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

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.)

2000 Sierra Point Parkway, Suite 500

Brisbane, CA 94005

(Address of Principal Executive Offices)

(650) 238-9600

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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
	Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. 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 July 31, 2017 was 109,360,744.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

INNOVIVA, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	June 30, 2017 (unaudited)	December 31, 2016 *
Assets		
Current assets:		
Cash and cash equivalents	$ 127,634	$ 118,016
Short-term marketable securities	7,992	32,417
Related party receivables from collaborative arrangements	61,796	46,847
Prepaid expenses and other current assets	642	766
Total current assets	198,064	198,046
Property and equipment, net	289	368
Capitalized fees paid to a related party, net	173,633	180,545
Other assets	37	37
Total assets	$ 372,023	$ 378,996
Liabilities and Stockholders Deficit		
Current liabilities:		
Accounts payable	$ 277	$ 128
Accrued personnel-related expenses	1,203	2,361
Accrued interest payable	7,103	7,828
Other accrued liabilities	2,460	1,095
Non-recourse notes, due 2029, current	15,181	7,752
Deferred revenue, current	885	885
Total current liabilities	27,109	20,049
Convertible subordinated notes, due 2023, net of issuance costs	237,858	237,597
Non-recourse notes, due 2029, net of issuance costs	400,854	470,744
Other long-term liabilities	1,159	1,383
Deferred revenue	1,772	2,214
Commitments and contingencies (Notes 9)		
Stockholders deficit:		
Preferred stock: $0.01 par value, 230 shares authorized, no shares issued and outstanding		
Common stock: $0.01 par value, 200,000 shares authorized, 109,510 and 108,585 shares issued as of June 30, 2017 and December 31, 2016, respectively	1,094	1,085
Treasury stock: 150 shares as of June 30, 2017 and December 31, 2016	(3,263)	(3,263)
Additional paid-in capital	1,286,340	1,282,077
Accumulated other comprehensive income		1
Accumulated deficit	(1,580,900)	(1,632,891)
Total stockholders deficit	(296,729)	(352,991)
Total liabilities and stockholders deficit	$ 372,023	$ 378,996

See accompanying notes to condensed consolidated financial statements.

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

See accompanying notes to condensed consolidated financial statements.

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INNOVIVA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

(Unaudited)

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

See accompanying notes to condensed consolidated financial statements.

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INNOVIVA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

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

Supplemental disclosure of cash flow information				
Cash paid for interest	$	24,310	$	24,132

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 Beta2 Agonist (LABA) Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the GSK Agreements), Innoviva is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. Innoviva is also entitled to 15% of any future payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC (TRC), relating to the combination FF/UMEC/VI and the Bifunctional Muscarinic Antagonist Beta2 Agonist (MABA) program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid, and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement (LABA Collaboration), which has been assigned to TRC other than RELVAR®/BREO®ELLIPTA® and ANORO® ELLIPTA®.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In our opinion, the unaudited condensed consolidated financial statements have been prepared on the same basis as audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of our financial position, results of operations, comprehensive income and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2017 or any other period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the Securities and Exchange Commission (SEC) on February 28, 2017.

Variable Interest Entity

We evaluate our ownership, contractual and other interest in entities to determine if they are variable interest entities (VIE), whether we have a variable interest in those entities and the nature and extent of those interests. Based on our evaluations, if we determine we are the primary beneficiary of such VIEs, we consolidate such entities into our financial statements. We consolidate the financial results of TRC, which we have determined to be a VIE, because we have the power to direct the economically significant activities of TRC and the obligation to absorb losses of, or the right to receive benefits from, TRC. The financial position and results of operations of TRC are not material for the periods presented.

Recently Issued Accounting Pronouncements Not Yet Adopted

In April 2016, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) 2016-10 to clarify the implementation guidance on licensing and the identification of performance obligations consideration included in ASU 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which is also known as ASC 606, was issued in May 2014 and outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. In March 2016, the FASB issued ASU 2016-08 to provide amendments to clarify the implementation guidance on principal versus agent considerations. ASU 2014-09 guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2017 (as amended through ASU 2015-14 issued in August 2015), with early adoption permitted. Companies can elect a full retrospective method to recast prior-period financial statements or a modified retrospective method to recognize the cumulative effect as an adjustment to the retained earnings in the initial year. We plan to implement the standard in the first quarter of 2018 on a modified retrospective basis and do not anticipate that this standard will have a material impact on our accounting for royalty revenues. We are continuing to assess the potential impacts of the standard on the accounting for other revenues associated with the collaboration agreements.

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

2. Net Income Per Share

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

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

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

Anti-Dilutive Securities

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

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

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3. Collaborative Arrangements

Net Revenue from Collaborative Arrangements

Net revenue recognized under our GSK Agreements was as follows:

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

LABA Collaboration

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

We are entitled to receive annual royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first $3.0 billion of annual global net sales and 5% for all annual global net sales above $3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA Collaboration, such as ANORO® ELLIPTA®, royalties are upward tiering and range from 6.5% to 10%.

GSK Contingent Payments and Revenue

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

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

Available-for-Sale Securities

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

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

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		December 31, 2016
		Gross Unrealized
(In thousands)	Amortized Cost	Gains