# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-Q**

(Mark One)

(Mark One)		
☑ QUARTERLY REPORT PURSUAL ACT OF 1934	NT TO SECTION 13 OR	15(d) OF THE SECURITIES EXCHANGE
For the	quarterly period ended Septen	nber 30, 2020
	OR	
☐ TRANSITION REPORT PURSUA ACT OF 1934	NT TO SECTION 13 OR	15(d) OF THE SECURITIES EXCHANGE
For the to	ransition period from	to
	Commission File Number: 000-	30319
(Exact	INNOVIVA, INC. Name of Registrant as Specified	
Delaware		94-3265960
(State or Other Jurisdiction of		(I.R.S. Employer
Incorporation or Organization)		Identification No.)
	350 Old Bayshore Highway Su Burlingame, CA 94010 Address of Principal Executive C	
(Registr	(650) 238-9600 ant's Telephone Number, Includi	ng Area Code)
Securities	s registered pursuant to Section 1	2(b) of the Act:
Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	INVA	The NASDAQ Global Select Market
		filed by Section 13 or 15(d) of the Securities Exchange Act of quired to file such reports), and (2) has been subject to such
		eractive Data File required to be submitted pursuant to or for such shorter period that the registrant was required to
		red filer, a non-accelerated filer, a smaller reporting company, ted filer," "smaller reporting company," and "emerging growth
Large accelerated filer ⊠		Accelerated filer $\square$
Non-accelerated filer $\square$		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.  $\Box$ 

The number of shares of registrant's common stock outstanding on October 19, 2020 was 101,391,634.

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

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# PART I. FINANCIAL INFORMATION

# **Item 1. Financial Statements**

# INNOVIVA, INC. CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

		ptember 30, 2020 unaudited)	D	ecember 31, 2019
Assets	(1	unauuneu)		
Current assets:				
Cash and cash equivalents	\$	479,193	\$	278,096
Short-term marketable securities		_		72,749
Related party receivables from collaborative arrangements		92,150		79,427
Prepaid expenses and other current assets		698		962
Total current assets		572,041		431,234
Property and equipment, net		33		33
Equity investments		111,745		_
Capitalized fees paid to a related party, net		128,708		139,076
Deferred tax assets, net		109,490		154,171
Other assets		239		312
Total assets	\$	922,256	\$	724,826
			-	
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	623	\$	10
Accrued personnel-related expenses		384		647
Accrued interest payable		1,668		4,152
Other accrued liabilities		1,223		562
Total current liabilities		3,898		5,371
Long-term debt, net of discount and issuance costs		383,350		377,120
Other long-term liabilities		136		219
Commitments and contingencies (Note 8)				
Stockholders' equity:				
Preferred stock: \$0.01 par value, 230 shares authorized, no shares issued and outstanding		_		_
Common stock: \$0.01 par value, 200,000 shares authorized, 101,391 and 101,288 issued and				
outstanding as of September 30, 2020 and December 31, 2019, respectively		1,014		1,013
Additional paid-in capital		1,260,447		1,258,859
Accumulated other comprehensive income		_		27
Accumulated deficit		(775,905)		(946,404)
Total Innoviva stockholders' equity		485,556		313,495
Noncontrolling interest		49,316		28,621
Total stockholders' equity		534,872		342,116
Total liabilities and stockholders' equity	\$	922,256	\$	724,826

<sup>\*</sup> Consolidated balance sheet as of December 31, 2019 has been derived from audited consolidated financial statements.

# INNOVIVA, INC. CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data) (Unaudited)

	Three Months Ended September 30,						ed Se	d September 30,		
		2020		2019		2020		2019		
Revenue:										
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 September 30, 2020 and 2019, and \$10,368 in the										
nine months ended September 30, 2020 and 2019	\$	88,694	\$	65,755	\$	236,318	\$	185,045		
Revenue from collaborative arrangements with a related party						10,000				
Total net revenue		88,694		65,755		246,318		185,045		
Operating expenses:										
Research and development		1,010		_		1,569		_		
General and administrative		3,254		4,962		8,413		12,324		
Total operating expenses		4,264		4,962		9,982		12,324		
Income from operations		84,430		60,793		236,336		172,721		
Other income (expense), net		(13)		(115)		85		(122)		
Interest income		41		1,624		1,501		4,002		
Interest expense		(4,603)		(4,693)		(13,680)		(13,971)		
Changes in fair values of equity investments		(29,368)		_		39,245		_		
Income before income taxes		50,487		57,609		263,487		162,630		
Income tax expense, net		8,866		10,558		44,689		29,499		
Net income		41,621		47,051		218,798		133,131		
Net income attributable to noncontrolling interest		13,403		7,242		48,299		21,792		
Net income attributable to Innoviva stockholders	\$	28,218	\$	39,809	\$	170,499	\$	111,339		
Basic net income per share attributable to Innoviva stockholders	\$	0.28	\$	0.39	\$	1.68	\$	1.10		
Diluted net income per share attributable to Innoviva stockholders	\$	0.26	\$	0.36	\$	1.53	\$	1.01		
Shares used to compute Innoviva basic and diluted net income per share:										
Shares used to compute basic net income per share		101,358		101,191		101,306		101,134		
Shares used to compute diluted net income per share		113,572		113,415	_	113,543		113,394		

# INNOVIVA, INC. CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands) (Unaudited)

	Three Months Ended September 30,					Nine Months Ended September 30				
		2020		2019		2020		2019		
Net income	\$	41,621	\$	47,051	\$	218,798	\$	133,131		
Unrealized gain (loss) on marketable securities, net		2		(8)		(27)		28		
Comprehensive income		41,623		47,043		218,771		133,159		
Comprehensive income attributable to noncontrolling interest		13,403		7,242		48,299		21,792		
Comprehensive income attributable to Innoviva stockholders	\$	28,220	\$	39,801	\$	170,472	\$	111,367		

# INNOVIVA, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands) (Unaudited)

	Nine Months Ended September 30, 2020											
				Additional	A	ccumulated Other						Total
	Comn	.on 6	tool	Additional Paid-In	Co	mprehensive		cumulated	No	ncontrolling	Sto	ckholders'
	Shares	-	mount	Capital		Income (Loss)		Deficit		Interest	Equity	
Balance as of December 31, 2019	101,288	\$	1,013	\$ 1,258,859	\$	27	\$	(946,404)	\$	28,621	\$	342,116
Distributions to noncontrolling interest	101,200	Ψ	1,015	\$ 1,230,037	Ψ		Ψ	(740,404)	Ψ	(15,810)	Ψ	(15,810)
Exercise of stock options, and issuance of common stock										(15,010)		(15,010)
units and stock awards, net of repurchase of shares to												
satisfy tax withholding	32		_	170		_				_		170
Stock-based compensation				435		_		_		_		435
Net income	_		_			_		65,437		13,515		78,952
Other comprehensive income	_		_	_		6						6
Balance as of March 31, 2020	101,320	\$	1,013	\$ 1,259,464	\$	33	\$	(880,967)	\$	26,326	\$	405,869
Equity activity of noncontrolling interest from a	101,520	Ψ	1,015	Ψ 1,2c>,	Ψ	55	Ψ	(000,507)	Ψ	20,320	Ψ	100,000
consolidated variable interest entity	_		_	_		_		_		350		350
Distributions to noncontrolling interest	_		_	_		_		_		(12,152)		(12,152)
Exercise of stock options, and issuance of common stock										, , ,		
units and stock awards, net of repurchase of shares to												
satisfy tax withholding	72		2	178		_		_		_		180
Stock-based compensation	_		_	375		_		_		_		375
Net income	_		_	_		_		76,844		21,381		98,225
Other comprehensive income						(35)						(35)
Balance as of June 30, 2020	101,392	\$	1,015	\$ 1,260,017	\$	(2)	\$	(804,123)	\$	35,905	\$	492,812
Equity activity of noncontrolling interest from a												
consolidated variable interest entity	_		_	_		_		_		8		8
Exercise of stock options, and issuance of common stock												
units and stock awards, net of repurchase of shares to												
satisfy tax withholding	(1)		(1)	(11)		_		_		_		(12)
Stock-based compensation	_		_	441		_						441
Net income	_		_	_				28,218		13,403		41,621
Other comprehensive income						2	_					2
Balance as of September 30, 2020	101,391	\$	1,014	\$ 1,260,447	\$		\$	(775,905)	\$	49,316	\$	534,872

				Nine N	Month	s Ended Sept	ember 30, 2019				
					A	ccumulated					
	_	_	_	Additional	_	Other				_	Total
	Comm			Paid-In					Noncontrolling		ckholders'
	Shares	_	mount	Capital	Inc	come (Loss)	Deficit		Interest		Equity
Balance as of December 31, 2018	101,098	\$	1,011	\$ 1,256,267	\$	(3)	\$ (1,103,692)	\$	5,469	\$	159,052
Exercise of stock options, and issuance of common stock											
units and stock awards, net of repurchase of shares to											
satisfy tax withholding	85		1	253		_	_		_		254
Stock-based compensation	_		_	605		_	_		_		605
Net income	_		_	_		_	33,790		6,229		40,019
Other comprehensive income						13					13
Balance as of March 31, 2019	101,183	\$	1,012	\$ 1,257,125	\$	10	\$ (1,069,902)	\$	11,698	\$	199,943
Exercise of stock options, and issuance of common stock											
units and stock awards, net of repurchase of shares to											
satisfy tax withholding	89		1	200		_	_		_		201
Stock-based compensation	_		_	474		_	_		_		474
Net income	_		_	_		_	37,740		8,321		46,061
Other comprehensive income			_	_		23	· —		· —		23
Balance as of June 30, 2019	101,272	\$	1,013	\$ 1,257,799	\$	33	\$ (1,032,162)	\$	20,019	\$	246,702
Distributions to noncontrolling interest				· · · · ·		_	`		(10,553)		(10,553)
Exercise of stock options, and issuance of common stock											
units and stock awards, net of repurchase of shares to											
satisfy tax withholding	7		_	82		_	_		_		82
Stock-based compensation	_		_	489		_	_		_		489
Net income	_		_	_		_	39,809		7,242		47,051
Other comprehensive income	_			_		(8)					(8)
Balance as of September 30, 2019	101,279	\$	1,013	\$ 1,258,370	\$	25	\$ (992,353)	\$	16,708	\$	283,763

# INNOVIVA, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands) (Unaudited)

	Nine Months Ended September 3				
		2020		2019	
Cash flows from operating activities					
Net income	\$	218,798	\$	133,131	
Adjustments to reconcile net income to net cash provided by operating activities:					
Deferred income taxes		44,689		29,499	
Depreciation and amortization		10,382		10,400	
Stock-based compensation		1,251		1,568	
Amortization of debt discount and issuance costs		6,230		5,789	
Amortization of discount on short-term investments		(343)		(1,739)	
Amortization of lease guarantee		135		(243)	
Loss on write-off of property and equipment		_		104	
Changes in fair values of equity investments		(39,245)		_	
Other non-cash items		14			
Changes in operating assets and liabilities:					
Receivables from collaborative arrangements		(12,723)		14,075	
Prepaid expenses and other current assets		264		466	
Other assets		_		(11)	
Accounts payable		613		24	
Accrued personnel-related expenses and other accrued liabilities		252		107	
Accrued interest payable		(2,484)		(2,491)	
Other long-term liabilities				(126)	
Net cash provided by operating activities		227,833		190,553	
Cash flows from investing activities					
Maturities of marketable securities		86,000		160,925	
Purchases of marketable securities		(12,943)		(230,922)	
Purchases of equity investments		(72,500)		_	
Purchases of property and equipment		(13)			
Net cash provided by (used in) investing activities		544		(69,997)	
Cash flows from financing activities		<u></u>			
Repurchase of shares to satisfy tax withholding		(83)		(81)	
Payments of cash dividends to stockholders		<u></u>		(11)	
Proceeds from issuances of common stock, net		421		618	
Net proceeds from the issuance of variable interest entity's equity		344		_	
Distributions to noncontrolling interest		(27,962)		(10,553)	
Net cash used in financing activities		(27,280)		(10,027)	
Net increase in cash and cash equivalents		201,097		110,529	
Cash and cash equivalents at beginning of period		278,096		62,417	
Cash and cash equivalents at end of period	\$	479,193	\$	172,946	
Supplemental disclosure of cash flow information					
Cash paid for interest	\$	9,933	\$	10,674	

# INNOVIVA, INC. NOTES TO 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 a company with a portfolio of royalties that includes 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 entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion; and royalties from the sales of ANORO® ELLIPTA® which tier upward at a range from 6.5% to 10%. Innoviva is also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ("TRC"), including TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered or developed in the future under the LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the "GSK Agreements"), which have been assigned to TRC other than RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

#### **Basis of Presentation**

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") for interim financial information. Accordingly, they do not include all of the information and notes required by US GAAP for complete financial statements. In our opinion, the unaudited 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, 2020 or any other period.

The accompanying unaudited consolidated financial statements include the accounts of Innoviva and certain variable interest entities for which we are the primary beneficiary. All intercompany transactions have been eliminated. For consolidated entities where we own or are exposed to less than 100% of the economics, we record net income (loss) attributable to noncontrolling interest in our unaudited consolidated statements of income equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties. The accompanying unaudited 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, 2019 filed with the Securities and Exchange Commission ("SEC") on February 19, 2020, and as amended on February 21, 2020 ("2019 Form 10-K").

# Variable Interest Entities

We evaluate our ownership, contractual and other interest in the entities that we invest in to determine if they are variable interest entities ("VIEs"), whether we have a variable interest in those entities and the nature and extent of those interests. Such evaluation is performed continually throughout the entire period when we stay involved with these entities. Based on our evaluation, if we determine we are the primary beneficiary of a VIE, we consolidate the entity's financial results into our financial statements.

We consolidate the financial results of TRC and Pulmoquine Therapeutics, Inc. ("Pulmoquine"), which we have determined to be VIEs, because we have the power to direct the economically significant activities of these entities and the obligation to absorb losses of, or the right to receive benefits from them, and we are the primary beneficiary of the entities.

#### **Equity Investments**

We invest from time to time in equity securities of private or public companies. If we determine that we do not have control over these companies under either voting or VIE models, we then determine if we have an ability to exercise significant influence via voting interests, board representation or other business relationships. We may account for the equity investments where we exercise significant influence using either an equity method of accounting or at fair value by electing the fair value option under Accounting Standards Codification ("ASC") Topic 825, *Financial Instruments*. If the fair value option is applied to an investment that would otherwise be accounted for under the equity method, we apply it to all our financial interests in the same entity (equity and debt, including guarantees) that are eligible items. All gains and losses from fair value changes, unrealized and realized, are presented as changes in fair values of equity investments, net on the consolidated statements of income.

If we conclude that we do not have an ability to exercise significant influence over an investee, we may elect to account for an equity security without a readily determinable fair value using a measurement alternative. This measurement alternative allows us to measure the equity investment at its cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

As of September 30, 2020, we accounted for our equity investments in common stock and warrants of Armata Pharmaceuticals, Inc. (NYSE American: ARMP) ("Armata") and Entasis Therapeutics Holdings Inc. (NASDAQ: ETTX) ("Entasis") at fair value by electing the fair value option and presented the investments as equity investments on the consolidated balance sheets.

#### Accounting Pronouncement Adopted by the Company

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13 *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*, as clarified in subsequent amendments to the initial guidance (collectively, Topic 326). Topic 326 requires measurement and recognition of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecast. ASC 326 must be adopted using a modified retrospective approach with a cumulative effect adjustment as of the beginning of the reporting period in which the guidance is adopted. Topic 326 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We adopted Topic 326 effective January 1, 2020. The adoption did not have a material impact on our consolidated financial statements.

#### Recently Issued Accounting Standards or Updates Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes", which is intended to simplify various aspects related to accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. We are currently in the process of evaluating the effects of the provisions of ASU 2019-12 on our financial statements.

In August 2020, the FASB issued ASU 2020-06, "Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity", which is intended to simplify the accounting for convertible instruments by removing certain separation models in Subtopic 470-20, Debt-Debt with Conversion and Other Options, for convertible instruments. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2021, with early adoption permitted. We are currently in the process of evaluating the effects of the provisions of ASU 2020-06 on our financial statements.

#### 2. Net Income Per Share

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

Our convertible senior notes due 2025 (the "2025 Notes") are convertible, based on the applicable conversion rate, into cash, shares of our common stock or a combination thereof, at our election. Our current intent is to settle the principal amount of the 2025 Notes in cash upon conversion. The impact of the assumed conversion premium to diluted net income per share is computed using the treasury stock method. As the average market price per share of our common stock as reported on The Nasdaq Global Select Market was lower than the initial conversion price of \$17.26 per share, there was no dilutive effect of the assumed conversion premium for the three and nine months ended September 30, 2020 and 2019, respectively.

The following table shows the computation of basic and diluted net income per share for the three and nine months ended September 30, 2020 and 2019:

	Thre	e Months En	ded Se	ptember 30,	Nir	otember 30,		
(In thousands except per share data)		2020		2019	2020			2019
Numerator:								
Net income attributable to Innoviva stockholders, basic	\$	28,218	\$	39,809	\$	170,499	\$	111,339
Add: interest expense on 2023 Notes		1,171		1,157		3,535		3,482
Net income attributable to Innoviva stockholders, diluted	\$	29,389	\$	40,966	\$	174,034	\$	114,821
		•						•
Denominator:								
Weighted-average shares used to compute basic net income per								
share attributable to Innoviva stockholders		101,358		101,191		101,306		101,134
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		25		35		48		71
Weighted-average shares used to compute diluted net income per								
share attributable to Innoviva stockholders		113,572		113,415		113,543		113,394
Net income per share attributable to Innoviva stockholders								
Basic	\$	0.28	\$	0.39	\$	1.68	\$	1.10
Diluted	\$	0.26	\$	0.36	\$	1.53	\$	1.01

#### 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 Ende	d September 30,	Nine Months Ende	ed September 30,
(In thousands)	2020	2019	2020	2019
Outstanding options and awards granted under equity incentive plan				
and employee stock purchase plan	1,268	1,144	1,172	1,128

#### 3. Revenue Recognition and Collaborative Arrangements

#### Net Revenue from Collaborative Arrangements

Net revenue recognized under our GSK Agreements was as follows:

	Three Months Ended September 30,					Nine Months Ended September				
(In thousands)		2020		2019		2020		2019		
Royalties from a related party — RELVAR/BREO	\$	63,893	\$	46,433	\$	165,612	\$	136,259		
Royalties from a related party — ANORO		11,882		11,548		32,931		30,753		
Royalties from a related party — TRELEGY		16,375		11,230		48,143		28,401		
Total royalties from a related party		92,150		69,211		246,686		195,413		
Less: amortization of capitalized fees paid to a related party		(3,456)		(3,456)		(10,368)		(10,368)		
Royalty revenue		88,694	-	65,755		236,318		185,045		
Strategic alliance — MABA program		_		_		10,000		_		
Total net revenue from GSK	\$	88,694	\$	65,755	\$	246,318	\$	185,045		

During the nine months ended September 30, 2020, we recognized \$10.0 million in revenue in connection with the termination of the Bifunctional Muscarinic Antagonist-Beta2 Agonist ("MABA") program under the Strategic Alliance Agreement with GSK in June 2020.

#### 4. Consolidated Entities

# Theravance Respiratory Company, LLC

As of September 30, 2020, and December 31, 2019, \$16.4 million and \$14.4 million, respectively, of the related party receivables from collaborative arrangements were attributable to TRC. The cash balance attributable to TRC as of September 30, 2020 was \$41.4 million. Total revenue for TRC related to TRELEGY® ELLIPTA® was \$16.4 million and \$11.2 million for the three months ended September 30, 2020 and 2019, respectively, and \$48.1 million and \$28.4 million for the nine months ended September 30, 2020 and 2019, respectively. Total revenue for TRC also included a \$10.0 million fee for the termination of the MABA program for the nine months ended September 30, 2020. Total operating expenses were \$0.6 million and \$1.4 million for the three and nine months ended September 30, 2020, respectively, compared to \$2.8 million and \$2.9 million for the same periods in 2019.

### Pulmoquine Therapeutics, Inc.

On April 20, 2020, we entered into a securities purchase agreement with Pulmoquine to purchase 5,808,550 shares of Series A preferred stock for \$5.0 million in cash. Upon consummation of the transaction, we owned approximately 90.9% of Pulmoquine's outstanding shares (excluding unvested restricted shares) and hold a majority voting interest. Pulmoquine is a biotechnology company focused on the research and development of an aerosolized formulation of hydroxychloroquine to treat respiratory infections, such as the novel coronavirus ("COVID-19"). As of September 30, 2020, total assets attributable to Pulmoquine were \$4.6 million, including \$4.3 million in cash and cash equivalents and \$0.3 million in other current assets. Pulmoquine does not currently generate revenue. Total operating expense was \$1.1 million and \$1.7 million for the three and nine months ended September 30, 2020.

# 5. Financial Instruments and Fair Value Measurements

#### Equity Investment in Armata

On January 27, 2020, we entered into a securities purchase agreement to acquire 8,710,800 shares of Armata's common stock and warrants to purchase up to 8,710,800 additional shares of its common stock for \$25.0 million in cash. Armata is a clinical stage biotechnology company focused on precisely targeted bacteriophage therapeutics for antibiotic-resistant infections. The investment is to support Armata's ongoing advancement of its bacteriophage development programs including the expected first in human studies related to Armata's lead phage candidate, AP-PA02, targeting *Pseudomonas aeruginosa*, as well as AP-SA02, its phage candidate targeting *Staphylococcus Aureus*.

The investment was closed in two tranches on February 12, 2020 and March 27, 2020. Two of our board members joined Armata's board. After the second closing, we owned approximately 46.7% of Armata's common stock.

The investment provides Innoviva the ability to have significant influence, but not control over Armata's operations. Based on our evaluation, we determined that Armata is a VIE, but Innoviva is not the primary beneficiary of the VIE. We elected the fair value option to account for both Armata's common stock and warrants. The fair value of Armata's common stock is measured based on its closing market price. The warrants have an exercise price of \$2.87 per share, are exercisable immediately within five years from the issuance date of the warrants, and include a cashless exercise option. We use the Black-Scholes-Merton pricing model to estimate the fair value of these warrants with the following input assumptions: Armata's closing market price on the valuation date, the risk-free interest rate computed based on the U.S. Treasury yield, the remaining contractual term as the expected term, and the expected stock price volatility calculated based on the historical volatility of the common stock of Armata and its peer companies.

As of September 30, 2020, the fair values of Armata's common stock and warrants were estimated at \$27.8 million and \$20.2 million, respectively. The total fair value of both financial instruments in the amount of \$48.0 million was recorded as equity investments on the consolidated balance sheets as of September 30, 2020. We recorded \$12.4 million in unrealized loss and \$23.0 million in unrealized gain from fair value changes in Armata's investments as changes in fair values of equity investments, net on the consolidated statements of income for the three and nine months ended September 30, 2020, respectively.

#### Equity Investment in Entasis

On April 12, 2020, we entered into a securities purchase agreement with Entasis ("April 2020 Entasis Agreement") to purchase 14,000,000 shares of Entasis common stock as well as warrants to purchase 14,000,000 additional shares of its common stock for approximately \$35.0 million in cash. Entasis is a clinical-stage biotechnology company focused on the discovery and development of novel antibacterial products. The investment is to support Entasis's ongoing advancement of its pathogen-targeted antibacterial product candidates, which include their global Phase 3 registration trial evaluating a fixed-dose combination of sulbactam and durlobactam (SUL-DUR) against *Acinetobacter baumanii* infections.

The investment was closed in two tranches on April 22, 2020 and June 11, 2020. Innoviva has a right to designate two members to Entasis's board. After the second closing, we owned approximately 51.3% of Entasis's common stock.

On August 27, 2020, we entered into another securities purchase agreement with Entasis ("August 2020 Entasis Agreement") to purchase 4,672,897 shares of Entasis common stock as well as warrants to purchase 4,672,897 additional shares of its common stock for approximately \$12.5 million in cash. On September 1, 2020, we completed the purchase and increased our ownership in Entasis's common stock to 52.6%.

The investment provides Innoviva the ability to have significant influence, but not control, over Entasis's operations. Based on our evaluation, we determined that Entasis is a VIE, but Innoviva is not the primary beneficiary of the VIE. We elected the fair value option to account for both Entasis's common stock and warrants at fair value. The fair value of Entasis's common stock is measured based on its closing market price at each balance sheet date. The warrants have an exercise price of \$2.50 per share under the April 2020 Entasis Agreement and an exercise price of \$2.675 under the August 2020 Entasis Agreement. The warrants are exercisable immediately within five years from the issuance date of the warrants and include a cashless exercise option. We use the Black-Scholes-Merton pricing model to estimate the fair value of these warrants with the following input assumptions: Entasis's closing market price on the valuation date, the risk-free interest rate computed based on the U.S. Treasury yield, the remaining contractual term as the expected term, and the expected stock price volatility calculated based on the historical volatility of the common stock of Entasis and its peer companies.

As of September 30, 2020, the fair values of Entasis's common stock and warrants were estimated at \$38.1 million and \$25.7 million, respectively. The total fair value of both financial instruments in the amount of \$63.8 million was recorded as equity investments on the consolidated balance sheets. We recorded \$17.0 million in unrealized loss and \$16.3 million in unrealized gain from fair value changes in Entasis's investments as changes in fair values of equity investments, net on the consolidated statements of income for the three and nine months ended September 30, 2020, respectively.

# 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:

	<b>September 30, 2020</b>												
(In thousands)	Am	ortized Cost	U	Gross nrealized Gains	U	Gross nrealized Losses		Estimated Fair Value					
Money market funds	\$	430,144	\$		\$		\$	430,144					
Total	\$	430,144	\$	_	\$	_	\$	430,144					
					21.2	2010							
			December 31, 2019 Gross Gross										
				nrealized	U	nrealized	Estimate						
(In thousands)	Am	ortized Cost		Gains		Losses	]	Fair Value					
U.S. government securities	\$	53,799	\$	35	\$	_	\$	53,834					
U.S. commercial paper		18,915		_		_		18,915					
Money market funds		233,992		_				233,992					
Total	\$	306,706	\$	35	\$		\$	306,741					

As of September 30, 2020, all investments were money market funds. There was no credit loss as of September 30, 2020.

# Fair Value Measurements

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

	E	, 202	0 Using:			
	M	uoted Price in Active Iarkets for	Significant Other Observable	gnificant observable		
Types of Instruments	Ide	ntical Assets	 Inputs	Inputs		
(In thousands)		Level 1	 Level 2	 Level 3		Total
Assets						
Money market funds	\$	430,144	\$ _	\$ _	\$	430,144
Equity investment - Armata Common Stock		27,787	_	_		27,787
Equity investment - Armata Warrants		_	20,167	_		20,167
Equity investment - Entasis Common Stock		38,093	_	_		38,093
Equity investment - Entasis Warrants		_	25,698	_		25,698
Total assets measured at estimated fair value	\$	496,024	\$ 45,865	\$ 	\$	541,889
Debt						
2023 Notes	\$	_	\$ 230,494	\$ _	\$	230,494
2025 Notes		_	191,491	_		191,491
Total fair value of debt	\$		\$ 421,985	\$ _	\$	421,985

	E	stimated Fair \	Value .	Measurements :	<u>, 201</u>	9 Using:		
Types of Instruments (In thousands)	M	uoted Price in Active larkets for ntical Assets Level 1		Significant Other Observable Inputs Level 2	Un	gnificant observable Inputs Level 3		Total
Assets								
U.S. government securities	\$	_	\$	53,834	\$	_	\$	53,834
U.S. commercial paper		_		18,915		_		18,915
Money market funds		233,992		_		_		233,992
Total assets measured at estimated fair value	\$	233,992	\$	72,749	\$	_	\$	306,741
Debt								
2023 Notes	\$	_	\$	243,394	\$	_	\$	243,394
2025 Notes		_		208,976		_		208,976
Total fair value of debt	\$		\$	452,370	\$		\$	452,370
							_	

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 values of our equity investments in Armata and Entasis's common stock are based on their respective closing market prices per share at the reporting date and are classified as Level 1 financial instruments. The fair values of our equity investments in Armata and Entasis's warrants are included within Level 2 as the assumptions used in the valuation model are based on the observable inputs that include their respective closing market prices per share, their respective comparable companies' market data and the U.S. Treasury yield.

The fair value of our 2023 Notes and of our 2025 Notes is based on recent trading prices of the instruments.

#### 6. Stock-Based Compensation

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

	Three M	Ionths En	tember 30,	Nin	e Months End	led Sej	otember 30,	
(In thousands)	20	20		2019		2020		2019
General and administrative	\$	441	\$	489	\$	1,251	\$	1,568

#### 7. Debt

Our debt consists of:

housands)		ptember 30, 2020	De	2019
2023 Notes	\$	240,984	\$	240,984
2025 Notes		192,500		192,500
Total debt		433,484		433,484
Unamortized debt discount and issuance costs		(50,134)		(56,364)
Net long-term debt	\$	383,350	\$	377,120

#### Convertible Senior Notes Due 2025

In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of the 2025 Notes by allocating the proceeds between the liability component and the embedded conversion option ("equity component") due to our ability to settle the conversion obligation of the 2025 Notes in cash, common stock or a combination of cash and common stock, at our option. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature using the income approach. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the 2025 Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2025 Notes and the fair value of the liability of the 2025 Notes on the date of issuance. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense using the effective interest method over the term of the 2025 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

Our outstanding 2025 Notes balances consisted of the following:

(In thousands)	Se	2020 2020		2019
Liability component				
Principal	\$	192,500	\$	192,500
Debt discount and issuance costs, net		(48,788)		(54,597)
Net carrying amount	\$	143,712	\$	137,903
Equity component, net	\$	65,361	\$	65,361

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The following table sets forth total interest expense recognized related to the 2025 Notes for the three and nine months ended September 30, 2020 and 2019:

	Thre	e Months En	ded Se	ptember 30,	Nine	e Months End	led Sep	tember 30,
(In thousands)		2020		2019		2020		2019
Contractual interest expense	\$	1,203	\$	1,203	\$	3,609	\$	3,609
Amortization of debt issuance costs		152		139		446		408
Amortization of debt discount		1,828		1,673		5,363		4,909
Total interest and amortization expense	\$	3,183	\$	3,015	\$	9,418	\$	8,926

#### **Debt Maturities**

The aggregate scheduled maturities of our long-term debt as of September 30, 2020, are as follows:

(In thousands)	
Years ending December 31:	
2020 to 2022	\$ _
2023	240,984
2024	_
Thereafter	192,500
Total	\$ 433,484

### 8. Commitments and Contingencies

#### Lease

Future minimum operating lease payments on our corporate headquarters as of September 30, 2020 are as follows:

(In thousands)	
Years ending December 31:	
Remainder of 2020	\$ 30
2021	123
2022	109
Thereafter	_
Total	\$ 262

# Legal Proceedings

From time to time, the Company is involved in legal proceedings in the ordinary course of its business. Currently, we believe that no litigation or arbitration, either individually or in the aggregate, to which we are presently a party is likely to have a material adverse effect on our operating results or financial position.

#### 9. Income Taxes

Provisional income tax expense for the three and nine months ended September 30, 2020 was \$8.9 million and \$44.7 million, respectively, compared to \$10.6 million and \$29.5 million for the same periods in 2019 respectively. The Company's effective income tax rate for the nine months ended September 30, 2020 was 17%, compared to 18% for the same period in 2019. The difference between the Company's effective income tax rate and the U.S. federal statutory income tax rate of 21% is primarily attributable to state income tax, non-deductible expenses and noncontrolling interest.

# 10. Subsequent Events

In early October 2020, TRC invested \$15.0 million in the equity securities of a privately held biopharmaceutical company.

#### 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 (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Important factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, risks related to: lower than expected future royalty revenue from respiratory products partnered with GSK; the commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA® in the jurisdictions in which these products have been approved; the strategies, plans and objectives of the Company (including the Company's growth strategy and corporate development initiatives beyond the existing respiratory portfolio); the timing, manner and amount of potential capital returns to stockholders; the status and timing of clinical studies, data analysis and communication of results; the potential benefits and mechanisms of action of product candidates; expectations for product candidates through development and commercialization; the timing of regulatory approval of product candidates; projections of revenue, expenses and other financial items; the impact of the COVID-19 pandemic; and risks discussed in "Risk Factors" in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission ("SEC") on February 19, 2020, and as amended on February 21, 2020 ("2019 Form 10-K") and Item 1A of Part II of our Quarterly Reports on Form 10-Q and below 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 Quarterly Report on Form 10-Q are based on current expectations as of the date hereof and we do not assume any obligation to update any forward-looking statements on account of new information, future events or otherwise, except as required by law.

We encourage you to read our consolidated financial statements contained in this Quarterly Report on Form 10-Q. We also encourage you to read Item 1A of Part I of our 2019 Form 10-K and Item 1A of Part II of our Quarterly Reports on Form 10-Q entitled "Risk Factors," which contain a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of Part I of our 2019 Form 10-K and Item 1A of Part II of this report, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the SEC from time to time, including on Form 10-K, Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

#### **OVERVIEW**

#### **Executive Summary**

Innoviva, Inc. ("Innoviva", the "Company", the "Registrant" or "we" and other similar pronouns) is a company with a portfolio of royalties that includes 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 entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion; and royalties from the sales of ANORO® ELLIPTA® which tier upward at a range from 6.5% to 10%. Innoviva is also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to TRC, including TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered or developed in the future under the LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the "GSK Agreements"), which have been assigned to TRC other than RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

Our company structure and organization are tailored to our focused activities of managing our respiratory assets with GSK, the commercial and developmental obligations associated with the GSK Agreements, intellectual property, licensing operations, business development activities and providing for certain essential reporting and management functions of a public company. As of September 30, 2020, we had five employees. Our revenues consist of royalties and potential milestone payments, if any, from our respiratory partnership agreements with GSK.

#### **Recent Highlights**

#### GSK Net Sales:

- Third quarter 2020 net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$426.0 million, up 38% from \$309.5 million in the third quarter of 2019, with \$219.2 million in net sales from the U.S. market and \$206.8 million from non-U.S. markets.
- Third quarter 2020 net sales of ANORO® ELLIPTA® by GSK were \$182.8 million, up 3% from \$177.7 million in the third quarter of 2019, with \$111.5 million net sales from the U.S. market and \$71.3 million from non-U.S. markets.
- Third quarter 2020 net sales of TRELEGY® ELLIPTA® by GSK were \$251.9 million, up 46% from \$172.8 million in the third quarter of 2019, with \$165.3 million in net sales from the U.S. market and \$86.6 million in net sales from non-U.S. markets.

#### • Capital Allocation:

During the third quarter of 2020, the Company invested an additional \$12.5 million in 4.7 million shares of Entasis's common stock and warrants to purchase up to an additional 4.7 million shares of the common stock at \$2.675 per share. With this additional investment, Innoviva owned approximately 52.6% of Entasis's common stock as of September 30, 2020. Innoviva has a right to designate two members to Entasis's board.

# Collaborative Arrangements with GSK

#### LABA Collaboration

In November 2002, we entered into our LABA Collaboration Agreement with GSK to develop and commercialize once-daily LABA products for the treatment of chronic obstructive pulmonary disease ("COPD") and asthma. The collaboration has developed three combination products: (1) RELVAR®/BREO® ELLIPTA® (FF/VI) (BREO® ELLIPTA® is the proprietary name in the U.S. and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF), (2) ANORO® ELLIPTA® (UMEC/VI), a once-daily medicine combining a long-acting muscarinic antagonist ("LAMA"), umeclidinium bromide (UMEC), with a LABA, VI and (3) TRELEGY® ELLIPTA®, fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI), a once-daily combination medicine consisting of an ICS, LAMA and LABA.

As a result of the launch and approval of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe, in accordance with the LABA Collaboration Agreement, we paid milestone fees to GSK totaling \$220.0 million during the year ended December 31, 2014. The milestone fees paid to GSK were recognized as capitalized fees paid to a related party, which are being amortized over their estimated useful lives commencing upon the commercial launch of the products.

# 2004 Strategic Alliance

In March 2004, we entered into the Strategic Alliance Agreement with GSK where GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Innoviva-discovered preclinical MABA compounds (the "Additional MABAs"). The development program was funded in full by GSK. In June of 2020, GSK terminated the program and agreed to pay a \$10.0 million termination fee to TRC. This fee was recognized as revenue from collaborative arrangements with a related party on our consolidated statements of income for the nine months ended September 30, 2020.

#### **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 accounting principles generally accepted in the United States of America ("US GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

As part of our capital allocation strategies, we invest from time to time in equity securities of private or public companies. If we determine that we do not have control over these companies under either voting or VIE models, we then determine if we have an ability to exercise significant influence via voting interests, board representation or other business relationships. We may account for the equity investments where we exercise significant influence using either an equity method of accounting or at fair value by electing the fair value option. If the fair value option is applied to an investment that would otherwise be accounted for under the equity method, we apply it to all our financial interests in the same entity (equity and debt, including guarantees) that are eligible items. All gains and losses from fair value changes, unrealized and realized, are presented as changes in fair values of equity investments, net on the consolidated statements of income.

If we conclude that we do not have an ability to exercise significant influence over an investee, we may elect to account for an equity security without a readily determinable fair value using a measurement alternative. This measurement alternative allows us to measure the equity investment at its cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

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, 2019 filed with the SEC on February 19, 2020, and as amended on February 21, 2020 provides a more complete discussion of our critical accounting policies and estimates.

### **Results of Operations**

#### Net Revenue

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

	Three Months Ended September 30,			Chang	ge	Nine Months End	ed Se	ptember 30,	Chang	ge .	
(In thousands)		2020		2019	\$	%	2020		2019	\$	%
Royalties from a related party - RELVAR/BREO	\$	63,893	\$	46,433	\$ 17,460	38 %	\$ 165,612	\$	136,259	\$ 29,353	22 %
Royalties from a related party - ANORO		11,882		11,548	334	3 %	32,931		30,753	2,178	7 %
Royalties from a related party - TRELEGY		16,375		11,230	5,145	<u>46 </u> %	48,143		28,401	19,742	<u>70 </u> %
Total royalties from a related party		92,150		69,211	22,939	33 %	246,686		195,413	51,273	26 %
Less: amortization of capitalized fees paid to a related party		(3,456)		(3,456)		0 %	ĺ		(10,368)		0 %
Royalty revenue		88,694		65,755	22,939	35 %	236,318		185,045	51,273	28 %
Strategic alliance -MABA program						*	10,000			10,000	*
Total net revenue from GSK	\$	88,694	\$	65,755	\$ 22,939	<u>35</u> %	\$ 246,318	\$	185,045	\$ 61,273	33 %

<sup>\*</sup> Not Meaningful

Total net revenue increased to \$88.7 million and \$246.3 million for the three and nine months ended September 30, 2020, compared to \$65.8 million and \$185.0 million, respectively, for the same period a year ago. Royalties for RELVAR®/BREO® ELLIPTA® increased due to favorable adjustments from better than expected pricing and continued volume growth in both U.S. and non-U.S. markets. ANORO® ELLIPTA® maintained its steady volume growth, offset by the increasing pricing pressure in the U.S. Royalties for TRELEGY® ELLIPTA® were higher due to the continued growth in prescriptions and market share.

#### Research & Development

Research and development expenses of \$1.0 million and \$1.6 million for the three and nine months ended September 30, 2020 were attributable to Pulmoquine's product development efforts.

#### General & Administrative

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

	Thre	e Months En	ded Se	eptember 30,	Chan	ge	Nine Months End	Chan	ge	
(In thousands)		2020	2020 2019			%	2020	2019	\$	%
General and administrative expenses	\$	3.254	\$	4.962	\$ (1.708)	(34)%5	\$ 8.413	\$ 12.324	\$ (3.911)	(32)%

General and administrative expenses for the three and nine months ended September 30, 2020 decreased compared to the same periods in 2019, attributable to overall lower operating expenses incurred. The amount for the three months ended September 30, 2019 includes \$2.8 million legal and related fees incurred for the arbitration initiated by Theravance Biopharma against the Company and TRC

#### Other Income, net and Interest Income

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

	Thre	Three Months Ended September 30,					nge	<u>I</u>	Nine Months En	ded S		Char	ıge	_	
(In thousands)		2020 2019			\$	\$ %		2020		2019	\$		%	_	
Other income (expense), net	\$	(13)	\$	(115)	\$	102		(89)%\$	85	\$	(122)	\$	207	*	,
Interest income		41	\$	1,624	(	1,583)		(97)%	1,501	\$	4,002		(2,501)	(62	2)%

<sup>\*</sup> Not Meaningful

Interest income decreased for the three and nine months ended September 30, 2020, as compared to the same periods a year ago primarily due to lower interest rates impacted by the COVID-19 pandemic.

#### Interest Expense

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

	Three	Three Months Ended September 30,			C	Change Nine Months Ended September 30,			Change		
(In thousands)		2020		2019	\$	%	2020		2019	\$	%
Interest expense	\$	4,603	\$	4,693	\$ (90	$(2)^{9/2}$	6\$ 13,680	\$	13,971	\$ (291)	(2)%

Interest expense decreased slightly for the three and nine months ended September 30, 2020, compared to the same periods a year ago primarily due to the lower average outstanding debt balance.

# Changes in Fair Values of Equity Investments

The decrease in fair values of equity investments of \$29.4 million was mainly due to the lower stock prices of our invested companies, Armata Pharmaceuticals Inc. ("Armata") and Entasis Therapeutics Holdings, Inc. ("Entasis") as of September 30, 2020, compared to the stock prices at the previous quarter ended June 30, 2020. For the nine ended September 30, 2020, the changes in the fair values of equity investments of \$39.2 million represent the net unrealized gains of our investments in Armata and Entasis.

As of September 30, 2020, the total fair value of Armata's common stock and warrants that we own was estimated at \$48.0 million. We recorded \$12.4 million in unrealized loss and \$23.0 million in unrealized gain from fair value changes and presented it in the changes in fair values of equity investments on the consolidated statements of income for the three and nine months ended September 30, 2020, respectively.

As of September 30, 2020, the total fair value of Entasis's common stock and warrants was estimated at \$63.8 million. We recorded \$17.0 million in unrealized loss and \$16.3 million in unrealized gain from fair value changes and presented it in the changes in fair values of equity investments on the consolidated statements of income for the three and nine months ended September 30, 2020, respectively.

#### **Provision for Income Taxes**

The provisional income tax expense for the three and nine months ended September 30, 2020 was \$8.9 million and \$44.7 million with an effective income tax rate of 17%, respectively, compared to \$10.6 million and \$29.5 million, respectively, with an effective interest rate of 18% in the same period a year ago. The difference between the Company's effective income tax rate and the U.S. federal statutory income tax rate of 21% is primarily attributable to state income tax, non-deductible expenses and noncontrolling interests.

#### Net Income Attributable to Noncontrolling Interest

Net income attributable to noncontrolling interest, as compared to the prior periods, was as follows:

	Three Months Ended September 30,			Change Nine Months End			led September 30,		Change		
(In thousands)		2020		2019	\$	%	2020		2019	\$	%
Net income attributable to											
noncontrolling interest	\$	13,403	\$	7,242	\$ 6,161	85 %	\$ 48,299	\$	21,792	\$ 26,507	*

<sup>\*</sup> Not Meaningful

This represents the 85% share of net income in Theravance Respiratory Company, LLC for Theravance Biopharma for the three and nine months ended September 30, 2020 and 2019. The increase was primarily due to the increase in the growth in prescriptions and market share for TRELEGY® ELLIPTA®.

#### **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. For the nine months ended September 30, 2020, we generated gross royalty revenues from GSK of \$246.7 million and a \$10.0 million fee from the termination of the MABA program. Net cash and cash equivalents, short term investments and marketable securities totaled \$479.2 million, and receivables from GSK totaled \$92.2 million as of September 30, 2020.

#### Adequacy of Cash Resources to Meet Future Needs

We believe that cash from projected future royalty revenues and our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated debt service and operating needs for at least the next 12 months based upon current operating plans and financial forecasts. If our current operating plans and financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings or debt financings. Furthermore, if in our view favorable financing opportunities arise, we may seek additional funding at any time. However, future financing may not be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as currently planned. In addition, from time to time we may restructure or reduce our debt, including through tender offers, redemptions, amendments, repurchases or otherwise, all allowable with the terms of our debt agreements.

#### Cash Flows

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

	Nine Months Ended September 30,				
(In thousands)		2020		2019	Change
Net cash provided by operating activities	\$	227,833	\$	190,553	\$ 37,280
Net cash provided by (used in) investing activities		544		(69,997)	70,541
Net cash used in financing activities		(27,280)		(10,027)	(17,253)

#### Cash Flows from Operating Activities

Net cash provided by operating activities for the nine months ended September 30, 2020 was \$227.8 million, consisting primarily of our net income of \$218.8 million, adjusted for net non-cash items such as \$44.7 million of deferred income taxes and \$10.4 million of depreciation and amortization, partially offset by \$39.2 million increase in the fair values of our equity investments and \$12.7 million increase in receivables from collaborative arrangements.

Net cash provided by operating activities for the nine months ended September 30, 2019 was \$190.6 million, consisting primarily of our net income of \$133.1 million, adjusted for non-cash items such as \$29.5 million of deferred income taxes, \$10.4 million of depreciation and amortization and \$5.8 million amortization of debt discount and issuance costs, as well as a decrease in receivables from collaborative arrangements of \$14.1 million.

#### Cash Flows from Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2020 of \$0.5 million was primarily due to \$86.0 million received from maturities of marketable securities, partially offset by \$12.9 million in purchases of marketable securities and \$72.5 million for our investments in Armata and Entasis.

Net cash used in investing activities for the nine months ended September 30, 2019 of \$70.0 million was primarily due to \$230.9 million in purchases of marketable securities, partially offset by \$160.9 million proceeds received from maturities of marketable securities.

# Cash Flows from Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2020 of \$27.3 million was primarily due to \$28.0 million in distributions to noncontrolling interest.

Net cash used in financing activities for the nine months ended September 30, 2019 of \$10.0 million was primarily due to \$10.6 million in distributions to noncontrolling interest.

#### Off-Balance Sheet Arrangements

In June 2014, our facility leases in South San Francisco, California were assigned to Theravance Biopharma, Inc. ("Theravance Biopharma") in connection with the spin-off of 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. This lease concluded in May 2020, and we have no further obligations for the lease.

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

There have been no significant changes in our market risk or how our market risk is managed compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

#### **Item 4. Controls and Procedures**

Evaluation of Disclosure Controls and Procedures.

We conducted an evaluation as of September 30, 2020, under the supervision and with the participation of our management, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 ("Exchange Act") is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Accounting Officer, concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance levels.

#### Limitations on the Effectiveness of Controls

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

# Changes in Internal Control over Financial Reporting

Internal control measures have been designed and continually evaluated for our equity investment and capital allocation process since our initial investment occurred in the first quarter ended March 31, 2020. There have been no other material changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) during the quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II. OTHER INFORMATION

#### Item 1. Legal Proceedings

In May 2019, Theravance Biopharma, which is the owner of 85% of the economic interests in TRC, initiated arbitration against the Company and TRC, relating to a dispute as to the determination by Innoviva (as manager of TRC) to cause TRC to explore potential reinvestment opportunities for the royalty proceeds received by GSK into initiatives that Innoviva believes will increase the value of TRC and TRELEGY® ELLIPTA®. Theravance Biopharma alleged that, in causing TRC to not distribute substantially all royalty proceeds received from GSK, Innoviva breached the limited liability company operating agreement governing TRC (the "Operating Agreement"), as well as the fiduciary duties applicable to Innoviva as manager of TRC. The hearing in respect of the arbitration was conducted from July 23, 2019 through July 25, 2019. Post-arbitration oral argument was heard on August 14, 2019. On September 26, 2019, the arbitrator issued a final decision. The arbitrator ruled that Innoviva did not breach the Operating Agreement or its fiduciary duties by withholding royalties or pursuing reinvestment opportunities. Accordingly, the Company is permitted to continue to pursue development and commercialization initiatives. The arbitrator did conclude that Innoviva breached a provision of the Operating Agreement requiring Innoviva to deliver quarterly financial plans to Theravance Biopharma. However, the arbitrator concluded that this technical breach did not cause any damages to Theravance Biopharma and the arbitrator awarded limited injunctive relief to expand and clarify the disclosure obligations under the Operating Agreement related to the delivery of financial plans and the pursuit of investment opportunities (if those opportunities related to TRELEGY® ELLIPTA®). Finally, the arbitrator ruled that the Company is entitled to indemnification from TRC for 95% of its fees and expenses incurred in connection with the arbitration.

On September 30, 2019, the Company and TRC filed a Verified Complaint in the Court of Chancery of the State of Delaware ("Court of Chancery") to confirm the arbitration award. The award was confirmed by the Court of Chancery on May 4, 2020.

On July 16, 2020, Innoviva and TRC initiated a lawsuit in the Court of Chancery against Theravance Biopharma, seeking a permanent injunction preventing Theravance Biopharma from interfering with Innoviva's ability to cause TRC to reserve cash to pursue non-Trelegy related investments opportunities and a declaration that the arbitration award conclusively established that Innoviva, as manager of TRC, has such authority. The Court of Chancery directed the parties to obtain the arbitrator's opinion as to whether the arbitration award addressed non-Trelegy related investment opportunities. On July 31, 2020, the arbitrator, while reiterating that Innoviva has broad authority as manager of TRC, found that his award did not specifically address this situation. Accordingly, on August 5, 2020, the parties stipulated to the dismissal of the Court of Chancery action.

On October 6, 2020, Theravance Biopharma initiated a new arbitration against the Company and TRC, challenging Innoviva's authority as manager of TRC to cause TRC to pursue non-Trelegy related investment opportunities and again alleging that Innoviva is required to cause TRC to distribute substantially all royalty proceeds from GSK. An arbitration hearing is scheduled for the first quarter of 2021

The Company intends to vigorously defend against the allegations in the new arbitration demand, but there can be no assurances that the defense will be successful.

#### Item 1A. Risk Factors

Our business is subject to a number of risks, including those previously reported in Item 1A of Part I of our 2019 Form 10-K and in Item 1A of Part II of our Form 10-Q for the three months ended March 31, 2020 (the "Q1 10-Q"). Except for the risk factors set forth in the Q1 10-Q and as set forth under "Item 1. Legal Proceedings" above, there have been no other material changes to the risk factors described in our 2019 Form 10-K.

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

None.

#### **Item 3: Defaults Upon Senior Securities**

None.

# **Item 4: Mine Safety Disclosures**

None.

# **Item 5: Other Information**

None.

# Item 6. Exhibits

# (a) Index to Exhibits

Exhibit Number	Description	Form	Exhibit	Incorporated by Reference Filing Date/Period End Date
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14 pursuant to the Securities Exchange Act of 1934			
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14 pursuant to the Securities Exchange Act of 1934			
32	Certifications Pursuant to 18 U.S.C. Section 1350			
101	Interactive Data File (Quarterly Report on Form 10-Q, for the quarterly period ended September 30, 2020) formatted in iXBRL (Inline eXtensible Business Reporting Language).			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101).			
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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: October 28, 2020 /s/ Pavel Raifeld **Pavel Raifeld** Chief Executive Officer (Principal Executive Officer) Date: October 28, 2020 /s/ Marianne Zhen Marianne Zhen Chief Accounting Officer (Principal Financial Officer) 28

#### Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Pavel Raifeld, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Innoviva, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report:
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions
    about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on
    such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Pavel Raifeld
Pavel Raifeld
Chief Executive Officer
(Principal Executive Officer)

#### Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Marianne Zhen, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Innoviva, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report:
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions
    about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on
    such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 28, 2020	/s/ Marianne Zhen
	Marianne Zhen
	Chief Accounting Officer
	(Principal Financial Officer)

# CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Pavel Raifeld, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Innoviva, Inc. on Form 10-Q for the period ended September 30, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Innoviva, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Innoviva, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

Date: October 28, 2020	By:	/s/ Pavel Raifeld			
		Pavel Raifeld			
		Chief Executive Officer			
		(Principal Executive Officer)			

# CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Marianne Zhen, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Innoviva, Inc. on Form 10-Q for the period ended September 30, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Innoviva, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Innoviva, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

Date: October 28, 2020

By: /s/ Marianne Zhen

Marianne Zhen

Chief Accounting Officer

(Principal Financial Officer)