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, 2019

OR

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

For the Transition Period from _____ to _____

Commission file number 001-37569

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 October 29, 2019, there were 54,205,852 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, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 79,608	$ 122,490
Accounts receivable	3,362	1,626
Inventory	2,399	3,946
Prepaid expenses and other current assets	2,079	4,236
Total current assets	87,448	132,298
Property and equipment, net	280	294
Right of use assets, net	867	—
Intangible asset, net	26,366	30,132
Goodwill	7,256	7,256
Other assets	743	305
Total assets	$ 122,960	$ 170,285
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,961	$ 1,184
Accrued and other current liabilities	18,648	16,065
Total current liabilities	20,609	17,249
Warrant liability	5,434	15,513
Supply agreement liability, noncurrent	16,099	24,568
Other long-term liabilities	1,177	—
Total liabilities	43,319	57,330
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Deferred shares, $1.098 par value, 40,000 shares authorized, issued and outstanding at September 30, 2019 and December 31, 2018	44	44
Ordinary shares, $0.01 par value, 600,000,000 shares authorized at September 30, 2019 and December 31, 2018; 54,205,852 and 54,122,074 shares issued and outstanding at September 30, 2019 and December 31, 2018	542	541
Additional paid-in capital	330,558	323,402
Accumulated deficit	(251,503)	(211,032)
Total stockholders' equity	79,641	112,955
Total liabilities and stockholders' equity	$ 122,960	$ 170,285

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

STRONGBRIDGE BIOPHARMA plc

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

	Three Months Ended September 30		Nine Months Ended September 30	
	2019	2018	2019	2018
Revenues:				
Net product sales	$ 5,677	$ 5,347	$ 16,083	$ 13,513
Royalty revenues	7	—	23	—
Total revenues	5,684	5,347	16,106	13,513
Cost and expenses:				
Cost of sales (excluding amortization of intangible assets)	$ 1,001	$ 1,441	$ 2,836	$ 2,861
Selling, general and administrative	12,806	19,564	37,088	47,137
Research and development	7,552	7,198	22,874	17,532
Amortization of intangible assets	1,255	1,876	3,766	5,517
Total cost and expenses	22,614	30,079	66,564	73,047
Operating loss	(16,930)	(24,732)	(50,458)	(59,534)
Other income, net:				
Income from field services agreement	1,725	—	5,466	—
Expense from field services agreement	(1,672)	—	(5,659)	—
Unrealized gain on fair value of warrants	3,202	7,131	10,079	16,448
Interest expense	—	(3,387)	—	(9,550)
Loss on extinguishment of debt	—	—	—	(500)
Other income, net	576	430	1,869	932
Total other income, net	3,831	4,174	11,755	7,330
Loss before income taxes	(13,099)	(20,558)	(38,703)	(52,204)
Income tax expense	(691)	—	(1,768)	(1)
Net loss	$ (13,790)	$ (20,558)	(40,471)	(52,205)
Net loss attributable to ordinary shareholders:				
Basic	$ (13,790)	$ (20,558)	$ (40,471)	$ (52,205)
Diluted	$ (16,992)	$ (27,690)	$ (50,550)	$ (68,653)
Net loss per share attributable to ordinary shareholders:				
Basic	$ (0.25)	$ (0.44)	$ (0.75)	$ (1.14)
Diluted	$ (0.31)	$ (0.55)	$ (0.91)	$ (1.37)
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:				
Basic	54,192,710	46,978,472	54,174,629	45,916,177
Diluted	54,540,646	50,317,423	55,844,719	49,985,483

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

STRONGBRIDGE BIOPHARMA plc

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

	Ordinary Shares		Deferred Shares		Additional Paid-In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance—June 30, 2018	46,710,048	$ 467	40,000	$ 44	$ 282,881	$ (274,530)	$ 8,862
Net loss	—	—	—	—	—	(20,558)	(20,558)
Stock-based compensation	—	—	—	—	2,116	—	2,116
Exercise of warrants	470,000	5	—	—	3,309	—	3,314
Exercise of stock options	5,000	*	—	—	20	—	20
Issuance of shares in connection with at-the-market facility, net of costs	—	—	—	—	(10)	—	(10)
Balance—September 30, 2018	47,185,048	$ 472	40,000	$ 44	$ 288,316	$ (295,088)	$ (6,256)
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
Ordinary shares issued, net of shares withheld for employee taxes	91,989	1	—	—	(442)	—	(441)
Balance—September 30, 2018	47,185,048	$ 472	40,000	$ 44	$ 288,316	$ (295,088)	$ (6,256)
Balance—June 30, 2019	54,186,268	$ 542	40,000	$ 44	$ 328,416	$ (237,713)	$ 91,289
Net loss	—	—	—	—	—	(13,790)	(13,790)
Stock-based compensation	—	—	—	—	2,175	—	2,175
Ordinary shares issued, net of shares withheld for employee taxes	19,584	*	—	—	(33)	—	(33)
Balance—September 30, 2019	54,205,852	$ 542	40,000	$ 44	$ 330,558	$ (251,503)	$ 79,641
Balance—December 31, 2018	54,122,074	$ 541	40,000	$ 44	$ 323,402	$ (211,032)	$ 112,955
Net loss	—	—	—	—	—	(40,471)	(40,471)
Stock-based compensation	—	—	—	—	7,070	—	7,070
Exercise of stock options	43,841	1	—	—	178	—	179
Ordinary shares issued, net of shares withheld for employee taxes	39,937	*	—	—	(92)	—	(92)
Balance—September 30, 2019	54,205,852	$ 542	40,000	$ 44	$ 330,558	$ (251,503)	$ 79,641

* 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,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (40,471)	$ (52,205)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	(10,079)	(16,448)
Stock-based compensation	7,070	5,789
Amortization of intangible assets	3,766	5,517
Interest and related guarantee fees paid in kind	—	2,890
Amortization of debt discounts and debt issuance costs	—	1,109
Loss on extinguishment of debt	—	500
Depreciation	56	28
Changes in operating assets and liabilities:		
Accounts receivable	(1,736)	(958)
Inventory	1,212	(5,750)
Prepaid expenses and other current assets	2,157	(1,134)
Other assets	(970)	381
Accounts payable	777	1,980
Accrued and other liabilities	(4,709)	6,437
Net cash used in operating activities	(42,927)	(51,864)
Cash flows from investing activities:		
Payment for acquisitions	—	(24,655)
Purchases of property and equipment	(42)	(310)
Net cash used in investing activities	(42)	(24,965)
Cash flows from financing activities:		
Proceeds from long-term debt, net	—	44,930
Payment for loss on extinguishment of debt	—	(500)
Proceeds from issuance of ordinary shares, net	—	33,508
Proceeds from issuance of ordinary shares in connection with at-the-market offering	—	7,951
Proceeds from exercise of warrants	—	1,175
Proceeds from exercise of stock options	179	79
Payments related to tax withholding for net-share settled equity awards	(92)	(441)
Net cash provided by financing activities	87	86,702
Net (decrease) increase in cash and cash equivalents	(42,882)	9,873
Cash and cash equivalents—beginning of period	122,490	57,510
Cash and cash equivalents—end of period	$ 79,608	$ 67,383
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	$ —	$ 5,400

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 Recorlev and veldoreotide have received orphan designation from the FDA and the European Medicines Agency ("EMA").

In January 2018, Strongbridge Ireland Ltd., 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 Ltd. to Novo Nordisk Healthcare AG ("Novo") for $145 million plus the right to receive tiered royalties on net sales of Macrilen through 2027.

Liquidity

We believe that our cash resources of $79.6 million at September 30, 2019 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 nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019.

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, 2018 filed with the U.S. Securities and Exchange Commission on February 27, 2019 (the "2018 Annual Report"). Our significant accounting policies are described in Note 2 of the notes to the audited consolidated financial statements included in our 2018 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.

Income and Expense from Field Services Agreement

In connection with our sale of Macrilen to Novo, Strongbridge U.S. Inc, one of our wholly-owned subsidiaries, entered into an agreement with Novo Nordisk Inc., a subsidiary of Novo ("NNI"), pursuant to which NNI agreed to fund 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.

Our income and expense under the field services agreement are recorded as non-operating income and expense, respectively.

As reported in a Current Report on Form 8-K filed by us with the Securities and Exchange Commission on November 5, 2019, we received a notice from Novo indicating that as of December 1, 2019, Novo intends to cease the use and funding of our field team for the promotion of Macrilen in the United States. We have objected to this notice and engaged in discussions with Novo regarding the notice and ongoing services. As of the date of this Quarterly Report, we reached an agreement in principle with Novo to terminate the services agreement, effective as of December 1, 2019.

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 September 30, 2019 and 2018, as they would be anti-dilutive:

	September 30,	
	2019	2018
Warrants	1,803,253	1,803,253
Stock options issued and outstanding	10,001,799	8,719,156
Unvested RSUs	990,700	173,400

Recent accounting pronouncements – not yet adopted

In January 2017, the FASB issued 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 do not expect any impact from this standard.

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.

Disaggregation of Revenue

The following table summarizes revenue by product for the three and nine months ended September 30, 2019 and 2018, respectively. (in thousands):

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018
Products		
Keveyis	$ 5,677	$ 4,207
Macrilen	—	1,140
Total	$ 5,677	$ 5,347

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Products		
Keveyis	$ 16,083	$ 12,373
Macrilen	—	1,140
Total	$ 16,083	$ 13,513

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.

Royalty Revenues

Royalty revenues are based on the net sales of Macrilen which is commercialized by Novo.

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 September 30, 2019			
	Level I	Level II	Level III	Total
Cash equivalents	79,554	—	—	79,554
Total assets	$ 79,554	$ —	$ —	$ 79,554
Warrant liability	—	—	5,434	5,434
Total liabilities	$ —	$ —	$ 5,434	$ 5,434

	As of December 31, 2018			
	Level I	Level II	Level III	Total
Cash equivalents	122,300	—	—	122,300
Total assets	$ 122,300	$ —	$ —	$ 122,300
Warrant liability	—	—	15,513	15,513
Total liabilities	$ —	$ —	$ 15,513	$ 15,513

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

	As of September 30, 2019
Balance as of December 31, 2018	$ 15,513
Unrealized gain on fair value of warrants for the nine months ended September 30, 2019	(10,079)
Balance as of September 30, 2019	$ 5,434

5. Intangible assets and goodwill

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

	As of September 30, 2019		
	Beginning of Period	Amortization	End of Period
Keveyis	$ 30,132	$ (3,766)	$ 26,366
Goodwill	7,256	—	7,256
Total	$ 37,388	$ (3,766)	$ 33,622

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 December 2016. 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 and $3.8 million for the three and nine months ended September 30, 2019, respectively, compared to $1.9 million and $5.5 million for the three and nine months ended September 30, 2018, respectively.

6. Accrued and other current liabilities

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

	September 30, 2019	December 31, 2018
Supply agreement - current portion	$ 4,730	$ 1,638
Employee compensation	4,632	5,717
Consulting and professional fees	3,973	4,145
Accrued taxes	2,202	535
Accrued sales allowances	1,785	2,233
Accrued royalties	577	802
Lease liability - current portion	364	—
Other	385	995
Total accrued liabilities	$ 18,648	$ 16,065

7. 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 September 30, 2019, our remaining obligation was $22.1 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.

8. Leases

We lease office space under operating leases. Our leases have initial lease terms ranging from one to five years. Our lease agreements contain provisions for future rent increases.

As of September 30, 2019, future minimum commitments under facility operating leases were as follows (in thousands):

	Operating leases
2019	116
2020	470
2021	481
2022	492
2023	207
Total minimum lease payments	$ 1,766

The components of lease cost for the quarter ended September 30, 2019 are as follows (in thousands):

	Nine Months Ended September 30, 2019
Lease costs	
Amortization of right of use assets	$ 289
Interest on lease liabilities	94
Total lease cost	$ 383

Amounts reported in the Consolidated Balance Sheet for leases where we are the lessee as of September 30, 2019 were as follows (in thousands):

	September 30, 2019
Operating Leases	
Right of use asset	$ 867
Lease liability	$ 1,541
Remaining lease term	
Operating leases	3 years 8 months
Discount rate	
Operating leases	7.69%

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 recorded income tax expense of $1.8 million for the nine months ended September 30, 2019 and $0.7 million for the three months ended September 30, 2019, as a result of tax liability expected in connection with the intercompany transfer of intellectual property, which occurred in the prior year.

10. Warrants

Warrants

Our outstanding warrants as of September 30, 2019 are as follows:

	Classification	Exercise Price	Expiration Date	Warrants Issued	Warrants Exercised	Warrants Outstanding September 30, 2019
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 September 30, 2019, 643,590 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, 2019, 303,250 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, 2019, no shares are available for issuance pursuant to the Non-Employee Director Plan.

A summary of our outstanding stock options as of September 30, 2019 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, 2019	8,579,511	$ 7.35	7.57	$ 3,281
Granted	2,432,900	$ 4.18		
Forfeited and cancelled	(966,771)	$ 6.72		
Exercised	(43,841)	$ 4.12		
Outstanding—September 30, 2019	10,001,799	$ 6.65	7.29	$ 6
Vested and exercisable—September 30, 2019	5,234,160	$ 7.95	6.11	$ 3

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,	
	2019	2018	2019	2018
Selling, general and administrative	$ 1,684	$ 1,649	$ 5,475	$ 4,450
Research and development	491	467	1,595	1,339
Total stock-based compensation	$ 2,175	$ 2,116	$ 7,070	$ 5,789

As of September 30, 2019, the total unrecognized compensation expense related to unvested stock options is $14.6 million, which we expect to recognize over an estimated weighted-average period of 2.70 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,	
	2019	2018
Expected term (in years)	6.13	6.13
Risk-free interest rate	1.38%-2.61%	2.25% - 2.99%
Expected volatility	78.7%-80.85%	78.19% - 85%
Dividend rate	—%	—%

Restricted stock units

We grant RSU 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 and $0.1 million for the three months ended September 30, 2019 and 2018, respectively, and $1.3 million and $0.4 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, the total unrecognized compensation expense related to unvested RSUs is $2.7 million, which we expect to recognize over an estimated weighted-average period of 1.25 years.

A summary of our unvested RSUs as of September 30, 2019 is as follows:

	Number of Shares
Outstanding—January 1, 2019	143,100
Granted	1,001,000
Forfeited	(84,150)
Vested	(69,250)
Unvested—September 30, 2019	990,700

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, 2019 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, 2018 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, 2018 (the "2018 Annual Report") filed with the Securities and Exchange Commission ("SEC") on February 27, 2019. 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,” “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 2018 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 (“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 Recorlev and veldoreotide have received orphan designation from the FDA and the European Medicines Agency (“EMA”).

In January 2018, Strongbridge Ireland Ltd., 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 Ltd. to Novo Nordisk Healthcare AG (“Novo”) for $145 million plus the right to receive tiered royalties on net sales of Macrilen through 2027.

We are building a rare disease, franchise-based business model focused on expansion through a disciplined in-licensing and acquisition strategy. 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 U. S. Senators Amy Klobuchar, Susan Collins and Tammy Baldwin, and Senator Claire McCaskill, Ranking Member of the Homeland Security and Governmental Affairs Committee, that requested information relating to the marketing and sales of Keveyis principally relating to the pricing

of Keveyis. We have cooperated with these voluntary requests for information, as well as additional follow-up requests in 2018.

Recent Developments

Changes in Management

As previously reported in a Current Report on Form 8-K filed with the Securities and Exchange Commission on November 1, 2019, our board of directors and Matthew Pauls, our former Chief Executive Officer ("CEO"), mutually agreed upon a CEO transition plan resulting in Mr. Paul's resignation from his positions as CEO and member of the board of directors, effective immediately. His resignation was not the result of any dispute or disagreement with us or any matter related to our operations, policies or practices. In connection with his resignation, Mr. Pauls will be paid termination benefits as set forth in his employment agreement.

In addition, on November 1, 2019, the board of directors appointed John H. Johnson, who has served as Chairman of our board of directors since 2015, as Executive Chairman of the Company, effective immediately. Mr. Johnson will lead the Company while the Board conducts a formal search to identify a new CEO. In connection with Mr. Johnson's new role, any changes to his existing compensatory arrangement will be determined at a later date.

LOGICS Trial

In March 2019, we conducted a Type C meeting with the Division of Metabolic and Endocrine Products (DMEP) of the FDA. The DMEP stated in its meeting minutes that the FDA generally requests that a sponsor conduct two adequate and well-controlled clinical studies for the proposed indication of a drug candidate under 21 CFR 314.126(b)(2). The DMEP also noted that the FDA recognizes situations when a single trial may be sufficient. The DMEP reiterated that the characteristics of an "adequate and well-controlled" investigation under 21 CFR 314.126 include the use of a control group (*e.g.*, placebo concurrent control, dose-comparison concurrent control), randomization and evaluation of primary endpoints that directly measure clinical benefits, or supported by evidence of clinical benefit. For this reason, while the DMEP indicated that it would consider, as a review issue, the adequacy of a New Drug Application (NDA) submission with data from our SONICS trial as the sole Phase 3 evidence supporting the efficacy of RECORLEV, the DMEP nonetheless recommended that we complete a second trial and include the results from that trial in addition to data from our SONICS trial in our NDA submission.

Our LOGICS trial is a Phase 3 clinical trial of Recorlev for the treatment of endogenous Cushing's syndrome. The LOGICS trial is intended to supplement the long-term efficacy and safety data from our SONICS trial via a double-blind, placebo-controlled, randomized-withdrawal design that targets approximately 46-54 patients for enrollment into the randomized withdrawal phase of the trial. The final number of patients enrolled into the randomized withdrawal phase will depend on the observed rate of early discontinuation in such phase. We currently expect to receive LOGICS top-line data in the second or third quarter of 2020 (an update to our prior projection of data release at the end of the first quarter of 2020). The addition of a concurrent control group to our LOGICS trial is an attempt to address the FDA's request for such a control group that was absent in our SONICS trial.

We currently expect, if supported by the data, to submit an NDA for Recorlev approximately six months after reporting top-line results from our LOGICS trial that will include data from each of the SONICS and LOGICS trials. The DMEP stated in its meeting minutes that our clinical pharmacology program for Recorlev, as described to them, appears reasonable to support an NDA filing for Recorlev provided that the data generated are found to be suitable.

Services Agreement with Novo Nordisk Inc.

In connection with our sale of Macrilen to Novo, Strongbridge U.S. Inc, one of our wholly-owned subsidiaries, entered into an agreement with Novo Nordisk Inc., a subsidiary of Novo ("NNI"), pursuant to which NNI agreed to fund the costs of 23 of our field-based employees to provide full-time ongoing services to NNI, including the promotion of Macrilen and other Novo growth hormone products in the United States, for a period of three years.

As reported in a Current Report on Form 8-K filed by us with the Securities and Exchange Commission on November 5, 2019, we received a notice from Novo indicating that as of December 1, 2019, Novo intends to cease the use and funding of our field team for the promotion of Macrilen in the United States. We objected to this notice and engaged in discussions with Novo regarding the notice and ongoing services. As of the date of this Quarterly Report, we reached an agreement in principle with Novo to terminate the services agreement, effective as of December 1, 2019. In connection with the termination of the agreement, Novo will pay us $6 million and we will no longer provide services to Novo. We expect to eliminate the approximately 23 field-based positions related to the Macrilen promotion efforts, effective December 1, 2019.

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

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.

Royalty Revenues

Royalty revenues are based on the net sales of Macrilen which is commercialized by Novo.

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.

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, 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; and
- costs of acquiring preclinical study and clinical trial materials, and costs associated with formulation and process development.

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 stages of 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.

Our research and development expenses could increase in absolute dollars in the future if 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 to market our product candidates. The process of conducting the necessary clinical research to obtain regulatory marketing approval of a product candidate is costly and time consuming. The probability that any of our product candidates receives regulatory marketing 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.

Amortization of Intangible Assets

Amortization of intangible assets 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, Net

Other income, 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. We record income and expenses relating to NNI service agreement to fund 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 beginning December 2018.

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 2018 Annual Report.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2019 and 2018.

The following table sets forth our results of operations for the three and nine months ended September 30, 2019 and 2018.

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2019	2018	$	2019	2018	$
	(in thousands)			(in thousands)		
Revenues:						
Net product sales	$ 5,677	$ 5,347	$ 330	$ 16,083	$ 13,513	$ 2,570
Royalty revenues	7	—	7	23	—	23
Total revenues	5,684	5,347	337	16,106	13,513	2,593
Cost and operating expenses:						
Cost of sales (excluding amortization of intangible assets)	$ 1,001	$ 1,441	$ (440)	$ 2,836	$ 2,861	$ (25)
Selling, general and administrative	12,806	19,564	(6,758)	37,088	47,137	(10,049)
Research and development	7,552	7,198	354	22,874	17,532	5,342
Amortization of intangible assets	1,255	1,876	(621)	3,766	5,517	(1,751)
Total cost and expenses	22,614	30,079	(7,465)	66,564	73,047	(6,483)
Operating loss	(16,930)	(24,732)	7,802	(50,458)	(59,534)	9,076
Other income, net	3,831	4,174	(343)	11,755	7,330	4,425
Loss before income taxes	(13,099)	(20,558)	7,459	(38,703)	(52,204)	13,501
Income tax expense	(691)	—	(691)	(1,768)	(1)	(1,767)
Net loss	$ (13,790)	$ (20,558)	$ 6,768	$(40,471)	$(52,205)	$ 11,734

Revenues

Net product sales were $5.7 million for the three months ended September 30, 2019, an increase of $0.3 million compared to the three months ended September 30, 2018. Product sales from Keveyis increased by $1.5 million due to the continued sales growth of Keveyis. Included in the three months ended September 30, 2018 is $1.1 million from Macrilen sales, the rights to which we sold in December 2018.

Net product sales were $16.1 million for the nine months ended September 30, 2019, an increase of $2.6 million compared to the nine months ended September 30, 2018. Product sales from Keveyis increased by $3.7 million due to the continued sales growth of Keveyis. Included in the nine months ended September 30, 2018 is $1.1 million from Macrilen sales, the rights to which we sold in December 2018.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses during the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2019	2018	$	2019	2018	$
	(in thousands)			(in thousands)		
Compensation and other personnel costs	$ 6,469	$ 8,458	$(1,989)	$18,465	$20,473	$ (2,008)
Outside professional and consulting services	4,462	9,142	(4,680)	12,463	21,423	(8,960)
Stock-based compensation expense	1,684	1,649	35	5,475	4,450	1,025
Facility costs	191	315	(124)	685	791	(106)
Total selling, general and administrative expenses	$12,806	$19,564	$(6,758)	$37,088	$47,137	$(10,049)

Selling, general and administrative expenses were $12.8 million for the three months ended September 30, 2019, a decrease of $6.8 million compared to the three months ended September 30, 2018. Outside professional and consulting services decreased $4.7 million during the three months ended September 30, 2019, with $1.5 million of this decrease due to a reduction in expenses relating to Keveyis and $3.2 million of this decreases due to the prior year period including expenses associated with the launch of Macrilen, the rights to which we sold in December 2018. Compensation and other personnel costs decreased $2.0 million due to employee costs associated with Macrilen being reimbursed by Novo in 2019.

Selling, general and administrative expenses were $37.1 million for the nine months ended September 30, 2019, a decrease of $10.0 million compared to the nine months ended September 30, 2018. Outside professional and consulting services decreased $9.0 million during the nine months ended September 30, 2019, with $1.7 million of this decrease due to a reduction in expenses relating to Keveyis and $7.3 million of this decrease due to the prior year period including expenses associated with the launch of Macrilen, the rights to which we sold in December 2018. Compensation and other personnel costs decreased $2.0 million due to employee costs associated with Macrilen being reimbursed by Novo in 2019.

Research and Development Expenses

The following table summarizes our research and development expenses during the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2019	2018	$	2019	2018	$
	(in thousands)			(in thousands)		
Product development and supporting activities	$5,412	$5,390	$ 22	$16,799	$12,441	$ 4,358
Compensation and other personnel costs	1,649	1,341	308	4,480	3,752	728
Stock-based compensation expense	491	467	24	1,595	1,339	256
Total research and development expenses	$7,552	$7,198	$ 354	$22,874	$17,532	$ 5,342

Research and development expenses were $7.6 million for the three months ended September 30, 2019, an increase of $0.4 million compared to the three months ended September 30, 2018. The small increase is due to increased employee costs.

Research and development expenses were $22.9 million for the nine months ended September 30, 2019, an increase of $5.3 million compared to the nine months ended September 30, 2018. The $4.4 million increase in expenses for product development and supporting activities was primarily due to additional clinical development expenses associated with Recorlev.

Amortization of Intangible Assets

Amortization of intangible assets was $1.3 million and $3.8 million for the three and nine months ended September 30, 2019, respectively, a decrease of $0.6 million and $1.7 million, respectively, due to the prior year including amortization of the intangible asset related to Macrilen, the rights to which we sold in December 2018.

Other Income, Net

The following table summarizes our other income, net, during the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2019	2018	$	2019	2018	$
	(in thousands)			(in thousands)		
Income from field services agreement	$ 1,725	$ —	$ 1,725	$ 5,466	$ —	$ 5,466
Expense from field services agreement	(1,672)	—	(1,672)	(5,659)	—	(5,659)
Unrealized gain on fair value of warrants	3,202	7,131	(3,929)	10,079	16,448	(6,369)
Interest expense	—	(3,387)	3,387	—	(9,550)	9,550
Loss on extinguishment of debt	—	—	—	—	(500)	500
Other income, net	576	430	146	1,869	932	937
Total other income, net	$ 3,831	$ 4,174	$ (343)	$ 11,755	$ 7,330	$ 4,425

Total other income, net, decreased by $0.3 million for the three months ended September 30, 2019 as compared to the three months ended September 30, 2018. The decrease was primarily due to a $3.9 million change in the unrealized gain on the fair value of our warrant liability in 2019, primarily resulting from a decrease in our stock price. The decrease was offset in part by $3.4 million of interest expense recorded during the three months ended September 2018. Our outstanding debt under the Term Loan Agreement, dated July 14, 2017, with CRG Servicing LLC (the "Term Loan Agreement"), was fully repaid in the fourth quarter of 2018 and, therefore, we recorded no interest expense related to this debt during the three months ended September 30, 2019. In addition, during the 2019 period, we incurred $1.7 million of expense relating to our field-based service agreement with NNI and recorded $1.7 million of related income.

Total other income, net, increased by $4.4 million for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018. The increase was primarily due to $9.5 million of interest expense recorded during the nine months ended September 2018. Our outstanding debt under the Term Loan Agreement was fully repaid in the fourth quarter of 2018 and, therefore, we recorded no interest expense related to this debt during the nine months ended September 30, 2019. The increase was partially offset by a $6.4 million change in the unrealized gain on the fair value of our warrant liability in 2019, primarily resulting from a decrease in our stock price. In addition, during the 2019 period, we incurred $5.7 million of expense relating to our field based service agreement with NNI and recorded $5.5 million of related income.

Income Tax

We recorded income tax expense of $0.7 million for the three months ended September 30, 2019 and $1.8 million for the nine months ended September 30, 2019, as a result of tax liability expected in connection with the intercompany transfer of intellectual property, which occurred in the prior year.

Cash Flows

Comparison for the Nine Months Ended September 30, 2019 and 2018:

	Nine Months Ended September 30	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (42,927)	$ (51,864)
Investing activities	(42)	(24,965)
Financing activities	87	86,702
Net (decrease) increase in cash and cash equivalents	$ (42,882)	$ 9,873

Operating Activities

Net cash used in operating activities was $42.9 million for the nine months ended September 30, 2019 compared to $51.9 million for the nine months ended September 30, 2018. The decrease in net cash used in operating activities resulted from an increase in total revenues of $2.6 million, a decrease in inventory purchases of $2.1 million and reduced expenditures in our commercial activities for Keveyis and Macrilen, which we sold in December 2018. The prior period had expenditures for the launch of Macrilen, the rights to which we sold in December 2018.

Investing Activities

The decrease in net cash used in investing activities resulted from the $24.7 million payment made to Aeterna Zentaris GmbH in 2018 for our acquisition of Macrilen and other expenses incurred with the acquisition.

Financing Activities

The decrease in net cash provided by financing activities resulted primarily from debt and equity financing activities that occurred during the nine months ended September 2018, as compared to no significant financing activities during the nine months ended September 2019.

Liquidity and Capital Resources

We believe that our cash resources of $79.6 million at September 30, 2019 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;
- 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.

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

There have been no material changes to our market risk exposures since December 31, 2018.

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 September 30, 2019, 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 September 30, 2019 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

There were no changes in our internal control over financial reporting that occurred during the fiscal quarter ended September 30, 2019 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 2018 Annual Report could materially and adversely affect our business, financial condition and results of operations. The risk factors discussed in our 2018 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 regulatory approval process of the FDA, EMA or any comparable foreign regulatory agency may be lengthy, time consuming and unpredictable.

We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. The FDA, EMA and other comparable foreign regulatory agencies have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA or any comparable foreign regulatory agency. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the product candidates.

Furthermore, while certain of our employees have prior experience with submitting marketing applications to the FDA, EMA and comparable foreign regulatory agencies, we, as a company, have not submitted such applications for our product candidates. Applications for any of our product candidates could fail to receive regulatory approval for many reasons, including, but not limited to, the following:

- the FDA, EMA or any comparable foreign regulatory agency may disagree with the design or implementation of our clinical trials or our interpretation of data from nonclinical trials or clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval, including reliance on foreign clinical data;
- the data collected from clinical trials of our product candidates may not be sufficient to support a finding that has statistical significance or clinical meaningfulness or support the submission of an NDA or other submission, or to obtain regulatory approval in the United States or elsewhere;

- we may be unable to demonstrate to the FDA, EMA or any comparable foreign regulatory agency that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or any comparable foreign regulatory agency may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or any comparable foreign regulatory agency may significantly change in a manner rendering our clinical data insufficient for approval.

In communications we had with the FDA, they recommended use of a concurrent control group in our SONICS Phase 3 clinical trial. However, SONICS utilizes an open-label, single-arm design because use of a placebo control in a parallel-arm monotherapy design was considered unethical or infeasible to enroll, depending on the specific country or clinical trial site under consideration. Studies lacking an active control group are more likely to be subject to unanticipated variability in study results that can potentially lead to flawed conclusions because they do not allow for discrimination of patient outcomes. In August 2018, we announced statistically significant positive top-line results from our SONICS Phase 3 clinical trial. However, even if we achieve the clinical trial's endpoints for this clinical trial, the FDA or other regulatory authorities could view our study results as potentially biased due to our lack of an active control group.

In March 2019, we conducted a Type C meeting with the Division of Metabolic and Endocrine Products (DMEP) of the FDA. The DMEP stated in its meeting minutes that the FDA generally requests that a sponsor conduct two adequate and well-controlled clinical studies for the proposed indication of a drug candidate under 21 CFR 314.126(b)(2). The DMEP also noted that the FDA recognizes situations when a single trial may be sufficient. The DMEP reiterated that the characteristics of an "adequate and well-controlled" investigation under 21 CFR 314.126 include the use of a control group (*e.g.*, placebo concurrent control, dose-comparison concurrent control), randomization and evaluation of primary endpoints that directly measure clinical benefits, or supported by evidence of clinical benefit. For this reason, while the DMEP indicated that it would consider, as a review issue, the adequacy of a New Drug Application (NDA) submission with data from our SONICS trial as the sole Phase 3 evidence supporting the efficacy of RECORLEV, the DMEP nonetheless recommended that we complete a second trial and include the results from that trial in addition to data from the SONICS trial in our NDA submission.

Our LOGICS study is a second Phase 3 clinical trial of Recorlev for the treatment of endogenous Cushing's syndrome. The LOGICS trial is intended to supplement the long-term efficacy and safety data from our SONICS trial via a double-blind, placebo-controlled, randomized-withdrawal design that target approximately 46-54 patients for enrollment into the randomized withdrawal phase of the trial. The final number of patients enrolled into the randomized withdrawal phase will depend on the observed rate of early discontinuation in such phase. We currently expect to receive LOGICS top-line data in the second or third quarter of 2020 (an update to our prior projection of data release at the end of the first quarter of 2020). The addition of a concurrent control group in LOGICS is an attempt to address FDA's request for such a control group that was lacking in SONICS.

We currently expect, if supported by the data, to submit an NDA for Recorlev approximately six months after reporting top-line results from the LOGICS trial that will include data from each of the SONICS and LOGICS trials. The DMEP stated in its meeting minutes that our clinical pharmacology program for Recorlev, as described to them, appears reasonable to support an NDA filing for Recorlev provided that the data generated are found to be suitable.

In addition, following FDA consultation, we have determined that the 505(b)(2) approval pathway, which permits an NDA applicant to rely on data from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, is the appropriate pathway for a Recorlev NDA. We intend to rely on published literature and the FDA's prior findings concerning the safety and/or effectiveness of ketoconazole in our NDA for Recorlev and on similar processes in other jurisdictions. There can be no assurances, however, that the 505(b)(2) approval pathway in the United States, or similar approval pathways outside of the United States, will be available for Recorlev or that the FDA or other regulatory authorities will approve Recorlev through an application based on such pathways.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and other key global markets. To obtain regulatory approval in other countries, we must comply with regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. Failure to obtain marketing authorization for our product candidates in any jurisdiction will result in our being unable to market and sell such products. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Any of our current or future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

Our success depends on key personnel and our ability to recruit, retain and motivate additional qualified personnel.

We are highly dependent on the leadership and strategic guidance of our executive officers. The loss, for any reason, of the services of these individuals and any negative market or industry perception arising from such loss could have a material adverse effect on our business. Although we have included non-compete provisions in their respective employment or consulting agreements, as the case may be, such arrangements might not be sufficient for the purpose of preventing such key personnel from entering into agreements with any of our competitors. The inability to recruit and retain qualified personnel, or the loss of these key employees, could result in competitive harm as we could experience delays in reaching our in-licensing, acquisition, development and commercialization objectives.

On November 1, 2019, our board of directors and Matthew Pauls, our former CEO, mutually agreed upon a CEO transition plan resulting in Mr. Paul's resignation from his positions as CEO and member of the board of directors, effective immediately. In connection with this transition, the board of directors appointed John H. Johnson, who has served as Chairman of our board of directors since 2015, as Executive Chairman of the Company, effective immediately. Mr. Johnson will lead the Company while the Board conducts a formal search to identify a new CEO. These changes, or any future changes in our management team, may create uncertainty in our business and future strategic direction. In addition, if we are unable to attract and retain a qualified candidate to become our permanent CEO in a timely manner, our ability to meet our financial and operational goals and strategic plans may be adversely impacted, as well as our financial performance.

We also depend substantially on highly qualified managerial, sales and technical personnel who are difficult to hire and retain. There is currently a shortage of skilled personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will be critical to our success.

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	Consulting Agreement by and between Strongbridge U.S. Inc. and A. Brian Davis, dated as of September 3, 2019.
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.
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: November 7, 2019

CONSULTING AGREEMENT

This agreement (the "Agreement") is entered into as of September 3, 2019 (the "Effective Date") by and between Strongbridge U.S. Inc., having an address at 900 Northbrook Drive, Suite 200, Trevose, PA 19053 ("Company") and A. Brian Davis, having an address at 504 School House Lane, Willow Grove, PA 19090 ("Consultant").

Consultant and Company agree as follows:

1. **Services**. Company hereby engages Consultant and Consultant hereby accepts Company's engagement to provide the consulting services described in Exhibit A attached hereto and made a part hereof (the "Services"). Consultant shall perform the Services in a diligent, workmanlike and professional manner in accordance with industry standards.

2. **Compensation**. As full and complete compensation for the performance of the Services and in consideration of the other obligations, representations and warranties made by Consultant hereunder, Company agrees to pay Consultant in accordance with Exhibit A attached hereto and made a part hereof.

3. **Options**. Exhibit B sets forth a list of all vested stock options held by Consultant as of the Effective Date. Notwithstanding the terms of Section 3(b)(i) of the Option Agreements or similar provisions of any other agreements or documents that govern stock option awards granted by Strongbridge Biopharma plc to Consultant (collectively, the "Option Agreements"), any vested stock options held by the Consultant as of the Effective Date shall continue to be exercisable during the Initial Term. In all other respects, the provisions of the Option Agreements shall continue in full force and effect.

4. **Term**. Unless terminated earlier in accordance with Section 12, this Agreement shall be effective from the Effective Date until the close of business on September 2, 2020 (the "Initial Term"). This Agreement may be extended upon the mutual agreement of the parties.

5. **Records**. Consultant shall keep accurate and complete records relating to the Services. All such records, whether paper or electronic, shall be the sole property of Company and subject to Company's control and review at any time. Promptly upon the termination or expiration of this Agreement, all such records, whether they were prepared by Consultant solely or jointly with others, all Confidential Information (as defined below), any other property of Company and any materials provided to Consultant by Company, shall be turned over by Consultant to Company.

6. **Representations**. Consultant represents, warrants and covenants that (i) Consultant is free to enter into this Agreement and (ii) Consultant will comply with all applicable laws, rules and regulations in performing Consultant's obligations hereunder.

7. **Debarment**. Consultant certifies that Consultant and Consultant's directors, officers, agents, subcontractors and employees: (i) have not been and are not currently excluded pursuant to 42 U.S.C. §1320a-7 or similar state exclusion authority, debarred, or otherwise ineligible to participate in any Federal health care program as that term is defined in 42 U.S.C. §1320a-7b(f) or comparable state programs; (ii) have not been convicted of a criminal offense related to the provision of health care items or services or any other offense that may lead to exclusion under 42 U.S.C. §1320a-7 or similar state exclusion authority; or (iii) to Consultant's knowledge are not under investigation or otherwise aware of any circumstances which may result in being excluded from participation in any Federal or state health care program. Consultant maintains an ongoing obligation to ensure the accuracy of this certification. If any change in circumstance occurs to make this certification inaccurate, Consultant must notify Company in writing immediately and Company shall have the right to immediately terminate this Agreement if the above certification is or becomes untrue.

8. **Confidential Information**. Consultant acknowledges that information or materials will be made available to Consultant or developed by Consultant in connection with the performance of the Services, including

without limitation e-mail files and other documents created by, reviewed by, or made available to Consultant during his employment with the Company ("Confidential Information"). During the term of this Agreement and thereafter, Consultant shall not: (i) disclose to any third party any of the Confidential Information; (ii) permit any third party to have access to the Confidential Information; or (iii) use the Confidential Information for any purpose other than in connection with Consultant's performance of the Services. Notwithstanding the foregoing (1) the term "Confidential Information" shall not include any information or material that: (a) is or becomes available in the public domain through no fault of, or act or failure to act on the part of Consultant; (b) is rightfully in Consultant's possession at the time of disclosure as evidenced by Consultant's written records maintained in the ordinary course of business; or (c) is obtained by Consultant from any third party that is lawfully in possession of such Confidential Information and not in violation of any contractual or legal obligation with respect to such Confidential Information and (2) Consultant shall have the right to disclose Confidential Information to a subcontractor provided that (a) Company has provided its written consent with respect to such subcontractor pursuant to Section 14 and (b) Consultant shall disclose only such Confidential Information as is necessary for subcontractor to perform its services.

Consultant acknowledges that remedies at law would be inadequate to protect Company against any actual or threatened breach of this Section 8 by Consultant, and, without prejudice to any other rights and remedies otherwise available to Company, Consultant agrees to the granting of injunctive relief in Company's favor without proof of actual damages.

If Consultant is (i) requested in any judicial or administrative proceeding or by any governmental or regulatory authority to disclose any Confidential Information, Consultant shall give Company prompt notice of such a request so that Company may seek an appropriate protective order or waive compliance or (ii) compelled by a judicial or administrative proceeding or by any governmental or regulatory authority to disclose the Confidential Information, it will give Company prompt notice of such event and will furnish only that portion that is legally required and will exercise all reasonable efforts to obtain reliable assurance that confidential treatment will be afforded to the Confidential Information.

9. **Ownership**. Company will own all right, title and interest in and to all Inventions conceived or reduced to practice by Consultant alone or jointly in connection with Consultant's performance of Services. For the purpose of this Agreement, "Inventions" shall mean any inventions, discoveries, patent applications, patents, certificates of invention, trademarks, copyrightable subject matter, writings, improvements, ideas, designs, drawings, computer models, data, concepts, know how, trade secrets, test results, packaging, logos, names, tradenames, tradedress and all materials incorporating the foregoing or business methods relating to the subject matter of this Agreement or otherwise to the affairs of Company.

Consultant warrants that (i) all Inventions conceived or reduced to practice in connection with the performance of the Services are or will be original creations; and (ii) Consultant shall not misappropriate the intellectual property rights of a third party in connection with the performance of the Services.

Consultant will assist Company, during the term of this Agreement and thereafter, in the procurement, maintenance, protection, assignment, and enforcement of Company's rights with respect to Inventions. In addition, Consultant will, upon Company's request, promptly deliver to Company (without further consideration but at Company's expense) executed assignments or other instruments and do such other acts as may be deemed necessary or desirable by Company to protect Company's worldwide rights with respect to any Inventions. It is understood that Consultant will take such action whenever Company shall make such request whether during the term of this Agreement or thereafter.

10. **Independent Contractor**. Consultant's status shall be that of an independent contractor without the capacity to bind Company. Neither Consultant nor any employee, agent or subcontractor of Consultant shall be considered an agent or employee of Company. Consultant shall be responsible for ensuring payment of all unemployment, social security, payroll, contributions and other taxes with respect to such employees, agents or subcontractors. Consultant shall be responsible to Company for all Services performed by Consultant's employees, agents and subcontractors.

11. **[Deleted]**

12. **Termination**. Consultant shall have the right to terminate this Agreement for any reason upon ten (10) days' written notice to Company, in which case the fees payable hereunder shall be pro-rated through the date of termination. If Consultant is in material breach of any of the terms of this Agreement, Company shall have the right to terminate this Agreement upon 30 days' written notice to Consultant specifying such breach; provided, however, if Consultant cures the default within a five (5) day period, this Agreement shall continue in full force and effect. Otherwise, except as provided in Section 7, Company may not terminate this Agreement prior to September 2, 2020.

13. **Survival**. Sections 5, 7, 8, 9, 10 and 12 of this Agreement shall survive the termination or expiration of this Agreement.

14. **Assignment and Subcontracting**. This Agreement may not be assigned by Consultant, including by the operation of law or otherwise. Subject to the foregoing, this Agreement is binding upon and shall inure to the benefit of Consultant and Company and its successors in interest. Consultant shall not subcontract the performance of the Services or any portion thereof to a third party without the prior written consent of Company.

15. **Waiver**. A waiver by either party of any term or condition of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All rights, remedies, undertakings or obligations contained in this Agreement shall be cumulative and none of them shall be in limitation of any other right, remedy undertaking or obligation of either party.

16. **Notices**. Any notice required or permitted by the Agreement shall be in writing and shall be (i) delivered personally, effective on the date of delivery, (ii) sent via overnight delivery by a nationally recognized overnight courier to be effective the day following deposit, or (iii) sent by certified or registered mail, postage prepaid, return receipt requested, to be effective three (3) days after deposit. Notices shall be addressed to the party concerned at the address set forth in the preamble of this Agreement or at such other address as such party may subsequently designate by like notice from time to time.

Any notice given to Company shall also be given to Strongbridge Biopharma plc, 900 Northbrook Drive, Suite 200, Trevose, PA 19053, Attn: Chief Legal Officer.

17. **Entire Agreement; Inconsistencies**. This Agreement and the Exhibits attached hereto constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all prior agreements between Company and Consultant with respect to the matters addressed herein and can only be modified by a written amendment signed by Consultant and Company. Notwithstanding the foregoing, the obligations of Consultant under any existing nondisclosure or confidentiality agreements with Company, the obligations of Company and Strongbridge Biopharma plc under Consultant's employment agreement and equity award agreements, and the obligations of the parties under the letter agreement between them dated August 29, 2019 shall continue.

18. **No Third Party Beneficiaries**. Nothing herein, express or implied, is intended to or shall confer upon any other person or entity any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

19. **Governing Law**. This Agreement shall be governed by and construed in accordance with the law of the Commonwealth of Pennsylvania.

20. **Severance**. If a court of competent jurisdiction determines that any portion of this Agreement is unenforceable, then (i) that portion shall be deemed to be amended to reflect the original intent of the parties to the extent permitted by law and, (ii) it shall not affect the enforceability of the remainder of this Agreement.

21. **Construction**. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against any party.

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

IN WITNESS WHEREOF, Company and Consultant have caused their duly authorized representatives to execute this Agreement as of the Effective Date.

STRONGBRIDGE U.S. INC.

A. Brian Davis

By: _____

Print Name: _____

Print Title: _____

For purposes of Section 3 of this Agreement only:

STRONGBRIDGE BIOPHARMA PLC

By: _____

Print Name: _____

Print Title: _____

EXHIBIT A

PART 1: DESCRIPTION OF THE SERVICES

Consultant will provide advisory services to the Company, as reasonably requested by the Company from time to time and at times mutually agreed, relating to the Company's business, financial reporting or statements, or other business matters. These Services may be provided remotely from Consultant's home or other location of his choice. The Company agrees to exercise its reasonable best efforts to schedule and limit the need for the Services to avoid disruption of Consultant's personal or other professional obligations. Given the limited scope of the Services, the parties agree that Consultant's resignation from employment on the Effective Date will constitute a "separation from service" within the meaning of Treas. Reg. § 1.409A-1(h).

PART 2: COMPENSATION/PAYMENT SCHEDULE

Consultant shall be paid Five Thousand Dollars ($5,000.00) per month (or such pro rata portion in the event of termination in accordance with Section 12) during the Initial Term.

EXHIBIT B

VESTED STOCK OPTIONS

Grant Type	Grant Date	Shares	Strike Price	Expiration
Stock Option	5/26/2015	36,362	$15.71	5/26/2025
Stock Option	7/21/2015	133,363	$18.80	7/21/2020
Stock Option	2/26/2016	56,875	$3.94	2/26/2026
Stock Option	2/23/2017	112,500	$2.90	2/23/2027
Stock Option	2/5/2018	43,125	$6.65	2/5/2028
Stock Option	2/20/2019	13,563	$4.67	2/20/2029

Exhibit 31.1

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 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: November 7, 2019

By: /s/ Robert Lutz

Robert Lutz
Chief Financial Officer
(Principal Executive Officer and 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, Robert Lutz, the Chief Financial Officer (principal executive officer and principal financial officer) of Strongbridge Biopharma plc (the "Company"), 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, 2019 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/ Robert Lutz

Robert Lutz
Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)
November 7, 2019