

**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 September 30, 2022

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.)

**1350 Old Bayshore Highway Suite 400
Burlingame, CA 94010**
(Address of Principal Executive Offices)

(650) 238-9600
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(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

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 every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

The number of shares of registrant's common stock outstanding on October 28, 2022 was 69,783,185.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

INNOVIVA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)
(Unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 300,789	\$ 201,525
Short-term marketable securities	282	—
Accounts receivable, net	6,743	—
Receivables from collaboration arrangement	65,606	110,711
Inventory	70,807	—
Prepaid expenses	7,932	1,367
Other current assets	2,432	70
Total current assets	454,591	313,673
Property and equipment, net	165	12
Equity and long-term investments	489,111	483,845
Capitalized fees paid to a related party, net	101,062	111,430
Right-of-use assets	3,679	97
Goodwill	15,995	—
Intangible assets	258,489	—
Deferred tax assets, net	—	17,327
Other assets	4,620	11
Total assets	\$ 1,327,712	\$ 926,395
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,805	\$ 27
Accrued personnel-related expenses	6,473	619
Accrued interest payable	5,702	4,152
Deferred revenue	2,849	—
Convertible subordinated notes due 2023, net of issuance costs	96,131	—
Income tax payable	33,804	—
Other accrued liabilities	15,120	1,009
Total current liabilities	163,884	5,807
Long-term debt, net of discount and issuance costs	443,679	394,653
Other long-term liabilities	78,421	—
Deferred tax liabilities	360	—
Commitments and contingencies (Note 11)		
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, 69,776 and 69,566 issued and outstanding as of September 30, 2022 and December 31, 2021 respectively	698	696
Treasury stock: at cost, 32,005 shares as of September 30, 2022 and December 31, 2021, respectively	(393,829)	(393,829)
Additional paid-in capital	1,171,096	1,264,024
Accumulated deficit	(136,597)	(456,148)
Total Innoviva stockholders' equity	641,368	414,743
Noncontrolling interest	—	111,192
Total stockholders' equity	641,368	525,935
Total liabilities and stockholders' equity	\$ 1,327,712	\$ 926,395

See accompanying notes to condensed consolidated financial statements.

INNOVIVA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except per share data)
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
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, 2022 and 2021, and \$10,368 in the nine months ended September 30, 2022 and 2021	\$ 62,150	\$ 97,862	\$ 260,429	\$ 284,186
Net product sales	5,107	—	5,107	—
Total revenue	<u>67,257</u>	<u>97,862</u>	<u>265,536</u>	<u>284,186</u>
Expenses:				
Cost of products sold (inclusive of amortization of inventory fair value adjustments, excluding depreciation and amortization of intangible assets)	3,680	—	3,680	—
Selling, general and administrative	27,810	2,860	46,084	13,074
Research and development	11,725	449	31,447	536
Amortization of acquired intangible assets	1,511	—	1,511	—
Gain on sale of Theravance Respiratory Company, LLC ("TRC")	(266,696)	—	(266,696)	—
Loss on debt extinguishment	—	—	20,662	—
Changes in fair values of equity and long-term investments, net	(130)	(33,613)	67,881	(133,973)
Interest and dividend income	(2,135)	(453)	(3,181)	(503)
Interest expense	5,096	4,790	11,761	14,229
Other expense (income), net	(28)	652	750	2,036
Total expenses	<u>(219,167)</u>	<u>(25,315)</u>	<u>(86,101)</u>	<u>(104,601)</u>
Income before income taxes	286,424	123,177	351,637	388,787
Income tax expense, net	57,077	20,531	63,061	65,600
Net income	<u>229,347</u>	<u>102,646</u>	<u>288,576</u>	<u>323,187</u>
Net income (loss) attributable to noncontrolling interests	<u>(36,176)</u>	<u>30,208</u>	<u>6,341</u>	<u>67,678</u>
Net income attributable to Innoviva stockholders	<u>\$ 265,523</u>	<u>\$ 72,438</u>	<u>\$ 282,235</u>	<u>\$ 255,509</u>
Basic net income per share attributable to Innoviva stockholders	<u>\$ 3.81</u>	<u>\$ 1.04</u>	<u>\$ 4.05</u>	<u>\$ 2.96</u>
Diluted net income per share attributable to Innoviva stockholders	<u>\$ 2.80</u>	<u>\$ 0.90</u>	<u>\$ 3.07</u>	<u>\$ 2.63</u>
Shares used to compute Innoviva basic and diluted net income per share:				
Shares used to compute basic net income per share	<u>69,731</u>	<u>69,458</u>	<u>69,640</u>	<u>86,298</u>
Shares used to compute diluted net income per share	<u>95,830</u>	<u>81,699</u>	<u>95,072</u>	<u>98,536</u>

See accompanying notes to condensed consolidated financial statements.

INNOVIVA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income	\$ 229,347	\$ 102,646	\$ 288,576	\$ 323,187
Comprehensive income	229,347	102,646	288,576	323,187
Comprehensive income (loss) attributable to noncontrolling interests	(36,176)	30,208	6,341	67,678
Comprehensive income attributable to Innoviva stockholders	<u>\$ 265,523</u>	<u>\$ 72,438</u>	<u>\$ 282,235</u>	<u>\$ 255,509</u>

See accompanying notes to condensed consolidated financial statements.

INNOVIVA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Nine Months Ended September 30, 2022							
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock		Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount			Shares	Amount		
Balance as of January 1, 2022	69,566	\$ 696	\$ 1,264,024	\$ (456,148)	32,005	\$ (393,829)	\$ 111,192	\$ 525,935
Cumulative adjustment due to adoption of ASU 2020-06	—	—	(65,361)	37,238	—	—	—	(28,123)
Distributions to noncontrolling interests	—	—	—	—	—	—	(6,507)	(6,507)
Fair value of noncontrolling interests in a consolidated variable interest entity	—	—	—	—	—	—	38,471	38,471
Exercise of stock options and issuance of common stock units and stock awards, net of repurchase of shares to satisfy tax withholding	28	—	214	—	—	—	—	214
Stock-based compensation	—	—	620	—	—	—	334	954
Capped call options associated with convertible senior notes due 2028	—	—	(16,585)	—	—	—	—	(16,585)
Net income	—	—	—	15,773	—	—	22,085	37,858
Balance as of March 31, 2022	69,594	\$ 696	\$ 1,182,912	\$ (403,137)	32,005	\$ (393,829)	\$ 165,575	\$ 552,217
Distributions to noncontrolling interests	—	—	—	—	—	—	(9,545)	(9,545)
Equity activity of noncontrolling interests in a consolidated variable interest entity	—	—	—	—	—	—	(2)	(2)
Exercise of stock options and issuance of common stock units and stock awards, net of repurchase of shares to satisfy tax withholding	112	1	67	—	—	—	—	68
Conversion of convertible subordinated notes due 2023	—	—	3	—	—	—	—	3
Stock-based compensation	—	—	685	—	—	—	665	1,350
Net income	—	—	—	939	—	—	20,432	21,371
Balance as of June 30, 2022	69,706	\$ 697	\$ 1,183,667	\$ (402,198)	32,005	\$ (393,829)	\$ 177,125	\$ 565,462
Distributions to noncontrolling interests	—	—	—	—	—	—	(53,759)	(53,759)
Derecognition of noncontrolling interests upon sale of TRC	—	—	—	78	—	—	(61,304)	(61,226)
Derecognition of noncontrolling interests upon acquisition of Entasis Therapeutics Holdings Inc. ("Entasis") minority interest	—	—	(14,153)	—	—	—	(28,009)	(42,162)
Exercise of stock options and issuance of common stock units and stock awards, net of repurchase of shares to satisfy tax withholding	70	1	(12)	—	—	—	—	(11)
Stock-based compensation	—	—	1,594	—	—	—	2,123	3,717
Net income	—	—	—	265,523	—	—	(36,176)	229,347
Balance as of September 30, 2022	69,776	\$ 698	\$ 1,171,096	\$ (136,597)	32,005	\$ (393,829)	\$ —	\$ 641,368

Nine Months Ended September 30, 2021

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock		Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount			Shares	Amount		
Balance as of December 31, 2020	101,392	\$ 1,014	\$ 1,260,900	\$ (722,002)	—	\$ —	\$ 67,925	\$ 607,837
Distributions to noncontrolling interests	—	—	—	—	—	—	(21,285)	(21,285)
Equity activity of noncontrolling interests in 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	16	—	(25)	—	—	—	—	(25)
Stock-based compensation	—	—	451	—	—	—	—	451
Net income	—	—	—	94,123	—	—	15,572	109,695
Balance as of March 31, 2021	101,408	\$ 1,014	\$ 1,261,326	\$ (627,879)	—	\$ —	\$ 62,220	\$ 696,681
Distributions to noncontrolling interests	—	—	—	—	—	—	(20,161)	(20,161)
Equity activity of noncontrolling interests in 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	92	1	49	—	—	—	—	50
Repurchase of common stock	(32,005)	(320)	—	—	32,005	(393,829)	—	(394,149)
Stock-based compensation	—	—	470	—	—	—	—	470
Net income	—	—	—	88,948	—	—	21,898	110,846
Balance as of June 30, 2021	69,495	\$ 695	\$ 1,261,845	\$ (538,931)	\$ 32,005	\$ (393,829)	\$ 63,965	\$ 393,745
Distributions to noncontrolling interests	—	—	—	—	—	—	(4,912)	(4,912)
Equity activity of noncontrolling interests in a consolidated variable interest entity	—	—	—	—	—	—	(267)	(267)
Exercise of stock options and issuance of common stock units and stock awards, net of repurchase of shares to satisfy tax withholding	(3)	—	51	—	—	—	—	51
Stock-based compensation	—	—	542	—	—	—	—	542
Net income	—	—	—	72,438	—	—	30,208	102,646
Balance as of September 30, 2021	<u>69,492</u>	<u>\$ 695</u>	<u>\$ 1,262,438</u>	<u>\$ (466,493)</u>	<u>32,005</u>	<u>\$ (393,829)</u>	<u>\$ 88,994</u>	<u>\$ 491,805</u>

See accompanying notes to condensed consolidated financial statements.

INNOVIVA, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities		
Net income	\$ 288,576	\$ 323,187
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income tax	29,258	65,600
Depreciation and amortization	12,507	10,376
Amortization of inventory fair value adjustments included in cost of products sold	2,743	—
Stock-based compensation	6,021	1,463
Amortization of debt discount and issuance costs	1,491	6,778
Amortization of deferred royalty obligation value adjustment	482	—
Changes in fair values of equity and long-term investments, net	66,448	(132,485)
Loss on extinguishment of debt	20,662	—
Net gain on sale of TRC	(266,696)	—
Other	995	(251)
Changes in operating assets and liabilities:		
Accounts receivable	(867)	—
Receivables from collaboration arrangement	2,385	(7,340)
Inventory	350	—
Prepaid expenses	277	770
Other assets, current	692	328
Other assets, non-current	(3,624)	—
Accounts payable	958	23
Accrued personnel-related expenses and other accrued liabilities	(1,709)	(533)
Accrued interest payable	(1,926)	(2,484)
Income tax payable	33,804	—
Net cash provided by operating activities	<u>192,827</u>	<u>265,432</u>
Cash flows from investing activities		
Purchases of equity and long-term investments	(58,725)	(46,373)
Purchases of equity investments managed by ISP Fund LP	(92,951)	(178,445)
Sales of equity investments managed by ISP Fund LP	24,281	21,426
Purchases and sales of other investments managed by ISP Fund LP, net	(41,330)	267,019
Purchases of property and equipment	(33)	—
Proceeds from sale of ownership interest in TRC, net	248,191	—
Cash acquired through the consolidation of Entasis	23,070	—
Cash paid for the acquisition of La Jolla Pharmaceutical Company, net of cash acquired	(150,459)	—
Net cash (used in) provided by investing activities	<u>(47,956)</u>	<u>63,627</u>
Cash flows from financing activities		
Distributions to noncontrolling interests	(69,811)	(46,358)
Purchase of Entasis minority interest	(42,395)	—
Repurchase of common stock	—	(394,149)
Repurchase of shares to satisfy tax withholding	(71)	(47)
Proceeds from issuances of common stock, net	342	123
Payment for repurchase of convertible subordinated notes due 2023	(165,131)	—
Purchases of capped call options associated with convertible senior notes due 2028	(21,037)	—
Proceeds from issuance of convertible senior notes due 2028, net of issuance costs	252,536	—
Net cash used in financing activities	<u>(45,567)</u>	<u>(440,431)</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	99,304	(111,372)
Cash and cash equivalents at beginning of period	201,525	246,487
Cash, cash equivalents and restricted cash at end of period	<u>\$ 300,829</u>	<u>\$ 135,115</u>

	Nine Months Ended September 30,	
	2022	2021
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	\$ 11,736	\$ 9,933
Cash paid for income taxes	3,859	—
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Adoption of ASU 2020-06	\$ 28,123	\$ —
Reconciliation of Cash, Cash Equivalents and Restricted Cash:		
Cash and cash equivalents	\$ 300,789	\$ 135,115
Restricted cash, included in “Other assets”	40	—
Total cash, cash equivalents and restricted cash at end of period shown in the condensed consolidated statements of cash flows	<u>\$ 300,829</u>	<u>\$ 135,115</u>

See accompanying notes to condensed consolidated financial statements.

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 a company with a portfolio of royalties and innovative healthcare assets. Our royalty portfolio contains respiratory assets partnered with Glaxo Group Limited (“GSK”), including RELVAR[®]/BREO[®] ELLIPTA[®] (fluticasone furoate/vilanterol, “FF/VI”) and ANORO[®] ELLIPTA[®] (umeclidinium bromide/ vilanterol, “UMEC/VI”), and up until July 2022, TRELEGY[®] ELLIPTA[®] (the combination FF/UMEC/VI). We sold our 15% ownership interest in Theravance Respiratory Company, LLC (“TRC”) on July 20, 2022, and are no longer entitled to receive royalties on sales of TRELEGY[®] ELLIPTA[®] products. 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%.

We expanded our portfolio of royalties and innovative healthcare assets through the acquisition of Entasis Therapeutics Holdings Inc. (“Entasis”) on July 11, 2022 and the acquisition of La Jolla Pharmaceutical Company (“La Jolla”) on August 22, 2022. Our commercial and marketed products include GIAPREZA[®] (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock, and XERAVA[®] (eravacycline) for the treatment of complicated intra-abdominal infections in adults. Our development pipeline includes medicines for the treatment of bacterial infections, such as our lead asset sulbactam-durlobactam (“SUL-DUR”).

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information. Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. The unaudited condensed consolidated financial statements have been prepared on the same basis as audited consolidated financial statements and, in our opinion, include all adjustments, consisting of all 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, 2022 or any other periods.

The accompanying unaudited condensed consolidated financial statements include the accounts of Innoviva, our wholly-owned subsidiaries, and certain variable interest entities (“VIEs”) for which we are the primary beneficiary. All intercompany balances and transactions have been eliminated in consolidation. For consolidated entities where we own or are exposed to less than 100% of the economics, we record net income attributable to noncontrolling interest in our unaudited condensed 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 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, 2021 filed with the Securities and Exchange Commission (“SEC”) on February 28, 2022, and as amended on March 17, 2022.

Factors Affecting Comparability

Our historical financial condition and results of operations for the periods presented may not be comparable, either between periods or going forward due to the factors below and as discussed in Note 5, “Consolidated Entities and Acquisitions”.

- Accounting consolidation of Entasis on February 17, 2022 and purchase of remaining minority interest in Entasis on July 11, 2022,
- Sale of our 15% ownership interest in Theravance Respiratory Company, LLC (“TRC”) on July 20, 2022, and
- Acquisition of La Jolla on August 22, 2022.

Prior Period Immaterial Correction

Subsequent to the issuance of the unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2021, the Company identified that (i) purchases of equity investments managed by ISP Fund LP for \$178.4 million, (ii) sales of equity investments managed by ISP Fund LP for \$21.4 million, and (iii) purchase and sales of other investments managed by ISP Fund LP, net for \$267.0 million were incorrectly included in the unaudited condensed consolidated statement of cash flows within the distribution of equity and long-term investments line item. The Company has corrected the presentation in the accompanying unaudited condensed consolidated statement of cash flows for the nine months ended September 30, 2021 from amounts previously reported to present such line items separately. The correction did not impact total cash flows from investing activities or the unaudited condensed consolidated balance sheet, statement of income, or statement of comprehensive income for the relevant period. Management assessed the correction on a quantitative and qualitative basis and determined that it is immaterial to the prior period unaudited condensed consolidated financial statements.

Use of Management's Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. Management evaluates its significant accounting policies and estimates on an ongoing basis. We base our estimates on historical experience and other relevant assumptions that we believe to be reasonable under the circumstances. These estimates also form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources.

Concentrations of Credit Risk and of Significant Suppliers and Partner

Our financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, equity and long-term investments. Although we deposit our cash with multiple financial institutions, our deposits, at times, may exceed federally insured limits.

We are dependent on third-party manufacturers to supply active pharmaceutical ingredients ("API") and drug products for research and development and commercial programs. These programs could be adversely affected by significant interruption in the supply of API or drug products.

Currently, we derive most of our revenues from GSK and our near-term success depends in large part on GSK's ability to successfully develop and commercialize the products in the respiratory programs partnered with GSK. Our near-term success depends in large part upon the performance by GSK of its commercial obligations under the GSK Agreements and the commercial success of RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®]. If GSK does not devote sufficient resources to the commercialization or development of these products, is unsuccessful in its efforts, or chooses to reprioritize its commercial programs, our business would be materially harmed. GSK is responsible for all clinical and other product development, regulatory, manufacturing and commercialization activities for products developed under the GSK Agreements, including RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®]. Our quarterly royalty revenues may fluctuate due to a variety of factors, many of which are outside of our control. Our royalty revenues under the GSK Agreements may not meet our, analysts' or investors' expectations, due to a number of important factors.

We also started recognizing revenue from product sales as a result of our acquisition of La Jolla. Hospitals and other healthcare organizations generally purchase our products through a network of specialty distributors. These specialty distributors, which are located in the U.S., are considered our customers for accounting purposes. We do not believe that loss of one of these distributors would significantly impact our ability to distribute our products, as we expect that sales volume would be absorbed by new or remaining distributors. Three of our customers each comprise 10% or more of our net product sales and they account for 32%, 32% and 29%, respectively, of our net product sales from the time of La Jolla's acquisition to September 30, 2022. These same customers account for 34%, 23% and 35%, respectively, of our receivables from net product sales, which is included in "Accounts receivables, net" in our unaudited consolidated balance sheet as of September 30, 2022.

Refer to Item 1A. "Risk Factors" disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021 and to the supplemental risk factors detailed in our Form 8-K filed on August 23, 2022 for further detail.

Segment Reporting

We operate in a single segment, which is to provide capital return to stockholders by maximizing the potential value of our portfolio of royalties and innovative healthcare assets. Our Chief Operating Decision Maker (“CODM”) is our Chief Executive Officer. The CODM allocates resources and evaluates the performance of Innoviva at the consolidated level using information about our revenues, operating results and other key financial data as needed. Our revenues are generated primarily from our collaborative arrangements and royalty payments from GSK, located in Great Britain. We also generate revenue from net sales of GIAPREZA[®] and XERAVA[®]. Our long-term assets are located within the United States.

Variable Interest Entities

We evaluate our ownership, contractual and other interest in entities to determine if they are a VIE. We evaluate whether we have a variable interest in those entities and the nature and extent of those interests. Based on our evaluation, if we determine we are the primary beneficiary of a VIE, we consolidate the entity in our financial statements.

Business Combination

When we acquire an entity in a business combination, we recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquiree and establish the acquisition date as the fair value measurement point. We recognize and measure goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired. Acquisition-related expenses and related restructuring costs are expensed as incurred.

Several valuation methods may be used to determine the fair value of assets acquired and liabilities assumed. For intangible assets, we typically use the income method. This method starts with a forecast of all of the expected future net cash flows for each asset. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income method or other methods include the amount and timing of projected future cash flows, the discount rate selected to measure the risks inherent in the future cash flows and the assessment of the asset’s life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry. Determining the useful life of an intangible asset also requires judgment as different types of intangible assets will have different useful lives and certain assets may even be considered to have indefinite useful lives.

Cash and Cash Equivalents

We consider all highly liquid investments purchased with a maturity of three months or less on the date of purchase to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value.

Accounts Receivable, Net

Accounts receivable, net are recorded net of estimates for prompt-pay discounts, chargebacks, returns, rebates, and administrative fees. Allowances for prompt-pay discounts and chargebacks are based on contractual terms. We estimate the allowance for credit losses based on existing contractual payment terms, actual payment patterns of customers and individual customer circumstances.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value on a first in, first out basis. We periodically analyze inventory levels and write down inventory as cost of products sold when the following occurs: inventory has become obsolete, inventory has a cost basis in excess of its estimated net realizable value, or inventory quantities are in excess of expected product sales.

Goodwill and Intangible Assets

Goodwill is recognized as the excess of the purchase consideration of an acquired entity over the fair value assigned to assets acquired and liabilities assumed in a business combination. Goodwill and intangible assets with indefinite lives are subject to impairment testing at least annually or more frequently if indicators for potential impairment exist. Intangible assets with definite lives are amortized on a straight-line basis over the remaining useful life of the intangible asset. These assets are tested for impairment whenever events or changes in circumstances indicate that an asset's carrying amount may not be recoverable. Significant judgments are involved in determining if an indicator of impairment has occurred.

Operating Leases

We account for our leases under ASC 842, *Leases*. Right-of-use assets represent our right to use an underlying asset over the lease term and include any lease payments made prior to the lease commencement date and are reduced by lease incentives. Lease liabilities represent the present value of the total lease payments over the lease term, calculated using an estimated incremental borrowing rate. Lease expense is recognized on a straight-line basis over the expected lease term.

Equity and Long-Term Investments

We invest from time to time in equity and debt securities of private or public companies. If we determine that we have control over these companies under either voting or VIE models, we consolidate them in our unaudited condensed consolidated financial statements. 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 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 and long-term investments, net within the unaudited condensed 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 the security without a readily determinable fair value using the measurement alternative method under ASC 321, *Investments - Equity Securities*. This measurement alternative method 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.

We also invest in ISP Fund LP, which investments consist of money market funds and equity and debt securities in the healthcare, pharmaceutical and biotechnology industries. Pursuant to the Partnership Agreement entered in December 2020, we became a limited partner of this partnership, and our contributions are subject to a 36-month lock-up period which prevents us from having control and access to the contributions and related investments. These investments are classified as long-term investments on the unaudited condensed consolidated balance sheets.

Revenue Recognition

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 the 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 as a performance obligation is satisfied.

Royalty Revenue from Collaboration Arrangement

We recognize the royalty revenue on net sales of products with respect to which we have contractual royalty rights in the period in which the royalties are earned. The net sales reports provided by our partner are based on its methodology and assumptions to estimate rebates and returns, which it monitors and adjusts regularly in light of contractual and legal obligations, historical trends, past experience and projected market conditions. Our partner may make significant adjustments to its sales based on actual results recorded, which could cause our royalty revenue to fluctuate. We conduct periodic royalty audits to evaluate the information provided by our partner. Royalties are recognized net of amortization of capitalized fees associated with any approval and launch milestone payments made to GSK.

Revenue from Product Sales

Revenue from product sales is recognized when our customers obtain control of the product and is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, discounts, returns, rebates and administrative fees. Variable consideration is estimated using the expected-value amount method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary materially from our estimates, we will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted. These items may include:

- **Chargebacks:** Chargebacks are discounts we provide to distributors in the event that the sales prices to end users are below the distributors' acquisition price. This may occur due to a direct contract with a health system, a group purchasing organization ("GPO") agreement or a sale to a government facility. Chargebacks are estimated based on known chargeback rates and recorded as a reduction of revenue on delivery to our customers.
- **Discounts:** We offer customers various forms of incentives and consideration, including prompt-pay and other discounts. We estimate discounts primarily based on contractual terms. These discounts are recorded as a reduction of revenue on delivery to our customers.
- **Returns:** We offer customers a limited right of return, generally for damaged or expired product. We estimate returns based on an internal analysis, which includes actual experience. The estimates for returns are recorded as a reduction of revenue on delivery to our customers.
- **Rebates:** We participate in Medicaid rebate programs, which provide assistance to certain low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, we pay a rebate to each participating state, generally within three months after the quarter in which product was sold. Additionally, we may offer customer incentives and consideration in the form of volume-based or other rebates. The estimates for rebates are recorded as a reduction of revenue on delivery to our customers.
- **Administrative Fees:** We pay administrative fees to GPOs for services and access to data. Additionally, we pay an Industrial Funding Fee as part of the U.S. General Services Administration's Federal Supply Schedules program. These fees are based on contracted terms and are paid after the quarter in which the product was purchased by the applicable GPO or government agency. Administrative fees are recorded as a reduction of revenue on delivery to customers.

We continue to assess our estimates of variable consideration as we accumulate additional historical data and will adjust these estimates accordingly.

Research and Development Costs

Research and development costs are expensed in the period that services are rendered or goods are received. Research and development costs consist of salaries and benefits, laboratory supplies, facilities and other overhead costs, research-related manufacturing costs, contract service and clinical-related service costs performed by third party research organizations, research institutions and other outside service providers. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the related goods are delivered or the related services are performed. We also utilize significant judgment and estimates to record accruals for estimated ongoing research costs based on the progress of the studies and progress of research manufacturing activities.

Interest Expense on Deferred Royalty Obligation

Interest expense related to the deferred royalty obligation is recognized over the expected repayment term of the deferred royalty obligation using the effective interest method. The assumptions used in determining the expected repayment term of the deferred royalty obligation require us to make estimates that could impact the effective interest rate. Each reporting period, we estimate the expected repayment term of the deferred royalty obligation based on forecasted net sales of GIAPREZA[®]. Changes in interest expense resulting from changes in the effective interest rate, if any, are recorded on a prospective basis. Refer to Note 6, “Financial Instruments and Fair Value Measurements” for more information.

Accounting Pronouncement Adopted by the Company

In August 2020, the FASB issued Accounting Standards Update (“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 for convertible instruments. Consequently, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new standard also requires the if-converted method to be used to calculate diluted earnings per share (“EPS”) for convertible instruments.

Effective January 1, 2022, we adopted the new standard using the modified retrospective approach and assessed the effect of this adoption on the accounting for our outstanding convertible notes. The effect of the adoption on our 2025 Notes (as defined below) resulted in a decrease to the opening balance of accumulated deficit of \$37.2 million, a reduction to additional paid-in capital of \$65.4 million, an increase to the balance of the notes by an aggregate amount of \$35.6 million, and an increase to deferred tax assets of \$7.4 million. The dilutive EPS of our 2025 Notes will be computed under the if-converted method going forward. There was no financial impact from the implementation of the standard for our 2023 Notes (as defined below). Refer to Note 10, “Debt” for more information.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805), Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires contract assets and contract liabilities (i.e., deferred revenue) acquired in a business combination to be recognized and measured by the acquirer on the acquisition date in accordance with ASC 606, *Revenue from Contracts with Customers*. During the third quarter of 2022, we elected to early adopt ASU 2021-08 effective July 1, 2022. The adoption did not have a material impact on our unaudited, condensed consolidated 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”), our convertible senior notes due 2025 (the “2025 Notes”) and our convertible senior notes due 2028 (the “2028 Notes”) using the if-converted method.

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 was historically computed using the treasury stock method until the adoption of ASU 2020-06. 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, 2021. The dilutive EPS of the notes was approximately \$0.37 and \$0.41 per share, respectively, using the if-converted method for the three and nine months ended September 30, 2022 as a result of the adoption of ASU 2020-06.

The following table shows the computation of basic and diluted net income per share for the three and nine months ended September 30, 2022 and 2021:

(In thousands except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net income attributable to Innoviva stockholders, basic	\$ 265,523	\$ 72,438	\$ 282,235	\$ 255,509
Add: interest expense on 2023 Notes	412	1,186	2,003	3,553
Add: interest expense on 2025 Notes	994	—	3,533	—
Add: interest expense on 2028 Notes	1,769	—	3,862	—
Net income attributable to Innoviva stockholders, diluted	<u>\$ 268,698</u>	<u>\$ 73,624</u>	<u>\$ 291,633</u>	<u>\$ 259,062</u>
Denominator:				
Weighted-average shares used to compute basic net income per share attributable to Innoviva stockholders	69,731	69,458	69,640	86,298
Dilutive effect of 2023 Notes	4,866	12,189	6,629	12,189
Dilutive effect of 2025 Notes	11,150	—	11,150	—
Dilutive effect of 2028 Notes	9,955	—	7,559	—
Dilutive effect of options and awards granted under equity incentive plan and employee stock purchase plan	128	52	94	49
Weighted-average shares used to compute diluted net income per share attributable to Innoviva stockholders	<u>95,830</u>	<u>81,699</u>	<u>95,072</u>	<u>98,536</u>
Net income per share attributable to Innoviva stockholders				
Basic	<u>\$ 3.81</u>	<u>\$ 1.04</u>	<u>\$ 4.05</u>	<u>\$ 2.96</u>
Diluted	<u>\$ 2.80</u>	<u>\$ 0.90</u>	<u>\$ 3.07</u>	<u>\$ 2.63</u>

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 for the periods presented:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Outstanding options and awards granted under equity incentive plan and employee stock purchase plan	705	891	577	1,048
Outstanding stock warrant	526	—	177	—
Total	<u>1,231</u>	<u>891</u>	<u>754</u>	<u>1,048</u>

3. Revenue Recognition

Net Revenue from Collaboration Arrangement

On July 13, 2022, Innoviva's wholly-owned subsidiary, Innoviva TRC Holdings, LLC ("ITH") entered into an equity purchase agreement ("TRC Equity Purchase Agreement") with Royalty Pharma Investments 2019 ICAV ("Royalty Pharma") to sell our ownership interest in Theravance Respiratory Company, LLC ("TRC"). As a result of the sale of our ownership interest in TRC, which was consummated on July 20, 2022, we are no longer entitled to receive 15% of royalty payments made by GSK stemming from sales of TRELEGY® ELLIPTA®. We retained our royalty rights with respect to RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

Net revenue recognized under our GSK Agreements was as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Royalties				
- RELVAR/BREO	\$ 55,663	\$ 54,092	\$ 170,753	\$ 176,398
Royalties				
- ANORO	9,943	11,641	28,015	34,101
Royalties				
- TRELEGY	—	35,585	72,029	84,055
Total royalties from a related party	65,606	101,318	270,797	294,554
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)	(10,368)	(10,368)
Royalty revenue from GSK	\$ 62,150	\$ 97,862	\$ 260,429	\$ 284,186

Transactions with GSK were considered related party transactions up until May 2021, when we completed the share repurchase agreement with GSK to buy back all of its shares of common stock in Innoviva. GSK is no longer considered a related party after the completion of the share repurchase.

Net Product Sales

Our net product sales of \$5.1 million, consisting of net sales of GIAPREZA[®] and XERAVA[®] for \$3.8 million and \$1.3 million, respectively, were recognized from the date of our acquisition of La Jolla, which occurred on August 22, 2022, to September 30, 2022.

4. License and Collaboration Arrangements

Out-License Agreements

Zai Lab

Entasis entered into a license and collaboration agreement with Zai Lab (Shanghai) Co., Ltd. (“Zai Lab”) (Nasdaq: ZLAB), pursuant to which Zai Lab licensed exclusive rights to durlobactam and SUL-DUR, in the Asia-Pacific region (“the Zai Agreement”). Under the terms of the Zai Agreement, Zai Lab will fund most of the registrational clinical trial costs in China for SUL-DUR, with the exception of Phase 3 patient drug supply of licensed products. Zai Lab will conduct development activities and plan and obtain regulatory approval in a specified number of countries in the Asia-Pacific region beyond China after receipt of regulatory approval of a licensed product in China. Zai Lab is also solely responsible for commercializing licensed products in the Asia-Pacific region and will commercialize licensed products for which it has obtained regulatory approval. We are obligated to supply Zai Lab with the licensed products for clinical development and, if the licensed product is approved, for commercial use for a certain period unless Zai Lab notifies otherwise. Zai Lab may take over manufacturing responsibilities for its own commercialization activities within a specified time period following the effective date of the Zai Agreement.

We are eligible to receive up to an aggregate of \$91.0 million in research and development support payments and development, regulatory and sales milestone payments related to SUL-DUR, imipenem and other combinations with the licensed products. Zai Lab will pay us a tiered royalty equal to from a high-single digit to low-double digit percentage based on annual net sales of licensed products in the territory, subject to specified reductions for the market entry of competing products, loss of patent coverage of licensed products and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory. During the three months ended September 30, 2022, no revenue was recognized under the Zai Agreement. Payments received for research support and reimbursable clinical trial costs are recorded as a reduction to research and development expense during the period in which the qualifying expenses are incurred. Such amounts recorded from the date of acquisition of Entasis to September 30, 2022 are not material.

GARDP

Entasis entered into a collaboration agreement with the Global Antibiotic Research and Development Partnership (“GARDP”) for the development, manufacture and commercialization of the product candidate zoliflodacin in certain countries (“the GARDP Collaboration Agreement”). Under the terms of the GARDP Collaboration Agreement, GARDP will use commercially reasonable endeavors to perform and fully fund the Phase 3 registrational trial, including the manufacture and supply of the product candidate containing zoliflodacin, in uncomplicated gonorrhea. We recorded reimbursements from GARDP under this agreement as reduction to research and development expense. Relevant amounts from the date of acquisition of Entasis to September 30, 2022 are not material.

In addition, under the GARDP Collaboration Agreement, GARDP was granted a worldwide, fully paid, exclusive and royalty-free license, with the right to sublicense, to use our zoliflodacin technology in connection with GARDP’s development, manufacture and commercialization of zoliflodacin in low-income and specified middle-income countries. We retained commercial rights in all other countries worldwide, including the major markets in North America, Europe and Asia-Pacific. We also retained the right to use and grant licenses to our zoliflodacin technology to perform our obligations under the GARDP Collaboration Agreement and for any purpose other than gonorrhea or community-acquired indications. If we believe that the results of the Phase 3 registrational trial of zoliflodacin would be supportive of an application for marketing approval, we are obligated to use our best efforts to file an application for marketing approval with the FDA within six months of the completion of the trial and to use commercially reasonable endeavors to file an application for marketing approval with the European Medicines Agency (“EMA”). Each party is responsible for using commercially reasonable efforts to obtain marketing authorizations for the product candidate in their respective territories.

PAION AG

Pursuant to the PAION AG (“PAION”) License, La Jolla granted PAION an exclusive license to commercialize GIAPREZA[®] and XERAVA[®] in the European Economic Area, the United Kingdom and Switzerland (collectively, the “PAION Territory”). We are entitled to receive potential commercial milestone payments of up to \$109.5 million and double-digit tiered royalty payments. Royalties payable in a given jurisdiction under the PAION License will be subject to reduction on account of generic competition and after patent expiration in that jurisdiction. Pursuant to the PAION License, PAION will be solely responsible for the future development and commercialization of GIAPREZA[®] and XERAVA[®] in the PAION Territory. PAION is required to use commercially reasonable efforts to commercialize GIAPREZA[®] and XERAVA[®] in the PAION Territory. We have not recognized any revenue from PAION related to commercial milestones from the date of acquisition of La Jolla to September 30, 2022. Royalty revenue recognized under this agreement from the date of acquisition of La Jolla to September 30, 2022 was not material.

La Jolla also entered into the PAION commercial supply agreement (the “PAION Supply Agreement”) whereby La Jolla will supply PAION a minimum quantity of GIAPREZA[®] and XERAVA[®] through July 13, 2024. The PAION supply agreement will automatically renew until the earlier of July 13, 2027, or until a new supply agreement is executed. During the initial term of the supply agreement, we will be reimbursed for direct and certain indirect manufacturing costs at cost. We have not recognized any cost reimbursements under this agreement from the date of acquisition of La Jolla to September 30, 2022.

Everest Medicines Limited

Pursuant to the Everest Medicines Limited (“Everest”) License, La Jolla granted Everest an exclusive license to develop and commercialize XERAVA[®] for the treatment of complicated intra-abdominal infections (“cIAI”) and other indications in mainland China, Taiwan, Hong Kong, Macau, South Korea, Singapore, the Malaysian Federation, the Kingdom of Thailand, the Republic of Indonesia, the Socialist Republic of Vietnam and the Republic of the Philippines (collectively, the “Everest Territory”). We are eligible to receive an additional \$8.0 million regulatory milestone payment and up to an aggregate of \$20.0 million in sales milestone payments. We are also entitled to receive tiered royalties from Everest at percentages in the low double digits on sales, if any, in the Everest Territory of products containing eravacycline. Royalties are payable with respect to each jurisdiction in the Everest Territory until the latest to occur of: (i) the last-to-expire of specified patent rights in such jurisdiction in the Everest Territory; (ii) expiration of marketing or regulatory exclusivity in such jurisdiction in the Everest Territory; or (iii) 10 years after the first commercial sale of a product in such jurisdiction in the Everest Territory. We have not recognized any revenue from Everest related to regulatory and sales milestones from the date of acquisition of La Jolla to September 30, 2022. Royalty revenue recognized under this agreement from the date of acquisition of La Jolla to September 30, 2022 was not material.

A new drug application (“NDA”) was submitted with the China National Medical Products Administration (“NMPA”) for XERAVA[®] for the treatment of cIAI in patients in China in 2021. XERAVA[®] was approved in Singapore by the Health Science Authority in 2020.

La Jolla also entered into the Everest commercial supply agreement (the “Everest Supply Agreement”) whereby La Jolla will supply Everest a minimum quantity of XERAVA[®] through December 31, 2023 and will transfer to Everest certain XERAVA[®]-related manufacturing know-how. We will be reimbursed for direct and certain indirect manufacturing costs at 110% of cost through December 31, 2023. We recognized \$2.8 million partial prepayment for XERAVA[®] that is expected to be delivered to Everest as deferred revenue as of September 30, 2022.

In-License Agreements

George Washington University

Pursuant to the George Washington University (“GW”) License, GW exclusively licensed to La Jolla certain intellectual property rights relating to GIAPREZA[®], including the exclusive rights to certain issued patents and patent applications covering GIAPREZA[®]. Under the GW License, we are obligated to use commercially reasonable efforts to develop, commercialize, market and sell GIAPREZA[®]. We are obligated to pay a 6% royalty on net sales of GIAPREZA[®] and 15% on payments received from sublicensees. The obligation to pay royalties under this agreement extends through the last-to-expire patent covering GIAPREZA[®]. From the date of acquisition of La Jolla to September 30, 2022, the amounts recognized under this agreement were not material.

Harvard University

Pursuant to the Harvard University (“Harvard”) License, Harvard exclusively licensed to La Jolla certain intellectual property rights relating to tetracycline-based products, including XERAVA[®], including the exclusive rights to certain issued patents and patent applications covering such products. Under the Harvard License, we are obligated to use commercially reasonable efforts to develop, commercialize, market and sell tetracycline-based products, including XERAVA[®]. For each product covered by the Harvard License, we are obligated to make certain payments for the following: (i) up to approximately \$15.1 million upon the achievement of certain clinical development and regulatory milestones; (ii) a 5% royalty on direct U.S. net sales of XERAVA[®]; (iii) a single-digit tiered royalty on direct ex-U.S. net sales of XERAVA[®], starting at a minimum royalty rate of 4.5%, with step-ups to a maximum royalty of 7.5% based on the achievement of annual net product sales thresholds; and (iv) 20% on payments received from sublicensees. The obligation to pay royalties under this agreement extends through the last-to-expire patent covering tetracycline-based products, including XERAVA[®]. From the date of acquisition of La Jolla to September 30, 2022, amounts recognized under this agreement were not material.

Paratek Pharmaceuticals, Inc.

Pursuant to the Paratek Pharmaceuticals, Inc. (“Paratek”) License, Paratek non-exclusively licensed to La Jolla certain intellectual property rights relating to XERAVA[®], including non-exclusive rights to certain issued patents and patent applications covering XERAVA[®]. We are obligated to pay Paratek a 2.25% royalty based on direct U.S. net sales of XERAVA[®]. Our obligation to pay royalties with respect to the licensed product is retroactive to the date of the first commercial sale of XERAVA[®] and shall continue until there are no longer any valid claims of the Paratek patents, which will expire in October 2023. From the date of acquisition of La Jolla to September 30, 2022, amounts recognized under this agreement were not material.

5. Consolidated Entities and Acquisitions

Consolidated Entities

Theravance Respiratory Company, LLC

Up until July 20, 2022, we consolidated TRC under the VIE model as we determined that TRC was a VIE and we were the primary beneficiary of the entity. We held 15% ownership interest of TRC. The primary source of revenue for TRC is the royalties generated from the net sales of TRELEGY[®] ELLIPTA[®] by GSK.

As discussed in Note 3, “Revenue Recognition”, on July 13, 2022, ITH entered into the TRC Equity Purchase Agreement to sell our ownership interest in TRC. Upon the closing of the transaction on July 20, 2022, we received \$277.5 million in cash from Royalty Pharma. We are also entitled to receive up to \$50.0 million in contingent sales-based milestone payments in the future. As part of the closing of the transaction, we also received our portion of TRC’s remaining cash balance of \$4.4 million from Royalty Pharma rather than through a cash distribution from TRC.

Prior to the closing of the transaction and as part of the agreement, TRC distributed its ownership interests and investments in InCarda Therapeutics, Inc., ImaginAb, Inc., Gate Neurosciences, Inc. and Nanolive SA, which had a total carrying value of \$39.4 million, to ITH.

The summarized financial information of TRC as of December 31, 2021 and for the relevant periods through the sale date in 2022 are presented as follows:

Balance sheet

(In thousands)	December 31, 2021
Assets	
Cash and cash equivalents	\$ 50,713
Receivables from collaboration arrangement	42,492
Prepaid expenses and other current assets	71
Equity and long-term investments	37,695
Total assets	<u>\$ 130,971</u>
Liabilities and LLC Members’ Equity	
Current liabilities	\$ 252
LLC members’ equity	130,719
Total liabilities and LLC members’ equity	<u>\$ 130,971</u>

Income statements

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022⁽¹⁾	2021	2022⁽²⁾	2021
Royalty revenue from a related party	\$ —	\$ 35,585	\$ 72,029	\$ 84,055
Operating expenses	(5)	194	332	3,811
Income from operations	5	35,391	71,697	80,244
Other income, net	—	—	10	—
Realized loss	(39,386)	—	(39,386)	—
Income tax expense, net	—	—	1	—
Changes in fair values of equity and long-term investments	—	148	(8,884)	(589)
Net income (loss)	<u>\$ (39,381)</u>	<u>\$ 35,539</u>	<u>\$ 23,438</u>	<u>\$ 79,655</u>

(1) Three months ended September 30, 2022 represents the period from July 1, 2022 to July 20, 2022, the date of the sale of our ownership interest in TRC.

(2) Nine months ended September 30, 2022 represents the period from January 1, 2022 to July 20, 2022, the date of the sale of our ownership interest in TRC.

ISP Fund LP

We consolidate ISP Fund LP under the VIE model as we have determined that ISP Fund LP is a VIE and we are the primary beneficiary of the entity via our related party relationships with Sarissa Capital entities.

The Partnership Agreement provides for Sarissa Capital to receive management fees from the Partnership, payable quarterly in advance, measured based on the Net Asset Value of Strategic Partners’ capital account in the Partnership. In addition, General Partner is entitled to an annual performance fee based on the Net Profits of the Partnership during the annual measurement period.

The Partnership Agreement includes a lock-up period of thirty-six months after which Strategic Partners is entitled to make withdrawals from the Partnership as of such lock-up expiration date and each anniversary thereafter, subject to certain limitations.

In May 2021, Strategic Partners received a distribution of \$110.0 million from the Partnership to provide funding to Innoviva for a strategic repurchase of shares held by GSK. On March 30, 2022, Strategic Partners made an additional capital contribution of \$110.0 million to the Partnership pursuant to the letter agreement entered into between Strategic Partners, the Partnership and Sarissa Capital Fund GP LP on May 20, 2021. The capital contribution is subject to a 36-month lock up period from the contribution date.

As of September 30, 2022, we held approximately 100% of the economic interest of the Partnership. As of September 30, 2022 and December 31, 2021, total assets of the Partnership were \$289.8 million and \$195.8 million, respectively, of which the majority was attributable to equity, debt and long-term investments. As of September 30, 2022 and December 31, 2021, total liabilities were \$0.2 million and \$0.2 million, respectively. The partnership's assets can only be used to settle its own obligations. During the three and nine months ended September 30, 2022, we recorded \$0.3 million and \$1.0 million, respectively, of net investment-related expenses incurred by the Partnership, and \$10.5 million and \$14.9 million, respectively, of net negative changes in fair values of equity and long-term investments on the unaudited condensed consolidated statements of income. During the three and nine months ended September 30, 2021, we recorded \$0.2 million and \$1.5 million, respectively, of net investment-related expenses incurred by the Partnership, and \$10.1 million and \$30.6 million, respectively, of net positive changes in fair values of equity and long-term investments on the unaudited condensed consolidated statements of income.

Acquisitions

Entasis Therapeutics Holdings Inc.

We started investing in Entasis in 2020 as part of our capital allocation strategy of deploying cash generated from royalty income and investing in different life sciences companies. Entasis is an advanced, late clinical-stage biopharmaceutical company focused on the discovery and development of novel antibacterial products. During the second quarter of 2020, we purchased 14,000,000 shares of common stock as well as warrants to purchase 14,000,000 additional shares of common stock of Entasis for approximately \$35.0 million in cash. During the third quarter of 2020, we purchased 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. Effective in June 2020, after certain conditions were met with respect to the sales of Entasis equity shares, Innoviva has the right to designate two members to Entasis' board. During the second quarter of 2021, Innoviva's wholly-owned subsidiary, Innoviva Strategic Opportunities, LLC ("ISO") entered into a securities purchase agreement with Entasis to acquire 10,000,000 shares of Entasis common stock and warrants to purchase 10,000,000 additional shares of Entasis common stock for approximately \$20.0 million.

The fair value of Entasis' common stock was measured based on its closing market price at each balance sheet date. The warrants had an exercise price of \$2.50 per share and \$2.675 per share for those warrants acquired in the second and third quarter of 2020, respectively. The warrants acquired in the second quarter of 2021 had an exercise price of \$2.00 per share. All of the warrants were exercisable immediately within five years from the issuance date of the warrants and included a cashless exercise option. We used the Black-Scholes-Merton pricing model to estimate the fair value of these warrants.

On February 17, 2022, ISO entered into a securities purchase agreement with Entasis pursuant to which ISO purchased a convertible promissory note for a total purchase price of \$15.0 million. The note bore an annual interest rate of 0.59% and matured and became payable on August 18, 2022 unless it was converted at a conversion price of \$1.48 before the maturity date. With this financing, we determined that we had both (i) the power to direct the economically significant activities of Entasis and (ii) the obligation to absorb the losses, or the right to receive the benefits, that could potentially be significant to Entasis and therefore, we were the primary beneficiary of Entasis. Accordingly, we consolidated Entasis' financial position and results of operations effective on February 17, 2022. Our equity ownership interest remained at 59.9% as of February 17, 2022, and the fair values of our holdings of Entasis common stock and warrants were remeasured and estimated at \$64.5 million and \$31.4 million, respectively.

The remeasurement resulted in a \$7.7 million loss in the first quarter of 2022 which was included in changes in fair values of equity and long-term investments, net on the unaudited condensed consolidated statement of income for the nine months ended September 30, 2022.

We completed our acquisition of Entasis' minority interest on July 11, 2022. No payments were made toward the convertible promissory note through the date of acquisition of Entasis. In connection with the acquisition, all of the Entasis warrants were replaced with Innoviva warrants (the "Replacement Warrants") of equivalent value and bearing the same terms. The Replacement Warrants are classified as equity.

We recognized the difference between the acquisition price and the carrying value of the acquired minority interest on July 11, 2022 in our additional paid-in capital.

The fair values assigned to assets acquired and liabilities assumed as of February 17, 2022 were based on management's best estimates and assumptions. After the acquisition in July 2022, we adjusted the purchase price allocation based on new and additional information related to product sales forecast provided by Entasis and deferred tax liabilities.

During the third quarter of 2022, we recorded measurement period adjustments of \$2.3 million decrease in goodwill, primarily related to a decrease in estimated purchase price of \$1.4 million, an increase in noncontrolling interests of \$1.7 million, and an increase in intangible assets of \$2.5 million. The cumulative impact of the measurement period adjustments included in the consolidated net income for the three and nine months ended September 30, 2022 was not material.

The Company has completed a preliminary valuation and expects to finalize it as soon as practical, but no later than one year from the acquisition date. The purchase accounting for this transaction is not yet finalized.

The following table represents the adjusted fair values of the assets acquired and liabilities assumed by us in the transaction:

(In thousands)	February 17, 2022
Cash and cash equivalents	\$ 23,070
Prepaid expenses	5,554
Other current assets	1,959
Property and equipment, net	185
Right-of-use assets	959
Goodwill	3,284
Intangible assets	107,500
Other assets	302
Total assets acquired	\$ 142,813
Accounts payable	\$ 1,583
Accrued personnel-related expenses	1,057
Other current liabilities	5,097
Deferred tax liabilities	360
Total liabilities assumed	\$ 8,097
Total assets acquired, net	\$ 134,716

The goodwill arising from the acquisition of Entasis is primarily attributable to Entasis' assembled workforce and the value associated with growing our business more efficiently. The goodwill from this acquisition is not expected to be deductible for tax purposes.

Refer to Note 7, "Goodwill and Intangible Assets" for more discussion on the intangible assets recognized as part of this acquisition.

Our unaudited condensed consolidated net income for the three and nine months ended September 30, 2022 included the net loss attributable to noncontrolling interest since the consolidation date until the date of acquisition of \$2.7 million and \$13.6 million, respectively.

La Jolla Pharmaceutical Company

On August 22, 2022, ISO acquired La Jolla for a total consideration of \$206.6 million. ISO acquired La Jolla at a price of \$6.23 per share. La Jolla is dedicated to the commercialization of innovative therapies that improve outcomes in patients suffering from life-threatening diseases. La Jolla brings to Innoviva an established product portfolio, including GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock and XERAVA® (eravacycline) for the treatment of complicated intra-abdominal infections (cIAIs).

The fair values assigned to assets acquired and liabilities assumed are based on management's best estimates and assumptions as of August 22, 2022. We have completed a preliminary valuation and expect to finalize it as soon as practicable, but no later than one year from the acquisition date. The purchase accounting for this transaction is not yet finalized.

We incurred approximately \$4.9 million in acquisition-related costs in connection with this acquisition and such amount is included in selling, general and administrative expenses for the three and nine months ended September 30, 2022.

The following table summarizes the preliminary allocation of the fair values assigned to the assets acquired and liabilities assumed as of the date of the acquisition:

(In thousands)	August 22, 2022	
Cash and cash equivalents	\$	47,415
Short-term marketable securities		471
Accounts receivable		5,876
Inventory		73,900
Prepaid expenses		1,261
Other current assets		907
Property and equipment, net		13
Right-of-use assets		226
Goodwill		12,711
Intangible assets		152,500
Other assets		710
Total assets acquired	\$	<u>295,990</u>
Accounts payable	\$	1,237
Deferred revenue, current		2,849
Other accrued liabilities		11,062
Other long-term liabilities		74,283
Total liabilities assumed	\$	<u>89,431</u>
Total assets acquired, net	\$	<u>206,559</u>

The goodwill arising from the acquisition of La Jolla is primarily attributable to La Jolla's assembled workforce and the value associated with leveraging the workforce to develop and commercialize new drug products in the future and growing our business more efficiently. The goodwill from this acquisition is not expected to be deductible for tax purposes.

Refer to Note 7, "Goodwill and Intangible Assets" for more discussion on the intangible assets recognized as part of this acquisition.

Pro Forma Financial Information

The following table presents certain unaudited pro-forma financial information for the three and nine months ended September 30, 2022 and 2021 as if the consolidation of Entasis and La Jolla occurred on January 1, 2021. The unaudited pro forma financial information is presented for informational purposes only, and is not indicative of the results of operations that would have been achieved if the acquisitions had taken place on January 1, 2022, or of results that may occur in the future. The unaudited pro forma financial information combines the historical results of the Entasis and La Jolla with the Company's consolidated historical results and includes certain adjustments including, but not limited to, fair value adjustments to equity investments in Entasis' common stock and warrants, fair value adjustments to inventory, amortization of intangible assets, and interest expense on deferred royalty obligations and acquisition-related costs.

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	\$ 72,830	\$ 111,176	\$ 292,077	\$ 347,696
Net income	\$ 221,473	\$ 45,109	\$ 266,797	\$ 183,252
Net income attributable to Innoviva stockholders	\$ 272,797	\$ 19,892	\$ 276,200	\$ 129,803

6. Financial Instruments and Fair Value Measurements

Equity Investment in Armata

During the first quarter of 2020, Innoviva acquired 8,710,800 shares of common stock as well as warrants to purchase 8,710,800 additional shares of common stock of Armata Pharmaceuticals, Inc. (“Armata”) for approximately \$25.0 million in cash. Armata is a clinical stage biotechnology company focused on precisely targeted bacteriophage therapeutics for antibiotic-resistant infections.

During the first quarter of 2021, ISO entered into a securities purchase agreement with Armata to acquire 6,153,847 shares of Armata common stock and warrants to purchase 6,153,847 additional shares of Armata common stock for approximately \$20.0 million. Armata also entered into a voting agreement with the Company and ISO, pursuant to which the Company and ISO agreed not to vote or take any action by written consent with respect to any common shares held by the Company and ISO that represent, in the aggregate, more than 49.5% of the total number of shares of Armata’s common stock for voting on the matters related to election or removal of Armata’s board members. The voting agreement will expire the earlier of the second anniversary of the agreement effective date and approval by the FDA of any of Armata’s product candidates for marketing and commercial distribution. During the fourth quarter of 2021, ISO also purchased an additional 1,212,122 shares of Armata common stock for approximately \$4.0 million.

On February 9, 2022, ISO entered into a securities purchase agreement with Armata to acquire 9,000,000 shares of Armata common stock and warrants to purchase 4,500,000 additional shares of common stock with an exercise price of \$5.00 per share for \$45.0 million. The investment closed in two tranches on February 9, 2022 and March 31, 2022. The investment is intended to aid Armata in advancing its clinical pipeline and strengthening its bacteriophage platform. On February 9, 2022, Armata also entered a second amended and restated voting agreement with the Company and ISO, pursuant to which the Company and ISO agreed not to vote or take any action by written consent with respect to any common shares held by the Company and ISO that represent, in the aggregate, more than 49.5% of the total number of shares of Armata’s common stock for voting on the matters related to election or removal of Armata’s board members or amend the bylaws of Armata to reduce the maximum number of directors or set the number of directors who may serve on the board of Armata. The voting agreement will expire the earlier of the second anniversary of the agreement effective date and approval by the FDA of any of Armata’s product candidates for marketing and commercial distribution. In addition, as of February 9, 2022, Armata entered into an amended and restated investor rights agreement with the Company and ISO, pursuant to which for as long as the Company and ISO hold at least 12.5% of the outstanding shares of Armata’s common stock on a fully-diluted, the Company and ISO shall have the right to designate two directors to Armata’s board of directors, and for so long as the Company and ISO hold at least 8%, but less than 12.5%, of the outstanding shares of Armata’s common stock on a fully-diluted basis, the Company and ISO shall have the right to designate one director to Armata’s board of directors, subject to certain conditions and qualifications set forth in the amended and restated investor rights agreement. As of September 30, 2022, three of the eight members of Armata’s board of directors are also members of the board of directors of Innoviva. As of September 30, 2022 and December 31, 2021, the Company and ISO owned approximately 69.4% and 59.3%, respectively, of Armata’s common stock.

The investments in Armata provide Innoviva and ISO the ability to have significant influence, but not control over Armata’s operations. Armata’s business and affairs are managed under the direction of its board of directors, which Innoviva and ISO do not control. Based on our evaluation, we determined that Armata is a VIE, but Innoviva and ISO are not the primary beneficiary of the VIE. We account for both Armata’s common stock and warrants under the equity method using the fair value option. The fair value of Armata’s common stock is measured based on its closing market price. The warrants purchased in 2020, 2021 and 2022 have an exercise price of \$2.87, \$3.25 and \$5.00 per share, respectively. All 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: 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, 2022, the fair values of our holdings of Armata common stock and warrants were estimated at \$105.8 million and \$50.6 million, respectively. As of December 31, 2021, the fair values of our holdings of Armata common stock and warrants were estimated at \$88.1 million and \$58.6 million, respectively. The total fair value of both financial instruments in the amount of \$156.4 million and \$146.7 million was recorded as equity and long-term investments on the unaudited condensed consolidated balance sheets as of September 30, 2022 and December 31, 2021, respectively. During the three and nine months ended September 30, 2022, we recorded \$11.7 million unrealized gain and \$35.3 million unrealized loss, respectively, as changes in fair values of equity and long-term investments, net on the unaudited condensed consolidated statements of income. During the three and nine months ended September 30, 2021, we recorded \$11.6 million unrealized loss and \$25.3 million unrealized gain, respectively, as changes in fair values of equity and long-term investments, net on the unaudited condensed consolidated statements of income.

The summarized financial information, including the portion we do not own, is presented for Armata on a one quarter lag regardless of the date of our investments as follows:

Income Statement Information

(In thousands)	Three Months Ended June 30,		Nine Months Ended June 30,	
	2022	2021	2022	2021
Revenue	\$ 1,883	\$ 1,168	\$ 4,108	\$ 2,738
Loss from operations	\$ (9,220)	\$ (6,196)	\$ (24,043)	\$ (18,084)
Net loss	\$ (9,215)	\$ (6,194)	\$ (24,036)	\$ (18,313)

Equity Investment in InCarda

During the third quarter of 2020, TRC purchased 20,469,432 shares of Series C preferred stock and a warrant to purchase 5,117,358 additional shares of Series C preferred stock of InCarda Therapeutics, Inc. (“InCarda”) (the “InCarda 2020 Warrant”) for \$15.8 million, which included \$0.8 million of transaction costs. InCarda is a privately held biopharmaceutical company focused on developing inhaled therapies for cardiovascular diseases. The investment is intended to fund the ongoing clinical development of InRhythm™ (flecainide for inhalation), InCarda’s lead program, for the treatment of a recent-onset episode of paroxysmal atrial fibrillation. On July 20, 2022, under the terms of the TRC Equity Purchase Agreement, TRC transferred to Innoviva’s wholly-owned subsidiary, Innoviva TRC Holdings, LLC (“ITH”) all of TRC’s ownership interests and investments in InCarda. ITH has the right to designate one member to InCarda’s board of directors. As of September 30, 2022, one of InCarda’s eight board members was designated by ITH. The InCarda 2020 Warrant is exercisable immediately with an exercise price of \$0.7328 per share. In September 2021, TRC and InCarda entered into an amendment to extend the expiration date of the InCarda 2020 Warrant from October 6, 2021 to March 31, 2022. On March 9, 2022, TRC and InCarda entered into an amendment to further extend the expiration date of the InCarda 2020 Warrant from March 31, 2022 to March 31, 2023. The InCarda 2020 Warrant is recorded at fair value and subject to remeasurement at each balance sheet date.

On March 9, 2022, TRC entered into a Note and Warrant Purchase Agreement (the “InCarda Agreement”) with InCarda to acquire a convertible promissory note (the “InCarda Convertible Note”) and warrants (the “InCarda 2022 Warrant”) for \$0.7 million. The InCarda Convertible Note bears an annual interest rate of 6% and will convert into Series D preferred stock upon a qualified financing, non-qualified financing, or maturity conversion. A qualified financing is defined as the first issuance or series of related issuances by InCarda of its equity securities following March 9, 2022 from which InCarda receives immediately available gross proceeds of at least \$10.0 million (excluding the aggregate amount of any notes converted into equity securities pursuant to the conversion of notes or any other debt securities converted into equity securities) (the “Qualified Financing Amount”). A non-qualified financing is defined as the first issuance or series of related issuances by InCarda of its equity securities following March 9, 2022 from which InCarda receives immediately available gross proceeds of less than the Qualified Financing Amount. The InCarda 2022 Warrant entitles TRC to purchase a number of shares of equity securities equal to 100% of the principal amount of the InCarda Convertible Note divided by the number of shares issued in InCarda’s next equity financing, which is defined as the earliest to occur of specific financing events, including capital raises through public offerings. The InCarda 2022 Warrant expires on March 9, 2027. The InCarda Convertible Note and InCarda 2022 Warrant are measured at fair value.

On June 15, 2022, the principal amount and the accrued interest of the InCarda Convertible Note were converted into equity securities. In addition, TRC participated in InCarda's Series D preferred stock financing by investing \$2.3 million. In connection with the new round of financing, InCarda recapitalized its equity structure resulting in TRC owning 4,093,886 shares of InCarda's common stock, 37,350 shares of its Series A-1 preferred stock, 20,469,432 shares of its Series C preferred stock, 8,771,780 shares of its Series D-1 preferred stock, 3,369,802 shares of its Series D-2 preferred stock, a warrant to purchase 5,117,358 shares of its Series C preferred stock at \$0.73 per share and a warrant to purchase 2,490,033 shares of its Series D-2 preferred stock at \$0.26 per share.

As of September 30, 2022, we held 8.9% of InCarda equity ownership. As of December 31, 2021, TRC held 13.0% of InCarda equity ownership. Our investment in InCarda does not provide us with the ability to control or have significant influence over InCarda's operations. Based on our evaluation, we determined that InCarda is a VIE, but we are not the primary beneficiary of the VIE. We account for our investments in InCarda under the measurement alternative. Under the measurement alternative, the equity investment is initially recorded at its allocated cost, but the carrying value may be adjusted through earnings upon an impairment or when there is an observable price change involving the same or a similar investment with the same issuer. Due to InCarda's equity recapitalization in the second quarter of 2022, TRC reassessed the value of its investments in InCarda using the Option Pricing Model Backsolve valuation methodology. Key assumptions used in the valuation model include an expected holding period of two years, a risk free interest rate of 3.2%, a dividend yield of 0.0% and an estimated volatility of 122.0%. The estimated volatility is calculated based on the historical volatility of a selected peer group of public companies comparable to InCarda. We recognized an impairment charge of \$9.0 million. There was no impairment or other change to the value of our investments in InCarda as of December 31, 2021.

As of September 30, 2022, we recorded \$6.8 million in fair value of InCarda's Series C preferred stock and \$0.5 million in fair value of Series C warrants and Series D warrants (the "InCarda Preferred Stock Warrants"). As of September 30, 2022, we recognized \$3.2 million for InCarda's Series D-1 preferred stock, Series D-2 preferred stock, and common stock using the measurement alternative. As of December 31, 2021, we recorded \$0.4 million in fair value of InCarda's 2020 Warrants. As of December 31, 2021, we recognized \$15.8 million for the investment in InCarda's Series C preferred stock using the measurement alternative. During the three and nine months ended September 30, 2022, we recorded \$0.2 million in net unrealized gain and \$8.8 million in net unrealized loss, respectively, as changes in fair values of equity and long-term investments, net on the unaudited condensed consolidated statements of income. During the three and nine months ended September 30, 2021, we recorded \$0.1 million unrealized gain and \$0.6 million of unrealized loss, respectively, as changes in fair values of equity and long-term investments, net on the unaudited condensed consolidated statements of income.

Equity Investment in ImaginAb

During the first quarter of 2021, TRC entered into a securities purchase agreement with ImaginAb, Inc. to purchase 4,051,724 shares of ImaginAb Series C preferred stock for \$4.7 million. On the same day, TRC also entered into a securities purchase agreement with one of ImaginAb's common stockholders to purchase 4,097,157 shares of ImaginAb common stock for \$1.3 million. ImaginAb is a privately held biotechnology company focused on clinically managing cancer and autoimmune diseases via molecular imaging. \$0.4 million was incurred for investment due diligence costs and execution and recorded as part of the equity investment on the condensed consolidated balance sheets.

On July 20, 2022, under the terms of the TRC Equity Purchase Agreement, TRC transferred to ITH all of TRC's ownership interests and investments in ImaginAb. As of September 30, 2022, one of ImaginAb's five board members was designated by ITH. As of September 30, 2022, we held 11.5% of ImaginAb equity ownership. As of December 31, 2021, TRC held 14.5% of ImaginAb equity ownership.

Our investment in ImaginAb does not provide us with the ability to control or have significant influence over ImaginAb's operations. Based on our evaluation, we determined that ImaginAb is a VIE, but we are not the primary beneficiary of the VIE. Because ImaginAb's equity securities are not publicly traded and do not have a readily determinable fair value, we account for our investment in ImaginAb's Series C preferred stock and common stock using the measurement alternative. Under the measurement alternative, the equity investment is initially recorded at its allocated cost, but the carrying value may be adjusted through earnings upon an impairment or when there is an observable price change involving the same or a similar investment with the same issuer. As of September 30, 2022 and December 31, 2021, \$6.4 million was recorded as equity and long-term investments on the unaudited condensed consolidated balance sheets and there was no change to the fair value of our investment.

Convertible Promissory Note in Gate Neurosciences

During the fourth quarter of 2021, TRC entered into a Convertible Promissory Note Purchase Agreement with Gate Neurosciences, Inc. (“Gate”) to acquire a convertible promissory note (the “Gate Convertible Note”) with a principal amount of \$15.0 million. Gate is a privately held biopharmaceutical company focused on developing the next generation of targeted nervous system therapies, leveraging precision medicine approaches to develop breakthrough drugs for psychiatric and neurologic diseases. The investment is intended to fund its ongoing development and research. The Gate Convertible Note bears an annual interest rate of 8% and will convert into shares of common stock of Gate upon a qualified event or into shares of shadow preferred stock of Gate (“Shadow Preferred”) upon a qualified financing. A qualifying event can be a qualified initial price offering, a qualified merger, or a merger with a special-purpose acquisition company (“SPAC”).

The number of common stock shares to be issued in a qualified event shall be equal to the amount due on the conversion date divided by the lesser of a capped conversion price (the “Capped Conversion Price”) and the qualified event price (the “Qualified Event Price”). The Capped Conversion Price is calculated as \$50.0 million divided by the number of shares of common stock outstanding at such time on a fully diluted basis. The Qualified Event Price is the price per share determined by the qualified event. A qualified financing is a sale or series of sales of preferred stock where (i) at least 50 percent of counterparties are not existing shareholders, (ii) net proceeds to Gate are at least \$35.0 million, and (iii) the stated or implied equity valuation of Gate is at least \$80.0 million. Shadow Preferred means preferred stock having identical rights, preferences and restrictions as the preferred stock that would be issued in a qualified financing.

On July 20, 2022, under the terms of the TRC Equity Purchase Agreement, TRC transferred to ITH all of TRC’s debt investments in Gate. Our investment in Gate does not provide us with the ability to control or have significant influence over Gate’s operations. Based on our evaluation, we determined that Gate is a VIE, but we are not the primary beneficiary of the VIE. We have accounted for the Gate Convertible Note as a trading security, measured at fair value using a Monte Carlo simulation model with the probability of certain qualified events and the assumptions of equity value of Gate, risk-free rate, expected stock price, volatility of its peer companies, and the time until a financing is raised. ITH has the right to designate one board member to Gate’s board. As of September 30, 2022, one board member was designated by ITH to Gate’s board, which currently consists of three directors. As of September 30, 2022 and December 31, 2021, the fair value of the Gate Convertible Note was estimated at \$15.4 million and \$15.1 million, respectively, and recorded as equity and long-term investments on the unaudited condensed consolidated balance sheets. We recorded \$0.2 million and \$0.3 million unrealized gain, respectively, as changes in fair values of equity and long-term investments, net on the unaudited condensed consolidated statement of income for the three and nine months ended September 30, 2022.

Equity Investment in Nanolive

On February 18, 2022, TRC entered into an investment and shareholders agreement with Nanolive SA (“Nanolive”) to purchase 18,750,000 shares of Nanolive Series C preferred stock for \$9.8 million (equivalent to 9.0 million CHF). Nanolive SA is a Swiss privately held life sciences company focused on developing breakthrough imaging solutions that accelerate research in growth industries such as drug discovery and cell therapy. \$0.7 million was incurred for investment due diligence costs and execution and recorded as part of the equity and long-term investment on the condensed consolidated balance sheets. On July 20, 2022, under the terms of the TRC Equity Purchase Agreement, TRC transferred to ITH all of TRC’s ownership interests and investments in Nanolive. ITH has the right to designate one member to Nanolive’s board. ITH also has the right to designate another member, who will be mutually acceptable to ITH and another majority common stockholder, to Nanolive’s board. As of September 30, 2022, one of Innoviva designees is serving on Nanolive’s seven-member board. As of September 30, 2022, we held 15.5% of Nanolive equity ownership.

Our investment in Nanolive does not provide us with the ability to control or have significant influence over Nanolive’s operations. Based on our evaluation, we determined that Nanolive is a VIE, but we are not the primary beneficiary of the VIE. Because Nanolive’s equity securities are not publicly traded and do not have a readily determinable fair value, we account for our investment in Nanolive’s Series C preferred stock using the measurement alternative. Under the measurement alternative, the equity investment is initially recorded at its allocated cost, but the carrying value may be adjusted through earnings upon an impairment or when there is an observable price change involving the same or a similar investment with the same issuer. As of September 30, 2022, \$10.6 million was recorded as equity and long-term investments on the unaudited condensed consolidated balance sheets and there was no change to the fair value of our investment.

Fair Value Measurements

Our equity and long-term investments and contingent value rights are measured at fair value on a recurring basis and our debt is carried at amortized cost basis.

Types of Instruments (In thousands)	Estimated Fair Value Measurements as of September 30, 2022 Using:			
	Quoted Price in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	Total
	Level 1	Level 2	Level 3	
Assets				
Money market funds	\$ 261,718	\$ —	\$ —	\$ 261,718
Short-term marketable securities	282	—	—	282
Investments held by ISP Fund LP ⁽¹⁾	236,624	—	53,163	289,787
Equity investment - Armata Common Stock	105,824	—	—	105,824
Equity investment - Armata Warrants	—	50,605	—	50,605
Equity investment - InCarda Series C Preferred Stock	—	—	6,809	6,809
Equity investment - InCarda Preferred Stock Warrants	—	—	501	501
Convertible debt investment - Gate Note	—	—	15,400	15,400
Total assets measured at estimated fair value	<u>\$ 604,448</u>	<u>\$ 50,605</u>	<u>\$ 75,873</u>	<u>\$ 730,926</u>
Liabilities				
Debt				
2023 Notes	\$ —	\$ 95,001	\$ —	\$ 95,001
2025 Notes	—	185,041	—	185,041
2028 Notes	—	202,241	—	202,241
Total fair value of debt	<u>\$ —</u>	<u>\$ 482,283</u>	<u>\$ —</u>	<u>\$ 482,283</u>
Contingent value rights	—	—	294	294
Total liabilities measured at estimated fair value	<u>\$ —</u>	<u>\$ 482,283</u>	<u>\$ 294</u>	<u>\$ 482,577</u>

⁽¹⁾ The investments held by ISP Fund LP, consisted of \$246.0 million in equity investments, which included private placement positions and convertible notes of \$53.2 million, \$38.7 million in money market funds and \$5.1 million in cash. Our total capital contribution of \$300.0 million is subject to a 36-month lock-up period from the date of such capital contributions.

Types of Instruments (In thousands)	Estimated Fair Value Measurements as of December 31, 2021 Using:			
	Quoted Price in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs	Total
	Level 1	Level 2	Level 3	
Assets				
Money market funds	\$ 145,132	\$ —	\$ —	\$ 145,132
Investments held by ISP Fund LP ⁽¹⁾	193,677	—	2,068	195,745
Equity investment - Armata Common Stock	88,101	—	—	88,101
Equity investment - Armata Warrants	—	58,595	—	58,595
Equity investment - Entasis Common Stock	62,794	—	—	62,794
Equity investment - Entasis Warrants	—	40,914	—	40,914
Equity investment - InCarda Warrants	—	—	411	411
Convertible debt investment - Gate Note	—	—	15,100	15,100
Total assets measured at estimated fair value	<u>\$ 489,704</u>	<u>\$ 99,509</u>	<u>\$ 17,579</u>	<u>\$ 606,792</u>
Debt				
2023 Notes	\$ —	\$ 261,769	\$ —	\$ 261,769
2025 Notes	—	234,498	—	234,498
Total fair value of debt	<u>\$ —</u>	<u>\$ 496,267</u>	<u>\$ —</u>	<u>\$ 496,267</u>

⁽¹⁾ The investments held by ISP Fund LP, consisted of \$192.2 million equity investments and \$3.5 million money market funds, are subject to a 36-month lock-up period from our initial contribution date, December 11, 2020.

The fair values of our equity investments in Armata's common stock and publicly traded investments held by ISP Fund LP are based on the quoted prices in active markets and are classified as Level 1 financial instruments. The fair values of the warrants of Armata classified within Level 2 are 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.

InCarda's equity securities, the Gate Convertible Note, private placement positions and convertible notes held by ISP Fund LP, and contingent value rights are classified as Level 3 financial instruments as these securities are not publicly traded and the assumptions used in the valuation model for valuing these securities are based on significant unobservable and observable inputs including those of publicly traded peer companies.

The fair values of our 2023 Notes, 2025 Notes and 2028 Notes are based on recent trading prices of the respective instruments.

7. Goodwill and Intangible Assets

Goodwill and intangible assets acquired are recognized at fair value as of the acquisition date. The carrying amount of goodwill as of September 30, 2022 was \$16.0 million. We have not recognized any impairment losses related to goodwill during the periods presented.

Intangible assets with definite lives are amortized over their estimated useful lives. The carrying basis and accumulated amortization of recognized intangible assets as of September 30, 2022 were as follows:

(In thousands)	Useful Life (Years)	Gross Amount	Accumulated Amortization	Net Carrying Amount
Marketed products	8-10	\$ 152,500	\$ (1,511)	\$ 150,989
In-process research and development		72,100	—	72,100
Collaboration agreement		35,400	—	35,400
Total		<u>\$ 260,000</u>	<u>\$ (1,511)</u>	<u>\$ 258,489</u>

Intangible assets recognized as a result of the acquisition of Entasis amounted to \$107.5 million, which consist of Entasis' in-process research and development related to its antibacterial therapeutic product candidates and a collaboration agreement amounting to \$72.1 million and \$35.4 million, respectively. The useful lives of these intangible assets will be determined upon commercialization of the underlying product candidates; thus, no amortization expense of determinable assets was recognized during the period ended September 30, 2022.

Intangible assets recognized as a result of the acquisition of La Jolla amounting to \$152.5 million pertain to product rights and developed technologies on La Jolla's currently marketed products. These are intangible assets with determinable lives and are amortized over their estimated useful lives. We recognized amortization expense of \$1.5 million for the three and nine months ended September 30, 2022. Future amortization expense is expected to be \$3.5 million for the remainder of 2022, \$13.8 million for each of the years from 2023 to 2026 and \$78.0 million thereafter.

8. Balance Sheet Components

Inventory

Inventory consisted of the following:

(in thousands)	September 30, 2022
Raw materials	\$ 5,757
Work-in-progress	54,126
Finished goods	10,924
Total inventory	<u>\$ 70,807</u>

As of September 30, 2022, total inventory included net fair value adjustments resulting from the acquisition of La Jolla of approximately \$64.1 million, which will be amortized and recognized as cost of products sold when sales occur in future periods. Amortization of fair value adjustments recorded as part of cost of products sold amounted to \$2.7 million for the three and nine months ended September 30, 2022. There was no inventory as of December 31, 2021.

Other Accrued Liabilities

Other accrued liabilities consisted of the following:

(in thousands)	September 30, 2022	December 31, 2021
Accrued contract manufacturing expenses	\$ 5,319	\$ —
Accrued clinical expenses	1,062	—
Accrued research expenses	692	—
Accrued professional services	3,542	894
Current portion of lease liabilities	1,170	106
Accrued license fees and royalties	1,155	—
Other	2,180	9
Total other accrued liabilities	<u>\$ 15,120</u>	<u>\$ 1,009</u>

Other Long-term Liabilities

Other long-term liabilities consisted of the following:

(in thousands)	September 30, 2022
Long-term portion of lease liabilities	\$ 2,703
Deferred royalty obligation	75,424
Contingent value rights liability	294
Total other long-term liabilities	<u>\$ 78,421</u>

There were no other long-term liabilities as of December 31, 2021.

9. Stock-Based Compensation

Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense, which included the expense associated with Entasis' equity awards due to consolidation from February 17, 2022 to July 11, 2022 and the expense for Innoviva replacement restricted stock units in connection with the acquisition of Entasis on July 11, 2022, for the three and nine months ended September 30, 2022:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Selling, general and administrative	\$ 2,422	\$ 542	\$ 4,240	\$ 1,463
Research and development	1,295	—	1,781	—
Total	<u>\$ 3,717</u>	<u>\$ 542</u>	<u>\$ 6,021</u>	<u>\$ 1,463</u>

Valuation Assumptions

Black-Scholes-Merton assumptions used in calculating the estimated value of stock options granted by Innoviva on the date of grant were as follows:

	Nine Months Ended September 30,	
	2022	2021
Risk-free interest rate	1.6% - 3.03%	1.07% - 1.13%
Expected term (in years)	5.50 - 6.11	6.00
Volatility	38.8% - 40.5%	45.0%
Dividend yield	—%	—%
Weighted-average estimated fair value of stock options granted	\$6.98 - \$7.73	\$5.61

There were no grants of stock options during the three months ended September 30, 2022 and 2021.

10. Debt

Our debt consisted of the following:

(In thousands)	September 30, 2022	December 31, 2021
2023 Notes	\$ 96,204	\$ 240,984
2025 Notes	192,500	192,500
2028 Notes	261,000	—
Total debt	549,704	433,484
Less: Unamortized debt discount and issuance costs	(9,894)	(38,831)
Total debt, net	<u>\$ 539,810</u>	<u>\$ 394,653</u>
Less: Current portion of long-term debt, net	96,131	—
Total long-term debt, net	<u>\$ 443,679</u>	<u>\$ 394,653</u>

Convertible Subordinated Notes Due 2023

In January 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of our 2023 Notes, which will mature on January 15, 2023. The financing raised proceeds, net of issuance costs, of approximately \$281.2 million, less \$36.8 million to purchase two privately negotiated capped call option transactions in connection with the issuance of the notes. The 2023 Notes bear interest at the rate of 2.125% per year that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2013.

At the option of the holders, the 2023 Notes may be converted into fully paid and non-assessable shares of our common stock prior to the close of the business on the second business day immediately preceding the final maturity date. The initial conversion rate was 35.9903 shares per \$1,000 principal amount of the 2023 Notes, subject to customary anti-dilution adjustment in certain circumstances, which represented an initial conversion price of approximately \$27.79 per share.

In the event of default or a fundamental change (as defined in the indenture governing the 2023 Notes), holders of the 2023 Notes may require us to repurchase all or a portion of their 2023 Notes at price equal to 100% of the principal amount of the 2023 Notes, plus any accrued and unpaid interest.

In connection with the offering of the 2023 Notes, we entered into two privately negotiated capped call option transactions with a single counterparty. The capped call option transaction is an integrated instrument consisting of a call option on our common stock purchased by us with a strike price equal to the initial conversion price of \$27.79 per share for the underlying number of shares and a cap price of \$38.00 per share, both of which are subject to adjustments consistent with the 2023 Notes. The cap component is economically equivalent to a call option sold by us for the underlying number of shares with an initial strike price of \$38.00 per share. As an integrated instrument, the settlement of the capped call coincides with the due date of the convertible debt. Upon settlement, we would receive from our hedge counterparty a number of shares of our common shares that would range from zero, if the stock price was below \$27.79 per share, to a maximum of 2,779,659 shares, if the stock price is above \$38.00 per share. However, if the market price of our common stock, as measured under the terms of the capped call transactions, exceeds \$38.00 per share, there is no incremental anti-dilutive benefit from the capped call.

As a result of the partial conversion by certain holders of the 2023 Notes in July 2014, and dividends declared and paid in 2014 and 2015, the conversion rate with respect to our 2023 Notes was adjusted in total to 50.5818 shares of our common stock per \$1,000 principal amount of the 2023 Notes, which represents a conversion price of approximately \$19.77 per share. As a result of the conversion rate adjustments, the capped call strike price and cap price were also adjusted to \$19.77 and \$27.04, respectively.

During 2016, we retired a portion of our 2023 Notes with a face value of \$14.1 million and carrying value of \$13.9 million by way of purchase in the open market.

On March 7, 2022, we used \$165.6 million from the sale of the 2028 Notes to repurchase 60% of the 2023 Notes with a face value of \$144.8 million. The carrying value of the repurchased 2023 Notes was \$144.5 million. Accrued interest was \$0.4 million and unamortized debt issuance costs were \$0.3 million on the date of repurchase. We recognized a loss on the extinguishment of the 2023 Notes of \$20.7 million in other expense, net in the unaudited condensed consolidated statement of operations. The repurchase reduced the outstanding principal balance to \$96.2 million and unamortized debt issuance costs to \$0.2 million. The annual effective interest rate of the 2023 Notes changed from 2.36% to 2.37%.

On April 18, 2022, certain 2023 Notes holders converted their notes of \$3.0 thousand into Innoviva's common stock. The outstanding principal balance was reduced slightly to \$96.2 million.

Our outstanding 2023 Notes balances consisted of the following:

<u>(In thousands)</u>	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Principal	\$ 96,204	\$ 240,984
Debt issuance costs, net	(73)	(620)
Net carrying amount	<u>\$ 96,131</u>	<u>\$ 240,364</u>

The following table sets forth total interest expense recognized related to the 2023 Notes for the three and nine months ended September 30, 2022 and 2021:

<u>(In thousands)</u>	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Contractual interest expense	\$ 511	\$ 1,280	\$ 2,106	\$ 3,840
Amortization of debt issuance costs	59	143	240	431
Total interest and amortization expense	<u>\$ 570</u>	<u>\$ 1,423</u>	<u>\$ 2,346</u>	<u>\$ 4,271</u>

Convertible Senior Notes Due 2025

On August 7, 2017, we completed a private placement of \$192.5 million aggregate principal amount of our 2025 Notes. The proceeds include the 2025 Notes sold pursuant to the \$17.5 million over-allotment option granted by us to the initial purchasers, which option was exercised in full. The 2025 Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The 2025 Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year, beginning on February 15, 2018.

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. The initial conversion rate for the 2025 Notes is 57.9240 shares of our common stock per \$1,000 principal amount of the 2025 Notes (which is equivalent to an initial conversion price of approximately \$17.26 per share), representing a 30.0% conversion premium over the last reported sale price of the Company's common stock on August 1, 2017, which was \$13.28 per share. The conversion rate is subject to customary anti-dilution adjustments in certain circumstances. The 2025 Notes will mature on August 15, 2025, unless repurchased or converted in accordance with their terms prior to such date. Prior to February 15, 2025, the 2025 Notes will be convertible at the option of the holders only upon the occurrence of specified events and during certain periods, as described below. From, and including, February 15, 2025, until the close of business on the second scheduled trading day immediately preceding the maturity date, the 2025 Notes will be convertible at any time.

Holders of the 2025 Notes may convert all or a portion of their 2025 Notes prior to the close of business on February 15, 2025 only under the following circumstances:

- after September 30, 2017, if our closing common stock price for at least 20 days out of the most recent 30 consecutive trading days of the preceding quarter is greater than 130% of the current conversion price of the 2025 Notes;
- for five consecutive business days, if the average trading price per \$1,000 of Notes during the prior 10 consecutive trading days is less than 98% of the product of our closing common stock price and the conversion rate of the 2025 Notes on such day; and,
- upon the occurrence of specified corporate events, including certain distributions, the occurrence of a fundamental changes (as defined in the indenture governing the 2025 Notes) or a transaction resulting in our common stock converting into other securities or property or assets.

On or after February 15, 2025, holders of the 2025 Notes may convert their 2025 Notes at any time until the close of business on the second scheduled trading day immediately preceding the maturity date of the 2025 Notes.

In the event of default or a fundamental change (as defined above), holders of the 2025 Notes may require us to repurchase all or a portion of their 2025 Notes at price equal to 100% of the principal amount of the 2025 Notes, plus any accrued and unpaid interest.

Effective January 1, 2022, we adopted ASU 2020-06 using a modified retrospective method, under which financial results reported in prior periods were not adjusted. The adoption of ASU 2020-06 had a material impact on the 2025 notes. Refer to Note 1, "Description of Operations and Summary of Significant Accounting Policies" for further information.

Prior to the adoption of ASU 2020-06, 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 of \$67.3 million 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") was amortized to interest expense using the effective interest method over the term of the 2025 Notes. The equity component was not remeasured as long as it continued to meet the conditions for equity classification. Additionally, we separated the total issuance costs of \$5.4 million incurred into liability and equity components in proportion to the allocation of the initial proceeds, resulting in liability issuance costs of \$3.5 million and equity issuance costs of \$1.9 million. Issuance costs attributable to the liability component were amortized on a straight-line basis, which approximated the effective interest rate method, to interest expense over the

term of the 2025 Notes. The issuance costs attributable to the equity component were netted against the equity component in additional paid-in capital. The annual effective interest rate of the liability component of the 2025 Notes was 8.87%.

Upon adoption of ASU 2020-06 on January 1, 2022, we combined the liability and equity components of the 2025 Notes assuming that the instrument was accounted for as a single liability from inception to the date of adoption. We similarly combined the liability and equity components of the issuance costs. The issuance costs are presented as a deduction from the outstanding principal balance of the 2025 Notes and are amortized on a straight-line basis over the term of the 2025 Notes under the effective interest rate method. As of January 1, 2022, the annual effective interest rate on the 2025 Notes was 2.88%.

Our outstanding 2025 Notes balances consisted of the following:

(In thousands)	September 30, 2022	December 31, 2021
Principal	\$ 192,500	\$ 192,500
Debt discount and issuance costs, net	(2,092)	(38,211)
Net carrying amount	\$ 190,408	\$ 154,289
Equity component, net	\$ —	\$ 65,361

The following table sets forth total interest expense recognized related to the 2025 Notes for the three and nine months ended September 30, 2022 and 2021:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Contractual interest expense	\$ 1,203	\$ 1,203	\$ 3,609	\$ 3,609
Amortization of debt issuance costs	174	166	517	487
Amortization of debt discount	—	1,997	—	5,859
Total interest and amortization expense	\$ 1,377	\$ 3,366	\$ 4,126	\$ 9,955

Convertible Senior Notes Due 2028

In March 2022, we completed a private placement of \$261.0 million aggregate principal amount of our 2028 Notes, which will mature on March 15, 2028. The proceeds include the 2028 Notes sold pursuant to the \$45.0 million over-allotment option granted by us to the initial purchasers, of which \$36.0 million was exercised. The 2028 Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act.

The net proceeds from the sale of the \$261.0 million aggregate principal amount of 2028 Notes were approximately \$252.6 million after deducting the initial purchasers' discounts and commissions and our estimated offering expenses. We used approximately \$21.0 million of the net proceeds from the offering to fund the cost of entering into the capped call transactions described below. In addition, we used \$165.6 million of the remaining net proceeds to repurchase \$144.8 million aggregate principal amount of the 2023 Notes in separate and individually negotiated transactions with certain holders of the 2023 Notes, which closed concurrently with the issuance of the 2028 Notes. We expect to use the remaining net proceeds for general corporate purposes.

The 2028 Notes bear interest at an annual rate of 2.125% that is payable semi-annually in arrears in cash on March 15 and September 15 of each year, beginning on September 15, 2022.

The 2028 Notes are convertible, based on the applicable conversion rate, into cash, shares of our common stock or a combination thereof, at our election. The initial conversion rate was 38.1432 shares per \$1,000 principal amount of the 2028 Notes, subject to customary anti-dilution adjustment in certain circumstances, which represented an initial conversion price of approximately \$26.22 per share.

Prior to September 15, 2027, the 2028 Notes will be convertible at the option of the holders only upon the occurrence of specified events and during certain periods, and will be convertible on or after September 15, 2027, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date of the 2028 Notes.

Holders of the 2028 Notes may convert all or a portion of their 2028 Notes prior to the close of business on September 15, 2027, only under the following circumstances:

- after March 31, 2022, if our closing common stock price for at least 20 days out of the most recent 30 consecutive trading days of the preceding quarter is greater than 130% of the current conversion price of the 2028 Notes;
- for five consecutive business days, if the average trading price per \$1,000 of Notes during the prior 10 consecutive trading days is less than 98% of the product of our closing common stock price and the conversion rate of the 2028 Notes on such day; and,
- upon the occurrence of specified corporate events, including certain distributions, the occurrence of a fundamental changes (as defined in the indenture governing the 2028 Notes) or a transaction resulting in our common stock converting into other securities or property or assets.

On or after September 15, 2027, holders of the 2028 Notes may convert their 2028 Notes at any time until the close of the business on the second day immediately preceding the maturity date of the 2028 Notes.

The 2028 Notes will be redeemable, in whole or in part, at our option at any time, and from time to time, on or after March 20, 2025, and on or before the 75th scheduled trading day immediately before the maturity date but only if the last reported sale price per share of our common stock exceeds 130% of the conversion price for a specified period of time. The redemption price will be equal to the principal amount of the 2028 Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date. In addition, calling any 2028 Note for redemption will constitute a make-whole fundamental change (as defined in the indenture governing the 2028 Notes) with respect to that 2028 Note, in which case the conversion rate applicable to the conversion of that 2028 Note will be increased in certain circumstances if it is converted after it is called for redemption.

If we undergo a fundamental change, subject to certain conditions, holders may require us to purchase for cash all or any portion of their 2028 Notes. The fundamental change purchase price will be 100% of the principal amount of the 2028 Notes to be purchased plus any accrued and unpaid interest to, but excluding, the fundamental change purchase date.

The indenture governing the 2028 Notes contains customary terms and covenants, including a merger covenant and that upon certain events of default occurring and continuing, either the Trustee or the holders of at least 25% of the aggregate principal amount of the outstanding Notes may declare 100% of the principal of, and accrued and unpaid interest, if any, on, all the Notes to be due and payable immediately.

In connection with the offering of the 2028 Notes, we entered into privately negotiated capped call transactions. The cap price of the capped call transaction is initially \$33.9850 per share and is subject to certain adjustments under the terms of the capped call transactions. The capped call transactions cover, subject to customary adjustments, the number of shares of common stock initially underlying the 2028 Notes. The capped call transactions are expected generally to reduce potential dilution to our common stock upon conversion of the 2028 Notes or at our election (subject to certain conditions) offset any cash payments we are required to make in excess of the aggregate principal amount of converted 2028 Notes, as the case may be, with such reduction or offset subject to a cap.

The annual effective interest rate on the 2028 Notes is 2.70%.

Our outstanding 2028 Notes balance as of September 30, 2022 consisted of the following:

(In thousands)	September 30, 2022
Principal	\$ 261,000
Debt issuance costs, net	(7,729)
Net carrying amount	<u>\$ 253,271</u>

The following table sets forth total interest expense recognized related to the 2028 Notes from the date of issuance through September 30, 2022:

<u>(In thousands)</u>	<u>Three Months Ended September 30, 2022</u>	<u>Date of Issuance through September 30, 2022</u>
Contractual interest expense	\$ 1,371	\$ 3,127
Amortization of debt issuance costs	328	735
Total interest and amortization expense	<u>\$ 1,699</u>	<u>\$ 3,862</u>

Debt Maturities

The aggregate scheduled maturities of our convertible debt as of September 30, 2022 were as follows:

<u>(In thousands)</u>	<u>September 30, 2022</u>
Years ending December 31:	
Remainder of 2022	\$ —
2023	96,204
2024	—
2025	192,500
2026	—
Thereafter	261,000
Total	<u>\$ 549,704</u>

Deferred Royalty Obligation

As part of our acquisition of La Jolla, we recorded the fair value of its deferred royalty obligation in connection with La Jolla's royalty financing agreement ("La Jolla Royalty Agreement") with HealthCare Royalty Partners ("HCR"). Under the terms of the La Jolla Royalty Agreement, HCR is entitled to receive quarterly royalties on worldwide net sales of GIAPREZA[®] until either January 1, 2031 or when the maximum aggregate royalty payments have been made, whichever occurs first. Quarterly payments to HCR under the Royalty Agreement start at a maximum royalty rate, with step-downs based on the achievement of annual net product sales thresholds. The current maximum royalty rate is 14%. Starting January 1, 2024, the maximum royalty rate may increase by an additional 4%, if an agreed-upon, cumulative net product sales threshold has not been met. The La Jolla Royalty Agreement is subject to maximum aggregate royalty payments to HCR of \$225.0 million.

For the three months ended September 30, 2022, we recognized interest expense, including amortization of the obligation discount of \$1.5 million. The carrying value of the deferred royalty obligation as of September 30, 2022 was \$79.9 million, net of unamortized obligation discount of \$0.5 million. \$75.4 million of the deferred royalty obligation, including the long-term portion of the accrued interest, was classified as a noncurrent liability and the remaining \$4.5 million represented the short-term accrued interest. During the three months ended September 30, 2022, we made royalty payments to HCR of \$1.0 million. The deferred royalty obligation was valued using Level 3 inputs, and its carrying value as of September 30, 2022 approximates fair value. The fair value of the deferred royalty obligation was calculated as the discounted deferred royalty obligations based on risk-adjusted revenue projections for GIAPREZA[®].

Under the terms of the La Jolla Royalty Agreement, if we are unable to meet certain obligations, including the obligation to use commercially reasonable and diligent efforts to commercialize GIAPREZA[®], HCR would have the right to terminate the La Jolla Royalty Agreement and demand payment of either \$125.0 million or \$225.0 million (depending on which obligation we have failed to meet) less aggregate royalties already paid to HCR. As of September 30, 2022, inclusive of the aggregate royalties paid to HCR by La Jolla under the La Jolla Royalty Agreement prior to our acquisition, La Jolla paid \$11.6 million of aggregate royalties to HCR. In the event that we fail to pay such amount if and when due in a timely manner, HCR would have the right to foreclose on the GIAPREZA[®]-related assets. HCR has no recourse against any asset other than GIAPREZA[®].

Certain contract provisions within the La Jolla Royalty Agreement that could result in an acceleration of amounts due under the La Jolla Royalty Agreement are recognized as embedded derivatives that require bifurcation from the deferred royalty obligation and fair value recognition. We determined the fair value of each derivative by assessing the probability of each event occurring, as well as the potential repayment amounts and timing of such repayments that would result under various scenarios. As a result of this assessment, we determined that the fair value of the embedded derivatives is immaterial and, therefore, not recognized as of September 30, 2022. We estimate the fair value of the embedded derivatives for each reporting period until either the features lapse or the La Jolla Royalty Agreement is terminated, whichever occurs first. Any material change in the fair value of the embedded derivatives will be recorded as either a gain or loss on the unaudited condensed consolidated statements of income.

11. Commitments and Contingencies

Operating Lease

We have operating leases for our corporate headquarters, office spaces and laboratory facilities.

The components of lease cost are as follows:

(In thousands)	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Straight line operating lease costs	\$ 640	\$ 1,101
Variable lease costs	35	110
Total lease costs	<u>\$ 675</u>	<u>\$ 1,211</u>

Supplemental cash flow information related to leases are as follows:

(In thousands)	Nine Months Ended September 30, 2022
Cash paid for amounts included in the measurement of operating lease liabilities:	\$ 540
Operating lease right-of-use assets obtained in exchange for operating lease obligations	3,323
Right-of-use assets obtained through acquisitions	1,185

As of September 30, 2022, our operating leases have weighted-average remaining term of approximately three years and the weighted average discount rate on our operating lease liabilities was 7.5%.

We have not presented the comparative information above as our operating lease in 2021 was not material.

The following table summarizes our operating leases as presented in the unaudited condensed consolidated balance sheets:

(In thousands)	September 30, 2022	December 31, 2021
Assets		
Right-of-use assets	<u>\$ 3,679</u>	<u>\$ 97</u>
Liabilities		
Current portion of lease liabilities	\$ 1,170	\$ 106
Long-term portion of lease liabilities	2,703	—
Total lease liabilities	<u>\$ 3,873</u>	<u>\$ 106</u>

Future minimum payments on our operating leases as of September 30, 2022 were as follows:

(In thousands)	September 30, 2022
Years ending December 31:	
Remainder of 2022	\$ 250
2023	1,542
2024	1,269
2025	1,289
Total undiscounted lease payments	4,350
Less: imputed interest	(477)
Total operating lease liabilities	<u>\$ 3,873</u>

Legal Proceedings

From time to time, the Company is involved in legal proceedings in the ordinary course of its business. We are not currently a party to any material legal proceedings except as discussed below.

As previously disclosed in the Quarterly Report on Form 10-Q filed by La Jolla on August 15, 2022, on February 15, 2022, La Jolla received a paragraph IV notice of certification (the "Notice Letter") from Gland Pharma Limited ("Gland") advising that Gland had submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to manufacture, use or sell a generic version of GIAPREZA[®] in the U.S. prior to the expiration of U.S. Patent No.s.: 9,220,745; 9,572,856; 9,867,863; 10,028,995; 10,335,451; 10,493,124; 10,500,247; 10,548,943; 11,096,983; and 11,219,662 (the "GIAPREZA[®] Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The Notice Letter alleges that the GIAPREZA[®] Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Gland's ANDA.

On March 29, 2022, La Jolla filed a complaint for patent infringement of the GIAPREZA[®] Patents against Gland and certain related entities in the United States District Court for the District of New Jersey in response to Gland's ANDA filing. In accordance with the Hatch-Waxman Act, because GIAPREZA[®] is a new chemical entity and La Jolla filed a complaint for patent infringement within 45 days of receipt of the Notice Letter, the FDA cannot approve Gland's ANDA any earlier than 7.5 years from the approval of the GIAPREZA[®] NDA unless the District Court finds that all of the asserted claims of the patents-in-suit are invalid, unenforceable and/or not infringed. We intend to vigorously enforce our intellectual property rights relating to GIAPREZA[®].

Indemnification

In the ordinary course of business, we may provide indemnifications of varying scope and terms to vendors, directors, officers, and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by us, our negligence or willful misconduct, violations of law, or intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with directors and certain officers and employees that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers, or employees. No material demands have been made upon us to provide indemnification under such agreements, and thus, there are no claims that we are aware of that could have a material effect on our unaudited condensed consolidated financial statements. We also maintain director and officer insurance, which may cover certain liabilities arising from our obligation to indemnify our directors. To date, we have not incurred any material costs and have not accrued any material liabilities in the condensed consolidated financial statements as a result of these provisions.

12. Income Taxes

We recorded provisional income tax expense of \$57.1 million and \$63.1 million for the three and nine months ended September 30, 2022, respectively, compared to provisional income tax expense of \$20.5 million and \$65.6 million for the three and nine months ended September 30, 2021, respectively. The Company's effective income tax rate for the nine months ended September 30, 2022 was 18.3%, compared to 16.9% for the same period in 2021. The income tax expense for the nine months ended September 30, 2022 and 2021 was determined based upon estimates of the Company's effective income tax rates in various jurisdictions. Our effective income tax rate for the nine months ended September 30, 2022 was lower than the U.S. federal statutory income tax rate due primarily to a decrease in the fair value of our equity investments.

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[®] and ANORO[®] ELLIPTA[®] in the jurisdictions in which these products have been approved; the strategies, plans and objectives of Innoviva (including Innoviva’s growth strategy and corporate development initiatives beyond the existing respiratory portfolio); the timing, manner, and amount of potential capital returns to shareholders; 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; and projections of revenue, expenses, and other financial items; the impact of the novel coronavirus (“COVID-19”); the timing, manner and amount of capital deployment, including potential capital returns to stockholders; risks related to the Company’s growth strategy; projections of revenue, expenses and other financial items 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, 2021 filed with the Securities and Exchange Commission (“SEC”) on February 28, 2022, and as amended on March 17, 2022 (“2021 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 unaudited condensed 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 2021 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 2021 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. (referred to as “Innoviva”, the “Company”, or “we” and other similar pronouns) is a company with a portfolio of royalties and innovative healthcare assets. Our royalty portfolio contains respiratory assets partnered with Glaxo Group Limited (“GSK”), including RELVAR[®]/BREO[®] ELLIPTA[®] (fluticasone furoate/vilanterol, “FF/VI”) and ANORO[®] ELLIPTA[®] (umeclidinium bromide/ vilanterol, “UMEC/VI”), and up until July 2022, TRELEGY[®] ELLIPTA[®] (the combination FF/UMEC/VI). We sold our 15% ownership interest in Theravance Respiratory Company, LLC (“TRC”) on July 20, 2022, and were no longer entitled to receive royalties on sales of TRELEGY[®] ELLIPTA[®] products. 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%.

We expanded our portfolio of royalties and innovative healthcare assets through the acquisition of Entasis Therapeutics Holdings Inc. (“Entasis”) on July 11, 2022 and the acquisition of La Jolla Pharmaceutical Company (“La Jolla”) on August 22, 2022. Our commercial and marketed products include GIAPREZA[®] (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock, and XERAVA[®] (eravacycline) for the treatment of complicated intra-abdominal infections in adults. Our development pipeline includes medicines for the treatment of bacterial infections, such as our lead asset sulbactam-durlobactam (“SUL-DUR”).

Our company structure and organization are tailored to our focused activities of managing our respiratory assets partnered with GSK, including the commercial and developmental obligations associated with the GSK Agreements, optimizing capital allocation and providing for certain essential reporting and management functions of a public company.

Recent Highlights

- GSK Net Sales:
 - Third quarter 2022 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$371.1 million, up 3% from \$360.6 million in the same quarter of 2021, with \$184.5 million in net sales from the U.S. market and \$186.6 million from non-U.S. markets.
 - Third quarter 2022 net sales of ANORO[®] ELLIPTA[®] by GSK were \$153.0 million, down 15% from \$179.1 million in the same quarter of 2021, with \$77.6 million net sales from the U.S. market and \$75.4 million from non-U.S. markets.
- Corporate Updates:
 - On July 11, 2022, we completed the purchase of all of the issued and outstanding equity securities of Entasis not already owned by Innoviva for \$42.4 million. Entasis brings to Innoviva an infectious disease focused research and development platform anchored by its lead asset sulbactam-durlobactam (SUL-DUR).
 - On July 20, 2022, we completed the sale of our 15% ownership interest in TRC to Royalty Pharma for \$282.0 million, including payment for our portion of TRC’s cash balance of \$4.4 million, and a potential \$50.0 million sales-based milestone payments and received full ownership of equity and other investments that TRC owned prior to the transaction.
 - On August 22, 2022, we completed the acquisition of La Jolla for a net cash price of \$150.5 million. La Jolla brings to Innoviva an established product portfolio, including GIAPREZA[®] (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock and XERAVA[®] (eravacycline) for the treatment of complicated intra-abdominal infections in adults.
- Clinical Updates:
 - At the annual meeting of the Infectious Disease Society of America which took place from October 19 to October 23, 2022 in Washington, D.C., our wholly-owned subsidiary, Entasis, had six presentations on SUL-DUR data reinforcing the positive safety and efficacy findings from the Company’s pivotal Phase 3 ATTACK trial, while our other wholly-owned subsidiary, La Jolla, had five abstracts on XERAVA[®] which focused primarily on its use in combination therapies.

Collaboration Arrangement with GSK

LABA Collaboration

In November 2002, we entered into the LABA collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of chronic obstructive pulmonary disorder (“COPD”) and asthma (the “LABA Collaboration Agreement”). For the treatment of COPD, the collaboration has developed three combination products:

- 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”),
- ANORO[®] ELLIPTA[®] (“UMEC/VI”), a once-daily medicine combining a long-acting muscarinic antagonist (“LAMA”), umeclidinium bromide (“UMEC”), with a LABA, vilanterol (VI), and
- TRELEGY[®] ELLIPTA[®] (the combination 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. Although we have no further milestone payment obligations to GSK pursuant to the LABA Collaboration Agreement, we continue to have ongoing commercialization activities under the LABA Collaboration Agreement, including participation in the joint steering committee that are expected to continue over the life of the agreement. 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.

As mentioned above, on July 20, 2022, we sold our ownership interest in TRC, which received royalty payments from GSK stemming from sales of TRELEGY[®] ELLIPTA[®]. We retained our royalty rights with respect to RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®].

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 (“U.S. 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. Except as discussed below, we believe there have been no significant changes in our critical accounting policies as described in the Form 10-K for the year ended December 31, 2021 filed with the SEC on February 28, 2022, and as amended on March 17, 2022.

Business Combinations

We use the acquisition method of accounting under ASC 805, Business Combinations. Each acquired company’s operating results are included in our condensed consolidated financial statements starting on the acquisition date. The purchase price is equivalent to the fair value of consideration transferred. Tangible and identifiable intangible assets acquired, liabilities assumed and any noncontrolling interest in the acquiree as of the acquisition date are recorded at the acquisition date fair value. Goodwill is recognized for the excess of purchase price over the net fair value of assets acquired and liabilities assumed.

Amounts allocated to assets and liabilities are based upon fair values. Such valuations require us to make significant estimates and assumptions, especially with respect to the identifiable intangible assets. We make estimates of fair value based upon assumptions believed to be reasonable and that of a market participant. These estimates are based on available historical information as well as future expectations, and the estimates are inherently uncertain. The separately identifiable intangible assets generally include marketed products, in-process research and development and collaboration agreement.

Revenue Recognition from Product Sales

We started recognizing revenue from product sales as a result of our acquisition of La Jolla. Prior to recognizing any revenue from product sales, we identify the contract, performance obligations, and transaction price, and allocate the transaction price to the performance obligations. Revenue from product sales is recognized when our customers obtain control of the product and is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, discounts, returns, rebates and administrative fees. Variable consideration is estimated using the expected-value amount method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary materially from our estimates, we will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted. These items may include:

- **Chargebacks:** Chargebacks are discounts we provide to distributors in the event that the sales prices to end users are below the distributors' acquisition price. This may occur due to a direct contract with a health system, a group purchasing organization ("GPO") agreement or a sale to a government facility. Chargebacks are estimated based on known chargeback rates and recorded as a reduction of revenue on delivery to our customers.
- **Discounts:** We offer customers various forms of incentives and consideration, including prompt-pay and other discounts. We estimate discounts primarily based on contractual terms. These discounts are recorded as a reduction of revenue on delivery to our customers.
- **Returns:** We offer customers a limited right of return, generally for damaged or expired product. We estimate returns based on an internal analysis, which includes actual experience. The estimates for returns are recorded as a reduction of revenue on delivery to our customers.
- **Rebates:** We participate in Medicaid rebate programs, which provide assistance to certain low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, we pay a rebate to each participating state, generally within three months after the quarter in which product was sold. Additionally, we may offer customer incentives and consideration in the form of volume-based or other rebates. The estimates for rebates are recorded as a reduction of revenue on delivery to our customers.
- **Administrative Fees:** We pay administrative fees to GPOs for services and access to data. Additionally, we pay an Industrial Funding Fee as part of the U.S. General Services Administration's Federal Supply Schedules program. These fees are based on contracted terms and are paid after the quarter in which the product was purchased by the applicable GPO or government agency. Administrative fees are recorded as a reduction of revenue on delivery to customers.

We continue to assess our estimates of variable consideration as we accumulate additional historical data and will adjust these estimates accordingly.

Factors Affecting Comparability

Our historical financial condition and results of operations for the periods presented may not be comparable, either between periods or going forward due to the factors described below.

- Accounting consolidation of Entasis on February 17, 2022 and purchase of remaining minority interest in Entasis on July 11, 2022,
- Sale of our 15% ownership interest in Theravance Respiratory Company, LLC ("TRC") on July 20, 2022, and
- Acquisition of La Jolla on August 22, 2022.

Refer to Note 5, "Consolidated Entities and Acquisitions" to our accompanying unaudited consolidated financial statement for more information.

Results of Operations

Net Revenue

Royalty Revenue

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Royalties - RELVAR/BREO	\$ 55,663	\$ 54,092	\$ 1,571	3%	\$ 170,753	\$ 176,398	\$ (5,645)	(3)%
Royalties - ANORO	9,943	11,641	(1,698)	(15)%	28,015	34,101	(6,086)	(18)%
Royalties - TRELEGY	—	35,585	(35,585)	(100)%	72,029	84,055	(12,026)	(14)%
Total royalties from a related party	65,606	101,318	(35,712)	(35)%	270,797	294,554	(23,757)	(8)%
Less: amortization of capitalized fees paid to a related party	(3,456)	(3,456)	—	*	(10,368)	(10,368)	—	*
Royalty revenue from GSK	\$ 62,150	\$ 97,862	\$ (35,712)	(36)%	\$ 260,429	\$ 284,186	\$ (23,757)	(8)%

*Not Meaningful

Total net royalty revenue decreased to \$62.2 million and \$260.4 million for the three and nine months ended September 30, 2022, compared to \$97.9 million and \$284.2 million, respectively, for the same period a year ago. The decrease of total net royalty revenue for the three and nine months ended September 30, 2022, compared to the same periods a year ago was primarily due to the sale of our ownership interest in TRC, which received royalties stemming from sales of TRELEGY® ELLIPTA®. For the three months ended September 30, 2022, there was a decrease in the net sales of ANORO® ELLIPTA® due to pricing pressures and foreign currency changes in the U.S. market offset by a slight increase in the net sales of RELVAR®/BREO® ELLIPTA® due to U.S. net sales growth compensating for foreign currency changes and a slowdown in non-U.S. markets.

Net Product Sales

Net product sales we recognized from the date of acquisition of La Jolla to September 30, 2022 was \$5.1 million, consisting of net sales of GIAPREZA® and XERAVAL® for \$3.8 million and \$1.3 million, respectively.

Research and Development

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Research and development	\$ 11,725	\$ 449	\$ 11,276	*	\$ 31,447	\$ 536	\$ 30,911	*

*Not Meaningful

Research and development expenses consist of the following:

(in thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Compensation and related personnel costs	\$ 4,238	\$ —	\$ 4,238	*	\$ 9,525	\$ —	\$ 9,525	*
External services	6,937	449	6,488	*	20,457	536	19,921	*
Facilities related	563	—	563	*	1,390	—	1,390	*
Other	(13)	—	(13)	*	75	—	75	*
Total research and development expense	\$ 11,725	\$ 449	\$ 11,276	*	\$ 31,447	\$ 536	\$ 30,911	*

*Not Meaningful

Research and development expenses, which is mainly attributable to Entasis' product development efforts for SUL-DUR, were \$11.7 million and \$31.4 million, respectively, for the three and nine months ended September 30, 2022. Research and development expenses for the three and nine months ended September 30, 2021 were attributable to the product development efforts of Pulmoquine Therapeutics Inc., which was dissolved at the end of 2021.

Selling, General & Administrative

Selling, general and administrative expenses, as compared to the prior year period, were as follows:

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Selling, general and administrative	\$ 27,810	\$ 2,860	\$ 0	*	\$ 46,084	\$ 13,074	\$ 0	*

*Not Meaningful

Selling, general and administrative expenses increased for the three and nine months ended September 30, 2022, compared to the same period in 2021 mainly due to the consolidation of Entasis' operating expenses starting February 17, 2022 and the consolidation of La Jolla's operating expenses starting August 22, 2022. This increase was inclusive of \$1.6 million and \$2.5 million of sales and marketing expenses for the three and nine months ended September 30, 2022.

Interest and dividend income and other expense, net

Interest and dividend income and other expense, net, as compared to the prior year period, were as follows:

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Interest and dividend income	\$ (2,135)	\$ (453)	\$ (1,682)	*	\$ (3,181)	\$ (503)	\$ (2,678)	*
Other expense (income), net	(28)	652	(680)	*	750	2,036	(1,286)	(63)%

*Not Meaningful

Interest and dividend income increased for the three and nine months ended September 30, 2022, compared to the same periods a year ago due to higher interest rates and higher average balances of our cash equivalents, money market funds and other interest-bearing investments.

Other expense, net, was primarily expenses incurred by ISP Fund L.P. Other expense, net was partially offset by grant income of \$0.6 million and \$1.3 million during the three and nine months ended September 30, 2022. There was no grant income during 2021.

Interest Expense

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Interest expense	\$ 5,096	\$ 4,790	\$ 306	6%	\$ 11,761	\$ 14,229	\$ (2,468)	(17)%

The change in interest expense was primarily due to the adoption of the new accounting standard, ASU 2020-06, which is to simplify the accounting for convertible debt instruments, and the debt discount associated with the cash settlement feature of our convertible notes due 2025 ("2025 Notes"), which was adjusted to zero as of January 1, 2022. The interest expense for the three and nine months ended September 30, 2022 included the contractual interest expense and the amortization of debt issuance costs for our 2023 Notes, 2025 Notes and 2028 Notes. Interest expense for the three and nine months ended September 30, 2021 included the amortization of debt discount in addition to the contractual interest expense and the amortization of debt issuance costs for our 2023 Notes and 2025 Notes. The increase for the three months ended September 30, 2022, compared to September 30, 2021, was mainly due to a higher debt balance and interest expense incurred for the deferred royalty obligation from the acquisition of La Jolla.

Loss on Debt Extinguishment

We recognized a loss of \$20.7 million due to the total premium payment of \$20.4 million and the write-off of \$0.3 million debt issuance costs in connection with the repurchase of \$144.8 million aggregate principal amount of our 2023 Notes in March 2022.

Gain on Sale of TRC

We recognized a net gain of \$266.7 million due to the sale of our ownership interest in TRC to Royalty Pharma, consummated on July 20, 2022.

Changes in Fair Values of Equity and Long-Term Investments

Changes in fair values of equity and long-term investments, as compared to the prior year period, were as follows:

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2022	2021	\$	%	2022	2021	\$	%
Changes in fair values of equity and long-term investments, net	\$ (130)	\$ (33,613)	\$ 33,483	*	\$ 67,881	\$ (133,973)	\$ 201,854	*

*Not Meaningful

The changes in fair values of equity and long-term investments for the three and nine months ended September 30, 2022 decreased compared to the same period in 2021 mainly due to the volatility in the capital markets. The changes in fair values of equity and long-term investments reflect the realized gains and losses and net unrealized gains and losses in our strategic investments in Armata, InCarda, Gate, and those investments managed by ISP Fund LP.

Provision for Income Taxes

We recorded a provisional income tax expense of \$57.1 million and \$63.1 million for the three and nine months ended September 30, 2022, respectively, compared to provisional interest tax expense of \$20.5 million and \$65.6 million for the three and nine months ended September 30, 2021, respectively. The effective income tax rate for the nine months ended September 30, 2022 and 2021 was 18.3% and 16.9%, respectively.

Net Income (Loss) Attributable to Noncontrolling Interest

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2022 ⁽¹⁾	2021	\$	%	2022 ⁽²⁾	2021	\$	%
Net income (loss) attributable to noncontrolling interests	\$ (36,176)	\$ 30,208	\$ (66,384)	*	\$ 6,341	\$ 67,678	\$ (61,337)	(91)%

*Not Meaningful

(1) Three months ended September 30, 2022 represents the period from July 1, 2022 through the date of the acquisition of Entasis on July 11, 2022, and the period from July 1, 2022 through the date of the sale of our ownership interest in TRC on July 20, 2022.

(2) Nine months ended September 30, 2022 represents the period from the initial date of consolidation of Entasis on February 17, 2022 to the date of the acquisition of Entasis on July 11, 2022, and the period from January 1, 2022 the date of the sale of our ownership interest in TRC on July 20, 2022.

Net income (loss) attributable to noncontrolling interest represents \$(33.5) million, which loss was mainly due to the distribution of TRC's equity and debt investments to Innoviva at zero cost prior to the sale of TRC, and \$19.9 million for the 85% share of net income in TRC for Theravance Biopharma and \$(2.7) million and \$(13.6) million for the 40% share of net loss in Entasis for the three and nine months ended September 30, 2022, respectively. The net income attributable to noncontrolling interest for the three and nine months ended September 30, 2021 represents the 85% share of net income in TRC for Theravance Biopharma.

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 collaboration arrangement. For the nine months ended September 30, 2022, we generated gross royalty revenues from GSK of \$270.8 million and net product sales revenues of \$5.1 million. Net cash and cash equivalents totaled \$300.8 million, and receivables from GSK totaled \$65.6 million as of September 30, 2022.

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:

(In thousands)	Nine Months Ended September 30,		Change
	2022	2021	
Net cash provided by operating activities	\$ 192,827	\$ 265,432	\$ (72,605)
Net cash (used in) provided by investing activities	(47,956)	63,627	(111,583)
Net cash used in financing activities	(45,567)	(440,431)	394,864

Cash Flows from Operating Activities

Net cash provided by operating activities for the nine months ended September 30, 2022 was \$192.8 million, consisting primarily of our net income of \$288.6 million, adjusted for net non-cash items, which included a net gain of \$266.7 million on the sale of TRC. Other non-cash items included \$29.3 million of deferred income tax, \$12.5 million of depreciation and amortization, \$20.7 million of loss on extinguishment of debt, and \$66.4 million decrease in the fair value of our equity and long-term investments. Net non-cash items were partially offset by increases of \$3.6 million in other assets, non-current and \$0.9 million in accounts receivable and decreases of \$1.9 million in accrued interest payable and \$1.7 million in accrued personnel-related expenses and other accrued liabilities.

Net cash provided by operating activities for the nine months ended September 30, 2021 was \$265.4 million, consisting primarily of our net income of \$323.2 million, adjusted for net non-cash items such as \$65.6 million of deferred income taxes, \$10.4 million of depreciation and amortization, and \$6.8 million of amortization of debt discount and issuance costs, partially offset by an increase of \$132.5 million in the fair value of our equity and long-term investments, net and an increase in receivables from collaboration arrangements of \$7.3 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 of \$48.0 million primarily consisted of \$150.5 million of cash used for the acquisition of La Jolla, \$93.0 million in purchases of equity investments managed by ISP Fund LP, \$41.3 million in purchases and sales of other investments managed by ISP Fund LP and \$58.7 million in purchases of equity and long-term investments. The use of cash for investing activities was partially offset by net proceeds of \$248.2 million from the sale of our ownership interest of TRC, \$24.3 million from the sale of equity investments managed by ISP Fund LP and \$23.1 million of cash acquired through the consolidation of Entasis.

Net cash provided by investing activities for the nine months ended September 30, 2021 of \$63.6 million primarily was due to \$21.4 million of sales of equity investments managed by ISP Fund LP and \$267.0 million of purchase and sales of other investments managed by ISP Fund LP, net, partially offset by \$178.4 million of purchases of equity investments managed by ISP Fund LP and \$46.4 million investments of Armata, ImaginAb and Entasis.

Cash Flows from Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2022 of \$45.6 million was primarily due to a payment of \$165.1 million for the repurchase of the 2023 Notes and \$21.0 million for the purchases of capped call options associated with the 2028 Notes, \$69.8 million in distributions to noncontrolling interests and \$42.4 million for the purchase of Entasis' minority interest. The use of cash for financing activities was partially offset by \$252.5 million in net proceeds from the issuance of the convertible senior notes due 2028.

Net cash used in financing activities for the nine months ended September 30, 2021 of \$440.4 million was primarily due to \$394.1 million used for our common stock repurchase from GSK and \$46.4 million distributions to noncontrolling interest.

Contractual Obligations

In March 2022, we completed a private placement of \$261.0 million aggregate principal amount of unsecured convertible senior notes, the 2028 Notes, which will mature on March 15, 2028. Under the terms of the 2028 Notes, we will make interest payments of approximately \$2.9 million during the year 2022 and \$5.5 million in each of the years from 2023 through 2027. The principal balance of \$261.0 million will become due in March 2028. As of September 30, 2022, our notes payable obligation also included \$96.2 million related to our 2023 Notes which are due in 2023 and \$192.5 million related to our 2025 Notes which are due in 2025. Refer to Note 10, "Debt" to the Consolidated Financial Statements for more information.

Our short-term and long-term obligations also include contractual payments related to our operating leases were \$4.4 million, with approximately \$0.3 million payable through December 31, 2022 and approximately \$1.3 million to \$1.5 million payable in each of the years from 2023 to 2025. Refer to Note 11, "Commitments and Contingencies" to the condensed consolidated financial statements for more information.

As part of our acquisition of La Jolla, we recognized its deferred royalty obligation in connection with La Jolla Royalty Agreement with HCR. Under the terms of the Agreement, HCR is entitled to receive quarterly royalties on worldwide net sales of GIAPREZA[®] until either January 1, 2031 or when the maximum aggregate royalty payments have been made, whichever occurs first. Quarterly payments to HCR under the Royalty Agreement start at a maximum royalty rate, with step-downs based on the achievement of annual net product sales thresholds. The current maximum royalty rate is 14%. Starting January 1, 2024, the maximum royalty rate may increase by an additional 4%, if an agreed-upon, cumulative net product sales threshold has not been met. The La Jolla Royalty Agreement is subject to maximum aggregate royalty payments to HCR of \$225.0 million.

Additionally, we have certain contingent payment obligations under various in-license agreements which we are required to make royalty payments or milestone payments upon successful completion and achievement of certain milestones. Refer to Note 4, "License and Collaboration Arrangements" to the Condensed Consolidated Financial Statements for more information.

We also enter into agreements in the normal course of business with vendors for manufacturing, clinical trials and preclinical studies, and other services and products for operating purposes.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

As of September 30, 2022, our debt bear fixed interest rates and we had not outstanding debt with variable interest rate. Our cash flows on these debt obligations are not subject to variability as a result of changes in interest rates.

We are exposed to changes in the fair value of certain of our investments in equity and debt securities. Fluctuations in the underlying fair value of the investments could result in material gains or losses. Refer to Note 6 "Financial Instruments and Fair Value Measurements" to the Condensed Consolidated Financial Statements for more information.

Inflation has increased during the period covered by this Quarterly Report on Form 10-Q and could continue to increase for the near future. Inflationary factors, such as increases in the cost of our raw materials, supplies, interest rates and overhead costs may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future if inflation rates continue to rise. Significant adverse changes in inflation and prices in the future could result in material losses.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation as of September 30, 2022, 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 the time periods specified in the Commission’s rules and forms and controls and procedures that are designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer’s management including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decision regarding required disclosure. 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

During the quarter ended September 30, 2022, we completed our acquisitions of Entasis and La Jolla. We are currently in the process of integrating the acquired operations and processes into our internal control environment and implementing necessary changes to our internal control over financial reporting, including, but not limited, to the creation of new controls related to inventory management, research and development activities and product sales.

Other than the above, there have been no 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, 2022 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

As previously disclosed in the Quarterly Report on Form 10-Q filed by La Jolla on August 15, 2022, on February 15, 2022, La Jolla received a paragraph IV notice of certification (the “Notice Letter”) from Gland Pharma Limited (“Gland”) advising that Gland had submitted an Abbreviated New Drug Application (“ANDA”) to the FDA seeking approval to manufacture, use or sell a generic version of GIAPREZA® in the U.S. prior to the expiration of U.S. Patent Nos.: 9,220,745; 9,572,856; 9,867,863; 10,028,995; 10,335,451; 10,493,124; 10,500,247; 10,548,943; 11,096,983; and 11,219,662 (the “GIAPREZA® Patents”), which are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”). The Notice Letter alleges that the GIAPREZA® Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Gland’s ANDA.

On March 29, 2022, La Jolla filed a complaint for patent infringement of the GIAPREZA[®] Patents against Gland and certain related entities in the United States District Court for the District of New Jersey in response to Gland's ANDA filing. In accordance with the Hatch-Waxman Act, because GIAPREZA[®] is a new chemical entity and La Jolla filed a complaint for patent infringement within 45 days of receipt of the Notice Letter, the FDA cannot approve Gland's ANDA any earlier than 7.5 years from the approval of the GIAPREZA[®] NDA unless the District Court finds that all of the asserted claims of the patents-in-suit are invalid, unenforceable and/or not infringed. The Company and La Jolla intend to vigorously enforce their intellectual property rights relating to GIAPREZA[®].

Item 1A. Risk Factors

The information presented below supplements the risk factors set forth in Item 1A of Part I of our 2021 Form 10-K. As previously disclosed, on July 11, 2022, we announced the completion of our acquisition of Entasis by acquiring all the issued and outstanding equity securities of Entasis not already owned by Innoviva. The Entasis business constitutes a significant portion of our business and additional significant risks may apply to the Entasis business as detailed in the Annual Report on Form 10-K filed by Entasis on March 3, 2022, and as amended on May 2, 2022, which are hereby incorporated by reference.

As previously disclosed, on August 22, 2022, we announced the completion of our acquisition of La Jolla by acquiring all the issued and outstanding equity securities of La Jolla. The La Jolla business constitutes a significant portion of our business and additional significant risks may apply to the La Jolla business as detailed in the Annual Report on Form 10-K filed by La Jolla on March 9, 2022, and as amended on May 2, 2022, which are hereby incorporated by reference.

On August 23, 2022, we filed supplemental risk factors as Exhibit 99.1 on Current Report on Form 8-K filed on August 23, 2022, which are hereby incorporated by reference.

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	Incorporated by Reference		
		Form	Exhibit	Filing Date/Period End Date
2.1	Agreement and Plan of Merger, dated as of May 23, 2022, by and among Innoviva, Inc., Innoviva Merger Sub, Inc. and Entasis Therapeutics Holdings Inc.	8-K	2.1	5/24/2022
2.2	Agreement and Plan of Merger, dated as of July 10, 2022, by and among Innoviva, Inc., Innoviva Acquisition Sub, Inc. and La Jolla Pharmaceutical Company	8-K	2.1	7/11/2022
3.1	Amended and Restated Certificate of Incorporation	S-1	3.3	7/26/2004
3.2	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3.4	3/31/2007
3.3	Certificate of Ownership and Merger Merging LABA Merger Sub, Inc. with and into Theravance, Inc., as filed with the Secretary of State of the State of Delaware, effective on January 7, 2016	8-K	3.1	1/8/2016
3.4	Amended and Restated Bylaws, amended and restated as of February 8, 2017	8-K	3.1	2/9/2017
4.1	Specimen certificate representing the common stock of the registrant	10-K	4.1	12/31/2006
4.2	Indenture, dated as of January 4, 2013 by and between Theravance, Inc. and the Bank of New York Mellon Trust Company, N.A., as trustee	8-K	4.1	1/25/2013
4.3	Form of 2.125% Convertible Subordinated Note Due 2023 (included in Exhibit 4.2)			
4.4	Indenture (including form of Note) with respect to Innoviva's 2.5% Convertible Senior Notes due 2025, dated as of August 7, 2017, between Innoviva and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	4.1	8/7/2017
4.5	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	4.9	2/19/2020
4.6	Indenture (including form of Note) with respect to Innoviva's 2.125% Convertible Senior Notes due 2028, dated as of March 7, 2022, between Innoviva and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	4.1	3/8/2022
10.1	Offer Letter between Innoviva, Inc. and Pavel Raifeld, dated April 29, 2022	8-K	10.1	5/2/2022
10.2	Amendment No. 1 to the Investor Rights Agreement, dated May 23, 2022, by and among Innoviva, Inc. and Entasis Therapeutics Holdings Inc.	8-K	10.1	5/24/2022
10.3	Support Agreement, dated July 10, 2022, by and among Innoviva, Inc., Innoviva Acquisition Sub, Inc., Tang Capital Partners, LP and Kevin C. Tang Foundation	8-K	10.1	7/11/2022
10.4	Equity Purchase Agreement, dated July 13, 2022, by and among Innoviva, Inc., Innoviva TRC Holdings LLC and Royalty Pharma Investments 2019 ICAV.	8-K	10.1	7/13/2022
10.5	Third Amendment to Collaboration Agreement, dated July 13, 2022, by and among Innoviva, Inc., Glaxo Group Limited, and Theravance Respiratory Company, LLC.	8-K	10.2	7/13/2022
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			
99.1	Risk Factors	8-K	99.1	8/23/2022
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.			
101.SCH	Inline XBRL Taxonomy Extension Schema Document			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document			

101.LAB Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document
104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 09, 2022

/s/ Pavel Raifeld

Pavel Raifeld

Chief Executive Officer
(Principal Executive Officer)

Date: November 09, 2022

/s/ Marianne Zhen

Marianne Zhen

Chief Accounting Officer
(Principal Financial Officer)

**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.;
2. 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;
 - c) 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: November 09, 2022

/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.;
2. 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;
 - c) 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: November 09, 2022

/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, 2022 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: November 09, 2022

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, 2022 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: November 09, 2022

By: _____ /s/ Marianne Zhen
Marianne Zhen
Chief Accounting Officer
(Principal Financial Officer)
