Innoviva, Inc.
Form 10-Q
May 05, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

OR

o 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	**94-3265960**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

951 Gateway Boulevard

South San Francisco, CA 94080

(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 x No o

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 x No o

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 x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The number of shares of registrant s common stock outstanding on April 30, 2016 was 113,069,974.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

INNOVIVA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	March 31, 2016 (unaudited)	December 31, 2015 *
Assets		
Current assets:		
Cash and cash equivalents	$ 151,778	$ 159,180
Short-term marketable securities	16,414	28,103
Related party receivables from collaborative arrangements	27,539	26,228
Prepaid expenses and other current assets	975	814
Total current assets	196,706	214,325
Property and equipment, net	193	221
Capitalized fees paid to a related party, net	190,912	194,368
Other assets	18	18
Total assets	$ 387,829	$ 408,932
Liabilities and Stockholders Deficit		
Current liabilities:		
Accounts payable	$ 576	$ 818
Accrued personnel-related expenses	913	1,659
Accrued interest payable	6,562	7,911
Other accrued liabilities	1,687	2,218
Deferred revenue	885	885
Total current liabilities	10,623	13,491
Convertible subordinated notes, due 2023	251,124	250,992
Non-recourse notes, due 2029	483,389	482,139
Other long-term liabilities	1,784	1,856
Deferred revenue	2,878	3,099
Commitments and contingencies (Notes 3, 6, and 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, 113,146 and 114,933 shares issued as of March 31, 2016 and December 31, 2015, respectively	1,132	1,149
Treasury stock: 150 shares as of March 31, 2016 and December 31, 2015	(3,263)	(3,263)
Additional paid-in capital	1,328,155	1,351,898
Accumulated other comprehensive loss	(1)	(2)
Accumulated deficit	(1,687,992)	(1,692,427)
Total stockholders deficit	(361,969)	(342,645)
Total liabilities and stockholders deficit	$ 387,829	$ 408,932

See accompanying notes to condensed consolidated financial statements.

* Condensed consolidated balance sheet as of December 31, 2015 has been derived from audited consolidated financial statements.

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INNOVIVA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended March 31,	
	2016	**2015**
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 March 31, 2016 and 2015	$ 23,955	$ 6,674
Revenue from collaborative arrangements from a related party, net	221	222
Total net revenue	24,176	6,896
Operating expenses:		
Research and development	392	712
General and administrative	6,252	5,439
Total operating expenses	6,644	6,151
Income from operations	17,532	745
Other income (expense), net	(32)	1,178
Interest income	92	116
Interest expense	(13,157)	(12,706)
Net income (loss)	$ 4,435	$ (10,667)
Basic and diluted net income (loss) per share	$ 0.04	$ (0.09)
Shares used to compute basic and diluted net income (loss) per share:		
Shares used to compute basic net income (loss) per share	112,482	114,658
Shares used to compute diluted net income (loss) per share	113,178	114,658
Cash dividend declared per common share	$	$ 0.25

See accompanying notes to condensed consolidated financial statements.

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INNOVIVA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Net income (loss)	$ 4,435	$ (10,667)
Other comprehensive income:		
Unrealized gain on marketable securities, net	1	1,226
Less: Realized gain on marketable securities, net		(1,151)
Comprehensive income (loss)	$ 4,436	$ (10,592)

See accompanying notes to condensed consolidated financial statements.

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INNOVIVA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2016	**2015**
Cash flows from operating activities		
Net income (loss)	$ 4,435	$ (10,667)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	3,483	3,483
Stock-based compensation	1,864	1,933
Amortization of premium (discount) on short-term investments	(3)	233
Interest added to the principal balance of the non-recourse term notes due 2029	683	6,427
Amortization of debt issuance costs	699	764
Realized gain on sale of marketable securities, net		(1,204)
Other non-cash items		(2)
Changes in operating assets and liabilities:		
Receivables from collaborative arrangements	(1,311)	311
Prepaid expenses and other current assets	(161)	121
Accounts payable	(242)	1,025
Payable to Theravance Biopharma, Inc., net		(930)
Accrued personnel-related expenses and other accrued liabilities	(625)	(1,516)
Accrued interest payable	(1,349)	(1,356)
Other long-term liabilities	(2)	(16)
Deferred revenue	(221)	(222)
Net cash provided by (used in) operating activities	7,250	(1,616)
Cash flows from investing activities		
Maturities of marketable securities	27,671	25,075
Purchases of marketable securities	(15,978)	(8,457)
Sales of marketable securities		57,098
Purchases of property and equipment		(6)
Net cash provided by investing activities	11,693	73,710
Cash flows from financing activities		
Repurchase of common stock	(25,357)	
Payments of cash dividends to stockholders	(719)	(28,794)
Repurchase of shares to satisfy tax withholding	(442)	(661)
Proceeds from issuances of common stock, net	173	1,747
Net cash used in financing activities	(26,345)	(27,708)
Net increase (decrease) in cash and cash equivalents	(7,402)	44,386
Cash and cash equivalents at beginning of period	159,180	96,800
Cash and cash equivalents at end of period	$ 151,778	$ 141,186
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 13,124	$ 6,870

See accompanying notes to condensed consolidated financial statements.

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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 Beta*2* 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- Beta*2* 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, 2016 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, 2015 filed with the Securities and Exchange Commission (SEC) on February 24, 2016.

Prior Period Reclassifications

Certain reclassifications of prior period amounts have been made to conform to the current period presentation. Refer to section on Recently Adopted Accounting Pronouncement below.

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 February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 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 beginning January 1, 2019, although early adoption is permitted. We are currently evaluating adoption methods and whether this standard will have a material impact on our consolidated financial statements.

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In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*, which provides guidance for the recognition, measurement, presentation, and disclosure of financial assets and liabilities. This standard is effective for us beginning January 1, 2018. We are evaluating the effects of the adoption of this ASU to our consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), requiring an entity to recognize the amount of revenue to which it expects to be entitled to in exchange for the transfer of promised goods or services to customers. The standard will replace nearly all existing revenue recognition guidance under GAAP when it becomes effective. In July 2015, the FASB decided to defer the effective date by one year. Thus, the standard will be effective for us beginning January 1, 2018, at which time we may adopt the standard under either the full retrospective method or the modified retrospective method. Early adoption on or after January 1, 2017 would be permitted. We are currently evaluating the effect that the new standard will have on our consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncement

In April 2015, the FASB issued ASU 2015-03, *Interest Imputation of Interest* (ASU 2015-03), to simplify the presentation of debt issuance costs. This standard amended existing guidance to require the presentation of debt issuance costs associated with term loans in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. We adopted ASU 2015-03 on January 1, 2016. Upon adoption of ASU 2015-03, we applied the guidance retrospectively to all periods presented and classified our debt issuance costs, which prior to adoption were included in other assets in the condensed consolidated financial statements, as a deduction to our respective long-term debts.

2. Net Income (Loss) per Share

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

The following table shows the computation of basic and diluted net income per share for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
(In thousands except for per share amounts)	**2016 (1)**	**2015**
Numerator:		
Net income (loss), basic and diluted	$ 4,435	$ (10,667)
Denominator:		
Weighted-average shares used to compute basic net income (loss) per share	112,482	114,658

Dilutive effect of options and awards granted under equity incentive plan and employee stock purchase plan		196		
Dilutive effect of unvested restricted stock awards (RSAs)		500		
Weighted-average shares used to compute diluted net income (loss) per share		113,178		114,658
Net income (loss) per share				
Basic	$	0.04	$	(0.09)
Diluted	$	0.04	$	(0.09)

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Anti-Dilutive Securities

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

	Three Months Ended March 31,	
(In thousands)	**2016 (1)**	**2015 (2)**
Outstanding options and awards granted under equity incentive plan and employee stock purchase plan	3,917	5,866
Unvested RSAs	510	1,930
Shares issuable upon conversion of convertible subordinated notes	12,904	12,494
	17,331	20,290

(1) Includes 3.3 million options, 0.1 million restricted stock units, and 0.4 million unvested RSAs retained by former employees who were transferred to Theravance Biopharma, Inc. (Theravance Biopharma) in connection with the Spin-Off of Theravance Biopharma in June 2014 (the Spin-Off). Subsequent to the Spin-Off, stock-based compensation expense associated with the awards held by Theravance Biopharma employees granted prior to the Spin-Off is recognized by Theravance Biopharma. Stock options of 3.3 million were excluded from the diluted net income per share calculation as their effect was anti-dilutive.

(2) Includes 4.5 million options, 0.6 million restricted stock units, and 1.2 million unvested RSAs retained by former employees who were transferred to Theravance Biopharma in connection with the Spin-Off. All of these awards were excluded from the diluted net loss per share calculation as their effect was anti-dilutive.

3. Collaborative Arrangements

Net Revenue from Collaborative Arrangements

Net revenue recognized under our GSK Agreements was as follows:

	Three Months Ended March 31,	
(In thousands)	**2016**	**2015**
Royalties from a related party	$ 27,411	$ 10,130
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)
Royalty revenue	23,955	6,674
Strategic alliance - MABA program	221	222

Total net revenue from GSK	$	24,176	$	6,896

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 development and commercialization activities under the GSK Agreements 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%.

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Agreements Entered into with GSK in Connection with the Spin-Off

On March 3, 2014, in contemplation of the Spin-Off, we, Theravance Biopharma and GSK entered into a series of agreements, including amendments to the GSK Agreements, clarifying how the companies would implement the Spin-Off and operate following the Spin-Off. Pursuant to a three-way master agreement, by and among us, Theravance Biopharma and GSK, we agreed to sell a certain number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had a right to purchase these shares of Theravance Biopharma from us, but this right expired unexercised. During the three months ended March 31, 2015, we sold all 436,802 ordinary shares of Theravance Biopharma that we held as of December 31, 2014. Refer to Note 4 Available-for-Sale Securities and Fair Value Measurements for further information.

GSK Contingent Payments and Revenue

The potential future contingent payments receivable related to the MABA program of $363 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 milestone payments.

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

Available-for-Sale Securities

The classification of available-for-sale securities in the condensed consolidated balance sheets is as follows:

(In thousands)	March 31, 2016	December 31, 2015
Cash and cash equivalents	$ 148,316	$ 148,673
Short-term marketable securities	16,414	28,103
Total	$ 164,730	$ 176,776

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

(In thousands)	Amortized Cost	March 31, 2016 Gross Unrealized	Estimated Fair Value

			Losses		
U.S. government agencies	$	6,532	$	(1)	$ 6,531
U.S. corporate notes		1,632			1,632
U.S. commercial paper		69,557			69,557
Money market funds		87,010			87,010
Total	$	164,731	$	(1)	$ 164,730

	December 31, 2015		
(In thousands)	**Amortized Cost**	**Gross Unrealized Losses**	**Estimated Fair Value**
U.S. government agencies	$ 14,406	$ (1)	$ 14,405
U.S. corporate notes	2,702	(1)	2,701
U.S. commercial paper	10,997		10,997
Money market funds	148,673		148,673
Total	$ 176,778	$ (2)	$ 176,776

As of March 31, 2016, all of the available-for-sale securities had contractual maturities within one year and the weighted average maturity of marketable securities was approximately two months. We do not intend to sell the investments in debt that are in an unrealized loss position, and it is unlikely that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. We have determined that the gross unrealized losses on our marketable securities as of March 31, 2016

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were temporary in nature. As of March 31, 2016, all marketable securities with unrealized losses have been in a loss position for less than twelve months.

During the three months ended March 31, 2015, we sold all of the ordinary shares of Theravance Biopharma, which resulted in a gain on sale of $1.2 million, which is included in other income (expense), net in the condensed consolidated statement of operations.

Fair Value Measurements

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

	Estimated Fair Value Measurements as of March 31, 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**
Assets				
U.S. government agencies	$	$ 6,531	$	$ 6,531
U.S. corporate notes		1,632		1,632
U.S. commercial paper		69,557		69,557
Money market funds	87,010			87,010
Total assets measured at estimated fair value	$ 87,010	$ 77,720	$	$ 164,730
Liabilities				
Convertible subordinated notes due 2023	$	$ 199,304	$	$ 199,304
Non-recourse notes due 2029		471,622		471,622
Total fair value of liabilities	$	$ 670,926	$	$ 670,926

	Estimated Fair Value Measurements as of December 31, 2015 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**
Assets				
U.S. government agencies	$	$ 14,405	$	$ 14,405
U.S. corporate notes		2,701		2,701
U.S. commercial paper		10,997		10,997
Money market funds	148,673			148,673
Total assets measured at estimated fair value	$ 148,673	$ 28,103	$	$ 176,776
Liabilities				
Convertible subordinated notes due 2023	$	$ 189,100	$	$ 189,100
Non-recourse notes due 2029		470,970		470,970
Total fair value of liabilities	$	$ 660,070	$	$ 660,070

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 convertible subordinated notes due 2023 and non-recourse notes due 2029 is based on recent trading prices of the instruments.

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5. Capitalized Fees Paid to a Related Party

Capitalized fees paid to a related party, which consist of registrational and launch-related milestone fees paid to GSK, were as follows:

		March 31, 2016			December 31, 2015		
(In thousands)	Weighted Average Remaining Amortization Period (Years)	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Approval and launch related milestone payments under the LABA Collaboration	13.9	$ 220,000	$ (29,088)	$ 190,912	$ 220,000	$ (25,632)	$ 194,368

These milestone fees are being amortized over their estimated useful lives commencing upon the commercial launch of the product in their respective regions with the amortization expense recorded as a reduction in revenue from collaborative arrangements. Additional information regarding these milestone fees is included in Note 3, Collaborative Arrangements. Amortization expense for the three months ended March 31, 2016 and 2015 was $3.5 million. As of March 31, 2016, the remaining estimated amortization expense is $10.4 million for 2016, $13.8 million for each of the years from 2017 to 2021, and $111.4 million thereafter.

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 grant of 1,290,000 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 employment. In connection with the Spin-Off, our Compensation Committee approved the modification of the remaining tranches related to these awards as the performance conditions associated with the remaining portions of these awards were unlikely to be consistent with the new strategies of each company following the Spin-Off. The remaining 63,000 RSAs for which service-based vesting was not triggered at the time of the Spin-Off remain subject to new performance conditions (as well as the original service conditions). In addition, the RSAs for which both the performance and service-based conditions were not achieved prior to the Spin-Off were entitled to the pro rata dividend distribution made by Innoviva on June 2, 2014 of one ordinary share of Theravance Biopharma for every 3.5 shares of Innoviva common stock subject to their awards, which will also be subject to the same new

performance and service conditions as the original RSAs to which they relate. As of March 31, 2016, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation cost was recognized for the remaining equity awards.

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 Relative Total Shareholder Return (TSR) and a service condition that requires continued employment, collectively the Performance Measures . 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 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. 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 service period and is not reversed if the market condition is not met.

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Stock-Based Compensation Expense

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

(In thousands)	Three Months Ended March 31, 2016	2015
Research and development	$ 175	$ 235
General and administrative	1,689	1,698
Total stock-based compensation expense	$ 1,864	$ 1,933

As of March 31, 2016, unrecognized compensation expense, net of expected forfeitures for awards expected to vest, including the market based awards was as follows: $1.4 million related to unvested stock options; $1.5 million related to unvested RSUs; and $12.0 million related to unvested RSAs.

At the time of the Spin-Off, all outstanding stock options, RSUs and RSAs held by former employees and directors, who transferred to Theravance Biopharma, were retained by them. As the vesting of these options and awards is based on continuing employment or service with Theravance Biopharma, all stock-based compensation expense associated with these options and awards is recognized by Theravance Biopharma.

Valuation Assumptions

No options were granted for the three months ended March 31, 2016 and 2015.

7. Long-Term Debt

Our long-term debt consists of:

(In thousands)	March 31, 2016	December 31, 2015
Convertible Subordinated Notes due 2023	$ 255,109	$ 255,109
Non-Recourse Notes Payable due 2029	493,845	493,162
Total long-term debt	748,954	748,271
Less: unamortized debt issuance costs	14,441	15,140
Net long-term debt	$ 734,513	$ 733,131

Convertible Subordinated Notes Due 2023

In January 2013, we completed an underwritten public offering of $287.5 million aggregate principal amount of unsecured convertible subordinated notes, which will mature on January 15, 2023 (the 2023 Notes). 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 2023 Notes were convertible, at the option of the holder, into shares of our common stock at an initial conversion rate of 35.9903 shares per $1,000 principal amount of the 2023 Notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately $27.79 per share. Following the Spin-Off of Theravance Biopharma, a number of adjustments to the initial conversion rate have been made as described below. Holders of the 2023 Notes will be able to require us to repurchase some or all of their notes upon the occurrence of a fundamental change, as defined in the 2013 Notes, at 100% of the principal amount of the notes being repurchased plus accrued and unpaid interest. We may not redeem the notes prior to their stated maturity date.

In connection with the offering of the 2023 Notes, we entered into two privately-negotiated capped call option transactions with a single counterparty. The capped call option transaction is an integrated instrument consisting of a call option on our common stock purchased by us with a strike price equal to the initial conversion price of $27.79 per share for the underlying number of shares and a cap price of $38.00 per share, both of which are subject to adjustments consistent with the 2023 Notes. The cap component is economically equivalent to a call option sold by us for the underlying number of shares with an initial strike price of $38.00 per share. As an integrated instrument, the settlement of the capped call coincides with the due date of the convertible debt. Upon settlement, we would receive from our hedge counterparty a number of shares of our common shares that would range from zero, if the stock price was below $27.79 per share, to a maximum of 2,779,659 shares, if the stock price is above $38.00 per share. However, if the market

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price of our common stock, as measured under the terms of the capped call transactions, exceeds $38.00 per share, there is no incremental anti-dilutive benefit from the capped call.

In accordance with the agreement for the 2023 Notes, the conversion rate was adjusted as a result of the completion of the Spin-Off of Theravance Biopharma. The conversion rate was adjusted based on the conversion rate immediately prior to the record date for the Spin-Off and the average of the stock dividend distributed to our common stockholders and our stock prices. This resulted in an adjusted conversion rate of 46.9087 shares per $1,000 principal amount of the 2023 Notes, which represents an adjusted conversion price of approximately $21.32 per share. As a result of the conversion rate adjustment, the capped call strike price and cap price were also adjusted accordingly to $21.32 and $29.16, respectively. On July 15, 2014, certain holders of the 2023 Notes converted their notes into 1,519,402 shares of our common stock at the adjusted conversion price of $21.32 per share. In connection with the partial conversion of the 2023 Notes, we received 149,645 shares of our common stock from our capped call option counterparty and the shares of common stock received were recorded as treasury stock.

In connection with the payments of the cash dividends during the year ended December 31, 2015 and 2014, the adjusted conversion rate with respect to our 2023 Notes was further adjusted in total from 46.9087 shares of our common stock per $1,000 principal amount of the 2023 Notes to 50.5818 shares of our common stock per $1,000 principal amount of the 2023 Notes, which represents an adjusted conversion price of approximately $19.77 per share. As a result of the conversion rate adjustment, the capped call strike price and cap price were also adjusted accordingly to $19.77 and $27.04.

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 non-recourse fixed rate term notes due 2029 (the 2029 Notes) issued by our wholly-owned subsidiary.

The 2029 Notes bear an annual 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. Prior to and including May 15, 2016, in the event that the specified portion of royalties received in a quarter is less than the interest accrued for the quarter, the principal amount of the 2029 Notes will increase by the interest shortfall amount for that period, and considered as payment in kind (PIK). Since issuance, $43.8 million of interest expense has been added to the principal balance of the 2029 Note, of which $0.7 million and $6.4 million was added during the three months ended March 31, 2016 and 2015, respectively. 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. The 2029 Notes can be prepaid subject to a prepayment premium of 2.5% until April 17, 2017, and without premium afterwards.

8. Shareholders Deficit

For the three months ended March 31, 2016, we repurchased 2,449,632 shares of our common stock in the open market at an average price of $10.35 per share for a total purchase price of $25.4 million, which were retired upon repurchase.

9. Commitments and Contingencies

Operating Lease and Lease Guarantee

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 March 31, 2016, the total remaining lease payments, which run through May 2020, were $26.2 million. The carrying value of this lease guarantee was $1.3 million as of March 31, 2016 and is reflected in other long-term liabilities in our consolidated balance sheet.

10. Income Taxes

The effective tax rate for the three months ended March 31, 2016 was 0.15%, compared to 0.00% for the same period in 2015. Should we generate taxable income in 2016, 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.

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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.

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OVERVIEW

Executive Summary

Innoviva, Inc. 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 LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein collectively as the GSK Agreements), 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. 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). In June 2014, we spun-off our research and development activities by distributing the outstanding shares of Theravance Biopharma on a pro-rata basis to our stockholders (the Spin-Off), which resulted in Theravance Biopharma becoming an independent, publicly traded company.

We have designed our company structure and organization to be tailored to our focused activities of managing our respiratory assets with GSK, the commercial and developmental obligations associated with the GSK Agreements, intellectual property, licensing operations, business development activities and providing for certain essential reporting and management functions of a public company. As of March 31, 2016, we had 13 employees. Our revenues consist of royalties and potential milestone payments, if any, from our respiratory partnership agreements with GSK.

Financial Highlights

- For the three months ended March 31, 2016, our net income from our operations was $4.4 million, an increase of $15.1 million from our net loss of $10.7 million for the three months ended March 31, 2015. The increase was primarily due to an increase in our royalty revenues. Cash, cash equivalents, and marketable securities, totaled $168.2 million as of March 31, 2016, a decrease of $19.1 million from December 31, 2015. The decrease was primarily due to repurchase of common stock of $25.4 million, partially offset by cash provided by operations of $7.3 million.

- Through March 31, 2016, we repurchased $25.4 million of stock under our previously announced $150 million share repurchase program through open market purchases, with an average purchase price of $10.35 per share.

- In the first quarter of 2016, net sales of RELVAR®/BREO® ELLIPTA® by GSK were $161.9 million, compared to $59.9 million in the first quarter of 2015 (a 170% increase), of which $80.7 million was U.S. sales and

$81.2 million was sales from non-U.S. markets.

- As of March 31, 2016, RELVAR®/BREO® ELLIPTA® has been launched in more than 50 countries.

- In the first quarter of 2016, net sales of ANORO® ELLIPTA® by GSK were $48.1 million, compared to $17.7 million in the first quarter of 2015 (a 172% increase), comprised of $32.7 million in the U.S. market and $15.4 million in non-U.S. markets.

- As of March 31, 2016, ANORO® ELLIPTA® has been launched in more than 40 countries.

Capital Return Plan

Declaration and Payment of Cash Dividends

During the first three quarters of 2015, our Board of Directors declared a quarterly dividend of $0.25 per share of common stock to stockholders resulting in aggregate cash dividends of $87.3 million paid to our stockholders in the year ended December 31, 2015. In connection with the payments of these cash dividends, the conversion rate with respect to our 2.125% Convertible Subordinated Notes due 2023 (the 2023 Notes) was adjusted.

Share Repurchase Plan

On October 28, 2015, we announced the acceleration of our capital return plan with a $150 million share repurchase program effective through the end of 2016 approved by our Board of Directors, replacing our quarterly dividend. The repurchases may be made by a combination of tender offers, open market purchases, private transactions, exchange offers or other means. The repurchase program will be funded using our working capital. Our announcement of the share repurchase program does not obligate us to

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repurchase any specific dollar amount or number of shares of common stock. 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, the results of the tender offer and 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 our shares of 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. The share repurchase program may be suspended or discontinued at any time. There can be no assurance as to the actual volume of any share repurchases in any given period or over the term of the program or as to the manner or terms of any such repurchases.

On October 30, 2015, we commenced a modified Dutch auction tender offer as a component of the share repurchase plan to purchase up to $75 million of our common stock, at a price per share of not less than $8.50 and not greater than $9.25. The tender offer expired on December 1, 2015 and we purchased an aggregate of 2,576,236 shares of our common stock at a purchase price of $9.25 per share for a total value of approximately $23.8 million, excluding fees and expenses relating to the tender offer.

From December 1, 2015 to December 31, 2015, we purchased 100,000 shares of our common stock at an average purchase price of $9.95 per share for a total value of approximately $1.0 million in the open market. From January 1, 2016 to March 31, 2016, we purchased 2,449,632 shares of our common stock at an average purchase price of $10.35 per share for a total value of approximately $25.4 million in the open market.

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.

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 were obligated to pay milestone fees to GSK totaling $220.0 million, all of which was paid as of 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 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.

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. 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 where GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Innoviva-discovered preclinical MABA compounds (the Additional MABAs). GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. As a result of the Spin-Off, we are 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. 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, 2015 filed with the SEC on February 24, 2016.

Agreements Entered into with GSK in Connection with the Spin-Off

On March 3, 2014, in contemplation of the Spin-Off, we, Theravance Biopharma and GSK entered into a series of agreements, including amendments to the GSK Agreements, clarifying how the companies would implement the Spin-Off and operate

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following the Spin-Off. Pursuant to a three-way master agreement, by and among us, Theravance Biopharma and GSK, we agreed to sell a certain number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had a right to purchase these shares of Theravance Biopharma from us, but this right expired unexercised. During the three months ended March 31, 2015, we sold all shares of Theravance Biopharma.

Purchases of Common Stock by GSK

Pursuant to its periodic top-up rights under our Amended and Restated Governance Agreement, dated as of June 4, 2004, as amended, among us, GSK and certain GSK affiliates, affiliates of GSK purchased an aggregate of 32.0 million shares of our common stock for an aggregate purchase price of $6.5 million until the expiration of the governance agreement in September 2015. As of April 30, 2016, GSK beneficially owned approximately 28.3% of our outstanding capital stock.

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 at 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.

During the three months ended March 31, 2016, we adopted ASU 2015-03, *Interest Imputation of Interest*, to simplify the presentation of debt issuance costs. There were no other significant changes to our critical accounting policies and estimates. Management s Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on February 24, 2016 provides a more complete discussion of our critical accounting policies and estimates.

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Results of Operations

Net Revenue

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

(In thousands)	Three Months Ended March 31, 2016	2015	Change $	Change %
Royalties from a related party	$ 27,411	$ 10,130	$ 17,281	171%
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)		
Royalty revenue	23,955	6,674	17,281	259
Strategic alliance - MABA program	221	222	(1)	
Total net revenue from GSK	$ 24,176	$ 6,896	$ 17,280	251%

Total net revenue increased for the three months ended March 31, 2016 compared to the same period a year ago primarily due to the growth in prescriptions and market shares quarter over quarter for both RELVAR®/BREO® ELLIPTA® and ANORO ELLIPTA .

Research & Development

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

(In thousands)	Three Months Ended March 31, 2016	2015	Change $	Change %
Research and development expenses	$ 392	$ 712	$ (320)	(45)%

Research and development expenses decreased for the three months ended March 31, 2016 compared to the same period a year ago primarily due to reduced activities and lower stock-based compensation expense. Currently, our research and development expenses are primarily due to expenses related to the late-stage partnered respiratory assets with GSK.

General & Administrative

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

(In thousands)	Three Months Ended March 31, 2016	2015	Change $	Change %
General and administrative expenses	$ 6,252	$ 5,439	$ 813	15%

General and administrative expenses increased for the three months ended March 31, 2016 compared to the same period a year ago primarily due to higher employee costs related to the addition of headcount during the course of 2015 and additional customary public company spending.

Other Income (Expense), net and Interest Income

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

(In thousands)	Three Months Ended March 31, 2016	2015	Change $	Change %
Other income (expense), net	$ (32)	$ 1,178	$ (1,210)	(103)%
Interest income	92	116	(24)	(21)

Other income (expense), net decreased for the three months ended March 31, 2016 compared to the same period in 2015 primarily related to a realized gain of $1.2 million from the sale of all of the ordinary shares of Theravance Biopharma in the first quarter of 2015.

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Interest income decreased for the three months ended March 31, 2016 as compared to the same period a year ago primarily due to lower average cash balances resulting from the repurchases of our common stock and cash dividends paid.

Interest Expense

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

	Three Months Ended March 31,		Change	
(In thousands)	**2016**	**2015**	**$**	**%**
Interest expense	$ (13,157)	$ (12,706)	$ (451)	4%

Interest expense increased for the three months ended March 31, 2016 compared to the same period a year ago primarily due an increase of $16.9 million to the outstanding principal balance on our 2029 Notes since March 31, 2015 in the form of payment in kind, of which $0.7 million was added during the quarter ended March 31, 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. In 2015 and the first quarter of 2016, we have also received royalty payments from GSK from sales of RELVAR®/ BREO® ELLIPTA®, which was launched in the fourth quarter of 2013, and from ANORO® ELLIPTA®, which was launched during 2014. As of March 31, 2016, we had $168.2 million in cash, cash equivalents, and marketable securities.

As discussed above, on October 28, 2015, we announced that our Board of Directors approved a $150 million share repurchase program to be in effect through December 31, 2016. As of March 31, 2016, we had repurchased an aggregate of $51.0 million of our common stock through the combination of a tender offer and open market purchases. There can be no assurance as to the actual volume of any share repurchases in any given period or over the term of the program or as to the manner or terms of any such repurchases.

Our Board of Directors declared a $0.25 per share dividend for each of the first, second and third quarters of 2015 for all stockholders of record as of the close of business on specified dates resulting in a total of $87.3 million in cash dividends to our stockholders in the year ended

December 31, 2015.

In April 2014, we entered into certain note purchase agreements relating to the private placement of $450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 (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 and ending upon the earlier of full repayment of principal or May 15, 2029 due to us under the LABA Collaboration Agreement with GSK. Prior to and including May 15, 2016, in the event that the specified portion of royalties received in a quarter is less than the interest accrued for the quarter, the principal amount of the 2029 Notes will increase by the interest shortfall amount for that period, and considered as payment in kind (PIK). As of March 31, 2016, interest expense of $43.8 million was added to the principal balance of the 2029 Notes. We incurred approximately $15.3 million in debt issuance costs, which are being amortized to interest expense over the estimated life of the 2029 Notes.

Adequacy of cash resources to meet future needs

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

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Cash Flows

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

(In thousands)	Three months ended March 31, 2016	2015	Change
Net cash provided by (used in) operating activities	$ 7,250	$ (1,616)	$ 8,866
Net cash provided by investing activities	11,693	73,710	(62,017)
Net cash used in financing activities	(26,345)	(27,708)	1,363

Cash Flows from Operating Activities

Cash provided by or used in operating activities is primarily driven by net income (loss), excluding the effect of non-cash charges and net changes in our operating assets and liabilities.

Net cash provided by operating activities for the three months ended March 31, 2016 of $7.3 million was primarily due to:

- $26.1 million provided by receipt of royalties from a related party and revenue from collaborative arrangements, after adjusting for a $1.3 million increase in receivables from collaborative arrangements
- $5.4 million used for operating expenses, after adjusting for $1.9 million of non-cash related items, consisting primarily of stock-based compensation expense;
- $13.1 million used for interest payments on the 2023 Notes and 2029 Notes; and

Net cash used in operating activities for the three months ended March 31, 2015 of $1.6 million was primarily due to:

- $5.1 million used for operating expenses, after adjusting for stock-based compensation expense of $1.9 million
- $6.9 million used for interest payments on the 2023 Notes and 2029 Notes; and
- $10.4 million provided by receipt of royalties from collaborative arrangements

Cash Flows from Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2016 of $11.7 million was primarily due to $27.7 million of proceeds received from the maturities of marketable securities, partially offset by $16.0 million in purchases of marketable securities.

Net cash provided by investing activities for the three months ended March 31, 2015 of $73.7 million was primarily due to $82.2 million of proceeds received from the sale of marketable securities and maturities of marketable securities, partially offset by $8.5 million in purchases of marketable securities.

Cash Flows from Financing Activities

Net cash used in financing activities for the three months ended March 31, 2016 of $26.3 million was primarily due to $25.4 million paid for the repurchase of common stock, $0.7 million of cash dividends paid to our stockholders, $0.4 million paid for repurchase of shares to satisfy tax withholding and $0.2 million of proceeds received from the issuance of our common stock.

Net cash used in financing activities for the three months ended March 31, 2015 of $27.7 million was primarily due to $28.8 million of cash dividends paid to our stockholders and $0.6 million paid for repurchase of shares to satisfy tax withholding, offset by $1.7 million of net proceeds received from the issuance of our common stock.

Off-Balance Sheet Arrangements

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 March 31, 2016, the total remaining lease payments, which run through May 2020, were $26.2 million. The carrying value of this lease guarantee was $1.3 million as of March 31, 2016 and is reflected in other long-term liabilities in our condensed consolidated balance sheet.

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Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of March 31, 2016.

Contractual Obligations and Commercial Commitments

There have been no significant changes in our payments due under contractual obligations, compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

During the three months ended March 31, 2016, 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, 2015.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

We conducted an evaluation as of March 31, 2016, 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.

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 error and all fraud. 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 March 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

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. Through March 31, 2016, sales of both BREO ® ELLIPTA ® and especially ANORO® ELLIPTA® by GSK have been significantly below our expectations which resulted in a decline in our stock price. Although we may receive milestone payments from GSK if certain development milestones are achieved in our MABA program, we believe that royalty revenues from 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 is unknown and highly uncertain. Our future success depends upon the performance by GSK of its commercial obligations under the GSK Agreements. 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 our partnered products;

- market acceptance and demand for our partnered products;

- the competitive landscape of generic and branded products and developing therapies that compete with our partnered products, including other 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;

- 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; or

- the unfavorable outcome of any potential litigation relating to our partnered products.

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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 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 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 United States (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. Further, if the ongoing Phase 3b studies with FF/VI do not show improved outcomes relative to the standard of care, obtaining payor coverage for RELVAR®/BREO® ELLIPTA® could become more difficult in the future. 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 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.

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 investor, analyst 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 commercial launch of both products has been below our expectations primarily due to lower overall pricing levels in the U.S. and longer timeframes to obtain payor coverage. For example, GSK recently stated that it has experienced more restrictive formulary access and lower net pricing in the U.S. respiratory market than it expected, which may indicate broader weakness in the respiratory markets targeted by RELVAR®/ BREO® ELLIPTA® and ANORO® ELLIPTA®. As a result, a number of analysts have adjusted their sales forecasts downward from previous projections. Any further 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 investor or our expectations, will significantly harm our business and the price of our securities could fall.

We are dependent on GSK for the successful commercialization and development of products under the GSK Agreements. If GSK does not devote sufficient resources to the commercialization or development of these products, is unsuccessful in its efforts, or chooses to reprioritize its commercial programs, 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, 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. For example, in January 2015, GSK launched Incruse® (Umec) 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®. In the event GSK does not devote sufficient resources to the commercialization of our

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partnered products or chooses to reprioritize its commercial programs, our business, operations and stock price would be negatively affected.

If the results of the Salford Lung Study in chronic obstructive pulmonary disease (COPD) are negative or do not meet market expectations, or if the data generated from the Salford study indicate safety concerns, sales of RELVAR®/BREO® ELLIPTA® could be diminished and our ability to generate royalties from such sales could be negatively affected, and the price of our securities could fall.

GSK is conducting the Salford Lung Study to explore the effectiveness of RELVAR®/BREO® ELLIPTA® compared to other COPD treatments when used in a broad group of people living and managing their COPD on a day-to-day basis. The Salford Lung Study is a Phase 3 multicenter, randomized open-label study of approximately 2,800 people being treated in primary care who have been diagnosed and receive regular treatment for COPD in Salford and the surrounding area. The primary endpoint is the mean annual rate of moderate and severe exacerbations while secondary endpoints will assess safety, contact with healthcare professionals and patient reported outcomes. GSK expects to report results for the Salford Lung Study in 2016.

If the data derived from the study are negative, do not meet market expectations, or identify other safety or efficacy concerns with RELVAR/BREO ELLIPTA, it could result in, among other things:

- decreased market acceptance and demand for RELVAR®/BREO® ELLIPTA®;
- decrease in the size of the market for RELVAR®/BREO® ELLIPTA®;
- safety concerns in the marketplace for RELVAR®/BREO® ELLIPTA®;
- shifts in the medical community to new treatment paradigms or standards of care;
- changes in the competitive landscape for approved and developing therapies that may compete with RELVAR®/BREO® ELLIPTA®;
- GSK s ability to obtain regulatory approval for RELVAR®/BREO® ELLIPTA®, in additional jurisdictions;

- the unfavorable outcome or other negative effects of any potential litigation relating to RELVAR®/BREO® ELLIPTA®.

- additional restrictions on the commercialization of RELVAR®/BREO® ELLIPTA® through changes to the approved RELVAR®/BREO® ELLIPTA® labels;

- the imposition of additional post-approval studies or trials; or

- the withdrawal of the approvals of RELVAR®/BREO® ELLIPTA®.

Our business, operations and stock price would be negatively affected if any of these or similar events occur.

If GSK s commercialization efforts to market BREO® ELLIPTA® for asthma encounters any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage do not meet investor, analyst or our expectations, our business will be harmed, and the price of our securities could fall.

On April 30, 2015, the U.S. Food and Drug Administration (FDA) approved BREO® ELLIPTA® (FF/VI) as a once-daily inhaled treatment for asthma in patients aged 18 years and older in the U.S. If GSK s commercialization efforts to market BREO® ELLIPTA® for asthma in the U.S. encounters any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage do not meet investor, analyst or our expectations, our business will be harmed, and the price of our securities could fall.

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

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LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid, that LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications, and that LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. In addition, in March 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as clinical trial design) to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of asthma in adults, adolescents, and children. Further, in April 2011, the FDA announced that to further evaluate the safety of LABAs, it is requiring the manufacturers of currently marketed LABAs to conduct additional randomized, double-blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. 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.

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® or 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 will 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. 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. 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.

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

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- 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 policy or guidance regarding the use of LABAs to treat asthma or the use of LABAs combined with a LAMA to treat COPD.

If the FDA or other applicable regulatory authorities approve generic products, including but not limited 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. 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 expire in 2016. Mylan N.V. has recently announced that its ANDA for fluticasone propionate 100, 250, 500 mcg and salmeterol 50 mcg inhalation powder has been accepted for filing by the FDA with a GDUFA goal date of March 28, 2017. Hikma Pharmaceuticals PLC (Hikma) also recently announced that their ANDA for fluticasone propionate and salmeterol inhalation powder has been accepted for filing by the FDA with a GDUFA goal date of May 10, 2017. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use, or labeling, as the branded product and that the generic product is bioequivalent to the branded product, meaning it is absorbed in the body at the same rate and to the same extent. These generic equivalents, which must meet the same 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, on April 14th 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.

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®.

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 infrastructures that facilitate 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.

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

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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 July 2014, we and GSK announced the initiation of a large, global Phase 3 study for the closed triple in patients with COPD. If this Phase 3 study (or any other closed triple Phase 3 studies that may be initiated in the future) is successful, GSK and the respiratory market in general may view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. In such event the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® could be adversely affected, which in turn could result in lower royalties to us. 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 March 31, 2016, the total remaining lease payments, which run through May 2020, were $26.2 million. In the event that Theravance Biopharma defaults on such obligations, our business and results of operations may be materially harmed.

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

Biopharma, our financial condition may be harmed

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

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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). We have conducted an analysis to determine whether an ownership change had occurred since inception through December 31, 2014, and concluded that we had undergone two ownership changes in prior years. We have approximately $1.2 billion of net operating loss carryforward as of December 31, 2015. 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 foreign countries, separate regulatory approvals must be obtained in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more country may make approval in other countries more difficult.

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

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

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

non-approval or further delays in the FDA s review and approval of any product candidates in any respiratory program partnered with GSK.

Even if product candidates in any respiratory program partnered with GSK receive regulatory approval, as is the case with RELVAR®/BREO® ELLIPTA® 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

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

- we may be unable to license or acquire the rights on terms that would allow us to make an appropriate return from the product;

- companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or

- we may be unable to identify suitable royalty generating products.

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

We 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 March 31, 2016, we had approximately $749.0 million in total long-term debt outstanding, comprised primarily of $255.1 million in principal that remains outstanding under our 2.125% Convertible Subordinated Notes due 2023 (the 2023 Notes) and $493.9 million in principal that remains outstanding under our 9% Fixed Rate Royalty term notes due 2029 (the 2029 Notes and with the 2023 Notes, 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, 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®, ANORO® ELLIPTA®, and VI monotherapy 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

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available on favorable terms. If any or all of the Convertible Subordinated 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 Fixed Rate Royalty are not refinanced or paid in full, then they will receive 40% of all future economics associated with RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA®, and VI monotherapy, 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. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our business operations, which may cause the price of our securities to fall.

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

We currently have 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 (FASB) 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.

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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.

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

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

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

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 Theravance Respiratory Company, LLC (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.

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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 28.3% of our outstanding capital stock as of April 30, 2016, 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, 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 UMEC/VI/FF 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 capital 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.

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

As of April 30, 2016, GSK beneficially owned approximately 28.3% of our outstanding capital 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 capital stock owned by it terminated upon the expiration of the governance agreement on September 1, 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

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expressly offered to one of our directors who is a director, officer or employee of GSK, primarily in his or her capacity as one of our directors.

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

As of April 30, 2016, GSK beneficially owned approximately 28.3% of our outstanding capital 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 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.

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

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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, 2015 and March 31, 2016, the high and low sales prices of our common stock as reported on The NASDAQ Global Select Market varied between $12.85 and $8.23 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, without limitation if the new Phase 3 study (or any other closed triple Phase 3 studies that may be initiated in the future) is successful and 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 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);

• 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;

• 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 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;

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• regulatory developments in the U.S. and foreign countries;

• 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;

• relative illiquidity in the public market for our common stock (our three largest stockholders other than GSK collectively owned approximately 44.1% of our outstanding capital stock as of April 30, 2016 based on our review of publicly available filings); and

• potential sales or purchases of our capital 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 have paid quarterly dividends during the third and fourth quarters of 2014 and during the first three quarters of 2015. On October 28, 2015, we announced the acceleration of our capital return plan with a $150 million share repurchase program approved by our Board of Directors, replacing our quarterly dividend. As of March 31, 2016, we had repurchased an aggregate of $51.0 million under the repurchase program through a combination of a tender offer and open market purchases. Our announcement of our share repurchase program does not obligate us to repurchase any specific dollar amount 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 repurchase programs; changes in federal and state income tax laws or corporate laws; and changes to our business model. Our capital returns may change from time to time, and we cannot provide assurance that we will continue to provide any particular amounts. A reduction or suspension in our capital returns programs could have a negative effect on our stock price.

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

As of April 30, 2016, GSK beneficially owned approximately 28.3% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 1.6% of our outstanding capital stock. Based on our review of publicly available filings as of April 30, 2016, our three largest stockholders other than GSK collectively owned approximately 44.1% of our outstanding capital 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 capital 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.

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

Purchases of Equity Securities by the Issuer

On October 28, 2015, we announced that our Board of Director approved the acceleration of our capital return plan with a $150 million share repurchase program effective through the end of 2016.

The following table reflects the repurchases of our common stock under the share repurchase program during the fiscal quarter ended March 31, 2016:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs
January 1, 2016 to January 31, 2016	1,258,000	$ 9.30	1,258,000	
February 1, 2016 to February 29, 2016	461,641	$ 11.37	461,641	
March 1, 2016 to March 31, 2016	729,991	$ 11.51	729,991	
				$ 99,006,701

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Item 6. Exhibits

(a) **Index to Exhibits**

Exhibit Number	Description	Incorporated by Reference Filing Form	Date/Period End Date
3.3	Amended and Restated Certificate of Incorporation	S-1	7/26/04
3.4	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3/31/07
3.6	Amended and Restated Bylaws (as amended by the board of directors January 15, 2016)	8-K	1/15/16
3.7	Certificate of Ownership and Merger Merging LABA Merger Sub, Inc. with and into Theravance, Inc.	8-K	1/8/2016
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	Financial statements from the quarterly report on Form 10-Q of the Company for the three months ended March 31, 2016 (unaudited), formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements		

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SIGNATURES

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

Innoviva, Inc.

Date: May 5, 2016	/s/ Michael W. Aguiar **Michael W. Aguiar** Chief Executive Officer (principal executive officer)
Date: May 5, 2016	/s/ Eric d Esparbes **Eric d Esparbes** Senior Vice President, Finance and Chief Financial Officer (principal financial and principal accounting officer)