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

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number: 001-39101

Baudax Bio, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	**47-4639500**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
490 Lapp Road, Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	**(Zip Code)**

(484) 395-2440
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.01	**BXRX**	**Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act:
None

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section13(a) of the Exchange Act. ☒

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

As of November 12, 2019, there were 100 shares of common stock, par value $0.01 per share, outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BAUDAX BIO, INC.
Combined Balance Sheets
(Unaudited)

(amounts in thousands)	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ —	$ —
Prepaid expenses and other current assets	1,658	2,514
Total current assets	1,658	2,514
Property, plant and equipment, net	4,968	3,982
Right-of-use asset	832	—
Intangible assets	26,400	26,400
Goodwill	2,127	2,127
Total assets	$ 35,985	$ 35,023
Liabilities and Parent Company Net Investment		
Current liabilities:		
Accounts payable	$ 361	$ 2,653
Accrued expenses and other current liabilities	4,500	9,773
Current operating lease liability	356	—
Current portion of contingent consideration	—	10,354
Total current liabilities	5,217	22,780
Long-term operating lease liability	520	—
Other long-term liabilities	—	32
Long-term portion of contingent consideration	65,671	80,558
Total liabilities	71,408	103,370
Commitments and contingencies (Note 10)		
Parent company net investment	(35,423)	(68,347)
Total liabilities and parent company net investment	$ 35,985	$ 35,023

See accompanying notes to combined financial statements.

BAUDAX BIO, INC.
Combined Statements of Operations
(Unaudited)

(amounts in thousands)	For the Three Months Ended September 30, 2019	For the Three Months Ended September 30, 2018	For the Nine Months Ended September 30, 2019	For the Nine Months Ended September 30, 2018
Operating expenses:				
Research and development	$ 1,845	$ 9,838	$ 18,578	$ 25,664
General and administrative	4,524	5,107	21,809	24,170
Change in contingent consideration valuation	3,909	4,115	(15,241)	7,030
Total operating expenses	10,278	19,060	25,146	56,864
Operating loss	(10,278)	(19,060)	(25,146)	(56,864)
Other income (expense):				
Other income (expense)	(37)	(32)	(86)	(122)
Net loss	$ (10,315)	$ (19,092)	$ (25,232)	$ (56,986)

See accompanying notes to combined financial statements.

BAUDAX BIO, INC.
Combined Statements of Parent Company Net Investment
(Unaudited)

For the Nine Months Ended September 30, 2019

(amounts in thousands)	Parent Company Net Investment
Balance, December 31, 2018	$ (68,347)
Net loss	(4,335)
Net transfer from parent	19,823
Parent allocation - share-based compensation	1,527
Balance, March 31, 2019	$ (51,332)
Net loss	(10,582)
Net transfer from parent	31,052
Parent allocation - share-based compensation	1,675
Balance, June 30, 2019	$ (29,187)
Net loss	(10,315)
Net transfer from parent	3,027
Parent allocation - share-based compensation	1,052
Balance, September 30, 2019	$ (35,423)

For the Nine Months Ended September 30, 2018

(amounts in thousands)	Parent Company Net Investment
Balance, December 31, 2017	$ (62,457)
Net loss	(17,457)
Net transfer from parent	18,609
Parent allocation - share-based compensation	1,006
Balance, March 31, 2018	$ (60,299)
Net loss	(20,437)
Net transfer from parent	14,514
Parent allocation - share-based compensation	1,096
Balance, June 30, 2018	$ (65,126)
Net loss	(19,092)
Net transfer from parent	15,925
Parent allocation - share-based compensation	1,268
Balance, September 30, 2018	$ (67,025)

See accompanying notes to combined financial statements.

BAUDAX BIO, INC.
Combined Statements of Cash Flows
(Unaudited)

(amounts in thousands)	For the Nine Months Ended September 30, 2019	2018
Cash flows from operating activities:		
Net loss	$ (25,232)	$ (56,986)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,254	3,370
Depreciation expense	369	273
Change in contingent consideration valuation	(15,241)	7,030
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	857	770
Right-of-use asset	342	—
Accounts payable, accrued expenses and other liabilities	(7,109)	(1,305)
Operating lease liability	(344)	—
Net cash used in operating activities	(42,104)	(46,848)
Cash flows from investing activities:		
Purchase of property and equipment	(1,633)	(2,118)
Acquisition of license agreement	(165)	(82)
Net cash used in investing activities	(1,798)	(2,200)
Cash flows from financing activities:		
Proceeds from Parent Company Investment	53,902	49,048
Payment of contingent consideration	(10,000)	—
Net cash provided by financing activities	43,902	49,048
Net decrease in cash and cash equivalents	—	—
Cash and cash equivalents, beginning of period	—	—
Cash and cash equivalents, end of period	$ —	$ —
Supplemental disclosure of cash flow information:		
Purchase of property, plant and equipment included in accrued expenses and accounts payable	$ —	$ 449

See accompanying notes to combined financial statements.

(1) Background and Basis of Presentation

Baudax Bio, Inc. (Baudax Bio or the Company) represents the Acute Care Business of Recro Pharma, Inc. (Recro) and will be a pharmaceutical company primarily focused on developing and commercializing innovative products for acute care settings and believes it can bring valuable therapeutic options for patients, prescribers and payers, such as its lead product candidate, intravenous (IV) meloxicam, to the acute care markets following the spin-off of Baudax Bio by Recro. Pursuant to the Separation Agreement to be entered into between Recro and Baudax Bio, Recro will transfer the assets, liabilities, and operations of its Acute Care business to the Company and, on November 21, 2019, the distribution date, each Recro shareholder will receive one share of the Company's common stock for every two and one-half shares of Recro common stock held of record at the close of business on November 15, 2019, the record date for the distribution (the Distribution). Following the Distribution, Baudax Bio will operate as a separate, independent company.

The accompanying unaudited combined financial statements are derived from Recro's consolidated financial statements and accounting records and should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2018 included in Recro's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and the Company's Registration Statement on Form 10, as amended and filed with the Securities and Exchange Commission. The Recro Acute Care Business did not consist of a separate, standalone group of legal entities for public company reporting and certain other corporate functions in the periods presented and, accordingly, allocations were required. These combined financial statements reflect the Company's historical financial position, results of operations and cash flows as the business was operated as part of Recro prior to the planned spin-off, in conformity with U.S. generally accepted accounting principles (U.S. GAAP).

The Company has determined that it operates in a single segment involved in the development of innovative products for hospital and other acute care settings.

The combined financial statements include certain assets and liabilities that have historically been held at the Recro corporate level, but which are specifically identifiable or allocable to the Company. All intracompany transactions and accounts have been eliminated. All intercompany transactions between the Company and Recro are considered to be effectively settled in the combined financial statements at the time the transaction is recorded. The total net effect of the settlement of these intercompany transactions is reflected in the combined statements of cash flows as a financing activity and in the combined balance sheet as parent company net investment. The Company does not record interest expense on amounts funded by Recro. Long-term debt held at the Recro corporate level will be retained by Recro and will not be assumed by the Company.

Historically, certain corporate level activity costs have been incurred and reported within the legal entity that includes the Recro Acute Care Business. A portion of these costs have been allocated out and the Company's combined financial statements include a remaining allocation of expenses related to these certain Recro corporate functions, including senior management, legal, human resources, finance, and information technology. These expenses are included in general and administrative expense and have been allocated based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, or other measures. The Company considers the expense allocation methodology and results to be reasonable for all periods presented, however, the allocations may not be indicative of the actual expense that would have been incurred had the Company operated as an independent, publicly-traded company for the periods presented. For the three and nine months ended September 30, 2019, a total of $1,516 and $6,467, respectively, of costs have been allocated to Recro's contract manufacturing and development segment (the CDMO business). For the three and nine months ended September 30, 2018, a total of $1,151 and $3,760, respectively, of costs have been allocated to the CDMO business.

The income tax amounts in these combined financial statements have been calculated based on a separate return methodology and presented as if the Company was a standalone taxpayer in each of its tax jurisdictions. Because of the Company's history of losses as a standalone entity, a full valuation allowance is recorded against deferred tax assets in all periods presented.

Recro maintains its stock-based compensation plan at a corporate level. The Company's employees participate in those programs and a portion of the cost of those plans is included in the Company's combined financial statements using an allocation methodology similar to the methodology used to allocate the cash compensation of the related employees.

The parent company net investment balances in these combined financial statements represents the accumulated deficit of the Recro Acute Care Business and the net funding provided to the Company, which are reflected as net transfers from parent in the combined statements of parent company net investment.

In April 2019, after receipt of a Complete Response Letter (CRL), received from the U.S. Food and Drug Administration (FDA), regarding the New Drug Application (NDA), for IV meloxicam, the Company announced it had implemented a strategic

restructuring initiative, and corresponding reduction in the Acute Care segment workforce, aimed at reducing operating expenses, while maintaining key personnel needed to partner and obtain FDA approval of IV meloxicam.

On October 31, 2019, the Company announced that it had received a written decision from the FDA granting its appeal of the CRL relating to the NDA seeking approval for IV meloxicam. The FDA granted the Company's appeal and indicated that the Company's application provides sufficient evidence of effectiveness and safety to support approval. The Company is now in the process of preparing a comprehensive response to the FDA that includes proposed labeling that aligns with the FDA guidance received in the written decision letter.

(2) Development-Stage Risks and Liquidity

The Company has a history of operating losses and negative cash flows while operating as part of Recro and, accordingly, was dependent upon Recro for its capital funding and liquidity needs. Recro will contribute $19,000 to the Company immediately prior to the Distribution, which management believes is sufficient to maintain operations of the Company for at least one year from the date of the spin-off. Recro has not committed any additional funding to the Company beyond the $19,000 to be contributed as of the Distribution date and the Company may be required to raise additional funds needed to operate as a standalone entity beyond one year from the Distribution date. The Company's ability to generate cash inflows is highly dependent on the approval and commercialization of IV meloxicam and there can be no assurance that such approval will be obtained or that IV meloxicam can be successfully commercialized. In addition, development activities, clinical and pre-clinical testing and commercialization of the Company's product candidates, if approved, will require significant additional funding. The Company could delay clinical trial activity or reduce funding of specific programs in order to reduce cash needs. Insufficient funds may cause the Company to delay, reduce the scope of or eliminate one or more of its development, commercialization or expansion activities. The Company may raise such funds through debt financings, bank or other loans, through strategic research and development, licensing (including out-licensing) and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and failure to raise capital when needed could materially adversely impact the Company's growth plans and its financial condition or results of operations. Additional equity financing, if available, may be dilutive to future holders of its common stock and may involve significant cash payment obligations and covenants that restrict the Company's ability to operate its business. The Company may be required to wind down operations if IV meloxicam is not approved or cannot be successfully commercialized.

(3) Summary of Significant Accounting Principles

(a) Basis of Presentation

The accompanying unaudited combined financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. GAAP, for interim financial information and with the instructions of Form 10-Q and Article 10 of Regulation S-X and, therefore, do not include all of the information and notes required by U.S. GAAP for complete annual financial statements. In the opinion of management, the accompanying combined financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's results for the interim periods. Operating results for the three and nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2019.

The accompanying unaudited interim combined financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2018 included in the Company's Form 10.

(b) Use of Estimates

The preparation of financial statements and the notes to the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates.

(c) Cash and Cash Equivalents

Cash and cash equivalents represent cash in banks and highly liquid short-term investments that have maturities of three months or less when acquired. These highly liquid short-term investments are both readily convertible to known amounts of cash and so near to their maturity that they present insignificant risk of changes in value because of the changes in interest rates.

(d) Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which are as follows: three to seven years for furniture and office equipment; six to ten years for manufacturing equipment; and the shorter of the lease term or useful life for leasehold improvements. Repairs and maintenance costs are expensed as incurred.

(e) Business Combinations

In accordance with Financial Accounting Standards Board (FASB), Accounting Standards Codification (ASC), Topic 805, "*Business Combinations*," or ASC 805, the Company allocates the purchase price of acquired companies to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values. Valuations are performed to assist in determining the fair values of assets acquired and liabilities assumed, which requires management to make significant estimates and assumptions, in particular with respect to intangible assets and contingent consideration. Management makes estimates of fair value based upon assumptions believed to be reasonable. These estimates are based in part on historical experience and information obtained from management of the acquired companies and expectations of future cash flows. Transaction costs and restructuring costs associated with the transaction are expensed as incurred. In-process research and development (IPR&D), is the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to IPR&D requires the Company to make significant estimates. In a business combination, the Company capitalizes IPR&D as an intangible asset, and for an asset acquisition the Company expenses IPR&D in the Combined Statements of Operations on the acquisition date.

(f) Goodwill and Intangible Assets

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company (see Note 4). Goodwill is not amortized but assessed for impairment on an annual basis or more frequently if impairment indicators exist. The impairment model prescribes a one-step method for determining impairment.

The one-step quantitative test calculates the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The Company has one reporting unit.

The Company's intangible asset is classified as an IPR&D asset. Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written-off, and the Company will record a noncash impairment loss on its Combined Statements of Operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess.

The Company performs its annual goodwill and indefinite-lived intangible asset impairment test as of November 30th, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of those assets. In performing the evaluation, the Company assesses qualitative factors such as overall financial performance of its reporting unit, anticipated changes in industry and market conditions, including recent tax reform, intellectual property protection, and competitive environments. Due to the receipt of the CRL in March 2019, an indicator of potential impairment, the Company performed an impairment test as of March 31, 2019, which indicated that there was no impairment to goodwill or indefinite-lived intangible assets. There have been no additional triggering events as of September 30, 2019. The Company will perform its annual test as of November 30, 2019.

(g) Research and Development

Research and development costs for the Company's proprietary products/product candidates are charged to expense as incurred. Research and development expenses consist primarily of funds paid to third parties for the provision of services for pre-commercialization and manufacturing scale-up activities, drug development, pre-clinical activities, clinical trials, statistical analysis and report writing and regulatory filing fees and compliance costs. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expenses relating to these costs.

Upfront and milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining product technology licenses are charged to research

and development expense as acquired IPR&D if the technology licensed has not reached technological feasibility and has no alternative future use.

(h) Stock-Based Awards

Share-based compensation is based upon the Recro share-based compensation plan. The Recro plan includes grants of stock options, time-based vesting restricted stock units (RSUs) and performance-based vesting RSUs. These carve out financial statements reflect share-based compensation related to stock options and RSUs issued to Baudax Bio employees as well as an allocation of a portion of share-based compensation issued to corporate employees and members of the Board of Directors.

The Company measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award. The Company accounts for forfeitures as they occur.

Determining the appropriate fair value of stock options requires the input of subjective assumptions, including the expected life of the option and expected stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and/or management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses the historical volatility of our publicly traded stock in order to estimate future stock price trends. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

(i) Income Taxes

The income tax amounts in these combined financial statements have been calculated based on a separate return methodology and presented as if the Company was a standalone taxpayer in each of its tax jurisdictions. Because of the Company's history of losses as a standalone entity, a full valuation allowance is recorded against deferred tax assets in all periods presented. Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the combined financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

(j) Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, "*Compensation – Stock Compensation (Topic 718)*" or ASU 2018-07. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 "*Compensation—Stock Compensation*" to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance in ASC 505-50 " *Equity-Based Payments to Non-Employees*". The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASU 2014-09 "*Revenue from Contracts with Customers (Topic 606)*". The Company adopted this guidance effective June 30, 2018. There was no impact upon adoption

In May 2017, the FASB issued ASU No. 2017-09, "*Stock Compensation – Scope of Modification Accounting"* or ASU 2017-09. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard was effective for fiscal years beginning after December 15, 2017. The Company adopted the guidance effective January 1, 2018. There was no impact upon adoption.

In January 2017, the FASB issued ASU No. 2017-04 "*Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*," or ASU 2017-04. ASU 2017-04 allows companies to apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The amendments of the ASU are effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted this guidance as of October 1, 2018 and there was no impact on its combined financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*," or ASU 2016-02. ASU 2016-02 establishes a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), *Targeted Improvements*, which provides an alternative transition method permitting the recognition of a cumulative-effect adjustment on the date of adoption rather than restating comparative periods in transition as originally prescribed by Topic 842. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company adopted this guidance as of January 1, 2019. The Company elected the optional transition method to account for the impact of the adoption with a cumulative-effect adjustment in the period of adoption and did not restate prior periods. The Company opted to elect the package of practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs, and certain other practical expedients, including the use of hindsight to determine the lease term for existing leases and in assessing impairment of the right-of-use asset, and the exception for short-term leases. For its current classes of underlying assets, the Company did not elect the practical expedient under which the lease components would not be separated from the nonlease components. At January 1, 2019, the Company recorded a right-of-use asset of $1,174 and an operating lease liability of $1,219. For additional information regarding how the Company is accounting for leases under the new guidance, refer to Note 10 (d).

Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU 2018-13, "*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,*" or ASU 2018-13. ASU 2018-13 removes, modifies and adds certain disclosure requirements in Topic 820 "*Fair Value Measurement*". ASU 2018-13 eliminates certain disclosures related to transfers and the valuations process, clarifies the measurement uncertainty disclosure, and requires additional disclosures for Level 3 fair value measurements, including the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact on its disclosures.

In June 2016, the FASB issued ASU No. 2016-13, "*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,"* or ASU 2016-13. ASU 2016-13 requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires consideration of a range of reasonable information to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, including those interim periods within those fiscal years. The Company is currently assessing the impact of adopting this standard, but based on a preliminary assessment, does not expect the adoption of this guidance to have a material impact on its combined financial statements.

(4) Acquisition of Gainesville Facility and Meloxicam

On April 10, 2015, Recro completed the acquisition of a manufacturing facility in Gainesville, Georgia and the licensing and commercialization rights to IV meloxicam (the Gainesville Transaction). The consideration paid in connection with the Gainesville Transaction consisted of $50,000 cash at closing, a $4,000 working capital adjustment and a seven-year warrant to purchase 350,000 shares of Recro's common stock at an exercise price of $19.46 per share. In addition, the Company may be required to pay up to an additional $125,000 in milestone payments including $45,000 upon regulatory approval of IV meloxicam, as well as net sales milestones related to IV meloxicam and a percentage of future product net sales related to IV meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). Under the acquisition method of accounting, the consideration paid and the fair value of the contingent consideration and royalties were allocated to the fair value of the assets acquired and liabilities assumed. The contingent consideration obligation is remeasured each reporting date with changes in fair value recognized as a period charge within the statement of operations (see Note 6 for further information regarding fair value).

The assets acquired, including goodwill, and liabilities assumed in the Gainesville Transaction were allocated to Recro's reporting units as of the date of the acquisition. The accompanying combined financial statements reflect the IPR&D asset of $26,400 and goodwill of $2,127 that were recorded by Baudax Bio related to the Gainesville transaction. The liability for the contingent consideration will be assumed by Baudax Bio following the spin-off and is included in the Company's Combined Balance Sheets.

The warrant associated with the transaction remains on Recro's Consolidated Balance Sheets with no allocation to the Company as it is a warrant to purchase Recro common stock.

In December 2018, Recro entered into a second amendment to the purchase and sale agreement among Alkermes Pharma Ireland Limited, Alkermes US Holdings (together with Alkermes Pharma Ireland Limited, Alkermes), Daravita Limited, Recro and Recro Gainesville LLC (Recro Gainesville) that restructured the $45,000 milestone to $60,000 therefore increasing the amount the Company may be required to pay Alkermes to $140,000, however, the amendment spread the payments of the development milestone over a seven-year period. In addition, Recro amended the warrant agreement with Alkermes, which decreased the exercise price of the warrant to $8.26 per share.

Based on the amended terms of the Alkermes agreement, the contingent consideration consists of four separate components. The first component is (i) a $5,000 payment made in the first quarter of 2019 and (ii) a $5,000 payment made in the second quarter of 2019. The second components will be payable upon certain regulatory approval and include (i) a $5,000 payment due within 180 days following regulatory approval for IV meloxicam and (ii) $45,000 payable in seven equal annual payments of approximately $6,400 beginning on the first anniversary of such approval. The third component consists of three potential payments, based on the achievement of specified annual revenue targets, the last of which represents over 60% of these milestone payments and currently does not have a fair value assigned to its achievement. The fourth component consists of a royalty payment between 10% and 12% (subject to a 30% reduction when no longer covered by patent) for a defined term on future meloxicam net sales. During the nine months ended September 30, 2019, the Company paid the first component consisting of two payments of $5,000 each to Alkermes.

The fair value of the contingent consideration liability is measured as the reporting date using inputs and assumptions as of the date of the financial statements. Events and circumstances impacting the fair value of the liability that occur after the balance sheet date, but before the date that the financial statements are available to be issued are adjusted in the period during which such events and circumstances occur. The fair value of the second contingent consideration component is estimated by applying a risk-adjusted discount rate to the probability-adjusted contingent payments and the expected approval dates. The fair value of the third contingent consideration component is estimated using the Monte Carlo simulation method and applying a risk-adjusted discount rate to the potential payments resulting from probability-weighted revenue projections based upon the expected revenue target attainment dates. The fair value of the fourth contingent consideration component is estimated by applying a risk-adjusted discount rate to the potential payments resulting from probability-weighted revenue projections and the defined royalty percentage.

These fair values are based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The contingent consideration components are classified as liabilities and are subject to the recognition of subsequent changes in fair value through the results of operations.

(5) NMBA Related License Agreement

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents, or NMBAs, and a proprietary reversal agent from Cornell University, or Cornell. The NMBAs and reversal agent are referred to herein as the NMBA Related Compounds. The NMBA Related Compounds include one novel intermediate-acting NMBA that has initiated Phase I clinical trials and two other agents, a novel short-acting NMBA, and a rapid-acting reversal agent specific to these NMBAs.

The transaction was accounted for as an asset acquisition, with the total cost of the acquisition of $766 allocated to acquired IPR&D. The Company recorded an upfront payment obligation of $350, as well as operational liabilities and acquisition-related costs of $416, primarily consisting of reimbursement to Cornell for specified past patent, legal and pre-clinical costs.

In addition, the Company is obligated to make: (i) an annual license maintenance fee payment until the first commercial sale of the NMBA Related Compounds; and (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMBA, of $5,000 for U.S. regulatory approval and commercialization milestones and $3,000 for European regulatory approval and commercialization milestones. The Company is also obligated to pay Cornell royalties on net sales of the NMBA Related Compounds at a rate ranging from low to mid-single digits, depending on the applicable NMBA Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMBA Related Compounds.

The Company accounted for the transaction as an asset acquisition based on an evaluation of the accounting guidance (ASC Topic 805) and considered the early clinical stage of the novel and unproven NMBA Related Compounds. The Company concluded that the acquired IPR&D of Cornell did not constitute a business as defined under ASC 805 due to the incomplete nature of the inputs and the absence of processes from a market participant perspective. Substantial additional research and development will be required to develop any NMBA Related Compounds into a commercially viable drug candidate, including completion of pre-clinical testing and clinical trials, and, if such clinical trials are successful, application for regulatory approvals and manufacturing repeatability and scale-up. There is risk that a marketable compound may not be well tolerated and may never be approved.

Acquired IPR&D in the asset acquisition was accounted for in accordance with FASB ASC Topic 730, "*Research and Development*." At the date of acquisition, the Company determined that the development of the projects underway at Cornell had

not yet reached technological feasibility and that the research in process had no alternative future uses. Accordingly, the acquired IPR&D was charged to expensein the Combined Statements of Operations on the acquisition date. The acquired IPR&D charge is expected to be deductible over a 15-year period for income tax purposes.

(6) Fair Value of Financial Instruments

The Company follows the provisions of FASB ASC Topic 820, "*Fair Value Measurements and Disclosures*," for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and contingent consideration. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2: Inputs that are other than quoted prices in active markets for identical assets and liabilities, inputs that are quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are either directly or indirectly observable; and
- Level 3: Unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The Company has classified assets and liabilities measured at fair value on a recurring basis as follows:

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At December 31, 2018:			
Liabilities:			
Contingent consideration (See Note 4)	$ —	$ —	$ 90,912
	$ —	$ —	$ 90,912
At September 30, 2019:			
Liabilities:			
Contingent consideration (See Note 4)	$ —	$ —	$ 65,671
	$ —	$ —	$ 65,671

The reconciliation of the contingent consideration measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	Contingent Consideration
Balance at December 31, 2018	$ 90,912
Payment of contingent consideration	(10,000)
Remeasurement	(15,241)
Total at September 30, 2019	$ 65,671
Current portion as of September 30, 2019	—
Long-term portion as of September 30, 2019	$ 65,671

The Company does not expect a portion of the contingent consideration to become payable within one year as of September 30, 2019 (see Note 4 for additional information). The Company plans to continue to reevaluate this classification and measurement as it progresses through discussions with the FDA regarding IV meloxicam.

The Company follows the disclosure provisions of FASB ASC Topic 825, "*Financial Instruments*" (ASC 825), for disclosure purposes for financial assets and financial liabilities that are not measured at fair value. As of September 30, 2019, the financial assets and liabilities recorded on the Combined Balance Sheets that are not measured at fair value on a recurring basis include accounts payable and accrued expenses and approximate fair value due to the short-term nature of these instruments.

(7) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	September 30, 2019	December 31, 2018
Building and improvements	$ 196	$ 196
Furniture, office and computer equipment	1,665	1,688
Manufacturing equipment	101	101
Construction in progress	3,814	2,469
	5,776	4,454
Less: accumulated depreciation and amortization	808	472
Property, plant and equipment, net	$ 4,968	$ 3,982

Depreciation expense for the three and nine months ended September 30, 2019 was $123 and $369, respectively. Depreciation expense for three and nine months ended September 30, 2018 was $161 and $273, respectively.

(8) Intangible Assets

The following represents the balance of the intangible assets at September 30, 2019 and December 31, 2018:

	Cost
In-process research and development	$ 26,400
Total	$ 26,400

There was no amortization expense for the nine months ended September 30, 2019 or the nine months ended September 30, 2018.

(9) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	September 30, 2019	December 31, 2018
Clinical trial and related costs	$ 101	$ 683
Professional and consulting fees	1,012	671
Payroll and related costs	1,753	2,172
Accrued restructuring costs	1,386	—
Property, plant and equipment	—	278
Pre-commercialization scale-up costs	—	4,445
Other research and development costs	136	678
Other	112	846
	$ 4,500	$ 9,773

After the receipt of the second CRL, the Company incurred approximately $7,200 in restructuring costs (all which was incurred in the first half of 2019), of which $1,386 remains accrued and unpaid as of September 30, 2019.

(10) Commitments and Contingencies

(a) Licenses and Supply Agreements

Recro is party to an exclusive license with Orion for the development and commercialization of Dexmedetomidine for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, but specifically excluding delivery vehicles for administration by injection or infusion, worldwide, except for Europe, Turkey and the CIS (currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), referred to herein as the Territory. Recro is required to pay Orion lump sum payments of up to €20,500 ($22,380 as of September 30, 2019) on the achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 20% depending on annual sales levels. Through September 30, 2019, no such milestones have been achieved.

Recro is also party to an exclusive license agreement with Orion for the development and commercialization of Fadolmidine for use as a human therapeutic, in any dosage form in the Territory. Recro is required to pay Orion lump sum payments of up to €12,200 ($13,320 as of September 30, 2019) on achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 15% depending on annual sales levels. Through September 30, 2019, no such milestones have been achieved.

Recro is party to a license agreement with Cornell for the exclusive license of the NMBA Related Compounds. Under the terms of the agreement, Recro will pay Cornell an initial upfront fee and Cornell is also entitled to receive additional milestone payments, annual license maintenance fees as well as royalties. See Note 5 for further information regarding these payment obligations.

These obligations will be transferred to the Company in connection with the spin-off.

(b) Contingent Consideration for the Gainesville Transaction

Pursuant to the purchase and sale agreement and subsequent amendment governing the Gainesville Transaction, Recro agreed to pay to Alkermes up to an additional $140,000 in milestone payments including $50,000 upon regulatory approval payable over a seven-year period as well as net sales milestones related to IV meloxicam and royalties on future product sales of injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). As of September 30, 2019, the Company has paid $10,000 in milestone payments to Alkermes.

Recro is party to a Development, Manufacturing and Supply Agreement (Supply Agreement), with Alkermes (through a subsidiary of Alkermes), pursuant to which Alkermes will (i) provide clinical and commercial bulk supplies of IV meloxicam formulation and (ii) provide development services with respect to the Chemistry, Manufacturing and Controls section of an NDA for IV meloxicam. Pursuant to the Supply Agreement, Alkermes will supply Recro with such quantities of bulk IV meloxicam formulation as shall be reasonably required for the completion of clinical trials of IV meloxicam. During the term of the Supply Agreement, Recro will purchase its clinical and commercial supplies of bulk IV meloxicam formulation exclusively from Alkermes, subject to certain exceptions, for a period of time.

These obligations will be transferred to the Company in connection with the spin-off.

(c) Litigation

Recro and the Company are involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. Except as disclosed below, Recro and the Company are not currently a party to any such claims or proceedings that, if decided adversely to it, would either individually or in the aggregate have a material adverse effect on its business, financial condition or results of operations.

On May 31, 2018, a securities class action lawsuit was filed against Recro and certain of its officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by Recro concerning the NDA for IV meloxicam. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. On December 10, 2018, lead plaintiff filed an amended complaint that asserted the same claims and sought the same relief but included new allegations and named additional officers and directors as defendants. On February 8, 2019, Recro filed a motion to dismiss the amended complaint in its entirety, which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, Recro filed its response and briefing was completed on the motion to dismiss. On June 26, 2019, the judge heard oral arguments on the motion to dismiss. The judge asked the plaintiffs to file a supplemental brief by August 30, 2019, and Recro will have 30 days to submit a reply brief. This matter will be transferred to the Company in connection with the spin-off. Recro and the Company believe that the lawsuit is without merit and intends to vigorously defend against it. The lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to Recro or the Company.

(d) Leases

The Company is a party to various operating leases in Malvern, Pennsylvania, and Dublin, Ireland for office space and office equipment.

The Company determines if an arrangement is a lease at inception. The arrangement is a lease if it conveys the right to the Company to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Lease terms vary based on the nature of operations, however, all leased facilities are classified as operating leases with remaining lease terms between 1 and 3 years. Most leases contain specific renewal options where notice to renew must be provided in advance of lease expiration or automatic renewals where no advance notice is required. Periods covered by an option to extend the lease were included in the non-cancellable lease term when exercise of the option was determined to be reasonably certain. Costs determined to be variable and not based on an index or rate were not included in the measurement of operating lease liabilities. As most leases do not provide an implicit rate, the Company's effective interest rate was used to discount its lease liabilities.

The Company's leases with an initial term of 12 months or less that do not have a purchase option or extension that is reasonably certain to be exercised are not included in the right of use asset or lease liability on the Combined Balance Sheets. Lease expense is recognized on a straight-line basis over the lease term.

As of September 30, 2019, undiscounted future lease payments for non-cancellable operating leases are as follows:

	Lease payments
2019	$ 121
2020	401
2021	362
2022	373
Total lease payments	1,257
Less imputed interest	(381)
Total operating liabilities	$ 876

As of December 31, 2018 under legacy ASC 840 "*Leases*", undiscounted future lease payments for non-cancellable operating leases were as follows:

	Lease payments
2019	$ 517
2020	414
2021	367
2022	373
Total	$ 1,671

For the nine months ended September 30, 2019, the weighted average remaining lease term was 3 years and the weighted average discount rate was 16%.

The components of the Company's lease cost were as follows for the three and nine months ended September 30, 2019:

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating lease cost	$ 121	$ 363
Short-term lease cost	-	14
Total lease cost	$ 121	$ 377

(e) Purchase Commitments

As of September 30, 2019, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of $4,863 related to inventory, capital expenditures and other goods and services, including pre-commercial/manufacturing scale-up and clinical activities. The timing of certain purchase commitments cannot be estimated as it is dependent on timing of FDA approval or the outcome of other strategic evaluations and agreements.

(f) Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers. As of September 30, 2019, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than $624, from that date through June 2020.

(11) Stock-Based Compensation

Certain employees of the Company participate in Recro's stock-based compensation plan, which provides for the grants of stock options and RSUs. The expense associated with the Company's employees who participate in the plan is included in the accompanying combined statements of operations. A portion of these costs have been allocated out of the Company as they relate to employees responsible for corporate level activities that historically were incurred by the entity that represents the Company. Additionally, the entity that represents the Company historically incurred the costs related to the board of directors, which has also been partially allocated out of the Company.

In October 2013, Recro established the 2013 Equity Incentive Plan (the 2013 Plan), which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 600,000 shares of common stock. In June 2015, Recro's shareholders approved the Amended and Restated Equity Incentive Plan (the A&R Plan), which amended and restated the 2013 Plan and increased the aggregate amount of shares of common stock available for issuance to 2,000,000. On December 1st of each year, pursuant to the "Evergreen" provision of the A&R Plan, the number of shares available under the plan may be increased by the Recro Board by an amount equal to 5% of the outstanding common stock on December 1st of that year. In December 2018 and 2017 the number of shares available for issuance under the A&R Plan was increased by 1,082,972 and 956,341, respectively. The total number of shares authorized for issuance under the A&R plan as of September 30, 2019 is 8,119,709. Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of September 30, 2019, 2,524,235 shares are available for future grants under Recro's A&R Plan.

All shares described herein represent shares of Recro. The share information included in this disclosure includes 100% of the shares issued to Baudax Bio employees, corporate employees and Board members of Recro; however, a portion of the expenses related to the corporate employees and Board members of Recro have been allocated out of share-based compensation expense in these carve out financial statements using an allocation methodology similar to the allocation methodology used to allocate cash compensation expense.

The weighted average grant-date fair value of the options awarded to employees during the nine months ended September 30, 2019 and 2018 was $5.53 and $6.18, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

	September 30,	
	2019	2018
Range of expected option life	5.5 - 6 years	5.5 - 6 years
Expected volatility	74.69% - 80.59%	74.05% - 81.47%
Risk-free interest rate	1.42 - 2.66%	2.32 - 2.98%
Expected dividend yield	—	—

The following table summarizes stock option activity during the nine months ended September 30, 2019:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2018	3,092,606	$ 7.32	7.3 years
Granted	1,094,756	$ 7.95	
Exercised	(408,170)	$ 5.94	
Expired/forfeited/cancelled	(678,645)	$ 7.84	
Balance, September 30, 2019	3,100,547	$ 7.61	6.9 years
Vested	1,973,108	$ 7.31	5.9 years
Vested and expected to vest	3,100,547	$ 7.61	6.9 years

Included in the table above are 482,876 options outstanding as of September 30, 2019 that were granted outside the plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

As a result of the Company's reduction in workforce announced in April 2019, the Company cancelled approximately 600,000 unvested stock options upon termination, which are reflected in the table above.

The following table summarizes restricted stock units (RSUs), activity during the nine months ended September 30, 2019.

	Number of shares
Balance, December 31, 2018	981,453
Granted	664,210
Vested and settled	(421,552)
Expired/forfeited/cancelled	(455,437)
Balance, September 30, 2019	768,674
Expected to vest	517,474

Included in the table above are 18,625 time-based RSUs outstanding as of September 30, 2019 that were granted outside the plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

As a result of the Company's reduction in workforce announced in April 2019, the Company cancelled approximately 300,000 shares related to RSUs upon termination, which is reflected in the table above.

Stock-based compensation expense for the nine months ended September 30, 2019 and 2018 was $4,254 and $3,370, respectively.

As of September 30, 2019, there was $7,532 of unrecognized compensation expense related to unvested options and time-based RSUs that are expected to vest and will be expensed over a weighted average period of 2.0 years. As of September 30, 2019, there was $1,621 of unrecognized compensation expense related to unvested performance-based RSUs and will be expensed if the performance criteria are met.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of September 30, 2019, the aggregate intrinsic value of the vested and unvested options was $7,514 and $3,331, respectively.

(12) Related Party Transactions

A Non-Executive Director of the Company's Irish subsidiary is a Managing Director and a majority shareholder of HiTech Health Ltd (HiTech Health), a consultancy firm for the biotech, pharmaceutical and medical device industry. Since 2016, HiTech Health has provided the Company with certain consulting services and in November 2017 both parties entered into a Service Agreement to engage in both regulatory and supply chain project support and consultancy. In consideration for such services, the Company recorded $11 and $25 for the three months ended September 30, 2019 and 2018, respectively. For the nine months ended September 30, 2019 and 2018 the Company recorded $115 and $278, in consideration for such services, respectively. A portion of the amount relates to consultancy services provided by the Non-Executive Director.

(13) Retirement Plan

The Company has a voluntary 401(k) Savings Plan (the 401(k) Plan) in which all employees are eligible to participate. The Company's policy is to match 100% of the employee contributions up to a maximum of 5% of employee compensation. Total Company contributions to the 401(k) plan for the three months ended September 30, 2019 and 2018 were $45 and $90, respectively. Total Company contributions to the 401(k) plan for the nine months ended September 30, 2019 and 2018 were $281 and $364, respectively.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the interim unaudited financial statements contained in Part I, Item 1 of this quarterly report, and the audited financial statements and notes thereto for the year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Company's Registration Statement on Form 10, as amended and filed with the Securities and Exchange Commission, or SEC, on October 22, 2019, which is referred to herein as the "Form 10." As used in this report, unless the context suggests otherwise, "we," "us," "our," the "Company" or "Baudax Bio" refer to Baudax Bio, Inc. and its combined subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. We may, in some cases, use terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements.

These forward-looking statements in this quarterly report on Form 10-Q include, among other things, statements about:

- the completion and timing of the separation of Recro Pharma, Inc.'s Acute Care business and transfer of such assets to the Company, or the Separation, our business and operations following the Separation and any benefits or costs of the Separation, including the tax treatment;
- our post-Separation relationships with Recro Pharma, Inc., or Recro, third parties, licensors, collaborators and our employees;
- our ability to operate as a standalone company and execute our strategic priorities;
- potential indemnification liabilities we may owe to Recro after the Separation;
- the tax treatment of the distribution to each Recro shareholder of one share of the Company's common stock for every two and one-half shares of Recro common stock held of record at the close of business on the record date for the distribution, or the Distribution, and any limitations imposed on us under the tax matters agreements that we intend to enter into with Recro;
- whether the U.S. Food and Drug Administration, or FDA will approve our amended new drug application, or NDA, for IV meloxicam and, if approved, the labeling under any such approval that we may obtain;
- our ability to successfully commercialize IV meloxicam before approval or upon regulatory approval;
- our ability to generate sales and other revenues from IV meloxicam or any of our other product candidates, once approved, including setting an acceptable price for and obtaining adequate coverage and reimbursement of such products;
- the results, timing and outcome of our clinical trials of IV meloxicam or our other product candidates, and any future clinical and preclinical studies;
- our ability to comply with the regulatory schemes applicable to our business and other regulatory developments in the United States and foreign countries;
- the performance of third-parties upon which we depend, including third-party contract research organizations, and third-party suppliers, manufacturers, distributers and logistics providers;
- our ability to obtain and maintain patent protection and defend our intellectual property rights against third-parties;
- our ability to maintain our relationships and contracts with our key commercial partners;
- our ability to defend the securities class action lawsuit filed against Recro, or any future material litigation filed against us;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers; and
- the effects of changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, tax impacts and net operating loss utilization related to the Acute Care segment separation and changes in the tax laws.

Any forward-looking statements that we make in this Quarterly Report speak 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 or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the "Risk Factors" included in the Company's Information Statement furnished to the SEC on October 22, 2019, as amended, to better understand significant risks and uncertainties inherent in our business

and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this report and you should not place undue reliance on any forward-looking statements.

Overview

We are a pharmaceutical company primarily focused on developing and commercializing innovative products for acute care settings. We believe that we can bring valuable therapeutic options for patients, prescribers and payers, such as our lead product candidate, IV meloxicam, to the acute care markets. We believe we can create value for our shareholders through the development, registration and commercialization of IV meloxicam and our other pipeline product candidates. In addition to our pipeline, we continue to evaluate acquisition, out-licensing and in-licensing opportunities. We have no revenue and our costs consist primarily of expenses incurred in conducting our manufacturing scale-up, clinical trials and preclinical studies, regulatory activities, pre-commercialization of meloxicam, public-company and personnel costs.

We expect to incur significant and increasing operating losses for at least the next few years. We expect substantially all of our operating losses to result from costs incurred in connection with our development programs, manufacturing, clinical trials, public-company and pre-commercialization activities. Our expenses over the next several years are expected to relate to the acquisition or in-license of a product and successful commercialization of the acquired or in-licensed product, obtaining regulatory approval for IV meloxicam and, if approved, successfully commercializing IV meloxicam, and continuing to develop our other current and future product candidates.

Separation from Recro Pharma, Inc.

In November 2019, Recro announced its plans to separate its acute care business from its CDMO business through a pro rata distribution of our common stock to shareholders of Recro. In preparation for the Separation, Recro will transfer the assets, liabilities and operations of its acute care business to us, pursuant to the terms of a Separation Agreement, entered into between Recro and Baudax Bio. On November 21, 2019, the distribution date, each Recro shareholder will receive one share of our common stock for every two and one-half shares of Recro common stock held of record at the close of business on November 15, 2019, the record date for the Distribution. Registered shareholders will receive cash in lieu of any fractional shares of our common stock that they would have received as a result of the application of the distribution ratio. Following the Distribution, we will operate as a separate, independent company. The Distribution is subject to the satisfaction or waiver by Recro of certain conditions. For a more detailed description of these conditions, see "The Separation and Distribution—Conditions to the Distribution" included in the Form 10.

Our historical combined financial statements have been prepared on a stand-alone basis and are derived from Recro's consolidated financial statements and accounting records and are presented in conformity with U.S. GAAP. Our financial position, results of operations and cash flows historically operated, and will continue to operate, as part of Recro's financial position, results of operations and cash flows prior to and until the Distribution to Recro's shareholders. These historical combined financial statements may not be indicative of our future performance and do not necessarily reflect what our combined results of operations, financial condition and cash flows would have been had we operated as a separate company during the periods presented. We expect that changes will occur in our operating structure and our capitalization as a result of the Separation from Recro.

Financial Overview

Research and Development Expenses

Research and development expenses currently consist primarily of costs in connection with the development of IV meloxicam and other pipeline activities. These expenses consist primarily of:

- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial drug supply and related manufacturing services and pre-commercial product validation and inventory manufacturing expenses;
- costs related to facilities, depreciation and other allocated expenses;
- acquired in-process research and development;
- costs associated with non-clinical and regulatory activities; and
- salaries and related costs for personnel in research and development and regulatory functions.

The majority of our external research and development costs have related to clinical trials, manufacturing of drug supply for pre-commercial products, analysis and testing of product candidates and patent costs. Costs related to facilities, depreciation and support are not charged to specific programs.

The successful development of IV meloxicam and our other product candidates is highly uncertain and subject to a number of risks, including, but not limited to:

- the costs, timing and outcome of regulatory review of a product;
- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;
- substantial requirements on the introduction of pharmaceutical products imposed by the FDA and comparable agencies in foreign countries, which require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- the possibility that data obtained from pre-clinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity or may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;
- risk involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- the emergence of competing technologies and products and other adverse market developments, which could impede our commercial efforts; and
- the other risks disclosed in the section titled "Risk Factors" section of the Form 10.

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we will assess additional information as we progress through our discussions with the FDA regarding obtaining regulatory approval for IV meloxicam, as well as assess IV meloxicam's commercial potential and available capital resources. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or costs that we will expend in the future on IV meloxicam prior to regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approval, we are currently unable to estimate precisely when, if ever, any of our product candidates will generate revenues and cash flows.

We expect our research and development costs to continue to relate to IV meloxicam as we seek to obtain regulatory approval for IV meloxicam, and if successful in obtaining regulatory approval, advance IV meloxicam through the commercialization scale-up and other activities. We also expect to have expenses related to work for maintenance of our other product candidates. We may elect to seek collaborative relationships in order to provide us with a diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, pre-commercial, finance and information technology functions. General and administrative expenses also include professional fees for legal, including patent-related expenses, consulting, auditing and tax services.

Change in Fair Value of Contingent Consideration

Pursuant to the Purchase and Sale Agreement entered into for the acquisition of a manufacturing facility in Gainesville, Georgia and the licensing and commercialization rights for IV meloxicam, or the Gainesville Transaction, as amended in December 2018, among Alkermes Pharma Ireland Limited and Alkermes US Holdings, or Alkermes, Daravita, Recro and Recro Gainesville LLC, we are required to pay up to an additional $140.0 million in milestone payments, including $10.0 million during the first half of 2019, another $5.0 million due within 180 days of approval of IV meloxicam and $45.0 million over seven years beginning one year after approval, as well as net sales milestones and a royalty percentage of future product net sales related to IV meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). The estimated fair value of the initial $54.6 million payment obligation was recorded as part of the purchase price for the Gainesville Transaction. We have continued to reevaluate the fair value each subsequent period and as of September 30, 2019 recorded a $65.7 million payment obligation, representing the estimated probability adjusted fair value. Each reporting period, we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or gain. As of September 30, 2019, we have paid $10.0 million in milestone payments to Alkermes.

Income Taxation

In December 2017, the federal government enacted numerous amendments to the Internal Revenue Code of 1986 pursuant to the Tax Cuts and Jobs Act, or the Tax Act. The Tax Act will impact our income tax expense/(benefit) from operations in the current and in future periods. The Tax Act resulted in the following impacts to us:

- Our federal statutory income tax rate was reduced from 34% to 21% for 2018 and tax years following.
- We will be able to claim an immediate deduction for investments in qualified fixed assets acquired and placed in service beginning September 27, 2017 through 2022. This provision phases out through 2026.
- Given our taxable losses in the U.S., we will be limited in our ability to deduct interest expense, and any disallowed interest expense for 2018 and tax years following will result in an indefinite carry forward until such time as we meet the taxable income thresholds required to deduct interest expense.

Results of Operations

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

	Three Months Ended September 30,	
	2019	2018
	(amounts in thousands)	
Operating expenses:		
Research and development	$ 1,845	$ 9,838
General and administrative	4,524	5,107
Change in contingent consideration valuation	3,909	4,115
Total operating expenses	10,278	19,060
Operating loss	(10,278)	(19,060)
Other income (expense):		
Other income (expense), net	(37)	(32)
Net loss	$ (10,315)	$ (19,092)

Research and Development. Our research and development expenses were $1.8 million and $9.8 million for the three months ended September 30, 2019 and 2018, respectively. The decrease of $8.0 million resulted from a decrease in pre-commercialization manufacturing and clinical costs for IV meloxicam of $4.8 million, a decrease in development costs for other pipeline products of $2.2 million and a decrease in personnel costs of $1.0 million.

General and Administrative. Our general and administrative expenses were $4.5 million and $5.1 million for the three months ended September 30, 2019 and 2018, respectively. The decrease of $0.6 million was primarily due to decreased commercial team personnel costs of $1.2 million and pre-commercial consulting costs of $0.4 million following the receipt of the second complete response letter, or CRL, for IV meloxicam. These decreases were partially offset by increases in public company costs including legal fees and CRL response costs of $1.0 million.

Change in Contingent Consideration Valuation. Our change in contingent consideration valuation was an increase of value of $3.9 million for the three months ended September 30, 2019 and an increase in value of $4.1 million for the three months ended September 30, 2018. The non-cash charge for contingent consideration in each period related to the revaluation of the probability adjusted fair value of the Gainesville Transaction payment obligation.

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

	Nine Months Ended September 30,	
	2019	2018
	(amounts in thousands)	
Operating expenses:		
Research and development	$ 18,578	$ 25,664
General and administrative	21,809	24,170
Change in contingent consideration valuation	(15,241)	7,030
Total operating expenses	25,146	56,864
Operating income (loss)	(25,146)	(56,864)
Other income (expense):		
Other income (expense), net	(86)	(122)
Net loss	$ (25,232)	$ (56,986)

Following the receipt of the second CRL, we implemented a strategic restructuring initiative, and corresponding reduction in workforce, aimed at reducing operating expenses, while maintaining key personnel needed to select a partner and obtain FDA approval of IV meloxicam. The restructuring initiative included a reduction of approximately 50 positions. During the nine months ended September 30, 2019, we have incurred approximately $7.2 million (all $7.2 million was incurred in the first half of 2019) of costs in connection with the strategic restructuring plan which includes severance and related termination benefits and canceled marketing and production costs

Research and Development. Our research and development expenses were $18.6 million and $25.7 million for the nine months ended September 30, 2019 and 2018, respectively. Excluding $2.8 of costs associated with the strategic restructuring initiative recorded in the nine months ended September 30, 2019, the decrease of $9.9 million resulted from a decrease in pre-commercialization manufacturing and clinical costs for IV meloxicam of $6.7 million, a decrease in personnel costs of $1.9 million, and a decrease in development costs for other pipeline products of $1.3 million.

General and Administrative. Our general and administrative expenses were $21.8 million and $24.2 million for the nine months ended September 30, 2019 and 2018, respectively. Excluding $4.4 million of costs associated with the strategic restructuring initiative recorded in the nine months ended September 30, 2019, the decrease of $6.8 million was due to a reduction in commercial team personnel of $5.5 million and reduced pre-commercial consulting costs of $2.5 million in preparation of the anticipated launch of IV meloxicam following the receipt of the second CRL. These decreases in costs were partially offset by increases in costs associated with the public company costs including legal fees, of $0.9 million as well as increased professional fees associated with addressing the first and second CRLs issued by the FDA regarding our NDA for IV meloxicam of $0.3 million.

Change in Contingent Consideration Valuation. Our change in contingent consideration valuation consisted of a reduction of value of $15.2 million for the nine months ended September 30, 2019 as compared to an increase in value of $7.0 million for the nine months ended September 30, 2018. The non-cash charge for contingent consideration in each period related to the revaluation of the probability adjusted fair value of the Gainesville Transaction payment obligation. The decrease of $22.2 million was due to the adjusted timing of estimated milestone and royalty payments after the receipt of the second CRL from the FDA in March 2019.

Liquidity and Capital Resources

Historically, the primary source of liquidity for our business was cash flow allocated to us from Recro. Prior to the Separation, transfers of cash to and from Recro are reflected in Net Parent Investment in the historical combined balance sheets, statements of cash flows and statements of changes in Net Parent Investment. We have not reported cash or cash equivalents for the periods presented in the combined balance sheets. We expect Recro to continue to fund our cash needs through the date of the Separation.

Under the terms of the Separation Agreement, prior to or upon the completion of the Distribution, Recro will make a cash capital contribution of $19 million to us to fund our operations. This cash capital contribution is in an amount that we estimate will, based on our current plans and expectations, meet our cash needs for at least 12 months after the completion of the Separation. Subsequent to the Separation, we will no longer participate in Recro's centralized cash management or benefit from direct funding from Recro. Our ability to fund our operations and capital needs will depend on our ability to raise additional funds through debt financings, bank or other loans, licensing, including out-licensing activities, sale of assets and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional debt or equity financing, if available, may be dilutive to the holders of our common stock and may involve significant cash payment obligations and covenants that restrict our ability to operate our business or access to capital.

We anticipate that our principal uses of cash in the future will be primarily to fund our operations, working capital needs, capital expenditures and other general corporate purposes.

Sources and Uses of Cash

Cash used in operations was $42.1 million and $46.8 million for the nine months ended September 30, 2019 and 2018, respectively, which represents our operating losses less our stock-based compensation, depreciation, changes in fair value of contingent consideration, as well as changes in operating assets and liabilities.

Cash used in investing activities was $1.8 million and $2.2 million for the nine months ended September 30, 2019 and 2018, respectively. During the nine months ended September 30, 2019 and 2018, our capital expenditures were $1.6 million and $2.1 million, respectively.

There was $43.9 million of cash provided by financing activities in the nine months ended September 30, 2019 from neproceeds of from parent company investment of $53.9 million, which was partially offset by $10.0 million of contingent consideration payments. There was $49.0 million of cash provided by financing activities in the nine months ended September 30, 2018 from net proceeds from parent company investment.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- our ability to operate as a standalone company and execute our strategic priorities;
- potential indemnification liabilities we may owe to Recro after the Separation;
- our ability to resolve the deficiencies identified by the FDA in the second CRL, for IV meloxicam;
- whether the FDA will approve an amended NDA for IV meloxicam and, if approved, the labeling under any such approval that we may obtain;
- the timing of the Gainesville Transaction regulatory milestone payments and other contingent consideration;
- the costs of manufacturing scale-up and commercialization activities, for IV meloxicam, if approved;
- the level of market acceptance of IV meloxicam, if approved;
- the extent to which we in-license, acquire or invest in products, businesses and technologies;
- our ability to raise additional funds through equity or debt financingsor sale of certain assets;
- our ability to defend the securities class action lawsuit filed against Recro, or any future material litigation filed against us;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- the effect of any changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, tax impacts and net operating loss utilization related to the Acute Care segment separation and changes in tax laws.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report, particularly under "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.

Contractual Commitments

The table below reflects our contractual commitments as of September 30, 2019:

	Payments Due by Period (in 000s)				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Purchase Obligations (1):	$ 4,863	$ 1,816	$ —	$ —	$ —
Operating Leases (2)	1,257	434	730	93	—
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (3), (4)	52,265	40	130	170	225
Alkermes Payments (5)	130,000	—	—	—	—
Employment Agreements (6)	624	624	—	—	—
Total Contractual Obligations	$ 189,009	$ 2,914	$ 860	$ 263	$ 225

(1) These obligations consist of cancelable and non-cancelable purchase commitments related to capital expenditures and other goods or services. The timing of certain purchase commitments cannot be estimated as it is dependent on timing of FDA approval or the outcome of other strategic evaluations. In accordance with U.S. GAAP, these obligations are not recorded on our Combined Balance Sheets. See Note 10(e) to the Combined Financial Statements included in this Quarterly Report on Form 10-Q.

(2) We have become party to certain operating leases for the leased space in Malvern, Pennsylvania, and Dublin, Ireland, as well as for office equipment, for which the minimum lease payments are presented.

(3) We are party to exclusive licenses with Orion for the development and commercialization of certain pipeline product candidates, under which we may be required to make certain milestone and royalty payments to Orion. See Note 5 and Note 10(a) to the Combined Financial Statements included in the Form 10-Q. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, these obligations are not recorded on our Combined Balance Sheets.

(4) We license the neuromuscular blocking agents, or NMBAs, from Cornell University pursuant to a license agreement under which we are obligated to make annual license maintenance fee payments, milestone payments and patent cost payments and to pay royalties on net sales of the NMBAs. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of certain of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, certain of these obligations are not recorded on our Combined Balance Sheets. See Note 5 and 10(a) to the Combined Financial Statements included in this Form 10-Q.

(5) Pursuant to the purchase and sale agreement governing the Gainesville Transaction, we agreed to pay to Alkermes milestone and royalty payments. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of these payments because they are in some instances, events that are not in our control and dependent on the commercial success of the product. In accordance with U.S. GAAP, the fair value of these obligations is recorded as contingent consideration on our Combined Balance Sheets. See Note 4 and Note 10(b) to the Combined Financial Statements included in this Form 10-Q.

(6) We have entered into employment agreements with certain of our named executive officers. As of September 30, 2019, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than this amount, from that date through June 2020. In accordance with U.S. GAAP, these obligations are not recorded on our Combined Balance Sheets. See Note 10 (f) to the Combined Financial Statements included in this Form 10-Q.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are disclosed in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of the Form 10. In the nine months ended September 30, 2019, there were no significant changes to the application of critical accounting policies previously disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Information Statement.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of September 30, 2019. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our 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 for timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of September 30, 2019, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

We are involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. Except as disclosed below, we are not currently a party to any such claims or proceedings that, if decided adversely to it, would either individually or in the aggregate have a material adverse effect on its business, financial condition or results of operations.

On May 31, 2018, a securities class action lawsuit was filed against Recro and certain of Recro's officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by us concerning the NDA for IV meloxicam. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. On December 10, 2018, lead plaintiff filed an amended complaint that asserted the same claims and sought the same relief but included new allegations and named additional officers and directors as defendants. On February 8, 2019, Recro filed a motion to dismiss the amended complaint in its entirety, which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, the Company filed its response and briefing was completed on the motion to dismiss. On June 26, 2019, the judge heard oral arguments on the motion to dismiss. The judge asked the plaintiffs to file a supplemental brief, which was completed on August 30, 2019, and Recro submitted a reply brief on September 27, 2019. As part of the Separation, we are assuming all liabilities related to this litigation from Recro. We believe that the lawsuit is without merit and intends to vigorously defend against it. The lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us.

Item 1A. Risk Factors.

Information regarding risk factors appears in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Information Related to Forward-Looking Statements," in Part I – Item 2 of this Form 10-Q and in the "Risk Factors" section of the Form 10. Except as set forth below, there were no material changes during the quarter ended September 30, 2019 to the risk factors reported in the "Risk Factors" section of the Information Statement.

Our appeal relating to the NDA for IV Meloxicam has been granted, however, there can be no certainty that our proposed labeling will address the FDA's concerns in order to successfully commercialize IV meloxicam.

In July 2017 we submitted an NDA for IV meloxicam for the management of moderate to severe pain to the FDA. On May 23, 2018, we received a CRL from the FDA regarding the NDA, which stated that the FDA determined it could not approve the NDA in its present form. In October 2019 we received written notification from the FDA that our appeal relating to the NDA seeking approval for IV meloxicam has been granted. The FDA's letter states that the appeal was granted and that the NDA provides sufficient evidence of effectiveness and safety to support approval. We are working to prepare a comprehensive response to the FDA that includes refiling the NDA with proposed labeling that addresses the FDA's concerns and to provide the relevant evidence from the filed NDA that supports the proposed label, but there can be no guarantee that we will be able to do so in a timely manner, or at all. In addition, if the approved labeling of IV meloxicam is for a more limited indication or different dosing interval than we originally requested, our ability to market to our full target market may be reduced. We could need to significantly revise our launch and commercialization strategy, which could delay commercial launch of IV meloxicam, if approved, and could significantly limit our ability to realize the full market potential of IV meloxicam. The approved labeling could decrease the target market to a point where we would be unable to achieve profitability from IV meloxicam, in which case we may be forced to limit or discontinue the commercialization of IV meloxicam, or seek a collaboration partner for the commercialization of IV meloxicam, all of which would have an adverse impact on our business.

Should we fail to obtain regulatory approval of IV meloxicam, we may be forced to rely on our other product candidates, which are at an earlier development stage and will require significant additional time and resources to obtain regulatory approval and proceed with commercialization.

Our planned spin-off from Recro is subject to various risks and uncertainties and may not be completed on the terms or timeline currently contemplated, if at all, and will involve significant time, effort and expense, which could harm our business, results of operations and financial condition.

In November 2019, Recro announced the intent to spin-off its acute care segment from its CDMO segment, resulting in two independent, publicly traded companies, Recro Pharma, Inc. and Baudax Bio, Inc. The separation of its business segments is expected to be completed in the fourth quarter of 2019 and is subject to the satisfaction of certain conditions. Adverse market conditions or delays or difficulties effecting the planned separation could delay or prevent, or adversely impact the anticipated benefits from, the planned separation. We may not complete the separation on the terms or on the timeline that we announced, or may, for any or no reason and at any time until the planned separation is complete, abandon the separation or modify or change its terms. Any of the foregoing may result in our not achieving the operational, financial, strategic and other benefits we anticipate, and in each case, our business, results of operations and financial condition could be adversely affected.

We have incurred and will continue to incur significant expenses in connection with the planned separation, and such costs and expenses may be greater than we anticipate. In addition, completion of the spin-off will require a significant amount of management time

and effort which may disrupt our business or otherwise divert management's attention from other aspects of our business. Any of the foregoing could adversely affect our business, results of operations and financial condition.

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.

(a) The following exhibits are filed herewith or incorporated by reference herein:

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial and Accounting Officer.	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101 INS	XBRL Instance Document	Filed herewith.
101 SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101 CAL	XBRL Taxonomy Extension Calculation Linkbase	Filed herewith.
101 DEF	XBRL Taxonomy Extension Definition Linkbase	Filed herewith.
101 LAB	XBRL Taxonomy Extension Label Linkbase	Filed herewith.
101 PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

SIGNATURES

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

BAUDAX BIO, INC.

Date: November 14, 2019

By: /s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2019

By: /s/ Ryan D. Lake
Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Gerri A. Henwood, certify that:

1. I have reviewed this Quarterly Report of Baudax Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2019

/s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Ryan D. Lake, certify that:

1. I have reviewed this Quarterly Report of Baudax Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2019

/s/ Ryan D. Lake
Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Baudax Bio, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2019

/s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Ryan D. Lake
Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)