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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-Q**

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 001-37569

**STRONGBRIDGE BIOPHARMA plc**

(Exact name of Registrant as specified in its charter)

**Ireland**

(State or other jurisdiction of  
incorporation or organization)

**98-1275166**

(I.R.S. Employer  
Identification Number)

**900 Northbrook Drive  
Suite 200**

**Trevoze, PA 19053**

(Address of principal executive offices)

Registrant's Telephone Number, Including Area Code: **+1 610-254-9200**

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

Large Accelerated Filer  Accelerated Filer

Non-Accelerated Filer  Smaller Reporting Company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of October 29, 2018, there were 47,185,048 ordinary shares of the registrant issued and outstanding.

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Solely for convenience, the trademarks and trade names in this Quarterly Report on Form 10-Q (this "Quarterly Report") are referred to without the ® and ™ symbols, but absence of such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. The trademarks, trade names and service marks appearing in this Quarterly Report are the property of their respective owners.

**PART I – FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****STRONGBRIDGE BIOPHARMA plc****Consolidated Balance Sheets  
(In thousands, except share and per share data)  
(unaudited)**

	September 30, 2018	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 67,383	\$ 57,510
Accounts receivable	2,542	1,584
Inventory	6,261	511
Prepaid expenses and other current assets	2,342	1,208
Total current assets	78,528	60,813
Property and equipment, net	297	15
Intangible assets, net	54,463	35,155
Goodwill	7,256	7,256
Other assets	305	686
Total assets	<u>\$ 140,849</u>	<u>\$ 103,925</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 3,227	\$ 1,247
Accrued liabilities	19,985	11,232
Total current liabilities	23,212	12,479
Long-term debt	79,061	37,794
Warrant liability	22,721	41,308
Supply agreement liability, noncurrent	22,111	24,258
Total liabilities	<u>147,105</u>	<u>115,839</u>
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Deferred shares, \$1.098 par value, 40,000 shares authorized, issued and outstanding at September 30, 2018 and December 31, 2017	44	44
Ordinary shares, \$0.01 par value, 600,000,000 shares authorized at September 30, 2018 and December 31, 2017; 47,185,048 and 40,149,812 shares issued and outstanding at September 30, 2018 and December 31, 2017	472	401
Additional paid-in capital	288,316	230,524
Accumulated deficit	(295,088)	(242,883)
Total stockholders' deficit	<u>(6,256)</u>	<u>(11,914)</u>
Total liabilities and stockholders' deficit	<u>\$ 140,849</u>	<u>\$ 103,925</u>

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

**STRONGBRIDGE BIOPHARMA plc**

**Consolidated Statements of Operations and Comprehensive Loss**  
(In thousands, except share and per share data)  
(unaudited)

	Three Months Ended September 30		Nine Months Ended September 30	
	2018	2017	2018	2017
<b>Revenues:</b>				
Net product sales	\$ 5,347	\$ 2,533	\$ 13,513	\$ 4,062
<b>Total revenues</b>	<b>5,347</b>	<b>2,533</b>	<b>13,513</b>	<b>4,062</b>
<b>Cost and expenses:</b>				
Cost of sales (excluding amortization of intangible assets)	\$ 1,441	\$ 591	\$ 2,861	\$ 968
Selling, general and administrative	19,564	8,484	47,137	26,068
Research and development	7,198	4,504	17,532	12,113
Amortization of intangible assets	1,876	1,256	5,517	3,767
Impairment of intangible asset	—	20,723	—	20,723
<b>Total cost and expenses</b>	<b>30,079</b>	<b>35,558</b>	<b>73,047</b>	<b>63,639</b>
Operating loss	(24,732)	(33,025)	(59,534)	(59,577)
<b>Other income (expense), net:</b>				
Unrealized gain (loss) on fair value of warrants	7,131	1,953	16,448	(28,194)
Interest expense	(3,387)	(1,364)	(9,550)	(2,838)
Foreign exchange loss	(15)	(11)	(22)	(36)
Loss on extinguishment of debt	—	(3,545)	(500)	(3,545)
Other income, net	445	82	954	107
<b>Total other income (expense), net</b>	<b>4,174</b>	<b>(2,885)</b>	<b>7,330</b>	<b>(34,506)</b>
Loss before income taxes	(20,558)	(35,910)	(52,204)	(94,083)
Income tax benefit (expense)	—	850	(1)	(652)
<b>Net loss</b>	<b>\$ (20,558)</b>	<b>\$ (35,060)</b>	<b>\$ (52,205)</b>	<b>\$ (94,735)</b>
<b>Net loss attributable to ordinary shareholders:</b>				
Basic	\$ (20,558)	\$ (35,060)	\$ (52,205)	\$ (94,735)
Diluted	\$ (27,690)	\$ (35,060)	\$ (68,653)	\$ (94,735)
<b>Net loss per share attributable to ordinary shareholders:</b>				
Basic	\$ (0.44)	\$ (0.98)	\$ (1.14)	\$ (2.67)
Diluted	\$ (0.55)	\$ (0.98)	\$ (1.37)	\$ (2.67)
<b>Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:</b>				
Basic	46,978,472	35,716,247	45,916,177	35,463,496
Diluted	50,317,423	35,716,247	49,985,483	35,463,496

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

**STRONGBRIDGE BIOPHARMA plc**

**Consolidated Statement of Stockholders' Deficit (In thousands, except share amounts)  
(unaudited)**

	<u>Ordinary Shares</u>		<u>Deferred Shares</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u>	<u>Deficit</u>	<u>Shareholders'</u>
					<u>Capital</u>		<u>(Deficit)</u>
							<u>Equity</u>
Balance—December 31, 2017	40,149,812	\$ 401	40,000	\$ 44	\$ 230,524	\$ (242,883)	\$ (11,914)
Net loss	—	—	—	—	—	(52,205)	(52,205)
Stock-based compensation	—	—	—	—	5,789	—	5,789
Issuance of shares, net of offering costs	5,255,683	53	—	—	33,455	—	33,508
Issuance of shares in connection with at-the-market facility, net of costs	1,172,557	12	—	—	7,939	—	7,951
Exercise of warrants	470,000	5	—	—	3,309	—	3,314
Issuance of warrants related to loan agreements	—	—	—	—	7,663	—	7,663
Exercise of stock options	45,007	*	—	—	79	—	79
Common stock issued, net of shares withheld for employee taxes	91,989	1	—	—	(442)	—	(441)
Balance—September 30, 2018	<u>47,185,048</u>	<u>\$ 472</u>	<u>40,000</u>	<u>\$ 44</u>	<u>\$ 288,316</u>	<u>\$ (295,088)</u>	<u>\$ (6,256)</u>

\* Represents an amount less than \$1.

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

**STRONGBRIDGE BIOPHARMA plc**  
**Consolidated Statements of Cash Flow**  
(In thousands)  
(unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (52,205)	\$ (94,735)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(16,448)	28,194
Impairment of intangible asset	—	20,723
Stock-based compensation	5,789	3,864
Amortization of intangible assets	5,517	3,767
Interest and related guarantee fees paid in kind	2,890	408
Amortization of debt discounts and debt issuance costs	1,109	371
Loss on extinguishment of debt	500	3,545
Deferred income tax benefit	—	804
Depreciation	28	8
Changes in operating assets and liabilities:		
Accounts receivable	(958)	(979)
Inventory	(5,750)	(1,003)
Prepaid expenses and other current assets	(1,134)	(923)
Other assets	381	(237)
Accounts payable	1,980	333
Accrued liabilities and other liabilities	6,437	1,410
Net cash used in operating activities	<u>(51,864)</u>	<u>(34,450)</u>
Cash flows from investing activities:		
Payment for acquisitions	(24,655)	(7,500)
Purchases of property and equipment	(310)	—
Net cash used in investing activities	<u>(24,965)</u>	<u>(7,500)</u>
Cash flows from financing activities:		
Proceeds from long-term debt, net	44,930	39,986
Payment for loss on extinguishment of debt	(500)	(1,300)
Payment of long-term debt	—	(22,261)
Proceeds from issuance of ordinary shares, net	33,508	2,981
Proceeds from issuance of ordinary shares in connection with at-the-market offering	7,951	73
Proceeds from exercise of warrants	1,175	—
Proceeds from exercise of stock options	79	—
Payments related to tax withholding for net-share settled equity awards	(441)	—
Net cash provided by financing activities	<u>86,702</u>	<u>19,479</u>
Net increase (decrease) in cash and cash equivalents	9,873	(22,471)
Cash and cash equivalents—beginning of period	57,510	66,837
Cash and cash equivalents—end of period	<u>\$ 67,383</u>	<u>\$ 44,366</u>
Supplemental non-cash financing activities:		
Issuance of shares from vested restricted share units	<u>\$ 1,048</u>	<u>\$ —</u>

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

## STRONGBRIDGE BIOPHARMA plc

### Notes to Unaudited Consolidated Financial Statements

#### 1. Organization

We are a global, commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs.

Our first commercial product is Keveyis (dichlorphenamide), the first and only treatment approved by the U.S. Food and Drug Administration (the “FDA”) for hyperkalemic, hypokalemic, and related variants of primary periodic paralysis (“PPP”), a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis.

Our second commercial product, Macrilen (macimorelin), is an oral growth hormone secretagogue receptor agonist, and is the first and only oral test approved by the FDA for the diagnosis of patients with adult growth hormone deficiency (“AGHD”). We acquired the U.S. and Canadian rights to Macrilen in January 2018 and launched Macrilen in the United States in July 2018.

In addition to our two commercial products, we have two clinical-stage product candidates for rare endocrine diseases, Recorlev and veldoreotide. Recorlev (levoketoconazole) is a cortisol synthesis inhibitor currently being studied for the treatment of endogenous Cushing's syndrome. Veldoreotide is a next-generation somatostatin analog being investigated for the treatment of acromegaly and potential additional applications in other conditions amenable to somatostatin receptor activation. Both Recorlev and veldoreotide have received orphan designation from the FDA and the European Medicines Agency (“EMA”).

Given the well-identified and concentrated prescriber base addressing our target markets, we intend to continue to use a small, focused sales force to market Keveyis, Macrilen and any future products, in the United States, the European Union and other key global markets. We believe that our ability to execute on our strategy is enhanced by the significant commercial and clinical development experience of key members of our management team.

We are building a rare disease, franchise-based business model focused on expansion through a disciplined in-licensing and acquisition strategy. In pursuit of our growth strategy, we have raised over \$283 million in equity and debt financings since December 2014. We will continue to identify and evaluate the acquisition of products and product candidates for licensing or acquisition that would be complementary to our existing rare neuromuscular and endocrine franchises or that would form the basis for new rare disease franchises. We believe this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

#### *Liquidity*

We believe that our cash resources of \$67.4 million at September 30, 2018 will be sufficient to allow us to fund planned operations for at least 12 months beyond the issuance date of the financial statements included in this Quarterly Report. We also expect our cash needs to increase to fund potential in-licenses, acquisitions or similar transactions as we pursue our strategy. These expenses may be offset only in part by sales of Keveyis and Macrilen. In addition, beginning in March 2021, we may be required to make quarterly principal payments to repay amounts borrowed under our credit facility.

We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. We plan to continue to fund our operations and capital funding needs through equity or debt financing along with revenues from Keveyis and Macrilen. There can be no assurances, however, that additional funding will be available on terms acceptable to us.

Our loan and security agreement, under which outstanding borrowings were \$88.3 million at September 30, 2018, contains financial and non-financial covenants including minimum annual amounts of net revenue in 2018 and beyond. Failure to comply with the covenants could result in the lenders declaring the loan immediately due and payable.

Our liquidity requirements are predicated on maintaining compliance with the debt covenants and repaying outstanding borrowings in accordance with the loan term, see Note 7 “Long-term debt”.

## **2. Summary of significant accounting policies and basis of presentation**

### ***Basis of presentation***

These unaudited consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (“U.S. GAAP”). The unaudited consolidated financial statements reflect all adjustments, which include only normal recurring adjustments that are, in the opinion of management, necessary to present a fair statement of the operating results and financial position for the periods presented.

The preparation of the unaudited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts and disclosures in the consolidated financial statements. Actual results could differ from those estimates. Results for the three months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

These unaudited consolidated financial statements should be read in conjunction with the accounting policies and notes to the audited consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed with the U.S. Securities and Exchange Commission on March 12, 2018 (the “2017 Annual Report”). Our significant accounting policies are described in Note 2 of the notes to the audited consolidated financial statements included in our 2017 Annual Report. Since the date of those financial statements, there have been no changes to our significant accounting policies.

### ***Revenue recognition***

We follow Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers*, effective April 1, 2017. Topic 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity 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 entity satisfies a performance obligation. We apply the five-step model to contracts only when it is probable that we will collect the consideration we are entitled to receive in exchange for the goods or services we transfer to our customers. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for net product revenue, see Note 3, “Revenue recognition”.

### ***Foreign currency translation***

The consolidated financial statements are reported in United States dollars, which is our functional currency, including each of our consolidated subsidiaries. Transactions in foreign currencies are remeasured into our functional currency at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these transactions are remeasured into our functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign exchange loss in our consolidated statements of operations.



***Use of estimates***

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. We must apply significant judgment in this process. Actual results could materially differ from those estimates.

***Segment information***

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. We view our operations and manage our business in one operating segment. Prior to March 31, 2018, our material long-lived intangible assets resided in Ireland, Sweden and the Cayman Islands. Effective March 31, 2018, all of our material long-lived intangible assets reside in Ireland. As of September 30, 2018, \$67.3 million of our cash and cash equivalents consisted primarily of bank deposits in the United States. For the nine months ended September 30, 2018, revenues from product sales were derived entirely from the United States.

***Net loss per share***

Basic net loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of ordinary shares outstanding during the period. Diluted net loss per share is calculated by dividing the net loss attributable to shareholders by the weighted-average number of ordinary shares outstanding for the period, including any dilutive effect from outstanding stock options or other equity-based awards. Shares used in the diluted net loss per share calculations exclude anti-dilutive ordinary share equivalents, which currently consist of outstanding stock options, unvested restricted stock units ("RSUs") and warrants.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of September 30, 2018 and 2017, as they would be anti-dilutive:

	Nine Months Ended	
	September 30,	
	2018	2017
Warrants	1,803,253	7,764,569
Stock options issued and outstanding	8,719,156	6,176,647
Unvested RSUs	173,400	274,250

***Recent accounting pronouncements***

In January 2017, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update ("ASU") 2017-04, *Intangibles - Goodwill and Other: Simplifying the Accounting for Goodwill Impairment*. ASU 2017-04 removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. This standard, which will be effective for us beginning in the first quarter of fiscal year 2020, is required to be applied prospectively. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We are currently evaluating the impact this new accounting guidance will have on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, that discusses how an entity should account for lease assets and lease liabilities. The guidance specifies that an entity who is a lessee under lease agreements should recognize lease assets and lease liabilities for those leases classified as operating leases under previous FASB guidance. Accounting for leases by lessors is largely unchanged under the new guidance. The guidance is effective for us beginning in the first quarter of fiscal year 2019. Early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective

approach. We are currently evaluating the impact this new accounting guidance will have on our consolidated financial statements but do not expect it will have a material impact on us.

### 3. Revenue recognition

#### *Product sales, net*

We launched our second commercial product, MacriLen, in July 2018. Our product sales result from sales of Keveyis and MacriLen. We recognize net product sales at the time our products are received by our customers (primarily wholesalers and specialty pharmacies). The products are subsequently sold to patients, who are covered by payors that may provide for government-mandated or privately negotiated rebates with respect to the purchase of our products.

Revenues from sales of our products are recognized when we satisfy a performance obligation by transferring control of the product to our customers. Transfer of control occurs upon receipt of the product by the customer. We expense incremental costs related to the set-up of contracts with our customers when incurred, as these costs do not meet the criteria for capitalization.

#### *Disaggregation of Revenue*

The following table summarizes revenue by product for the three and nine months ended September 30, 2018 (in thousands):

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
<b>Products</b>		
Keveyis	\$ 4,207	\$ 12,373
MacriLen	1,140	1,140
Total	<u>\$ 5,347</u>	<u>\$ 13,513</u>

#### *Reserves for variable consideration*

Revenues from sales of our products are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and that result from rebates, co-pay assistance and other allowances that are offered by us and the patients' payors. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to our customer) or a current liability (if the amount is payable to a party other than our customer). Where appropriate, these estimates may take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. We reassess our estimates on an ongoing basis. If actual results in the future vary from our estimates, we will adjust our estimates. Any such adjustments would affect net product revenue and earnings in the period such variances become known.

*Trade Discount:* Our contracts with our customers provide for a discount, that is recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we receive sales order management, data and distribution services from our customers. To the extent the services received are distinct from our sale of products to

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our customers, these payments are classified in selling, general and administrative expenses in our consolidated statement of operations and comprehensive loss.

*Prompt Pay Discount:* We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We estimate for cash discounts using the most likely amount method by reducing accounts receivable by the prompt pay discount amount. The discount is recognized as a reduction of revenue in the same period as the related revenue.

*Funded Co-pay Assistance Program:* We contract with a third-party to manage the co-pay assistance program intended to provide financial assistance to qualified insured patients. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with the product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. These payments are consideration payable to our customers and the related reserve is recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the consolidated balance sheet.

*Government Rebates:* We are subject to discount obligations under state Medicaid programs and Medicare. We estimate our Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated patient mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included in accrued expenses on the consolidated balance sheet. For Medicaid, accruals are based on estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. Effective January 1, 2011, manufacturers of pharmaceutical products are responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this Medicare coverage gap responsibility, we estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consists of estimates of claims for the current quarter and estimated future claims that will be made that have been recognized as revenue, but remain in the distribution channel inventories at the end of each reporting period.

*Temporary Supply and Patient Assistance Programs:* We provide free product to uninsured patients who satisfy pre-established criteria for either the Temporary Supply Program for Keveyis or the Patient Assistance Program for Keveyis and Macrilen. Patients who meet the Temporary Supply Program eligibility criteria may receive a temporary supply of free Keveyis for no more than sixty days while we determine the patient's third-party insurance, prescription drug benefit or other third-party coverage for Keveyis. The Patient Assistance Program provides free Keveyis for up to twelve months to patients who satisfy pre-established criteria for financial need. We do not recognize any revenue related to these free products and the associated costs are classified in selling, general and administrative expenses in our consolidated statements of operations and comprehensive loss.

**4. Fair value measurement**

We follow FASB accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. Because of their short-term nature, the amounts reported in the balance sheet for cash and accounts payable approximate fair value.

The guidance requires fair value measurements to maximize the use of “observable inputs.” The three-level hierarchy of inputs to measure fair value are as follows:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities. Because of their short-term nature, the amounts reported in the balance sheet for cash and accounts payable approximate fair value.

Level 2: Significant observable inputs other than Level 1 prices such as quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity). The fair values of the outstanding warrants were measured using the Black-Scholes option-pricing model. Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

We did not have any transfers between the different levels.

The following table presents our assets and liabilities that are measured at fair value on a recurring basis for the periods presented (in thousands):

	As of September 30, 2018			Total
	Level I	Level II	Level III	
Cash equivalents	66,996	—	—	66,996
Total assets	\$ 66,996	\$ —	\$ —	\$ 66,996
Warrant liability	—	—	22,721	22,721
Total liabilities	\$ —	\$ —	\$ 22,721	\$ 22,721

  

	As of December 31, 2017			Total
	Level I	Level II	Level III	
Cash equivalents	57,024	—	—	57,024
Total assets	\$ 57,024	\$ —	\$ —	\$ 57,024
Warrant liability	—	—	41,308	41,308
Total liabilities	\$ —	\$ —	\$ 41,308	\$ 41,308

## 5. Intangible assets and goodwill

The following represents the balance of our intangible assets as follows (in thousands):

	As of September 30, 2018				
	Beginning of Period	Additions	Impairment	Amortization	End of Period
Keveys	35,155	—	—	(3,767)	31,388
Macrilen	—	24,825	—	(1,750)	23,075
Goodwill	7,256	—	—	—	7,256
Total	\$ 42,411	\$ 24,825	\$ —	\$ (5,517)	\$ 61,719

  

	As of December 31, 2017				
	Beginning of Period	Additions	Impairment	Amortization	End of Period
IPR&D	\$ 20,723	\$ —	\$ (20,723)	\$ —	\$ —
Keveys	40,177	—	—	(5,022)	35,155
Goodwill	7,256	—	—	—	7,256
Total	\$ 68,156	\$ —	\$ (20,723)	\$ (5,022)	\$ 42,411

Our finite lived intangible assets consist of acquired developed product rights obtained from our acquisitions of Keveys (dichlorphenamide) from a subsidiary of Taro Pharmaceutical Industries Ltd. (“Taro”) and Macrilen from Aeterna Zentaris GmbH.

Pursuant to the terms of the Asset Purchase Agreement and Supply Agreement that we entered into with Taro, we paid Taro an upfront payment in two installments of \$1 million in December 2016 and \$7.5 million in March 2017. We concluded that the supply price payable by us exceeds fair value and, therefore, used a discounted cash flow method with a probability assumption to value the payments in excess of fair value at \$29.3 million, for which we have recorded an intangible asset and corresponding liability. This liability will be reduced as we purchase inventory over the term of the Supply Agreement. In addition, we incurred transaction costs of \$2.4 million. The overall recording of the transaction resulted in the recording of an intangible asset of \$40.2 million. This asset is being amortized over an eight-year period using the straight-line method.

We entered into a License and Assignment Agreement in 2018 with Aeterna Zentaris GmbH, pursuant to which we acquired the U.S. and Canadian rights to manufacture and commercialize Macrilen (macimorelin) for \$24 million and incurred transaction costs of \$0.7 million, resulting in an initial intangible of \$24.7 million. We record any royalty liability as an increase to the intangible asset. This asset is being amortized over a ten-year period using the straight-line method.

We recorded amortization expense of \$1.9 million and \$5.5 for the three and nine months ended September 30, 2018, respectively, compared to \$1.3 million and \$3.8 million for the three and nine months ended September 30, 2017, respectively.

## 6. Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Consulting and professional fees	\$ 5,550	\$ 2,465
Supply agreement - current portion	4,783	4,237
Employee compensation	3,813	3,668
Accrued sales allowances	2,204	742
Accrued inventory	1,734	—
Accrued royalties	1,210	—
Other	691	120
Total accrued liabilities	\$ 19,985	\$ 11,232

## 7. Long-term debt

On January 16, 2018 (the “First Loan Amendment Effective Date”), we and our subsidiaries, Strongbridge U.S. Inc., Strongbridge Ireland Limited, Cortendo AB (publ) and Cortendo Cayman Ltd., entered into an amendment (the “First Loan Amendment”), to the Term Loan Agreement (the “Loan Agreement”), dated July 14, 2017, with CRG Servicing LLC (“CRG”), as administrative agent and collateral agent, and the lenders named therein (the “Lenders”).

The primary purpose of the First Loan Amendment was to increase the total potential borrowing under the Loan Agreement from \$50 million to \$100 million. The First Loan Amendment provided for (i) an additional disbursement of \$45.0 million (the “Second Tranche”) to the Company on the First Loan Amendment Effective Date, and (ii) an additional disbursement of \$5.0 million (the “Fourth Tranche”) to us at our election, contingent upon our achievement of certain revenue milestones and a market capitalization condition on or before December 31, 2018, as described in the First Loan Amendment. Under the First Loan Amendment, we continued to be eligible to borrow up to an additional \$10.0 million (the “Third Tranche”), contingent upon our achievement of certain revenue milestones on or before June 30, 2018, as previously provided in the Loan Agreement; provided, however, that under the Loan Agreement, as amended, the Third Tranche would be subject to a market capitalization condition, as described in the First Loan Amendment. As a condition to the addition of the Second Tranche under the First Loan Amendment, we issued to the Lenders on the First Loan Amendment Effective Date warrants to purchase an aggregate of 1,248,250 of our ordinary shares, at an exercise price of \$10.00 per share.

On June 6, 2018, we and our subsidiaries, Strongbridge U.S. Inc., Cortendo Cayman Ltd., Strongbridge Ireland Limited and Cortendo AB (publ), entered into a second amendment (the “Second Loan Amendment”), to the Loan Agreement. The primary purposes of the Second Loan Amendment (as requested by the Company) was to reduce the aggregate commitments under the Loan Agreement from \$100 million to \$95 million and to combine the Third Tranche and the Fourth Tranche under the Loan Agreement into one final borrowing tranche for up to \$10 million (the “Final Tranche”). Under the terms of the Second Loan Amendment, the Final Tranche borrowing must occur on or before March 19, 2019. The Final Tranche is subject to the Company’s achievement of a certain revenue milestone, which under the Second Loan Amendment must be satisfied on or prior to December 31, 2018, and satisfaction of a market capitalization condition for the 20 consecutive trading days ending on the trading day immediately prior to the Final Tranche borrowing date (as described in the Loan Agreement, as amended).

Pursuant to the terms of the Second Loan Amendment, if we borrow the Final Tranche, we must issue to the Lenders, or their designees, one or more warrants to purchase a number of our ordinary shares equal to an aggregate of (i) 0.10% of our ordinary shares outstanding following such issuance on a fully diluted basis (inclusive of the ordinary shares underlying all such warrants issued), at an exercise price equal to 110% of the closing price of our ordinary shares on the date immediately preceding the Final Tranche borrowing date and (ii) 0.25% of our ordinary shares outstanding following such issuance on a fully diluted basis (inclusive of the ordinary shares underlying all such warrants issued), at an exercise price equal to 140% of the 10-day volume weighted-average price (VWAP) per share of our ordinary shares for the consecutive 10-trading-day period ending on the trading day prior to the Final Tranche borrowing date.

The term of the Loan Agreement, as amended, is six years, with interest-only payments until December 31, 2020, after which quarterly principal and interest payments will be due through the June 30, 2023 maturity date. We have the option to extend the interest-only period to six years based upon the achievement of certain milestones during the interest-only period. The Loan Agreement provides for interest payable at an annual rate of 12.5% and a final payment fee of 5% of the principal balance.

The Loan Agreement includes a payment-in-kind (“PIK”) provision, which allows us to defer 4.0% of the 12.5% annual interest payable under the loan during the first three years of the term of the loan (which may be extended for the entire term of the loan, subject to the satisfaction of certain conditions) by adding such amount to the principal loan amount. We have elected to PIK each period so far, resulting in an additional \$3.3 million added to our outstanding principal balance as of September 30, 2018. We have granted a security interest in substantially all of our existing assets and assets acquired by us in the future, including intellectual property. The Loan Agreement contains facility and prepayment fees, and customary affirmative and negative covenants, including a financial covenant regarding minimum

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amounts of net revenue and restrictions on our ability to pay cash dividends, and a list of events that will constitute “events of default” under the loan agreement, and permit the lenders to declare all amounts under the Loan Agreement immediately due and payable, including a material adverse change in our business, operations or financial condition. We recorded \$10.6 million in debt discounts and \$0.2 million of debt issuance costs relating to the Loan Agreement which have been recorded as a reduction to the long-term debt. These amounts will be amortized over the outstanding period of the debt to interest expense using the effective interest rate method.

Due to a greater than 10% change in cash flows as compared to the original debt instrument under the First Loan Amendment, the First Loan Amendment was accounted for as a debt extinguishment, which resulted in a \$0.5 million loss during the nine months ended September 30, 2018.

Future principal payments due under the Loan Agreement are as follows (in thousands):

	<b>Principal Payments</b>
2018	\$ —
2019	—
2020	—
2021	35,320
2022	35,320
2023	17,660
Total future payments	<u>\$ 88,300</u>

## 8. Commitments and contingencies

### Lease obligations

In March 2015, we entered into a 52-month building sublease agreement for 14,743 square feet of office space in Trevoze, Pennsylvania. The lease has annual rent escalations and is recognized on a straight-line basis over the term of the lease. In November 2017, the Company entered into a 60-month building lease agreement for an additional 7,326 square feet of office space in the same building in Trevoze, Pennsylvania. The lease has annual rent escalations. We obtained access to this newly leased space on November 27, 2017, and this was considered the lease commencement date for accounting purposes. Thus, rent expense began on this date and is recognized on a straight-line basis over the term of the lease. The lease provides for us the ability to continue leasing its currently subleased office space upon expiration of the sublease described above.

As of September 30, 2018, future minimum commitments under facility operating leases were as follows (in thousands):

	<b>Operating leases</b>
2018	113
2019	439
2020	470
2021	481
2022	492
2023	207
Total minimum lease payments	<u>\$ 2,202</u>

Rent expense recognized under our operating lease was approximately \$535,000 and \$205,000 for the nine months ended September 30, 2018 and 2017, respectively.

#### **Commitments to Taro Pharmaceuticals Industries Ltd.**

In December 2016, we acquired the U.S. marketing rights to Keveyis (dichlorphenamide) from a subsidiary of Taro. Under the terms of the Asset Purchase Agreement, we paid Taro an upfront payment in two installments of \$1 million in December 2016 and \$7.5 million in March 2017, and will pay an aggregate of \$7.5 million in potential milestones upon the achievement of certain product sales targets. Taro has agreed to continue to manufacture Keveyis for us under an exclusive supply agreement through the orphan exclusivity period. We are obligated to purchase certain annual minimum amounts of product totaling approximately \$29 million over a six-year period. The Supply Agreement may extend beyond the orphan exclusivity period unless terminated by either party pursuant to the terms of the agreement. If terminated by Taro at the conclusion of the orphan exclusivity period, we have the right to manufacture the product on our own or have the product manufactured by a third party on our behalf. We are required to reimburse Taro for their royalty obligation resulting from their sale of Keveyis to us.

#### **Commitments to Aeterna Zentaris GmbH**

In January 2018, we acquired the U.S. and Canadian rights to Macrilen (macimorelin) from Aeterna Zentaris GmbH. Under the terms of the License and Assignment Agreement, we paid Aeterna Zentaris GmbH \$24 million and will pay tiered royalties of 15%-18% on net sales as well as an aggregate of \$174 million in potential milestones upon the achievement of certain product sales targets. Additionally, Aeterna Zentaris GmbH will remain responsible for a pediatric development program to support regulatory submission for approval with Strongbridge sharing oversight and paying for 70 percent of the cost of the program, or approximately \$4 million over a three-year period as well as \$5 million upon the receipt of regulatory approval for the use of Macrilen in pediatric patients in the United States and Canada.

#### **9. Income taxes**

Deferred tax assets and liabilities are recognized for the future tax consequences of differences between the carrying amounts and tax bases of assets and liabilities and operating loss carryforwards and other attributes using enacted rates expected to be in effect when those differences reverse. Valuation allowances are provided against deferred tax assets that are not more likely than not to be realized.

We assess our ability to realize deferred tax assets. Changes in future earnings projections, among other factors, may cause us to adjust our valuation allowance on deferred tax assets. Any such adjustments would impact our income tax expense in the period in which it is determined that these factors have changed.

For the nine months ended September 30, 2018, we recorded full valuation allowances against our deferred tax asset and deferred tax liability, resulting in no income tax expense.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the top U.S. federal corporate tax rate from 35 percent to 21 percent; requiring companies to pay a onetime transition tax on certain un-repatriated earnings of foreign subsidiaries; generally eliminating U.S. federal income taxes on dividends from foreign subsidiaries; requiring a current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations; eliminating the corporate alternative minimum tax (AMT) and changing how existing AMT credits can be realized; creating the base erosion anti-abuse tax (BEAT), a new minimum tax; creating a new limitation on deductible interest expense; and changing rules related to uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

The Tax Act reduces our U.S. corporate income tax rate from 34% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 34% to 21% under the Tax Act, we revalued our ending net deferred tax assets and liabilities at December 31, 2017.



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The Tax Act provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits (“E&P”). We did not have to recognize any income tax expense related to the transition tax as we own no controlled foreign corporations.

The global intangible low-taxed income tax and base erosion provisions are effective for taxable years beginning after December 31, 2017. We do not currently expect these provisions to have a material impact on our tax rate as we do not own any controlled foreign corporations and they are currently below the gross receipts threshold for purposes of the base erosion provisions.

## 10. Ordinary shares

### *Equity transactions*

On January 30, 2018, we sold 5,000,000 ordinary shares in a public offering at a price to the public of \$6.75 per ordinary share for net proceeds of approximately \$31.8 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

On February 27, 2018, we sold an additional 255,683 ordinary shares to the underwriters of our January 2018 public offering in connection with their partial exercise of their option to purchase additional shares to cover over-allotments at a price of \$6.75 per ordinary share for net proceeds of approximately \$1.7 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

We entered into an equity distribution agreement with JMP Securities LLC (“JMP”) on April 28, 2017, pursuant to which we may sell, at our option, from time to time, up to an aggregate of \$40 million of our ordinary shares through JMP, as sales agent. We will pay JMP a commission equal to 3% of the gross proceeds from the sale of our ordinary shares under this at-the-market (“ATM”) facility. Pursuant to the terms of the equity distribution agreement, we reimbursed JMP for certain out-of-pocket expenses, including the fees and disbursements of counsel to JMP, incurred in connection with establishing the ATM facility and have provided JMP with customary indemnification rights. During the nine months ended September 30, 2018, we sold an aggregate of 1,172,557 ordinary shares under the ATM facility at an average selling price of \$7.00 per share, resulting in net proceeds of approximately \$8.0 million after payment of fees to JMP of \$246,000. As of September 30, 2018, we have approximately \$32 million available for sale under our ATM facility.

### *Warrants*

During the three months ended September 30, 2018, a warrant previously issued in connection with a private equity placement was exercised in full, resulting in the issuance of 470,000 ordinary shares.

Our outstanding warrants as of September 30, 2018 are as follows:

	<u>Classification</u>	<u>Exercise Price</u>	<u>Expiration Date</u>	<u>Warrants Issued</u>	<u>Warrants Exercised</u>	<u>Warrants Outstanding September 30, 2018</u>
Warrants in connection with private equity placement	Liability	\$ 2.50	6/28/2022	7,000,000	(470,000)	6,530,000
Warrants in connection with Horizon and Oxford loan agreement	Equity	\$ 2.45	12/28/2026	428,571	(267,857)	160,714
Warrants in connection with CRG loan agreement	Equity	\$ 7.37	7/14/2024	394,289	—	394,289
Warrants in connection with CRG loan amendment in January 2018	Equity	\$ 10.00	1/16/2025	<u>1,248,250</u>	—	<u>1,248,250</u>
				<u>9,071,110</u>		<u>8,333,253</u>

## 11. Stock-based compensation

Our board of directors has adopted the 2017 Inducement Plan (the “Inducement Plan”). The Inducement Plan provides for the grant of equity-based awards to new employees. The purpose of the Inducement Plan is to attract valued employees by offering them a greater stake in our success and a closer identity with us, and to encourage ownership of our ordinary shares by such employees. The Inducement Plan became effective on February 23, 2017. As of September 30, 2018, 620,200 shares are available for issuance pursuant to the Inducement Plan.

Our board of directors has adopted, and our shareholders have approved, the 2015 Equity Compensation Plan (the “2015 Plan”). The 2015 Plan provides for the grant of incentive stock options to our employees and any parent or subsidiary corporation’s employees, and for the grant of nonstatutory stock options, stock awards, and RSUs to our employees, directors and consultants and our parent or subsidiary corporations’ employees and consultants. The 2015 Plan became effective on September 3, 2015. As of September 30, 2018, 163,006 shares are available for issuance pursuant to the 2015 Plan.

Our board of directors has adopted, and our shareholders have approved, the Non-Employee Director Equity Compensation Plan (the “Non-Employee Director Plan”). The Non-Employee Director Plan provides for the grant of nonstatutory stock options, stock awards, and RSUs to our non-employee directors. The Non-Employee Director Plan became effective on September 3, 2015. As of September 30, 2018, 1,541 shares are available for issuance pursuant to the Non-Employee Director Plan.

A summary of our outstanding stock options as of September 30, 2018 is as follows:

	<u>Options Outstanding</u>			
	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Outstanding—January 1, 2018	6,104,715	\$ 7.50	7.70	\$ 14,021
Granted	2,881,255	\$ 6.78		
Forfeited and cancelled	(196,871)	\$ 6.24		
Exercised	(69,943)	\$ 4.31		
Outstanding—September 30, 2018	<u>8,719,156</u>	\$ 7.33	7.79	\$ 4,541
Vested and exercisable—September 30, 2018	<u>3,547,271</u>	\$ 9.08	6.30	\$ 1,749

Included in the stock options outstanding at September 30, 2018 are unvested stock options to purchase 88,908 shares at a weighted average exercise price of \$18.80 per share for which the vesting of certain tranches will accelerate if the fair value per share of our stock reaches \$31.46. In addition, the options outstanding as of September 30, 2018 include 97,652 shares that vest upon a market appreciation event, so long as it occurs prior to the date specified in the applicable award agreement and 97,652 shares that will vest upon the one year anniversary of the market appreciation event. The market appreciation event, which had not yet occurred as of September 30, 2018, is defined as the last trading day in the period in which our closing stock price on each of 20 consecutive trading days reported on Nasdaq has been at least \$30.14 or \$33.66 for the respective grantee.

**Stock-based compensation expense**

We recognized stock-based compensation expense for employees and directors for stock options and RSUs as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Selling, general and administrative	\$ 1,649	\$ 1,007	\$ 4,450	\$ 3,042
Research and development	467	324	1,339	822
Total stock-based compensation	\$ 2,116	\$ 1,331	\$ 5,789	\$ 3,864

As of September 30, 2018, the total unrecognized compensation expense related to unvested stock options, net of estimated forfeitures, is \$17.9 million, which we expect to recognize over an estimated weighted-average period of 2.85 years.

In determining the estimated fair value of our service-based awards, we use the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment. The fair value of our service-based awards that were granted during the years was estimated with the following assumptions:

	Nine Months Ended September 30,	
	2018	2017
Expected term (in years)	6.13	5.96
Risk-free interest rate	2.25% - 2.99%	1.78% - 2.26%
Expected volatility	78.19% - 85%	78.2% - 105.9%
Dividend rate	—%	—%

**Restricted stock units**

Our board of directors have approved grants of RSUs to employees. These RSUs vest two years from the date of issuance, provided that the employee is employed by us on such vesting date. All RSUs will fully vest upon a change of control of our company. If and when the RSUs vest, we will issue one ordinary share for each whole RSU that has vested, subject to satisfaction of the executive's tax withholding obligations. The RSUs will cease to be outstanding upon such issuance of ordinary shares. We recorded expense, which is included in the stock-based compensation table above, of \$126,000 and \$124,000 for the three months ended September 30, 2018 and 2017, respectively, and \$390,000 and \$309,000 for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, the total unrecognized compensation expense related to unvested RSUs is \$0.5 million, which we expect to recognize over an estimated weighted-average period of 1.2 years.

A summary of our unvested RSUs as of September 30, 2018 is as follows:

	Number of Shares
Outstanding—January 1, 2018	267,250
Granted	69,150
Forfeited	(4,000)
Vested	(159,000)
Unvested—September 30, 2018	173,400

## 12. Subsequent Events

### ***Macrilen Acquisition Agreement***

On October 31, 2018, we entered into the Macrilen Acquisition Agreement with Novo Nordisk Healthcare AG, a Swiss corporation, ("Novo") (the "Macrilen Acquisition Agreement"). Under the Macrilen Acquisition Agreement, the Company grants Novo a call option and Novo grants the Company a put option, in each case with respect to the entire issued share capital of Strongbridge Ireland Limited, a wholly-owned subsidiary of the Company, which holds the Company's Macrilen product. The exercise price of each of the put and call options is \$145,000,000 (the "Acquisition"), plus a future royalty on sales of the pharmaceutical product for assessing growth hormone deficiency in adults and children known as Macrilen. Each party has the right to exercise its put option or call option, as applicable, before May 1, 2019 and only after all conditions in the Macrilen Acquisition Agreement have been satisfied or waived. Upon exercise of the put or call option, Strongbridge Ireland Limited will become a wholly-owned subsidiary of Novo. We expect the transaction to close in December 2018.

The foregoing description of the Macrilen Acquisition Agreement is not complete and is subject to and qualified in its entirety by reference to the copy of the Macrilen Acquisition Agreement, which will be filed with the Company's Current Report on Form 8-K.

### ***Share Purchase Agreement***

On October 31, 2018, we entered into a Share Purchase Agreement with Novo Nordisk A/S, a company organized and existing under the law of Denmark, providing for the sale of 5,242,000 shares of our ordinary shares for \$7.00 per share and an aggregate purchase price of \$36,694,000 (the "Investor Agreement").

As a condition to the closing of the Investor Agreement, we will enter into a Registration Rights Agreement with Novo Nordisk A/S, and certain parties that execute a joinder to that agreement, in which we will provide Novo Nordisk A/S with certain registration rights to the shares they own in the Company pursuant to the Investor Agreement. We expect the transaction to close in December 2018.

The foregoing description of the Investor Agreement is not complete and is subject to and qualified in its entirety by reference to the copy of the Investor Agreement, which will be filed with the Company's Current Report on Form 8-K.

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

*The following discussion and analysis should be read in conjunction with our interim unaudited consolidated financial statements and related notes for the three and nine months ended September 30, 2018 included elsewhere in this Quarterly Report on 10-Q (this "Quarterly Report") and the audited financial statements and related notes for the year ended December 31, 2017 and related Management's Discussion and Analysis of Financial Condition and Results of Operations that are included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the "2017 Annual Report") filed with the Securities and Exchange Commission ("SEC") on March 12, 2018. As used in this Quarterly Report, unless the context suggests otherwise, "we," "us," "our," or "Strongbridge" refer to Strongbridge Biopharma plc.*

### **Special Note Regarding Forward-Looking Statements**

This Quarterly Report contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, prospective products, size or market or patient population, plans, objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential,"

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“predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

Any forward-looking statement that we make in this Quarterly Report speaks only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report except as required by law. You should also read carefully the factors described in the “Risk Factors” section of our 2017 Annual Report and this Quarterly Report to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements.

### **Overview**

We are a global, commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs.

Our first commercial product is Keveyis (dichlorphenamide), the first and only treatment approved by the U.S. Food and Drug Administration (the “FDA”) for hyperkalemic, hypokalemic, and related variants of primary periodic paralysis (“PPP”), a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis.

Our second commercial product, Macrilen (macimorelin), is an oral growth hormone secretagogue receptor agonist, and is the first and only oral test approved by the FDA for the diagnosis of patients with adult growth hormone deficiency (“AGHD”). We acquired the U.S. and Canadian rights to Macrilen in January 2018 and launched Macrilen in the United States in July 2018.

In addition to our two commercial products, we have two clinical-stage product candidates for rare endocrine diseases, Recorlev and veldoreotide. Recorlev (levoketoconazole) is a cortisol synthesis inhibitor currently being studied for the treatment of endogenous Cushing's syndrome. Veldoreotide is a next-generation somatostatin analog being investigated for the treatment of acromegaly and potential additional applications in other conditions amenable to somatostatin receptor activation. Both Recorlev and veldoreotide have received orphan designation from the FDA and the European Medicines Agency (“EMA”).

In August 2018, we announced top-line results from our multinational, pivotal Phase 3 SONICS study evaluating Recorlev for treatment of endogenous Cushing's syndrome. The open-label, single-arm SONICS study achieved statistical significance of its pre-specified primary endpoint, with 30 percent of patients achieving normalization of mean urinary free cortisol (UFC) following six months of maintenance treatment with Recorlev without a dose increase (one-sided  $p=0.154$ ). Sensitivity analyses as well as secondary and exploratory endpoints of UFC response were supportive of the primary endpoint.

For key secondary endpoints of cardiovascular risk, including fasting blood glucose, hemoglobin A1C, total cholesterol, low density lipoprotein (LDL)-cholesterol, body weight and body mass index (BMI), Recorlev demonstrated statistically significant and clinically meaningful improvements from baseline ( $p<.0001$  for each). Safety and tolerability

findings based upon data collected through the six-month maintenance phase indicate that Recorlev was generally well tolerated.

Given the well-identified and concentrated prescriber base addressing our target markets, we intend to continue to use a small, focused sales force to market Keveyis, Macrilen and any future products, in the United States, the European Union and other key global markets. We believe that our ability to execute on our strategy is enhanced by the significant commercial and clinical development experience of key members of our management team.

We are building a rare disease, franchise-based business model focused on expansion through a disciplined licensing and acquisition strategy. In pursuit of our growth strategy, we have raised over \$283 million in equity and debt financings since December 2014. We will continue to identify and evaluate the acquisition of products and product candidates for licensing or acquisition that would be complementary to our existing rare neuromuscular and endocrine franchises or that would form the basis for new rare disease franchises. We believe this approach will enable us to maximize our commercial potential by further leveraging our existing resources and expertise.

In December 2017, we received letters from the offices of United States Senators Amy Klobuchar, Susan Collins and Tammy Baldwin, and Senator Claire McCaskill, Ranking Member of the Homeland Security and Governmental Affairs Committee, requesting information relating to the marketing and sales of Keveyis. The letters requested information principally relating to the pricing of Keveyis, among other things. We are cooperating with these voluntary requests for information.

## **Recent Business Update**

### ***Macrilen Acquisition Agreement***

On October 31, 2018, we entered into the Macrilen Acquisition Agreement with Novo Nordisk Healthcare AG, a Swiss corporation, ("Novo") (the "Macrilen Acquisition Agreement"). Under the Macrilen Acquisition Agreement, the Company grants Novo a call option and Novo grants the Company a put option, in each case with respect to the entire issued share capital of Strongbridge Ireland Limited, a wholly-owned subsidiary of the Company, which holds the Company's Macrilen product. The exercise price of each of the put and call options is \$145,000,000 (the "Acquisition"), plus a future royalty on sales of the pharmaceutical product for assessing growth hormone deficiency in adults and children known as Macrilen. Each party has the right to exercise its put option or call option, as applicable, before May 1, 2019 and only after all conditions in the Macrilen Acquisition Agreement have been satisfied or waived. Upon exercise of the put or call option, Strongbridge Ireland Limited will become a wholly-owned subsidiary of Novo. We expect the transaction to close in December 2018.

The foregoing description of the Macrilen Acquisition Agreement is not complete and is subject to and qualified in its entirety by reference to the copy of the Macrilen Acquisition Agreement, which will be filed with the Company's Current Report on Form 8-K.

### ***Share Purchase Agreement***

On October 31, 2018, we entered into a Share Purchase Agreement with Novo Nordisk A/S, a company organized and existing under the law of Denmark, providing for the sale of 5,242,000 shares of our ordinary shares for \$7.00 per share and an aggregate purchase price of \$36,694,000 (the "Investor Agreement").

As a condition to the closing of the Investor Agreement, we will enter into a Registration Rights Agreement with Novo Nordisk A/S, and certain parties that execute a joinder to that agreement, in which we will provide Novo Nordisk A/S with certain registration rights to the shares they own in the Company pursuant to the Investor Agreement. We expect the transaction to close in December 2018.

The foregoing description of the Investor Agreement is not complete and is subject to and qualified in its entirety by reference to the copy of the Investor Agreement, which will be filed with the Company's Current Report on Form 8-K.

## **Financial Operations Overview**

The following discussion sets forth certain components of our statements of operations as well as factors that impact those items.

### ***Net Product Sales***

We launched our second commercial product, Macrilen, in July 2018. Our product sales result from sales of Keveyis and Macrilen. We recognize net product sales at the time our products are received by our customers (primarily wholesalers and specialty pharmacies). The products are subsequently sold to patients, who are covered by payors that may provide for government-mandated or privately negotiated rebates with respect to the purchase of our products. We expense incremental costs related to the set-up of the contracts with our customers when incurred, as these costs do not meet the criteria for capitalization.

### ***Cost of Sales***

Cost of sales includes third-party acquisition costs, third-party warehousing and product distribution charges.

### ***Selling, General and Administrative Expenses***

Selling, general and administrative expenses include personnel costs, costs for outside professional services and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits, travel and stock-based compensation. Outside professional services consist of legal, accounting and audit services, commercial evaluation and strategy services, sales, marketing and other consulting services. We expect to incur additional selling, general and administrative costs as a result of our initial and on-going commercial activities in support of Keveyis and our commercial launch of Macrilen.

### ***Research and Development Expenses***

Our research and development expenses consist primarily of costs incurred in connection with the development of our product candidates, including:

- personnel-related costs, such as salaries, bonuses, benefits, travel and other related expenses, including stock-based compensation;
- expenses incurred under our agreements with contract research organizations (“CROs”), clinical sites, contract laboratories, medical institutions and consultants that plan and conduct our preclinical studies and clinical trials, including, in the case of consultants, stock-based compensation;
- costs associated with regulatory filings;
- upfront and milestone payments under in-license or acquisition agreements with third parties;
- costs of acquiring preclinical study and clinical trial materials, and costs associated with formulation and process development; and
- depreciation, maintenance and other facility-related expenses.

We expense all research and development costs as incurred. Clinical development expenses for our product candidates are a significant component of our current research and development expenses as we progress our product candidates into and through clinical trials. Product candidates in later stage clinical development generally have higher research and development costs than those in earlier stages of development, primarily due to increased size and duration of the clinical trials. We recognize costs for each grant project, preclinical study or clinical trial that we conduct based on our evaluation of the progress to completion, including the use of information and data provided to us by clinical sites and our external research and development vendors.

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We expect our research and development expenses to increase in absolute dollars in the future as we continue to in-license or acquire product candidates and as we advance our existing and any future product candidates into and through clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval of a product candidate is costly and time consuming. The probability that any of our product candidates receives regulatory approval and eventually is able to generate revenue depends on a variety of factors, including the quality of our product candidates, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability. As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates, if approved. We may never succeed in achieving regulatory approval for any of our product candidates.

We do not allocate personnel-related research and development costs, including stock-based compensation or other indirect costs, to specific programs, as they are deployed across multiple projects under development.

### ***Interest Expense***

Interest expense represents interest paid to our lender, amortization of our debt discount, and issuance costs associated with loan and security agreements.

### ***Amortization of Intangible Assets***

Amortization of intangible assets relates to the amortization of our product rights to Keveyis and Macrilen. Both intangible assets are being amortized using the straight-line method, using an amortization period of eight years for Keveyis and ten years for Macrilen.

### ***Other Income (Expense), Net***

Other income (expense), net, consists of unrealized gain (loss) on the remeasurement of the fair value of warrant liability, interest expense recognized on our long-term debt, the loss on the extinguishment of our pre-existing long-term debt, interest income generated from our cash and cash equivalents, foreign exchange gains and losses and gains and losses on investments.

### **Critical Accounting Policies and Significant Judgments and Estimates**

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe there have been no significant changes in our critical accounting policies and significant judgments and estimates as discussed in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2017 Annual Report.



**Results of Operations**

**Comparison of the Three and Nine Months Ended September 30, 2018 and 2017**

The following table sets forth our results of operations for the three and nine months ended September 30, 2018 and 2017.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
	(in thousands)			(in thousands)		
<b>Revenues:</b>						
Net product sales	\$ 5,347	\$ 2,533	\$ 2,814	\$ 13,513	\$ 4,062	\$ 9,451
Total revenues	<u>5,347</u>	<u>2,533</u>	<u>2,814</u>	<u>13,513</u>	<u>4,062</u>	<u>9,451</u>
<b>Cost and operating expenses:</b>						
Cost of sales (excluding amortization of intangible assets)	\$ 1,441	\$ 591	\$ 850	\$ 2,861	\$ 968	\$ 1,893
Selling, general and administrative	19,564	8,484	11,080	47,137	26,068	21,069
Research and development	7,198	4,504	2,694	17,532	12,113	5,419
Amortization of intangible assets	1,876	1,256	620	5,517	3,767	1,750
Impairment of intangible asset	—	20,723	(20,723)	—	20,723	(20,723)
Total cost and expenses	<u>30,079</u>	<u>35,558</u>	<u>(5,479)</u>	<u>73,047</u>	<u>63,639</u>	<u>9,408</u>
Operating loss	(24,732)	(33,025)	8,293	(59,534)	(59,577)	43
Other income (expense), net	4,174	(2,885)	7,059	7,330	(34,506)	41,836
Loss before income taxes	(20,558)	(35,910)	15,352	(52,204)	(94,083)	41,879
Income tax benefit (expense)	—	850	(850)	(1)	(652)	651
Net loss	<u>\$ (20,558)</u>	<u>\$ (35,060)</u>	<u>\$ 14,502</u>	<u>\$ (52,205)</u>	<u>\$ (94,735)</u>	<u>\$ 42,530</u>

*Net Product Sales and Cost of Sales*

Net revenue was \$5.3 million, and cost of sales were \$1.4 million for the three months ended September 30, 2018, an increase of \$2.8 million and \$0.9 million, respectively, compared to the three months ended September 30, 2017. The increase is due increased Keveyis sales of \$1.7 million compared to the prior period and \$1.1 million in sales of Macrilen, which we launched in July 2018.

Net revenue was \$13.5 million, and cost of sales were \$2.9 million for the nine months ended September 30, 2018, an increase of \$9.5 million and \$1.9 million, respectively, compared to the nine months ended September 30, 2017. The increase is due to increased Keveyis sales of \$8.4 million compared to the prior period and \$1.1 million in sales of Macrilen, which we launched in July 2018.

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*Selling, General and Administrative Expenses*

The following table summarizes our selling, general and administrative expenses during the three and nine month periods ended September 30, 2018 and 2017:

	Three Months Ended			Nine Months Ended		
	September 30, 2018	September 30, 2017	Change \$	September 30, 2018	September 30, 2017	Change \$
	(in thousands)			(in thousands)		
Compensation and other personnel costs	\$ 8,458	\$ 3,365	\$ 5,093	\$ 20,473	\$ 12,904	\$ 7,569
Outside professional and consulting services	9,142	4,013	5,129	21,423	9,840	11,583
Stock-based compensation expense	1,649	1,007	642	4,450	3,042	1,408
Facility costs	315	99	216	791	282	509
<b>Total selling, general and administrative expenses</b>	<b>\$19,564</b>	<b>\$8,484</b>	<b>\$11,080</b>	<b>\$47,137</b>	<b>\$26,068</b>	<b>\$21,069</b>

Selling, general and administrative expenses were \$19.6 million for the three months ended September 30, 2018, an increase of \$11.1 million compared to the three months ended September 30, 2017. Compensation and other personnel costs increased by \$5.1 million during the three months ended September 30, 2018, primarily due to increased headcount of commercial personnel for the commercialization of Keveyis and our launch of Macrilen. Outside professional and consulting services increased \$5.1 million due to expenses relating to the commercialization of Keveyis and our launch of Macrilen.

Selling, general and administrative expenses were \$47.1 million for the nine months ended September 30, 2018, an increase of \$21.1 million compared to the nine months ended September 30, 2017. Compensation and other personnel costs increased by \$7.6 million during the nine months ended September 30, 2018, primarily due to increased headcount of commercial personnel for the commercialization of Keveyis and our launch of Macrilen. Outside professional and consulting services increased \$11.6 million due to expenses relating to the commercialization of Keveyis and our launch of Macrilen.

*Research and Development Expenses*

The following table summarizes our research and development expenses during the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended			Nine Months Ended		
	September 30, 2018	September 30, 2017	Change \$	September 30, 2018	September 30, 2017	Change \$
	(in thousands)			(in thousands)		
Product development and supporting activities	\$5,390	\$3,290	\$2,100	\$12,441	\$ 8,735	\$3,706
Compensation and other personnel costs	1,340	890	450	3,752	2,556	1,196
Stock-based compensation expense	468	324	144	1,339	822	517
<b>Total research and development expenses</b>	<b>\$7,198</b>	<b>\$4,504</b>	<b>\$2,694</b>	<b>\$17,532</b>	<b>\$12,113</b>	<b>\$5,419</b>

Research and development expenses were \$7.2 million for the three months ended September 30, 2018, an increase of \$2.7 million compared to the three months ended September 30, 2017. The \$2.1 million increase in expenses for product development and supporting activities was primarily due to additional clinical development expenses for Recorlev and life cycle management activities for Keveyis. Compensation and other personnel costs increased by \$0.5

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million for the three months ended September 30, 2018 as compared to the same period in 2017 due to increased headcount in research and development.

Research and development expenses were \$17.5 million for the nine months ended September 30, 2018, an increase of \$5.4 million compared to the nine months ended September 30, 2017. The \$3.7 million increase in expenses for product development and supporting activities was primarily due to additional clinical development expenses for Recorlev and life cycle management activities for Kevevis. Compensation and other personnel costs increased by \$1.2 million for the nine months ended September 30, 2018 as compared to the same period in 2017 due to increased headcount in research and development.

*Amortization of Intangible Assets*

Amortization of intangible assets was \$1.9 million and \$5.5 million for the three and nine months ended September 30, 2018, respectively, an increase of \$0.6 million and \$1.8 million respectively, due to the commencement of amortization of the Macrilen product rights that we acquired in January 2018.

*Impairment of Intangible Asset*

Impairment of intangible asset decreased by \$20.7 million for each of the three and nine months ended September 30, 2018, due to a \$20.7 million impairment charge recorded in the third quarter of 2017 related to the in-process research and development recorded from our 2015 acquisition of veldoreotide from Aspireo Pharmaceuticals, Ltd.

*Other Income (Expense), Net*

The following table summarizes our other income (expense), net, during the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended			Nine Months Ended		
	September 30,		Change	September 30,		Change
	2018	2017	\$	2018	2017	\$
	(in thousands)			(in thousands)		
Unrealized gain (loss) on fair value of warrants	\$ 7,131	\$ 1,953	\$ 5,178	\$16,448	\$(28,194)	\$44,642
Interest expense	(3,387)	(1,364)	(2,023)	(9,550)	(2,838)	(6,712)
Foreign exchange loss	(15)	(11)	(4)	(22)	(36)	14
Loss on extinguishment of debt	—	(3,545)	3,545	(500)	(3,545)	3,045
Other income, net	445	82	363	954	107	847
Total other income (expense), net	<u>\$ 4,174</u>	<u>\$(2,885)</u>	<u>\$ 7,059</u>	<u>\$ 7,330</u>	<u>\$(34,506)</u>	<u>\$41,836</u>

Other income (expense), net, increased by \$7.1 million for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. The increase was primarily due to a \$5.2 million greater unrealized gain on the fair value of our warrant liability in 2018, offset in part by a \$2.0 million increase in interest expense. The change in the warrant liability is primarily due to changes in our stock price. In addition, the 2017 period included \$3.5 million of expense relating to the loss on the extinguishment of debt.

Other income (expense), net, increased by \$41.8 million for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017. The increase was primarily due to a \$44.6 million greater unrealized gain on the fair value of our warrant liability in 2018, offset in part by a \$6.7 million increase in interest expense. The change in the warrant liability is primarily due to changes in our stock price. In addition, the 2017 period included \$3.5 million of expense relating to the loss on the extinguishment of debt, compared to \$0.5 million in 2018.

### *Income Tax*

We recorded no income tax expense for the three and nine months ended September 30, 2018 as a result of recording full valuation allowances against our deferred tax asset and deferred tax liability.

### *Cash Flows*

#### **Comparison for the Nine Months Ended September 30, 2018 and 2017:**

	Nine Months Ended September 30	
	2018	2017
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (51,864)	\$ (34,450)
Investing activities	(24,965)	(7,500)
Financing activities	86,702	19,479
Net increase (decrease) in cash and cash equivalents	<u>\$ 9,873</u>	<u>\$ (22,471)</u>

#### *Operating Activities*

Net cash used in operating activities was \$51.9 million for the nine months ended September 30, 2018 compared to \$34.5 million for the nine months ended September 30, 2017. The increase in net cash used in operating activities resulted primarily from expenditures during 2018 to support the commercialization of Keveyis and the launch of Macrilen, offset in part by increased net revenues from sales of Keveyis and Macrilen.

#### *Investing Activities*

Net cash used in investing activities was \$25.0 million for the nine months ended September 30, 2018 compared to \$7.5 million for the nine months ended September 30, 2017. The increase in net cash used in investing activities resulted from the \$24 million payment made to Aeterna Zentaris GmbH in January 2018 for our acquisition of Macrilen product rights and other expenses incurred with the acquisition.

#### *Financing Activities*

Net cash provided by financing activities was \$86.7 million for the nine months ended September 30, 2018 compared to net cash used in financing activities for the nine months ended September 30, 2017 of \$19.5 million. The increase in net cash provided by financing activities resulted primarily from our receipt of \$44.9 million in proceeds from the amendment to our senior credit facility with CRG Servicing LLC ("CRG") and \$42.7 million in net proceeds from issuance of our ordinary shares and exercise of warrants.

### **Liquidity and Capital Resources**

We believe that our cash resources of \$67.4 million at September 30, 2018 will be sufficient to allow us to fund planned operations for at least 12 months beyond the issuance date of the financial statements included in this Quarterly Report. We also expect our cash needs to increase to fund potential in-licenses, acquisitions or similar transactions as we pursue our strategy. These expenses may be offset only in part by sales of Keveyis and Macrilen. In addition, beginning in March 2021, we may be required to make quarterly principal payments to repay amounts borrowed under our credit facility.

Cash used to fund operating expenses is affected by the timing of when we are invoiced by our vendors, as reflected in the change in our outstanding accounts payable and accrued expenses set forth in the financial statements, included in this Quarterly Report.

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Our future funding requirements will depend on many factors, including the following:

- the amount of revenue that we receive from sales of Keveyis and Macrilen;
- the cost and timing of establishing sales, marketing, distribution and administrative capabilities;
- the scope, rate of progress, results and cost of our clinical trials testing and other related activities for Recorlev and veldoreotide;
- whether we borrow any additional amounts under our credit facility;
- the number and characteristics of product candidates that we pursue, including any additional product candidates we may in-license or acquire;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the cost, timing and outcomes of regulatory approvals;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder; and
- the emergence of competing technologies and their achieving commercial success before we do or other adverse market developments.

As of September 30, 2018, we held cash and cash equivalents of \$67.4 million.

On January 16, 2018 (the “First Loan Amendment Effective Date”), we and our subsidiaries, Strongbridge U.S. Inc., Strongbridge Ireland Limited, Cortendo AB (publ) and Cortendo Cayman Ltd., entered into an amendment (the “First Loan Amendment”), to the Term Loan Agreement (the “Loan Agreement”), dated July 14, 2017, with CRG Servicing LLC (“CRG”), as administrative agent and collateral agent, and the lenders named therein (the “Lenders”).

The primary purpose of the First Loan Amendment was to increase the total potential borrowing under the Loan Agreement from \$50 million to \$100 million. The First Loan Amendment provided for (i) an additional disbursement of \$45.0 million (the “Second Tranche”) to the Company on the First Loan Amendment Effective Date, and (ii) an additional disbursement of \$5.0 million (the “Fourth Tranche”) to us at our election, contingent upon our achievement of certain revenue milestones and a market capitalization condition on or before December 31, 2018, as described in the Loan Amendment. Under the First Loan Amendment, we continued to be eligible to borrow up to an additional \$10.0 million (the “Third Tranche”), contingent upon our achievement of certain revenue milestones on or before June 30, 2018, as previously provided in the Loan Agreement; provided, however, that under the Loan Agreement, as amended, the Third Tranche became subject to market capitalization condition, as described in the Loan Amendment.

On June 6, 2018, we and our subsidiaries, Strongbridge U.S. Inc., Cortendo Cayman Ltd., Strongbridge Ireland Limited and Cortendo AB (publ), entered into a second amendment (the “Second Loan Amendment”), to the Loan Agreement. The primary purposes of the Second Loan Amendment (as requested by the Company) was to reduce the aggregate commitments under the Loan Agreement from \$100 million to \$95 million and to combine the Third Tranche and the Fourth Tranche under the Loan Agreement into one final borrowing tranche for up to \$10 million (the “Final Tranche”). Under the terms of the Second Loan Amendment, the Final Tranche borrowing must occur on or before March 19, 2019. The Final Tranche is subject to the Company’s achievement of a certain revenue milestone, which under the Second Loan Amendment must be satisfied on or prior to December 31, 2018, and satisfaction of a market

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capitalization condition for the 20 consecutive trading days ending on the trading day immediately prior to the Final Tranche borrowing date (as described in the Loan Agreement, as amended).

The Loan Agreement, as amended, and security agreement entered into with CRG each contain financial and non-financial covenants including minimum amounts of net revenue we must achieve in 2017 and beyond. Failure to comply with the covenants could result in the lenders declaring the loan immediately due and payable. Our liquidity requirements are predicated on maintaining compliance with the debt covenants and repaying outstanding borrowings in accordance with the loan agreement. See Note 7 of the financial statements included in this Quarterly Report for additional information concerning the Loan Agreement, as amended.

On January 30, 2018, we sold 5,000,000 ordinary shares in a public offering at a price to the public of \$6.75 per ordinary share for net proceeds of approximately \$31.8 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

On February 27, 2018, we sold an additional 255,683 ordinary shares to the underwriters of our January 2018 public offering in connection with their partial exercise of their option to purchase additional shares to cover over-allotments at a price of \$6.75 per ordinary share for net proceeds of approximately \$1.7 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

During the nine months ended September 30, 2018, we sold an aggregate of 1,172,557 ordinary shares under our at-the-market facility at an average selling price of \$7.00 per share, resulting in net proceeds of approximately \$8.0 million after payment of fees and expenses.

Our ability to achieve and maintain profitability is dependent upon the successful commercialization of Keveyis and Macrilen, the development, regulatory approval and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. If we need to raise additional capital to fund our operations and complete our ongoing and planned clinical trials, funding may not be available to us on acceptable terms, or at all.

We plan to continue to fund our operations and capital funding needs through equity or debt financing along with revenues from Keveyis and Macrilen. The sale of additional equity would result in additional dilution to our shareholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. In addition, lack of funding would limit any strategic initiatives to in-license or acquire additional product candidates or programs.

#### Contractual Obligations and Other Commitments

The following table summarizes our future minimum commitments at September 30, 2018:

	Payments due by period				Total
	Less than 1 year	1 to 3 years	3 to 5 years (in thousands)	More than 5 years	
Minimum contract purchases pursuant to supply agreements	\$ 503	\$ 14,035	\$ 8,025	\$ —	\$ 22,563
Debt and interest payments	\$ 11,362	\$ 65,224	\$ 59,652	\$ —	\$ 136,238
Operating leases	\$ 436	\$ 1,434	\$ 332	\$ —	\$ 2,202
Total contractual obligations	\$ 12,301	\$ 80,693	\$ 68,009	\$ —	\$ 161,003

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We enter into agreements in the normal course of business with vendors for clinical trials, preclinical studies, and other services and products for operating purposes. Future payment obligations under these agreements, which are cancelable at any time by us, generally upon 30 days prior written notice, are not included in this table of contractual obligations.

We are obligated to make future payments to third parties due to payments that become due and payable upon the achievement certain commercialization milestones. As the amount and timing of these milestones are not probable and estimable, such commitments have not been included on our consolidated balance sheets or in the contractual obligations table above.

### **Off-Balance Sheet Arrangements**

We do not have variable interests in variable interest entities or any off-balance sheet arrangements.

### **ITEM 3. Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to certain market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities as follows:

#### **Interest Rate Risk**

We had cash and cash equivalents of \$67.4 million as September 30, 2018, which consisted primarily of bank deposits in the United States. Our cash and cash equivalents are held in a variety of interest-earning instruments, including money market funds. Such interest-earning instruments carry a degree of interest rate risk. To date, fluctuations in interest income have not been significant. We also had total outstanding long-term debt principal of \$88.3 million as of September 30, 2018, none of which was due within 12 months. The interest rate of our borrowings under the Loan Agreement with CRG is fixed. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

### **ITEM 4. Controls and Procedures**

#### ***Evaluation of Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018, the end of the period covered by this Quarterly Report. Based on their evaluation, we believe that our disclosure controls and procedures as of September 30, 2018 were effective to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting that occurred during the fiscal quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II – OTHER INFORMATION**

**ITEM 1. Legal Proceedings**

The Company is not currently involved in any legal matters arising in the normal course of business. From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters.

**ITEM 1A. Risk Factors**

The risks described in Item 1A. Risk Factors of our 2017 Annual Report could materially and adversely affect our business, financial condition and results of operations. The risk factors discussed in our 2017 Annual Report do not identify all risks that we face because our business operations could also be affected by additional factors that are not presently known to us or that we currently consider to be immaterial to our operations. There have been no material changes in the risk factors discussed in our 2017 Annual Report.

**ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None

**ITEM 3. Defaults Upon Senior Securities**

None.

**ITEM 4. Mine Safety Disclosures**

Not applicable.

**ITEM 5. Other Information**

None.



**ITEM 6. Exhibits**

**EXHIBIT INDEX**

31.1	<a href="#">Certificate of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2	<a href="#">Certificate of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1	<a href="#">Certificate of principal executive officer and principal financial officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definitions Linkbase Document

## 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.

### STRONGBRIDGE BIOPHARMA PLC

By:           /s/ A. BRIAN DAVIS            
Name: **A. Brian Davis**  
Title: Chief Financial Officer

Date: October 31, 2018

**CERTIFICATIONS**

I, Matthew Pauls, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Strongbridge Biopharma plc;
2. Based on my knowledge, this Quarterly 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 Quarterly Report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2018

By: /s/ Matthew Pauls  
Matthew Pauls  
Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATIONS**

I, A. Brian Davis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Strongbridge Biopharma plc;
2. Based on my knowledge, this Quarterly 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 Quarterly Report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2018

By: /s/ A. Brian Davis  
A. Brian Davis  
Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATIONS PURSUANT TO 18 U.S.C. 1350**

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Matthew Pauls, the Chief Executive Officer (principal executive officer) of Strongbridge Biopharma plc (the “Company”), and A. Brian Davis, the Chief Financial Officer (principal financial officer) of the Company, each hereby certifies that, to his knowledge on the date hereof:

(a) The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2018 filed on the date hereof with the Securities and Exchange Commission (the “Quarterly Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(b) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Quarterly Report.

This certification shall not be deemed to be filed with the Securities and Exchange Commission and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained and furnished to the Securities and Exchange Commission or its staff upon request.

By: /s/ Matthew Pauls

Matthew Pauls  
Chief Executive Officer  
(Principal Executive Officer)  
October 31, 2018

By: /s/ A. Brian Davis

A. Brian Davis  
Chief Financial Officer  
(Principal Financial Officer)  
October 31, 2018

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