

Innoviva, Inc.  
Form 10-Q  
May 04, 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 March 31, 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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   
(Do not check if a smaller reporting company)

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 April 30, 2018 was 101,470,190.

---

Table of Contents

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

Item 1. Financial Statements

<u>Condensed Consolidated Balance Sheets as of March 31, 2018 and December 31, 2017</u>	3
<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2018 and 2017</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income for the Three Months Ended March 31, 2018 and 2017</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 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>	21
---	----

<u>Item 4. Controls and Procedures</u>	21
--	----

**PART II. OTHER INFORMATION**

<u>Item 1. Legal Proceedings</u>	22
----------------------------------	----

<u>Item 1A. Risk Factors</u>	22
------------------------------	----

<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	38
--	----

<u>Item 6. Exhibits</u>	39
-------------------------	----

<u>Signatures</u>	40
-------------------	----

Exhibits

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

(In thousands, except per share data)

	<b>March 31, 2018 (unaudited)</b>	<b>December 31, 2017 *</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 27,138	\$ 73,336
Short-term marketable securities	29,322	55,739
Related party receivables from collaborative arrangements	55,835	70,540
Prepaid expenses and other current assets	950	754
Total current assets	113,245	200,369
Property and equipment, net	197	209
Capitalized fees paid to a related party, net	163,266	166,722
Other assets	37	37
Total assets	\$ 276,745	\$ 367,337
<b>Liabilities and Stockholders Deficit</b>		
Current liabilities:		
Accounts payable	\$ 66	\$ 601
Accrued personnel-related expenses	537	1,721
Accrued interest payable	2,545	5,920
Other accrued liabilities	918	1,500
Current portion of long-term debt		25,000
Total current liabilities	4,066	34,742
Long-term debt, net of current portion, discount and issuance costs	484,591	574,362
Other long-term liabilities	835	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, 101,475 and 102,046 shares issued as of March 31, 2018 and December 31, 2017, respectively	1,014	1,019
Treasury stock: 150 shares as of March 31, 2018 and December 31, 2017	(3,263)	(3,263)
Additional paid-in capital	1,257,880	1,258,151
Accumulated other comprehensive loss	(22)	(18)
Accumulated deficit	(1,469,167)	(1,498,748)
Total Innoviva stockholders deficit	(213,558)	(242,859)
Noncontrolling interest	811	152
Total stockholders deficit	(212,747)	(242,707)
Total liabilities and stockholders deficit	\$ 276,745	\$ 367,337

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

*See accompanying notes to condensed consolidated financial statements.*

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

Table of Contents

## INNOVIVA, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended March 31,	
	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 March 31, 2018 and 2017	\$ 52,380	\$ 40,271
Revenue from collaborative arrangements from a related party		221
Total net revenue	52,380	40,492
Operating expenses:		
Research and development		354
General and administrative	8,985	10,795
General and administrative - related party	2,700	
Total operating expenses	11,685	11,149
Income from operations	40,695	29,343
Other (expense) income, net	(3,099)	47
Interest income	391	236
Interest expense	(7,657)	(12,781)
Net income	30,330	16,845
Net income attributable to noncontrolling interest	749	
Net income attributable to Innoviva stockholders	\$ 29,581	\$ 16,845
Basic net income per share attributable to Innoviva stockholders	\$ 0.29	\$ 0.16
Diluted net income per share attributable to Innoviva stockholders	\$ 0.27	\$ 0.15
Shares used to compute Innoviva basic and diluted net income per share:		
Shares used to compute basic net income per share	100,604	107,487
Shares used to compute diluted net income per share	113,566	120,336

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents

**INNOVIVA, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(In thousands)

(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Net income	\$ 30,330	\$ 16,845
Unrealized loss on marketable securities, net	(4)	(2)
Comprehensive income	30,326	16,843
Comprehensive income attributable to noncontrolling interest	749	
Comprehensive income attributable to Innoviva stockholders	\$ 29,577	\$ 16,843

*See accompanying notes to condensed consolidated financial statements.*



Table of Contents

## INNOVIVA, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2018	2017
<b>Cash flows from operating activities</b>		
Net income	\$ 30,330	\$ 16,845
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,468	3,496
Stock-based compensation	2,169	2,507
Amortization of debt discount and issuance costs	2,092	687
Loss on extinguishment of debt	3,137	
Amortization of premium (discount) on short-term investments	(100)	17
Amortization of lease guarantee	(81)	(81)
Changes in operating assets and liabilities:		
Receivables from collaborative arrangements	14,705	3,120
Prepaid expenses and other current assets	(196)	(114)
Accounts payable	(535)	2,176
Accrued personnel-related expenses and other accrued liabilities	(1,702)	752
Accrued interest payable	(3,375)	(1,428)
Other long-term liabilities	2	5
Deferred revenue		(221)
Net cash provided by operating activities	49,914	27,761
<b>Cash flows from investing activities</b>		
Maturities of marketable securities	31,875	26,387
Purchases of marketable securities	(5,362)	(3,992)
Net cash provided by investing activities	26,513	22,395
<b>Cash flows from financing activities</b>		
Repurchase of shares to satisfy tax withholding	(2,611)	(553)
Payments of principal on senior secured term loans	(120,000)	
Payments of cash dividends to stockholders	(38)	(67)
Proceeds from issuances of common stock, net	114	8
Payment of principal on non-recourse notes due 2029		(7,752)
Distributions to noncontrolling interest	(90)	
Net cash used in financing activities	(122,625)	(8,364)
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(46,198)</b>	<b>41,792</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>73,336</b>	<b>118,016</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 27,138</b>	<b>\$ 159,808</b>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 8,941	\$ 13,522

*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 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.

*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.

***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 the treatment of the lease on 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 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 months ended March 31, 2018.

The following table shows the computation of basic and diluted net income per share for the three months ended March 31, 2018 and 2017:

<b>(In thousands except per share data)</b>	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Numerator:</b>		
Net income attributable to Innoviva stockholders, basic	\$ 29,581	\$ 16,845
Add: interest expense on 2023 Notes	1,412	1,407
Net income attributable to Innoviva stockholders, diluted	\$ 30,993	\$ 18,252
<b>Denominator:</b>		
Weighted-average shares used to compute basic net income per share attributable to Innoviva stockholders	100,604	107,487

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

Dilutive effect of 2023 Notes	12,189	12,189
Dilutive effect of options and awards granted under equity incentive plan and employee stock purchase plan	773	660
Weighted-average shares used to compute diluted net income per share attributable to Innoviva stockholders	113,566	120,336
Net income per share attributable to Innoviva stockholders		
Basic	\$ 0.29	\$ 0.16
Diluted	\$ 0.27	\$ 0.15

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 March 31,	
	2018	2017
Outstanding options and awards granted under equity incentive plan and employee stock purchase plan	1,492	3,062

**3. Revenue Recognition and Collaborative Arrangements**

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 prospective 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.

Adoption of this standard did not have an impact on the method in which we account for royalties, our main source of revenue. 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.

*Net Revenue from Collaborative Arrangements*

Net revenue recognized under our GSK Agreements was as follows:

(In thousands)	Three Months Ended March 31,	
	2018	2017
Royalties from a related party - RELVAR/BREO	\$ 46,160	\$ 38,689
Royalties from a related party - ANORO	8,724	5,038
Royalties from a related party - TRELEGY	952	
Total royalties from a related party	55,836	43,727
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)
Royalty revenue	52,380	40,271
Strategic alliance - MABA program license		221
Total net revenue from GSK	\$ 52,380	\$ 40,492

*LABA Collaboration*

As a result of the launch and approval of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe, we paid milestone fees to GSK totaling \$220.0 million during the year ended December 31, 2014. Although we have no further milestone payment obligations to GSK pursuant to the LABA Collaboration Agreement, we continue to have ongoing participation as part of the collaboration, including joint steering and joint project committees that are expected to continue over the life of the agreement. 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 product. The amortization expense is recorded as a reduction to the royalties from GSK.

We are entitled to receive annual 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. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA Collaboration, such as ANORO® ELLIPTA®, which royalties are upward tiering and range from 6.5% to 10%.



Table of Contents

We are also entitled to 15% of any future royalty payments made by GSK under its agreements originally entered into with us, and since assigned to TRC, including TRELEGY® ELLIPTA®, which royalties are upward tiering and range from 6.5% to 10%

**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	March 31, 2018		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government securities	\$ 9,978	\$	\$ (3)	\$ 9,975
U.S. corporate notes	11,884		(19)	11,865
U.S. commercial paper	12,476			12,476
Money market funds	17,118			17,118
Total	\$ 51,456	\$	\$ (22)	\$ 51,434

(In thousands)	Amortized Cost	December 31, 2017		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
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 March 31, 2018, all of the available-for-sale securities had contractual maturities within one year and the weighted average maturity of marketable securities was approximately two months.

Table of Contents***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:

**Estimated Fair Value Measurements as of March 31, 2018 Using:**

<b>Types of Instruments (In thousands)</b>	<b>Quoted Price in Active Markets for Identical Assets Level 1</b>	<b>Significant Other Observable Inputs Level 2</b>	<b>Significant Unobservable Inputs Level 3</b>	<b>Total</b>
<i>Assets</i>				
U.S. government securities	\$	\$ 9,975	\$	\$ 9,975
U.S. corporate notes		11,865		11,865
U.S. commercial paper		12,476		12,476
Money market funds	17,118			17,118
Total assets measured at estimated fair value	\$ 17,118	\$ 34,316	\$	\$ 51,434
<i>Liabilities</i>				
Term B Loan	\$	\$ 123,750	\$	\$ 123,750
2023 Notes		259,058		259,058
2025 Notes		223,106		223,106
Total fair value of liabilities	\$	\$ 605,914	\$	\$ 605,914

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

<b>Types of Instruments (In thousands)</b>	<b>Quoted Price in Active Markets for Identical Assets Level 1</b>	<b>Significant Other Observable Inputs Level 2</b>	<b>Significant Unobservable Inputs Level 3</b>	<b>Total</b>
<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>Liabilities</i>				
Term B Loan	\$	\$ 243,750	\$	\$ 243,750
2023 Notes		241,259		241,259
2025 Notes		205,975		205,975
Total fair value of liabilities	\$	\$ 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.

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

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.

Table of Contents

**5. Stock-Based Compensation**

*Performance-Contingent RSAs and RSUs*

Since 2011, the Compensation Committee of our Board of Directors (the Compensation Committee) have approved grants of performance-contingent RSAs and RSUs to senior management and a non-executive officer. Generally, these awards have dual triggers of vesting based upon the achievement of certain performance goals by a pre-specified date, as well as a requirement for continued employment. Recognition of stock-based compensation expense begins when the performance goals are deemed probable of achievement.

Included in these performance-contingent RSAs was the remaining grant of 63,000 special long-term retention and incentive performance-contingent RSAs to senior management in 2011. The awards had dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and required continued service to the Company. During the year ended December 31, 2016, we determined that the achievement of the requisite performance conditions was met. These awards were released in November 2017 upon vesting.

*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, collectively the Performance Measures I. The vesting percentages of these awards are calculated based on the two-year TSR with a catch-up provision opportunity measured on January 13, 2019 for RSAs and on September 30, 2018 for RSUs. Two-thirds of amounts earned at the end of year two would vest and be distributed on February 20, 2018, while the final one-third earned after two years as well as the catch-up amount earned will vest and be distributed on February 20, 2019 for RSAs and November 20, 2018 for RSUs. The actual payout of shares may range from a minimum of zero shares to a maximum of 328,688 shares granted upon the actual performance against the Performance Measures I. The grant date fair value of these awards was determined using a Monte Carlo valuation model. The aggregate value of \$2.0 million is recognized as compensation expense over the implied service period and will not be reversed if the market condition is not met, but with the exception of such person's continued employment with the Company.

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, and the remaining 34,720 RSAs and 15,432 RSUs will vest on February 20, 2019 subject to each eligible person's continued employment with the Company. Additionally, in connection with certain members of senior management's separation 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.

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, collectively the Performance Measures II . The vesting percentages of these awards are calculated based on the two-year performance period with a catch-up provision opportunity measured on December 31, 2019 for RSAs and on September 30, 2019 for RSUs. Two-thirds of amounts earned at the end of year two will vest and be distributed on February 20, 2019, while the final one-third earned after two years as well as the catch-up amount earned will vest and be distributed on February 20, 2020 for RSAs and November 20, 2019 for RSUs. The actual payout of shares may range from a minimum of zero shares to a maximum of 406,868 shares granted upon the actual performance against the Performance Measures II. The grant date fair value of these awards is determined using a Monte Carlo valuation model. The aggregate value of \$3.2 million is recognized as compensation expense over the implied service period and will not be reversed if the market condition is not met, but with the exception of such person's continued employment with the Company.

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

Table of Contents

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, collectively the Performance Measures III. The actual payout of shares may range from a minimum of zero shares to a maximum of 161,298 shares granted upon the actual performance against the Performance Measures III. The grant date fair value of these awards was determined using a Monte Carlo valuation model. The aggregate value of \$1.7 million is recognized as compensation expense over the implied service period and will not be reversed if the market condition is not met, but with the exception of such person's continued employment with the Company.

*Stock-Based Compensation Expense*

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

(In thousands)	Three Months Ended March 31,	
	2018	2017
Research and development	\$	\$ 178
General and administrative		2,329
Total stock-based compensation expense	\$	\$ 2,507

As of March 31, 2018, unrecognized stock-based compensation cost, including performance-contingent RSAs for which the performance milestones were determined to be probable of achievement, was as follows:

(In thousands)	Unrecognized Compensation Cost	
Stock options	\$	157
RSUs		1,657
RSAs		4,068
Market-based RSUs		728
Market-based RSAs		1,705
Total unrecognized compensation cost	\$	8,315

**6. Debt**

Our debt consists of:

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

<b>(In thousands)</b>	<b>March 31, 2018</b>	<b>December 31, 2017</b>
Senior secured term loans	\$ 123,750	\$ 243,750
Convertible subordinated notes due 2023	240,984	240,984
Convertible senior notes due 2025	192,500	192,500
Total debt	557,234	677,234
Unamortized debt discount and issuance costs	(72,643)	(77,872)
Current portion of senior secured term loan		(25,000)
Net long-term debt	\$ 484,591	\$ 574,362

Table of Contents***Prepayment of Senior Secured Term Loans***

On February 28, 2018, we paid down the principal balance of the Term B Loan by \$120.0 million. With the prepayment, we incurred a loss on the extinguishment of debt of \$3.1 million representing unamortized debt issuance costs. The loss on the extinguishment of debt is presented as part of other income (expense), net in our consolidated statements of operations. As of March 31, 2018, the outstanding principal balance of the Term B Loan was reduced to \$123.8 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 March 31, 2018, consisted of the following:

(In thousands)

Liability component		
Principal	\$	192,500
Debt discount and issuance costs, net		(66,740)
Net carrying amount	\$	125,760
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.

The following table sets forth total interest expense recognized related to the 2025 Notes for the three months ended March 31, 2018:

(In thousands)



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

Contractual interest expense	\$	1,190
Amortization of debt issuance costs		123
Amortization of debt discount		1,479
Total interest and amortization expense	\$	2,792

Table of Contents**Debt Maturities**

The aggregate scheduled maturities of our long-term debt as of March 31, 2018, are as follows:

**(In thousands)**

Years ending December 31:		
2018 to 2021	\$	
2022		123,750
Thereafter		433,484
Total	\$	557,234

**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**

The effective tax rate for the three months ended March 31, 2018 was minimal, compared to 0.1% for the same period in 2017. 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. 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.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations****Forward-Looking Statements**

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

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 below in "Risk Factors" in Item 1A of Part II and 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.

Table of Contents

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 II of this Quarterly Report on Form 10-Q, entitled Risk Factors, which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of Part II of this report, other unknown or unpredictable factors also could affect our results. 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-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® 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 March 31, 2018, we had nine employees. Our revenues consist of royalties from our respiratory partnership agreements with GSK.

**Recent Highlights**

- GSK Net Sales:

- First quarter 2018 net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$307.7 million, up 19% from \$257.9 million in the first quarter of 2017, with \$137.0 million in net sales from the U.S. market and \$170.7 million from non-U.S. markets.
- First quarter 2018 net sales of ANORO® ELLIPTA® by GSK were \$134.2 million, up 73% from \$77.5 million in the first quarter of 2017, with \$83.5 million net sales from the U.S. market and \$50.7 million from non-U.S. markets.
- First quarter 2018 net sales of TRELEGY® ELLIPTA® by GSK were \$14.6 million.
- Product Updates:
  - Announced in March 2018 the positive European Commission approval for labelling update to RELVAR® ELLIPTA® in patients with asthma.

#### **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.

Table of Contents

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. Although we have no further milestone payment obligations to GSK pursuant to the LABA Collaboration Agreement, we continue to have ongoing commercialization activities under the LABA Collaboration Agreement including participation on the joint steering committee and joint project committee that are expected to continue over the life of the agreement. 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.

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. For other products combined with a LABA from the LABA collaboration, such as ANORO® ELLIPTA®, royalties are upward tiering and range from 6.5% to 10%.

We are also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to TRC, including TRELEGY® ELLIPTA®, which royalties are upward tiering and range from 6.5% to 10%.

*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 and is in Phase II clinical studies stage. 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 Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on February 23, 2018.

**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.

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 prospective 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.

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 March 31,		Change	
	2018	2017	\$	%
Royalties from a related party - RELVAR/BREO	\$ 46,160	\$ 38,689	\$ 7,471	19%
Royalties from a related party - ANORO	8,724	5,038	3,686	73%
Royalties from a related party - TRELEGY	952		952	
Total royalties from a related party	55,836	43,727	12,109	28%
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)		
Royalty revenue	52,380	40,271	12,109	30%
Strategic alliance - MABA program license		221	(221)	
Total net revenue from GSK	\$ 52,380	\$ 40,492	\$ 11,888	29%

Total net revenue increased for the three months ended March 31, 2018, compared to the same period 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.

*Research & Development*

We did not incur research and development expenses during the three months ended March 31, 2018. For the three months ended March 31, 2017, we incurred \$0.4 million 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 March 31,		Change	
	2018	2017	\$	%
	\$ 8,985	\$ 10,795	\$ (1,810)	(17)%



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

General and administrative expenses

General and administrative expenses - related party

2,700

2,700

General and administrative expenses for the three months ended March 31, 2018 included \$3.2 million cash severance payments 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. General and administrative expenses for the three months ended March 31, 2017 included proxy contest and related legal costs of \$4.2 million.

*Other Income (Expense), net and Interest Income*

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

(In thousands)	Three Months Ended		Change	%
	2018	2017		
Other (expense) income, net	\$ (3,099)	\$ 47	\$ (3,146)	*
Interest income	391	236	155	66%

Table of Contents


---

\*Not meaningful

Other income (expense), net for the three months ended March 31, 2018, mainly consists of the loss on the extinguishment of debt of \$3.1 million in relation to the \$120.0 million prepayment of our Term B Loan.

Interest income increased for the three months ended March 31, 2018, as compared to the same period a year ago primarily due to higher interest generated from our investments in marketable securities.

***Interest Expense***

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

(In thousands)	Three Months Ended March 31,		Change	
	2018	2017	\$	%
Interest expense	\$ (7,657)	\$ (12,781)	\$ 5,124	(40)%

Interest expense decreased for the three months ended March 31, 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. Since the start of the commercialization of RELVAR®/ BREO® ELLIPTA® in the fourth quarter of 2013, ANORO® ELLIPTA® during 2014 and TRELEGY® ELLIPTA® in fourth quarter of 2017, we have complemented the source of financing with royalty revenues from the global net sales of these products by GSK. In the three months ended March 31, 2018, we generated gross royalty revenues from GSK of \$55.8 million. Net cash and cash equivalents, short term investments and marketable securities totaled \$56.5 million, and royalties receivable from GSK totaled \$55.8 million as of March 31, 2018.

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

In April 2014, we entered into certain note purchase agreements relating to the private placement of \$450.0 million aggregate principal amount of our 2029 Notes. In May 2017, we redeemed \$50.0 million on the 2029 Notes. In August 2017, we used the net proceeds of the 2025 Notes and Term B Loan (both described below) to redeem the 2029 Notes in full.

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, 2018, we paid down the principal balance of the Term B Loan by \$120.0 million. The outstanding principal balance of the Term B Loan as of March 31, 2018 was \$123.8 million.

### *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

Table of Contents

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)	Three Months Ended			Change
	March 31,			
	2018		2017	
Net cash provided by operating activities	\$ 49,914	\$	27,761	\$ 22,153
Net cash provided by investing activities	26,513		22,395	4,118
Net cash used in financing activities	(122,625)		(8,364)	(114,261)

*Cash Flows from Operating Activities*

Cash provided by operating activities for the three months ended March 31, 2018 was \$49.9 million, consisting primarily of our net income of \$30.3 million, adjusted for non-cash items such as \$3.5 million of depreciation and amortization, \$3.1 million of loss on extinguishment of debt and \$2.2 million of stock-based compensation expense, as well as changes in operating assets and liabilities, including a decrease in receivables from collaborative arrangements of \$14.7 million, partially offset by a reduction in accrued interest payable of \$3.4 million.

Cash provided by operating activities for the three months ended March 31, 2017 was \$27.8 million, consisting primarily of our net income of \$16.9 million, adjusted for non-cash items such as \$3.5 million of depreciation and amortization and \$2.5 million for stock-based compensation expense, offset by changes in operating assets and liabilities, including \$46.8 million provided by receipt of royalties from a related party and revenue from collaborative arrangements, after adjusting for a \$3.1 million decrease in receivables from collaborative arrangements, and \$13.5 million used for interest payments on 2023 Notes and 2029 Notes.

*Cash Flows from Investing Activities*

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

Net cash flows from investing activities for the three months ended March 31, 2018 of \$26.5 million was primarily due to \$31.9 million proceeds received from maturities of marketable securities, partially offset by \$5.4 million in purchases of marketable securities.

Net cash flows from investing activities for the three months ended March 31, 2017 of \$22.4 million was primarily due to \$26.4 million proceeds received from maturities of marketable securities, partially offset by \$4.0 million in purchases of marketable securities.

Table of Contents*Cash Flows from Financing Activities*

Net cash used in financing activities for the three months ended March 31, 2018 of \$122.6 million was primarily due to \$120.0 million prepayment on our Term B Loan and \$2.6 million paid for the repurchase of shares to satisfy tax withholding.

Net cash used in financing activities for the three months ended March 31, 2017 of \$8.4 million was primarily due to \$7.8 million partial payment on the principal of the 2029 Notes and \$0.6 million paid for the repurchase of shares to satisfy tax withholding.

*Off-Balance Sheet Arrangements*

In June 2014, our facility leases in South San Francisco, California were assigned to Theravance Biopharma, Inc. ( 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 March 31, 2018, the total remaining lease payments for the duration of the lease, which runs through May 2020, were \$14.0 million. The carrying value of this lease guarantee was \$0.7 million as of March 31, 2018 and is reflected in other long-term liabilities in our condensed consolidated balance sheet.

**Contractual Obligations and Commercial Commitments**

In the table below, we set forth our significant enforceable and legally binding obligations and future commitments as of March 31, 2018.

(In thousands)	Total	Payment Due by Period			
		Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
2023 Notes	\$ 266,589	\$ 5,121	\$ 10,242	\$ 251,226	\$
2025 Notes	228,594	4,813	9,625	9,625	204,531
Term B Loan	123,750			123,750	
Facility leases	2,185	395	825	875	90
Total	\$ 621,118	\$ 10,329	\$ 20,692	\$ 385,476	\$ 204,621

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**

There have been no 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 March 31, 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, who is also our Principal Financial Officer and Chief Financial 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.

Table of Contents

*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 March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

On February 6, 2018, our Chief Executive Officer resigned and our Chief Financial Officer assumed the position of interim Principal Executive Officer in addition to his position of Chief Financial Officer, pending a search for a new Chief Executive Officer. As a result, there was a lack of segregation of duties between the position of principal executive officer and principal financial officer over the period subsequent to February 6, 2018. To address this lack of segregation of duties, management ensured that additional oversight procedures were performed to ensure the financial statements included herein fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented. Accordingly, we believe the financial statements included in this report present fairly, in all material respects, our financial condition, results of operations and cash flows for the periods presented. Management will continue to evaluate this segregation of duties for future periods.

**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**

**Risks Related to our Business**

*For the foreseeable future we will derive all of our royalty revenues from GSK and our future success depends on GSK's ability to successfully develop and commercialize the products in the respiratory programs partnered with GSK.*

Pursuant to the GSK Agreements, GSK is responsible for the development and commercialization of products in the partnered respiratory programs. Royalty revenues from RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are expected to represent the majority of our foreseeable future revenues from GSK. The amount and timing of revenue from such royalties are unknown and highly uncertain. Our future success depends upon the performance by GSK of its commercial obligations under the GSK Agreements and the commercial success of RELVAR®/BREO® ELLIPTA®,



ANORO® ELLIPTA® and TRELEGY® ELLIPTA®. We have no control over GSK's marketing and sales efforts, and GSK might not be successful, which would harm our business and cause the price of our securities to fall.

Our quarterly royalty revenues may fluctuate due to a variety of factors, many of which are outside of our control. The amount of royalties we receive will depend on many factors, including the following:

- the extent and effectiveness of the sales and marketing and distribution support GSK provides to our partnered products;
- market acceptance and demand for our partnered products;
- changes in the treatment paradigm or standard of care for COPD or asthma, for instance through changes to the GOLD (Global Initiative for Chronic Obstructive Lung Disease) guidelines;
- the competitive landscape of generic and branded products and developing therapies that compete with our partnered products, including TRELEGY® ELLIPTA® or products owned by GSK (such as Advair®) but which are not partnered with us and pricing pressure in the respiratory markets targeted by our partnered products;
- the size of the market for our partnered products;
- the mix of sales of our partnered products;
- decisions as to the timing of product launches, pricing and discounts;

Table of Contents

- GSK reprioritizing its commercial efforts on other products, including TRELEGY® ELLIPTA® or products owned by GSK (such as Advair®) but which are not partnered with us;
- GSK's ability to expand the indications for which our partnered products can be marketed;
- a satisfactory efficacy and safety profile as demonstrated in a broad patient population;
- acceptance of, and ongoing satisfaction with, our partnered products by the medical community, patients receiving therapy and third party payors;
- timing and amounts of payor rebate adjustments;
- seasonal fluctuations of demand;
- the ability of patients to be able to afford our partnered products or obtain health care coverage that covers our partnered products;
- safety concerns in the marketplace for respiratory therapies in general and with our partnered products in particular;
- regulatory developments relating to the manufacture or continued use of our partnered products;
- the requirement to conduct additional post-approval studies or trials for our partnered products;
- decisions by GSK with respect to the MABA program;

- GSK's ability to obtain regulatory approval of our partnered products in additional countries;
- the unfavorable outcome of any potential litigation relating to our partnered products;
- general economic conditions in the jurisdictions where our partnered products are sold, including microeconomic disruptions or slowdowns; or
- if our royalty revenue or operating results fall below the expectations of investors or securities analysts or below any guidance we may provide to the market, the price of our common stock could decline substantially.

***If the FDA or other applicable regulatory authorities approve generic products, including but not limited to generic forms of Advair®, that compete with RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, or generic form of RELVAR®/BREO® ELLIPTA®, the royalties payable to us pursuant to the LABA Collaboration Agreement will be less than anticipated, which in turn would harm our business and the price of our securities could fall.***

Once an NDA or marketing authorization application outside the United States is approved, the product covered thereby becomes a listed drug that can, in turn, be cited by potential competitors in support of approval of an Abbreviated New Drug Application (ANDA) in the United States. Agency regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes in the United States and in nearly every pharmaceutical market around the world. Numerous companies like Mylan N.V., Hikma Pharmaceuticals PLC (Hikma), Novartis Sandoz division and Teva Pharmaceuticals Industries Ltd. (Teva) have publicly stated their intentions to bring generic forms of the ICS/LABA drug Advair®, when certain patents covering the Advair® delivery device expired in 2016. In March 2017, Mylan N.V. received a complete response letter from the FDA relating to its ANDA for fluticasone propionate 100, 250, 500 mcg and salmeterol 50 mcg inhalation powder, and is expecting a final decision by the FDA in June 2018. In May 2017, Hikma announced that it received a complete response letter from the FDA relating to its ANDA for fluticasone propionate and salmeterol inhalation powder, and in February 2018, Novartis announced that its generic division Sandoz, had received a complete response letter from FDA in response to its ANDA for a third fluticasone propionate and salmeterol product. Lastly, Teva announced that the FDA approved two of their products for adolescent and adult patients with asthma, one of which is AirDuo™ RespiClick® (fluticasone propionate and salmeterol inhalation powder) a non-AB substitutable generic versions of Advair®. In general, these manufactures are required to conduct a restricted number of clinical efficacy, pharmacokinetic and device studies to demonstrate equivalence to Advair, per FDA's September 2013 Draft Guidance document. These studies are designed to demonstrate that the generic product has the same active ingredient(s), dosage form, strength, exposure and clinical efficacy as the branded product. These generic equivalents, which must meet the same exacting quality standards as branded products, may be significantly less costly to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product and products that may compete with such branded product is typically lost to the generic product. In addition, in April 2016, the FDA

Table of Contents

issued draft guidelines documents covering Fluticasone Furoate/Vilanterol Trifenatate (FF/VI), the active ingredients used in RELVAR®/BREO® ELLIPTA®. Accordingly, introduction of generic products that compete against ICS/LABA products, like RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, would materially adversely impact our future royalty revenue, profitability and cash flows. We cannot yet ascertain what impact these generic products and any future approved generic products will have on any sales of RELVAR®/BREO® ELLIPTA® or ANORO® ELLIPTA®, if approved.

*Reduced prices and reimbursement rates due to the actions of governments, payors, or competition or other healthcare cost containment initiatives such as restrictions on use, may negatively impact royalties generated under the GSK Agreements.*

The continuing efforts of governments, pharmaceutical benefit management organizations (PBMs), insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care has adversely affected the price, market access, and total revenues of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® and may continue to adversely affect them in the future. In addition, we have experienced and expect to continue to experience increased competitive activity which has resulted in lower overall prices for our products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, PPACA ) and other legislative or regulatory requirements or potential legislative or regulatory actions regarding healthcare and insurance matters, along with the trend toward managed healthcare in the U.S., could adversely influence the purchase of healthcare products and reduce demand and prices for our partnered products. This could harm GSK's ability to market our partnered products and significantly reduce future revenues. For example, when GSK launched BREO® ELLIPTA® for the treatment of COPD in the U.S. in October 2013, GSK experienced significant challenges gaining coverage at some of the largest PBMs, healthcare payors, and providers and lower overall prices than expected. Recent actions by U.S. PBMs in particular have increased discount levels for respiratory products resulting in lower net sales pricing realized for products in our collaboration. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures will continue and may increase. This may make it difficult for GSK to sell our partnered products at a price acceptable to us or GSK or to generate revenues in line with our analysts' or investors' expectations, which may cause the price of our securities to fall.

More recently, the current presidential administration and the U.S. Congress have taken actions in an effort to replace PPACA and related legislation with new healthcare legislation. There is uncertainty with respect to the impact these potential changes may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by PPACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures, and may adversely affect our operating results.

***The majority of our current revenues are from royalties derived from sales of respiratory products partnered with GSK, specifically RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. If the treatment paradigm for the indications our partnered products are approved for change or if GSK is unable to, or does not devote sufficient resources to, maintain or continue increasing sales of these products, our results of operations will be adversely affected.***

We currently depend on royalties from sales of our products partnered with GSK to support our existing operations. The treatment paradigm for COPD and asthma constantly evolve. For instance, in December 2016, the GOLD guidelines were revised to favorably position LABA/LAMA treatment compared to ICS/LABA for the treatment of COPD. If the treatment paradigms were to change further, causing our partnered products to fall out of favor, or if GSK was unable, or did not devote sufficient resources, to maintain or continue increasing RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® sales, our results of operations would likely suffer and we may need to scale back our operations.

***If the commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® or TRELEGY® ELLIPTA® in the countries in which they have received regulatory approval encounters any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage do not meet investors, analysts or our expectations, our business will be harmed, and the price of our securities could fall.***

Under our agreements with our collaborative partner GSK, GSK has full responsibility for commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® or TRELEGY® ELLIPTA®. GSK has launched RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in a number of countries including the United States (U.S.), Canada, Japan, the United Kingdom, and Germany among others. The commercialization of both products in countries where they are already launched and the commercialization launch

Table of Contents

in new countries are still subject to fluctuating overall pricing levels and uncertain timeframes to obtain payor coverage. Any delays or adverse developments or perceived additional delays or adverse developments with respect to the commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA® including if sales or payor coverage do not meet investors, analysts or our expectations, will significantly harm our business and the price of our securities could fall.

***We are dependent on GSK for the successful commercialization and development of products under the GSK Agreements. If GSK does not devote sufficient resources to the commercialization or development of these products, is unsuccessful in its efforts, or chooses to reprioritize its commercial programs, including TRELEGY® ELLIPTA®, our business will be materially harmed.***

GSK is responsible for all clinical and other product development, regulatory, manufacturing and commercialization activities for products developed under the GSK Agreements, including RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA®. Our royalty revenues under the GSK Agreements may not meet our, analysts', or investors' expectations, due to a number of important factors. GSK has a substantial respiratory product portfolio in addition to the partnered products that are covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with us. For instance, GSK has wide discretion in determining the efforts and resources that it will apply to the development and commercialization of our partnered products. GSK is currently evaluating next steps with respect to the MABA program. In the event that GSK terminates this or any other development program (other than RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®) pursuant to agreements entered into in connection with the Spin-Off of Theravance Biopharma in June 2014 (the "Spin-Off"), the right to such programs would revert to Theravance Biopharma. The timing and amount of royalties that we may receive will depend on, among other things, the efforts, allocation of resources and successful development and commercialization of these product candidates by GSK. In addition, GSK may determine to focus its commercialization efforts on its own products or TRELEGY® ELLIPTA®. For example, in January 2015, GSK launched Incruse® (Umeç) in the U.S., which is a LAMA for the treatment of COPD. GSK may determine to focus its marketing efforts on Incruse, which could have the effect of decreasing the potential market share of ANORO® ELLIPTA® and lowering the royalties we may receive for such product. Alternatively, GSK may decide to market TRELEGY® ELLIPTA® to eventually compete directly against sales of RELVAR®/BREO® ELLIPTA®. Following the FDA approval of TRELEGY® ELLIPTA® in September 2017, GSK's diligent efforts obligations regarding commercialization matters now has the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following this regulatory approval is guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future. If GSK prioritizes TRELEGY® ELLIPTA®, we will only be entitled to a 15% economic interest of the royalties paid pursuant to the GSK Agreements with respect to this product. In the event GSK does not devote sufficient resources to the development or commercialization of our partnered products or chooses to reprioritize its commercial programs, our business, operations and stock price would be negatively affected.

***Any adverse change in FDA policy or guidance regarding the use of LABAs to treat asthma may significantly harm our business and the price of our securities could fall.***

On February 18, 2010, the FDA announced that LABAs should not be used alone in the treatment of asthma and it will require manufacturers to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medicines. The FDA now requires that the product labels for LABA medicines reflect, among other things, that the use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid, that LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications, and that LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. In addition, in March 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as clinical trial design) to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of asthma in adults, adolescents, and children. Further, in April 2011, the FDA announced that to further evaluate the safety of LABAs, it is requiring the manufacturers of currently marketed LABAs to conduct additional randomized, double-blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. These post-marketing studies have been completed, and although the black box warning was removed by the FDA for FF/VI and other ICS/LABA, it is unknown at this time what, if any, effect these or future FDA actions will have on the prospects for FF/VI. The current uncertainty regarding the FDA's position on LABAs for the treatment of asthma and the lack of consensus expressed at the March 2010 Advisory Committee may result in the FDA requiring additional asthma clinical trials in the U.S. for FF/VI and increase the overall risk of FF/VI for the treatment of asthma in the U.S. We cannot predict the extent to which new FDA policy or guidance might significantly impede the discovery, development, production and marketing of FF/VI. Any adverse change in FDA policy or guidance regarding the use of LABAs to treat asthma may significantly harm our business and the price of our securities could fall.

Table of Contents

***Any adverse developments to the regulatory status of either RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® or TRELEGY® ELLIPTA® in the countries in which they have received regulatory approval including labeling restrictions, safety findings, or any other limitation to usage, will harm our business and may cause the price of our securities to fall.***

Although RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® or TRELEGY® ELLIPTA® are approved and marketed in a number of countries, it is possible that adverse changes to the regulatory status of these products could occur in the event new safety issues are identified, treatment guidelines are changed, or new studies fail to demonstrate product benefits. A number of notable pharmaceutical products have experienced adverse developments during commercialization that have resulted in the product being withdrawn, approved uses being limited, or new warnings being included. In the event that any adverse regulatory change was to occur to any of our products, our business will be harmed and the price of our securities could fall.

***Any adverse developments or results or perceived adverse developments or results with respect to the ongoing studies for FF/VI in asthma or COPD, for UMEC/VI in COPD, or any future studies will significantly harm our business and the price of our securities could fall, and if regulatory authorities in those countries in which approval has not yet been granted determine that the ongoing studies for FF/VI in asthma or COPD or the ongoing studies for UMEC/VI for COPD do not demonstrate adequate safety and efficacy, the continued development of FF/VI or UMEC/VI or both may be significantly delayed, they may not be approved by these regulatory authorities, and even if approved it may be subject to restrictive labeling, any of which will harm our business, and the price of our securities could fall.***

Although we have announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma, additional studies of FF/VI are underway or may commence in the future. Any adverse developments or perceived adverse developments with respect to any prior, current or future studies in these programs will significantly harm our business and the price of our securities could fall. For example, in September 2015, GSK and we announced that the Study to Understand Mortality and Morbidity (SUMMIT) did not meet its primary endpoints, which resulted in a significant decline in the price of our stock.

Although the FDA, the European Medicines Agency, the Japanese Ministry of Health, Labour and Welfare and Health Canada and other jurisdictions have approved ANORO® ELLIPTA®, it has not yet been approved in all jurisdictions.

Any adverse developments or results or perceived adverse developments or results with respect to other pending or future regulatory submissions for the FF/VI program or the UMEC/VI program will significantly harm our business and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

- not every study, nor every dose in every study, in the Phase 3 programs for FF/VI achieved its primary endpoint and regulatory authorities may determine that additional clinical studies are required;



- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs having to do with the LABA VI, which is a component of FF/VI and UMEC/VI;
- analysts adjusting their sales forecasts downward from previous projections based on results or interpretations of results of prior, current or future studies;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs;
- regulatory authorities determining that the Phase 3 programs in asthma or in COPD raise safety concerns or do not demonstrate adequate efficacy; or
- any change in FDA (or comparable foreign regulatory agency) policy or guidance regarding the use of LABAs to treat asthma or the use of LABAs combined with a LAMA to treat COPD.

***RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® face substantial competition for their intended uses in the targeted markets from products discovered, developed, launched and commercialized both by GSK and by other pharmaceutical companies, which could cause the royalties payable to us pursuant to the LABA Collaboration Agreement to be less than expected, which in turn would harm our business and the price of our securities could fall.***

GSK has responsibility for obtaining regulatory approval, launching and commercializing RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® for their intended uses in the targeted markets around the world. While these products have received regulatory approval and been launched and commercialized in the U.S. and certain other targeted markets, the products face

Table of Contents

substantial competition from existing products previously developed and commercialized both by GSK and by other competing pharmaceutical companies and can expect to face additional competition from new products that are discovered, developed and commercialized by the same pharmaceutical companies and other competitors going forward. For example, sales of Advair®, GSK's approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has indicated publicly that it intends to continue commercializing Advair®.

Many of the pharmaceutical companies competing in respiratory markets are international in scope with substantial financial, technical and personnel resources that permit them to discover, develop, obtain regulatory approval and commercialize new products in a highly efficient and low cost manner at competitive prices to consumers. In addition, many of these competitors have substantial commercial infrastructure that facilitates commercializing their products in a highly efficient and low cost manner at competitive prices to consumers. The market for products developed for treatment of COPD and asthma continues to experience significant innovation and reduced cost in bringing products to market over time. There can be no assurance that RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® will not be replaced by new products that are deemed more effective at lower cost to consumers. The ability of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® to succeed and achieve the anticipated level of sales depends on the commercial and development performance of GSK to achieve and maintain a competitive advantage over other products with the same intended use in the targeted markets.

In addition, following the September 2017 FDA approval of TRELEGY® ELLIPTA®, GSK's diligent efforts obligations regarding commercialization matters has the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following this regulatory approval is guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future. GSK also received in April 2018 an expanded label approval for TRELEGY® ELLIPTA®, allowing it to be used by US physicians to treat a broader population of COPD patients. If GSK prioritizes TRELEGY® ELLIPTA®, we would only be entitled to a 15% economic interest in the future payments made by GSK under the GSK Agreements with respect to this product.

If sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are less than anticipated because of existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, our royalty payments will be less than anticipated, which in turn would harm our business and the price of our securities could fall.

***We and GSK recently received regulatory approval in the U.S. and positive regulatory opinion in Europe for TRELEGY® ELLIPTA® as triple combination treatments for COPD. As a result of the Spin-Off, most of our economic rights in this program and other programs were assigned to Theravance Biopharma. If these programs are successful and GSK and the respiratory market in general views triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, our business could be harmed, and the price of our securities could fall.***

The use of triple therapy is supported by the GOLD guidelines in high-risk patients with severe COPD and a high risk of exacerbations. Prior to the Spin-Off of Theravance Biopharma, we were entitled to receive 100% of any royalties payable under the GSK Agreements arising from sales of TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered and developed in the future under the GSK Agreements. As a result of the transactions effected by the Spin-Off, however, we are now only entitled to receive 15% of any contingent payments and royalties payable by GSK from sales of TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered and developed in the future under the GSK Agreements which were assigned to TRC while Theravance Biopharma receives 85% of those same payments. The commercial success of RELVAR®/BREQ® ELLIPTA® may be adversely effected if GSK or the respiratory markets view TRELEGY® ELLIPTA® or other combination therapies as more beneficial. GSK's diligent efforts obligations regarding commercialization matters has the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following this regulatory approval is guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future.

*In the event that Theravance Biopharma defaults or breaches the agreements we entered into with them in connection with the Spin-Off, our business and results of operations may be materially harmed.*

Upon the Spin-Off, our facility leases in South San Francisco, California were assigned to 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

Table of Contents

utilities, property taxes, and common area maintenance, which may be as much as the actual lease payments. As of March 31, 2018, the total remaining lease payments, which run through May 2020, were \$14.0 million. In the event that Theravance Biopharma defaults on such obligations, our business and results of operations may be materially harmed.

Under the terms of a separation and distribution agreement entered into between us and Theravance Biopharma, Theravance Biopharma will indemnify us from (i) all debts, liabilities and obligations transferred to Theravance Biopharma in connection with the Spin-Off (including its failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the Spin-Off), (ii) any misstatement or omission of a material fact in its information statement filed with the SEC, resulting in a misleading statement and (iii) any breach by it of certain agreements entered into between the parties in connection with the Spin-Off. Theravance Biopharma's ability to satisfy these indemnities, if called upon to do so, will depend upon its future financial strength and if we are not able to collect on indemnification rights from Theravance Biopharma, our financial condition may be harmed.

***U.S. federal income tax reform could adversely affect us.***

On December 22, 2017, U.S. federal tax legislation, commonly referred to as the Tax Cuts and Jobs Act (TCJA), was signed into law, significantly reforming the U.S. Internal Revenue Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, puts into effect the migration from a worldwide system of taxation to a territorial system and modifies or repeals many business deductions and credits.

We continue to examine the impact the TCJA may have on our business. We will evaluate the effect of the TCJA on our net operating losses and our projection of taxes. As a result of the passage of the TCJA, corporate tax rates in the United States will decrease in 2018, which resulted in the remeasurement of our deferred tax assets at the new statutory rate and a reduction in the value of our deferred tax assets in 2017.

The TCJA is a far-reaching and complex revision to the U.S. federal income tax laws with disparate and, in some cases, countervailing impacts on different categories of taxpayers and industries, and will require subsequent rulemaking and interpretation in a number of areas. The long-term impact of the TCJA on the overall economy, the industries in which we operate and our and our partners business cannot be reliably predicted at this early stage of the new law's implementation. There can be no assurance that the TCJA will not negatively impact our operating results, financial condition, and future business operations. The estimated impact of the TCJA is based on our management's current knowledge and assumptions, following consultation with our tax advisors, and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. The impact of the TCJA on holders of common stock is uncertain and could be materially adverse. This report does not discuss any such tax legislation or the manner in which it might affect investors in common stock. Investors should consult with their own tax advisors with respect to such legislation and the potential tax consequences of investing in common stock.

***We may not be able to utilize all of our net operating loss carryforwards.***

We have net operating loss carryforwards and other significant U.S. tax attributes that we believe could offset otherwise taxable income in the U.S. As a part of the overall Spin-Off transaction, the transfer of certain assets by us to Theravance Biopharma and our distribution of Theravance Biopharma ordinary shares resulted in taxable transfers pursuant to applicable provisions of the Internal Revenue Code of 1986, as

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

amended (the Code ) and Treasury Regulations. The taxable gain recognized by us attributable to the transfer of certain assets to Theravance Biopharma will generally equal the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. Although we will not recognize any gain with respect to the cash we transferred to Theravance Biopharma, we may recognize substantial gain based on the fair market value of the other assets (other than cash) transferred to Theravance Biopharma. The determination of the fair market value of these assets is subjective and could be subject to adjustments or future challenge by the Internal Revenue Service ( IRS ), which could result in an increase in the amount of gain realized by us as a result of the transfer. Our U.S. federal income tax resulting from any gain recognized upon the transfer of our assets to Theravance Biopharma (including any increased U.S. federal income tax that may result from a subsequent determination of higher fair market values for the transferred assets), may be reduced by our net operating loss carryforward. The net operating loss carryforwards available in any year to offset our net taxable income will be reduced following a more than 50% change in ownership during any period of 36 consecutive months (an ownership change ) as determined under the Internal Revenue Code of 1986 (the Code ). Transactions involving our common stock, even those outside our control, such as purchases or sales by investors, within the testing period could result in an ownership change. We have conducted an analysis to determine whether an ownership change had occurred since inception through December 31, 2016, and concluded that we had undergone two ownership changes in prior years. Subsequent changes in our ownership or sale of our stock could have the effect of limiting the use of our net operating losses in the future. We have approximately \$1.0 billion of net operating loss carryforward as of December 31, 2017. There may be certain annual limitations for utilization based on the above-described ownership change provisions. In addition, we may not be able to have sufficient future taxable income prior to their expiration because net operating losses have carryforward periods. As a result of the

Table of Contents

passage of the Tax Cuts and Job Act, corporate tax rates in the United States will decrease in 2018, resulted in the remeasurement of our deferred tax assets at the new statutory rate and a reduction in the value of our deferred tax assets in 2017. Future changes in federal and state tax laws pertaining to net operating loss carryforwards may also cause limitations or restrictions from us claiming such net operating losses. If the net operating loss carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U.S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced.

***If any product candidates in any respiratory program partnered with GSK are not approved by regulatory authorities or are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities could fall.***

The FDA must approve any new medicine before it can be marketed and sold in the U.S. Our partner GSK must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that the product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. GSK will not obtain this approval for a partnered product candidate unless and until the FDA approves a NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. In order to market medicines in foreign countries, separate regulatory approvals must be obtained in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more country may make approval in other countries more difficult.

Clinical studies involving product candidates partnered with GSK may reveal that those candidates are ineffective, inferior to existing approved medicines, unacceptably toxic, or that they have other unacceptable side effects. In addition, the results of preclinical studies do not necessarily predict clinical success, and larger and later-stage clinical studies may not produce the same results as earlier-stage clinical studies.

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later clinical or non-clinical studies. In addition, clinical and non-clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If these studies are substantially delayed or fail to prove the safety and effectiveness of product candidates in development partnered with GSK, GSK may not receive regulatory approval for such product candidates and our business and financial condition will be materially harmed and the price of our securities may fall.

Several well-publicized Complete Response letters issued by the FDA and safety-related product withdrawals, suspensions, post-approval labeling revisions to include boxed warnings and changes in approved indications over the last several years, as well as growing public and governmental scrutiny of safety issues, have created a conservative regulatory environment. The implementation of new laws and regulations and revisions to FDA clinical trial design guidance have increased uncertainty regarding the approvability of a new drug. Further, there are additional requirements for approval of new drugs, including advisory committee meetings for new chemical entities, and formal risk evaluation and mitigation strategy at the FDA's discretion. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of any product candidates in any respiratory program partnered with GSK.

***Even if product candidates in any respiratory program partnered with GSK receive regulatory approval, as is the case with RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA®, commercialization of such***

*products may be adversely affected by regulatory actions and oversight.*

Even if GSK receives regulatory approval for product candidates in any respiratory program partnered with GSK, this approval may include limitations on the indicated uses for which GSK can market the medicines or the patient population that may utilize the medicines, which may limit the market for the medicines or put GSK at a competitive disadvantage relative to alternative therapies. These restrictions make it more difficult to market the approved products.

For example, at the joint meeting of the Pulmonary-Allergy Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA regarding the sNDA for BREO® ELLIPTA® as a treatment for asthma, the advisory committee recommended that a large LABA safety trial with BREO® ELLIPTA® should be required in adults and in 12-17 year olds, similar to the ongoing LABA safety trials being conducted as an FDA Post-Marketing Requirement by each of the manufacturers of LABA containing asthma treatments.

Table of Contents

In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we or GSK become aware of previously unknown problems with an approved product in the U.S. or overseas or at contract manufacturers' facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on GSK, including requiring it to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities. GSK is also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies as well as governmental authorities in those foreign countries in which any of the product candidates in any respiratory program partnered with GSK are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. Any failure to maintain regulatory approval will limit GSK's ability to commercialize the product candidates in any respiratory program partnered with GSK, which would materially and adversely affect our business and financial condition and which may cause the price of our securities to fall.

***We may not be successful in our efforts to expand our portfolio of royalty generating products.***

In the future, we may choose to acquire interests in or rights to one or more additional royalty generating products. However, we may be unable to license or acquire rights to suitable royalty generating products for a number of reasons. In particular, the licensing and acquisition of pharmaceutical product rights is a competitive area. Several more established companies are also pursuing strategies to license or acquire rights to royalty generating products. These established companies may have a competitive advantage over us. Other factors that may prevent us from licensing or otherwise acquiring rights to suitable royalty generating products include the following:

- we may be unable to license or acquire the rights on terms that would allow us to make an appropriate return from the product;
- companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or
- we may be unable to identify suitable royalty generating products.

If we are unable to acquire or license rights to suitable royalty generating product candidates, our business may suffer.

We are engaged in a continual review of opportunities to acquire income generating assets, whether royalty-based or otherwise, or to acquire companies that hold royalty or other income generating assets. We currently, and generally at any time, have acquisition opportunities in various stages of active review, including, for example, our engagement of consultants and advisors to analyze particular opportunities, technical, financial and other confidential information, submission of indications of interest and involvement as a bidder in competitive auctions or other processes for the acquisition of income generating assets. Many potential acquisition targets do not meet our criteria, and for those that do, we



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

may face significant competition for these acquisitions from other financial investors and enterprises whose cost of capital may be lower than ours. Competition for future asset acquisition opportunities in our markets is competitive and we may be forced to increase the price we pay for such assets or face reduced potential acquisition opportunities. The success of any future income generating asset acquisitions is based on our ability to make accurate assumptions regarding the valuation, timing and amount of payments, which is highly complex and uncertain. The failure of any of these acquisitions to produce anticipated revenues may materially and adversely affect our financial condition and results of operations.

***We have a significant amount of debt including Term Loans, Convertible Subordinated Notes and Convertible Senior Notes that are senior in capital structure and cash flow, respectively, to our common stockholders. Satisfying the obligations relating to our debt could adversely affect the amount or timing of distributions to our stockholders.***

As of March 31, 2018, we had approximately \$557.2 million in total debt outstanding, comprised primarily of, \$123.7 million in principal outstanding on our term B loan (the Term B Loan), \$241.0 million in principal that remains outstanding under our convertible subordinated notes, due 2023 (the 2023 Notes) and \$192.5 million in principal outstanding under our convertible senior notes due 2025 (the 2025 Notes) (the 2023 Notes and 2025 Notes hereinafter, the Notes). The Notes are unsecured debt and are not redeemable by us prior to the maturity date. Holders of the Notes may require us to purchase all or any portion of their Notes at 100% of their principal amount, plus any unpaid interest, upon a fundamental change. A fundamental change is generally defined to include a merger involving us, an acquisition of a majority of our outstanding common stock, and, under the 2023 Notes, the change of a majority of our board without the approval of the board. In addition, to the extent we pursue and complete a monetization transaction or a transaction that modifies our corporate structure, the structure of such transaction may qualify as a fundamental change under the Notes, which could trigger the put rights of the holders of the Notes, in which case we would be required to use a portion of the net proceeds from such transaction to repurchase any Notes put to us.

Table of Contents

Our Term B Loan is secured by a lien on substantially all of our and the guarantors' personal property and material real property assets (if any). If we default under the terms of the Term B Loan, the lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse effect as defined under the Term B Loan agreement. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Satisfying the obligations of this debt could adversely affect the amount or timing of any distributions to our stockholders. We may choose to satisfy repurchase, or refinance this debt through public or private equity or debt financings if we deem such financings available on favorable terms. If any or all of the Notes are not converted into shares of our common stock before the maturity date, we will have to pay the holders the full aggregate principal amount of the Notes then outstanding. Any of the above payments could have a material adverse effect on our cash position. If we fail to satisfy these obligations, it may result in a default under the indenture, which could result in a default under certain of our other debt instruments, if any. Any such default would harm our business and the price of our securities could fall.

***If we lose key management personnel, or if we fail to retain our key employees, our ability to manage our business may be impaired.***

We have a small management team and very few employees. We are highly dependent on principal members of our management team and a small group of key employees to operate our business. In February 2018, we announced the resignation of our chief executive officer. The Board of Directors plans to commence a search to identify and hire a permanent principal executive officer. Our company is located in northern California, which is headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market remains intense. None of our employees have employment commitments for any fixed period of time and they all may leave our employment at will. In April 2017, we announced that our Board of Directors had determined to undertake a comprehensive review of all of our costs, including executive compensation structures. The result of this review has led us to make changes to our compensation structure. If we fail to hire a qualified chief executive officer or retain our qualified personnel or replace them when they leave, our ability to manage our business may be impaired, which may cause the price of our securities to fall.

***We rely and will continue to rely on outsourcing arrangements for many of our activities, including financial reporting and accounting and human resources.***

As of March 31, 2018, we had only nine employees and, as a result, we rely, and expect to continue to rely, on outsourcing arrangements for a significant portion of our activities, including financial reporting and accounting and human resources, as well as for certain functions as a public company. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

***If we fail to maintain proper and effective internal control over financial reporting or if the interpretations, estimates or judgments utilized in preparing our financial statements prove to be incorrect, our operating results and our ability to operate our business could be harmed.***

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

The Sarbanes-Oxley Act requires, among other things, that we establish and maintain effective internal control over financial reporting and disclosure controls and procedures. Under the SEC's current rules, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our independent registered public accounting firm is also required to report on our internal control over financial reporting. Our testing and our independent registered public accounting firm's testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses and render our internal control over financial reporting ineffective. We have and expect to continue to incur substantial accounting and auditing expense and to expend significant management time in complying with the requirements of Section 404. In February 2018, we announced the resignation of our Chief Executive Officer, which reduced our already small employee base and resulted in our Senior Vice President and Chief Financial Officer assuming the duties of interim Principal Executive Officer. Having many of the key responsibilities of our business assigned to one individual, our interim Principal Executive Officer, Senior Vice President and Chief Financial Officer, may make it difficult in the future to maintain appropriate segregation of duties in the initiating and recording of transactions, which may exacerbate the risk of a material misstatement or lack of disclosure within the annual or interim financial statements not being prevented or detected. To address this lack of segregation of duties, we have implemented additional oversight procedures and compensating controls with the goal of mitigating this risk and, although we plan to continue to monitor this matter, we currently do not believe that this lack of segregation of duties will have an adverse effect on our internal

Table of Contents

controls. If we are not able to maintain compliance with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to investigations or sanctions by the SEC, FINRA, The Nasdaq Global Select Market or other regulatory authorities. In addition, we could be required to expend significant management time and financial resources to correct any material weaknesses that may be identified or to respond to any regulatory investigations or proceedings.

We are also subject to complex tax laws, regulations, accounting principles and interpretations thereof. The preparation of our financial statements requires us to interpret accounting principles and guidance and make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our interpretations, estimates and judgments 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 the preparation of our financial statements. GAAP presentation is subject to interpretation by the SEC, the Financial Accounting Standards Board and various other bodies formed to interpret and create appropriate accounting principles and guidance. In the event that one of these bodies disagrees with our accounting recognition, measurement or disclosure or any of our accounting interpretations, estimates or assumptions, it may have a significant effect on our reported results and may retroactively affect previously reported results. The need to restate our financial results could, among other potential adverse effects, result in us incurring substantial costs, affect our ability to timely file our periodic reports until such restatement is completed, divert the attention of our management and employees from managing our business, result in material changes to our historical and future financial results, result in investors losing confidence in our operating results, subject us to securities class action litigation, and cause our stock price to decline.

***If we determine to expand our portfolio of royalty generating products, our mix of assets and our sources of income may require that we register with the SEC as an investment company in accordance with the Investment Company Act of 1940.***

We have not been and have no current intention to register as an investment company under the Investment Company Act of 1940, or the 40 Act, because we believe the nature of our assets and the sources of our income currently exclude us from the definition of an investment company pursuant to Sections (3)(a)(1)(A), (3)(a)(1)(C) under the 40 Act and Rule 270.3a-1 of Title 17 of the Code of Federal Regulations. Accordingly, we are not currently subject to the provisions of the 40 Act, such as compliance with the 40 Act's registration and reporting requirements, capital structure requirements, affiliate transaction restrictions, conflict of interest rules, requirements for disinterested directors, and other substantive provisions. Generally, to avoid being a company that is an investment company under the 40 Act, it must both: (a) not be or hold itself out as being engaged primarily in the business of investing, reinvesting or trading in securities, and (b) either (i) not be engaged or propose to engage in the business of investing in securities or own or propose to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis or (ii) not have more than 45% of the value of its total assets (exclusive of Government securities and cash items) consist of or more than 45% of its net income after taxes (for the last four fiscal quarters combined) be derived from securities. In addition, we would not be an investment company if an exception, exemption, or safe harbor under the 40 Act applies.

We monitor our assets and income for compliance with the tests under the 40 Act and seek to conduct our business activities to ensure that we do not fall within its definitions of investment company. If we were to become an investment company and be subject to the strictures of the 40 Act, the restrictions imposed by the 40 Act would likely require changes in the way we do business and add significant administrative burdens to our operations. In order to ensure that we do not fall within the 40 Act, we may need to take various actions which we might otherwise not pursue. These actions may include restructuring the Company and/or modifying our mixture of assets and income.

Specifically, our mixture of debt vs. royalty assets is important to our classification as an investment company or not. In this regard, while we currently believe that none of the definitions of investment company apply to us, we may in the future rely on an exception under the 40 Act

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

provided by Section 3(c)(5)(A). To qualify for Section 3(c)(5)(A), as interpreted by the staff of the SEC, we would be required to have at least 55% of our total assets in notes, drafts, acceptances, open accounts receivable, and other obligations representing part or all of the sales price of merchandise, insurance, and services (or Qualifying Assets). In a no-action letter issued to Royalty Pharma on August 13, 2010, the staff stated that royalty interests are Qualifying Assets under this exception. If the SEC or its staff in the future adopts a contrary interpretation or otherwise restricts the conclusions in the staff's no-action letter such that our royalty interests are no longer Qualifying Assets for purposes of Section 3(c)(5)(A), we could be required to register under the 40 Act.

The rules and interpretations of the SEC and the courts, relating to the definition of investment company are highly complex in numerous respects. While we currently intend to conduct our operations so that we will not be deemed an investment

Table of Contents

company, we can give no assurances that we will not determine it to be in the Company's and our stockholders' interest to register as an investment company, not be deemed an investment company and not be required to register under the 40 Act.

***Prolonged economic uncertainties or downturns, as well as unstable market, credit and financial conditions, may exacerbate certain risks affecting our business and have serious adverse consequences on our business.***

The global economic downturn and market instability has made the business climate more volatile and more costly. These economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control and may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a lingering economic downturn or significant increase in our expenses could require additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our stock price and could require us to delay or abandon clinical development plans.

Sales of our partnered products will be dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of negative trends in the general economy in the U.S. or other jurisdictions in which we may do business, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our or our partners' product sales and revenue.

In addition, we rely on third parties for several important aspects of our business. During challenging and uncertain economic times and in tight credit markets, there may be a disruption or delay in the performance of our third party contractors, suppliers or partners. If such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected.

***We have incurred litigation and may incur additional litigation.***

We have been subject to various legal proceedings, and, in the future, we may be exposed to, or threatened with, litigation, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. In addition, agreements entered into by us sometimes include indemnification provisions which may subject us to costs and damages in the event of a claim against an indemnified third party.

Regardless of the merit of particular claims, litigation may be expensive, time-consuming, disruptive to our operations and distracting to management. In recognition of these considerations, we may enter into agreements or other arrangements to settle litigation and resolve such disputes. No assurance can be given that such agreements can be obtained on acceptable terms or that litigation will not occur. These agreements may also significantly increase our operating expenses.

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

If one or more legal matters were resolved against us or an indemnified third party in a reporting period for amounts in excess of management's expectations, our consolidated financial statements for that reporting period could be materially adversely affected. Further, such an outcome could result in significant compensatory, punitive or trebled monetary damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief against us that could materially adversely affect our financial condition and operating results.

While we maintain insurance coverage for certain types of claims, such insurance coverage may be insufficient to cover all losses or all types of claims that may arise.

***We have determined to undertake a comprehensive review of our costs, including our executive compensation structure, which review may not result in meaningful cost savings, may have unintended consequences and could negatively impact our business.***

In April 2017, we announced that our Board of Directors had determined to undertake a fresh, comprehensive review of all of our costs, including executive compensation structures, with the goal that this review would result in meaningful savings in our core operating costs that will benefit our financial performance. In October 2017, we announced that a special committee of our independent directors and the Compensation Committee of our Board of Directors completed a comprehensive review of our spending, including executive and board compensation structures, outside services, travel and entertainment and other expenses. The Compensation Committee of our Board of Directors and the full Board also reviewed and made certain changes to executive and board compensation plans. Future cost reduction efforts may result in the elimination of certain functional areas and/or reductions of our business operations, including the recently announced management changes, which may limit our ability to effectively manage our business. It is likely that we will incur short-term costs to implement any longer-term expense reduction initiatives.

Table of Contents

While our cost reduction efforts are expected to reduce our operating costs, we cannot be certain that such efforts will be successful. There can be no assurances that any meaningful cost savings will correlate with an increase in the price of our common stock. In the event that the aggregate amount of cost reductions implemented as a result of our review, if any, do not meet investor or analyst expectations, the price of our common stock could be adversely affected.

**Risks Related to our Alliance with GSK**

*Because all our current and projected revenues are derived from products under the GSK Agreements, disputes with GSK could harm our business and cause the price of our securities to fall.*

All of our current and projected revenues are derived from products under the GSK Agreements. Any action or inaction by either GSK or us that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between the parties may be interpreted negatively by the market or by our investors, could harm our business and cause the price of our securities to fall. Examples of these kinds of issues include but are not limited to non-performance of contractual obligations and allegations of non-performance, disagreements over the relative marketing and sales efforts for our partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In addition, while we obtained GSK's consent to the Spin-Off as structured, GSK could decide to challenge various aspects of our post-Spin-Off operation of TRC, the limited liability company jointly owned by us and Theravance Biopharma as violating or allowing it to terminate the GSK Agreements. Although we believe our operation of TRC fully complies with the GSK Agreements and applicable law, there can be no assurance that we would prevail against any such claims by GSK. Moreover, regardless of the merit of any claims by GSK, we may incur significant cost and diversion of resources in defending them. In addition, any market or investor uncertainty about the respiratory programs partnered with GSK or the enforceability of the GSK Agreements could result in significant reduction in the market price of our securities and other material harm to our business.

*Because GSK is a strategic partner as well as a significant stockholder, it may take actions that in certain cases are materially harmful to both our business or to our other stockholders.*

Although GSK beneficially owns approximately 31.5% of our outstanding common stock as of April 30, 2018, it is also a strategic partner with rights and obligations under the GSK Agreements that cause its interests to differ from the interests of us and our other stockholders. In particular, GSK has a substantial respiratory product portfolio in addition to the partnered products that are covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with us. For example, GSK could promote its non-GSK/Innoviva respiratory products or a partnered product for which we are entitled to receive a lower percentage of royalties, delay or terminate the development or commercialization of the respiratory programs covered by the GSK Agreements, or take other actions, such as making public statements, that have a negative effect on our stock price. In this regard and by way of example, sales of Advair®, GSK's approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has indicated publicly that it intends to continue commercializing Advair®. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK Agreements, GSK may seek to acquire us to reduce those payment obligations. The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by the GSK Agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other stockholders. In addition, following the FDA regulatory approval of TRELEGY® ELLIPTA® in September 2017, GSK's diligent efforts obligations as to commercialization matters under



the GSK Agreements has the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following this regulatory approval is guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the products covered by the GSK Agreements in the future. In addition, following the expiration of our governance agreement with GSK in September 2015, GSK is no longer subject to the restrictions thereunder regarding the voting of the shares of our common stock owned by it.

*GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements has the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements, which may be harmful to both our business and our stockholders.*

Following the FDA approval of TRELEGY® ELLIPTA® in September 2017, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements has the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. As such, GSK may prioritize TRELEGY® ELLIPTA®, and if GSK and the respiratory market in general view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, this may be harmful to our business, operations and

Table of Contents

stock price. If GSK prioritizes TRELEGY® ELLIPTA®, we will only be entitled to a 15% economic interest of the royalties paid pursuant to the commercialization of our partnered products or chooses to reprioritize its commercial programs, our businesses, operations and stock price would be negatively affected.

*GSK has also indicated to us that it believes its consent may be required before we can engage in certain royalty monetization transactions with third parties, which may inhibit our ability to engage in these transactions.*

In the course of our discussions with GSK concerning the Spin-Off of Theravance Biopharma, GSK indicated to us that it believes that its consent may be required before we can engage in certain transactions designed to monetize the future value of royalties that may be payable to us from GSK under the GSK Agreements. GSK has informed us that it believes that there may be certain covenants included in these types of transactions that might violate certain provisions of the GSK Agreements. Although we believe that we can structure royalty monetization transactions in a manner that fully complies with the requirements of the GSK Agreements without GSK's consent, a third party in a proposed monetization transaction may nonetheless insist that we obtain GSK's consent for the transaction or re-structure the transaction on less favorable terms. We have obtained GSK's agreement that (i) we may grant certain pre-agreed covenants in connection with monetization of our interests in RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy and portions of our interests in TRC, and (ii) it will not unreasonably withhold its consent to our requests to grant other covenants, provided, among other conditions, that in each case, the covenants are not granted in favor of pharmaceutical or biotechnology company with a product either being developed or commercialized for the treatment of respiratory disease. If we seek GSK's consent to grant covenants other than pre-agreed covenants, we may not be able to obtain GSK's consent on reasonable terms, or at all. If we proceed with a royalty monetization transaction that is not otherwise covered by the GSK Agreement without GSK's consent, GSK could request that its consent be obtained or seek to enjoin or otherwise challenge the transaction as violating or allowing it to terminate the GSK Agreements. Regardless of the merit of any claims by GSK, we would incur significant cost and diversion of resources in defending against GSK's claims or asserting our own claims and GSK may seek concessions from us in order to provide its consent. Any uncertainty about whether or when we could engage in a royalty monetization transaction, the potential impact on the enforceability of the GSK Agreements or the loss of potential royalties from the respiratory programs partnered with GSK, could impair our ability to pursue a return of capital strategy for our stockholders ahead of our receipt of significant royalties from GSK, result in significant reduction in the market price of our securities and cause other material harm to our business.

*GSK's ownership of a significant percentage of our stock and its ability to acquire additional shares of our stock may create conflicts of interest, and may inhibit our management's ability to continue to operate our business in the manner in which it is currently being operated.*

As of April 30, 2018, GSK beneficially owned approximately 31.5% of our outstanding common stock. As such, GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over certain changes in our business. The procedures previously governing and restricting GSK offers to our stockholders to acquire outstanding voting stock and the restrictions regarding the voting of shares of our common stock owned by it terminated upon the expiration of the governance agreement in September 2015. Further, pursuant to our Certificate of Incorporation, we renounce our interest in and waive any claim that a corporate or business opportunity taken by GSK constitutes a corporate opportunity of ours unless such corporate or business opportunity is expressly offered to one of our directors who is a director, officer or employee of GSK, primarily in his or her capacity as one of our directors.

***GSK's significant ownership position may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.***

As of April 30, 2018, GSK beneficially owned approximately 31.5% of our outstanding common stock. As a result of GSK's significant ownership, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

***GSK could sell or transfer a substantial number of shares of our common stock, which could depress the price of our securities or result in a change in control of our company.***

GSK is not subject to any contractual restrictions with us on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party. Sales by GSK of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

Table of Contents

**Risks Related to Legal and Regulatory Uncertainty**

*If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.*

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which are necessary to build name and brand recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks or trade names similar to ours, thereby impeding our ability to build name and brand identity and possibly leading to market confusion. In addition, there could be potential trademark or trade name infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. There was also a risk that if there is confusion in the marketplace, the reputation, performance and/or actions of such third parties may negatively impact our stock price and our business. We therefore adopted a new brand, Innoviva, in January 2016. Over the long term, if we are unable to establish name and brand recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If we fail to promote and maintain our brand successfully, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our business may be harmed.

*If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to products in any respiratory program partnered with GSK are not adequate, the future commercialization of any such product could be delayed, limited or prevented, which would materially harm our business and the price of our securities could fall.*

To the extent the intellectual property protection of products in any respiratory program partnered with GSK are successfully challenged or encounter problems with the U.S. Patent and Trademark Office or other comparable agencies throughout the world, the commercialization of these products could be delayed, limited or prevented. Any challenge to the intellectual property protection of a late-stage development asset or approved product arising from any respiratory program partnered with GSK could harm our business and cause the price of our securities to fall.

Our commercial success depends in part on products in any respiratory program partnered with GSK not infringing the patents and proprietary rights of third parties. Third parties may assert that these products are using their proprietary rights without authorization. In addition, third parties may obtain patents in the future and claim that use of GSK's technologies infringes upon these patents. Furthermore, parties making claims against GSK may obtain injunctive or other equitable relief, which could effectively block GSK's ability to further develop or commercialize one or more of the product candidates or products in any respiratory program partnered with GSK.

In the event of a successful claim of infringement against GSK, it may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, GSK may need to obtain licenses from third parties to advance its research or allow commercialization of the products. GSK may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, GSK would be unable to further develop and commercialize one or more of the products, which could harm our business significantly. In addition, in the future GSK could be required to initiate litigation to enforce its proprietary rights against infringement by third parties. Prosecution of these claims to enforce its rights against others would involve substantial litigation expenses. If GSK fails to effectively enforce its proprietary rights related to our partnered respiratory programs against others, our business will be harmed, and the price of our securities could fall.

**Risks Related to Ownership of our Common Stock**

*The price of our securities has been volatile and may continue to be so, and purchasers of our securities could incur substantial losses.*

The price of our securities has been volatile and may continue to be so. Between January 1, 2018 and March 31, 2018, the high and low sales prices of our common stock as reported on The Nasdaq Global Select Market varied between \$13.80 and \$16.99 per share. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the companies' operating performance, in particular during the last several years. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our securities:

- any adverse developments or results or perceived adverse developments or results with respect to the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® with GSK, including, without limitation, if payor coverage is lower than anticipated or if sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are less than anticipated because of pricing pressure in the respiratory markets targeted by our partnered products or existing or future

Table of Contents

competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, and our royalty payments are less than anticipated;

- any positive developments or results or perceived positive developments or results with respect to the commercialization of TRELEGY® ELLIPTA® with GSK, including, if GSK and the respiratory market in general view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®;
- any adverse developments or results or perceived adverse developments or results with respect to the on-going development of FF/VI with GSK, including, without limitation, any difficulties or delays encountered with the regulatory path for FF/VI or any indication from clinical or non-clinical studies, including the large Phase 3b program, that FF/VI is not safe or efficacious or does not sufficiently differentiate itself from alternative therapies;
- any adverse developments or results or perceived adverse developments or results with respect to the on-going development of UMEC/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for UMEC/VI, any indication from clinical or non-clinical studies that UMEC/VI is not safe or efficacious;
- any adverse developments or perceived adverse developments in the field of LABAs, including any change in FDA (or comparable foreign regulatory authority) policy or guidance (such as the pronouncement in February 2010 warning that LABAs should not be used alone in the treatment of asthma and related labeling requirements, the impact of the March 2010 FDA Advisory Committee discussing LABA clinical trial design to evaluate serious asthma outcomes or the FDA's April 2011 announcement that manufacturers of currently marketed LABAs conduct additional clinical studies comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone);
- GSK reprioritizing its development or commercial efforts on other products, including TRELEGY® ELLIPTA® or products owned by GSK (such as Advair®) but which are not partnered with us;
- the occurrence of a fundamental change triggering a put right of the holders of the Notes or our inability, or perceived inability, to satisfy the obligations under the Notes when they become due;
- our incurrence of expenses in any particular quarter that are different than market expectations;

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

- announcements regarding the cost review undertaken by our Board of Directors and the implementation of any cost-saving measures resulting from such review;
- changes in the treatment paradigm or standards of care for COPD or asthma;
- the extent to which GSK advances (or does not advance) FF/VI, UMEC/VI and TRELEGY® ELLIPTA®, through commercialization in all indications in all major markets;
- any adverse developments or perceived adverse developments with respect to our relationship with GSK, including, without limitation, disagreements that may arise between us and GSK;
- decisions by GSK with respect to the MABA program;
- announcements by or regarding GSK generally;
- announcements of patent issuances or denials, technological innovations or new commercial products by GSK;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by GSK;
- regulatory developments in the U.S. and foreign countries, including recent tax reform and the possibility that the current presidential administration and the U.S. Congress may replace PPACA and related legislation with new healthcare legislation;
- economic and other external factors beyond our control;

Table of Contents

- sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended;
- relative illiquidity in the public market for our common stock (our three largest stockholders other than GSK collectively owned approximately 31.2% of our outstanding common stock as of April 30, 2018 based on our review of publicly available filings); and,
- potential sales or purchases of our common stock by GSK.

*We may be unable to or elect not to continue returning capital to our stockholders*

Recently, we have focused on returning capital to stockholders and paid quarterly dividends during the third and fourth quarters of 2014 and during the first three quarters of 2015. From October 2015 through December 31, 2017, we repurchased an aggregate of 17,307,790 shares of our common stock for a total of \$201.2 million. The payment of, or continuation of, capital returns to stockholders is at the discretion of our Board of Directors and is dependent upon our financial condition, results of operations, capital requirements, general business conditions, tax treatment of capital returns, potential future contractual restrictions contained in credit agreements and other agreements and other factors deemed relevant by our Board of Directors. Future capital returns may also be affected by, among other factors: our views on potential future capital requirements for investments in acquisitions and our working capital and debt maintenance requirements; legal risks; stock or debt repurchase programs; changes in federal and state income tax laws or corporate laws; and changes to our business model. Our capital return programs may change from time to time, and we cannot provide assurance that we will continue to provide any particular amounts. Our announcement of future capital return programs does not obligate us to repurchase any specific dollar amount of debt or equity or number of shares of common stock. A reduction, suspension or change in our capital return programs could have a negative effect on our stock price.

*Concentration of ownership will limit your ability to influence corporate matters.*

As of April 30, 2018, GSK beneficially owned approximately 31.5% of our outstanding common stock. Based on our review of publicly available filings as of April 30, 2018, our three largest stockholders other than GSK collectively owned approximately 31.2% of our outstanding common stock. These stockholders could control the outcome of actions taken by us that require stockholder approval, including a transaction in which stockholders might receive a premium over the prevailing market price for their shares. Following the expiration of the governance agreement in September 2015, GSK is no longer subject to the restrictions thereunder regarding the voting of the shares of our common stock owned by it.

*Anti-takeover provisions in our charter and bylaws and in Delaware law could prevent or delay a change in control of our company.*



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

Provisions of our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

- requiring supermajority stockholder voting to effect certain amendments to our Certificate of Incorporation and Bylaws;
- restricting the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to the Board or for proposing matters that can be acted on by stockholders at meetings.

In addition, some provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

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

None.

Table of Contents**Item 6. Exhibits****(a) Index to Exhibits**

<b>Exhibit Number</b>	<b>Description</b>	<b>Form</b>	<b>Exhibit</b>	<b>Incorporated by Reference Filing Date/Period End Date</b>
3.1	<u>Amended and Restated Certificate of Incorporation</u>	8-K	99.2	4/28/16
3.2	<u>Amended and Restated Bylaws, amended and restated as of February 8, 2017</u>	8-K	3.1	2/9/17
10.77	<u>Agreement between Innoviva, Inc. and Eric d. Esparbes dated as of February 7, 2018</u>	8-K	10.1	2/7/18
10.78	<u>Separation Letter between Innoviva, Inc. and Michael Aguiar dated as of February 6, 2018</u>	8-K	10.2	2/7/18
10.79	<u>Agreement, dated as of February 12, 2018, by and among Innoviva, Inc., Sarissa Capital Domestic Fund LP, and certain of its affiliates</u>	8-K	10.1	2/13/18
10.80	<u>Separation Letter between Innoviva, Inc. and Michael Faerm dated as of February 21, 2018</u>			
31	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14 pursuant to the Securities Exchange Act of 1934</u>			
32	<u>Certifications Pursuant to 18 U.S.C. Section 1350</u>			
101	Interactive Data File (Quarterly Report on Form 10-Q, for the quarterly period ended March 31, 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: May 3, 2018

/s/ Eric d Esparbes

**Eric d Esparbes**

Interim Principal Executive Officer and Senior Vice President and Chief  
Financial Officer

*(Principal Executive Officer and Principal Financial Officer)*