
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2018

OR

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

For the transition period from to

Commission File Number: 001-38670

Entasis Therapeutics Holdings Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

82-4592913
(I.R.S. Employer
Identification No.)

**35 Gatehouse Drive
Waltham, MA 02451
(781) 810-0120**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

As of November 9, 2018, the registrant had 13,099,735 shares of common stock, \$0.001 par value per share, outstanding.

Table of Contents

	<u>Page</u>
<u>PART I.</u>	
<u>FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	
<u>Financial Statements (Unaudited)</u>	2
<u>Consolidated Balance Sheets</u>	2
<u>Consolidated Statements of Operations</u>	3
<u>Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</u>	4
<u>Consolidated Statements of Cash Flows</u>	5
<u>Notes to Consolidated Financial Statements</u>	6
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	28
<u>Item 4.</u>	
<u>Controls and Procedures</u>	28
<u>PART II.</u>	
<u>OTHER INFORMATION</u>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	29
<u>Item 1A.</u>	
<u>Risk Factors</u>	29
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	68
<u>Item 3.</u>	
<u>Defaults Upon Senior Securities</u>	68
<u>Item 4.</u>	
<u>Mine Safety Disclosures</u>	68
<u>Item 5.</u>	
<u>Other Information</u>	68
<u>Item 6.</u>	
<u>Exhibits</u>	69

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect,” or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- our plans to develop and commercialize our product candidates;
- our planned clinical trials for our product candidates;
- the timing of the availability of data from our clinical trials;
- the timing of our selection of an initial clinical candidate from our program to develop a novel class of antibiotics, non- β -lactam inhibitors of the penicillin-binding proteins, or NBPs;
- our ability to obtain grants or other government funding to develop our product candidates;
- our ability to take advantage of benefits offered by current and pending legislation related to the development of products addressing antimicrobial resistance;
- the timing of our planned regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our product candidates and their potential advantages compared to other treatments;
- our commercialization, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of our product candidates;
- our ability to establish and maintain collaborations and to recognize the potential benefits of such collaborations;
- our estimates regarding the market opportunities for our product candidates;
- our intellectual property position and the duration of our patent rights;
- our estimates regarding future expenses, capital requirements and needs for additional financing; and
- the factors that may impact our financial results.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail under the heading “Risk Factors” and elsewhere in this report. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements in this report, whether as a result of new information, future events or otherwise, after the date of this report.

Unless the context otherwise requires, the terms “Entasis,” “Entasis Therapeutics Holdings Inc.,” “the Company,” “we,” “us,” “our” and similar references in this Quarterly Report on Form 10-Q refer to Entasis Therapeutics Holdings Inc. and its subsidiaries.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ENTASIS THERAPEUTICS HOLDINGS INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited, amounts in thousands, except par value, share and per-share amounts)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 94,021	\$ 55,101
Grants receivable	2,930	722
Prepaid expenses and other current assets	2,392	497
Total current assets	99,343	56,320
Property and equipment, net	654	646
Deferred offering costs	—	1,765
Other assets	63	63
Total assets	<u>\$ 100,060</u>	<u>\$ 58,794</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 1,735	\$ 2,218
Accrued expenses and other current liabilities	7,695	7,615
Total current liabilities	9,430	9,833
Deferred rent	147	38
Total liabilities	9,577	9,871
Commitments (Note 8)		
Series A redeemable convertible preferred stock, par value \$0.001; 0 and 33,499,900 shares authorized, issued and outstanding as of September 30, 2018 and December 31, 2017	—	23,866
Series B redeemable convertible preferred stock, par value \$0.001; 0 and 25,000,000 shares authorized, issued and outstanding as of September 30, 2018 and December 31, 2017	—	24,550
Series B-1 Tranche A redeemable convertible preferred stock, par value \$0.001; 0 and 42,372,882 shares authorized, issued and outstanding as of September 30, 2018 and December 31, 2017	—	24,423
Series B-1 Tranche B redeemable convertible preferred stock, par value \$0.001; 0 and 54,067,796 shares authorized, issued and outstanding as of September 30, 2018 and December 31, 2017	—	31,874
Stockholders' equity (deficit):		
Common stock, par value \$0.001; 125,000,000 authorized and 13,097,961 shares issued and outstanding as of September 30, 2018; 250,000,000 shares authorized; 12,639 shares issued and outstanding as of December 31, 2017	13	3
Additional paid-in capital	172,500	1,377
Accumulated deficit	(82,030)	(57,170)
Total stockholders' equity (deficit)	90,483	(55,790)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 100,060</u>	<u>\$ 58,794</u>

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

ENTASIS THERAPEUTICS HOLDINGS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, amounts in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$ —	\$ —	\$ 5,000	\$ —
Operating expenses:				
Research and development	8,086	7,167	26,115	17,995
General and administrative	2,075	1,346	7,840	3,448
Total operating expenses	10,161	8,513	33,955	21,443
Loss from operations	(10,161)	(8,513)	(28,955)	(21,443)
Other income:				
Grant income	1,669	183	4,507	674
Interest income	19	6	47	18
Total other income	1,688	189	4,554	692
Loss before income taxes	(8,473)	(8,324)	(24,401)	(20,751)
Provision for income taxes	—	—	472	—
Net loss	(8,473)	(8,324)	(24,873)	(20,751)
Dividends declared	(9,142)	—	(9,142)	—
Net loss attributable to common shareholders—basic and diluted	\$ (17,615)	\$ (8,324)	\$ (34,015)	\$ (20,751)
Net loss per share attributable to common shareholders—basic and diluted	\$ (20.33)	\$ (5,106.75)	\$ (113.22)	\$ (25,183.25)
Weighted average common shares outstanding—basic and diluted	866,641	1,630	300,435	824

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

ENTASIS THERAPEUTICS HOLDINGS INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited, amounts in thousands, except share amounts)

	Redeemable Convertible Preferred Stock								Common Stock		Additional	Accumulated	Total
	A		B		B-1 A		B-1 B		Shares	Amount	Paid-in	Deficit	Shareholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			Capital		Equity (Deficit)
Balances as of December 31, 2017	33,499,900	\$23,866	25,000,000	\$24,550	42,372,882	\$24,423	54,067,796	\$31,874	12,639	\$3	\$1,377	\$(57,170)	\$(55,790)
ASU 2018-07 modified retrospective adjustment	—	—	—	—	—	—	—	—	—	—	(13)	13	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	806	—	806
Reorganization adjustment	—	—	—	—	—	—	—	—	—	(3)	3	—	—
Conversion of preferred stock into common stock upon initial public offering	(33,499,900)	(23,866)	(25,000,000)	(24,550)	(42,372,882)	(24,423)	(54,067,796)	(31,874)	8,084,414	8	104,705	—	104,713
Issuance of common stock upon initial public offering, net of issuance costs of \$9,376	—	—	—	—	—	—	—	—	5,000,000	5	65,619	—	65,624
Exercise of stock options	—	—	—	—	—	—	—	—	908	—	3	—	3
Net loss	—	—	—	—	—	—	—	—	—	—	—	(24,873)	(24,873)
Balances as of September 30, 2018	—	\$—	—	\$—	—	\$—	—	\$—	13,097,961	\$13	\$172,500	\$(82,030)	\$90,483

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

ENTASIS THERAPEUTICS HOLDINGS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, amounts in thousands)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (24,873)	\$ (20,751)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	125	146
Stock-based compensation expense	806	269
Changes in operating assets and liabilities:		
Grants receivable	(2,208)	(622)
Prepaid expenses and other assets	(1,896)	(875)
Accounts payable	536	490
Due to related party	—	(620)
Accrued expenses and other current liabilities	(386)	241
Deferred rent	109	4
Net cash used in operating activities	<u>(27,787)</u>	<u>(21,718)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(322)	(15)
Net cash used in investing activities	<u>(322)</u>	<u>(15)</u>
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	24,657
Proceeds from exercise of stock options	3	16
Proceeds from initial public offering, net of issuance costs paid in the period	67,026	—
Net cash provided by financing activities	<u>67,029</u>	<u>24,673</u>
Net increase in cash and cash equivalents	<u>38,920</u>	<u>2,940</u>
Cash and cash equivalents at beginning of period	55,101	26,256
Cash and cash equivalents at end of period	<u>\$ 94,021</u>	<u>\$ 29,196</u>
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of property and equipment included in accounts payable	\$ —	\$ 11
Initial public offering costs included in accounts payable and accrued expenses	\$ 1,105	\$ —
Conversion of preferred stock to common stock upon initial public offering	\$ 104,713	\$ —

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

ENTASIS THERAPEUTICS HOLDINGS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization and Description of Business

Entasis Therapeutics Holdings Inc. (“Entasis” or the “Company”) and its subsidiaries is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel antibacterial products to treat serious infections caused by multi-drug resistant Gram-negative bacteria.

The Company was initially formed as Entasis Therapeutics Limited (“Entasis Limited”) on March 6, 2015 in the United Kingdom (“U.K.”) as a wholly owned subsidiary of AstraZeneca AB (“AstraZeneca”). In connection with the spin-out of Entasis Limited from AstraZeneca in May 2015, Entasis Limited issued 4 ordinary shares to AstraZeneca. Additionally, pursuant to a business transfer and subscription agreement with AstraZeneca (the “A Subscription Agreement”), Entasis Limited also issued 33,499,900 shares of A redeemable convertible preference shares (“A Preferred Stock”) to AstraZeneca in May 2015. In March 2016, Entasis Limited issued 25,000,000 shares of B redeemable convertible preference shares (“B Preferred Stock”) to third-party investors, at which point AstraZeneca no longer held a controlling interest in Entasis Limited.

On April 23, 2018, Entasis Limited completed a corporate reorganization (the “Reorganization”). As part of the Reorganization, Entasis Limited formed Entasis Therapeutics Holdings Inc., a Delaware corporation, in March 2018 with nominal assets and liabilities for the purpose of consummating the Reorganization. In connection with the Reorganization, the existing shareholders of Entasis Limited exchanged each of their classes of shares of Entasis Limited for the same number and classes of common stock and preferred stock of Entasis Therapeutics Holdings Inc. on a one-to-one basis. The newly issued stock of Entasis Therapeutics Holdings Inc. have substantially identical rights to the exchanged shares of Entasis Limited. As a result of the exchange, Entasis Therapeutics Holdings Inc. became the sole shareholder of Entasis Limited. In connection with the Reorganization, Entasis Therapeutics Holdings Inc. assumed the Entasis Limited amended and restated stock incentive plan, and each outstanding share option to purchase ordinary shares of Entasis Limited was assumed by Entasis Therapeutics Holdings Inc. and converted into an option to purchase the same number of shares of common stock of Entasis Therapeutics Holdings Inc. at the same exercise price per share and on the same vesting schedule. Each new option has and is subject to the same terms and conditions as were in effect immediately prior to the assumption and conversion. No share options of Entasis Limited are outstanding following the assumption and conversion. Upon the completion of the Reorganization on April 23, 2018, the historical consolidated financial statements of Entasis Limited became the historical consolidated financial statements of Entasis Therapeutics Holdings Inc.

On September 28, 2018, the Company completed an initial public offering of its common stock, in which the Company issued and sold 5,000,000 shares of common stock at a price to the public of \$15.00 per share. The aggregate net proceeds to the Company from the initial public offering were approximately \$65.6 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. Upon the completion of the Company’s initial public offering, all of the outstanding shares of redeemable convertible preferred stock of the Company, including accrued dividends, automatically converted into 8,084,414 shares of the Company’s common stock.

Risks and Uncertainties

As of September 30, 2018, the Company had \$94.0 million in cash and cash equivalents and an accumulated deficit of \$82.0 million. Since its inception through September 25, 2018, the Company had funded its operations primarily with proceeds from the sale of redeemable convertible preferred stock. The Company has also either directly received funding or financial commitments from, or has had its program activities conducted and funded by, United States (“U.S.”) government agencies and non-profit entities. In the absence of positive cash flows from operations, the Company is highly dependent on its ability to find additional sources of funding in the form of debt or equity financing.

ENTASIS THERAPEUTICS HOLDINGS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

The Company believes its existing cash and cash equivalents will enable it to fund its operating expenses and capital expenditure requirements through 2020.

As an early-stage company, the Company is subject to a number of risks common to other life science companies, including, but not limited to, raising additional capital, development by its competitors of new technological innovations, risk of failure in preclinical and clinical studies, safety and efficacy of its product candidates in clinical trials, the risk of relying on external parties such as contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”), the regulatory approval process, market acceptance of the Company’s products once approved, lack of marketing and sales history, dependence on key personnel and protection of proprietary technology. The Company’s therapeutic programs are currently pre-commercial, spanning discovery through early development and will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization of any product candidates. These efforts require significant amounts of additional capital, adequate personnel, infrastructure, and extensive compliance-reporting capabilities. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company may never achieve profitability, and unless and until it does, it will continue to need to raise additional capital or obtain financing from other sources, such as strategic collaborations or partnerships.

Reverse Stock Split

In September 2018, the Company’s board of directors and stockholders approved, and on September 17, 2018, the Company filed, an Amended and Restated Certificate of Incorporation effecting a 1-for-20.728 reverse stock split of its issued and outstanding common stock. All common share and per share data included in the consolidated financial statements reflect the reverse stock split.

2. Summary of Significant Accounting Policies

Significant Accounting Policies

The Company’s significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2017 and the notes thereto, which are included in the Company’s prospectus that forms a part of the Company’s Registration Statement on Form S-1 (File No. 333-226920), which was filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) on September 26, 2018 (the “Prospectus”). Since the date of those financial statements, there have been no material changes to its significant accounting policies.

Basis of Presentation and Consolidation

The accompanying consolidated balance sheet as of September 30, 2018, the consolidated statements of operations for the three and nine months ended September 30, 2018 and 2017, redeemable convertible preferred stock and stockholders’ equity (deficit) for the nine months ended September 30, 2018 and cash flows for the nine months ended September 30, 2018 and 2017 are unaudited. 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, 2018, the results of operations for the three and nine months ended and cash flows for the nine months ended September 30, 2018 and 2017. The financial data and other information disclosed in these notes as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017 are unaudited. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018, any other interim periods, or any future year or period. The consolidated financial statements include the accounts of Entasis Therapeutics Holdings Inc. and its wholly owned subsidiaries Entasis Limited (a U.K. corporation) and Entasis Therapeutics Inc. (a U.S. corporation). The functional and reporting currency of the parent entity, Entasis Therapeutics Holdings Inc., and subsidiaries is U.S. dollars. All intercompany accounts and transactions have been eliminated in consolidation. These interim unaudited consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements contained in the Prospectus.

Use of Estimates

The preparation of the Company’s consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the recognition of revenue, the recognition of research and development expenses and the valuation of common stock and options

ENTASIS THERAPEUTICS HOLDINGS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

to purchase common stock. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from the Company's estimates.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. See Note 5 for a further discussion of accounting for revenue.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes existing revenue recognition guidance under GAAP. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle, and will require companies to use more judgment and make more estimates than under the current guidance. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, and is effective for public entities for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations* ("ASU 2016-08"), which further clarifies the implementation guidance on principal versus agent considerations in ASU 2014-09. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, clarifying the implementation guidance on identifying performance obligations and licensing. Specifically, the amendments in this update reduce the cost and complexity of identifying promised goods or services and improve the guidance for determining whether promises are separately identifiable. The amendments in this update also provide implementation guidance on determining whether an entity's promise to grant a license provides a customer with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). The Company adopted this guidance in connection with the execution of the license and collaboration agreement (the "Zai Agreement") with Zai Lab (Shanghai) Co., Ltd. ("Zai Lab") in April 2018. See Note 5. Prior to the Zai Agreement, the Company did not have any revenue from contracts with customers.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory* ("ASU 2016-16"), which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. On January 1, 2018, the Company adopted this guidance, and the adoption did not have a material impact on the Company's unaudited consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). The amendments of ASU 2016-15 were issued to address eight specific cash flow issues for which stakeholders have indicated to the FASB that a diversity in practice existed in how entities were presenting and classifying these items in the statement of cash flows. The issues addressed by ASU 2016-15 include but are not limited to the classification of debt prepayment and debt extinguishment costs, payments made for contingent consideration for a business combination, proceeds from the settlement of insurance proceeds, distributions received from equity method investees and separately identifiable cash flows and the application of the predominance principle. The amendments of ASU 2016-15 are effective for public entities for fiscal years beginning after December 15, 2017 and interim periods in those fiscal years. The adoption of ASU 2016-15 is

ENTASIS THERAPEUTICS HOLDINGS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

required to be applied retrospectively. On January 1, 2018, the Company adopted this guidance and the adoption did not have a material impact on the Company's unaudited consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for annual periods beginning after December 15, 2017. On January 1, 2018, the Company adopted this guidance and the adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which expands the scope of Topic 718 to include share-based payment awards to nonemployees. The amendments in ASU 2018-07 are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. During the nine months ended September 30, 2018, the Company early adopted this guidance and the adoption did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 — *Leases (Topic 842)*, which replaces the existing accounting guidance for leases. This standard requires entities that lease assets to recognize the assets and liabilities for the rights and obligations created by those leases on the balance sheet. The standard is effective for fiscal years and the interim periods within those fiscal years beginning after December 15, 2018. The guidance is required to be applied by the modified retrospective transition approach and early adoption is permitted. The Company is continuing to evaluate the new lease guidance and is in the process of evaluating its existing population of contracts to ensure all contracts that meet the definition of a lease contract under the new standard are identified. As a result, the Company is currently assessing the impact that adoption of this guidance will have on its financial statements and footnote disclosures and it anticipates it will result in an increase in assets and liabilities.

3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued compensation and benefits	\$ 1,214	\$ 1,286
Accrued contract manufacturing	1,992	3,633
Accrued clinical costs	1,250	1,096
Accrued professional services	1,816	1,246
Accrued research costs	742	135
Other	681	219
Total accrued expenses and other current liabilities	<u>\$ 7,695</u>	<u>\$ 7,615</u>

4. Funding Arrangements

In December 2016, the Company entered into a funding arrangement with the U.S. Army Medical Research Acquisition Activity (the "USAMRAA grant") that covers up to \$1.1 million of specified research expenditures of the Company incurred from December 2016 through December 2018 (the "performance period"). The Company has until September 2022 to obtain the reimbursements from USAMRAA for the specified research expenditures incurred and paid by the Company during the performance period.

The Company recognized grant income of \$0.1 million for both of the three month periods ended September 30, 2018 and 2017, and \$0.4 million for both of the nine month periods ended September 30, 2018 and 2017. The Company received \$0.7 million of funding under the grant for the nine months ended September 30, 2018 and no funding under the grant for the nine months ended September 30, 2017. The Company recorded a receivable to reflect unreimbursed, eligible costs incurred under the grant in the amount of \$0.2 million and \$0.5 million as of September 30, 2018 and December 31, 2017, respectively.

In March 2017 and October 2017, the Company entered into funding arrangements with the Trustees of Boston University to utilize funds from the U.S. government through the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program. These funding arrangements will cover up to \$16.4 million of specified research expenditures of the Company from April 2017 through September 2021.

The Company recognized grant income in connection with the CARB-X agreements of \$1.5 million and \$0.1 million for the three months ended September 30, 2018 and 2017, respectively, and \$4.1 million and \$0.3 million for the nine months ended September 30, 2018 and 2017, respectively. The Company received \$1.9 million and \$0.1 million of funding under the grant for the nine months ended September 30, 2018 and 2017, respectively. The Company recorded a receivable to reflect unreimbursed, eligible

ENTASIS THERAPEUTICS HOLDINGS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

costs incurred under the CARB-X agreements in the amount of \$2.7 million and \$0.2 million as of September 30, 2018 and December 31, 2017, respectively.

Collaboration Agreement

In July 2017, the Company entered into a collaboration agreement (the “Agreement”) with the Drugs for Neglected Disease Initiative (“DNDi”) for the development, manufacture and commercialization of a product candidate containing zoliflodacin in certain countries. The Phase 3 clinical trial has not commenced and there have been no material transactions with respect to the agreement as of September 30, 2018.

We have also had zoliflodacin program activities conducted and funded by the U.S. government through our arrangements with the U.S. National Institute of Allergy and Infectious Diseases, or NIAID.

5. License and Collaboration Agreement with Zai Lab

In April 2018, the Company entered into a license and collaboration agreement with Zai Lab, pursuant to which Zai Lab licensed exclusive rights to ETX2514 and ETX2514SUL in the Asia-Pacific region (the “Zai Agreement”). Under the terms of the Zai Agreement, Zai Lab will fund most of the Company’s clinical trial costs in China for ETX2514SUL, including all costs in China for the Company’s planned Phase 3 clinical trial of ETX2514SUL, with the exception of patient drug supply. Zai Lab will conduct development activities, plan and obtain regulatory approval in a specified number of countries in the Asia-Pacific region beyond China after regulatory approval of a licensed product in China. Zai Lab is also solely responsible for commercializing licensed products in the Asia-Pacific region and will commercialize licensed products for which it has obtained regulatory approval. The Company is obligated to conduct specified development activities for the Asia-Pacific region. The Company is also obligated to supply Zai Lab with the licensed products for clinical development, although Zai Lab may take over manufacturing responsibilities for its own commercialization activities within a specified time period following the effective date of the Zai Agreement. Both parties are prohibited from developing and commercializing products in the Asia-Pacific region that would compete with the licensed products.

In addition, under the Zai Agreement, either party may propose that Zai Lab pursue a combination of imipenem together with ETX2514SUL in the territory. If the parties decide to pursue an imipenem combination, Zai Lab would provide the Company with limited research and development support for the combination.

The Company received an upfront, non-refundable payment of \$5.0 million, less applicable taxes of \$0.8 million, from Zai Lab and the Company is eligible to receive up to an aggregate of \$98.6 million in research and development support payments and development, regulatory and sales milestone payments related to ETX2514SUL, imipenem and other combinations with the licensed products. In the event the China Food and Drug Administration requires a modification or supplement to the trial protocol, and the Company delays Zai Lab from providing the required information and subsequently from obtaining regulatory approval for the pivotal study of ETX2514SUL in China, then the sales-based milestone payments that become due to the Company will be reduced by an agreed amount that increases with the length of the delay. Zai Lab will pay the Company a tiered royalty equal to a high-single digit to low-double digit percentage based on annual net sales of licensed products in the territory, subject to specified reductions for the market entry of competing products, loss of patent coverage of licensed products and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory.

The Company evaluated the Zai Agreement under Topic 606 and identified two material promises: (1) an exclusive license to develop, manufacture and commercialize products containing ETX2514 or ETX2514SUL in the territory and (2) the initial technology transfer of licensed know-how. The Company determined that the exclusive license and initial technology transfer were not distinct from one another, as the license has limited value without the transfer of the Company’s technology and Zai Lab would incur additional costs to recreate the Company’s know-how. Therefore, the license and initial technology transfer were combined as a single performance obligation.

The Company determined the \$5.0 million non-refundable upfront payment is the entire transaction price at the outset of the Zai Agreement. All other future potential milestone payments were excluded from the transaction price as they are fully constrained as the risk of significant reversal has not yet been resolved. The achievement of the future potential milestones is not within the Company’s control and is subject to certain research and development success, regulatory approvals or commercial success and therefore carry significant uncertainty. The Company will reevaluate the likelihood of achieving future milestones at the end of each reporting period. Future development milestone revenue from the arrangement will be recognized as revenue in the period when it is no longer probable that revenue attributable to the milestone will result in a significant reversal.

The Company delivered the exclusive license and performed the initial technology transfer of licensed know-how prior to June 30, 2018 and recognized the entire \$5.0 million transaction price as revenue during the three months ended June 30, 2018. The Company recognized \$5.0 million of revenue during the nine months ended September 30, 2018. Additionally, the Company recorded a provision for income taxes of \$0.5 million for the nine months ended September 30, 2018, associated with China withholding taxes on the upfront payment under the Zai Agreement.

ENTASIS THERAPEUTICS HOLDINGS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

6. Stock-Based Compensation

Stock Incentive Plan

In September 2018, the Company's board of directors adopted and its stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"), which became effective on September 25, 2018, at which point no further grants will be made under the 2015 Stock Incentive Plan (the "2015 Plan") described below. Under the 2018 Plan, the Company may grant incentive stock options ("ISOs"), non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. As of September 30, 2018, options to purchase an aggregate of 243,106 shares had been granted and 944,725 shares were available for future issuance under the 2018 Plan.

Initially, subject to adjustment as provided in the 2018 Plan, the aggregate number of shares of the Company's common stock available for issuance under the 2018 Plan was 1,181,972. The number of shares of the Company's common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each year, for a period of 10 years, from January 1, 2019 continuing through January 1, 2028, by 4% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Company's board of directors. The maximum number of shares that may be issued pursuant to the exercise of ISOs under the 2018 Plan is 7,500,000.

The maximum number of shares of the Company's common stock subject to awards granted under the 2018 Plan or otherwise during a single calendar year to any non-employee directors, taken together with any cash fees paid by us to such non-employee director during the calendar year for serving on the Company's board of directors, will not exceed \$500,000 in total value, or, with respect to the calendar year in which a non-employee director is first appointed or elected to the Company's board of directors, \$800,000.

All options and awards granted under the 2015 Plan consisted of the Company's common stock. As of September 25, 2018, no additional stock awards have been or will be granted under the 2015 plan. The 2015 Plan was terminated as to future awards in September 2018, although it continues to govern the terms of options that remain outstanding under the 2015 Plan.

ENTASIS THERAPEUTICS HOLDINGS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Stock Option Activity

Stock option activity under both plans for the nine months ended September 30, 2018 is summarized as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	811,627	\$ 3.73	9.09	\$ 6,062
Granted	606,349	10.12		
Exercised	(908)	3.74		
Cancelled or forfeited	(11,793)	3.97		
Outstanding as of September 30, 2018	<u>1,405,275</u>	\$ 6.48	8.95	\$ 7,181
Options exercisable as of September 30, 2018	385,178	\$ 7.89	7.89	\$ 2,618
Options unvested as of September 30, 2018	1,020,097	\$ 9.35	9.35	\$ 4,562

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock.

During the nine months ended September 30, 2018 and 2017 the weighted-average grant date fair value per granted option was \$6.22 and \$2.33, respectively. The total fair value of options vested during the three months ended September 30, 2018 and 2017 was \$0.6 million and \$0.2 million, respectively. The total fair value of options vested during the nine months ended September 30, 2018 and 2017 was \$0.8 million and \$0.4 million, respectively.

Employee Stock Purchase Plan

In September 2018, the Company's board of directors and its stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"), which became effective as of September 25, 2018. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the U.S. Internal Revenue Code of 1986, as amended. The number of shares of common stock initially reserved for issuance under the ESPP was 140,000 shares. The ESPP provides for an annual increase on the first day of each year beginning in 2019 and ending in 2028, in each case subject to the approval of the board of directors, equal to the lesser of (i) 1% of the shares of common stock outstanding on the last day of the prior fiscal year or (ii) 250,000 shares; provided, that prior to the date of any such increase, the board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). As of September 30, 2018, no shares of common stock had been issued under the ESPP and 140,000 shares remained available for future issuance under the ESPP. No offering period under the ESPP has been set by the Company's board of directors.

AstraZeneca Shares Option and Incentive Plan

Certain employees of the Company participated in the AstraZeneca Shares Option and Incentive Plan (the "AstraZeneca Plan"), whereby employees of the Company continue to vest in the restricted shares ("AstraZeneca RSUs") of AstraZeneca ordinary shares issued by AstraZeneca to the employees prior to employment by the Company. AstraZeneca RSUs vested 100% after 36 months and were fully vested in March 2017 and therefore stock-based compensation expense for the AstraZeneca RSUs was recognized in full by September 30, 2017. The Company recorded stock-based compensation expense for AstraZeneca RSUs of \$14,604 during the nine months ended September 30, 2017.

Stock-Based Compensation

Stock-based compensation expense was classified in the consolidated statement of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 128	\$ 30	\$ 307	\$ 173
General and administrative	205	34	499	96
Total stock-based compensation expense	<u>\$ 333</u>	<u>\$ 64</u>	<u>\$ 806</u>	<u>\$ 269</u>

As of September 30, 2018, total unrecognized stock-based compensation expense related to unvested options was \$7.9 million, which is expected to be recognized over the weighted average period of approximately 2.7 years. The total unrecognized stock-based compensation expense will be adjusted for actual forfeitures as they occur.

7. Net Loss per Share

Basic and diluted net loss per share is determined by dividing net loss attributable to common shareholders by the weighted average number of shares of common stock outstanding during the period. For all periods presented, outstanding share options, outstanding A Preferred Stock, outstanding B Preferred Stock and outstanding Series B-1 A redeemable convertible preferred stock ("B-1 A Preferred Stock") and Series B-1 B redeemable convertible preferred stock ("B-1 B Preferred Stock") have been excluded from the calculation because their effects would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

ENTASIS THERAPEUTICS HOLDINGS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Basic and diluted net loss per share of the Company was calculated as follows (in thousands, except share and per share amounts):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Numerator:				
Net loss	\$ (8,473)	\$ (8,324)	\$ (24,873)	\$ (20,751)
Less: Dividends declared	(9,142)	—	(9,142)	—
Net loss attributable to common shareholders—basic and diluted	<u>\$ (17,615)</u>	<u>\$ (8,324)</u>	<u>\$ (34,015)</u>	<u>\$ (20,751)</u>
Denominator:				
Weighted average common shares outstanding—basic and diluted	<u>866,641</u>	<u>1,630</u>	<u>300,435</u>	<u>824</u>
Net loss per share attributable to common shareholders —basic and diluted	<u>\$ (20.33)</u>	<u>\$ (5,106.75)</u>	<u>\$ (113.22)</u>	<u>\$ (25,183.25)</u>

The Company excluded the following potential shares of common stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

	<u>As of September 30,</u>	
	<u>2018</u>	<u>2017</u>
Options to purchase shares of common stock	1,405,275	434,933
Redeemable convertible preferred stock (as converted to common stock)	—	4,866,491
	<u>1,405,275</u>	<u>5,301,424</u>

8. Commitments

Lease Commitments

In May 2015, the Company entered into an operating lease agreement for its office and laboratory space with AstraZeneca, which extended through May 2020. In February 2018, the Company amended its operating lease to extend the term through December 2022 and expand the premises to include an additional 7,257 square feet. The facility lease requires the Company to pay certain operating costs. During the three months September 30, 2018 and 2017, the Company recorded rental expense of \$0.2 million and \$0.1 million, respectively. During the nine months ended September 30, 2018 and 2017, the Company recorded rental expense of \$0.5 million and \$0.3 million, respectively.

ENTASIS THERAPEUTICS HOLDINGS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Future minimum lease payments for the combined spaces as of September 30, 2018 were as follows (in thousands):

<u>Year Ending December 31,</u>		
2018	\$	130
2019		597
2020		656
2021		710
2022		730
	<u>\$</u>	<u>2,823</u>

A Subscription Agreement

In connection with the A Subscription Agreement, the Company agreed to pay AstraZeneca a one-time milestone payment of \$5.0 million within three months of achieving a specified cumulative net sales milestone for ETX2514. This milestone payment will be automatically waived should the Company's common stock trade on Nasdaq at or above a specified price at the time it achieves such specified cumulative net sales milestone for ETX2514. The Company is also obligated to pay AstraZeneca a one-time milestone payment of \$10.0 million within two years of achieving the first commercial sale of zoliflodacin. At the Company's election, either milestone payment may be paid in cash, common stock, or a combination of cash and common stock. Additionally, the Company is obligated to pay AstraZeneca tiered, single-digit, per-country royalties on the annual worldwide net sales of ETX2514 and zoliflodacin.

9. Related Party Transactions

The Company was formed in May 2015 as a wholly owned subsidiary of AstraZeneca, which maintained a controlling interest in the Company until the B Preferred Stock were issued in March 2016. Prior to the closing of the initial public offering on September 28, 2018, AstraZeneca was the sole A Preferred Stockholder. Upon the closing of the initial public offering, all shares of preferred stock converted into shares of common stock.

Subscription Receivable Due from AstraZeneca

In connection with the issuance and sale of A Preferred Stock, AstraZeneca agreed to provide cash management services for the net proceeds due to the Company under the A Preferred Stock financing for as long as the Company remained a majority-controlled subsidiary. As a result, the full amount of the funds due to the Company were held by AstraZeneca, as property of the Company. This arrangement ceased upon the closing the B Preferred Stock financing in March 2016. During 2016, \$17.6 million of the funds were transferred to the Company, with the remaining \$0.2 million received during the nine months ended September 30, 2017.

Lease Commitments

The Company has an operating lease agreement for its office and laboratory space with AstraZeneca. See Note 8.

AstraZeneca Transition Services Agreement

The Company and AstraZeneca entered into a transition services agreement (the "Transition Agreement"), which commenced on May 11, 2015 and expired in November 2015. The Company owed \$0.6 million as of December 31, 2016 related to this arrangement, included in due to related party on the consolidated balance sheet, which it paid during the nine months ended September 30, 2017.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following information should be read in conjunction with the unaudited consolidated financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited consolidated financial information and the notes thereto included in the prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-226920), which was filed with the Securities and Exchange Commission, or SEC, pursuant to Rule 424(b)(4) on September 26, 2018, or the Prospectus.

This discussion contains certain forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in the "Risk Factors" section in this Quarterly Report on Form 10-Q. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and except as required by law, we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel antibacterial products to treat serious infections caused by multi-drug resistant Gram-negative bacteria. Leveraging our targeted-design platform, we have engineered and developed product candidates that target clinically validated mechanisms in order to address antibiotic resistance. Our lead product candidate, ETX2514, as well as one of our other product candidates, ETX0282, inhibit one of the most prevalent forms of bacterial resistance, β -lactamase enzymes, so-named because of their ability to inactivate β -lactam antibiotics, one of the most commonly used classes of antibiotics. By blocking this resistance mechanism, these product candidates, when administered in combination with β -lactam antibiotics, are designed to restore the efficacy of those antibiotics. Our other product candidate, zoliflodacin, targets the validated mechanism of action of the fluoroquinolone class of antibiotics, but does so in a novel manner to avoid existing fluoroquinolone resistance.

ETX2514SUL is a fixed dose combination of ETX2514, a novel broad spectrum intravenous, or IV, β -lactamase inhibitor, or BLI, with sulbactam, an IV β -lactam antibiotic, that we are developing for the treatment of a variety of serious multi drug resistant infections caused by *Acinetobacter baumannii*, or *Acinetobacter*. We have completed two Phase 1 clinical trials, including one evaluating the penetration of ETX2514SUL into the lung. We have also completed enrollment of an additional Phase 1 trial in renally impaired patients. In addition, we have completed a Phase 2 clinical trial in patients with complicated urinary tract infections, or UTIs and have received positive top-line results. We expect to receive final data from our Phase 1 trial in renally impaired patients and our Phase 2 clinical trial by the end of 2018. Based on a series of discussions with the U.S. Food and Drug Administration, or FDA, we plan to initiate a single Phase 3 clinical trial in the first quarter of 2019 with data expected in 2020.

Zoliflodacin is a novel orally administered molecule that targets bacterial gyrase for the treatment of drug-resistant *Neisseria gonorrhoeae*, the bacterial pathogen responsible for gonorrhea. Intramuscular ceftriaxone now represents the last-resort treatment option for gonorrhea, although resistant strains are beginning to emerge. We believe that there is a growing unmet need for an oral antibiotic, which will reliably treat patients with gonorrhea, including multi-drug resistant gonorrhea. We have completed several Phase 1 clinical trials and a Phase 2 clinical trial of zoliflodacin in patients with uncomplicated gonorrhea and intend to initiate a Phase 3 clinical trial in 2019 with data expected in 2021. The Phase 3 clinical trial will be funded by our non-profit collaborator, the Drugs for Neglected Diseases initiative, or DNDi. NIAID has fully funded the Phase 2 clinical trial of zoliflodacin for the treatment of uncomplicated gonorrhea and has provided funding commitments for the Phase 3 clinical trial preparatory activities.

We are also developing ETX0282CPDP for the treatment of complicated urinary tract infections, or UTIs, including those caused by extended spectrum β -lactamase, or ESBL, producing bacterial strains or carbapenem resistant *Enterobacteriaceae*, or CRE. ETX0282CPDP is an oral, fixed dose combination of ETX0282, a novel oral BLI, with cefpodoxime proxetil, an oral β -lactam antibiotic. We believe there is a significant unmet need for new oral antibiotics that reliably treat patients with multi drug resistant Gram-negative infections. We initiated a multi-part Phase 1 clinical trial of ETX0282CPDP in Australia in the second quarter of 2018 and expect to receive data from the Phase 1 trial in the first half of 2019.

We are using our targeted-design platform in an attempt to develop a novel class of antibiotics, non β -lactam inhibitors of the penicillin binding proteins, or NBPs. Penicillin binding proteins, or PBPs, are clinically validated targets of β -lactam antibiotics, such as penicillins and carbapenems. Due to their differentiated chemical structure, our NBPs are not subject to inactivation by β -lactamases, unlike β -lactam antibiotics. Accordingly, we believe our NBPs constitute a potential new class of Gram negative

[Table of Contents](#)

antibacterial agents with no pre-existing resistance that are designed to target a broad spectrum of pathogens, including *Pseudomonas aeruginosa*, or *Pseudomonas*. Lead optimization work is ongoing and we expect to select an initial clinical candidate from our NBP program in 2019.

Since our inception in May 2015, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring or discovering product candidates and securing related intellectual property rights, conducting discovery and development activities for our programs and planning for potential commercialization. We do not have any products approved for sale and have not generated any revenue from product sales. As of September 30, 2018, we have funded our operations primarily with net cash proceeds of \$104.2 million from the sale of our preferred stock and net cash proceeds of approximately \$65.6 million from the sale of common stock in our initial public offering, or IPO. We have also either directly received funding or financial commitments from, or have had our program activities conducted and funded by, the U.S. government through our arrangements with the U.S. National Institute of Allergy and Infectious Diseases, or NIAID, the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator program, or CARB-X, and the U.S. Department of Defense, and have received non-profit awards from the Drugs for Neglected Diseases *initiative*, or DNDi, and an upfront payment from our license and collaboration agreement with Zai Lab (Shanghai), Co., Ltd., or Zai Lab.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates and programs. Our net losses were \$24.9 million and \$29.9 million for the nine months ended September 30, 2018 and the year ended December 31, 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$82.0 million. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on completing the necessary development, obtaining regulatory approval and preparing for potential commercialization of our product candidates.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures on other research and development activities. We expect our expenses will increase substantially over time as we:

- continue our ongoing and planned preclinical and clinical development of our product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any product candidate for which we may obtain regulatory approval and intend to commercialize on our own;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and chemistry, manufacturing and controls personnel; and
- add additional operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

Furthermore, we now incur additional costs associated with operating as a public company that we did not previously incur or previously incurred at lower rates, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

Initial Public Offering

On September 28, 2018, we completed our IPO, in which we issued and sold 5,000,000 shares of common stock at a price to the public of \$15.00 per share. The aggregate net proceeds to us from the IPO were approximately \$65.6 million after deducting underwriting discounts and commissions and offering expenses payable by us. The shares began trading on The Nasdaq Global Market on September 26, 2018. Upon the completion of the IPO, all of our outstanding shares of redeemable convertible preferred stock, including accrued dividends, automatically converted into 8,084,414 shares of our common stock.

The Corporate Reorganization

We completed a corporate reorganization on April 23, 2018. As part of the corporate reorganization, we formed Entasis Therapeutics Holdings Inc., a Delaware corporation, in March 2018 with nominal assets and liabilities for the purpose of consummating the corporate reorganization described herein. In connection with the corporate reorganization, the existing shareholders of Entasis Therapeutics Limited exchanged their shares for the same number and classes of newly issued shares in Entasis Therapeutics Holdings Inc. As a result, Entasis Therapeutics Limited became a wholly owned subsidiary of Entasis Therapeutics Holdings Inc.

Upon completion of the corporate reorganization on April 23, 2018, the historical consolidated financial statements of Entasis Therapeutics Limited became the historical consolidated financial statements of Entasis Therapeutics Holdings Inc.

Funding Arrangements

In December 2016, we entered into a funding arrangement with the U.S. Army Medical Research Acquisition Activity, or USAMRAA, a division of the U.S. Department of Defense, through which we received a grant. This grant covers funding for up to \$1.1 million of specified research expenditures incurred from December 2016 through December 2018, or the performance period. Specified research expenditures are the reimbursable expenses associated with agreed upon activities needed to advance the research project supported by the grant. These expenditures can include internal labor, laboratory supplies and equipment, travel, consulting and third-party vendor research and development support costs. We have until September 30, 2022 to obtain reimbursements from USAMRAA for the fully paid, specified research expenditures incurred during the performance period. As of September 30, 2018, we had received \$0.7 million of funding and we had recorded \$0.9 million of grant income under this grant.

In March 2017 and October 2017, we entered into funding arrangements with the Trustees of Boston University to utilize funds from the U.S. government, through the CARB-X program, for support of the ETX0282 and NBP programs. These funding arrangements will cover up to \$16.4 million of our specified research expenditures from April 2017 through September 2021. As of September 30, 2018, we had received \$2.5 million in funding and we had recorded \$5.0 million of grant income under this grant.

In July 2017, we entered into a collaboration agreement with DNDi for the development and commercialization of a product candidate containing zoliflodacin in certain countries. Under the terms of the collaboration agreement, DNDi will fully fund the Phase 3 clinical trial, including the manufacture and supply of the product candidate containing zoliflodacin, in uncomplicated gonorrhea.

In April 2018, we entered into a license and collaboration agreement with Zai Lab (Shanghai) Co., Ltd., or Zai Lab, pursuant to which Zai Lab licensed exclusive rights to ETX2514 and ETX2514SUL in the Asia-Pacific region. Under the terms of the agreement, Zai Lab will fund most of our clinical trial costs in China for ETX2514SUL, including all costs in China for our planned Phase 3 clinical trial of ETX2514SUL, with the exception of patient drug supply. As of September 30, 2018, we had received a payment of \$4.2 million, the \$5.0 million upfront payment less applicable taxes, from Zai Lab and we had recognized revenue of \$5.0 million under the agreement.

Recent Developments

Announced positive topline results from a Phase 2 clinical trial of ETX2514SUL in patients with complicated urinary tract (cUTI) infections, including acute pyelonephritis.

The Phase 2 double-blind, randomized, placebo-controlled clinical trial of intravenous (IV) ETX2514SUL, administered with imipenem/cilastatin (IMI), showed similar microbiological success in the microbiologically evaluable population as placebo plus IMI (80% vs. 81%) and both treatment groups achieved 100% clinical success in the clinically evaluable population. In an exploratory analysis, the trial evaluated the efficacy of ETX2514SUL plus IMI against cUTIs caused by imipenem-non-susceptible pathogens. Eight patients had a cUTI caused by imipenem-non-susceptible pathogens (three in the ETX2514SUL arm and five in the placebo arm). ETX2514SUL plus IMI eradicated isolates in all patients, 100% (3/3), compared to 60% (3/5) in patients receiving placebo plus IMI. ETX2514SUL was generally well tolerated with no serious adverse events (SAEs) reported in either arm.

Results from an investigator-sponsored Phase 2 clinical trial evaluating zoliflodacin in patients with uncomplicated gonorrhea published in the New England Journal of Medicine (NEJM).

The Phase 2 clinical trial described in the NEJM was a multi-center randomized, open-label study that enrolled 179 participants between the ages of 18 to 55 with either symptoms of uncomplicated urogenital gonorrhea, untreated urogenital gonorrhea or sexual contact with someone with gonorrhea within 14 days of enrollment and was conducted by The National Institute of Allergy

[Table of Contents](#)

and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). Zoliflodacin was well-tolerated and successfully treated a majority of uncomplicated gonorrhea cases. Zoliflodacin received Fast Track designation and qualified infectious disease product (QIDP) designation by the U.S. Food and Drug Administration for development solely as oral treatment for gonococcal infections and is expected to enter a Phase 3 clinical trial in 2019.

Components of Results of Operations

Revenue

All of our revenue has been derived from our license and collaboration agreement with Zai Lab. To date, we have not generated any revenue from product sales, and we do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates and preclinical program are successful and result in regulatory approval, we may generate revenue in the future from product sales.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our product discovery efforts and the development of our preclinical and clinical product candidates. These expenses include:

- employee-related expenses, including salaries and benefits, travel and share-based compensation expense for employees engaged in research and development functions;
- fees paid to consultants for services directly related to our product development and regulatory efforts;
- expenses incurred under agreements with contract research organizations, or CROs, as well as contract manufacturing organizations, or CMOs, and consultants that conduct and provide supplies for our preclinical studies and clinical trials;
- costs associated with preclinical activities and development activities;
- costs associated with our technology and our intellectual property portfolio;
- costs related to compliance with regulatory requirements; and
- facilities-related expenses, which include allocated rent and maintenance of facilities and other operating costs.

Costs associated with research and development activities are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or other information provided to us by our vendors. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and preclinical program and consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and central laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under service, license or option agreements. We do not allocate employee costs or facility expenses to specific programs because these costs are deployed across multiple programs and, accordingly, are not separately classified. We primarily use internal resources and our own employees to conduct our research and discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities.

[Table of Contents](#)

To date, substantially all of our research and development expenses have been related to the preclinical and clinical development of our product candidates and preclinical program. The following table shows our research and development expenses by development program and type of activity for the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands)			
Direct research and development expenses by program:				
ETX2514	\$ 4,127	\$ 2,283	\$ 12,719	\$ 7,176
ETX0282	964	2,432	4,480	3,820
Zoliflodacin	34	39	69	60
Other preclinical programs	666	421	1,637	848
Unallocated expenses:				
Personnel related (including stock-based compensation)	1,717	1,376	5,362	4,424
Facility related and other	578	616	1,848	1,667
Total research and development expenses	<u>\$ 8,086</u>	<u>\$ 7,167</u>	<u>\$ 26,115</u>	<u>\$ 17,995</u>

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase over the next several years as we progress our product candidates through clinical development. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

The duration, costs and timing of clinical trials and development of our product candidates and preclinical program will depend on a variety of factors that include, but are not limited to, the following:

- the number of trials required for approval and any requirement for extension trials;
- per-patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profiles of the product candidates.

Any changes in the outcome of any of these factors with respect to the development of our product candidates could mean a significant change in the costs and timing associated with the development of these product candidates. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing and supply, and commercial viability. We will determine which programs to pursue and how much to fund each program based on the scientific and clinical success of each product candidate, as well as an assessment of each candidate's commercial potential.

[Table of Contents](#)

General and Administrative Expenses

General and administrative expenses consist of salaries and benefits, travel and share-based compensation expense for personnel in executive, finance and administrative functions. General and administrative costs also include facilities-related costs not otherwise included in research and development expenses, professional fees for legal, patent, consulting and accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will continue to incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing functions for that product candidate.

Other Income

Grant Income

Grant income consists of income recognized in connection with grants we received under our funding arrangements with USAMRAA and the Trustees of Boston University through the CARB-X program. Grant income is recognized in the period during which the related specified expenses are incurred, provided that the conditions under which the grants were provided have been met.

Interest Income

Interest income primarily consists of interest earned on cash equivalents in our sweep account. Our interest income has not been significant due to low interest earned on invested balances.

Income Taxes

Income taxes consists of China withholding taxes on the upfront payment under our license and collaboration agreement with Zai Lab.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our critical accounting policies from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in our Prospectus.

Results of Operations*Three Months Ended September 30, 2018 and 2017*

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,	
	2018	2017
	(in thousands)	
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	8,086	7,167
General and administrative	2,075	1,346
Total operating expenses	10,161	8,513
Loss from operations	(10,161)	(8,513)
Other income:		
Grant income	1,669	183
Interest income	19	6
Total other income	1,688	189
Loss before income taxes	(8,473)	(8,324)
Provision for income taxes	—	—
Net loss	\$ (8,473)	\$ (8,324)

Research and Development Expenses

	Three Months Ended	
	September 30,	
	2018	2017
	(in thousands)	
Personnel related (including stock-based compensation)	\$ 1,717	\$ 1,376
Preclinical and clinical development expenses	5,791	5,175
Facilities and supplies	443	460
Other expenses	135	156
Total research and development expenses	\$ 8,086	\$ 7,167

Research and development expenses were \$8.1 million for the three months ended September 30, 2018, compared to \$7.2 million for the three months ended September 30, 2017. The increase of \$0.9 million was primarily due to an increase of \$2.1 million in preclinical and clinical development expenses related to the advancement of our ETX2514SUL product candidate and our NBP and other preclinical programs and an increase of \$0.3 million in personnel expenses associated with higher headcount, offset in part by a decrease of \$1.5 million in drug manufacturing costs and preclinical study costs associated with our ETX0282CPDP product candidate. The increase in preclinical and clinical development expenses of \$2.1 million was associated with the advancement of ETX2514SUL and our NBP and other preclinical programs and was primarily due to an increase of \$1.7 million in drug manufacturing costs and an increase of \$0.6 million in clinical development costs, offset by a decrease of \$0.2 million in preclinical expenses.

[Table of Contents](#)*General and Administrative Expenses*

	Three Months Ended September 30,	
	2018	2017
	(in thousands)	
Personnel related (including stock-based compensation)	\$ 794	\$ 520
Legal and professional fees	963	658
Other expenses	318	168
Total general and administrative expenses	<u>\$ 2,075</u>	<u>\$ 1,346</u>

General and administrative expenses were \$2.1 million for the three months ended September 30, 2018, compared to \$1.3 million for the three months ended September 30, 2017. The increase of \$0.7 million was primarily due to increases of \$0.3 million in legal and professional fees associated with our IPO and preparation for becoming a public company and the preparation, audit and review of our consolidated financial statements, \$0.2 million in stock-based compensation expense resulting from options granted during the year ended December 31, 2017 and the nine months ended September 30, 2018, \$0.1 million in salaries and benefits resulting from higher headcount and \$0.1 million in other costs, such as facilities, recruiting, and insurance.

Other Income

Other income was \$1.7 million for the three months ended September 30, 2018, compared to \$0.2 million for the three months ended September 30, 2017. The increase of \$1.5 million was due to an increase in grant income of \$1.5 million associated with our grant agreements with the CARB-X program.

Income Taxes

There was no provision for income taxes for the three months ended September 30, 2018 and 2017 due to our operating losses and the maintenance of a full valuation allowance against our net deferred tax assets. Our losses before income taxes were generated in the United States and the United Kingdom.

Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Revenue	\$ 5,000	\$ —
Operating expenses:		
Research and development	26,115	17,995
General and administrative	7,840	3,448
Total operating expenses	<u>33,955</u>	<u>21,443</u>
Loss from operations	<u>(28,955)</u>	<u>(21,443)</u>
Other income:		
Grant income	4,507	674
Interest income	47	18
Total other income	<u>4,554</u>	<u>692</u>
Loss before income taxes	<u>(24,401)</u>	<u>(20,751)</u>
Provision for income taxes	472	—
Net loss	<u>\$ (24,873)</u>	<u>\$ (20,751)</u>

Revenue

We recognized revenue of \$5.0 million for the nine months ended September 30, 2018 associated with the delivering of the exclusive license and the initial technology transfer of licensed know-how pursuant to the collaboration agreement with Zai Lab, which we entered into in April 2018.

Research and Development Expenses

	Nine Months Ended	
	September 30,	
	2018	2017
	(in thousands)	
Personnel related (including stock-based compensation)	\$ 5,362	\$ 4,424
Preclinical and clinical development expenses	18,905	11,904
Facilities and supplies	1,386	1,328
Other expenses	462	339
Total research and development expenses	<u>\$ 26,115</u>	<u>\$ 17,995</u>

Research and development expenses were \$26.1 million for the nine months ended September 30, 2018, compared to \$18.0 million for the nine months ended September 30, 2017. The increase of \$8.1 million was primarily due to increases of \$6.2 million in preclinical and development expenses and \$0.9 million in personnel expenses, in each case related to the advancement of our ETX2514SUL and ETX0282CPDP product candidates, and \$0.8 million in expenses associated with the advancement of our NBP and other preclinical programs. The \$6.2 million increase in preclinical and development expenses for our ETX2514SUL and ETX0282CPDP product candidates was primarily due to increases of \$4.4 million in clinical development expenses and \$3.6 million in drug manufacturing costs, offset by a decrease of \$1.8 million in preclinical expenses.

[Table of Contents](#)*General and Administrative Expenses*

	Nine Months Ended	
	September 30,	
	2018	2017
	(in thousands)	
Personnel related (including stock-based compensation)	\$ 2,414	\$ 1,391
Legal and professional fees	4,256	1,722
VAT	300	—
Other expenses	870	335
Total general and administrative expenses	<u>\$ 7,840</u>	<u>\$ 3,448</u>

General and administrative expenses were \$7.8 million for the nine months ended September 30, 2018, compared to \$3.4 million for the nine months ended September 30, 2017. The increase of \$4.4 million was primarily due to increases of \$2.5 million in legal and professional fees associated with our IPO and preparation for becoming a public company and the preparation, audit and review of our consolidated financial statements, \$0.6 million in salaries and benefits resulting from higher headcount, \$0.4 million in stock-based compensation expense resulting from options granted during the year ended December 31, 2017 and the nine months ended September 30, 2018, \$0.3 million of VAT tax associated with the Zai Lab upfront payment and \$0.6 million in other costs, such as facilities, recruiting, and insurance.

Other Income

Other income was \$4.6 million for the nine months ended September 30, 2018, compared to \$0.7 million for the nine months ended September 30, 2017. The increase of \$3.9 million was primarily due to an increase in grant income of \$3.8 million associated with our grant agreements with USAMRAA and the CARB-X program.

Income Taxes

Provision for income taxes was \$0.5 million for the nine months ended September 30, 2018, which represents Chinese withholding taxes on the Zai Lab upfront payment we received under the license and collaboration agreement with Zai Lab. Other than the withholding tax for China in 2018, we have not recorded any income tax provision or benefit due to our operating losses and the maintenance of a full valuation allowance against our net deferred tax assets. Our losses before income taxes were generated in the United States and the United Kingdom.

Liquidity and Capital Resources*Overview*

As of September 30, 2018, we had raised aggregate net cash proceeds of \$104.2 million from the sale of redeemable convertible preferred stock and approximately \$65.6 million of net proceeds from the sale of common stock in our IPO, which we have used to fund our operations. In May 2015, we entered into a Business Transfer and Subscription Agreement with AstraZeneca. Pursuant to the terms of the agreement, we sold 33,499,900 shares of Series A redeemable convertible preferred stock to AstraZeneca in consideration for property and equipment, clinical materials, intellectual property and net cash proceeds of \$23.3 million. In March 2016, we received net proceeds of \$24.6 million from the sale of 25,000,000 shares of Series B redeemable convertible preferred stock. In August 2017, we received net proceeds of \$24.4 million from the sale of 42,372,882 shares of Series B-1 Tranche A redeemable convertible preferred stock and in December 2017, we received net cash proceeds of \$31.9 million from the closing of the sale of 54,067,796 shares of Series B-1 Tranche B redeemable convertible preferred stock. In addition, we have also either directly received funding or financial commitments from, or have had our program activities conducted and funded by, the U.S. government through our arrangements with NIAID, CARB-X and the U.S. Department of Defense, and have received non-profit awards from DNDi and an upfront payment from Zai Lab. As of September 30, 2018, we had cash and cash equivalents of \$94.0 million.

We have incurred operating losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses for at least the next several years. Our net loss was \$24.9 million for the nine months ended September 30, 2018. As of September 30, 2018, we had an accumulated deficit of \$82.0 million.

[Table of Contents](#)

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through 2020. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, manufacturing development costs, legal and other regulatory expenses and general administrative costs.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the clinical development of our product candidates and obtain regulatory approvals. We are also unable to predict when, if ever, net cash inflows will commence from product sales. This is due to the numerous risks and uncertainties associated with developing drugs, including, among others, the uncertainty of:

- successful enrollment in, and completion of clinical trials;
- performing preclinical studies and clinical trials in compliance with the FDA, the EMA or any comparable regulatory authority requirements;
- the ability of collaborators to manufacture sufficient quantity of product for development, clinical trials or potential commercialization;
- obtaining marketing approvals with labeling for sufficiently broad patient populations and indications, without unduly restrictive distribution limitations or safety warnings, such as black box warnings or a Risk Evaluation and Mitigation Strategies program;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third parties for manufacturing capabilities;
- launching commercial sales of products, if and when approved, whether alone or in collaboration with others;
- acceptance of the therapies, if and when approved, by physicians, patients and third-party payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of our drugs following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

We will not generate revenue from product sales unless and until we or a collaborator successfully complete clinical development and obtain regulatory approval for our current and future product candidates. If we obtain regulatory approval for any of our product candidates that we intend to commercialize on our own, we will incur significant expenses related to commercialization, including developing our internal commercialization capability to support product sales, marketing and distribution.

As a result, we will need substantial additional funding to support our continuing operations and to pursue our growth strategy. Until such time, if ever, when we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license and development agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing

[Table of Contents](#)

and preferred equity 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 be required 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 drug development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our failure to raise capital as and when needed would compromise our ability to pursue our business strategy.

We will also continue to incur costs as a public company that we did not previously incur or previously incurred at lower rates, including increased fees payable to the non-employee members of our board of directors, increased personnel costs, increased director and officer insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with public-company reporting requirements under the Exchange Act and rules implemented by the SEC and Nasdaq.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Cash Flows

The following table summarizes our cash flows for the periods presented:

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	\$ (27,787)	\$ (21,718)
Net cash used in investing activities	(322)	(15)
Net cash provided by financing activities	67,029	24,673
Net increase in cash and cash equivalents	<u>\$ 38,920</u>	<u>\$ 2,940</u>

Operating Activities

During the nine months ended September 30, 2018, operating activities used \$27.8 million of cash, resulting from our net loss of \$24.9 million and net cash used for changes in operating assets and liabilities of \$3.8 million, partially offset by non-cash charges of \$0.9 million. Net cash used for changes in operating assets and liabilities for the nine months ended September 30, 2018 consisted primarily of a \$2.2 million increase in grants receivable, a \$1.9 million increase in prepaid expenses and other assets and a \$0.4 million decrease in accrued expenses and other current liabilities. These were partially offset by a \$0.5 million increase in accounts payable.

During the nine months ended September 30, 2017, operating activities used \$21.7 million of cash, resulting from our net loss of \$20.8 million and net cash used for changes in operating assets and liabilities of \$1.4 million, partially offset by non-cash charges of \$0.4 million. Net cash used for changes in operating assets and liabilities for the nine months ended September 30, 2017 consisted primarily of a \$0.9 million increase in prepaid expenses and other assets, a \$0.6 million increase in grants receivable and a \$0.6 million decrease in due to related party, as a result of payments made to AstraZeneca related to our transition service agreement. These were partially offset by a \$0.5 million increase in accounts payable and a \$0.2 million increase in accrued expenses and other current liabilities.

Investing Activities

During the nine months ended September 30, 2018 and 2017, net cash used in investing activities was \$0.3 million and \$15,000, respectively, consisting of our purchase of property and equipment.

[Table of Contents](#)

Financing Activities

During the nine months ended September 30, 2018, net cash provided by financing activities was \$67.0 million, which consists of \$67.0 million of proceeds from our IPO net of issuance costs paid in the period.

During the nine months ended September 30, 2017, net cash provided by financing activities was \$24.7 million, which related to net proceeds from the sale of redeemable convertible preferred stock. In March 2017, we received \$0.2 million from AstraZeneca, representing a portion of the net proceeds from our issuance and sale of 33,499,900 shares of Series A redeemable convertible preferred stock. These proceeds were held by AstraZeneca pursuant to our cash management services arrangement.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of September 30, 2018:

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease commitments (1)	\$ 2,823	\$ 576	\$ 1,340	\$ 907	\$ —
Total	\$ 2,823	\$ 576	\$ 1,340	\$ 907	\$ —

(1) Amounts in the table reflect minimum payments due for our lease with AstraZeneca for office and laboratory space, which extends through December 2022.

Except as disclosed in the table above, we have no long-term debt or capital leases and no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase-order basis. We enter into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are cancelable by us upon prior notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the preceding table as the amount and timing of such payments are not known.

We have not included any contingent payment obligations, such as milestone payments and royalties, in the preceding table as the amount, timing and likelihood of such payments are not known. Such contingent payment obligations are described below.

The contractual obligations table does not include any potential contingent payments upon the achievement by us of clinical, regulatory and commercial events, as applicable, or royalty payments that we may be required to make under commercial agreements we have entered into with various entities, including our Business Transfer and Subscription Agreement with AstraZeneca. We excluded the contingent payments given that the timing and amount, if any, of any such payments cannot be reasonably estimated at this time.

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 in the rules and regulations of the SEC.

Recent Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. The market risk inherent in our financial instruments and in our financial position reflects the potential losses arising from adverse changes in interest rates and concentration of credit risk. We had cash and cash equivalents of \$94.0 million as of September 30, 2018, which consisted of cash and sweep accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates. Due to the short-term nature of the instruments in our portfolio, we would not expect a sudden change in market interest rates to have a material impact on our financial position or results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting.

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ending December 31, 2018. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q, including our financial statements and related notes hereto, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock could decline; and you may lose all or part of your investment.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have not generated any revenue from the sale of products and have incurred losses in each year since our inception in 2015. Our net loss was \$29.9 million for the year ended December 31, 2017 and \$24.9 million for the nine months ended September 30, 2018. As of September 30, 2018, we had an accumulated deficit of \$82.0 million. We have funded our operations to date primarily with proceeds from the sale of convertible preferred stock in private placements and the sale of common stock in our initial public offering. We have also either directly received funding or financial commitments from, or have had our program activities conducted and funded by, the U.S. government through our arrangements with the U.S. National Institute of Allergy and Infectious Diseases, or NIAID, the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator program, or CARB-X, and the U.S. Department of Defense, and have received non-profit awards from the Drugs for Neglected Diseases *initiative*, or DNDi, and an upfront payment of \$5.0 million, less applicable taxes, from our license and collaboration agreement with Zai Lab (Shanghai), Co., Ltd., or Zai Lab.

We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We are still in the early stages of development of our product candidates, and we have not completed development of any drugs. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing and planned preclinical and clinical development of our product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any product candidate for which we may obtain regulatory approval and intend to commercialize on our own;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific, and chemistry, manufacturing and controls personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and

[Table of Contents](#)

- incur additional legal, accounting and other expenses associated with operating as a public company.

To become and remain profitable, we and our collaborators must succeed in developing and eventually commercializing drugs that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates and preclinical program, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

The report of our independent registered public accounting firm included a “going concern” explanatory paragraph.

The report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, 2017 included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. On September 25, 2018, we completed an initial public offering of our common stock, in which we issued and sold 5,000,000 shares of our common stock for aggregate net proceeds of approximately \$65.6 million after deducting underwriting discounts and commissions and offering expenses. We expect that we will require additional capital and our ability to continue as a going concern is dependent upon our ability to obtain additional capital when needed. If we are unable to raise sufficient capital, we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. No assurance can be given that additional capital will be available, or, if available, will be on terms acceptable to us. The inclusion of a going concern explanatory paragraph by our auditors and our potential inability to continue as a going concern may materially adversely affect our ability to raise new capital or to enter into critical contractual relations with third parties.

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.

We commenced active operations in 2015, and our operations to date have been largely focused on raising capital, identifying and developing our product candidates and preclinical program, broadening our expertise in the development of our product candidates, and undertaking preclinical studies and conducting early-stage clinical trials. As an organization, we have not yet demonstrated an ability to successfully complete Phase 3 clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful 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.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce or altogether cease our product development programs or commercialization efforts.

We believe that the net proceeds from our initial public offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through 2020, which is at least 12 months from the date the financial

[Table of Contents](#)

statements included in this report were issued. However, we will need to obtain substantial additional funding in connection with our continuing operations and planned activities. Our future capital requirements will depend on many factors, including:

- the timing, progress and results of our ongoing clinical trials of our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- the number and development requirements of other product candidates that we may pursue;
- the amount of funding that we receive under our government awards and government awards that we have applied for;
- our ability to establish collaborations on favorable terms, if at all;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on 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 we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license and development agreements and government and non-profit awards. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity 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 be required 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 drug development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Development of Our Product Candidates and Preclinical Program

We depend to a large degree on the success of our most advanced product candidates, which are in clinical development but have not completed Phase 3 clinical trials. If we do not obtain regulatory approval for and successfully commercialize one or more of our product candidates or if we experience significant delays in doing so, we may never become profitable.

We currently have no products approved for sale and have invested a significant portion of our efforts and financial resources on the development of ETX2514SUL and ETX0282CPDP as product candidates for the treatment of serious infections caused by multi-drug resistant Gram-negative bacteria. We expect that a substantial portion of our efforts and expenses over the next few years will be devoted to the development of ETX2514SUL, ETX0282CPDP and any other product candidates we develop. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of ETX2514SUL, zoliflodacin, ETX0282CPDP and any other product candidates we develop. We cannot be certain that our product candidates will receive regulatory approval or will be successfully commercialized even if they receive regulatory approval. The research, development, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to comprehensive regulation by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates in the United States will prevent us from commercializing and marketing our product candidates. The success of our product candidates and preclinical program will depend on several additional factors, including:

- successful completion of preclinical studies and requisite clinical trials;
- performing preclinical studies and clinical trials in compliance with the FDA, the EMA or any comparable regulatory authority requirements;
- receipt of marketing approvals from applicable regulatory authorities;
- the ability of collaborators to manufacture sufficient quantity of product for development, clinical trials or potential commercialization;
- obtaining marketing approvals with labeling for sufficiently broad patient populations and indications, without unduly restrictive distribution limitations or safety warnings, such as black box warnings or a Risk Evaluation and Mitigation Strategies, or REMS, program;
- obtaining and maintaining patent, trademark and trade secret protection, and regulatory exclusivity for our product candidates and preclinical program;
- making arrangements with third-parties for manufacturing capabilities;
- launching commercial sales of products, if and when approved, whether alone or in collaboration with others;
- acceptance of the therapies, if and when approved, by physicians, patients and third-party payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- protecting our rights in our intellectual property portfolio; and
- maintaining a continued acceptable safety profile of our drugs following approval.

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 our product candidates, which would harm our business.

We may not be successful in our efforts to build a pipeline of product candidates.

A key element of our strategy is to build a pipeline of product candidates and to progress these product candidates through clinical development for the treatment of serious infections caused by multi-drug resistant Gram-negative bacteria. We may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of significant safety, tolerability or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval, achieve market acceptance or obtain reimbursements from third-party payors. If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our common stock.

Success in preclinical studies or clinical trials may not be indicative of results in future clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. For instance, with respect to ETX2514SUL, we cannot guarantee that the dose regimen used in the Phase 3 clinical trial will be effective. We cannot guarantee that the rigorous pharmacokinetic and pharmacodynamic modeling approach, including input from the ongoing Phase 1 clinical trial assessing pharmacokinetics in renally impaired patients and the completed Phase 2 clinical trial in patients with complicated urinary tract infections, or UTIs, that we will use to select the Phase 3 dosing regimen will be validated in the Phase 3 clinical trial in patients with *Acinetobacter* infections. The dose regimen to be used in the single Phase 3 clinical trial will be the first evaluation of ETX2514SUL in patients with pneumonia and bloodstream infections caused by *Acinetobacter*. Our observation of ETX2514SUL penetration into the lung in the Phase 1 clinical trial may not be predictive of efficacy in pneumonia caused by *Acinetobacter*.

In addition, 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. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for drugs and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

If clinical trials of ETX2514SUL, zoliflodacin, ETX0282CPDP or any other product candidate that we may advance to clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other comparable 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 ETX2514SUL, zoliflodacin, ETX0282CPDP or any other product candidate.

We may not commercialize, market, promote, or sell any product candidate without obtaining marketing approval from the FDA, the EMA or other comparable regulatory authority, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive 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. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize ETX2514SUL, zoliflodacin, ETX0282CPDP or any of our future product candidates, including:

- the FDA, the EMA or other comparable regulatory authority may disagree as to the design or implementation of our clinical trials;

[Table of Contents](#)

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results; for example, the mortality rate among patients with *Acinetobacter* infections is high and may confound the execution and analysis of our Phase 3 clinical trial;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;
- 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 may issue a clinical hold, or regulators or institutional review boards 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;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA, the EMA or other comparable regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with whom we enter into agreements for clinical and commercial supplies;
- 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;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and
- the approval policies or regulations of the FDA, the EMA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If we are required to conduct additional clinical trials or other testing of ETX2514SUL, zoliflodacin, ETX0282CPDP or any of our future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing of ETX2514SUL, zoliflodacin, ETX0282CPDP or any of our future product candidates, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, such as black box warnings or a REMS program; for example, ETX2514SUL may initially be approvable only for *Acinetobacter* use despite our belief that it has broader clinical utility;
- be subject to additional post-marketing testing requirements; or
- be required to remove the product from the market after obtaining marketing approval.

Our product development costs may also increase if we experience delays in testing or marketing approvals and we may be required to obtain additional funds to complete clinical trials. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical

[Table of Contents](#)

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. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of ETX2514SUL, zoliflodacin, ETX0282CPDP or any of our future product candidates.

If we are not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort will focus on the continued clinical testing and potential regulatory approval of ETX2514SUL, zoliflodacin and ETX0282CPDP an element of our strategy is to discover, develop and commercialize a portfolio of product candidates to treat serious infections caused by multi-drug resistant Gram-negative bacteria. We are seeking to do so by utilizing our targeted-design platform, which uses bacterial genomics and state-of-the-art molecular and dynamic models to design active new compounds that target validated mechanisms of resistance. We focus our clinical development on multi-drug resistant pathogens and patients with high, unmet medical needs to leverage the development and regulatory paths available for first-in-class or best-in-class antibiotics. Research efforts to identify and develop product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable; and
- the FDA, the EMA or other regulatory authorities may not approve or agree with the intended use of a new product candidate.

If we fail to develop and successfully commercialize other current and future product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing ETX2514SUL, zoliflodacin or ETX0282CPDP.

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

We may not be able to initiate, continue or complete clinical trials of ETX2514SUL, zoliflodacin, ETX0282CPDP or any other product candidate that we develop if we and our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or other comparable regulatory authority. We have limited experience enrolling patients in our clinical trials and cannot predict how successful we will be in enrolling patients in future clinical trials.

For instance, patients involved in our clinical trials are generally in the hospital setting and the decision to participate can be made by the caregiver or doctor. Accordingly, seeking consent for patient participation may become difficult when the family and/or the patient may not be available to consider participation in a clinical trial and the providers/investigators seeking the consent often have no established relationship with the family or patient. This relationship and trust is what many potential participants depend on when making medical decisions, including participating in clinical trials. Patients may also be reluctant to participate in a clinical trial with an investigational drug. In addition, some of our competitors have ongoing clinical trials to treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors. If we are not successful at enrolling patients in one clinical trial, it may affect when we are able to initiate our next clinical trial, which could result in significant delays in our efforts to pursue regulatory approval of and commercialize our product candidates. Patient enrollment is affected by other factors including:

- the size and nature of the patient population;

[Table of Contents](#)

- the severity of the disease under investigation;
- the proximity and availability of clinical trial sites for prospective patients;
- the eligibility criteria for participation in the clinical trial;
- the design of the clinical trial;
- the perceived risks and benefits of the product candidate under study;
- our ability to recruit clinical trial investigators with appropriate experience;
- the availability of drugs approved to treat the diseases under study;
- the patient referral practices of physicians;
- our ability to obtain and maintain patient consents;
- the ability to monitor patients adequately during and after treatment; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Additionally, infections with *Acinetobacter* are relatively uncommon compared to other serious bacterial infections and finding a sufficient number of suitable patients with *Acinetobacter* infections, including patients infected with carbapenem-resistant *Acinetobacter*, to enroll in our planned Phase 3 clinical trial of ETX2514SUL may be a potential challenge. Patients enrolled into the clinical trial may have up to 48-hours of prior antimicrobial therapy to allow for identification of *Acinetobacter* using routine microbiologic culture and organism identification, but this time window may be insufficient in some cases for identifying *Acinetobacter*, thereby limiting patient enrollment. Additionally, patients with *Acinetobacter* infections are generally very sick and, in some cases, may be unconscious and requiring mechanical ventilation, providing a further potential enrollment challenge. Furthermore, although mortality in some patients is to be expected and is the endpoint of our planned Phase 3 clinical trial of ETX2514SUL, enrollment of near-terminally ill patients could result in a failure to meet our clinical trial endpoints because the patients are too ill to be expected to respond to effective therapy.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would reduce the capital we have available to support our current and future product candidates and may result in our need to raise additional capital earlier than planned and could cause the value of our common stock to decline and limit our ability to obtain additional financing.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. For example, in the single-ascending dose portion of the Phase 1 clinical trial of ETX0282CPDP, 4 out of 36 subjects experienced mild-to-moderate emesis, or vomiting. We are in the process of analyzing data from these healthy volunteers as well as exploring options to mitigate this effect, including co-administration with food and modified release formulations. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical programs, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our current product candidates, including ETX2514SUL, zoliflodacin and ETX0282CPDP, or any future product candidates of ours, has side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

[Table of Contents](#)

Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may significantly harm our business, financial condition and prospects.

Additionally, if any of our product candidates receive marketing approval, regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or the adoption of a REMS program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials, including one or more post-market studies;
- we could be sued and held liable for harm caused to patients;
- we may be required to implement REMS, including the creation of a medication guide outlining the risks of such side effects for distribution to patients;
- we may need to conduct a recall; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We cannot predict whether or when bacteria may develop resistance to our product candidates, which could affect the revenue potential of our product candidates.

We are developing our product candidates to treat drug-resistant bacterial infections. The bacteria responsible for these infections evolve quickly and readily transfer their resistance mechanisms within and between species. Prescription or use of our products, if approved, may depend on the type and rate of resistance of the targeted bacteria. Although we do analyze the potential of our product candidates to develop resistance and only select product candidates that we believe have low resistance potential, we cannot predict whether or when bacterial resistance to our product candidates may develop should our products obtain market approval and be broadly prescribed. The growth of drug-resistant infections in community settings or in countries with poor public health infrastructures, or the potential use of our product candidates outside of controlled hospital settings, could contribute to the rise of resistance. In addition, if resistance in some of our targeted pathogens emerges more slowly than anticipated, or fails to emerge in one or more areas where we intend to commercialize our products, we may be unable to enroll patients for certain of our clinical trials and we may fail to obtain regulatory approval for our product candidates, which could affect our ability to generate revenue.

[Table of Contents](#)

Interim “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

We expect to develop ETX2514 and ETX0282 in combination with approved drugs. If the FDA, the EMA or comparable regulatory authority revokes their approval, we may be unable to obtain approval for our product candidates.

Our lead product candidate, ETX2514, and one of other product candidates, ETX0282, inhibit one of the most prevalent forms of bacterial resistance, β -lactamase enzymes, so-named because of their ability to inactivate β -lactam antibiotics, one of the most commonly used classes of antibiotics. By blocking this resistance mechanism, these product candidates, when administered in combination with β -lactam antibiotics, are designed to restore the efficacy of those antibiotics. ETX2514 is a novel intravenous, or IV, broad-spectrum β -lactamase inhibitor, or BLI, that we are developing in combination with sulbactam, an IV β -lactam antibiotic, for the treatment of a variety of serious multi-drug resistant infections caused by *Acinetobacter*. ETX0282 is a novel, oral BLI that we are developing in combination with cefpodoxime proxetil, or cefpodoxime, an oral β -lactam antibiotic, for the treatment of complicated UTIs, including those caused by extended-spectrum β -lactamase, or ESBL, —producing bacterial strains or carbapenem-resistant *Enterobacteriaceae*, or CRE.

We did not develop or obtain marketing approval for, nor do we manufacture or sell, sulbactam or cefpodoxime or any other currently approved drug that we may study in combination with our product candidates. If the FDA, the EMA or comparable regulatory authority revokes the approval of the drug or drugs in combination with which we determine to develop our product candidates, we may not be able to market our product candidates in such jurisdictions.

Furthermore, if safety or efficacy issues arise with any of these drugs, we could experience significant regulatory delays, and the FDA, the EMA or comparable regulatory authority may require us to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a shortage of supply of the drugs with which we determine to combine with our product candidates, we may not be able to complete their clinical development on our current timeline or at all.

Even if our product candidates were to receive marketing approval or be commercialized for use in combination with other existing drugs, we would continue to be subject to the risks that the FDA, the EMA or comparable regulatory authority could revoke approval of the drug used in combination with our product candidates or that safety, efficacy, manufacturing or supply issues could arise with these existing drugs.

Demand for our product candidates, if approved, will depend in part on continued resistance to empirically used broad-spectrum antibiotics and continued use of pathogen identification and resistance profiling in the hospital setting.

Each of our hospital-based product candidates, including ETX2514SUL and ETX0282CPDP, is aimed at treating antibiotic resistant gram-negative bacteria of a specific genus and/or species, such as *Acinetobacter baumannii*, *Pseudomonas aeruginosa* or certain strains of *Enterobacteriaceae*. Typically, when a patient presents in the hospital with an infection and the bacteria causing the infection is not known or only suspected, a broad-spectrum antibiotic is administered as a first-line treatment pending tests to identify the particular bacterial pathogen causing the infection and its resistance profile. Our product candidates are being developed for use following the identification of the bacterial pathogen and if the resistance profile of the bacterial pathogen suggests that the first-line broad-spectrum antibiotic is not likely to be effective. Our product candidates are designed to treat specific antibiotic-resistant bacteria where broad-spectrum antibiotics are typically not effective due to the development of antibiotic resistance. However, in those cases when first-line treatment with a broad-spectrum antibiotic has been effective, there would not be a need for second-line treatment with our product candidates. If the bacteria we target become less resistant to existing broad-spectrum antibiotics, or if new broad-spectrum antibiotics are developed that are equally effective against the specific bacteria we target, then the potential demand for our product candidates could be diminished.

In addition, while pathogen identification and resistance profiling are common tests that have been employed for decades and are standard practice in hospital microbiology laboratories as a guide for the appropriate use of antibiotics, these tests can be costly

[Table of Contents](#)

and time consuming. If these tests do not remain standard procedure, for example because their coverage and reimbursement status by third-party payors is reduced or eliminated, this could also limit the potential demand for our product candidates.

There are a variety of risks associated with marketing our product candidates internationally, which could affect our business.

We or our collaborators may seek regulatory approval for our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct the clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

We have engaged contract research organizations, or CROs, to conduct our ongoing and planned clinical trials. We also expect to engage CROs for any of our other product candidates that may progress to clinical development. We expect to rely on CROs, as well as other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will 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 regulatory standards, commonly referred to as good clinical practices, or GCPs, 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. Similar regulatory requirements apply outside the United States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, or ICH.

[Table of Contents](#)

We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so by us or third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties 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.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any new drug application, or NDA, we submit. Any such delay or rejection could prevent us from commercializing ETX2514SUL, zoliflodacin, ETX0282CPDP or future product candidates.

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

We rely on collaborations with third parties for the development of our product candidates, and we may seek additional collaborations in the future. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We have limited capabilities for drug development and do not yet have any capabilities for sales, marketing or distribution. We are, and expect to continue to be, dependent on collaborations relating to the development and commercialization of our existing and future product candidates. We currently have a collaborative relationship with Zai Lab to develop ETX2514 and ETX2514SUL in the Asia-Pacific region and with DNDi to co-develop zoliflodacin in a Phase 3 clinical trial in uncomplicated gonorrhea. We have had and will continue to have discussions on potential partnering opportunities with various pharmaceutical companies. In addition, we may seek third-party collaborators for the development and commercialization of our product candidates, particularly for the development and commercialization of our product candidates outside the United States. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future product candidates could be delayed, the commercial potential of our products could change and our costs of development and commercialization could increase. If we enter into any future collaboration arrangements with any third parties, 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 to successfully perform the functions assigned to them in these arrangements.

Our collaborations with Zai Lab and DNDi and any future collaborations we might enter into may pose a number of risks, including:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected or contractually obligated;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

[Table of Contents](#)

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such 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;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators' decisions may limit the availability of the product supplies required for development, clinical and commercial activities.

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

The failure of Zai Lab or DNDi to adequately perform their obligations and responsibilities in the conduct of our planned Phase 3 clinical trials of ETX2514SUL and zoliflodacin, respectively, could harm our business because we may not obtain regulatory approval for ETX2514SUL or zoliflodacin in a timely manner, or at all.

We have entered into a license and collaboration agreement with Zai Lab, pursuant to which they will manage the portion of our Phase 3 clinical trial of ETX2514SUL for *Acinetobacter* infections conducted in China. We have also entered into an arrangement with DNDi pursuant to which it is conducting the Phase 3 clinical trial of zoliflodacin in patients with uncomplicated gonorrhea. Under our arrangement with Zai Lab, Zai Lab will fund most of our clinical trial costs in China for ETX2514SUL, including all costs for our planned Phase 3 clinical trial for *Acinetobacter* infections. Under our agreement with DNDi, DNDi will fund all of the Phase 3 development costs for zoliflodacin, including costs of the manufacture and supply of the product candidate, and will take the lead in Phase 3 clinical development activities. While we expect to provide operational and logistical support for the planned Phase 3 clinical trials, we have limited control of the activities of our collaborators. We cannot control whether or not our collaborators will devote sufficient time and resources to the planned Phase 3 clinical trials. If either Zai Lab or DNDi does not successfully carry out its obligations and responsibilities or meet expected deadlines or if the quality or accuracy of the clinical data either obtains is compromised due to the failure to adhere to clinical protocols, regulatory requirements or for other reasons, either of the Phase 3 clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, ETX2514SUL or zoliflodacin. As a result, our results of operations and the commercial prospects for ETX2514SUL or zoliflodacin would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Although Zai Lab and DNDi are each responsible for conducting specified planned Phase 3 clinical trial activities, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on our collaborators does not relieve us of our regulatory responsibilities. We are required to comply with GCP for any product candidate of ours in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we fail to comply with applicable GCP, the clinical data generated in our trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, we must conduct our clinical trials with drug product manufactured under current good manufacturing practices, or cGMP, requirements. Failure to

comply with any of these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

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

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of our product candidates, and our strategy is to outsource all manufacturing of our product candidates and approved products, if any, to third parties.

In order to conduct clinical trials of our product candidates, we will need to identify suitable manufacturers with the capabilities to manufacture our compounds in large quantities in a manner consistent with existing regulations. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. If our manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

In addition, we plan to develop certain of our product candidates for use as a fixed-dose combination therapy. If manufacturing or other issues result in a supply shortage of sulbactam, cefpodoxime or any other currently approved drug that we may study in combination with ETX2514, ETX0282 or any of our future product candidates, we may not be able to complete clinical development of our product candidates on our current timeline or at all.

We do not currently have any agreements with third-party manufacturers for the long-term commercial supply of any of our product candidates. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of our product candidates, or may be unable to do so on acceptable terms.

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

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

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Furthermore, we intend to develop certain product candidates as a fixed-dose combination with β -lactams and only a limited number of cGMP manufacturers are capable of handling β -lactam antibiotics.

If the third parties that we engage to supply any materials or manufacture product for our preclinical tests 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. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them or any of approved drug we use in our combination trials, it will be more difficult for us to develop our product candidates and compete effectively.

[Table of Contents](#)

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

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the future development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or other comparable regulatory authorities, 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. Any potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such 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 increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may not be able to win government or non-profit contracts or grants to fund our product development activities.

Historically, we have relied in part on funding from contracts or grants from government agencies and non-profit entities and it is part of our strategy to continue to do so. Such contracts or grants can be highly attractive because they provide capital to fund the on-going development of our product candidates without diluting our stockholders. However, there is often significant competition for these contracts or grants. Entities offering contracts or grants may have requirements to apply for or to otherwise be eligible to receive certain contracts or grants that our competitors may be able to satisfy that we cannot. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants will be awarded and the size of the contracts or grants to each awardee. Even if we are able to satisfy the award requirements, there is no guarantee that we will be selected to receive any contract or grant. If we are not successful in achieving this form of funding for our clinical trials, we will need to seek alternative means of funding which may not be available to the same extent, if at all.

Our reliance on government funding for certain of our programs adds uncertainty to our research, development and commercialization efforts with respect to those programs and may impose requirements that increase the costs of the research, development and commercialization of product candidates developed under those government-funded programs.

Aspects of our development programs are currently being supported, in part, with funding from the NIAID, CARB-X and the U.S. Department of Defense. Contracts and grants awarded by the U.S. government, its agencies and its partners, including our awards from the NIAID, CARB-X and the U.S. Department of Defense, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason at all;
- provide grant support to potential competitor programs;
- reduce or modify the government's obligations under such agreements without the consent of the other party;

[Table of Contents](#)

- claim rights, including intellectual property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

We may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

In addition, government contracts and grants, and subcontracts and subawards awarded in the performance of those contracts and grants, normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government awards;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- adhering to stewardship principals imposed by CARB-X as a condition of the award;
- public disclosures of certain award information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

As an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we fail to maintain compliance with those obligations, we may be subject to potential liability and termination of our contracts.

As a U.S. government contractor, we are subject to financial audits and other reviews by the U.S. government of our costs and performance on their contracts, as well as our accounting and general business practices related to these contracts. Based on the results of its audits, the government may adjust our contract-related costs and fees, including allocated indirect costs.

Risks Related to the Commercialization of Our Product Candidates

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

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval, we

[Table of Contents](#)

will need to establish a sales and marketing organization or enter into collaboration, distribution and other marketing arrangements with one or more third parties to commercialize our product candidates. In the United States, we intend to build a commercial organization to target hospitals with the greatest incidence of serious and life-threatening multi-drug resistant infections and recruit experienced sales, marketing and distribution professionals. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. We plan to work with multi-national pharmaceutical companies to leverage their commercialization capabilities to commercialize any product candidate for which we may obtain regulatory approval outside of the United States.

If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise to target the hospital setting that we intend to target. If we are unable to establish a sales force and marketing and distribution capabilities, our operating results may be adversely affected.

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

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

If we are unable to establish our own sales, marketing and distribution capabilities in the United States and, instead, enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. We intend to use collaborators to assist with the commercialization outside the United States of any of our product candidates that receive regulatory approval. 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 limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA, the EMA or other comparable regulatory agencies and are able to initiate commercialization of ETX2514SUL, zoliflodacin, ETX0282CPDP or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the potential and perceived advantages and disadvantages of the product candidates, including cost and clinical benefit relative to alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- acceptance by physicians, patients, operators of hospitals, including in-hospital formularies, and treatment facilities and parties responsible for coverage and reimbursement of the product;

[Table of Contents](#)

- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the ability to manufacture our product in sufficient quantities and yields;
- the strength and effectiveness of marketing and distribution support;
- the prevalence and severity of any side effects;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling or an approved REMS;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- the approval of other new products for the same indications;
- the timing of market introduction of the approved product as well as competitive products;
- the emergence of bacterial resistance to the product; and
- the rate at which resistance to other drugs in the target infections grow.

Any failure by any of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would have a material adverse effect on our business prospects.

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 from major multi-national pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies and generic drug companies with respect to ETX2514SUL, zoliflodacin, ETX0282CPDP and other product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of drug-resistant infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, more effectively marketed and sold or less costly than ETX2514SUL, zoliflodacin, ETX0282CPDP or any other product candidates that we may develop, which could render our product candidates non-competitive and obsolete.

We are initially developing ETX2514SUL for the treatment of multi-drug resistant *Acinetobacter* infections. Due to rising resistance rates, standard-of-care treatment for multi-drug resistant *Acinetobacter* often includes a combination of several last-line treatment options, including carbapenems, tetracyclines and polymyxins, all generically available agents. We are aware of other potentially competitive approved products, or product candidates in clinical development that have shown *in vitro* activity against *Acinetobacter*: eravacycline, recently approved by the FDA for complicated intra-abdominal infections (CIAI) and TP-6076 currently in a Phase 3 clinical trial, and TP-6076, currently in a Phase 1 clinical trial, from Tetrphase Pharmaceuticals, Inc. and cefiderocol, currently in a Phase 3 clinical trial, from Shionogi & Co., Ltd.

We are initially developing zoliflodacin for the treatment of gonorrhea. Gonorrhea is commonly treated with the combination therapy of intramuscular ceftriaxone injection and oral azithromycin, both generically available agents. Additional generic cephalosporins and fluoroquinolones are also prescribed, but not recommend as primary treatment options given current resistance rates. Gepotidacin, currently under development for a variety of infections by GlaxoSmithKline plc, is the only potentially competitive product candidate in clinical development that we are aware of that is addressing gonorrhea.

We are initially developing ETX0282CPDP for the treatment of complicated UTIs. There are a variety of generically available antibiotic classes available for the treatment of such infections, including cephalosporins, carbapenems and fluoroquinolones. Additionally, there are several recently approved and likely to be approved branded agents targeting multi-drug resistant complicated UTIs, including Avycaz, Vabomere and Zemdri™. We are aware of additional potentially competitive oral product candidates in clinical development that may address a limited breadth of multi-drug resistant Gram-negative pathogens: sulopenem from Iterum Therapeutics Limited, currently in a Phase 3 clinical trial, C-Scape from Achaogen, Inc., currently in a Phase 1 clinical trial, and tebipenem from Spero Therapeutics Inc., currently in a Phase 1 clinical trial.

[Table of Contents](#)

If our competitors obtain marketing approval from the FDA, the EMA or other comparable regulatory authorities for their product candidates more rapidly than we do, it could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do as an organization. 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.

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 more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain approval from the FDA, the EMA or other comparable regulatory agencies for their product candidates more rapidly than we may obtain approval for ours, which could result in product approval delays if a competitor obtains market exclusivity from the FDA or the EMA, or our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs. Additional drugs may become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic drugs.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs, and providers are unlikely to prescribe our drugs, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs and their administration.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;

[Table of Contents](#)

- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any drugs that we may develop.

We currently hold \$10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of \$10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Business and Managing Our Growth

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

We are highly dependent on the management, research and development, clinical, financial and business development expertise of Manoussos Perros, Ph.D., our chief executive officer, Michael Gutch, Ph.D., our chief financial officer and chief business officer, Robin Isaacs, M.D., our chief medical officer, John Mueller, Ph.D., our chief development officer, and Ruben Tommasi, Ph.D., our chief scientific officer, as well as the other members of our scientific and clinical teams. Although we have employment agreements with our executive officers, each of them may nevertheless terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2018, we had 33 full-time employees. As the clinical development of our product candidates progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations, including elements of our information technology infrastructure, to third parties and, as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to other third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our, our third-party vendors’ or business partners’ information technology systems or other similar data security incidents could adversely affect our business operations and result in the loss, misappropriation, and unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and state breach notification laws and foreign law equivalents, subject us to time-consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us, or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses, as deemed appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;

[Table of Contents](#)

- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Risks Related to Our Intellectual Property

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

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 product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technology and product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. To protect our proprietary positions, we file patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive and time-consuming. We and our current licensees, or any future licensors and licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or our current licensees, or any future licensors or licensees may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. 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. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which 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. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future our product candidates. 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 be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, should we own any patents or patent applications in the future, we may not be certain that we were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover,

[Table of Contents](#)

we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable and/or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable.

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

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 issued patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. 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 and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary chemistry technology without infringing the intellectual property and other proprietary rights of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of antibacterial treatment, including compounds, formulations, treatment methods and synthetic processes that may be applied towards the synthesis of antibiotics. If any of their patents cover our product candidates or technologies, we may not be free to manufacture or market our product candidates as planned.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in a number of areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. 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. 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. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

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. Although we try to ensure that our employees do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that these employees or we have inadvertently or otherwise used intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own.

Our business was founded as a spin-out from AstraZeneca AB, or AstraZeneca. Although all patent applications are fully owned by us and were either filed by AstraZeneca with all rights fully transferred to us, or filed in our sole name, because we acquired certain of our patents from AstraZeneca, we must rely on their prior practices, with regard to the assignment of such intellectual property. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our products if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in

[Table of Contents](#)

substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our products.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with ETX2514SUL, zoliflodacin, ETX0282CPDP or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

In addition to seeking patent and trademark protection for our 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, 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. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any 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.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. 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 disclosed to or independently developed by a competitor, our competitive position would be harmed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain licensed technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our

proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export, and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA, the EMA and other foreign regulatory agencies. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to 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. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and 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. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to 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. The FDA, the EMA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. 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.

In addition, 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. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical 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. Any marketing approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we 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 impaired.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed in these territories. Any approval we are granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions.

In order to market and sell our products in the European Union and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain approval from the FDA. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining approval from the FDA. In addition, in many countries outside the United States, it is required that the product be approved for

reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Additionally, in June 2016, the electorate in the United Kingdom voted in favor of withdrawing from the European Union, commonly referred to as “Brexit.” On March 29, 2017, the United Kingdom formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Treaty on European Union. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the withdrawal could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or the European Union for our product candidates, which could significantly and materially harm our business.

Fast Track designation for one or more of our product candidates may not actually lead to a faster development or regulatory review or approval process.

In September 2017, we received Fast Track designation from the FDA for ETX2514SUL for the treatment of a variety of serious multi-drug resistant infections caused by *Acinetobacter*, and in May 2014, we received Fast Track designation for zoliflodacin for the treatment of uncomplicated gonorrhea. If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address the unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. Even though we have received Fast Track designation for ETX2514SUL for the treatment of a variety of serious multi-drug resistant infections caused by *Acinetobacter* and for zoliflodacin for the treatment of uncomplicated gonorrhea, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation 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.

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

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

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

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

The FDA and other federal and state agencies, including the U.S. Department of Justice, or DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in

[Table of Contents](#)

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

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

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

Non-compliance with EU 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 EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our employees, independent contractors, principal investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct or failure to comply with applicable regulatory requirements. Misconduct by employees and independent contractors, such as principal investigators, CROs, consultants, commercial partners and vendors, could include failures to comply with regulations of the FDA, the EMA and other comparable regulatory authorities, to provide accurate information to such regulators, to comply with manufacturing standards we have established, to comply with healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to

[Table of Contents](#)

prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. It is not always possible to identify and deter employee and independent contractor misconduct, and any precautions we take to detect and prevent improper activities 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. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

Our current and future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which 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, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal False Claims Act, which impose 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, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “business associates” that

create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

- the federal Physician Payments Sunshine Act, created under Section 6002 of Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations, created annual reporting requirements for manufacturers of drugs, devices, biologicals and medical supplies for certain payments and “transfers of value” provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws requiring the licensure of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may 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. 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, including, without limitation, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

Future legislation, and/or regulations and policies adopted by the FDA, the EMA or comparable regulatory authorities, may increase the time and cost required for us or our collaborator to conduct and complete clinical trials of ETX2514SUL, zoliflodacin, ETX0282CPDP and our other product candidates and potential product candidates.

The FDA and the EMA have each established regulations to govern the product development and approval process, as have other foreign regulatory authorities. The policies of the FDA, the EMA and other regulatory authorities may change. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but not all of its provisions have yet been implemented. Additionally, in August 2017, the FDA issued final guidance setting forth its current thinking with respect to development programs and clinical trial designs for antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need. We cannot predict what if any effect the Cures Act or any existing or future guidance from the FDA or other regulatory authorities will have on the development of our product candidates.

Recently enacted and future legislation may increase the difficulty and cost for us and our collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we 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 prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

[Table of Contents](#)

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, the ACA, which was enacted in the United States in March 2010, includes measures to change health care delivery, decrease the number of individuals without insurance, ensure access to certain basic health care services, and contain the rising cost of care. The healthcare reform movement, including the enactment of the ACA, has significantly changed health care financing by both governmental and private insurers in the United States. With respect to pharmaceutical manufacturers, the ACA increased the number of individuals with access to health care coverage, including prescription drug coverage, but it simultaneously imposed, among other things, increased liability for rebates and discounts owed to certain entities and government health care programs, new fees for the manufacture or importation of certain branded drugs, and new transparency reporting requirements under the Physician Payments Sunshine Act.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” Congress may consider other legislation to repeal and replace elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

In addition to the ACA, other federal health reform measures have been proposed and adopted in the United States. For example, legislation has been enacted to reduce the level of reimbursement paid to providers under the Medicare program over time, as well as phase in alternative payment models for provider services under the Medicare program with the goal of incentivizing the attainment of pre-defined quality measures. As these measures are not fully in effect, and since the U.S. Congress could intervene to prevent their full implementation, at this time, it is unclear how payment reductions or the introduction of the quality payment program will impact overall physician reimbursement under the Medicare program. It is also unclear if changes in Medicare payments to providers would impact such providers’ willingness to prescribe and administer our products, if approved. Further, there has been heightened governmental scrutiny over the manner in which companies set prices for their marketed products. For example, there have been several recent 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 patient programs, and reform government program reimbursement methodologies for drug products.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for 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 product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our product candidates may be subject to government price controls that may affect our revenue.

There has been heightened governmental scrutiny in the United States and abroad of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement

[Table of Contents](#)

methodologies for products. At the state level, legislatures have become 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. Outside of the United States, particularly in 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. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. 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 harmed.

We are subject to the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or the Bribery Act, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage.

Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We, our collaborators, and those acting on our behalf operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anticorruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. 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 which existing laws might be administered or interpreted.

Compliance with the Bribery Act, the FCPA and these other laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, anti-corruption laws present 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 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 the United Kingdom, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, 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 Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United States, United Kingdom or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. Further, the failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting.

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 harm 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 involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally 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, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

[Table of Contents](#)

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 do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Ownership of Our Common Stock

The trading price of our common stock may be volatile and fluctuate substantially, and you could lose all or part of your investment.

Since our initial public offering, our stock price has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their shares at or above the price paid for the shares. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our planned and future clinical trials;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes to our relationships with collaborators, manufacturers or suppliers;
- the results of our testing and clinical trials;
- unanticipated safety concerns;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our common stock on The Nasdaq Global Market;
- sales of our common stock by us, our executive officers and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or the United Kingdom;

[Table of Contents](#)

- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares of our common stock at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

An active trading market for our common stock may not continue to develop or be sustained.

Prior to our initial public offering, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Global Market, we cannot assure you that an active trading market for our shares will continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for investors in our common stock to sell shares without depressing the market price for the shares or to sell the shares at all.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate research coverage of our common stock or may discontinue research coverage, and a lack of research coverage may adversely affect the market price of our common stock. We do not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

The issuance of additional stock in connection with financings, acquisitions, investments, our equity incentive plan or otherwise will dilute all other stockholders.

Our certificate of incorporation authorizes us to issue up to 125,000,000 shares of common stock and up to 10,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our equity incentive plans or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

A significant portion of our total outstanding shares are restricted from immediate resale, but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. We have outstanding 13,097,961 shares of our common stock as of September 30, 2018. Of these shares, the 5,000,000 shares of our common stock sold in our initial public offering are freely tradable, except shares purchased by our affiliates, and 8,097,961 additional shares of our common stock will be available for sale in the public market beginning in March 2019 following the expiration of lock-up agreements between our stockholders and the underwriters. The representatives of the underwriters may release these stockholders from their lock-up agreements with the underwriters at any time, which would allow for earlier sales of shares in the public market. Moreover, the holders of an aggregate of 8,084,414 shares of our

[Table of Contents](#)

common stock or their transferees will have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. In addition, we intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions and matters submitted to stockholders for approval.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own, in the aggregate, 86.9% of our outstanding common stock, based on the number of shares of our common stock outstanding as of September 30, 2018. As a result, these persons, acting together, would be able to control all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation or sale of all or substantially all of our assets, or other significant corporate transactions. The interests of this group of stockholders may not coincide with our interests or the interests of other stockholders. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by: delaying, deferring, or preventing a change in control; entrenching our management and/or the board of directors; impeding a merger, consolidation, takeover, or other business combination involving us; or by discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66²/₃% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired more than 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of

[Table of Contents](#)

discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, including claims under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us or any of our directors, officers, employees or agents arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us or any of our directors, officers, employees or agents that is governed by the internal-affairs doctrine.

Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board 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 obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We currently take advantage of some or all of these reporting exemptions and we may continue to do so until we are no longer an emerging growth company, or EGC. We will remain an EGC until the earlier of (1) the last day of 2023, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

[Table of Contents](#)

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Sarbanes-Oxley Act and the rules and regulations of The Nasdaq Stock Market, or Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Beginning with our second annual report following our initial public offering, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our initial public offering, we have never been required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the Securities and Exchange Commission, or SEC, or other regulatory authorities.

We have broad discretion in the use of our cash and cash equivalents and may invest or spend them in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management will have broad discretion in the application of our cash and cash equivalents and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our common stock to decline and delay the development of our product candidates and preclinical program. Pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. Pursuant to our Business Transfer and Subscription Agreement with AstraZeneca, we also agreed to pay AstraZeneca a one-time milestone payment of \$5.0 million within three months of achieving a specified cumulative net sales milestone for ETX2514. This milestone payment will be automatically waived should our common stock trade on Nasdaq at or above a specified price at the time we achieve such specified cumulative net sales milestone for ETX2514, subject to adjustment for share splits, dividends and other similar events. We are also obligated to pay AstraZeneca a one-time milestone payment of \$10.0 million within two years of achieving the first commercial sale of zoliflodacin. Following the achievement of either milestone, we are not permitted to pay dividends or make other distributions to any of our stockholders until the applicable milestone payment has been paid in full or otherwise waived. We have never declared or paid a dividend on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, on our common stock will be your sole source of gains for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

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

As of December 31, 2017, we had U.S. federal, state and foreign net operating loss carryforwards, or NOLs, of \$10.8 million, \$11.1 million and \$35.2 million, respectively. Our pre-2018 U.S. NOLs begin to expire in 2035. Under the newly enacted Tax Cuts and Jobs Act, U.S. federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the

[Table of Contents](#)

deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various U.S. states will conform to the Tax Cuts and Jobs Act. To the extent that we continue to generate taxable losses in the United States, unused losses will carry forward to offset future taxable income (subject to any applicable limitations), if any, until such unused losses expire. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change U.S. federal income or U.S. federal taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future and/or subsequent shifts in our share ownership (some of which shifts are outside our control). As a result, if we earn net taxable income for U.S. federal income tax purposes, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of U.S. state tax law may also apply to limit our use of accumulated state tax attributes, including our state NOLs. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could negatively impact our future cash flows.

Recent and potential future changes to U.S. and non-U.S. tax laws could materially adversely affect our company.

Existing, new or future changes in tax laws, regulations and treaties, or the interpretation thereof, in addition to tax policy initiatives and reforms under consideration in the United States or internationally and other initiatives could have an adverse effect on the taxation of international businesses. Furthermore, countries where we are subject to taxes, including the United States, are independently evaluating their tax policy and we may see significant changes in legislation and regulations concerning taxation. On December 22, 2017, President Trump signed into law new legislation, commonly referred to as the Tax Cuts and Jobs Act, that significantly revises the Code. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. Other legislative changes could also affect the taxation of holders of our common stock. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we have operations and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden and cost of tax compliance. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislative changes and the potential tax consequences of investing in or holding our common stock.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. The foregoing are only selected examples of potential challenges, and other tax positions we have taken or may take in the future could become the subject of disputes with one or more tax authorities. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

We will incur significantly increased costs as a result of operating as a company whose common stock is publicly traded in the United States, and our management is required to devote substantial time to new compliance initiatives.

As a public company in the United States, we will incur significant legal, accounting and other expenses that we did not incur previously. These expenses will likely be even more significant after we no longer qualify as an EGC. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance

[Table of Contents](#)

of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our senior management on our internal control over financial reporting. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for compliance with Section 404, we will be 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 or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Equity Securities

During the three months ended September 30, 2018, we granted to our employee's stock options to purchase an aggregate of 243,106 shares of our common stock at an exercise price of \$15.00 per share pursuant to our 2018 Equity Incentive Plan.

On September 28, 2018, we completed our initial public offering, or IPO, and issued an aggregate of 609,484 shares of our common stock as settlement of the accrued dividends through September 27, 2018 due to the holders of our convertible preferred stock. Holders of our convertible preferred stock were entitled to receive a cumulative preferred dividend at a fixed rate of 4.0% of the issuance price of such preferred stock annually. No dividends will accrue after September 27, 2018.

The offers, sales and issuances of the securities described in this section were exempt from registration either under Rule 701 promulgated under the Securities Act of 1933, as amended, or the Securities Act, in that the transactions were underwritten compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act in that the transactions did not involve any public offering within the meaning of Section 4(a)(2) or, in certain cases, were acquired by accredited investors. Appropriate legends were affixed to the securities issued in these transactions.

Use of Proceeds from Our IPO

On September 28, 2018, we issued 5,000,000 shares of our common stock in the IPO at an initial offering price of \$15.00 per share. We received net proceeds from the IPO of approximately \$65.6 million, after deducting underwriting discounts and commissions and expenses. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates. Credit Suisse Securities (USA) LLC and BMO Capital Markets Corp. acted as lead book-running managers. SunTrust Robinson Humphrey, Inc. and Wedbush Securities Inc. acted as co-managers for the IPO.

Shares of our common stock began trading on The Nasdaq Global Market on September 26, 2018. The offer and sale of the shares were registered under the Securities Act on Registration Statement on Form S-1 (Registration No. 333-226920), which was declared effective on September 25, 2018.

There has been no material change in the planned use of proceeds from our IPO as described in our Prospectus. We invested the funds received in cash equivalents and other marketable securities in accordance with our investment policy. None of the proceeds from our IPO were used 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

[Table of Contents](#)

Item 6. Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38670), filed with the SEC on September 28, 2018).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38670), filed with the SEC on September 28, 2018).
4.1	Form of Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-226920), filed with the SEC on August 17, 2018).
4.2	Registration Rights Agreement, by and among the Company and certain of its stockholders, dated September 14, 2018 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-226920), filed with the SEC on September 18, 2018).
10.1+	2018 Equity Incentive Plan.
10.2+	Forms of Option Grant Notice and Option Agreement under 2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-226920), filed with the SEC on August 17, 2018).
10.3+	Form of Restricted Stock Unit Grant Notice and Unit Award Agreement under 2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-226920), filed with the SEC on August 17, 2018).
10.4+	2018 Employee Stock Purchase Plan.
10.5+	Employment Agreement between the Company and Manoussos Perros, effective September 25, 2018 (incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-226920), filed with the SEC on September 18, 2018).
10.6+	Employment Agreement between the Company and Michael Gutch, effective September 25, 2018 (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-226920), filed with the SEC on September 18, 2018).
10.7+	Employment Agreement between the Company and Robin Isaacs, effective September 25, 2018 (incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-226920), filed with the SEC on September 18, 2018).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates a management contract or compensatory plan.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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.

Company Name

Date: November 14, 2018

By: /s/ Manoussos Perros, Ph.D.
Manoussos Perros, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2018

By: /s/ Michael Gutch, Ph.D.
Michael Gutch, Ph.D.
Chief Financial Officer and Chief Business Officer
(Principal Financial and Accounting Officer)

ENTASIS THERAPEUTICS HOLDINGS INC.

2018 EQUITY INCENTIVE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: September 13, 2018

APPROVED BY THE STOCKHOLDERS: September 14, 2018

IPO DATE: September 25, 2018

1. GENERAL.

(a) **Successor to and Continuation of Prior Plan.** The Plan is intended as the successor to and continuation of the Entasis Therapeutics Holdings Inc. Amended and Restated Stock Incentive Plan (the "*Prior Plan*"). From and after 12:01 a.m. Eastern time on the IPO Date, no additional stock awards will be granted under the Prior Plan. All Awards granted on or after 12:01 a.m. Eastern Time on the IPO Date will be granted under this Plan. All stock awards granted under the Prior Plan will remain subject to the terms of the Prior Plan.

(i) Any shares that would otherwise remain available for future grants under the Prior Plan as of 12:01 a.m. Eastern Time on the IPO Date (the "*Prior Plan's Available Reserve*") will cease to be available under the Prior Plan at such time. Instead, that number of shares of Common Stock equal to the Prior Plan's Available Reserve will be added to the Share Reserve (as further described in Section 3(a) below) and will be immediately available for grants and issuance pursuant to Stock Awards hereunder, up to the maximum number set forth in Section 3(a) below.

(ii) In addition, from and after 12:01 a.m. Eastern time on the IPO Date, any shares subject, at such time, to outstanding stock awards granted under the Prior Plan that (i) expire or terminate for any reason prior to exercise or settlement; (ii) are forfeited because of the failure to meet a contingency or condition required to vest such shares or otherwise return to the Company; or (iii) are reacquired, withheld (or not issued) to satisfy a tax withholding obligation in connection with an award or to satisfy the purchase price or exercise price of a stock award (such shares the "*Returning Shares*") will immediately be added to the Share Reserve (as further described in Section 3(a) below) as and when such shares become Returning Shares, up to the maximum number set forth in Section 3(a) below.

(b) **Eligible Award Recipients.** Employees, Directors and Consultants are eligible to receive Awards.

(c) **Available Awards.** The Plan provides for the grant of the following types of Awards: (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards.

(d) **Purpose.** The Plan, through the granting of Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and provide a means by which the eligible recipients may benefit from increases in value of the Common Stock.

2. ADMINISTRATION.

(a) **Administration by Board.** The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) **Powers of Board.** The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement or in the written terms of a Performance Cash Award, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which an Award may be exercised or vest (or the time at which cash or shares of Common Stock may be issued in settlement thereof).

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Agreement, suspension or termination of the Plan will not materially impair a Participant's rights under the Participant's then-outstanding Award without the Participant's written consent except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to Incentive Stock Options and certain nonqualified deferred compensation under Section 409A of the Code and/or bringing the Plan or Awards granted under the Plan into compliance with the requirements for Incentive Stock Options or ensuring that they are exempt from or compliant with the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan that (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan, (D) materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (E) materially extends the term of the Plan, or (F) materially expands the types of Awards available for issuance under the Plan. Except as otherwise provided in the Plan or an Award Agreement, no amendment of the Plan will materially impair a Participant's rights under an outstanding Award without the Participant's written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 422 of the Code regarding incentive stock options or (B) Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however*, that a Participant's rights under any Award will not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, (1) a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights, and (2) subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant's consent (A) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (B) to change the terms of an Incentive Stock Option, if such change results in impairment of the Award solely because it impairs the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (C) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code; or (D) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees, Directors or Consultants who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction).

(xi) To effect, with the consent of any adversely affected Participant, (A) the reduction of the exercise, purchase or strike price of any outstanding Stock Award, (B) the cancellation of any outstanding Stock Award and the grant in substitution therefor of a new (1) Option or SAR, (2) Restricted Stock Award, (3) Restricted Stock Unit Award, (4) Other Stock Award, (5) cash and/or (6) other valuable consideration determined by the Board, in its sole discretion, with any such substituted award (x) covering the same or a different number of shares of Common Stock as the cancelled Stock Award and (y) granted under the Plan or another equity or compensatory plan of the Company; or (C) any other action that is treated as repricing under generally accepted accounting principles.

(c) Delegation to Committee.

(i) **General.** The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Committee may, at any time, abolish the subcommittee and/or revert in the Committee any powers delegated to the subcommittee. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revert in the Board some or all of the powers previously delegated.

(ii) **Rule 16b-3 Compliance.** The Committee may consist solely of two or more Non-Employee Directors, in accordance with Rule 16b-3.

(d) **Delegation to an Officer.** The Board may delegate to one or more Officers the authority to do one or both of the following (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by applicable law, other Stock Awards) and, to the extent permitted by applicable law, the terms of such Awards, and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; *provided, however*, that the Board resolutions regarding such delegation will specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Any such Stock Awards will be granted on the form of Stock Award Agreement most recently approved for use by the Committee or the Board, unless otherwise provided in the resolutions approving the delegation authority. The Board may not delegate authority to an Officer who is acting solely in the capacity of an Officer (and not also as a Director) to determine the Fair Market Value pursuant to Section 13(w)(iii) below.

(e) **Effect of Board's Decision.** All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

3. SHARES SUBJECT TO THE PLAN.

(a) **Share Reserve.** Subject to Section 9(a) relating to Capitalization Adjustments, and the following sentence regarding the annual increase, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards will not exceed 2,350,000 shares (the "**Share Reserve**"), which number is the sum of (i) 1,095,864 new shares, *plus* (ii) the number of shares subject to the Prior Plan's Available Reserve *plus* (iii) the number of shares that are Returning Shares, as such shares become available from time to time. In addition, the Share Reserve will automatically increase on January 1st of each year, for a period of not more than ten years, commencing on January 1st of the year following the year in which the IPO Date occurs and ending on (and including) January 1, 2028, in an amount equal to 4% of the total number of shares of Capital Stock outstanding on December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that there will be no January 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

For clarity, the Share Reserve in this Section 3(a) is a limitation on the number of shares of Common Stock that may be issued pursuant to the Plan. Accordingly, this Section 3(a) does not limit the granting of Stock Awards except as provided in Section 7(a). Shares may be issued in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c) or, if applicable, NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) **Reversion of Shares to the Share Reserve.** If a Stock Award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that may be available for issuance under the Plan. If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the Plan. Any shares reacquired by the Company in satisfaction of tax withholding obligations on a Stock Award or as consideration for the exercise or purchase price of a Stock Award will again become available for issuance under the Plan.

(c) **Incentive Stock Option Limit.** Subject to the Share Reserve and Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options will be 7,500,000 shares of Common Stock.

(d) **Limitation on Grants to Non-Employee Directors.** The maximum number of shares of Common Stock subject to Stock Awards granted under the Plan or otherwise during a single calendar year to any Non-Employee Director, taken together with any cash fees paid by the Company to such Non-Employee Director during such calendar year for service on the Board, will not exceed five hundred thousand dollars (\$500,000) in total value (calculating the value of any such Stock Awards based on the grant date fair value of such Stock Awards for financial reporting purposes), or, with respect to the calendar year in which a Non-Employee Director is first appointed or elected to the Board, eight hundred thousand dollars (\$800,000).

(e) **Source of Shares.** The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. ELIGIBILITY.

(a) **Eligibility for Specific Stock Awards.** Incentive Stock Options may be granted only to employees of the Company or a “parent corporation” or “subsidiary corporation” thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; provided, however, that Stock Awards may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any “parent” of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Stock Awards is treated as “service recipient stock” under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from Section 409A of the Code, or (iii) the Company, in consultation with its legal counsel, has determined that such Stock Awards comply with the distribution requirements of Section 409A of the Code.

(b) **Ten Percent Stockholders.** A Ten Percent Stockholder will not be granted an Incentive Stock Option unless the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five years from the date of grant.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, or if an Option is designated as an Incentive Stock Option but some portion or all of the Option fails to qualify as an Incentive Stock Option under the applicable rules, then the Option (or portion thereof) will be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; *provided, however*, that each Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:

(a) **Term.** Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Award Agreement.

(b) Exercise Price. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value of the Common Stock subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a corporate transaction and in a manner consistent with the provisions of Section 409A of the Code and, if applicable, Section 424(a) of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

- (i)** by cash, check, bank draft or money order payable to the Company;
- (ii)** pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;
- (iii)** by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;
- (iv)** if an Option is a Nonstatutory Stock Option, by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the “net exercise,” (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or
- (v)** in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Award Agreement.

(d) Exercise and Payment of a SAR. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Agreement evidencing such SAR.

(e) **Transferability of Options and SARs.** The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board will determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) **Restrictions on Transfer.** An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration.

(ii) **Domestic Relations Orders.** Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation Section 1.421-1(b)(2). If an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) **Beneficiary Designation.** Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, upon the death of the Participant, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) **Vesting Generally.** The total number of shares of Common Stock subject to an Option or SAR may vest and become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) **Termination of Continuous Service.** Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date that is three (3) months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Award Agreement) and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR (as applicable) within the applicable time frame, the Option or SAR will terminate.

(h) **Extension of Termination Date.** Except as otherwise provided in the applicable Award Agreement or other written agreement between the Participant and the Company, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of time (that need not be

consecutive) equal to the applicable post termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement. In addition, unless otherwise provided in a Participant's Award Agreement, if the sale of any Common Stock received on exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement.

(i) Disability of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service (or such longer or shorter period specified in the Award Agreement) and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) Death of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Award Agreement for exercisability after the termination of the Participant's Continuous Service for a reason other than death, then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Award Agreement) and (ii) the expiration of the term of such Option or SAR as set forth in the Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR (as applicable) will terminate.

(k) Termination for Cause. Except as explicitly provided otherwise in a Participant's Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon such Participant's termination of Continuous Service, and the Participant will be prohibited from exercising his or her Option or SAR from and after the time of such termination of Continuous Service.

(l) Non-Exempt Employees. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six (6) months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Award Agreement, in another agreement between the Participant and the

Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six (6) months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from the employee's regular rate of pay, the provisions of this Section 5(l) will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Agreements.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARs.

(a) **Restricted Stock Awards.** Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock may be (i) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (ii) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) **Consideration.** A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past or future services to the Company or an Affiliate, or (C) any other form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) **Vesting.** Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) **Termination of Participant's Continuous Service.** If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) **Transferability.** Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board will determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) **Dividends.** A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) **Restricted Stock Unit Awards.** Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted

Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) **Consideration.** At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) **Vesting.** At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) **Payment.** A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) **Additional Restrictions.** At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) **Dividend Equivalents.** Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) **Termination of Participant's Continuous Service.** Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement or other written agreement between a Participant and the Company or an Affiliate, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) **Performance Awards.**

(i) **Performance Stock Awards.** A Performance Stock Award is a Stock Award that is payable (including that may be granted, may vest or may be exercised) contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may, but need not, require the Participant's completion of a specified period of Continuous Service. The length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Board or Committee, in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board or the Committee may determine that cash may be used in payment of Performance Stock Awards.

(ii) **Performance Cash Awards.** A Performance Cash Award is a cash award that is payable contingent upon the attainment during a Performance Period of certain Performance Goals. A

Performance Cash Award may also require the completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Board or Committee, in its sole discretion. The Board or Committee may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property.

(iii) **Board Discretion.** The Board retains the discretion to adjust or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for a Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement or the written terms of a Performance Cash Award.

(d) **Other Stock Awards.** Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value of the Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. COVENANTS OF THE COMPANY.

(a) **Availability of Shares.** The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Stock Awards.

(b) **Securities Law Compliance.** The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan, as necessary, such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise or vesting of the Stock Awards; *provided, however*, that this undertaking will not require the Company to register under the Securities Act or other securities or applicable laws, the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary or advisable for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise or vesting of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) **No Obligation to Notify or Minimize Taxes.** The Company will have no duty or obligation to any Participant to advise such holder as to the tax treatment or time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award.

8. MISCELLANEOUS.

(a) **Use of Proceeds from Sales of Common Stock.** Proceeds from the sale of shares of Common Stock pursuant to Stock Awards will constitute general funds of the Company.

(b) **Corporate Action Constituting Grant of Awards.** Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action approving the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(c) **Stockholder Rights.** No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to an Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Award has been entered into the books and records of the Company.

(d) **No Employment or Other Service Rights.** Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state or foreign jurisdiction in which the Company or the Affiliate is domiciled or incorporated, as the case may be.

(e) **Change in Time Commitment.** In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(f) **Incentive Stock Option Limitations.** To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds \$100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(g) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that such Participant is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(h) Withholding Obligations. Unless prohibited by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Stock Award; *provided, however*, that no shares of Common Stock are withheld with a value exceeding the maximum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Award Agreement.

(i) Electronic Delivery. Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(j) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(k) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not

limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a "resignation for good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

(l) **Compliance with Section 409A of the Code.** Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) **Capitalization Adjustments.** In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities by which the share reserve is to increase automatically each year pursuant to Section 3(a), (iii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c), (iv) the class(es) and maximum number of securities that may be awarded to any Non-Employee Director pursuant to Section 3(d), and (v) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) **Dissolution.** Except as otherwise provided in the Stock Award Agreement, in the event of a Dissolution of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such Dissolution, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service; *provided, however*, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the Dissolution is completed but contingent on its completion.

(c) **Transaction.** The following provisions will apply to Stock Awards in the event of a Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly

provided by the Board at the time of grant of a Stock Award. In the event of a Transaction, then, notwithstanding any other provision of the Plan, the Board may take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Transaction as the Board determines (or, if the Board does not determine such a date, to the date that is five days prior to the effective date of the Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Transaction; *provided, however*, that the Board may require Participants to complete and deliver to the Company a notice of exercise before the effective date of a Transaction, which exercise is contingent upon the effectiveness of such Transaction;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Transaction, over (B) any exercise price payable by such holder in connection with such exercise. For clarity, this payment may be \$0 if the value of the property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of the Company's Common Stock in connection with the Transaction is delayed as a result of escrows, earn outs, holdbacks or any other contingencies.

The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

(d) **Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. PLAN TERM; EARLIER TERMINATION OR SUSPENSION OF THE PLAN.

The Board may suspend or terminate the Plan at any time. No Incentive Stock Options may be granted after the tenth anniversary of the earlier of (i) the date the Plan is adopted by the Board (the

“*Adoption Date*”), or (ii) the date the Plan is approved by the stockholders of the Company. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. EXISTENCE OF THE PLAN; TIMING OF FIRST GRANT OR EXERCISE.

The Plan will come into existence on the Adoption Date; *provided, however*, that no Stock Award may be granted prior to the IPO Date. In addition, no Stock Award will be exercised (or, in the case of a Restricted Stock Award, Restricted Stock Unit Award, Performance Share Award, or Other Stock Award, no Stock Award will be granted) and no Performance Cash Award will be settled unless and until the Plan has been approved by the stockholders of the Company, which approval will be within 12 months after the date the Plan is adopted by the Board.

12. CHOICE OF LAW.

The laws of the State of Delaware will govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state’s conflict of laws rules.

13. DEFINITIONS. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) “*Affiliate*” means, at the time of determination, any “parent” or “subsidiary” of the Company as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which “parent” or “subsidiary” status is determined within the foregoing definition.

(b) “*Award*” means a Stock Award or a Performance Cash Award.

(c) “*Award Agreement*” means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.

(d) “*Board*” means the Board of Directors of the Company.

(e) “*Capital Stock*” means each and every class of common stock of the Company, regardless of the number of votes per share.

(f) “*Capitalization Adjustment*” means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Adoption Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(g) “*Cause*” shall have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant’s commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant’s attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant’s intentional, material violation of

any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) such Participant's gross misconduct. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause shall be made by the Company, in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant shall have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(h) "**Change in Control**" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, (C) on account of the acquisition of securities of the Company by any individual who is, on the IPO Date, either an executive officer or a Director (either, an "**IPO Investor**") and/or any entity in which an IPO Investor has a direct or indirect interest (whether in the form of voting rights or participation in profits or capital contributions) of more than 50% (collectively, the "**IPO Entities**") or on account of the IPO Entities continuing to hold shares that come to represent more than 50% of the combined voting power of the Company's then outstanding securities as a result of the conversion of any class of the Company's securities into another class of the Company's securities having a different number of votes per share pursuant to the conversion provisions set forth in the Company's Amended and Restated Certificate of Incorporation; or (D) solely because the level of Ownership held by any Exchange Act Person (the "**Subject Person**") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction; *provided, however*, that a merger, consolidation or similar transaction will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing

more than 50% of the combined voting power of the surviving Entity or its parent are owned by the IPO Entities;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; *provided, however*, that a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing more than 50% of the combined voting power of the acquiring Entity or its parent are owned by the IPO Entities;

(iv) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company will otherwise occur, except for a liquidation into a parent corporation; or

(v) individuals who, on the IPO Date, are members of the Board (the “*Incumbent Board*”) cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of the Plan, the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company and the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

(i) “*Code*” means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(j) “*Committee*” means a committee of one or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(k) “*Common Stock*” means, as of the IPO Date, the common stock of the Company, having one vote per share.

(l) “*Company*” means Entasis Therapeutics Holdings Inc., a Delaware corporation.

(m) “*Consultant*” means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a “Consultant” for purposes of the Plan. Notwithstanding the foregoing, a person is treated as

a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(n) **"Continuous Service"** means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; *provided, however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(o) **"Corporate Transaction"** means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of more than 50% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(p) **"Director"** means a member of the Board.

(q) **"Disability"** means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(r) **"Dissolution"** means when the Company, after having executed a certificate of dissolution with the State of Delaware (or other applicable state), has completely wound up its affairs. Conversion of the Company into a Limited Liability Company (or any other pass-through entity) will not be considered a "Dissolution" for purposes of the Plan.

(s) “**Employee**” means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an “Employee” for purposes of the Plan.

(t) “**Entity**” means a corporation, partnership, limited liability company or other entity.

(u) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(v) “**Exchange Act Person**” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the IPO Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company’s then outstanding securities.

(w) “**Fair Market Value**” means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(x) “**Incentive Stock Option**” means an option granted pursuant to Section 5 of the Plan that is intended to be, and qualifies as, an “incentive stock option” within the meaning of Section 422 of the Code.

(y) “**IPO Date**” means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

(z) “**Non-Employee Director**” means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act (“**Regulation S-K**”)), does not possess an

interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a “non-employee director” for purposes of Rule 16b-3.

- (aa) “*Nonstatutory Stock Option*” means any Option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.
- (bb) “*Officer*” means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.
- (cc) “*Option*” means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.
- (dd) “*Option Agreement*” means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.
- (ee) “*Optionholder*” means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.
- (ff) “*Other Stock Award*” means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(d).
- (gg) “*Other Stock Award Agreement*” means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement will be subject to the terms and conditions of the Plan.
- (hh) “*Own,*” “*Owned,*” “*Owner,*” “*Ownership*” means a person or Entity will be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.
- (ii) “*Participant*” means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.
- (jj) “*Performance Cash Award*” means an award of cash granted pursuant to the terms and conditions of Section 6(c)(ii).
- (kk) “*Performance Criteria*” means the one or more criteria that the Board will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by the Board: (i) sales; (ii) revenues; (iii) assets; (iv) expenses; (v) market penetration or expansion; (vi) earnings from operations; (vii) earnings before or after deduction for all or any portion of interest, taxes, depreciation, amortization, incentives, service fees or extraordinary or special items, whether or not on a continuing operations or an aggregate or per share basis; (viii) net income or net income per common share (basic or diluted); (ix) return on equity, investment, capital or assets; (x) one or more operating ratios; (xi) borrowing levels, leverage ratios or credit rating; (xii) market share; (xiii) capital expenditures; (xiv) cash flow, free cash flow, cash flow return on investment, or net cash provided by operations; (xv) stock price, dividends or total stockholder return; (xvi) development of

new technologies or products; (xvii) sales of particular products or services; (xviii) economic value created or added; (xix) operating margin or profit margin; (xx) customer acquisition or retention; (xxi) raising or refinancing of capital; (xxii) successful hiring of key individuals; (xxiii) resolution of significant litigation; (xxiv) acquisitions and divestitures (in whole or in part); (xxv) joint ventures and strategic alliances; (xxvi) spin-offs, split-ups and the like; (xxvii) reorganizations; (xxviii) recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; (xxix) or strategic business criteria, consisting of one or more objectives based on the following goals: achievement of timely development, design management or enrollment, meeting specified market penetration or value added, payor acceptance, patient adherence, peer reviewed publications, issuance of new patents, establishment of or securing of licenses to intellectual property, product development or introduction (including, without limitation, any clinical trial accomplishments, regulatory or other filings, approvals or milestones, discovery of novel products, maintenance of multiple products in pipeline, product launch or other product development milestones), geographic business expansion, cost targets, cost reductions or savings, customer satisfaction, operating efficiency, acquisition or retention, employee satisfaction, information technology, corporate development (including, without limitation, licenses, innovation, research or establishment of third party collaborations), manufacturing or process development, legal compliance or risk reduction, patent application or issuance goals, or goals relating to acquisitions, divestitures or other business combinations (in whole or in part), joint ventures or strategic alliances; and (xxx) other measures of performance selected by the Board.

(II) **“Performance Goals”** means, for a Performance Period, the one or more goals established by the Board for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. The Board is authorized at any time in its sole discretion, to adjust or modify the calculation of a Performance Goal for such Performance Period in order to prevent the dilution or enlargement of the rights of Participants, (a) in the event of, or in anticipation of, any unusual or extraordinary corporate item, transaction, event or development; (b) in recognition of, or in anticipation of, any other unusual or nonrecurring events affecting the Company, or the financial statements of the Company in response to, or in anticipation of, changes in applicable laws, regulations, accounting principles, or business conditions; or (c) in view of the Board's assessment of the business strategy of the Company, performance of comparable organizations, economic and business conditions, and any other circumstances deemed relevant. Specifically, the Board is authorized to make adjustment in the method of calculating attainment of Performance Goals and objectives for a Performance Period as follows: (i) to exclude the dilutive effects of acquisitions or joint ventures; (ii) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; and (iii) to exclude the effect of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends. In addition, the Board is authorized to make adjustment in the method of calculating attainment of Performance Goals and objectives for a Performance Period as follows: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated net sales and operating earnings; (iii) to exclude the effects of changes to generally accepted accounting standards required by the Financial Accounting Standards Board; (iv) to exclude the effects of any items that are “unusual” in nature or occur “infrequently” as determined under generally accepted accounting principles; (v) to exclude the effects to any statutory adjustments to corporate tax rates; and (vi) to make other appropriate adjustments determined by the Board.

(mm) “*Performance Period*” means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant’s right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(nn) “*Performance Stock Award*” means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(oo) “*Plan*” means this Entasis Therapeutics Holdings Inc. 2018 Equity Incentive Plan.

(pp) “*Restricted Stock Award*” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(qq) “*Restricted Stock Award Agreement*” means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(rr) “*Restricted Stock Unit Award*” means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(ss) “*Restricted Stock Unit Award Agreement*” means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(tt) “*Rule 16b-3*” means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(uu) “*Securities Act*” means the Securities Act of 1933, as amended.

(vv) “*Stock Appreciation Right*” or “*SAR*” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(ww) “*Stock Appreciation Right Agreement*” means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(xx) “*Stock Award*” means any right to receive Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award or any Other Stock Award.

(yy) “*Stock Award Agreement*” means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

(zz) “*Subsidiary*” means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is

at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(aaa) “*Ten Percent Stockholder*” means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any Affiliate.

(bbb) “*Transaction*” means a Corporate Transaction or a Change in Control.

ENTASIS THERAPEUTICS HOLDINGS INC.

2018 EMPLOYEE STOCK PURCHASE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: September 13, 2018

APPROVED BY THE STOCKHOLDERS: September 14, 2018

1. GENERAL; PURPOSE.

(a) The Plan provides a means by which Eligible Employees of the Company and certain designated Related Corporations may be given an opportunity to purchase shares of Common Stock. The Plan permits the Company to grant a series of Purchase Rights to Eligible Employees under an Employee Stock Purchase Plan.

(b) The Company, by means of the Plan, seeks to retain the services of such Employees, to secure and retain the services of new Employees and to provide incentives for such persons to exert maximum efforts for the success of the Company and its Related Corporations.

2. ADMINISTRATION.

(a) The Board will administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine how and when Purchase Rights will be granted and the provisions of each Offering (which need not be identical).

(ii) To designate from time to time which Related Corporations of the Company will be eligible to participate in the Plan.

(iii) To construe and interpret the Plan and Purchase Rights, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan, in a manner and to the extent it deems necessary or expedient to make the Plan fully effective.

(iv) To settle all controversies regarding the Plan and Purchase Rights granted under the Plan.

(v) To suspend or terminate the Plan at any time as provided in Section 12.

(vi) To amend the Plan at any time as provided in Section 12.

(vii) Generally, to exercise such powers and to perform such acts as it deems necessary or expedient to promote the best interests of the Company and its Related Corporations and to carry out the intent that the Plan be treated as an Employee Stock Purchase Plan.

(viii) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees who are foreign nationals or employed outside the United States.

(c) The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revert in the Board some or all of the powers previously delegated. Whether or not the Board has delegated administration of the Plan to a Committee, the Board will have the final power to determine all questions of policy and expediency that may arise in the administration of the Plan.

(d) All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

3. SHARES OF COMMON STOCK SUBJECT TO THE PLAN.

(a) Subject to the provisions of Section 11(a) relating to Capitalization Adjustments, the maximum number of shares of Common Stock that may be issued under the Plan will not exceed 140,000 shares of Common Stock, plus the number of shares of Common Stock that are automatically added on January 1st of each year for a period of up to ten years, commencing on the first January 1 following the IPO Date and ending on (and including) January 1, 2028, in an amount equal to the lesser of (i) 1% of the total number of shares of Capital Stock outstanding on December 31st of the preceding calendar year, and (ii) 250,000 shares of Common Stock. Notwithstanding the foregoing, the Board may act prior to the first day of any calendar year to provide that there will be no January 1st increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(b) If any Purchase Right granted under the Plan terminates without having been exercised in full, the shares of Common Stock not purchased under such Purchase Right will again become available for issuance under the Plan.

(c) The stock purchasable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market.

4. GRANT OF PURCHASE RIGHTS; OFFERING.

(a) The Board may from time to time grant or provide for the grant of Purchase Rights to Eligible Employees under an Offering (consisting of one or more Purchase Periods) on an Offering Date or Offering Dates selected by the Board. Each Offering will be in such form and will contain such terms and conditions as the Board will deem appropriate, and will comply with the requirement of Section 423(b)(5) of the Code that all Employees granted Purchase Rights will have the same rights and privileges. The terms and conditions of an Offering shall be incorporated by reference into the Plan and treated as part of the Plan. The provisions of separate Offerings need not be identical, but each Offering will include (through incorporation of the provisions of this Plan by reference in the document comprising the Offering or otherwise) the period during which the Offering will be effective, which period will not exceed 27 months beginning with the Offering Date, and the substance of the provisions contained in Sections 5 through 8, inclusive.

(b) If a Participant has more than one Purchase Right outstanding under the Plan, unless he or she otherwise indicates in forms delivered to the Company: (i) each form will apply to all of his or her Purchase Rights under the Plan, and (ii) a Purchase Right with a lower exercise price (or an earlier-granted

Purchase Right, if different Purchase Rights have identical exercise prices) will be exercised to the fullest possible extent before a Purchase Right with a higher exercise price (or a later-granted Purchase Right if different Purchase Rights have identical exercise prices) will be exercised.

(c) The Board will have the discretion to structure an Offering so that if the Fair Market Value of a share of Common Stock on the first Trading Day of a new Purchase Period within that Offering is less than or equal to the Fair Market Value of a share of Common Stock on the Offering Date for that Offering, then (i) that Offering will terminate immediately as of that first Trading Day, and (ii) the Participants in such terminated Offering will be automatically enrolled in a new Offering beginning on the first Trading Day of such new Purchase Period.

5. ELIGIBILITY.

(a) Purchase Rights may be granted only to Employees of the Company or, as the Board may designate in accordance with Section 2(b), to Employees of a Related Corporation. Except as provided in Section 5(b), an Employee will not be eligible to be granted Purchase Rights unless, on the Offering Date, the Employee has been in the employ of the Company or the Related Corporation, as the case may be, for such continuous period preceding such Offering Date as the Board may require, but in no event will the required period of continuous employment be equal to or greater than two years. In addition, the Board may provide that no Employee will be eligible to be granted Purchase Rights under the Plan unless, on the Offering Date, such Employee's customary employment with the Company or the Related Corporation is more than 20 hours per week and more than five months per calendar year or such other criteria as the Board may determine consistent with Section 423 of the Code.

(b) The Board may provide that each person who, during the course of an Offering, first becomes an Eligible Employee will, on a date or dates specified in the Offering which coincides with the day on which such person becomes an Eligible Employee or which occurs thereafter, receive a Purchase Right under that Offering, which Purchase Right will thereafter be deemed to be a part of that Offering. Such Purchase Right will have the same characteristics as any Purchase Rights originally granted under that Offering, as described herein, except that:

(i) the date on which such Purchase Right is granted will be the "Offering Date" of such Purchase Right for all purposes, including determination of the exercise price of such Purchase Right;

(ii) the period of the Offering with respect to such Purchase Right will begin on its Offering Date and end coincident with the end of such Offering; and

(iii) the Board may provide that if such person first becomes an Eligible Employee within a specified period of time before the end of the Offering, he or she will not receive any Purchase Right under that Offering.

(c) No Employee will be eligible for the grant of any Purchase Rights if, immediately after any such Purchase Rights are granted, such Employee owns stock possessing five percent or more of the total combined voting power or value of all classes of stock of the Company or of any Related Corporation. For purposes of this Section 5(c), the rules of Section 424(d) of the Code will apply in determining the stock ownership of any Employee, and stock which such Employee may purchase under all outstanding Purchase Rights and options will be treated as stock owned by such Employee.

(d) As specified by Section 423(b)(8) of the Code, an Eligible Employee may be granted Purchase Rights only if such Purchase Rights, together with any other rights granted under all Employee Stock Purchase Plans of the Company and any Related Corporations, do not permit such Eligible Employee's

rights to purchase stock of the Company or any Related Corporation to accrue at a rate which exceeds \$25,000 of Fair Market Value of such stock (determined at the time such rights are granted, and which, with respect to the Plan, will be determined as of their respective Offering Dates) for each calendar year in which such rights are outstanding at any time.

(e) Officers of the Company and any designated Related Corporation, if they are otherwise Eligible Employees, will be eligible to participate in Offerings under the Plan. Notwithstanding the foregoing, the Board may provide in an Offering that Employees who are highly compensated Employees within the meaning of Section 423(b)(4)(D) of the Code will not be eligible to participate.

6. PURCHASE RIGHTS; PURCHASE PRICE.

(a) On each Offering Date, each Eligible Employee, pursuant to an Offering made under the Plan, will be granted a Purchase Right to purchase up to that number of shares of Common Stock purchasable either with a percentage or with a maximum dollar amount, as designated by the Board, but in either case not exceeding 15% of such Employee's earnings (as defined by the Board in each Offering) during the period that begins on the Offering Date (or such later date as the Board determines for a particular Offering) and ends on the date stated in the Offering, which date will be no later than the end of the Offering.

(b) The Board will establish one or more Purchase Dates during an Offering on which Purchase Rights granted for that Offering will be exercised and shares of Common Stock will be purchased in accordance with such Offering.

(c) In connection with each Offering made under the Plan, the Board may specify (i) a maximum number of shares of Common Stock that may be purchased by any Participant on any Purchase Date during such Offering, (ii) a maximum aggregate number of shares of Common Stock that may be purchased by all Participants pursuant to such Offering and/or (iii) a maximum aggregate number of shares of Common Stock that may be purchased by all Participants on any Purchase Date under the Offering. If the aggregate purchase of shares of Common Stock issuable upon exercise of Purchase Rights granted under the Offering would exceed any such maximum aggregate number, then, in the absence of any Board action otherwise, a pro rata (based on each Participant's accumulated Contributions) allocation of the shares of Common Stock available will be made in as nearly a uniform manner as will be practicable and equitable.

(d) The purchase price of shares of Common Stock acquired pursuant to Purchase Rights will be not less than the lesser of:

- (i) an amount equal to 85% of the Fair Market Value of the shares of Common Stock on the Offering Date; or
- (ii) an amount equal to 85% of the Fair Market Value of the shares of Common Stock on the applicable Purchase Date.

7. PARTICIPATION; WITHDRAWAL; TERMINATION.

(a) An Eligible Employee may elect to authorize payroll deductions as the means of making Contributions by completing and delivering to the Company, within the time specified in the Offering, an enrollment form provided by the Company. The enrollment form will specify the amount of Contributions not to exceed the maximum amount specified by the Board. Each Participant's Contributions will be credited to a bookkeeping account for such Participant under the Plan and will be deposited with the general funds of the Company except where applicable law requires that Contributions be deposited with a third party. If permitted in the Offering, a Participant may begin such Contributions with the first payroll occurring on or

after the Offering Date (or, in the case of a payroll date that occurs after the end of the prior Offering but before the Offering Date of the next new Offering, Contributions from such payroll will be included in the new Offering). If permitted in the Offering, a Participant may thereafter reduce (including to zero) or increase his or her Contributions. If specifically provided in the Offering, in addition to making Contributions by payroll deductions, a Participant may make Contributions through the payment by cash or check prior to a Purchase Date.

(b) During an Offering, a Participant may cease making Contributions and withdraw from the Offering by delivering to the Company a withdrawal form provided by the Company. The Company may impose a deadline before a Purchase Date for withdrawing. Upon such withdrawal, such Participant's Purchase Right in that Offering will immediately terminate and the Company will distribute to such Participant all of his or her accumulated but unused Contributions and such Participant's Purchase Right in that Offering shall thereupon terminate. A Participant's withdrawal from that Offering will have no effect upon his or her eligibility to participate in any other Offerings under the Plan, but such Participant will be required to deliver a new enrollment form to participate in subsequent Offerings.

(c) Purchase Rights granted pursuant to any Offering under the Plan will terminate immediately if the Participant either (i) is no longer an Employee for any reason or for no reason (subject to any post-employment participation period required by law) or (ii) is otherwise no longer eligible to participate. The Company will distribute to such individual all of his or her accumulated but unused Contributions.

(d) During a Participant's lifetime, Purchase Rights will be exercisable only by such Participant. Purchase Rights are not transferable by a Participant, except by will, by the laws of descent and distribution, or, if permitted by the Company, by a beneficiary designation as described in Section 10.

(e) Unless otherwise specified in the Offering, the Company will have no obligation to pay interest on Contributions.

8. EXERCISE OF PURCHASE RIGHTS.

(a) On each Purchase Date, each Participant's accumulated Contributions will be applied to the purchase of shares of Common Stock, up to the maximum number of shares of Common Stock permitted by the Plan and the applicable Offering, at the purchase price specified in the Offering. No fractional shares will be issued unless specifically provided for in the Offering.

(b) Unless otherwise provided in the Offering, if any amount of accumulated Contributions remains in a Participant's account after the purchase of shares of Common Stock and such remaining amount is less than the amount required to purchase one share of Common Stock on the final Purchase Date of an Offering, then such remaining amount will be held in such Participant's account for the purchase of shares of Common Stock under the next Offering under the Plan, unless such Participant withdraws from or is not eligible to participate in such Offering, in which case such amount will be distributed to such Participant after the final Purchase Date, without interest. If the amount of Contributions remaining in a Participant's account after the purchase of shares of Common Stock is at least equal to the amount required to purchase one whole share of Common Stock on the final Purchase Date of an Offering, then such remaining amount will not roll over to the next Offering and will instead be distributed in full to such Participant after the final Purchase Date of such Offering without interest.

(c) No Purchase Rights may be exercised to any extent unless the shares of Common Stock to be issued upon such exercise under the Plan are covered by an effective registration statement pursuant to the Securities Act and the Plan is in material compliance with all applicable federal, state, foreign and other securities and other laws applicable to the Plan. If on a Purchase Date the shares of Common Stock are not

so registered or the Plan is not in such compliance, no Purchase Rights will be exercised on such Purchase Date, and the Purchase Date will be delayed until the shares of Common Stock are subject to such an effective registration statement and the Plan is in material compliance, except that the Purchase Date will in no event be more than 6 months from the Offering Date. If, on the Purchase Date, as delayed to the maximum extent permissible, the shares of Common Stock are not registered and the Plan is not in material compliance with all applicable laws, no Purchase Rights will be exercised and all accumulated but unused Contributions will be distributed to the Participants without interest.

9. COVENANTS OF THE COMPANY.

The Company will seek to obtain from each federal, state, foreign or other regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Purchase Rights and issue and sell shares of Common Stock thereunder. If, after commercially reasonable efforts, the Company is unable to obtain the authority that counsel for the Company deems necessary for the grant of Purchase Rights or the lawful issuance and sale of Common Stock under the Plan, and at a commercially reasonable cost, the Company will be relieved from any liability for failure to grant Purchase Rights and/or to issue and sell Common Stock upon exercise of such Purchase Rights.

10. DESIGNATION OF BENEFICIARY.

(a) The Company may, but is not obligated to, permit a Participant to submit a form designating a beneficiary who will receive any shares of Common Stock and/or Contributions from the Participant's account under the Plan if the Participant dies before such shares and/or Contributions are delivered to the Participant. The Company may, but is not obligated to, permit the Participant to change such designation of beneficiary. Any such designation and/or change must be on a form approved by the Company.

(b) If a Participant dies, and in the absence of a valid beneficiary designation, the Company will deliver any shares of Common Stock and/or Contributions to the executor or administrator of the estate of the Participant. If no executor or administrator has been appointed (to the knowledge of the Company), the Company, in its sole discretion, may deliver such shares of Common Stock and/or Contributions to the Participant's spouse, dependents or relatives, or if no spouse, dependent or relative is known to the Company, then to such other person as the Company may designate.

11. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; CORPORATE TRANSACTIONS.

(a) In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities by which the share reserve is to increase automatically each year pursuant to Section 3(a), (iii) the class(es) and number of securities subject to, and the purchase price applicable to outstanding Offerings and Purchase Rights, and (iv) the class(es) and number of securities that are the subject of the purchase limits under each ongoing Offering. The Board will make these adjustments, and its determination will be final, binding and conclusive.

(b) In the event of a Corporate Transaction, then: (i) any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or continue outstanding Purchase Rights or may substitute similar rights (including a right to acquire the same consideration paid to the stockholders in the Corporate Transaction) for outstanding Purchase Rights, or (ii) if any surviving or acquiring corporation (or its parent company) does not assume or continue such Purchase Rights or does not substitute similar rights for such Purchase Rights, then the Participants' accumulated Contributions will be used to purchase shares of Common Stock within ten business days prior to the

Corporate Transaction under the outstanding Purchase Rights, and the Purchase Rights will terminate immediately after such purchase.

12. AMENDMENT, TERMINATION OR SUSPENSION OF THE PLAN.

(a) The Board may amend the Plan at any time in any respect the Board deems necessary or advisable. However, except as provided in Section 11(a) relating to Capitalization Adjustments, stockholder approval will be required for any amendment of the Plan for which stockholder approval is required by applicable law or listing requirements, including any amendment that either (i) materially increases the number of shares of Common Stock available for issuance under the Plan, (ii) materially expands the class of individuals eligible to become Participants and receive Purchase Rights, (iii) materially increases the benefits accruing to Participants under the Plan or materially reduces the price at which shares of Common Stock may be purchased under the Plan, (iv) materially extends the term of the Plan, or (v) expands the types of awards available for issuance under the Plan, but in each of (i) through (v) above only to the extent stockholder approval is required by applicable law or listing requirements.

(b) The Board may suspend or terminate the Plan at any time. No Purchase Rights may be granted under the Plan while the Plan is suspended or after it is terminated.

(c) Any benefits, privileges, entitlements and obligations under any outstanding Purchase Rights granted before an amendment, suspension or termination of the Plan will not be materially impaired by any such amendment, suspension or termination except (i) with the consent of the person to whom such Purchase Rights were granted, (ii) as necessary to comply with any laws, listing requirements, or governmental regulations (including, without limitation, the provisions of Section 423 of the Code and the regulations and other interpretive guidance issued thereunder relating to Employee Stock Purchase Plans) including without limitation any such regulations or other guidance that may be issued or amended after the date the Plan is adopted by the Board, or (iii) as necessary to obtain or maintain favorable tax, listing, or regulatory treatment. To be clear, the Board may amend outstanding Purchase Rights without a Participant's consent if such amendment is necessary to ensure that the Purchase Right and/or the Plan complies with the requirements of Section 423 of the Code.

13. EFFECTIVE DATE OF PLAN.

The Plan will become effective immediately prior to and contingent upon the IPO Date. No Purchase Rights will be exercised unless and until the Plan has been approved by the stockholders of the Company, which approval must be within 12 months before or after the date the Plan is adopted (or if required under Section 12(a) above, materially amended) by the Board.

14. MISCELLANEOUS PROVISIONS.

(a) Proceeds from the sale of shares of Common Stock pursuant to Purchase Rights will constitute general funds of the Company.

(b) A Participant will not be deemed to be the holder of, or to have any of the rights of a holder with respect to, shares of Common Stock subject to Purchase Rights unless and until the Participant's shares of Common Stock acquired upon exercise of Purchase Rights are recorded in the books of the Company (or its transfer agent).

(c) The Plan and Offering do not constitute an employment contract. Nothing in the Plan or in the Offering will in any way alter the at will nature of a Participant's employment or be deemed to create in any way whatsoever any obligation on the part of any Participant to continue in the employ of the Company

or a Related Corporation, or on the part of the Company or a Related Corporation to continue the employment of a Participant.

- (d) The provisions of the Plan will be governed by the laws of the State of Delaware without resort to that state's conflicts of laws rules.

15. DEFINITIONS.

As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

- (a) "**Board**" means the Board of Directors of the Company.
- (b) "**Capital Stock**" means each and every class of common stock of the Company, regardless of the number of votes per share.
- (c) "**Capitalization Adjustment**" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Purchase Right after the date the Plan is adopted by the Board without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.
- (d) "**Code**" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.
- (e) "**Committee**" means a committee of one or more members of the Board to whom authority has been delegated by the Board in accordance with Section 2(c).
- (f) "**Common Stock**" means, as of the IPO Date, the common stock of the Company.
- (g) "**Company**" means Entasis Therapeutics Holdings Inc., a Delaware corporation.
- (h) "**Contributions**" means the payroll deductions and other additional payments specifically provided for in the Offering that a Participant contributes to fund the exercise of a Purchase Right. A Participant may make additional payments into his or her account if specifically provided for in the Offering, and then only if the Participant has not already had the maximum permitted amount withheld during the Offering through payroll deductions.
- (i) "**Corporate Transaction**" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:
 - (i) a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its subsidiaries;
 - (ii) a sale or other disposition of more than 50% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(j) “*Director*” means a member of the Board.

(k) “*Eligible Employee*” means an Employee who meets the requirements set forth in the document(s) governing the Offering for eligibility to participate in the Offering, provided that such Employee also meets the requirements for eligibility to participate set forth in the Plan.

(l) “*Employee*” means any person, including an Officer or Director, who is “employed” for purposes of Section 423(b)(4) of the Code by the Company or a Related Corporation. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an “Employee” for purposes of the Plan.

(m) “*Employee Stock Purchase Plan*” means a plan that grants Purchase Rights intended to be options issued under an “employee stock purchase plan,” as that term is defined in Section 423(b) of the Code.

(n) “*Exchange Act*” means the Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder.

(o) “*Fair Market Value*” means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the **closing sales price** for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) **on the date of determination**, as reported in such source as the Board deems reliable. Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing sales price on the last preceding date for which such quotation exists.

(ii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith in compliance with applicable laws and in a manner that complies with Sections 409A of the Code.

(iii) Notwithstanding the foregoing, for any Offering that commences on the IPO Date, the Fair Market Value of the shares of Common Stock on the Offering Date will be the price per share at which shares are first sold to the public in the Company’s initial public offering as specified in the final prospectus for that initial public offering.

(p) “*IPO Date*” means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

(q) “**Offering**” means the grant to Eligible Employees of Purchase Rights, with the exercise of those Purchase Rights automatically occurring at the end of one or more Purchase Periods. The terms and conditions of an Offering will generally be set forth in the “**Offering Document**” approved by the Board for that Offering.

(r) “**Offering Date**” means a date selected by the Board for an Offering to commence.

(s) “**Officer**” means a person who is an officer of the Company or a Related Corporation within the meaning of Section 16 of the Exchange Act.

(t) “**Participant**” means an Eligible Employee who holds an outstanding Purchase Right.

(u) “**Plan**” means this Entasis Therapeutics Holdings Inc. 2018 Employee Stock Purchase Plan.

(v) “**Purchase Date**” means one or more dates during an Offering selected by the Board on which Purchase Rights will be exercised and on which purchases of shares of Common Stock will be carried out in accordance with such Offering.

(w) “**Purchase Period**” means a period of time specified within an Offering, generally beginning on the Offering Date or on the first Trading Day following a Purchase Date, and ending on a Purchase Date. An Offering may consist of one or more Purchase Periods.

(x) “**Purchase Right**” means an option to purchase shares of Common Stock granted pursuant to the Plan.

(y) “**Related Corporation**” means any “parent corporation” or “subsidiary corporation” of the Company whether now or subsequently established, as those terms are defined in Sections 424(e) and (f), respectively, of the Code.

(z) “**Securities Act**” means the Securities Act of 1933, as amended.

(aa) “**Trading Day**” means any day on which the exchange(s) or market(s) on which shares of Common Stock are listed, including but not limited to the NYSE, Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market or any successors thereto, is open for trading.

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Manoussos Perros, certify that:

1. I have reviewed this Form 10-Q of Entasis Therapeutics Holdings Inc.;
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(s) 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)) 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) 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
 - (c) 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(s) 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.

Date: November 14, 2018

By: /s/ Manoussos Perros
Manoussos Perros
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael Gutch, certify that:

1. I have reviewed this Form 10-Q of Entasis Therapeutics Holdings Inc.;
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(s) 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)) 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) 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
 - (c) 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(s) 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.

Date: November 14, 2018

By: /s/ Michael Gutch
Michael Gutch
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer)

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Manoussos Perros, President and Chief Executive Officer of Entasis Therapeutics Holdings Inc. (the "Company"), and Michael Gutch, Chief Financial Officer and Chief Business Officer of the Company, each hereby certifies that, to the best of his knowledge:

- (1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2018

/s/ Manoussos Perros

Manoussos Perros
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Michael Gutch

Michael Gutch
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer)
