' Equity for the three months and nine months ended September 30, 2019 and 2020 and (v) Notes to Unaudited Consolidated Financial Statements.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					X

SIGNATURES

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

NABRIVA THERAPEUTICS plc

Date: November 5, 2020

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

Date: November 5, 2020

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

VIA EMAIL

August 5, 2020

Jennifer Schranz

Re: Retention Agreement

Dear Jennifer:

As we have discussed, Nabriva Therapeutics US, Inc. (the "Company") recognizes and appreciates the contributions you have made to the Company during your employment and wants you to remain committed and focused on delivering your goals and objectives during this important time for the Company. As an incentive for you to remain employed and enthusiastically engaged, the Company is offering you the Retention Benefits set forth below, subject to the terms and conditions set forth herein.

Please review this Retention Agreement (the "Agreement") and let me know if you have any questions. Otherwise, please sign where indicated below to acknowledge your receipt of this Agreement and your acceptance of its terms, and return the signed Agreement to me no later than August 7, 2020. Provided you timely sign and return this Agreement, it shall become effective as of the signature date (the "Effective Date").

1. Retention Benefits.

a. Retention Bonus. You will receive a lump sum retention bonus of one hundred thousand dollars ($100,000) (the "Retention Bonus") on the next regular payroll date following the Effective Date (the date of such payment, the "Retention Bonus Payment Date"), provided that you remain continuously employed through the Retention Bonus Payment Date. Should the Company terminate your employment for Cause (as defined in the Employment Agreement between you and the Company dated as of March 21, 2018 (the "Employment Agreement")), or should you voluntarily terminate your employment with the Company without Good Reason (as defined in the Employment Agreement), in either case within one (1) year following the Retention Bonus Payment Date, you must repay to the Company within thirty (30) days thereafter fifty percent (50%) of the Retention Bonus (the "Repayment Amount"). If your employment terminates for any other reason (including in the case of your termination by the Company without Cause, your resignation for Good Reason, or your death or disability), you are not required to repay the Retention Bonus.

b. Guaranteed Minimum Corporate Performance Percentage for 2020 Annual Discretionary Bonus. If you remain continuously employed by the Company through January 31, 2021, the current 2020 annual discretionary bonus for which you are eligible *(i.e.,* forty percent (40%) of your Base Salary (as defined in the Employment Agreement, provided, however, for the avoidance of doubt, that this calculation shall be prorated across any adjustments made to your Base Salary through 2020), based on the performance of the Company and Nabriva Therapeutics plc (as determined by the Board of Directors of Nabriva Therapeutics plc in its sole discretion)), will be determined based on the assumption that no less than eighty percent (80%) of the corporate performance target has been achieved.

c. Increase in Base Salary. As of August 3, 2020, your Base Salary (as defined in the Employment Agreement) will be increased from its current annualized rate of four hundred forty-nine thousand six hundred dollars ($449,600) to the annualized rate of four hundred sixty thousand dollars ($460,000).

d. Equity Retention. You will be eligible to participate in a Nabriva Management Team equity retention plan under which you would be granted 157,500 options to purchase Company common stock and 78,750 restricted stock units, each representing the right to receive one share of Company common stock. Further details on this plan, including the vesting schedule and applicable performance metrics, will be provided to you once finalized by the Company and subject to the approval of such Management Team equity retention plan, and the equity awards granted thereunder, by the Board of Directors.

2. Amendment. This Agreement shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto.

3. Withholding; Section 409A. All payments and benefits hereunder will be subject to reduction for applicable tax withholdings. Any payments made over time are to be treated as a series of separate payments for purposes of Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A" of the "Code"). This Agreement is intended to provide for payments that are exempt from or comply with the provisions of Section 409A and this Agreement must, to the extent practicable, be construed in accordance therewith. Terms defined in this Agreement will have the meanings given such terms under Section 409A if and to the extent required to comply with Section 409A. In any event, the Company makes no representations or warranty and will have no liability to you or any other person if any provisions of or payments under this Agreement are determined to constitute deferred compensation subject to Section 409A but not to satisfy the conditions thereof.

4. Source of Payment. Nothing herein may be construed as establishing a trust or as requiring the Company to set aside funds to meet its obligations hereunder.

5. Interpretation. The parties agree that this Agreement will be construed without regard to any presumption or rule requiring construction or interpretation against the drafting party. References in this Agreement to "include" or "including" should be read as though they said "without limitation" or equivalent forms.

6. Counterparts. This Agreement may be executed in two or more counterparts, each of which will be an original and all of which together will constitute one and the same instrument.

7. Binding Effect; Assignment and Assumption. This Agreement will be binding upon and inure to the benefit of the parties, any successors or assigns of the Company and your heirs and the personal representative(s) or executor(s) of your estate.

8. At-Will Employment; Effects of Agreement. This Agreement shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will, under which both the Company and you remain free to end the employment relationship for any reason, at any time, with or without Cause or notice. This Agreement supersedes any written or oral communications between the Company and you with respect to retention benefits of any kind. For the avoidance of doubt, the Employment Agreement remains in full force and effect and shall govern your right to receive severance payments and

benefits upon a termination of your employment, except as and to the extent the Employment Agreement has been explicitly modified by Section 1 above.

9. Governing Law; Jury Trial Waiver. This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania without regard to conflicts of law provisions. Any action, suit or other legal proceeding arising under or relating to any provision of this Agreement shall be commenced only in a court in the Commonwealth of Pennsylvania (or, if appropriate, a federal court located therein), and you consent to the jurisdiction of such a court. You hereby irrevocably waive any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

Jennifer, we are looking forward to continuing to work closely with you as we move forward. Please sign where indicated below to acknowledge your receipt of this Agreement and your acceptance of all of its terms and conditions.

Sincerely,

By: /s/ Ted Schroeder
Ted Schroeder
CEO

I acknowledge that I have read, understand and agree with the terms set forth herein:

/s/ Jennifer Schranz	8/5/2020
Jennifer Schranz	Date

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 5, 2020

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 5, 2020

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, 2020 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 5, 2020

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, 2020 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 5, 2020