

Innoviva, Inc.
Form 10-Q
October 31, 2018
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

OR

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

For the transition period from _____ to _____

Commission File Number: 000-30319

INNOVIVA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

94-3265960
(I.R.S. Employer
Identification No.)

2000 Sierra Point Parkway, Suite 500

Brisbane, CA 94005

(Address of Principal Executive Offices)

(650) 238-9600

(Registrant's Telephone Number, Including Area Code)

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Edgar Filing: Innoviva, Inc. - Form 10-Q

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

The number of shares of registrant's common stock outstanding on October 25, 2018 was 101,039,707.

Table of Contents

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

<u>Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2018 and 2017</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income for the Three and Nine Months Ended September 30, 2018 and 2017</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7

<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
--	----

<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	22
---	----

<u>Item 4. Controls and Procedures</u>	22
--	----

PART II. OTHER INFORMATION

<u>Item 1. Legal Proceedings</u>	23
----------------------------------	----

<u>Item 1A. Risk Factors</u>	23
------------------------------	----

<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
--	----

<u>Item 6. Exhibits</u>	23
-------------------------	----

<u>Signatures</u>	24
-------------------	----

Exhibits

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****INNOVIVA, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands, except per share data)

	September 30, 2018 (unaudited)	December 31, 2017 *
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,615	\$ 73,336
Short-term marketable securities	6,865	55,739
Related party receivables from collaborative arrangements	65,136	70,540
Prepaid expenses and other current assets	513	754
Total current assets	121,129	200,369
Property and equipment, net	173	209
Capitalized fees paid to a related party, net	156,354	166,722
Other assets	37	37
Total assets	\$ 277,693	\$ 367,337
Liabilities and Stockholders Deficit		
Current liabilities:		
Accounts payable	\$ 109	\$ 601
Accrued personnel-related expenses	1,550	1,721
Accrued interest payable	1,775	5,920
Other accrued liabilities	865	1,500
Current portion of long-term debt		25,000
Total current liabilities	4,299	34,742
Long-term debt, net of current portion, discount and issuance costs	381,002	574,362
Other long-term liabilities	668	940
Commitments and contingencies		
Stockholders deficit:		
Preferred stock: \$0.01 par value, 230 shares authorized, no shares issued and outstanding		
Common stock: \$0.01 par value, 200,000 shares authorized, 101,189 and 102,046 shares issued as of September 30, 2018 and December 31, 2017, respectively	1,011	1,019
Treasury stock: 150 shares as of September 30, 2018 and December 31, 2017	(3,263)	(3,263)
Additional paid-in capital	1,258,350	1,258,151
Accumulated other comprehensive loss	(3)	(18)
Accumulated deficit	(1,367,452)	(1,498,748)
Total Innoviva stockholders deficit	(111,357)	(242,859)
Noncontrolling interest	3,081	152
Total stockholders deficit	(108,276)	(242,707)
Total liabilities and stockholders deficit	\$ 277,693	\$ 367,337

Edgar Filing: Innoviva, Inc. - Form 10-Q

*Condensed consolidated balance sheet as of December 31, 2017 has been derived from audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

Table of Contents

INNOVIVA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Royalty revenue from a related party, net of amortization of capitalized fees paid to a related party of \$3,456 in the three months ended September 30, 2018 and 2017 and \$10,368 in the nine months ended September 30, 2018 and 2017	\$ 61,680	\$ 48,422	\$ 181,146	\$ 147,034
Revenue from collaborative arrangements from a related party		221		663
Total net revenue	61,680	48,643	181,146	147,697
Operating expenses:				
Research and development		311		1,013
General and administrative	4,019	8,310	17,415	29,489
General and administrative - related party			2,700	
Total operating expenses	4,019	8,621	20,115	30,502
Income from operations	57,661	40,022	161,031	117,195
Other expense, net	(2,626)	(6,369)	(5,686)	(7,108)
Interest income	370	376	1,141	918
Interest expense	(5,238)	(10,262)	(19,373)	(35,247)
Net income	50,167	23,767	137,113	75,758
Net income attributable to noncontrolling interest	3,078		5,817	
Net income attributable to Innoviva stockholders	\$ 47,089	\$ 23,767	\$ 131,296	\$ 75,758
Basic net income per share attributable to Innoviva stockholders	\$ 0.47	\$ 0.22	\$ 1.30	\$ 0.71
Diluted net income per share attributable to Innoviva stockholders	\$ 0.43	\$ 0.21	\$ 1.19	\$ 0.67
Shares used to compute Innoviva basic and diluted net income per share:				
Shares used to compute basic net income per share	100,936	106,841	100,806	107,236
Shares used to compute diluted net income per share	113,363	119,796	113,444	120,120

See accompanying notes to condensed consolidated financial statements.

Table of Contents

INNOVIVA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income	\$ 50,167	\$ 23,767	\$ 137,113	\$ 75,758
Unrealized income (loss) on marketable securities, net	7	(3)	15	(4)
Comprehensive income	50,174	23,764	137,128	75,754
Comprehensive income attributable to noncontrolling interest	3,078		5,817	
Comprehensive income attributable to Innoviva stockholders	\$ 47,096	\$ 23,764	\$ 131,311	\$ 75,754

See accompanying notes to condensed consolidated financial statements.

Table of Contents

INNOVIVA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities		
Net income	\$ 137,113	\$ 75,758
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	10,404	10,487
Stock-based compensation	2,747	7,406
Amortization of debt discount and issuance costs	5,895	2,953
Loss on extinguishment of debt	5,745	7,256
Amortization of discount on short-term investments	(224)	(6)
Amortization of lease guarantee	(243)	(243)
Changes in operating assets and liabilities:		
Receivables from collaborative arrangements	5,404	(5,031)
Prepaid expenses and other current assets	241	327
Accounts payable	(492)	501
Accrued personnel-related expenses and other accrued liabilities	(695)	(606)
Accrued interest payable	(4,145)	(4,262)
Other long-term liabilities	4	13
Deferred revenue		(663)
Net cash provided by operating activities	161,754	93,890
Cash flows from investing activities		
Maturities of marketable securities	71,375	44,387
Purchases of marketable securities	(22,262)	(41,743)
Net cash provided by investing activities	49,113	2,644
Cash flows from financing activities		
Repurchase of shares to satisfy tax withholding	(3,082)	(1,183)
Payments of principal on senior secured term loans	(230,000)	
Payments of cash dividends to stockholders	(72)	(146)
Proceeds from issuances of common stock, net	454	188
Proceeds from issuance of convertible senior notes due 2025		192,500
Proceeds from senior secured term loans		250,000
Payments of debt issuance costs and debt discount		(12,803)
Payments of principal on non-recourse notes due 2029		(487,189)
Repurchase of common stock		(17,500)
Distributions to noncontrolling interest	(2,888)	
Net cash used in financing activities	(235,588)	(76,133)
Net increase (decrease) in cash and cash equivalents	(24,721)	20,401
Cash and cash equivalents at beginning of period	73,336	118,016
Cash and cash equivalents at end of period	\$ 48,615	\$ 138,417
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 17,622	\$ 36,556

See accompanying notes to condensed consolidated financial statements.

Table of Contents

INNOVIVA, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Description of Operations and Summary of Significant Accounting Policies

Description of Operations

Innoviva, Inc. (referred to as *Innoviva*, the *Company*, or *we* and other similar pronouns) is focused on royalty management. Innoviva's portfolio includes the respiratory assets partnered with Glaxo Group Limited (*GSK*), including RELVAR®/BREO®ELLIPTA® (fluticasone furoate/ vilanterol, *FF/VI*), ANORO® ELLIPTA®(umeclidinium bromide/ vilanterol, *UMEC/VI*) and TRELEGY® ELLIPTA® (the combination *FF/UMEC/VI*). Under the Long-Acting Beta2 Agonist (*LABA*) Collaboration Agreement, Innoviva is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. Innoviva is also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to our consolidated variable interest entity, Theravance Respiratory Company, LLC (*TRC*), relating to TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the *GSK Agreements*), which have been assigned to TRC other than RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (*GAAP*) for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In our opinion, the unaudited condensed consolidated financial statements have been prepared on the same basis as audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of our financial position, results of operations, comprehensive income and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2018 or any other period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission (*SEC*) on February 23, 2018 (*2017 Form 10-K*).

Variable Interest Entity

We evaluate our ownership, contractual and other interest in entities to determine if they are variable interest entities (VIE), whether we have a variable interest in those entities and the nature and extent of those interests. Based on our evaluations, if we determine we are the primary beneficiary of such VIEs, we consolidate such entities into our financial statements. We consolidate the financial results of TRC, which we have determined to be a VIE, because we have the power to direct the economically significant activities of TRC and the obligation to absorb losses of, or the right to receive benefits from, TRC. As of September 30, 2018, \$3.6 million of the related party receivable from collaborative arrangements was attributable to TRC.

Accounting Pronouncement Adopted by the Company

In April 2016, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) 2016-10 to clarify the implementation guidance on licensing and the identification of performance obligations consideration included in ASU 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which is also known as ASC 606, was issued in May 2014 and outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. In March 2016, the FASB issued ASU 2016-08 to provide amendments to clarify the implementation guidance on principal versus agent considerations. We implemented the standard on the effective date of January 1, 2018 on a modified retrospective basis to contracts which were not completed as of this date. Adoption of this standard did not have a material impact on our consolidated financial statements as we did not have any unrecognized transaction price, other than sales-based royalty revenue, or any remaining performance obligations under our collaboration agreements. We continue to recognize royalty revenue when it is earned.

Table of Contents**Recently Issued Accounting Pronouncement Not Yet Adopted**

In February 2016, the FASB issued ASU 2016-02, *Leases*, which supersedes the lease recognition requirements in ASC Topic 840, *Leases*. The standard requires an entity to recognize right-of-use assets and lease liabilities arising from a lease for both financing and operating leases in the consolidated balance sheets but recognize the impact on the consolidated statement of operations and cash flows in a similar manner under current GAAP. The standard also requires additional qualitative and quantitative disclosures. The standard is effective for us at the beginning January 1, 2019 and requires transition under a modified retrospective method. The most significant impact of the update to us is that we will be required to recognize a right-of-use asset and lease liability for the operating lease agreement that was not previously included on the balance sheet under the existing lease guidance. We anticipate that our consolidated statement of operations and cash flows will not materially be affected by the adoption of the new standard.

2. Net Income Per Share

Basic net income per share attributable to Innoviva stockholders is computed by dividing net income attributable to Innoviva stockholders by the weighted-average number of shares of common stock outstanding. Diluted net income per share attributable to Innoviva stockholders is computed by dividing net income attributable to Innoviva stockholders by the weighted-average number of shares of common stock and dilutive potential common stock equivalents then outstanding. Dilutive potential common stock equivalents include the assumed exercise, vesting and issuance of employee stock awards using the treasury stock method, as well as common stock issuable upon assumed conversion of our convertible subordinated notes due 2023 (the 2023 Notes) using the if-converted method.

Our convertible senior notes due 2025 (the 2025 Notes) are convertible, based on the applicable conversion rate, into cash, shares of our common stock or a combination thereof, at our election. Our current intent is to settle the principal amount of the 2025 Notes in cash upon conversion. The impact of the assumed conversion premium to diluted net income per share is computed using the treasury stock method. As the average market price per share of our common stock as reported on The Nasdaq Global Select Market during the relevant periods was lower than the initial conversion price of \$17.26 per share, there was no dilutive effect of the assumed conversion premium for the three and nine months ended September 30, 2018.

The following table shows the computation of basic and diluted net income per share for the three and nine months ended September 30, 2018 and 2017:

(In thousands except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net income attributable to Innoviva stockholders, basic	\$ 47,089	\$ 23,767	\$ 131,296	\$ 75,758
Add: interest expense on 2023 Notes	1,413	1,410	4,242	4,231
Net income attributable to Innoviva stockholders, diluted	\$ 48,502	\$ 25,177	\$ 135,538	\$ 79,989

Edgar Filing: Innoviva, Inc. - Form 10-Q

Denominator:

Weighted-average shares used to compute basic net income per share attributable to Innoviva

stockholders	100,936	106,841	100,806	107,236
--------------	---------	---------	---------	---------

Dilutive effect of 2023 Notes	12,189	12,189	12,189	12,189
-------------------------------	--------	--------	--------	--------

Dilutive effect of options and awards granted under equity incentive plan and employee stock purchase plan	238	766	449	695
--	-----	-----	-----	-----

Weighted-average shares used to compute diluted net income per share attributable to Innoviva

stockholders	113,363	119,796	113,444	120,120
--------------	---------	---------	---------	---------

Net income per share attributable to Innoviva stockholders

Basic	\$	0.47	\$	0.22	\$	1.30	\$	0.71
-------	----	------	----	------	----	------	----	------

Diluted	\$	0.43	\$	0.21	\$	1.19	\$	0.67
---------	----	------	----	------	----	------	----	------

Table of Contents*Anti-Dilutive Securities*

The following common stock equivalents were not included in the computation of diluted net income per share because their effect was anti-dilutive:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Outstanding options and awards granted under equity incentive plan and employee stock purchase plan	1,557	1,779	1,561	2,287

3. Revenue Recognition and Collaborative Arrangements

Revenue is recognized when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. Revenue is recognized through a five-step process: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price for the contract; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied. We recognize the royalty revenue on licensee net sales of products with respect to which we have contractual royalty rights in the period in which the royalties are earned and reported to us. Royalties are recognized net of amortization of capitalized fees associated with any approval and launch milestone payments made to GSK.

Net Revenue from Collaborative Arrangements

Net revenue recognized under our GSK Agreements was as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Royalties from a related party - RELVAR/BREO	\$ 51,745	\$ 44,604	\$ 155,420	\$ 137,938
Royalties from a related party - ANORO	9,769	7,274	29,149	19,464
Royalties from a related party - TRELEGY	3,622		6,945	
Total royalties from a related party	65,136	51,878	191,514	157,402
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)	(10,368)	(10,368)
Royalty revenue	61,680	48,422	181,146	147,034
Strategic alliance - MABA program license		221		663
Total net revenue from GSK	\$ 61,680	\$ 48,643	\$ 181,146	\$ 147,697

4. Available-for-Sale Securities and Fair Value Measurements

Available-for-Sale Securities

The estimated fair value of available-for-sale securities is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service. Available-for-sale securities are summarized below:

(In thousands)	Amortized Cost	September 30, 2018		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. corporate notes	\$ 3,876	\$	\$ (3)	\$ 3,873
U.S. commercial paper	7,988			7,988
Money market funds	38,685			38,685
Total	\$ 50,549	\$	\$ (3)	\$ 50,546

Table of Contents

(In thousands)	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	\$ 9,943	\$	\$ (1)	\$ 9,942
U.S. government agencies	9,987		(2)	9,985
U.S. corporate notes	10,881		(15)	10,866
U.S. commercial papers	29,945			29,945
Money market funds	61,971			61,971
Total	\$ 122,727	\$	\$ (18)	\$ 122,709

As of September 30, 2018, all of the available-for-sale securities had contractual maturities within one year and the weighted average maturity of marketable securities was approximately one month.

Fair Value Measurements

Our available-for-sale securities are measured at fair value on a recurring basis and our debt is carried at the amortized cost basis. The estimated fair values were as follows:

Types of Instruments (In thousands)	Estimated Fair Value Measurements as of September 30, 2018 Using:				Total
	Quoted Price in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs		
	Level 1	Level 2	Level 3		
<i>Assets</i>					
U.S. corporate notes	\$	\$ 3,873	\$	\$	3,873
U.S. commercial paper		7,988			7,988
Money market funds	38,685				38,685
Total assets measured at estimated fair value	\$ 38,685	\$ 11,861	\$	\$	50,546
<i>Debt</i>					
Term B Loan	\$	\$ 13,750	\$	\$	13,750
2023 Notes		247,310			247,310
2025 Notes		211,917			211,917
Total fair value of debt	\$	\$ 472,977	\$	\$	472,977

Table of Contents

Estimated Fair Value Measurements as of December 31, 2017 Using:

Types of Instruments (In thousands)	Quoted Price in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
<i>Assets</i>				
U.S. government securities	\$	\$ 9,942	\$	\$ 9,942
U.S. government agencies		9,985		9,985
U.S. corporate notes		10,866		10,866
U.S. commercial papers		29,945		29,945
Money market funds	61,971			61,971
Total assets measured at estimated fair value	\$ 61,971	\$ 60,738	\$	\$ 122,709
<i>Debt</i>				
Term B Loan	\$	\$ 243,750	\$	\$ 243,750
2023 Notes		241,259		241,259
2025 Notes		205,975		205,975
Total fair value of debt	\$	\$ 690,984	\$	\$ 690,984

The fair value of our marketable securities classified within Level 2 is based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data, including market research publications.

The fair value of our 2023 Notes and of our 2025 Notes is based on recent trading prices of the instruments. The carrying amount of our initial senior secured term loan (the Term B Loan) before deducting debt issuance costs approximates fair value as the loan carries a variable interest rate that is tied to the LIBOR rate plus an applicable spread.

5. Stock-Based Compensation

Market-Based RSAs and RSUs

2016 Market-Based RSAs and RSUs

On January 14, 2016, the Compensation Committee approved and granted 282,394 RSAs and 46,294 RSUs to senior management. These awards include a market condition based on Total Shareholder Return (TSR) and a service condition that requires continued employment.

In February 2018, the Compensation Committee certified the maximum achievement of the TSR as of the first measurement date, January 12, 2018. 69,440 RSAs and 30,862 RSUs representing two-thirds of the amounts were released on February 20, 2018. In connection with the separation of certain members of senior management from the Company in early February 2018, the Board agreed to accelerate the vesting and distribution of an aggregate of 118,821 RSAs to these members of senior management. The remaining 59,411 RSAs for these members of senior management were forfeited. As a net result of the vesting acceleration of the RSAs and the forfeiture of those unvested RSAs, an additional \$0.7 million compensation expense was recognized during the three months ended March 31, 2018.

Edgar Filing: Innoviva, Inc. - Form 10-Q

During the three months ended September 30, 2018, the remaining 34,721 RSAs and 15,432 RSUs were forfeited due to the additional separation of senior management members, and \$0.2 million of previously recognized compensation expense was reversed.

2017 Market-Based RSAs and RSUs

On January 17, 2017, the Compensation Committee approved and granted 353,508 RSAs and 53,360 RSUs to senior management. These awards include a market condition based on the TSR of Innoviva's common stock as compared to the TSR of NASDAQ Biotechnology Index (Index) and a service condition that requires continued employment.

Table of Contents

In connection with the separation of certain members of senior management from the Company in February 2018, an aggregate of 233,448 RSAs were forfeited, and \$0.8 million of previously recognized compensation expense was reversed during the three months ended March 31, 2018.

In connection with the separation of additional members of senior management from the Company during the three months ended September 30, 2018, the remaining 120,060 RSAs and 53,360 RSUs were forfeited, and \$0.9 million of previously recognized compensation expense was reversed.

2018 Market-Based RSAs and RSUs

On March 2, 2018, the Compensation Committee approved and granted 111,668 RSAs and 49,630 RSUs to senior management. These awards include a market condition based on the TSR of Innoviva's common stock over a three-year performance period from the date of grant for the RSAs and from the date of grant until September 30, 2020 for RSUs, and a service condition that requires continued employment. The grant date fair value of these awards was determined using a Monte Carlo valuation model. The aggregate value of \$1.7 million was recognized as compensation expense over the implied service period and were not reversed if the market condition was not met, but with the exception of such person's continued employment with the Company.

In connection with the separation of the senior management members from the Company during the three months ended September 30, 2018, all of 111,668 RSAs and 49,630 RSUs were forfeited, and \$0.2 million of previously recognized compensation expense was reversed.

Stock-Based Compensation Expense

Stock-based compensation expense is included in the condensed consolidated statements of operations as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,			
	2018	2017	2018	2017		
Research and development	\$	\$	180	\$	533	
General and administrative		(874)	2,292	2,747	6,873	
Total stock-based compensation expense	\$	(874)	\$	2,472	\$	7,406

For the three months ended September 30, 2018, \$1.9 million of stock based compensation was reversed for the forfeited market based awards and service based awards noted above due to the separation of senior management members.

As of September 30, 2018, unrecognized stock-based compensation cost was as follows:

Edgar Filing: Innoviva, Inc. - Form 10-Q

(In thousands)	Unrecognized Compensation Cost	
RSUs	\$	1,044
RSAs		872
Total unrecognized compensation cost	\$	1,916

Table of Contents**6. Debt**

Our debt consists of:

(In thousands)	September 30, 2018	December 31, 2017
Term B Loan	\$ 13,750	\$ 243,750
2023 Notes	240,984	240,984
2025 Notes	192,500	192,500
Total debt	447,234	677,234
Unamortized debt discount and issuance costs	(66,232)	(77,872)
Current portion of Term B Loan		(25,000)
Net long-term debt	\$ 381,002	\$ 574,362

Prepayments of Senior Secured Term Loans

On February 28 and August 1, 2018, we prepaid the principal balance of the Term B Loan by \$120.0 million and \$110.0 million, respectively. With the prepayments, we incurred a loss on the extinguishment of debt of \$3.1 million and \$2.6 million, respectively, representing unamortized debt issuance costs. The loss on the extinguishment of debt is presented as part of other expense, net in our consolidated statements of operations. As of September 30, 2018, the outstanding principal balance of the Term B Loan was \$13.8 million.

Convertible Senior Notes Due 2025

In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of the 2025 Notes by allocating the proceeds between the liability component and the embedded conversion option (equity component) due to our ability to settle the conversion obligation of the 2025 Notes in cash, common stock or a combination of cash and common stock, at our option. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature using the income approach. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the 2025 Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2025 Notes and the fair value of the liability of the 2025 Notes on the date of issuance. The excess of the principal amount of the liability component over its carrying amount (debt discount) is amortized to interest expense using the effective interest method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

Our outstanding 2025 Notes balances as of September 30, 2018, consisted of the following:

(In thousands)	
Liability component	
Principal	\$ 192,500
Debt discount and issuance costs, net	(63,460)

Edgar Filing: Innoviva, Inc. - Form 10-Q

Net carrying amount	\$	129,040
Equity component, net	\$	65,361

In connection with the issuance of the 2025 Notes, we incurred approximately \$5.4 million of debt issuance costs, which primarily consisted of placement, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total \$5.4 million of debt issuance costs, \$1.9 million were allocated to the equity component and recorded as a reduction to additional paid-in capital and \$3.5 million were allocated to the liability component and recorded as a reduction to the carrying amount of the liability component on the consolidated balance sheet. The portion allocated to the liability component is amortized to interest expense over the expected life of the 2025 Notes using the effective interest method.

Edgar Filing: Innoviva, Inc. - Form 10-Q

Table of Contents

The following table sets forth total interest expense recognized related to the 2025 Notes for the three and nine months ended September 30, 2018 and 2017:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Contractual interest expense	\$ 1,203	\$ 722	\$ 3,596	\$ 722
Amortization of debt issuance costs	127	69	375	69
Amortization of debt discount	1,532	834	4,507	834
Total interest and amortization expense	\$ 2,862	\$ 1,625	\$ 8,478	\$ 1,625

Debt Maturities

The aggregate scheduled maturities of our long-term debt (consisting of our Term B Loan, 2023 Notes and 2025 Notes) as of September 30, 2018, are as follows:

(In thousands)	
Years ending December 31:	
2018 to 2021	\$
2022	13,750
Thereafter	433,484
Total	\$ 447,234

7. Related Party Transaction

On February 12, 2018, the Company entered into an agreement with Sarissa Capital Management LP, and certain of its affiliates (collectively, the Sarissa Group) related to the Company's 2018 Annual Meeting of Stockholders (the 2018 Annual Meeting). The agreement provided for, among other things, the concurrent appointment of three designees of the Sarissa Group as members of the Company's Board of Directors and an agreement to recommend and nominate a five-person slate of directors for election at the 2018 Annual Meeting composed of the three new directors and two current directors of the Company and partially reimburse the Sarissa Group \$2.7 million for expenses, which reimbursement obligation relating to the 2018 Annual Meeting arose upon execution of the agreement. The Sarissa Group is considered to be a related party due to its representation on the Board of Directors.

8. Income Taxes

There was no income tax expense for the three and nine months ended September 30, 2018. Should we continue to generate taxable income in 2018, we expect that the taxable income will be substantially offset by the utilization of net operating losses or other deferred tax assets, and potential release of valuation allowance. The difference between the consolidated effective income tax rate and the U.S. federal statutory rate is primarily attributable to a change in valuation allowance against net deferred tax assets.

Table of Contents

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

Forward-Looking Statements

The information in this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements contained herein that are not of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives, may be forward-looking statements. The words anticipates, believes, could, designed, estimates, expects, goal, intends, may, objective, plans, projects, pursue, will, would and similar expressions thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Important factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, risks related to: lower than expected future royalty revenue from respiratory products partnered with GSK; the commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA® in the jurisdictions in which these products have been approved; the strategies, plans and objectives of the Company (including the Company's growth strategy and corporate development initiatives beyond the existing respiratory portfolio); the timing, manner, amount and planned growth of anticipated potential capital returns to stockholders (including, without limitation, statements regarding the Company's expectations of future purchases under its future share repurchase authorizations and future cash dividends); the status and timing of clinical studies, data analysis and communication of results; the potential benefits and mechanisms of action of product candidates; expectations for product candidates through development and commercialization; the timing of regulatory approval of product candidates; projections of revenue, expenses and other financial items; and risks discussed in "Risk Factors" in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 23, 2018 ("2017 Form 10-K") and Item 1A of Part II of our Quarterly Reports on Form 10-Q and below in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Item 2 of Part I. All forward-looking statements in this document are based on information available to us as of the date hereof and we assume no obligation to update any such forward-looking statements on account of new information, future events or otherwise, except as required by law.

We encourage you to read our consolidated financial statements contained in this Quarterly Report on Form 10-Q. We also encourage you to read Item 1A of Part I of our 2017 Form 10-K and Item 1A of Part II of our Quarterly Reports on Form 10-Q entitled "Risk Factors," which contain a more complete discussion of the risks and uncertainties associated with our business. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission (SEC) from time to time, including on Form 10-K, Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

OVERVIEW

Executive Summary

Innoviva, Inc. (Innoviva , the Company or we) is focused on the management of royalty revenues from RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, FF/VI), ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, UMEC/VI) and TRELEGY® ELLIPTA® (the combination FF/UMEC/VI). Under the Long-Acting Beta2 Agonist (LABA) Collaboration Agreement, we are entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion; and royalties from the sales of ANORO® ELLIPTA® which tier upward at a range from 6.5% to 10%. Innoviva is also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC (TRC), including TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered or developed in the future under the LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the GSK Agreements), which have been assigned to TRC other than RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

Our company structure and organization are tailored to our focused activities of managing our respiratory assets with GSK, the commercial and developmental obligations associated with the GSK Agreements, intellectual property, licensing operations, business development activities and providing for certain essential reporting and management functions of a public company. As of September 30, 2018, we had six employees. Our revenues consist of royalties from our respiratory partnership agreements with GSK.

Table of Contents

Recent Highlights

- GSK Net Sales:

- Third quarter 2018 net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$345.0 million, up 16.0% from \$297.4 million in the third quarter of 2017, with \$180.4 million in net sales from the U.S. market and \$164.6 million from non-U.S. markets.

- Third quarter 2018 net sales of ANORO® ELLIPTA® by GSK were \$150.8 million, up 34.7% from \$111.9 million in the third quarter of 2017, with \$99.7 million net sales from the U.S. market and \$51.1 million from non-U.S. markets.

- Third quarter 2018 net sales of TRELEGY® ELLIPTA® by GSK were \$55.7 million with \$41.3 million in net sales from the U.S. market and \$14.4 million in net sales from non-U.S. markets. TRELEGY® ELLIPTA® was approved in September 2017.

- Product Updates:

- In September 2018, European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion supporting the expanded label of TRELEGY® ELLIPTA® (fluticasone furoate/umeclidinium/ vilanterol FF/UMEC/VI) in chronic obstructive pulmonary disease (COPD).

- Capital Structure:

- Made a partial prepayment in August 2018 of \$110.0 million on the principal amount outstanding under the Company's Term B loan.

Collaborative Arrangements with GSK

LABA Collaboration

In November 2002, we entered into our LABA Collaboration Agreement with GSK to develop and commercialize once-daily LABA products for the treatment of chronic obstructive pulmonary disease (COPD) and asthma. The collaboration has developed three combination products: (1) RELVAR®/BREO® ELLIPTA® (FF/VI) (BREO® ELLIPTA® is the proprietary name in the U.S. and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF), (2) ANORO® ELLIPTA® (UMEC/VI), a once-daily medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI and (3) TRELEGY® ELLIPTA®, fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI), a once-daily combination medicine consisting of an ICS, LAMA and LABA.

As a result of the launch and approval of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe, in accordance with the LABA Collaboration Agreement, we paid milestone fees to GSK totaling \$220.0 million during the year ended December 31, 2014. The milestone fees paid to GSK were recognized as capitalized fees paid to a related party, which are being amortized over their estimated useful lives commencing upon the commercial launch of the products.

2004 Strategic Alliance

In March 2004, we entered into the Strategic Alliance Agreement with GSK where GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Innoviva-discovered preclinical MABA compounds (the Additional MABAs). The development program has been funded in full by GSK. GSK is in the process of determining next steps for the program. For a detailed discussion of our alliance with GSK, see Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our 2017 Form 10-K.

Critical Accounting Policies and Estimates

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

Table of Contents

Revenue recognition

In May 2014, the FASB issued a new comprehensive revenue recognition standard, ASC 606. We adopted this standard on January 1, 2018 on a modified retrospective basis. Under the new guidance, revenue is recognized when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. Revenue is recognized through a five-step process: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price for the contract; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The adoption of ASC 606 did not have a material impact on our consolidated financial statements as we do not have any unrecognized transaction price, other than sales-based royalty revenue, or any remaining performance obligations under our collaboration agreements. We continue to recognize the royalty revenue on licensee net sales of products with respect to which we have contractual royalty rights in the period in which the royalties are earned and reported to us. Royalties are recognized net of amortization of capitalized fees associated with any approval and launch milestone payments made to GSK.

Income tax valuation allowance

As of December 31, 2017, we had federal net operating loss carryforwards of approximately \$1.0 billion and federal research and development tax credit carryforwards of approximately \$45.2 million. As of September 30, 2018, the Company continues to maintain a full valuation allowance on its gross deferred taxes. In assessing whether a valuation allowance is required against the deferred tax assets, the Company has considered the positive and negative evidence as well as sources of taxable income in assessing the realizability of the deferred tax assets. Realization of the deferred tax assets is dependent on future taxable income. We have considered our 3-year cumulative income position as well as strategic options available to the Company that may raise uncertainty regarding continued profitability. Provided that Innoviva continues to generate profits in future quarters and also narrows its strategic options to exclude those that raise uncertainty regarding future profitability, it is reasonably possible that the valuation allowance on the federal deferred tax assets could be removed in the near term. This change in estimate on the realization of the deferred tax asset could result in an income tax benefit of approximately \$0.2 billion in the period of change.

Utilization of net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code Section 382. Annual limitations may result in expiration of net operating loss and tax credit carryforwards before some or all of such amounts have been utilized. The Company conducted a Section 382 analysis through December 31, 2017 to determine whether an ownership change had occurred since inception. The Section 382 study concluded that it is more likely than not that the Company did not experience an ownership change during the testing period. However, notwithstanding the applicable annual limitations, no portion of the net operating loss or credit carryforwards are expected to expire before becoming available to reduce federal and state income tax liabilities as a result of those identified ownership changes. If we undergo another ownership change, the utilization of the pre-ownership change net operating loss carryforwards or pre-ownership change tax attributes, such as research tax credits, to offset the post-ownership change income may be subject to an annual limitation, pursuant to Section 382 and 383 of the Internal Revenue Code of 1986, as amended.

There were no other significant changes to our critical accounting policies and estimates. Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 23, 2018 provides a more complete discussion of our critical accounting policies and estimates.

Table of Contents**Results of Operations****Net Revenue**

Total net revenue, as compared to the prior year period, was as follows:

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017	\$	%	2018	2017	\$	%
Royalties from a related party - RELVAR/BREO	\$ 51,745	\$ 44,604	\$ 7,141	16%	\$ 155,420	\$ 137,938	\$ 17,482	13%
Royalties from a related party - ANORO	9,769	7,274	2,495	34%	29,149	19,464	9,685	50%
Royalties from a related party - TRELEGY	3,622		3,622	*	6,945		6,945	*
Total royalties from a related party	65,136	51,878	13,258	26%	191,514	157,402	34,112	22%
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)			(10,368)	(10,368)		
Royalty revenue	61,680	48,422	13,258	27%	181,146	147,034	34,112	23%
Strategic alliance - MABA program license		221	(221)	*		663	(663)	*
Total net revenue from GSK	\$ 61,680	\$ 48,643	\$ 13,037	27%	\$ 181,146	\$ 147,697	\$ 33,449	23%

*Not meaningful

Total net revenue increased to \$61.7 million and \$181.1 million for the three and nine months ended September 30, 2018, compared to \$48.6 million and \$147.7 million, respectively, for the same periods a year ago primarily due to the growth in prescriptions and market share quarter over quarter for both RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, and initiation of sales by GSK of TRELEGY® ELLIPTA® in the fourth quarter of 2017.

Table of Contents**Research & Development**

We did not incur research and development expenses during the three and nine months ended September 30, 2018. For the three and nine months ended September 30, 2017, we incurred \$0.3 million and \$1.0 million, respectively, in research and development activities related to the late-stage partnered respiratory assets with GSK.

General & Administrative

General and administrative expenses, as compared to the prior year period, were as follows:

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017	\$	%	2018	2017	\$	%
General and administrative expenses	\$ 4,019	\$ 8,310	\$ (4,291)	(52)%	\$ 17,415	\$ 29,489	\$ (12,074)	(41)%
General and administrative expenses - related party					2,700		2,700	

General and administrative expenses for the three months ended September 30, 2018 were \$4.0 million compared with \$8.3 million in the three months ended September 30, 2017, a decrease of \$4.3 million. The amount for the three months ended September 30, 2017 included \$2.5 million of proxy contest and associated litigation costs. The amount for the three months ended September 30, 2018 included \$2.5 million cash severance costs and a reversal of \$1.9 million stock based compensation expense in connection with the separation of senior management members. See Note 5 Stock-Based Compensation to our condensed consolidated financial statements. The rest of the decrease in general and administrative expenses in the three months ended September 30, 2018 is mainly attributable to lower personnel-related expenses, including stock-based compensation expenses, as a result of lower headcount.

General and administrative expenses for the nine months ended September 30, 2018 were \$17.4 million compared with \$29.5 million in the nine months ended September 30, 2017, a decrease of \$12.1 million. The amount for the nine months ended September 30, 2017 included \$11.0 million of proxy contest and associated litigation costs. General and administrative expenses for the nine months ended September 30, 2018 included \$5.7 million cash severance costs in connection with certain members of senior management's separation from the Company and payment of \$2.7 million to Sarissa to partially reimburse expenses pursuant to a settlement agreement in February 2018. The rest of the decrease in general and administrative expenses in the nine months ended September 30, 2018 is mainly attributable to lower personnel-related expenses, including net reversal of stock-based compensation expenses, as a result of lower headcount.

Other Expense, net and Interest Income

Other expense, net and interest income, as compared to the prior year period, were as follows:

Edgar Filing: Innoviva, Inc. - Form 10-Q

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017	\$	%	2018	2017	\$	%
Other expense, net	\$ (2,626)	\$ (6,369)	\$ 3,743	*	\$ (5,686)	\$ (7,108)	\$ 1,422	*
Interest income	370	376	(6)	(2)%	1,141	918	223	24%

*Not meaningful

Other expense, net for the three and nine months ended September 30, 2018, mainly consists of the loss on the extinguishment of debt of \$2.6 million and \$5.7 million, respectively, in relation to the prepayments of our Term B Loan. Other expense, net for the three and nine months ended September 30, 2017 mainly consists of the write-off of debt issuance costs of \$6.4 million and \$7.3 million, respectively, in relation to the redemptions of our non-recourse notes due 2029.

Interest income increased for the nine months ended September 30, 2018, as compared to the same period a year ago primarily due to higher interest generated from our investments in marketable securities.

Table of Contents**Interest Expense**

Interest expense, as compared to the prior year period, was as follows:

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2018	2017	\$	%	2018	2017	\$	%
Interest expense	\$ (5,238)	\$ (10,262)	\$ 5,024	(49)%	\$ (19,373)	\$ (35,247)	\$ 15,874	(45)%

Interest expense decreased for the three and nine months ended September 30, 2018, compared to the same period a year ago primarily due to the lower average outstanding debt balance. See Liquidity section below for further information.

Liquidity and Capital Resources**Liquidity**

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under collaborative arrangements. In the nine months ended September 30, 2018, we generated gross royalty revenues from GSK of \$191.5 million. Net cash and cash equivalents, short term investments and marketable securities totaled \$55.5 million, and royalties receivable from GSK totaled \$65.1 million as of September 30, 2018.

On August 7, 2017, we completed a private placement of \$192.5 million aggregate principal amount of our 2025 Notes. The proceeds include the 2025 Notes sold pursuant to the \$17.5 million over-allotment option granted by us to the initial purchasers, which option was exercised in full. The 2025 Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the Securities Act). The 2025 Notes will mature on August 15, 2025, unless repurchased or converted in accordance with their terms prior to such date. Concurrently with the pricing of the offering, we repurchased and retired 1,317,771 shares of our common stock for approximately \$17.5 million of the net proceeds from the offering, in privately negotiated transactions effected through one of the initial purchasers or its affiliate, as our agent. The remaining net proceeds from the sale of the 2025 Notes in the offering were used to redeem a portion of the principal outstanding under the 2029 Notes on August 15, 2017.

On August 18, 2017, we entered into a Credit Agreement and completed a financing of \$250.0 million Term B Loan, the proceeds of which were used to repay the remaining balance of the 2029 Notes. The Term B Loan will mature on August 18, 2022. Two and a half percent (2.5%) of the initial principal amount was originally due quarterly beginning December 31, 2017. The remaining outstanding balance is due at maturity. Prepayments, in whole or in part, can be made at any time without a penalty. The Credit Agreement also provides us the ability to request one or more additional tranches of term loans (or increase an existing term loan) at any time prior to maturity. On February 28 and August 1, 2018, we paid down the principal balance of the Term B Loan by \$120.0 million and \$110.0 million, respectively. The outstanding principal balance of the Term B Loan as of September 30, 2018 was \$13.8 million.

Edgar Filing: Innoviva, Inc. - Form 10-Q

Adequacy of Cash Resources to Meet Future Needs

We believe that cash from projected future royalty revenues and our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated debt service and operating needs for at least the next twelve months based upon current operating plans and financial forecasts. If our current operating plans and financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings or debt financings. Furthermore, if in our view favorable financing opportunities arise, we may seek additional funding at any time. However, future financing may not be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as currently planned. In addition, from time to time we may restructure or reduce our debt, including through tender offers, redemptions, amendments, repurchases or otherwise, all consistent with the terms of our debt agreements.

Cash Flows

Cash flows, as compared to the prior year period, were as follows:

(In thousands)	Nine Months Ended		
	September 30,		
	2018	2017	Change
Net cash provided by operating activities	\$ 161,754	\$ 93,890	\$ 67,864
Net cash provided by investing activities	49,113	2,644	46,469
Net cash used in financing activities	(235,588)	(76,133)	(159,455)

Table of Contents

Cash Flows from Operating Activities

Cash provided by operating activities for the nine months ended September 30, 2018 was \$161.8 million, consisting primarily of our net income of \$137.1 million, adjusted for non-cash items such as \$10.4 million of depreciation and amortization, \$5.9 million amortization of debt discount and issuance costs, \$5.7 million of loss on extinguishment of debt and \$2.7 million of stock-based compensation expense, as well as decrease in receivables from collaborative arrangements of \$5.4 million, partially offset by a reduction in accrued interest payable of \$4.1 million.

Cash provided by operating activities for the nine months ended September 30, 2017 was \$93.9 million, consisting primarily of our net income of \$75.8 million, adjusted for non-cash items such as \$10.5 million of depreciation and amortization and \$7.4 million for stock-based compensation expense, offset by changes in operating assets and liabilities, including an increase in receivables from collaborative arrangements of \$5.0 million and a reduction in accrued interest payable of \$4.3 million.

Cash Flows from Investing Activities

Net cash flows from investing activities for the nine months ended September 30, 2018 of \$49.1 million was primarily due to \$71.4 million proceeds received from maturities of marketable securities, partially offset by \$22.3 million in purchases of marketable securities.

Net cash flows from investing activities for the nine months ended September 30, 2017 of \$2.6 million was primarily due to \$44.4 million proceeds received from maturities of marketable securities, partially offset by \$41.7 million in purchases of marketable securities.

Cash Flows from Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2018 of \$235.6 million was primarily due to \$230.0 million prepayments on our Term B Loan, \$3.1 million paid for the repurchase of shares to satisfy tax withholding and distributions to noncontrolling interest of \$2.9 million.

Net cash used in financing activities for the nine months ended September 30, 2017 of \$76.1 million was primarily due to \$487.2 million principal repayments of the 2029 Notes and \$17.5 million paid for repurchase of our common stock, offset by the net proceeds of \$242.6 million from our Term B Loan financing and the net proceeds of \$187.1 million from the issuance of our 2025 Notes.

Off-Balance Sheet Arrangements

In June 2014, our facility leases in South San Francisco, California were assigned to Theravance Biopharma, Inc. (Theravance Biopharma) in connection with the spin-off of Theravance Biopharma. However, if Theravance Biopharma were to default on its lease obligations, we would be held liable by the landlord and thus, we have in substance guaranteed the lease payments for these facilities. We would also be responsible for lease-related payments including utilities, property taxes, and common area maintenance, which may be as much as the actual lease payments. As of September 30, 2018, the total remaining lease payments for the duration of the lease, which runs through May 2020, were \$10.8 million. The carrying value of this lease guarantee was \$0.5 million as of September 30, 2018 and is reflected in other long-term liabilities in our condensed consolidated balance sheet.

Table of Contents**Contractual Obligations and Commercial Commitments**

In the table below, we set forth our significant enforceable and legally binding obligations and future commitments as of September 30, 2018.

(In thousands)	Total	Payment Due by Period			
		Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
2023 Notes	\$ 264,028	\$ 5,121	\$ 10,242	\$ 248,665	
2025 Notes	226,188	4,813	9,625	9,625	202,125
Term B Loan	13,750			13,750	
Facility leases	1,988	401	837	750	
Total	\$ 505,954	\$ 10,335	\$ 20,704	\$ 272,790	\$ 202,125

The Term B Loan balances reflect the principal repayment obligations and do not include the interest payments as the loan bears interest at a varying rate of three-month LIBOR plus 4.5% margin.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Our debt portfolio includes the senior secured term loans under the Term B Loan which bear interest at a variable rate based on LIBOR plus 4.5% or a certain alternate base rate plus 3.5%. We are exposed to market risks related to fluctuations in interest rates on these loans. However, the outstanding principal balance of the Term B Loan has been significantly reduced from \$243.8 million as of December 31, 2017 to \$13.8 million as of September 30, 2018.

There have been no other significant changes in our market risk or how our market risk is managed compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Item 4. Controls and Procedures*Evaluation of Disclosure Controls and Procedures.*

We conducted an evaluation as of September 30, 2018, under the supervision and with the participation of our management, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Interim

Principal Executive Officer and Chief Accounting Officer, concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance levels.

Limitations on the Effectiveness of Controls

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all frauds. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit 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 Innoviva have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no material changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents**PART II. OTHER INFORMATION****Item 1. Legal Proceedings**

From time to time, we may be involved in legal proceedings in the ordinary course of business.

Item 1A. Risk Factors

Our business is subject to a number of risks, including those identified in Item 1A of Part I of our 2017 Form 10-K. There have been no material changes to the risk factors described in our 2017 Form 10-K, except as set forth in the Risk Factors section in Item 1A of Part II of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, which is incorporated by reference herein.

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

None.

Item 6. Exhibits**(a) Index to Exhibits**

Exhibit Number	Description	Form	Exhibit	Incorporated by Reference Filing Date/Period End Date
10.1	<u>Agreement between Innoviva, Inc. and Marianne Zhen dated as of September 7, 2018</u>	8-K	10.1	9/11/2018
10.2	<u>Form of Indemnification Agreement between Innoviva, Inc. and its directors and executive officers</u>	8-K	10.2	9/11/2018
10.3	<u>Separation and Release Agreement between Innoviva, Inc. and Eric d Esparbes, dated August 8, 2018</u>	8-K	10.1	8/8/2018

31.1

Edgar Filing: Innoviva, Inc. - Form 10-Q

Certification of Principal Executive Officer pursuant to
Rules 13a-14 pursuant to the Securities Exchange Act of 1934

31.2 Certification of Principal Financial Officer pursuant to
Rules 13a-14 pursuant to the Securities Exchange Act of 1934

32 Certifications Pursuant to 18 U.S.C. Section 1350

101 Interactive Data File (Quarterly Report on Form 10-Q, for the
quarterly period ended September 30, 2018)

Table of Contents

SIGNATURES

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

Innoviva, Inc.

Date: October 31, 2018

/s/ Geoffrey Hulme
Geoffrey Hulme
Interim Principal Executive Officer
(Principal Executive Officer)

Date: October 31, 2018

/s/ Marianne Zhen
Marianne Zhen
Chief Accounting Officer
(Principal Financial Officer)