

Innoviva, Inc.  
Form 10-Q  
August 08, 2017  
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 June 30, 2017

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   
Non-accelerated filer   
(Do not check if a smaller reporting company)

Accelerated filer   
Smaller reporting company   
Emerging growth company

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

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

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

The number of shares of registrant's common stock outstanding on July 31, 2017 was 109,360,744.

---

Table of Contents

**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

Item 1. Financial Statements

<u>Condensed Consolidated Balance Sheets as of June 30, 2017 (unaudited) and December 31, 2016</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2017 and 2016 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income for the Three and Six Months Ended June 30, 2017 and 2016 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2017 and 2016 (unaudited)</u>	6
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</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>	20
---	----

<u>Item 4. Controls and Procedures</u>	20
--	----

**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>	39
--	----

<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>June 30, 2017 (unaudited)</b>	<b>December 31, 2016 *</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 127,634	\$ 118,016
Short-term marketable securities	7,992	32,417
Related party receivables from collaborative arrangements	61,796	46,847
Prepaid expenses and other current assets	642	766
Total current assets	198,064	198,046
Property and equipment, net	289	368
Capitalized fees paid to a related party, net	173,633	180,545
Other assets	37	37
Total assets	\$ 372,023	\$ 378,996
<b>Liabilities and Stockholders Deficit</b>		
Current liabilities:		
Accounts payable	\$ 277	\$ 128
Accrued personnel-related expenses	1,203	2,361
Accrued interest payable	7,103	7,828
Other accrued liabilities	2,460	1,095
Non-recourse notes, due 2029, current	15,181	7,752
Deferred revenue, current	885	885
Total current liabilities	27,109	20,049
Convertible subordinated notes, due 2023, net of issuance costs	237,858	237,597
Non-recourse notes, due 2029, net of issuance costs	400,854	470,744
Other long-term liabilities	1,159	1,383
Deferred revenue	1,772	2,214
Commitments and contingencies (Notes 9)		
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, 109,510 and 108,585 shares issued as of June 30, 2017 and December 31, 2016, respectively	1,094	1,085
Treasury stock: 150 shares as of June 30, 2017 and December 31, 2016	(3,263)	(3,263)
Additional paid-in capital	1,286,340	1,282,077
Accumulated other comprehensive income		1
Accumulated deficit	(1,580,900)	(1,632,891)
Total stockholders deficit	(296,729)	(352,991)
Total liabilities and stockholders deficit	\$ 372,023	\$ 378,996

*See accompanying notes to condensed consolidated financial statements.*

---

\*Condensed consolidated balance sheet as of December 31, 2016 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Royalty revenue from a related party, net of amortization for capitalized fees paid to a related party of \$3,456 for the three months ended June 30, 2017 and 2016 and \$6,912 for the six months ended June 30, 2017 and 2016	\$ 58,341	\$ 32,251	\$ 98,612	\$ 56,206
Revenue from collaborative arrangements from a related party	221	221	442	442
Total net revenue	58,562	32,472	99,054	56,648
Operating expenses:				
Research and development	348	370	702	762
General and administrative	10,384	6,225	21,179	12,477
Total operating expenses	10,732	6,595	21,881	13,239
Income from operations	47,830	25,877	77,173	43,409
Other income (expense), net	(786)	1,719	(739)	1,687
Interest income	306	157	542	249
Interest expense	(12,204)	(13,156)	(24,985)	(26,313)
Net income	\$ 35,146	\$ 14,597	\$ 51,991	\$ 19,032
Basic net income per share	\$ 0.33	\$ 0.13	\$ 0.48	\$ 0.17
Diluted net income per share	\$ 0.30	\$ 0.13	\$ 0.46	\$ 0.17
Shares used to compute basic and diluted net income per share:				
Shares used to compute basic net income per share	107,614	111,359	107,468	112,005
Shares used to compute diluted net income per share	120,463	124,316	120,317	112,531

*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 June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Net income	\$ 35,146	\$ 14,597	\$ 51,991	\$ 19,032
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities, net	1	8	(1)	9
Less: realized gain on marketable securities, net		(1)		(1)
Comprehensive income	\$ 35,147	\$ 14,604	\$ 51,990	\$ 19,040

*See accompanying notes to condensed consolidated financial statements.*



Table of Contents

## INNOVIVA, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2017	2016
<b>Cash flows from operating activities</b>		
Net income	\$ 51,991	\$ 19,032
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	6,991	6,967
Stock-based compensation	4,934	4,705
Amortization of debt issuance costs	1,401	1,414
Loss (gain) on extinguishment of debt	830	(1,752)
Amortization of premium (discount) on short-term investments	6	(14)
Amortization of lease guarantee	(162)	(28)
Interest added to the principal balance of non-recourse notes due 2029		855
Realized gain on sale of marketable securities, net		1
Changes in operating assets and liabilities:		
Receivables from collaborative arrangements	(14,949)	(9,589)
Prepaid expenses and other current assets	124	76
Other assets		(40)
Accounts payable	149	(681)
Accrued personnel-related expenses and other accrued liabilities	242	(627)
Accrued interest payable	(725)	(88)
Other long-term liabilities	10	(78)
Deferred revenue	(442)	(443)
Net cash provided by operating activities	50,400	19,710
<b>Cash flows from investing activities</b>		
Maturities of marketable securities	36,387	44,101
Purchases of marketable securities	(11,969)	(59,893)
Sales of marketable securities		2,995
Purchases of property and equipment		(8)
Net cash provided by (used in) investing activities	24,418	(12,805)
<b>Cash flows from financing activities</b>		
Payments of principal on non-recourse notes due 2029	(64,431)	
Repurchase of shares to satisfy tax withholding	(847)	(597)
Payments of cash dividends to stockholders	(107)	(843)
Proceeds from issuances of common stock, net	185	335
Repurchase of common stock		(44,331)
Repurchase of convertible subordinated notes due 2023		(8,095)
Proceeds from capped-call options		391
Net cash used in financing activities	(65,200)	(53,140)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>9,618</b>	<b>(46,235)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>118,016</b>	<b>159,180</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 127,634</b>	<b>\$ 112,945</b>

**Supplemental disclosure of cash flow information**

Cash paid for interest	\$	24,310	\$	24,132
------------------------	----	--------	----	--------

*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 bringing compelling new medicines to patients in areas of unmet need by leveraging its significant expertise in the development, commercialization and financial management of bio-pharmaceuticals. Innoviva's portfolio is anchored by the respiratory assets partnered with Glaxo Group Limited ( *GSK* ), including RELVAR®/BREO®ELLIPTA® (fluticasone furoate/ vilanterol, *FF/VI* ) and ANORO® ELLIPTA®(umeclidinium bromide/ vilanterol, *UMEC/VI* ). Under the Long-Acting Beta2 Agonist ( *LABA* ) Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the *GSK Agreements* ), Innoviva is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. Innoviva is also entitled to 15% of any future payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ( *TRC* ), relating to the combination FF/UMEC/VI and the Bifunctional Muscarinic Antagonist Beta2 Agonist ( *MABA* ) program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid, and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement ( *LABA Collaboration* ), which has 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, 2017 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, 2016 filed with the Securities and Exchange Commission ( *SEC* ) on February 28, 2017.

***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. The financial position and results of operations of TRC are not material for the periods presented.

***Recently Issued Accounting Pronouncements Not Yet Adopted***

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. ASU 2014-09 guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2017 (as amended through ASU 2015-14 issued in August 2015), with early adoption permitted. Companies can elect a full retrospective method to recast prior-period financial statements or a modified retrospective method to recognize the cumulative effect as an adjustment to the retained earnings in the initial year. We plan to implement the standard in the first quarter of 2018 on a modified retrospective basis and do not anticipate that this standard will have a material impact on our accounting for royalty revenues. We are continuing to assess the potential impacts of the standard on the accounting for other revenues associated with the collaboration agreements.

Table of Contents

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 is computed by dividing net income by the weighted-average number of shares of common stock outstanding. Diluted net income per share is computed by dividing net income adjusted with the interest expense on our unsecured convertible subordinated notes due 2023 (the 2023 Notes ) 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 2023 Notes using the if-converted method.

The following table shows the computation of basic and diluted net income per share for the three and six months ended June 30, 2017 and 2016:

(In thousands except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
<b>Numerator:</b>				
Net income, basic	\$ 35,146	\$ 14,597	\$ 51,991	\$ 19,032
Add: interest expense on 2023 Notes	1,414	1,457	2,821	
Net income, diluted	\$ 36,560	\$ 16,054	\$ 54,812	\$ 19,032
<b>Denominator:</b>				
Weighted-average shares used to compute basic net income per share	107,614	111,359	107,468	112,005
Dilutive effect of 2023 Notes	12,189	12,602	12,189	
Dilutive effect of options and awards granted under equity incentive plan and employee stock purchase plan	660	355	660	526
Weighted-average shares used to compute diluted net income per share	120,463	124,316	120,317	112,531
<b>Net income per share</b>				
Basic	\$ 0.33	\$ 0.13	\$ 0.48	\$ 0.17
Diluted	\$ 0.30	\$ 0.13	\$ 0.46	\$ 0.17

***Anti-Dilutive Securities***

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

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Outstanding options and awards granted under equity incentive plan and employee stock purchase plan	2,019	4,276	2,541	4,383
Shares issuable upon conversion of 2023 Notes				12,753
	2,019	4,276	2,541	17,136

Table of Contents**3. Collaborative Arrangements***Net Revenue from Collaborative Arrangements*

Net revenue recognized under our GSK Agreements was as follows:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Royalties from a related party - RELVAR/BREO	\$ 54,645	\$ 31,482	\$ 93,334	\$ 55,769
Royalties from a related party - ANORO	7,152	4,225	12,190	7,349
Total royalties from a related party	61,797	35,707	105,524	63,118
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)	(6,912)	(6,912)
Royalty revenue	58,341	32,251	98,612	56,206
Strategic alliance - MABA program license	221	221	442	442
Total net revenue from GSK	\$ 58,562	\$ 32,472	\$ 99,054	\$ 56,648

*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 agreements. 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®, royalties are upward tiering and range from 6.5% to 10%.

*GSK Contingent Payments and Revenue*

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

The potential future contingent payments receivable related to the MABA program of up to \$363.0 million are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to GSK's performance of future development, manufacturing and commercialization activities for product candidates after licensing the program. We are entitled to 15% of any contingent payments and royalties payable by GSK through our ownership interest in TRC.

### 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)	June 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government agencies	\$ 9,989	\$	\$	\$ 9,989
U.S. commercial paper	68,365			68,365
Money market funds	51,906			51,906
Total	\$ 130,260	\$	\$	\$ 130,260



Table of Contents

(In thousands)	Amortized Cost	December 31, 2016		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government agencies	\$ 12,428	\$ 1	\$	\$ 12,429
U.S. commercial paper	72,065			72,065
Money market funds	64,319			64,319
Total	\$ 148,812	\$ 1	\$	\$ 148,813

As of June 30, 2017, all of the available-for-sale securities had contractual maturities within one year and the weighted average maturity of marketable securities was approximately one month.

**Fair Value Measurements**

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

Estimated Fair Value Measurements as of June 30, 2017 Using:

Types of Instruments (In thousands)	Quoted Price in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
<i>Assets</i>				
U.S. government agencies	\$	\$ 9,989	\$	\$ 9,989
U.S. commercial paper		68,365		68,365
Money market funds	51,906			51,906
Total assets measured at estimated fair value	\$ 51,906	\$ 78,354	\$	\$ 130,260
<i>Liabilities</i>				
2023 Notes	\$	\$ 220,356	\$	\$ 220,356
Non-recourse notes due 2029 (the 2029 Notes )		430,156		430,156
Total fair value of liabilities	\$	\$ 650,512	\$	\$ 650,512

Estimated Fair Value Measurements as of December 31, 2016 Using:

Types of Instruments (In thousands)	Quoted Price in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
<i>Assets</i>				
U.S. government agencies	\$	\$ 12,429	\$	\$ 12,429
U.S. commercial paper		72,065		72,065
Money market funds	64,319			64,319
Total assets measured at estimated fair value	\$ 64,319	\$ 84,494	\$	\$ 148,813
<i>Liabilities</i>				

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

2023 Notes	\$	\$	202,125	\$	\$	202,125
2029 Notes			487,189			487,189
Total fair value of liabilities	\$	\$	689,314	\$	\$	689,314

Table of Contents

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

The fair value of our 2023 Notes and of our 2029 Notes is based on recent trading prices of the instruments.

**5. Capitalized Fees Paid to a Related Party**

We capitalize fees paid to licensors related to agreements for approved products or commercialized products and amortize these fees on a straight-line basis over their estimated useful lives upon the commercial launch of the product. The estimated useful lives of these capitalized fees are based on a country-by-country and product-by-product basis, as the later of the expiration or termination of the last patent right covering the compound in such product in such country and 15 years from first commercial sale of such product in such country, unless the agreement is terminated earlier. Capitalized fees paid to a related party of \$220.0 million consist registrational and launch-related milestone fees paid to GSK. Accumulated amortization of these capitalized fees is \$46.4 million as of June 30, 2017.

**6. 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 is the remaining grant of 63,000 special long-term retention and incentive performance-contingent RSAs to senior management in 2011. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and require 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 remain subject to continued employment and will vest in November 2017. The stock-based compensation cost for these awards was not material for the three and six months ended June 30, 2017.

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 will 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

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

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 is 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.

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.

Table of Contents**Stock-Based Compensation Expense**

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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Research and development	\$ 175	\$ 172	\$ 353	\$ 347
General and administrative	2,252	2,669	4,581	4,358
Total stock-based compensation expense	\$ 2,427	\$ 2,841	\$ 4,934	\$ 4,705

As of June 30, 2017, 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	\$ 603
RSUs	2,176
RSAs	10,346
Performance-based RSAs	107
Market-based RSUs	436
Market-based RSAs	2,906
Total stock-based compensation expense	\$ 16,574

**7. Debt**

Our debt consists of:

(In thousands)	June 30, 2017	December 31, 2016
Convertible subordinated notes due 2023	\$ 240,984	\$ 240,984
Non-recourse notes due 2029	422,758	487,189
Total debt	663,742	728,173
Unamortized debt issuance cost	(9,849)	(12,080)
Current portion of non-recourse notes due 2029	(15,181)	(7,752)
Net long-term debt	\$ 638,712	\$ 708,341

**Convertible Subordinated Notes Due 2023**

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

In January 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of our unsecured 2023 Notes, which will mature on January 15, 2023. The financing raised proceeds, net of issuance costs, of approximately \$281.2 million, less \$36.8 million to purchase two privately-negotiated capped call option transactions in connection with the issuance of the notes. The 2023 Notes bear interest at the rate of 2.125% per year that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2013. The principal balance of the 2023 Notes was reduced to \$241.0 million by the partial conversion of \$32.4 million in 2014 and repurchase of \$14.1 million in the open market in 2016. As of June 30, 2017, the capped call strike price and cap price are at \$19.77 and \$27.04, respectively.

### *Non-Recourse Notes Due 2029*

In April 2014, we entered into certain note purchase agreements relating to the private placement of \$450.0 million aggregate principal amount of the 2029 Notes issued by our wholly-owned subsidiary. The 2029 Notes bear an annual fixed interest rate of 9%, with interest and principal paid quarterly beginning November 15, 2014. The 2029 Notes may be redeemed at any time prior to maturity, in whole or in part, at specified redemption premiums. The redemption premium was 2.5% until April 17, 2017, and there is no redemption premium after such date.

Table of Contents

Since the principal and interest payments on the 2029 Notes are based on royalties from product sales recorded by GSK, which will vary from quarter to quarter and are unknown to us, the 2029 Notes may be repaid prior to the final maturity date in 2029. Prior to June 30, 2017, the principal balance of the 2029 Notes was paid down by \$71.3 million, of which \$64.4 million was made during the six months ended June 30, 2017. The 2017 principal payments on the 2029 Notes consist of (1) \$14.4 million based on our royalty revenues generated in the previous quarters ended December 31, 2016 and March 31, 2017, and (2) \$50.0 million from our previously announced plan to prepay a portion of the outstanding principal of the 2029 Notes as part of the 2017 Capital Return Plan discussed below. In connection with the \$50.0 million principal prepayment, we wrote off the corresponding pro-rata unamortized debt issuance cost of \$0.8 million and these are presented as part of Other income (expense), net in our consolidated statements of operations for the three and six months ended June 30, 2017. As of June 30, 2017, the principal balance of the 2029 Notes was \$422.8 million, which will be partially paid down by \$15.2 million in the next quarterly payment expected to be made in August 2017. This payment is based on our royalty revenues of \$61.8 million for the three months ended June 30, 2017.

**8. Shareholders Deficit**

In February 2017, we announced a new capital return plan, the 2017 Capital Return Plan. The 2017 Capital Return Plan authorizes a combination of repurchases of stock and/or repurchases, redemptions or prepayments of debt up to \$150.0 million, through tender offers, open market purchases, private transactions, exchange offers or other means through December 31, 2017. Other than the \$50.0 million prepayment on our 2029 Notes described in Note 7, there were no other activities related to the 2017 Capital Return Plan during the six months ended June 30, 2017.

**9. Commitments and Contingencies**

Commitments

We have an existing lease agreement for our corporate headquarters with term expiring in June 2023. We also have a lease guarantee obligation for our former facility, which was assigned to Theravance Biopharma Inc. through the end of the lease in May 2020.

Legal Proceedings

In April 2017, Sarissa Capital Domestic Fund LP and certain of its affiliates (together, Sarissa ) filed a Verified Complaint Pursuant to Section 225 of the Delaware General Corporation Law and for Specific Performance in the Delaware Court of Chancery, captioned Sarissa Capital Domestic Fund LP, et al. v. Innoviva, Inc., C.A. No. 2017-0309-JRS (the Specific Performance Litigation ). Sarissa alleges that it had entered into a binding agreement to settle its proxy contest in exchange for the inclusion of each of George W. Bickerstaff, III and Odysseas Kostas, M.D. on our Board of Directors. Sarissa seeks specific performance of the alleged agreement. On April 30, 2017, we filed a motion to dismiss the Specific Performance Litigation. On May 17, 2017, the Court entered an Order Maintaining Status Quo, which ordered that, during the pendency of the Specific Performance Litigation, the Innoviva Board of Directors shall remain in place, and prohibits the Company from

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

entering or agreeing to any transactions, the consummation of which would require the approval of or vote by Innoviva stockholders or amending, modifying, or repealing Innoviva's bylaws or charter in the absence of an affirmative vote of five of the then-seven member board of directors or without providing plaintiffs' counsel five business days' advance written notice. Trial in the Specific Performance Litigation occurred on July 27, 2017, and the parties are currently awaiting the Court's ruling. We believe the Specific Performance Litigation is without merit and intend to defend it vigorously. Legal fees relating to this claim have been submitted to the Company's insurance carrier for reimbursement pursuant to the terms of its directors' and officers' insurance policy; however, as of August 8, 2017, the insurance carrier has not yet made a determination as to the extent to which these costs are covered, if at all, under the Company's policy. We can provide no assurances that such coverage is or will be available and the Company may not be able to recover any portion of the cost of such litigation.

### 10. Income Taxes

The effective tax rate for the three and six months ended June 30, 2017 was 0.06%, compared to 0.15% for the same periods in 2016. Should we continue to generate taxable income in 2017, 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.



Table of Contents

**11. Subsequent Events**

On August 7, 2017, we completed an offering of \$175.0 million aggregate principal amount of our 2.50% convertible senior notes due 2025 (the 2025 Notes ). The 2025 Notes were sold in a private placement under a purchase agreement, dated as of August 1, 2017, entered into by and among Innoviva and Morgan Stanley & Co. LLC and Deutsche Bank Securities Inc., as the initial purchasers (collectively, the Initial Purchasers ), for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the Securities Act ). We also granted the Initial Purchasers a right to purchase, within a 30-day period, up to an additional \$17.5 million principal amount of additional 2025 Notes on the same terms and conditions, which the Initial Purchasers exercised in full on August 4, 2017 and which additional purchase was also completed on August 7, 2017. We intend, as part of our ongoing commitment to optimize our capital structure and reduce our overall cost of capital, to use a portion of the net proceeds of this offering to redeem on the next interest payment date of August 15, 2017 a portion of the principal outstanding under our 2029 Notes. We also used approximately \$17.5 million of the net proceeds from this offering to repurchase 1,317,771 shares of our common stock concurrently with the pricing of this offering in privately negotiated transactions effected through one of the initial purchasers or its affiliate, as our agent.

Table of Contents

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

**Forward-Looking Statements**

The information in this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements contained herein that are not of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives, may be forward-looking statements. The words anticipates, believes, could, designed, estimates, expects, goal, intends, may, objective, plans, projects, pursue, will, would and similar expressions thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could materially differ from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited, to those 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.

**OVERVIEW**

**Executive Summary**

Innoviva, Inc. (Innoviva, the Company or we) is focused on bringing compelling new medicines to patients in areas of unmet need by leveraging its significant expertise in the development, commercialization and financial management of bio-pharmaceuticals, to maximize the commercial potential of its respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, FF/VI) and ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, UMEC/VI). Under the Long-Acting Beta2 Agonist (LABA) Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein collectively as the GSK Agreements), 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%. Innoviva is also entitled to 15% of any future payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC (TRC), including the closed triple combination therapy for COPD (FF/UMEC/VI).

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 June 30, 2017, we had 13 employees. Our

revenues consist of royalties and potential milestone payments, if any, from our respiratory partnership agreements with GSK.

**Recent Highlights**

- Second quarter 2017 net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$364.3 million, up 74% from \$ 209.9 million in the second quarter of 2016, with \$232.4 million in net sales from the U.S. market and \$131.9 million from non-U.S. markets.
- Second quarter 2017 net sales of ANORO® ELLIPTA® by GSK were \$110.0 million, up 69% from \$65.0 million in the second quarter of 2016, with \$75.5 million of sales from the U.S. market and \$34.5 million from non-U.S. markets.
- We announced in May 2017 that Relvar Ellipta significantly improved asthma control in Salford Lung Study patients compared to their usual care.

Table of Contents

**Capital Return Plan**

In February 2017, we announced a new capital return plan, the 2017 Capital Return Plan. The 2017 Capital Return Plan authorizes a combination of repurchases of stock and/or repurchases, redemptions or prepayments of debt up to \$150.0 million, through tender offers, open market purchases, private transactions, exchange offers or other means through December 31, 2017. The 2017 Capital Return Plan is expected to be funded using our working capital. We are not obligated to repurchase any specific dollar amount of debt or equity or number of shares of common stock under the 2017 Capital Return Plan. We will determine when, if and how to proceed with any repurchase transactions under the program, as well as the amount of any such repurchase transactions, based upon, among other things, our evaluation of our liquidity and capital needs (including for strategic and other opportunities), our business, results of operations, and financial position and prospects, general financial, economic and market conditions, prevailing market prices for shares of our common stock and notes, corporate, regulatory and legal requirements, and other conditions and factors deemed relevant by our management and Board of Directors from time to time. Our 2017 Capital Return Plan may be suspended or discontinued at any time. There can be no assurance as to the actual volume of any debt or share repurchases in any given period or over the term of the program or as to the manner or terms of any such transactions.

As previously announced in April 2017, we prepaid \$50.0 million in outstanding principal on our 2029 Notes in May 2017 as part of the 2017 Capital Return Plan discussed above.

In August 2017, as part of the 2017 Capital Return Plan, we used approximately \$17.5 million of the net proceeds from the offering of our 2025 Notes to repurchase 1,317,771 shares of our common stock concurrently with the pricing of the offering in privately negotiated transactions effected through one of the initial purchasers or its affiliate, as our agent.

**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 COPD and asthma. For the treatment of COPD, the collaboration has developed two 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) and
- (2) ANORO® ELLIPTA® (UMEC/VI), a once-daily medicine combining a long-acting muscarinic antagonist ( LAMA ), umeclidinium bromide (UMEC), with a LABA, VI. Under the LABA Collaboration Agreement, GSK and Innoviva are exploring various paths to create triple therapy medications.

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 GSK Agreements, 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 development and commercialization activities under the GSK Agreements including participation on the joint steering committee and joint project committees that are expected to continue over the life of the agreements. 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%.

#### *2004 Strategic Alliance*

In March 2004, we entered into the Strategic Alliance Agreement with GSK in which 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 ). GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. We are entitled to receive 15% of any contingent payments and royalties payable by GSK from sales of FF/UMEC/VI (and MABA, and MABA/FF). 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, 2016 filed with the SEC on February 28, 2017.

Table of Contents**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.

There were no 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, 2016 filed with the SEC on February 28, 2017 provides a more complete discussion of our critical accounting policies and estimates.

**Results of Operations****Net Revenue**

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

(In thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	2016	Change \$	%	2017	2016	Change \$	%
Royalties from a related party - RELVAR/BREO	\$ 54,645	\$ 31,482	\$ 23,163	74%	\$ 93,334	\$ 55,769	\$ 37,565	67%
Royalties from a related party - ANORO	7,152	4,225	2,927	69%	12,190	7,349	4,841	66%
Total royalties from a related party	61,797	35,707	26,090	73%	105,524	63,118	42,406	67%
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)		%	(6,912)	(6,912)		%
Royalty revenue	58,341	32,251	26,090	81%	98,612	56,206	42,406	75%
Strategic alliance - MABA program license	221	221		%	442	442		%
Total net revenue from GSK	\$ 58,562	\$ 32,472	\$ 26,090	80%	\$ 99,054	\$ 56,648	\$ 42,406	75%

Total net revenue increased for the three and six months ended June 30, 2017 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®.

**Research & Development**

Research and development expenses, as compared to the prior year periods, were as follows:

(In thousands)	Three Months Ended				Six Months Ended			
	June 30,		Change		June 30,		Change	
	2017	2016	\$	%	2017	2016	\$	%
Research and development expenses	\$ 348	\$ 370	\$ (22)	(6)%	\$ 702	\$ 762	\$ (60)	(8)%

Research and development expenses decreased for the three and six months ended June 30, 2017 compared to the same periods a year ago primarily due to reduced activities related to the late-stage partnered respiratory assets with GSK.

**General & Administrative**

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

(In thousands)	Three Months Ended				Six Months Ended			
	June 30,		Change		June 30,		Change	
	2017	2016	\$	%	2017	2016	\$	%
General and administrative expenses	\$ 10,384	\$ 6,225	\$ 4,159	67%	\$ 21,179	\$ 12,477	\$ 8,702	70%

General and administrative expenses for the three months ended June 30, 2017 were \$10.4 million compared with \$6.2 million in the three months ended June 30, 2016, an increase of \$4.2 million. The entire increase was due to \$4.3 million of proxy contest and associated litigation costs. General and administrative expenses for the six months ended June 30, 2017 were \$21.2 million compared with \$12.5 million in the six months ended June 30, 2016, an increase of \$8.7 million. The increase was mainly due to \$8.5 million of proxy contest and associated litigation costs.

Table of Contents

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

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

(In thousands)	Three Months Ended June 30,					Six Months Ended June 30,				
	2017	2016	Change	%	2017	2016	Change	%		
Other income (expense), net	\$ (786)	\$ 1,719	\$ (2,505)	*	\$ (739)	\$ 1,687	\$ (2,426)	*		
Interest income	306	157	149	95%	542	249	293	118%		

\*Not meaningful

Other income (expense), net for the three and six months ended June 30, 2017 mainly consists of the write-off of debt issuance costs of \$0.8 million in relation to our partial prepayment of the 2029 Notes. Other income (expense), net for the three and six months ended June 30, 2016 primarily pertains to a realized gain of \$1.7 million from the repurchase of our 2023 Notes.

Interest income increased for the three and six months ended June 30, 2017 as compared to the same periods 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 periods, was as follows:

(In thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2017	2016	Change	%	2017	2016	Change	%
Interest expense	\$ (12,204)	\$ (13,156)	\$ 952	(7)%	\$ (24,985)	\$ (26,313)	\$ 1,328	(5)%

Interest expense decreased for the three and six months ended June 30, 2017 compared to the same periods a year ago primarily due to lower outstanding average principal balances on our 2029 Notes, of which \$71.3 million was repaid since June 30, 2016, and on our 2023 Notes, of which \$4.1 million was repurchased since June 30, 2016. 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 and ANORO® ELLIPTA® during 2014, we have complemented the source of financing with royalty revenues from the global net sales of these products by GSK. In the six months ended June 30, 2017, we generated gross royalty revenues from GSK of \$105.5 million. Net cash and cash equivalents, short term investments and marketable securities totaled \$135.6 million, and royalties receivable from GSK totaled \$61.8 million as of June 30, 2017.

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. The 2029 Notes are secured exclusively by a security interest in a segregated bank account established to receive 40% of the royalties from global net sales due to us under the LABA Collaboration Agreement with GSK and ending upon the earlier of full repayment of principal or May 15, 2029. As of June 30, 2017, the remaining principal balance of the 2029 Notes was \$422.8 million. \$64.4 million of principal payments on the 2029 Notes were made during the six months ended June 30, 2017. The 2017 principal payments on the 2029 Notes comprise of \$14.4 million based on our royalty revenues generated in the previous quarters ended December 31, 2016 and March 31, 2017, and \$50.0 million from our prepayment of a portion the outstanding principal of the 2029 Notes as part of the 2017 Capital Return Plan discussed in the preceding section.

On August 7, 2017, we completed an offering of \$175.0 million aggregate principal amount of our 2025 Notes. The 2025 Notes were sold in a private placement under a purchase agreement, dated as of August 1, 2017, entered into by and among Innoviva and Morgan Stanley & Co. LLC and Deutsche Bank Securities Inc., as the initial purchasers (collectively, the Initial Purchasers), for resale to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the Securities Act). We also granted the Initial Purchasers a right to purchase, within a 30-day period, up to an additional \$17.5 million principal amount of additional 2025 Notes on the same terms and conditions, which the Initial Purchasers exercised in full on August 4, 2017 and which additional purchase was also completed on August 7, 2017. We intend, as part of our ongoing commitment to optimize our capital structure and reduce our overall cost of capital, to use a portion of the net proceeds of this offering to redeem on the next interest payment date of August 15, 2017 a portion of the principal outstanding under our 2029 Notes. As part of the 2017 Capital Return Plan, we also used approximately \$17.5 million of the net proceeds from this offering to repurchase 1,317,771 shares of our common stock concurrently with the pricing of this offering in privately negotiated transactions effected through one of the initial purchasers or its affiliate, as our agent.

### *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, including the funding of the 2017 Capital Return Plan discussed in the preceding section, for at least the next twelve months based upon current operating plans and financial forecasts. If our current

Table of Contents

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, repurchases or otherwise, all consistent with the terms of our debt agreements.

*Cash Flows*

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

(In thousands)	Six Months Ended			Change		
	2017	June 30,	2016			
Net cash provided by operating activities	\$	50,400	\$	19,710	\$	30,690
Net cash provided by (used in) investing activities		24,418		(12,805)		37,223
Net cash used in financing activities		(65,200)		(53,140)		(12,060)

*Cash Flows from Operating Activities*

Cash provided by operating activities for the six months ended June 30, 2017 was \$50.4 million, consisting primarily of our net income of \$52.0 million, adjusted for non-cash items such as \$7.0 million of depreciation and amortization and \$4.9 million for stock-based compensation expense, offset by changes in operating assets and liabilities, including an increase in receivables from collaborative arrangements of \$14.9 million.

Cash provided by operating activities for the six months ended June 30, 2016 was \$19.7 million, consisting primarily of our net income of \$19.0 million, adjusted for non-cash items such as \$7.0 million of depreciation and amortization and \$4.7 million for stock-based compensation expense, offset by changes in operating assets and liabilities, including an increase in receivables from collaborative arrangements of \$9.6 million.

*Cash Flows from Investing Activities*

Net cash flows from investing activities for the six months ended June 30, 2017 of \$24.4 million was primarily due to \$36.4 million proceeds received from maturities of marketable securities, partially offset by \$12.0 million in purchases of marketable securities.

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

Net cash used in investing activities for the six months ended June 30, 2016 of \$12.8 million was primarily due to purchases of marketable securities of \$59.9 million, partially offset by \$47.1 million of proceeds received from sales and maturities of marketable securities.

### *Cash Flows from Financing Activities*

Net cash used in financing activities for the six months ended June 30, 2017 of \$65.2 million was primarily due to \$64.4 million principal repayments of the 2029 Notes and \$0.8 million paid for repurchase of shares to satisfy tax withholding.

Net cash used in financing activities for the six months ended June 30, 2016 of \$53.1 million was primarily due to \$44.3 million paid for the repurchase of common stock and \$8.1 million paid for the repurchase of our 2023 Notes, offset with \$0.4 million received from the termination of the corresponding portion of the capped call arrangement.

Table of Contents**Off-Balance Sheet Arrangements**

In June 2014, 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 utilities, property taxes, and common area maintenance, which may be as much as the actual lease payments. As of June 30, 2017, the total remaining lease payments for the duration of the lease, which runs through May 2020, were \$18.6 million. The carrying value of this lease guarantee was \$0.9 million as of June 30, 2017 and is reflected in other long-term liabilities in our condensed consolidated balance sheet.

**Contractual Obligations and Commercial Commitments**

Other than scheduled payments made in the ordinary course, there have been no material changes to our contractual obligations from the information provided in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our annual report on Form 10-K for the year ended December 31, 2016.

In the table below, we set forth our significant enforceable and legally binding obligations and future commitments as of June 30, 2017.

(In thousands)	Total	Payment Due by Period			
		Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
2023 Notes	\$ 271,710	\$ 5,121	\$ 10,242	\$ 10,242	\$ 246,105
2029 Notes	422,758	*	*	*	*
Facility leases	2,474	386	808	856	424
Total	\$ 696,942	\$ 5,507	\$ 11,050	\$ 11,098	\$ 246,529

\* The 2029 Notes are secured by a security interest in a segregated bank account established to receive 40% of royalties due to us under the LABA Collaboration with GSK. Since the principal and interest payments on the 2029 Notes are based on royalties from product sales recorded by GSK, which can vary from quarter to quarter and are unknown to us, these amounts are not included in the above table on a period by period basis. See Note 7, Debt of the accompanying consolidated financial statements for further information.

**Item 3. Quantitative and Qualitative Disclosure about Market Risk**

During the six months ended June 30, 2017, 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, 2016.

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.*

We conducted an evaluation as of June 30, 2017, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, 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 Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance levels.

Table of Contents

*Limitations on the Effectiveness of Controls*

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

*Changes in Internal Control over Financial Reporting*

There were no 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 June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

As disclosed in our Current Report on Form 8-K, filed with the SEC on April 26, 2017, on April 20, 2017, Sarissa Capital Domestic Fund LP and certain of its affiliates (together, Sarissa ) filed a Verified Complaint Pursuant to Section 225 of the Delaware General Corporation Law and for Specific Performance in the Delaware Court of Chancery, captioned Sarissa Capital Domestic Fund LP, et al. v. Innoviva, Inc., C.A. No. 2017-0309-JRS (the Specific Performance Litigation ). Sarissa alleges that it had entered into a binding agreement to settle its proxy contest in exchange for the inclusion of each of George W. Bickerstaff, III and Odysseas Kostas, M.D. on our Board of Directors. Sarissa seeks specific performance of the alleged agreement. With the complaint, Sarissa also filed a Motion for Entry of Status Quo Order, which seeks, among other things, to prevent us from engaging in any action outside the ordinary course of business without first giving Sarissa ten (10) business days notice until the Specific Performance Litigation is resolved. On April 30, 2017, we filed a motion to dismiss the Specific Performance Litigation. On May 17, 2017, the Court entered an Order Maintaining Status Quo, which ordered that, during the pendency of the Specific Performance Litigation, the Innoviva Board of Directors shall remain in place, and prohibits the Company from entering or agreeing to any transactions, the consummation of which would require the approval of or vote by Innoviva stockholders or amending, modifying, or repealing Innoviva's bylaws or charter in the absence of an affirmative vote of five of the then-seven member board of directors or without providing plaintiffs' counsel five business days' advance written notice. Trial in the Specific Performance Litigation occurred on July 27, 2017, and the parties are currently awaiting the Court's ruling. We believe the Specific Performance Litigation is without merit and intend to defend it vigorously. Legal fees relating to this claim have been submitted to the Company's insurance carrier for reimbursement pursuant to the terms of its directors' and officers' insurance policy; however, as of August 8, 2017, the insurance carrier has not yet made a determination as to the extent to which these costs are covered, if at all, under the Company's policy. We can provide no assurances that such coverage is or will be available and the Company may not be able to recover any portion of the cost of such litigation.

From time to time, we may also 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. Although we may receive milestone payments from GSK if certain development milestones are achieved in our MABA program, we believe that royalty revenues from RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® will represent the majority of our future revenues from GSK. The amount and timing of revenue from such royalties and milestones 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® and ANORO® 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.

The amount of royalties and milestone payments, if any, 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 the closed triple combination for COPD 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;
- decisions as to the timing of product launches, pricing and discounts;



Table of Contents

- GSK reprioritizing its commercial efforts on other products, including the closed triple combination for COPD 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;
- 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;
- GSK's ability to successfully achieve development milestones with respect to our partnered 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; or

- general economic conditions in the jurisdictions where our partnered products are sold, including microeconomic disruptions or slowdowns.

***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. 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. 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 with a GDUFA goal date of May 10, 2017. In addition, Teva Pharmaceutical Industries Ltd., (NYSE and TASE: TEVA) announced recently that the FDA approved two of their products for adolescent and adult patients with asthma, AirDuo™ RespiClick® (fluticasone propionate and salmeterol inhalation powder) and ArmonAir™ RespiClick® (fluticasone propionate inhalation powder), which are non-AB 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 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.

Table of Contents

***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 new 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.

***All of our current revenues are from royalties derived from sales of our respiratory products partnered with GSK, 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. Were the treatment paradigm for COPD or asthma to change, for instance through changes to the GOLD (Global Initiative for Chronic Obstructive Lung Disease) guidelines, 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 our partnered product sales, our results of operations would likely suffer and we may need to scale back our operations and capital return programs.

***If the commercialization of RELVAR®/BREO® ELLIPTA® or ANORO® 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® and ANORO® ELLIPTA®. GSK has launched RELVAR®/BREO® 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 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® and ANORO® 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.

Table of Contents

***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 the closed triple product for COPD, 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® and ANORO® 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 commercialization of our partnered products. 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 the closed triple product for COPD following approval, if any. For example, in January 2015, GSK launched Incruse® (Umeclidinium) 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 Incruse® in combination with RELVAR®/BREO® ELLIPTA® as an open triple therapy in anticipation of future commercialization of the closed triple therapy for which we only receive limited amount of royalty revenues, and eventually compete directly against sales of RELVAR®/BREO® ELLIPTA®. For example, GSK filed for regulatory approval of the closed triple combination therapy for COPD in the U.S. in November 2016 and in the EU in December 2016. If the closed triple (or MABA /FF) receives regulatory approval in either the U.S. or the EU, GSK's diligent efforts obligations regarding commercialization matters will have 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 such regulatory approval will be 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 the closed triple product for COPD following regulatory approval, if any, 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 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

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

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. Results from these post-marketing studies are expected in 2017. 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® or ANORO® 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® and ANORO® 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 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®.



Table of Contents

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, GSK made regulatory submissions for the approval of the closed triple combination therapy for COPD in the U.S. and EU at the end of 2016. If the closed triple combination (or MABA /FF) receives regulatory approval in either the U.S. or the EU, GSK's diligent efforts obligations regarding commercialization matters will have 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 such regulatory approval will be 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 the closed triple product for COPD following regulatory approval, if any, 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 are developing UMEC/VI/FF (LAMA/LABA/ICS) and MABA/FF as potential triple combination treatments for COPD and, potentially, asthma. As a result of the Spin-Off, most of our economic rights in these 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.***

Under our LABA Collaboration Agreement with GSK, we and GSK are exploring various paths to create triple therapy respiratory medications. The use of triple therapy is supported by the GOLD ( Global initiative for chronic Obstructive Lung Disease ) guidelines in high-risk patients with severe COPD and a high risk of exacerbations. One potential triple therapy path is the combination of UMEC/VI (two separate bronchodilators) and FF (an inhaled corticosteroid), to be administered via the ELLIPTA® dry powder inhaler, referred to as UMEC/VI/FF or the closed triple. Prior to the Spin-Off, we were entitled to receive 100% of any royalties payable under the GSK Agreements arising from sales of UMEC/VI/FF (as well as MABA and MABA/FF) if such products were successfully developed, approved and commercialized. In June 2016, we and GSK announced positive top-line results from the pivotal phase III FULFIL of the investigational once-daily closed triple combination therapy (FF/UMEC/VI) in

patients with COPD. GSK made regulatory submissions for the approval of the closed triple combination therapy for COPD in the U.S. and EU at the end of 2016. The commercial success of RELVAR®/BREO® ELLIPTA® may be adversely effected if GSK or the respiratory markets view this closed triple combination or other combination therapies more beneficial. Furthermore, if the closed triple (or MABA /FF) receives regulatory approval in either the U.S. or the EU, GSK's diligent efforts obligations regarding commercialization matters will have 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 such regulatory approval will be 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. 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 FF/UMEC/VI (and MABA, and MABA/FF) while Theravance Biopharma receives 85% of those same payments.

***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 utilities, property taxes, and common area maintenance, which may be as much as the actual lease payments. As of June 30, 2017, the total remaining lease payments, which run through May 2020, were \$18.6 million. In the event that Theravance Biopharma defaults on such obligations, our business and results of operations may be materially harmed.

Table of Contents

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.

*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 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, 2015, 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 \$1.1 billion of net operating loss carryforward as of December 31, 2016. 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. 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

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

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.

Table of Contents

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® and ANORO® 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.

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

Table of Contents

- 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 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 Convertible Subordinated Notes and Non-Recourse 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 June 30, 2017, we had approximately \$663.8 million in total debt outstanding, comprised primarily of \$241.0 million in principal that remains outstanding under our convertible subordinated notes, due 2023 (the 2023 Notes ) and \$422.8 million in principal that remains outstanding under our non-recourse fixed rate term notes due 2029 (the 2029 Notes ) (the 2023 Notes and 2029 Notes hereinafter, the Notes ). The 2023 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 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. Our 2029 Notes have rights to 40% of all royalty payments received from GSK related to RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® until the notes are paid in full.

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 2023 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. If the 2029 Notes are not refinanced or paid in full, then they will receive 40% of all future economics associated with RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® until the notes are paid in full. 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 will 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. 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 results of this review may lead us to make changes to our compensation structure. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to successfully continue our business operations or grow our business, which may cause the price of our securities to fall.



Table of Contents

***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 June 30, 2017, we had only 13 full-time 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.***

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. 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, NASDAQ 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.

***As we continue to develop our business, 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.***

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

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.

Table of Contents

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 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 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.

*Our business could be negatively affected as a result of the actions of activist stockholders, including future proxy contests.*

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last several years. We have been the subject of actions taken by activist stockholders. On February 8, 2017, Sarissa, which on that date reported beneficial ownership of approximately 3.9% of our outstanding common stock, delivered a notice, dated February 7, 2017 (the "Notice"), to the Company indicating Sarissa's intent to nominate four candidates to stand for election as directors at the 2017 annual meeting of stockholders (the "Annual Meeting"). In the Notice, Sarissa also notified us that it would present for a vote of stockholders a proposal calling for repeal of any provision of our amended and restated bylaws in effect at the time of the Annual Meeting that was not included in our amended and restated bylaws publicly filed with the SEC on or prior to February 6, 2017 (the "Sarissa Bylaw Proposal"). On March 13, 2017, Sarissa reduced its slate to nominate three candidates for election as directors in opposition to our director nominees. At the Annual Meeting, held on April 20, 2017, representatives of Sarissa withdrew the Sarissa Bylaw Proposal. Also at the Annual Meeting, our stockholders elected each of our seven director nominees and did not elect any of Sarissa's candidates. At the Annual Meeting, representatives of Sarissa indicated that Sarissa intended to continue its activist campaign against the Company.

Table of Contents

Another proxy contest or an activist campaign launched by Sarissa or another activist stockholder(s) would require us to incur significant professional fees (including, but not limited to, legal fees, fees for financial advisors, fees for investor relations advisors, and proxy solicitation expenses) and the time-consuming nature of our response to any such activity may significantly divert the attention of management, the Board of Directors and our employees. Further, any perceived uncertainties as to our future direction and control resulting from any proxy contest or similar actions by activist stockholders could result in the loss of potential business opportunities and may make it more difficult to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results.

Even if we are successful in any proxy contest, our business could be adversely affected by any such proxy contest because:

- responding to proxy contests and other actions by activist stockholders can be costly (resulting in significant professional fees and proxy solicitation expenses) and time-consuming, disrupting operations and diverting the attention of our Board of Directors, management and employees;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or other strategic opportunities, and may make it more difficult to attract and retain qualified personnel and business partners;
- if individuals are elected to our Board of Directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders; and
- if individuals are elected to our Board of Directors who do not agree with our strategic plan, the ability of our Board of Directors to function effectively could be adversely affected, which could in turn adversely affect our business, operating results and financial condition.

Uncertainties related to, or the results of, such actions could cause our stock price to experience periods of volatility.

In addition, under certain circumstances arising out of or related to a proxy contest or threatened proxy contest or the nomination of directors by an activist stockholder, a change in the composition of a majority of our Board of Directors may (1) trigger the requirement that we make an offer to repurchase all of our outstanding 2023 Notes at a price equal to 100% of the principal and unpaid interest on such Notes, (2) constitute a change in control under the terms of our severance plans, which provide for payment of severance if a covered executive officer is subject to an involuntary termination within 3 months prior to or 24 months after a change in control of the Company and (3) constitute a change in control under the terms of certain of the Company's equity award grants and equity plans for its employees, and depending on the terms of the award or plan, may result in the accelerated vesting of such award. In the event we were required to offer to repurchase all of the Notes, which as of June 30, 2017 had an aggregate outstanding principal of approximately \$663.8 million, we would be required to obtain additional financing. As of June 30, 2017, we had cash, cash equivalents, and marketable securities of \$135.6 million. We cannot assure stockholders that we would be able to timely obtain such financing on commercially reasonable terms, if at all. To the extent that additional capital is raised through the sale of equity or equity-linked securities, the issuance of those securities could result in substantial dilution for our current stockholders and the terms

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

may include liquidation or other preferences that adversely affect the rights of our current stockholders. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline and existing stockholders may not agree with our financing plans or the terms of such financings. We also could be required to seek funds through arrangements with partners or otherwise that may require us to relinquish rights to our intellectual property, our product candidates or otherwise agree to terms unfavorable to us. The occurrence of any of the foregoing events could materially adversely affect our business.

We cannot predict, and no assurances can be given as to, the outcome or timing of any matters relating to actions by activist stockholders or the ultimate impact on our business, liquidity, financial condition or results of operations.

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

On March 10, 2017, Sarissa, in connection with its proxy contest, requested that we provide certain of its books and records pursuant to Section 220 of the Delaware General Corporation Law (the "DGCL"). We offered to provide Sarissa with certain of the confidential materials that Sarissa requested subject to executing a confidentiality agreement. On March 21, 2017, Sarissa filed a complaint in the Delaware Court of Chancery (the "Court"), captioned Sarissa Capital Domestic Fund LP v. Innoviva, Inc., C.A. No. 2017-0216-JRS (the "220 Litigation"), demanding that we provide books and records pursuant to Section 220 of the DGCL. Sarissa additionally requested that the Court grant a motion to expedite so that a trial on the 220 Litigation would be held prior to the Annual Meeting. On March 27, 2017, we provided Sarissa with certain of the confidential books and records requested pursuant to an executed confidentiality agreement. At a hearing held on March 28, 2017, the Court denied Sarissa's motion to expedite the trial. In connection with the hearing on March 28, 2017, we agreed to provide minutes of recently completed Nominating/Corporate Governance Committee meetings responsive to Sarissa's demand as such minutes become available for production. We intend to vigorously defend against the 220 Litigation.

Table of Contents

On April 20, 2017, several Sarissa entities filed a Verified Complaint Pursuant to Section 225 of the DGCL and for Specific Performance in the Court, captioned Sarissa Capital Domestic Fund LP, et al. v. Innoviva, Inc., C.A. No. 2017-0309-JRS (the "Specific Performance Litigation"). Sarissa alleges that it had entered into a binding agreement to settle its proxy contest in exchange for the inclusion of each of George W. Bickerstaff, III and Odysseas Kostas, M.D. on our Board of Directors. Sarissa seeks specific performance of the alleged agreement. On May 17, 2017, the Court entered an Order Maintaining Status Quo, which ordered that, during the pendency of the Specific Performance Litigation, the Innoviva Board of Directors shall remain in place, and prohibits the Company from entering or agreeing to any transactions, the consummation of which would require the approval of or vote by Innoviva stockholders or amending, modifying, or repealing Innoviva's bylaws or charter in the absence of an affirmative vote of five of the then-seven member board of directors or without providing plaintiffs' counsel five business days advance written notice. Trial in the Specific Performance Litigation occurred on July 27, 2017, and the parties are currently awaiting the Court's ruling. We believe the Specific Performance Litigation is without merit and intend to defend it vigorously.

Sarissa could decide to expand the current litigation or bring additional litigation against us and/or against directors and officers whom we are obliged to indemnify and defend. Separately, we may be exposed to, or threatened with, future litigation, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business.

Litigation is inherently uncertain, and there is no assurance as to the outcome of the matters described above. We could incur substantial unreimbursed legal fees and other expenses in connection with these and any other future legal and regulatory proceedings, which could adversely affect our results of operations. These matters also may distract the time and attention of our officers and directors or divert our other resources away from our ongoing commercial and development programs. An unfavorable outcome in any of these matters could damage our business, reputation and our image with customers or result in additional claims or proceedings against us.

*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. There can be no assurances that this review will result in meaningful cost savings, if any, and there can also be no assurances that any meaningful cost savings will correlate with an increase in the price of our common stock.

Our cost reduction efforts may result in the elimination of certain functional areas and/or reductions of our business operations, which may limit our ability to effectively manage and grow our business and which could result in the potential decrease in our royalty revenues. It is likely that we will incur short-term costs to implement any longer-term expense reduction initiatives. In addition, in the event that the results of our review are delayed or 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. While our cost reduction efforts are expected to reduce our operating costs, we cannot be certain that such efforts will be successful.

**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.



Table of Contents

***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 29.3% of our outstanding common stock as of July 31, 2017, 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, upon regulatory approval of the closed triple combination or a MABA/ICS in either the U.S. or the EU, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have 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 such regulatory approval will be 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 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.

Table of Contents

***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 July 31, 2017, GSK beneficially owned approximately 29.3% 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 July 31, 2017 GSK beneficially owned approximately 29.3% 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.

**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

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

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 have, as of January 2016, adopted a new brand, Innoviva. 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.

Table of Contents

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, 2017 and June 30, 2017, the high and low sales prices of our common stock as reported on The NASDAQ Global Select Market varied between \$10.43 and \$14.42 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 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 development of UMEC/VI/FF 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 commercial efforts on other products, including the closed triple combination for COPD or products owned by GSK (such as Advair®) but which are not partnered with us;

Table of Contents

- 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;
- 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, UMEC/VI/FF, VI monotherapy and the MABA program through development into 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;
- 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 the possibility that the new 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;

- 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 30.8% of our outstanding common stock as of July 31, 2017 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*

We have a corporate goal of returning capital to stockholders and paid quarterly dividends during the third and fourth quarters of 2014 and during the first three quarters of 2015. In October 2015, we announced the acceleration of our capital return plan with an up to \$150.0 million share repurchase program approved by our Board of Directors effective through December 31, 2016, which replaced our quarterly dividends. As of December 31, 2016, we had repurchased an aggregate of \$103.7 million under the share repurchase program through a combination of a tender offer and open market purchases and \$11.6 million of our 2023 Notes. In February 2017, we announced a new capital return plan, the 2017 Capital Return Plan. The 2017 Capital Return Plan authorizes a combination of repurchases of stock and/or repurchases, redemptions or prepayments of debt up to \$150.0 million, through tender offers, open market purchases, private transactions, exchange offers or other means through December 31, 2017. The 2017 Capital Return Plan is expected to be funded using our working capital. Our announcement of this or 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.

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. A reduction, suspension or change in our capital return programs could have a negative effect on our stock price.



Table of Contents

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

As of July 31, 2017, GSK beneficially owned approximately 29.3% of our outstanding common stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 2.3% of our outstanding common stock. Based on our review of publicly available filings as of July 31, 2017, our three largest stockholders other than GSK collectively owned approximately 30.8% 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.*

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**

*Purchases of Equity Securities by the Issuer*

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

In February 2017, we announced a new capital return plan, the 2017 Capital Return Plan. The 2017 Capital Return Plan authorizes a combination of repurchases of stock and/or repurchases, redemptions or prepayments of debt up to \$150.0 million, through tender offers, open market purchases, private transactions, exchange offers or other means through December 31, 2017. There have been no repurchase of our common stock under the 2017 Capital Return Plan during the six months ended June 30, 2017.

As previously announced in April 2017, we prepaid \$50.0 million in outstanding principal on our 2029 Notes in May 2017 as part of the 2017 Capital Return Plan. As of June 30, 2017, \$100.0 million remained available under the 2017 Capital Return Plan.

In August 2017, as part of the 2017 Capital Return Plan, we used approximately \$17.5 million of the net proceeds from the offering of our 2025 Notes to repurchase 1,317,771 shares of our common stock concurrently with the pricing of the offering in privately negotiated transactions effected through one of the initial purchasers or its affiliate, as our agent.

### 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	Amended and Restated Certificate of Incorporation	8-K	99.2	4/28/16
3.2	Amended and Restated Bylaws (as amended by the board of directors February 8, 2017)	8-K	3.1	2/8/17
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended			
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended			
32	Certifications Pursuant to 18 U.S.C. Section 1350			
101	Interactive Data File (Quarterly Report on Form 10-Q, for the quarterly period ended June 30, 2017)			

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: August 8, 2017

/s/ Michael W. Aguiar  
**Michael W. Aguiar**  
Chief Executive Officer  
(principal executive officer)

Date: August 8, 2017

/s/ Eric d Esparbes  
**Eric d Esparbes**  
Senior Vice President, Finance and Chief Financial Officer (principal  
financial and principal accounting officer)