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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 March 31, 2020

OR

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

For the Transition Period from _____ to _____

Commission file number 001-37569

STRONGBRIDGE BIOPHARMA plc
(Exact name of Registrant as specified in its charter)

Ireland	**98-1275166**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

900 Northbrook Drive
Suite 200
Trevose, PA 19053
(Address of principal executive offices)

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

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of each class:	**Trading Symbol**	**Name of each exchange on which registered:**
Ordinary shares, par value $0.01 per share	SBBP	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T 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 May 1, 2020, there were 54,247,501 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)

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,554	$ 57,032
Marketable securities	6,293	21,072
Accounts receivable	2,690	2,289
Inventory	1,343	1,993
Prepaid expenses and other current assets	1,078	1,157
Total current assets	67,958	83,543
Property and equipment, net	270	291
Right of use asset, net	744	789
Intangible asset, net	23,855	25,110
Goodwill	7,256	7,256
Other assets	977	649
Total assets	$ 101,060	$ 117,638
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,285	$ 3,331
Accrued and other current liabilities	18,513	20,962
Total current liabilities	23,798	24,293
Warrant liability	3,547	4,127
Supply agreement liability, noncurrent	11,556	15,947
Other long-term liabilities	980	1,080
Total liabilities	39,881	45,447
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Deferred shares, $1.098 par value, 40,000 shares authorized, issued and outstanding at March 31, 2020 and December 31, 2019	44	44
Ordinary shares, $0.01 par value, 600,000,000 shares authorized at March 31, 2020 and December 31, 2019; 54,247,501 and 54,205,852 shares issued and outstanding at March 31, 2020 and December 31, 2019	542	542
Additional paid-in capital	333,768	332,085
Accumulated deficit	(273,181)	(260,483)
Accumulated other comprehensive income	6	3
Total stockholders' equity	61,179	72,191
Total liabilities and stockholders' equity	$ 101,060	$ 117,638

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 March 31	
	2020	2019
Revenues:		
Net product sales	$ 6,663	$ 4,333
Royalty revenue	11	10
Total revenues	6,674	4,343
Cost and expenses:		
Cost of sales (excluding amortization of intangible asset)	$ 969	$ 813
Selling, general and administrative	10,403	12,100
Research and development	7,552	6,583
Amortization of intangible asset	1,256	1,256
Total cost and expenses	20,180	20,752
Operating loss	(13,506)	(16,409)
Other income (expenses), net:		
Unrealized gain (loss) on fair value of warrants	580	(1,820)
Income from field services agreement	—	2,016
Expense from field services agreement	—	(2,229)
Other income, net	228	685
Total other income (expenses), net	808	(1,348)
Loss before income taxes	(12,698)	(17,757)
Income tax expense	—	(677)
Net loss	$ (12,698)	$ (18,434)
Other comprehensive income		
Unrealized gain on marketable securities	3	—
Comprehensive loss	$ (12,695)	$ (18,434)
Net loss attributable to ordinary shareholders:		
Basic	$ (12,698)	$ (18,434)
Diluted	$ (13,278)	$ (18,434)
Net loss per share attributable to ordinary shareholders:		
Basic	$ (0.23)	$ (0.34)
Diluted	$ (0.24)	$ (0.34)
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:		
Basic	54,231,024	54,155,034
Diluted	54,444,681	54,155,034

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

STRONGBRIDGE BIOPHARMA plc

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

	Strongbridge Biopharma plc Shareholders							
	Ordinary Shares		Deferred Shares		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity
	Shares	Amount	Shares	Amount				
Balance—December 31, 2018	54,122,074	$ 541	40,000	$ 44	$ 323,402	$ (211,032)	—	$ 112,955
Net loss	—	—	—	—	—	(18,434)	—	(18,434)
Stock-based compensation	—	—	—	—	2,323	—	—	2,323
Exercise of stock options	39,728	1	—	—	165	—	—	166
Ordinary shares issued, net of shares withheld for employee taxes	6,146	*	—	—	(27)	—	—	(27)
Balance—March 31, 2019	54,167,948	$ 542	40,000	$ 44	$ 325,863	$ (229,466)	—	$ 96,983
Balance—December 31, 2019	54,205,852	$ 542	—	$ 44	$ 332,085	$ (260,483)	3	$ 72,191
Net loss	—	—	—	—	—	(12,698)	—	(12,698)
Stock-based compensation	—	—	—	—	1,751	—	—	1,751
Ordinary shares issued, net of shares withheld for employee taxes	41,649	*	—	—	(68)	—	—	(68)
Unrealized gain on marketable securities		—	—	—	—	—	3	3
Balance—March 31, 2020	54,247,501	$ 542	—	$ 44	$ 333,768	$ (273,181)	6	$ 61,179

* 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)

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (12,698)	$ (18,434)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(580)	1,820
Stock-based compensation	1,751	2,323
Amortization of intangible asset	1,256	1,256
Accretion of discounts on marketable securities	(48)	—
Depreciation	21	18
Changes in operating assets and liabilities:		
Accounts receivable	(401)	(2,290)
Inventory	101	(649)
Prepaid expenses and other current assets	79	1,510
Other assets	266	(1,210)
Accounts payable	1,954	539
Accrued and other liabilities	(6,941)	(3,191)
Net cash used in operating activities	(15,240)	(18,308)
Cash flows from investing activities:		
Purchases of property and equipment	—	(15)
Maturities of marketable securities	14,830	—
Net cash provided by (used in) investing activities	14,830	(15)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	166
Payments related to tax withholding for net-share settled equity awards	(68)	(27)
Net cash (used in) provided by financing activities	(68)	139
Net decrease in cash and cash equivalents	(478)	(18,184)
Cash and cash equivalents—beginning of period	57,032	122,490
Cash and cash equivalents—end of period	$ 56,554	$ 104,306
Supplemental non-cash financing activities:		
Changes in unrealized gain on marketable securities	$ 3	$ —

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.

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 potential applications in conditions amenable to somatostatin receptor activation, such as acromegaly. Both levoketoconazole and veldoreotide have received orphan designation from the FDA and the European Medicines Agency ("EMA").

In January 2018, Strongbridge Ireland Limited, one of our wholly-owned subsidiaries, acquired the U.S. and Canadian rights to Macrilen (macimorelin), the first and only oral drug approved by the FDA for the diagnosis of patients with adult growth hormone deficiency. We launched Macrilen in the United States in July 2018. In December 2018, we sold Strongbridge Ireland Limited to Novo Nordisk Healthcare AG ("Novo") for $145 million plus the right to receive tiered royalties on net sales of Macrilen through 2027. In addition, Strongbridge U.S. Inc., another of our wholly-owned subsidiaries, entered into an agreement with Novo Nordisk Inc. ("NNI"), a subsidiary of Novo, pursuant to which NNI funded the costs of 23 of our field-based employees to provide full-time ongoing services to NNI, including the promotion of Macrilen in the United States, for a period of three years. Novo also purchased 5.2 million of our ordinary shares at a purchase price of $7.00 per share. In December 2019, we reached an agreement with Novo to terminate the services agreement. We received a $6 million payment in connection with such termination and we no longer provide services to Novo.

Liquidity

We believe that our cash, cash equivalents and marketable securities of $62.8 million at March 31, 2020 will be sufficient to allow us to fund planned operations for at least 12 months beyond the issuance date of these unaudited consolidated financial statements.

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. There can be no assurances, however, that additional funding will be available on terms acceptable to us.

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 March 31, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020.

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, 2019 filed with the U.S. Securities and Exchange Commission on February 28, 2020 (the "2019 Annual Report"). Our significant accounting policies are described in Note 2 of the notes to the audited consolidated financial statements included in our 2019 Annual Report. Since the date of those financial statements, there have been no changes to our significant accounting policies.

Leases

We account for leases in accordance with Accounting Standards Codification Topic 842, *Leases*, ("ASC 842"). We determine if an arrangement is a lease at contract inception. A lease exists when a contract conveys to us the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. The definition of a lease embodies two conditions: (1) there is an identified asset in the contract that is land or a depreciable asset (*i.e.*, property, plant, and equipment), and (2) we have the right to control the use of the identified asset.

Operating leases where we are the lessee are included in Right of use ("ROU") assets and Other current liabilities and Other long-term liabilities on our Consolidated Balance Sheets. The lease liabilities are initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date.

Key estimates and judgments include how we determined (1) the discount rate we use to discount the unpaid lease payments to present value, (2) lease term and (3) lease payments.

ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. Because our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Our incremental borrowing rate for a lease is the rate of interest we would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms.

The lease term for all of our leases includes the noncancellable period of the lease. Lease payments included in the measurement of the lease asset or liability are comprised of our fixed payments.

The ROU asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date less any lease incentives received.

For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

We monitor for events or changes in circumstances that require a reassessment of a lease. If a reassessment results in the remeasurement of a lease liability, a corresponding adjustment is made to the carrying amount of the corresponding ROU asset unless doing so would reduce the carrying amount of the ROU asset to an amount less than zero. In that case, the amount of the adjustment that would result in a negative ROU asset balance is recorded in profit or loss.

We have elected not to recognize ROU assets and lease liabilities for all short-term leases that have a lease term of 12 months or less. We recognize the lease payments associated with our short-term leases as an expense on a straight-line basis over the lease term. Variable lease payments associated with these leases are recognized and presented in the same manner as for all our other leases.

We adopted ASC 842 using a modified retrospective transition approach as of the effective date, as permitted by the amendments in ASU 2018-11. As a result, we were not required to adjust our comparative period financial information for effects of the standard or make the new required lease disclosures for periods before the date of adoption (*i.e.*, January 1, 2019). We have elected to adopt the package of transition practical expedients and, therefore, have not reassessed (1) whether existing or expired contracts contain a lease, (2) lease classification for existing or expired leases or (3) the accounting for initial direct costs that were previously capitalized. We did not elect the practical expedient to use hindsight for leases existing at the adoption date. Further, we do not expect the amendments in ASU 2018-01: Land Easement Practical Expedient to have an effect on us because we do not enter into land easement arrangements.

Cash, cash equivalents and marketable securities

We consider all short-term highly liquid investments with an original maturity at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents consist of account balances at banks and money market accounts, respectively.

We invest our excess cash balances in marketable securities of highly rated financial institutions. We seek to diversify our investments and limit the amount of investment concentrations for individual institutions, maturities and investment types. We classify marketable debt securities as available-for-sale and, accordingly, record such securities at fair value. We classify these securities as current assets as these investments are intended to be available to us for use in funding current operations. There were no marketable securities with a maturity of greater than one year as of March 31, 2020.

Unrealized gains and losses on marketable debt securities are recorded as a separate component of accumulated other comprehensive income (loss) included in stockholders' equity.

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.

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 equity-classified warrants.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of March 31, 2020 and 2019, as they would be anti-dilutive:

	March 31,	
	2020	2019
Warrants	1,803,253	6,833,253
Stock options issued and outstanding	10,334,368	10,205,851
Unvested RSUs	925,800	758,850

Recent accounting pronouncements – not yet adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments.* ASU 2016-13 requires an entity to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the current other-than-temporary impairment model. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 for SEC filers, excluding smaller reporting companies, who have until fiscal years beginning after December 15, 2022. We do not expect the adoption of this standard to have a significant impact on our financial statements or internal controls.

3. Revenue recognition

Product sales, net

We sell Keveyis to one specialty pharmacy provider (the “Customer”), who is the exclusive distributor of Keveyis in the United States. The Customer subsequently resells Keveyis to patients, most of whom are covered by payors that may provide for government-mandated or privately negotiated rebates with respect to the purchase of Keveyis.

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

Reserves for variable consideration

Revenues from sales of Keveyis 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 between us and the patients’ payors. There is no variable consideration reserve for returns as we do not accept returns of Keveyis. 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 the Customer) or a current liability (if the amount is payable to a party other than the 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: We provide the Customer with a discount that is explicitly stated in our contract and 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 the Customer. To the extent the services received are distinct from our sale of Keveyis to the Customer, these payments are classified in selling, general and administrative expenses in our consolidated statement of operations and comprehensive loss.

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 Keveyis 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 the Customer 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 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, 2019, manufacturers of pharmaceutical products are responsible for 70% 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 for Keveyis that have been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Temporary Supply and Patient Assistance Programs: We provide free Keveyis to uninsured patients who satisfy pre-established criteria for either the Temporary Supply Program or the Patient Assistance Program. Patients who meet the Temporary Supply Program eligibility criteria may receive a temporary supply of free Keveyis for no more than sixty days while there is a determination of 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 uninsured 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, 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 March 31, 2020			
	Level I	Level II	Level III	Total
Cash equivalents	56,078	—	—	56,078
Marketable securities	—	6,293	—	6,293
Total assets	$ 56,078	$ 6,293	$ —	$ 62,371
Warrant liability	—	—	3,547	3,547
Total liabilities	$ —	$ —	$ 3,547	$ 3,547

	As of December 31, 2019			
	Level I	Level II	Level III	Total
Cash equivalents	56,544	—	—	56,544
Marketable securities	—	21,072	—	21,072
Total assets	$ 56,544	$ 21,072	$ —	$ 77,616
Warrant liability	—	—	4,127	4,127
Total liabilities	$ —	$ —	$ 4,127	$ 4,127

The following table presents a reconciliation of our level 3 warrant liability (in thousands):

	As of March 31, 2020
Balance as of December 31, 2019	$ 4,127
Unrealized gain on fair value of warrants for three months ended March 31, 2020	(580)
Balance as of March 31, 2020	$ 3,547

5. Marketable securities

Marketable securities consist of the following:

	As of March 31, 2020		
	Amortized Cost	Net Unrealized Gain	Fair Value
Commercial paper	$ 3,293	$ —	$ 3,293
U.S. treasury securities	2,994	6	3,000
Total marketable securities	$ 6,287	$ 6	$ 6,293

6. Intangible asset and goodwill

The following represents the balance of our intangible asset and goodwill as follows (in thousands):

	As of March 31, 2020		
	Beginning of Period	Amortization	End of Period
Keveyis	$ 25,110	$ (1,256)	$ 23,855
Goodwill	7,256	—	7,256
Total	$ 32,366	$ (1,256)	$ 31,111

Our finite-lived intangible asset consists of acquired developed product rights obtained from our acquisition of Keveyis (dichlorphenamide) from a subsidiary of Taro Pharmaceutical Industries Ltd. (“Taro”).

Pursuant to the terms of the Asset Purchase Agreement and Supply Agreement that we entered into with Taro in December 2016, 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 is being reduced as we purchase inventory over the term of the Supply Agreement that we entered into with Taro. In addition, we incurred transaction costs of $2.4 million. 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 recorded amortization expense of $1.3 million the three months ended March 31, 2020 and three months ended March 31, 2019, respectively.

7. Accrued and other current liabilities

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

	March 31, 2020	December 31, 2019
Consulting and professional fees	$ 5,640	$ 4,335
Supply agreement - current portion	4,391	2,773
Accrued sales allowances	2,229	2,990
Employee compensation	2,078	4,452
Accrued taxes	1,892	1,892
Severance	1,088	2,968
Lease liability - current portion	384	374
Accrued royalties	302	806
Other	509	372
Total accrued liabilities	$ 18,513	$ 20,962

8. Commitments and contingencies

(a) Commitments to Taro Pharmaceuticals Industries Ltd.

In December 2016, we acquired the U.S. marketing rights to Keveyis (dichlorphenamide) from Taro. Under the terms of an 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. As of March 31, 2020, our remaining obligation was $19.0 million. Our Supply Agreement with Taro 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 also required to reimburse Taro for their royalty obligation resulting from their sale of Keveyis to us.

(b) Indemnifications

In the ordinary course of business and in connection with the sale of assets and businesses and other transactions, we often indemnify our counterparties against certain liabilities that may arise in connection with the transaction or that are related to events and activities prior to or following a transaction, such as breaches of contracts, unfavorable tax consequences and employee liabilities. If the indemnified party were to make a successful claim pursuant to the terms of the indemnification, we may be required to reimburse the loss and such amount could be material to our financial statements. Where appropriate, the obligation for such indemnifications is recorded as a liability. Because the amount of these types of indemnifications generally is not specifically stated, the overall maximum

amount of the obligation under such indemnifications cannot be reasonably estimated. However, we believe that the likelihood of a material liability being triggered under these indemnification obligations is not probable at this time.

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.

We did not incur income any tax expense for the three months ended March 31, 2020.

10. Warrants

Warrants

Our outstanding warrants as of March 31, 2020 are as follows:

	Classification	Exercise Price	Expiration Date	Warrants Issued	Warrants Exercised	Warrants Outstanding March 31, 2020
Warrants in connection with private equity placement	Liability	$ 2.50	6/28/2022	7,000,000	(1,970,000)	5,030,000
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	1,248,250	—	1,248,250
				9,071,110		6,833,253

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 March 31, 2020, 1,374,528 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 March 31, 2020, 561,158 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 March 31, 2020, 271,029 shares are available for issuance pursuant to the Non-Employee Director Plan.

A summary of our outstanding stock options as of March 31, 2020 is as follows:

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding—January 1, 2020	9,192,684	$ 6.58	5.96	$ 164
Granted	2,393,000	$ 2.97		
Forfeited and cancelled	(1,133,316)	$ 10.66		
Exercised	—	$ —		
Outstanding—March 31, 2020	10,452,368	$ 5.31	2.01	$ 104
Vested and exercisable—March 31, 2020	5,100,335	$ 6.86	5.39	$ 6

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 March 31,	
	2020	2019
Selling, general and administrative	$ 1,270	$ 1,811
Research and development	481	512
Total stock-based compensation	$ 1,751	$ 2,323

As of March 31, 2020, the total unrecognized compensation expense related to unvested stock options is $12.4 million, which we expect to recognize over an estimated weighted-average period of 2.89 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:

	Three Months Ended March 31,	
	2020	2019
Expected term (in years)	6.07	6.09
Risk-free interest rate	1.47%-1.48%	2.47%-2.61%
Expected volatility	78.15%-78.21%	80.00%-80.85%
Dividend rate	—%	—%

Restricted stock units

We grant RSUs to employees and to members of our board of directors. RSUs that are granted to employees vest two years from the date of issuance, provided that the employee is employed by us on such vesting date. RSUs that are granted to directors, vest on the one-year anniversary of the grant date, provided that the director continues to serve as a member of the board of directors continuously from the grant date through such one-year anniversary. 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 employee's or director's tax withholding obligations. The RSUs will cease to be outstanding upon the issuance of ordinary shares upon vesting. We recorded expense, which is included in the stock-based compensation table above, of $0.5 million for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, the total unrecognized compensation expense related to unvested RSUs is $1.6 million, which we expect to recognize over an estimated weighted-average period of 1.21 years.

A summary of our unvested RSUs as of March 31, 2020 is as follows:

	Number of Shares
Outstanding—January 1, 2020	791,350
Granted	212,650
Forfeited	(17,200)
Vested	(61,000)
Unvested—March 31, 2020	925,800

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 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, 2019 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, 2019 (the "2019 Annual Report") filed with the Securities and Exchange Commission ("SEC") on February 28, 2020. 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, expected market growth and the anticipated effects of the coronavirus (COVID-19) pandemic on our business, operating results and financial condition are forward-looking statements. The words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "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 2019 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.

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 potential applications in conditions amenable to somatostatin receptor activation. Both levoketoconazole and veldoreotide have received orphan designation from the FDA and the European Medicines Agency ("EMA").

In January 2018, Strongbridge Ireland Limited, one of our wholly-owned subsidiaries, acquired the U.S. and Canadian rights to Macrilen (macimorelin), the first and only oral drug approved by the FDA for the diagnosis of patients with adult growth hormone deficiency. We launched Macrilen in the United States in July 2018. In December 2018, we sold Strongbridge Ireland Limited to Novo Nordisk Healthcare AG ("Novo") for $145 million plus the right to receive tiered royalties on net sales of Macrilen through 2027. In addition, Strongbridge U.S. Inc., another of our wholly-owned subsidiaries, entered into an agreement with Novo Nordisk Inc. ("NNI"), a subsidiary of Novo, pursuant to which NNI funded the costs of 23 of our field-based employees to provide full-time ongoing services to NNI, including the promotion of Macrilen in the United States, for a period of three years. Novo also purchased 5.2 million of our ordinary shares at a purchase price of $7.00 per share. In December 2019, we reached an agreement with Novo to terminate the services agreement. We received a $6 million payment in connection with such termination and we no longer provide services to Novo.

Recent Developments

COVID-19 emerged in Asia at the end of calendar year 2019. On March 11, 2020 the World Health Organization declared COVID-19 a pandemic, and on March 13, 2020 the United States declared a national emergency with respect to COVID-19. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption in the financial markets.

While the COVID-19 outbreak did not have a material impact on our business, financial condition or results of operations for the three months ended March 31, 2020, we have experienced business disruptions as a result of the outbreak. For example, all of our employees are currently working remotely from home, we have suspended all travel for business, and our field teams are no longer able to visit physicians.

We continue to monitor the impacts of COVID-19 on the global economy and on our business operations. However, at this time, it is difficult to predict how long the potential operational impacts of COVID-19 will remain in effect or to what degree they will impact our operations and financial results. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity and financial condition, as well as our ability to execute our business strategies and initiatives in their respective expected time frames.

Financial Operations Overview

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

Product Sales, net

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. For a complete discussion of accounting for net product revenue, see Note 3, "Revenue recognition" to our consolidated financial statements.

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, market access, marketing, investor relations, public relations, recruiting and other consulting services.

Research and Development Expenses

We expense all research and development costs as incurred. 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. 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 our external research and development vendors and clinical sites;
- costs associated with regulatory filings; and
- costs of acquiring preclinical study and clinical trial materials, and costs associated with formulation, process development and statistical analysis.

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.

Amortization of Intangible Asset

Amortization of intangible asset relates to the amortization of our product rights to Keveyis. This intangible asset is being amortized over an eight-year period using the straight-line method.

Other Income (Expense), Net

Other income (expense), net, consists of unrealized gain on the remeasurement of the fair value of warrant liability, interest income generated from our cash and cash equivalents, foreign exchange gains and losses and gains and losses on investments. In 2019, we recorded income and expenses relating to our service agreement with NNI to fund the costs of 23 of our field-based employees who provided full-time ongoing services to NNI, including the promotion of Macrilen in the United States.

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 2019 Annual Report.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019.

The following table sets forth our results of operations for the three months ended March 31, 2020 and 2019.

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Revenues:			
Net product sales	$ 6,663	$ 4,333	$ 2,330
Royalty revenues	11	10	1
Total revenues	6,674	4,343	2,331
Cost and operating expenses:			
Cost of sales (excluding amortization of intangible asset)	$ 969	$ 813	$ 156
Selling, general and administrative	10,403	12,100	(1,697)
Research and development	7,552	6,583	969
Amortization of intangible asset	1,256	1,256	—
Total cost and expenses	20,180	20,752	(572)
Operating loss	(13,506)	(16,409)	2,903
Other income (expense), net	808	(1,348)	2,156
Loss before income taxes	(12,698)	(17,757)	5,059
Income tax expense	—	(677)	677
Net loss	$ (12,698)	$ (18,434)	$ 5,736

Revenues

Net product sales were $6.7 million for the three months ended March 31, 2020, an increase of $2.3 million compared to the three months ended March 31, 2019. Product sales from Keveyis increased by $2.3 million, primarily due to growth in the number of patients on Keveyis and price.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses during the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Compensation and other personnel costs	$ 5,185	$ 5,863	$ (678)
Outside professional and consulting services	3,780	4,160	(380)
Stock-based compensation expense	1,270	1,811	(541)
Facility costs	168	266	(98)
Total selling, general and administrative expenses	$ 10,403	$ 12,100	$ (1,697)

Selling, general and administrative expenses were $10.4 million for the three months ended March 31, 2020, a decrease of $1.7 million compared to the three months ended March 31, 2019. Outside professional and consulting services decreased $0.4 million during the three months ended March 31, 2020. Compensation and other personnel costs and stock compensation decreased $1.2 million due to reduced headcount in 2020.

Research and Development Expenses

The following table summarizes our research and development expenses during the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Product development and supporting activities	$ 5,537	$ 4,735	$ 802
Compensation and other personnel costs	1,534	1,336	198
Stock-based compensation expense	481	512	(31)
Total research and development expenses	$ 7,552	$ 6,583	$ 969

Research and development expenses were $7.6 million for the three months ended March 31, 2020, an increase of $1.0 million compared to the three months ended March 31, 2019. The increase is due to increase product development and supporting activities for our LOGICS trial.

Amortization of Intangible Asset

Amortization of intangible asset was $1.3 million for the three months ended March 31, 2020 and 2019, respectively.

Other Income (Expense), Net

The following table summarizes our other income, net, during the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,		Change
	2020	2019	$
	(in thousands)		
Unrealized gain (loss) on fair value of warrants	$ 580	$ (1,820)	$ 2,400
Income from field services agreement	—	2,016	(2,016)
Expense from field services agreement	—	(2,229)	2,229
Other income, net	228	685	(457)
Total other income (expense), net	$ 808	$ (1,348)	$ 2,156

Total other income (expense), net, increased by $2.2 million for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. The increase is largely due to a net $2.4 million increase in unrealized gain on fair value of warrants for the three months ended March 31, 2020.

Income Tax

We recorded no income tax expense for the three months ended March 31, 2020 as a result of recording full valuation allowances against our deferred tax asset and deferred tax liability.

Cash Flows

Comparison for the Three Months Ended March 31, 2020 and 2019:

	Three Months Ended March 31	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (15,240)	$ (18,308)
Investing activities	14,830	(15)
Financing activities	(68)	139
Net decrease in cash and cash equivalents	$ (478)	$ (18,184)

Operating Activities

Net cash used in operating activities was $15.2 million for the three months ended March 31, 2020 compared to $18.3 million for the three months ended March 31, 2019. The decrease in net cash used in operating activities resulted from an increase in total revenues of $2.3 million and reduced expenditures in our commercial activities for Keveyis.

Investing Activities

The increase in net cash provided by investing activities resulted from the maturities of our marketable securities.

Financing Activities

The decrease in net cash provided by financing activities was a result of the prior year amount including proceeds from stock option exercises, which were not present in the current period.

Liquidity and Capital Resources

We are continuously and critically reviewing our liquidity and anticipated capital requirements in light of our clinical trial activities and the significant uncertainty created by the COVID-19 global pandemic. However, we currently believe that our cash, cash equivalents and marketable securities of $62.8 million at March 31, 2020 will be sufficient to allow us to fund planned operations for at least 12 months beyond the issuance date of the unaudited consolidated financial statements included in this Quarterly Report.

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.

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

- the amount of revenue that we receive from sales of Keveyis;
- 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 and our ability to prepare and file our NDA submissions on a timely basis;
- 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, including product labeling;
- adequate reimbursement from payors for Recorlev on a timely basis;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder;
- the emergence of competing technologies and their achieving commercial success before we do or other adverse market developments; and
- any extended impact of COVID-19.

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. There can be no assurances, however, that additional funding will be available on terms acceptable to us.

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

Except for the broad effects of COVID-19 including its negative impact on the global economy and major financial markets, there have been no material changes to our market risk exposures since December 31, 2019. In addition, as described in “Item 1A. Risk Factors,” there may be implications for our business with regard to the coronavirus, COVID-19.

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, under the supervision and with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2020, the end of the period covered by this Quarterly Report. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of March 31, 2020 were effective to provide reasonable assurance that the information required to be disclosed by us in reports filed or submitted 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

We have begun remote working but this has not caused a material change in our internal control over financial reporting during the fiscal quarter ended March 31, 2020 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 2019 Annual Report could materially and adversely affect our business, financial condition and results of operations. The risk factors discussed in our 2019 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. The following is an update to our risk factors.

The current outbreak of the novel coronavirus, or COVID-19, or the future outbreak of any other highly infectious or contagious diseases, could materially and adversely affect our results of operations, financial condition and cash flows. Further, the spread of the COVID-19 outbreak has caused severe disruptions in the U.S. and global economy and financial markets and could potentially create widespread business continuity issues of an as yet unknown magnitude and duration.

In December 2019, a novel strain of coronavirus (COVID-19) was reported to have surfaced in Wuhan, China. COVID-19 has since spread to over 185 countries, including every state in the United States. On March 11, 2020 the World Health Organization declared COVID-19 a pandemic, and on March 13, 2020 the United States declared a national emergency with respect to COVID-19.

The outbreak of COVID-19 has severely impacted global economic activity and caused significant volatility and negative pressure in financial markets. The global impact of the outbreak has been rapidly evolving and many countries, including the United States, have reacted by instituting quarantines, mandating business and school closures and restricting travel, among other protective measures. Many experts predict that the outbreak will trigger a period of global economic slowdown or a global recession. COVID-19 or another pandemic could have material and adverse effects on our ability to successfully operate our business due to, among other factors:

- a general decline in business activity;
- the destabilization of the markets and negative impacts on the healthcare system globally could negatively impact our ability to market and sell Keveyis, including through the disruption of health care activities in general, the inability of our sales team to contact and/or visit doctors in person, patients' interest in starting or

staying on drugs, patients' ability to obtain or maintain insurance coverage for Keveyis and our ability to support patients that presently use Keveyis;

- difficulty accessing the capital and credit markets on favorable terms, or at all, and a severe disruption and instability in the global financial markets, or deteriorations in credit and financing conditions which could affect our access to capital necessary to fund business operations;
- the potential negative impact on the health of our employees, especially if a significant number of them are impacted;
- the potential negative impact on our clinical trials, including as a result of any difficulty enrolling new patients in our clinical trials during the outbreak and ensuring that patients already enrolled complete our clinical trials, as well the disruption of normal business activities at our CROs and any other potential trial delays caused by or related to COVID-19;
- potential delays in the preparation and submission of applications for regulatory approval of our products, as well as potential delays in FDA's ability to review applications in a timely manner consistent with past practices;
- the potential negative impact on our ability to manufacture and distribute our products, including potential disruptions with third parties that manufacture and distribute products on our behalf; and
- a deterioration in our ability to ensure business continuity during a disruption.

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

10.1	Amendment to Executive Chairman Agreement by and among Strongbridge Biopharma plc, Strongbridge U.S. Inc. and John Johnson, dated as of April 8, 2020 (incorporated by reference to Exhibit 10.1 to the Form 8-K (File No. 001-37569) filed with the SEC on April 10, 2020)
31.1	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.
31.2	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.
32.1	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.
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/ Robert Lutz
Name: **Robert Lutz**
Title: Chief Financial Officer

Date: May 6, 2020

Exhibit 31.1

CERTIFICATIONS

I, John Johnson, 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. I am 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 my 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 my 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 my 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. I have disclosed, based on my 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: May 6, 2020

By: /s/ John Johnson

John Johnson
Executive Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Robert Lutz, 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. I am 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 my 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 my 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 my 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. I have disclosed, based on my 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: May 6, 2020

By: /s/ Robert Lutz

Robert Lutz
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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, John Johnson, the Executive Chairman (principal executive officer) of Strongbridge Biopharma plc (the "Company"), and Robert Lutz, 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 March 31, 2020 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/ John Johnson
John Johnson
Executive Chairman
(Principal Executive Officer)
May 6, 2020

By: /s/ Robert Lutz
Robert Lutz
Chief Financial Officer
(Principal Financial Officer)
May 6, 2020