

Innoviva, Inc.
Form 10-Q
July 26, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

OR

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

For the transition period from _____ to _____

Commission File Number: 000-30319

INNOVIVA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

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

2000 Sierra Point Parkway, Suite 500

Brisbane, CA 94005

(Address of Principal Executive Offices)

(650) 238-9600

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Emerging growth company

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

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

The number of shares of registrant's common stock outstanding on July 19, 2018 was 101,507,745.

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(In thousands, except per share data)

	June 30, 2018 (unaudited)	December 31, 2017 *
Assets		
Current assets:		
Cash and cash equivalents	\$ 87,226	\$ 73,336
Short-term marketable securities	20,316	55,739
Related party receivables from collaborative arrangements	70,542	70,540
Prepaid expenses and other current assets	576	754
Total current assets	178,660	200,369
Property and equipment, net	185	209
Capitalized fees paid to a related party, net	159,810	166,722
Other assets	37	37
Total assets	\$ 338,692	\$ 367,337
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 58	\$ 601
Accrued personnel-related expenses	695	1,721
Accrued interest payable	5,115	5,920
Other accrued liabilities	909	1,500
Current portion of long-term debt		25,000
Total current liabilities	6,777	34,742
Long-term debt, net of current portion, discount and issuance costs	486,527	574,362
Other long-term liabilities	752	940
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock: \$0.01 par value, 230 shares authorized, no shares issued and outstanding		
Common stock: \$0.01 par value, 200,000 shares authorized, 101,657 and 102,046 shares issued as of June 30, 2018 and December 31, 2017, respectively	1,015	1,019
Treasury stock: 150 shares as of June 30, 2018 and December 31, 2017	(3,263)	(3,263)
Additional paid-in capital	1,259,443	1,258,151
Accumulated other comprehensive loss	(10)	(18)
Accumulated deficit	(1,414,541)	(1,498,748)
Total Innoviva stockholders' deficit	(157,356)	(242,859)
Noncontrolling interest	1,992	152
Total stockholders' deficit	(155,364)	(242,707)
Total liabilities and stockholders' deficit	\$ 338,692	\$ 367,337

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

See accompanying notes to condensed consolidated financial statements.

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INNOVIVA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Royalty revenue from a related party, net of amortization of capitalized fees paid to a related party of \$3,456 in the three months ended June 30, 2018 and 2017 and \$6,912 in the six months ended June 30, 2018 and 2017	\$ 67,086	\$ 58,341	\$ 119,466	\$ 98,612
Revenue from collaborative arrangements from a related party		221		442
Total net revenue	67,086	58,562	119,466	99,054
Operating expenses:				
Research and development		348		702
General and administrative	4,411	10,384	13,396	21,179
General and administrative - related party			2,700	
Total operating expenses	4,411	10,732	16,096	21,881
Income from operations	62,675	47,830	103,370	77,173
Other income (expense), net	39	(786)	(3,060)	(739)
Interest income	380	306	771	542
Interest expense	(6,478)	(12,204)	(14,135)	(24,985)
Net income	56,616	35,146	86,946	51,991
Net income attributable to noncontrolling interest	1,990		2,739	
Net income attributable to Innoviva stockholders	\$ 54,626	\$ 35,146	\$ 84,207	\$ 51,991
Basic net income per share attributable to Innoviva stockholders	\$ 0.54	\$ 0.33	\$ 0.84	\$ 0.48
Diluted net income per share attributable to Innoviva stockholders	\$ 0.49	\$ 0.30	\$ 0.77	\$ 0.46
Shares used to compute Innoviva basic and diluted net income per share:				
Shares used to compute basic net income per share	100,873	107,614	100,739	107,468
Shares used to compute diluted net income per share	113,399	120,463	113,483	120,317

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,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net income	\$ 56,616	\$ 35,146	\$ 86,946	\$ 51,991
Unrealized income (loss) on marketable securities, net	12	1	8	(1)
Comprehensive income	56,628	35,147	86,954	51,990
Comprehensive income attributable to noncontrolling interest	1,990		2,739	
Comprehensive income attributable to Innoviva stockholders	\$ 54,638	\$ 35,147	\$ 84,215	\$ 51,990

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,	
	2018	2017
Cash flows from operating activities		
Net income	\$ 86,946	\$ 51,991
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	6,936	6,991
Stock-based compensation	3,621	4,934
Amortization of debt discount and issuance costs	4,028	1,401
Loss on extinguishment of debt	3,137	830
Amortization of premium (discount) on short-term investments	(160)	6
Amortization of lease guarantee	(162)	(162)
Changes in operating assets and liabilities:		
Receivables from collaborative arrangements	(2)	(14,949)
Prepaid expenses and other current assets	178	124
Accounts payable	(543)	149
Accrued personnel-related expenses and other accrued liabilities	(1,539)	242
Accrued interest payable	(805)	(725)
Other long-term liabilities	4	10
Deferred revenue		(442)
Net cash provided by operating activities	101,639	50,400
Cash flows from investing activities		
Maturities of marketable securities	54,875	36,387
Purchases of marketable securities	(19,284)	(11,969)
Net cash provided by investing activities	35,591	24,418
Cash flows from financing activities		
Repurchase of shares to satisfy tax withholding	(2,840)	(847)
Payments of principal on senior secured term loans	(120,000)	
Payments of cash dividends to stockholders	(55)	(107)
Proceeds from issuances of common stock, net	454	185
Payment of principal on non-recourse notes due 2029		(64,431)
Distributions to noncontrolling interest	(899)	
Net cash used in financing activities	(123,340)	(65,200)
Net increase in cash and cash equivalents	13,890	9,618
Cash and cash equivalents at beginning of period	73,336	118,016
Cash and cash equivalents at end of period	\$ 87,226	\$ 127,634
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 10,913	\$ 24,310

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

Basis of Presentation

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

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

Variable Interest Entity

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

Recently Issued Accounting Pronouncement Not Yet Adopted

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

2. Net Income Per Share

Basic net income per share attributable to Innoviva stockholders is computed by dividing net income attributable to Innoviva stockholders by the weighted-average number of shares of common stock outstanding. Diluted net income per share attributable to Innoviva stockholders is computed by dividing net income attributable to Innoviva stockholders by the weighted-average number of shares of common stock and dilutive potential common stock equivalents then outstanding. Dilutive potential common stock

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equivalents include the assumed exercise, vesting and issuance of employee stock awards using the treasury stock method, as well as common stock issuable upon assumed conversion of our convertible subordinated notes due 2023 (the 2023 Notes) using the if-converted method.

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

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

(In thousands except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Numerator:				
Net income attributable to Innoviva stockholders, basic	\$ 54,626	\$ 35,146	\$ 84,207	\$ 51,991
Add: interest expense on 2023 Notes	1,417	1,414	2,829	2,821
Net income attributable to Innoviva stockholders, diluted	\$ 56,043	\$ 36,560	\$ 87,036	\$ 54,812
Denominator:				
Weighted-average shares used to compute basic net income per share attributable to Innoviva stockholders	100,873	107,614	100,739	107,468
Dilutive effect of 2023 Notes	12,189	12,189	12,189	12,189
Dilutive effect of options and awards granted under equity incentive plan and employee stock purchase plan	337	660	555	660
Weighted-average shares used to compute diluted net income per share attributable to Innoviva stockholders	113,399	120,463	113,483	120,317
Net income per share attributable to Innoviva stockholders				
Basic	\$ 0.54	\$ 0.33	\$ 0.84	\$ 0.48
Diluted	\$ 0.49	\$ 0.30	\$ 0.77	\$ 0.46

Anti-Dilutive Securities

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

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Outstanding options and awards granted under equity incentive plan and employee stock purchase plan	1,633	2,019	1,562	2,541

3. Revenue Recognition and Collaborative Arrangements

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

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Net revenue recognized under our GSK Agreements was as follows:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Royalties from a related party - RELVAR/BREO	\$ 57,515	\$ 54,645	\$ 103,675	\$ 93,334
Royalties from a related party - ANORO	10,656	7,152	19,380	12,190
Royalties from a related party - TRELEGY	2,371		3,323	
Total royalties from a related party	70,542	61,797	126,378	105,524
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)	(6,912)	(6,912)
Royalty revenue	67,086	58,341	119,466	98,612
Strategic alliance - MABA program license		221		442
Total net revenue from GSK	\$ 67,086	\$ 58,562	\$ 119,466	\$ 99,054

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

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

(In thousands)	Amortized Cost	June 30, 2018		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. corporate notes	\$ 3,879	\$	\$ (10)	\$ 3,869
U.S. commercial paper	16,447			16,447
Money market funds	81,426			81,426
Total	\$ 101,752	\$	\$ (10)	\$ 101,742

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