

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **September 14, 2022**

**INNOVIVA, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation)

**000-30319**  
(Commission File Number)

**94-3265960**  
(I.R.S. Employer Identification  
Number)

**1350 Old Bayshore Highway,  
Suite 400  
Burlingame, California 94010  
(650) 238-9600**

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

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**Item 7.01. Regulation FD Disclosure.**

On September 14, 2022, Innoviva, Inc. (the “Company”) made available on its website a revised Company investor presentation. A copy of the presentation is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information included in this Current Report on Form 8-K that is furnished pursuant to this Item 7.01, including the information contained in Exhibit 99.1 hereto, shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, the information included in this Current Report on Form 8-K that is furnished pursuant to this Item 7.01, including the information contained in Exhibit 99.1 hereto, shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference into such filing.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits**

99.1 Investor Presentation

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**SIGNATURE**

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

Date: September 14, 2022

**INNOVIVA, INC.**

By: /s/ Pavel Raifeld

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**Pavel Raifeld**  
**Chief Executive Officer**

# INNOVIVA

September 2022 | Corporate  
Presentation

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## Forward-looking statements

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The information in this presentation 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. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. 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 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<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup>, ANORO<sup>®</sup> ELLIPTA<sup>®</sup> and TRELEGY<sup>®</sup> ELLIPTA<sup>®</sup> in the jurisdictions in which these products have been approved; substantial competition from products discovered, developed, launched and commercialized both by GSK and by other pharmaceutical companies; our strategies, plans and objectives (related to our growth strategy and corporate development initiatives beyond our existing portfolio); the timing, manner and amount of capital deployment, including potential capital returns to stockholders; risks related our growth strategy; projections of revenue, expenses and other financial items. 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.

Any person reviewing this presentation is advised to review our “Risk Factors” and other information 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, (“2021 Form 10-K”), and the information in the other reports and documents that we file with the SEC from time to time. All information in this presentation should be read in conjunction with the information we have filed with the SEC. All forward-looking statements in this presentation 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.

## Innoviva overview

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### Company description






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**Diversified biopharmaceutical company** with a portfolio of royalties and a growing portfolio of innovative healthcare assets

- **Royalty portfolio** consists of respiratory products that were jointly developed with, and are licensed to, GSK and collectively make up a large portion of GSK's leading respiratory franchise (RELVAR®/ BREO® ELLIPTA®, ANORO® ELLIPTA®)
- **Integrated infectious disease / hospital business** formed via recent acquisitions of Entasis Therapeutics and La Jolla Pharmaceutical companies with strong growth prospects and significant operating leverage
- **Strategic healthcare assets** – assets in areas with high unmet medical need and significant long-term value creation potential, including a majority stake in bacteriophage leader Armata Pharmaceuticals

### Company highlights

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-  1 **Strongly cashflow-generative, diversified and durable core royalty business**
-  2 **High-potential, robust operating platform in hospital / infectious disease space and other valuable assets**
-  3 **Thoughtful, robust, long-term approach to capital deployment**
-  4 **Deep and proven healthcare expertise across governance, strategy, medicine / science, R&D, finance, and operations**
-  5 **Strong track record of growth and value creation focus**

# Innoviva combines sustainable royalty cashflows and valuable operating platform with a long-term capital deployment strategy to maximize shareholder value



**Robust, valuable royalty portfolio**

Significant royalties from a sizeable, durable portfolio of blockbuster respiratory products



**Thoughtful, accretive capital deployment**

Strategic healthcare asset acquisitions and capital structure optimization to drive sustainable growth



**Strong, promising operating business and other assets**

An integrated operating platform focused on hospital / anti-infectives drugs complemented by other healthcare assets



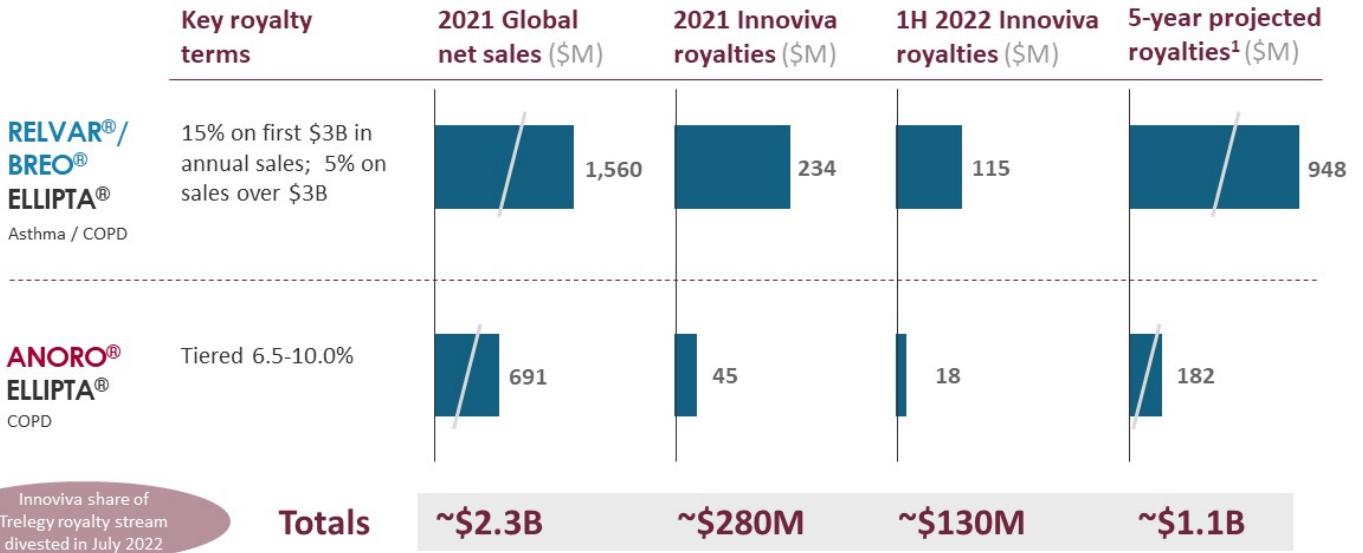
**Long-term shareholder value creation**

Strong record of growth and capital deployment position the company for continued value creation

**Over \$250M net income generated in 2021**



# Innoviva has a valuable royalty portfolio comprised of robust, durable revenues stemming from widely used respiratory therapies commercialized by GSK



Innoviva share of Trelegy royalty stream divested in July 2022

1 – Projections per analyst consensus on GSK forecast website accessed Sept 8, 2022; GBP converted to USD using Sept 8 exchange rate of \$1.15; 2022-2026E royalties shown





## Our royalty product portfolio has demonstrated resilience and growth, contributing to our excitement about its long-term potential

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### Sizeable and differentiated

- Differentiated respiratory portfolio with over \$2B 2021 sales (for Breo and Anoro)
- Consensus projections imply royalties of **>\$1B over the next 5 years<sup>1</sup>**

### Resilient and durable

- Robust products have performed well across environments despite competitive pressures
- **Meaningful longevity** afforded by strong IP estate, with the “moat” amplified by manufacturing complexity

### Diversified and established

- Portfolio covers **key respiratory drug classes** in easy-to-use single daily dose form for both asthma and COPD
- Therapies are well-established **standards of care**
- Products successfully marketed in **multiple geographies and indications**, reducing single-market risk

1 – Projections per analyst consensus on GSK forecast website accessed Sept 8, 2022; GBP converted to USD using Sept 8 exchange rate of \$1.15; 2022-2026E royalties shown



## Innoviva has actively deployed its capital to maximize shareholder value

### We thoughtfully approach capital deployment with a strong value focus

Continued **active search for strategically appealing opportunities** with external support

- Long-term, deliberate approach to direct strategic investments into promising healthcare assets, matching the meaningful duration of our cashflows
- Concentrated exposure to fundamentally robust, **attractively priced assets with significant upside**

**Opportunistic asset monetization** as appropriate to drive value creation

- E.g., divestiture of 15% stake in Theravance Respiratory Company (which owned Trelegy royalties) in July 2022 for \$282M and a milestone plus rights to equity investments valued at \$43M
- Transaction values our stake in TRC at 17x 2021 royalties accruing to Innoviva and a significant premium relative to underlying consensus-based NPV<sup>1</sup>

Potential **capital return to shareholders as appropriate**, especially when strong economic value accretion is coupled with compelling strategic benefits

- E.g., GSK's 32% equity stake repurchase in May 2021 at \$12.25 per share for \$392M

**Since the beginning of 2021 we strategically repurchased GSK's equity stake for ~\$400M, monetized our share of Trelegy royalties for over \$275M, and deployed approximately \$400M into acquiring high-potential assets**

<sup>1</sup> – Royalties accruing to Innoviva based on 15% of \$127M Trelegy royalties; valuation includes cash upfront and balance sheet value of equity investments as of June 30, 2022; NPV based on Bloomberg Consensus at the time of the transaction with management forecasts



## We approach strategic acquisitions in a thoughtful and disciplined manner

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### Opportunity identification

We target **fundamentally attractive**, yet often **overlooked or contrarian**, healthcare areas where our capital and capabilities can make a difference

We look for **differentiated assets** with meaningful **value creation potential**

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### Individual acquisition execution and oversight

We **structure and negotiate** asset acquisitions on mutually beneficial terms to maximize long-term value

- Focus on concentrated, long-term investments, often by purchasing majority or other large stakes
- Openness to smaller investments in companies with compelling growth and risk profiles

We **proactively manage risks through ongoing asset stewardship** and appropriate diversification

- Operational and strategic support and management (across strategy, finance, development, commercial, governance, and other areas) as a key value creation driver
- 

### Strategic vision

We seek to build and own **strategically viable, economically sustainable businesses**

- Oftentimes, we pursue acquisitions of complementary assets to generate meaningful synergies, including a potential “roll up” strategy in the hospital / infectious disease space



## Our non-royalty healthcare asset portfolio provides for both growth and resilience

			Est. cost or fair market asset value (\$M) <sup>1</sup>
Robust, differentiated infectious disease / hospital business	<ul style="list-style-type: none"> <li>Entasis / La Jolla combination creates an integrated therapeutics platform with strong R&amp;D engine and superior hospital-focused commercial operations, driving synergies and de-risking the business</li> <li>Strong backbone creates an opportunity to “layer on” other assets</li> </ul>	 	~330
	<ul style="list-style-type: none"> <li>Armata adds cutting edge R&amp;D and manufacturing capabilities with a novel therapeutic modality, bacteriophages, meaningfully de-risked through use across the globe and multiple shots on goal in the pipeline</li> </ul>		145
Minority investments in high growth areas	<ul style="list-style-type: none"> <li>Strategic equity investments in high-growth healthcare companies with significant promise</li> </ul>	   	43
ISP Fund providing further exposure to healthcare	<ul style="list-style-type: none"> <li>\$300M initially committed to ISP Fund in Dec 2020 primarily to public equity investments in healthcare in areas of significant value dislocation, providing long-term upside</li> <li>Benchmark outperformance on long-term and year-to-date bases</li> </ul>		307

1 – Based on balance sheet as of June 30, 2022. Asset value for Entasis and La Jolla based on capital invested to date, excluding transaction costs



# Differentiated hospital / infectious disease business: a case study



**Infectious disease is a promising area of high unmet medical need with currently scarce capital access**

Infectious disease therapeutics have focused primarily on common bacteria diseases; however, **there is a clear need for improved therapeutics for bacterial, viral and fungal diseases**

This area has recently fallen out of favor due to idiosyncratic challenges, and historical underinvestment exacerbated development and commercial challenges, creating a “vicious cycle”

**A player with long-term vision, capital, and expertise can take advantage of market dislocations and facilitate R&D and commercialization of novel, differentiated treatments** capable of generating significant value for patients and health systems – and producing strong returns



## Sample Innoviva transactions



**Wholly-owned subsidiary**

**Novel antibacterial platform validated by lead asset’s highly differentiated profile in an area of unmet need**

- Strong anti-bacterial pipeline led by SUL-DUR with positive Phase 3 data in Oct 2021
- Innoviva made an initial investment in April 2020 and acquired remaining stake in July 2022



**Wholly-owned subsidiary**

**Commercial stage company with a robust hospital product portfolio including a growing anti-infective asset**

- Markets Xerava, a 4G tetracycline antibiotic for CIAI, and Giapreza, an angiotensin injection for treatment of shock
- Acquired in August 2022 at ~\$149M EV



**\$94M cost basis<sup>1</sup>  
\$145M fair value<sup>1</sup>  
~70% ownership**

**Pathogen-specific bacteriophage therapeutics platform for the treatment of drug resistant infections and other uses**

- Highly differentiated novel biologic platform with broad applicability, rooted in a well-known modality and supported by strong manufacturing capabilities

1 – As of June 30, 2022



# Entasis / La Jolla combination transforms Innoviva by giving us a robust, organically growing platform with significant operating leverage and clear path to profitability



World-class infectious disease R&D engine anchored by SUL-DUR







~\$45M<sup>1</sup> revenue hospital business with strong commercial platform



Fully integrated, complementary hospital / ID operating platform

## When combined under the Innoviva umbrella, the hospital / ID businesses are significantly more valuable than standalone

-  Growing portfolio of marketed hospital and infectious disease products with significant embedded operating leverage and potential for further revenue trajectory acceleration with appropriate resourcing
-  Existing platform provides de-risked, synergistic commercialization for SUL-DUR launch with minimal incremental investment
-  Commercial infrastructure and built-in expertise can be used to add further complementary products in the future
-  Meaningful upside potential from possible future industry or reimbursement paradigm changes

1 – Giapreza and Xerava net products sales of \$44M in 2021



# Innoviva's management and board have world-class expertise in healthcare

## Innoviva Team

Superior capabilities and network

Unique and complementary skill sets

Strong value creation focus

Proven track record of success

### Relevant experience

<b>Management Team</b>	<b>Pavel Raifeld, Chief Executive Officer</b>	Experienced finance and life sciences professional; formerly with Sarissa Capital, Credit Suisse, McKinsey and BCG	
	<b>Marianne Zhen, CPA, Chief Accounting Officer</b>	Experienced finance professional with over 20 years in accounting and strategic operations	
<b>Board of Directors</b>	<b>George Bickerstaff, Chairperson</b>	Managing Director at M.M. Dillon & Co.; former CFO of Novartis Pharma AG and IMS Health; director at CareDx	
	<b>Deborah L. Birx, M.D.</b> <i>Joined in 2021</i>	Physician-scientist and healthcare leader; former response coordinator of The White House Coronavirus Task Force	
	<b>Mark DiPaolo, Esq.</b>	Senior Partner and General Counsel at Sarissa Capital; former senior member Icahn Capital's investment team	
	<b>Jules Haimovitz</b>	Founder, executive, and director of multiple companies in life sciences and entertainment; former director of Ariad Pharma	
	<b>Odysseas Kostas, M.D.</b>	Partner and Senior Managing Director at Sarissa Capital; former life sciences analyst at Evercore ISI and physician	
	<b>Sarah J. Schlesinger, M.D.</b>	Professor at Rockefeller University with governance and clinical / medical expertise; former director of MDCO and Ariad Pharma	



# The past 18 months have seen strong financial growth and advancement of our core strategy

	Financial highlights	Business highlights
2021	\$406M revenues	Strategically repurchased GSK's 32% equity stake for <b>\$392M</b> (at \$12.25 per share)
	\$375M income from operations	Invested <b>~\$65M</b> into innovative healthcare assets
	\$364M net cash provided by operating activities	Added healthcare and infectious disease leader <b>Deborah L. Birx</b> to the Board
1H 2022	\$205M revenues	Fully acquired <b>Entasis</b> and <b>La Jolla</b> and invested additional \$58M into other innovative assets
	\$160M income from operations	Sold rights to Trelegy royalties for <b>\$282M cash upfront</b> , milestones, and equity investments
	\$177M net cash provided by operating activities	Issued <b>\$261M</b> '28 convertible notes on favorable terms, refinancing a portion of '23 notes





## Why Innoviva

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1 Strongly cashflow-generative, diversified and durable core royalty business



2 High-potential, robust operating platform in hospital / infectious disease space and other valuable assets



3 Thoughtful, robust, long-term approach to capital deployment



4 Deep and proven healthcare expertise across governance, strategy, medicine / science, R&D, finance, and operations



5 Strong track record of growth and value creation focus

# Appendix



# Relvar / Breo detail: First once-daily inhaled corticosteroid / long-acting beta-agonist for asthma and chronic obstructive pulmonary disease

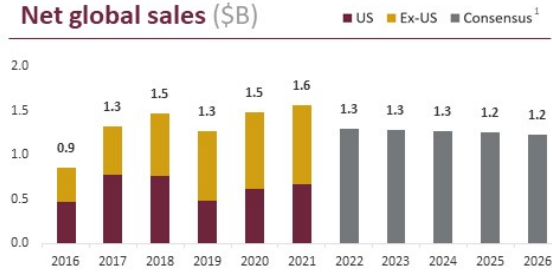
**RELVAR® / BREO®**  
**ELLIPTA®**  
 (fluticasone furoate 100 mcg and vilanterol 25 mcg inhalation powder)



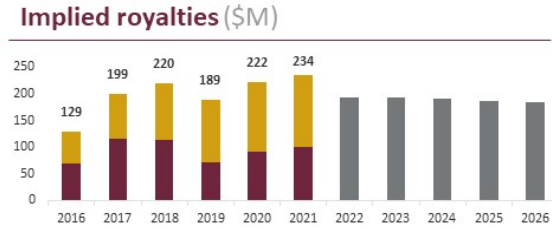
**Indications (US)**

- Long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with COPD
- Once-daily treatment of asthma in patients aged 18 years and older

Net global sales (\$B)



Implied royalties (\$M)



- Launched in 2013 as first and only once-daily ICS / LABA in the U.S.
- Relvar / Breo delivers superior, lasting proactive asthma control, with simple once-daily dosing in an easy-to-use device
- Fastest growing major ICS / LABA therapy globally
- Historical resilience in a competitive, volatile environment supported by positive demographic trends

1 – Projections per analyst consensus on GSK forecast website accessed Sept 8, 2022; GBP converted to USD using Sept 8 exchange rate of \$1.15; 2022-2026E royalties shown



# Anoro detail: Best-in-class long-acting beta-agonist / long-acting muscarinic antagonist for COPD

**ANORO<sup>®</sup>**  
**ELLIPTA<sup>®</sup>**  
 (umeclidinium 62.5 mcg and vilanterol 25 mcg inhalation powder)



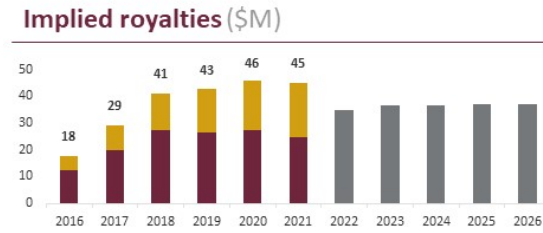
**Indications (US)**

- Long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with COPD

Net global sales (\$B)



Implied royalties (\$M)



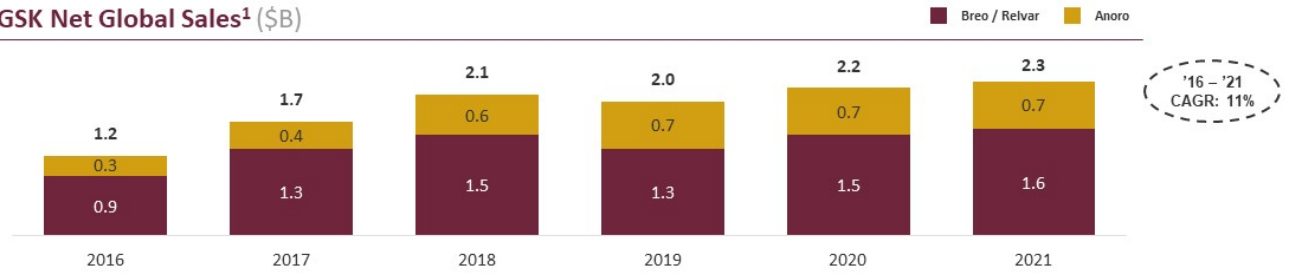
- Launched in 2014 as first-in-class LABA / LAMA single inhaler product in the U.S.
- ANORO delivers superior lung function improvement vs common initial maintenance therapy options<sup>2</sup>
- Class leader in the U.S. due to clear differentiation
- Long-term prospects supported by positive demographics

1 – Projections per analyst consensus on GSK forecast website accessed Sept 8, 2022; GBP converted to USD using Sept 8 exchange rate of \$1.15; 2022-2026E royalties shown  
 2 – Superior improvement in lung function has been demonstrated in clinical trials of ANORO vs. Tiotropium (LAMA) and Spiolto (LAMA/LABA)

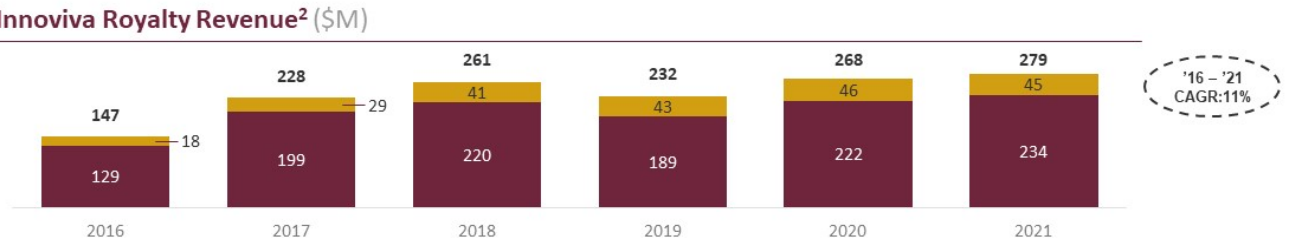


# Meaningful net global sales and royalty revenues from respiratory portfolio

### GSK Net Global Sales<sup>1</sup> (\$B)



### Innoviva Royalty Revenue<sup>2</sup> (\$M)



Note: May not sum due to rounding

1 - Reflects sales from Breo / Relvar, Anoro

2 - Excludes the impacts of amortization of capitalized fees and the MABA strategic alliance; reflects Trelegy royalties received by TRC; may not sum due to rounding



# Innoviva's portfolio products are protected by a robust IP estate with meaningful remaining exclusivity

	Primary US patent	Potential expiration	Key secondary US patent	Potential expiration
<b>RELVAR®/ BREO® ELLIPTA®</b>	Vilanterol drug substance <sup>1</sup>	2025	ELLIPTA device <sup>3</sup>	2030
<b>ANORO® ELLIPTA®</b>	Specified LABA/LAMA combination for treatment of COPD and asthma <sup>2</sup>	2030	Process for aggregating particles of umeclidinium and/or vilanterol and/or fluticasone furoate <sup>4</sup>	2033

Manufacturing complexity provides further protection

The terms of the collaboration agreement with GSK indicate that royalties will be paid until the later of:

- The expiration of the last patent covering each product in such country
- 15 years from first commercial sale of each product in such country

For each of the portfolio products, the secondary patent expiration date would be the later date for purposes of royalties

IP protection in international markets is generally longer dated than in the US

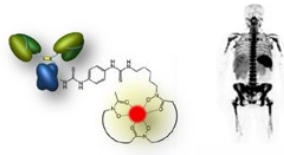
1 – US patent 7,439,393. Original expiration 9/11/2022, granted additional exclusivity to 2025 through 35 USC §156  
 2 – US patents 9,750,726 and 11,090,294  
 3 – US patent 8,746,242  
 4 – US patent 9,763,965



# Additional minority portfolio investments



ImaginAb is a leader in radio-pharmaceutical imaging with a differentiated solution for IO<sup>2</sup> patient care and other areas of unmet medical need



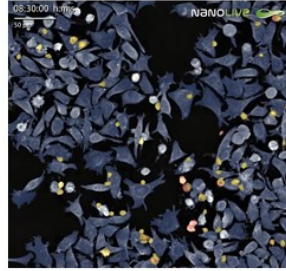
Gate Neurosciences is developing next-generation therapies for psychiatric and neurological disorders

Program	Mechanism	Disease Area	Preclinical	Ph1	Ph2a	Ph2	Ph3
Zelipratidol	NMDAR Modulator	Major Depressive Disorder (MDD) + other psychiatric disorders	█	█	█	█	█
Aprimetral	NMDAR Modulator	Acute Severe MDD + other acute psychiatric disorders	█	█	█	█	
GATE-252	NMDAR Modulator	Neurocognitive Disorders	█				
GATE-102	mGluR2/3 Antagonist	Central Sleep Disorders	█				
GATE-301	β2FP2 Mimetic	Neurocognitive Disorders	█				

\*Next Phase 2 study to be initiated in 2022.



Nanolive is a microscopy company that has developed a method for live cell 3D imaging and analysis with applications across drug discovery and biotech R&D



InCarda focuses on cardiovascular diseases; its lead drug is in late-stage development for large, attractive PAF<sup>1</sup> market

Product Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory Approval
InRhythm™ Under Medical Supervision INSTANT Phase 2	█	█	█		
InRhythm™ For Patient Self-Administration (At-Home, Out of Hospital)	█	█	█		
Persistent AF Programs	█	█			
Additional Cardiology Programs	█				

1 – Paroxysmal atrial fibrillation  
2 – Immuno-oncology



# Innoviva's platform optimizes for lean, focused value creation leveraging superior capabilities

**Innoviva is well positioned for strong execution**

## Low-cost, efficient operating platform



Our key operations principles are **cost discipline, flexibility, and value orientation**, while ensuring we are well-resourced to execute

- Lean expense structure; 2021 G&A expense totaled ~\$16m
- Flexibility and scalability are key
- Strong revenue conversion to income and cashflows

## Best-in-class internal capabilities



Management team and board members have **significant functional and industry expertise** with **proven track records** in key areas utilized both at Innoviva and our investees

- Medicine, science, and R&D; M&A and investments; governance and management; strategy and planning; commercial and operations

## Superior external resources access



**Deep, multi-year relationships across healthcare ecosystem** enabling differentiated market exposure and talent pool access

- External advisors, investment community, industry, government, patient groups, and others