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): **May 24, 2023**

INNOVIVA, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-30319**	**94-3265960**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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. ☐

Item 7.01. Regulation FD Disclosure.

On May 24, 2023, 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
104	Cover Page Interactive File (the cover page tags are embedded within the Inline XBRL document)

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.

INNOVIVA, INC.

Date: May 24, 2023

By: /s/ Pavel Raifeld
Pavel Raifeld
Chief Executive Officer

INNOVIVA™

Corporate Presentation

May 2023

Forward-looking statements

The information in this presentation contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Securities Act"). Such forward looking statements involve substantial risks, uncertainties and assumptions. All statements in this herein, other than statements 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," "pursuing," "will," "would" and similar expressions (including the negatives thereof) are intended to identify forward looking statements, although not all forward looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward looking statements and the assumptions underlying our forward looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward looking statements. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward looking statements that we make. All written and verbal forward looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Important factors that we believe could cause actual results or events to differ materially from our forward looking statements include, but are not limited to, risks related to: lower than expected future royalty revenue from respiratory products partnered with GSK, the commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA®, GIAPREZA®, XERAVA® and XACDURO® in the jurisdictions in which these products have been approved; the strategies, plans and objectives of the Company (including the Company's growth strategy and corporate development initiatives); 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.

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, 2022 filed with the Securities and Exchange Commission ("SEC") on February 28, 2023, ("2022 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 at a glance

- Strongly cashflow-positive, durable core royalty business stemming from widely used respiratory products
- Commercial stage, growth-oriented critical care and infectious disease assets supported by late-stage pipeline
- Diversified, valuable portfolio of healthcare assets
- Thoughtful, robust approach to long-term capital deployment
- Strong track record and value creation focus

INNOVIVA

Innoviva has a diversified, valuable portfolio of royalties and other healthcare assets

Royalty assets

Durable royalty stream from two widely used, differentiated respiratory products marketed by GSK

	LTM royalty revenue
RELVAR® / BREO® ELLIPTA®	$210M
ANORO® ELLIPTA®	$39M

Innoviva Specialty Therapeutics assets

Robust, growing therapeutic platform anchored by two marketed products, an upcoming launch, and a late-stage pipeline

$55M[1] LTM net product sales and license revenue

GIAPREZA® (angiotensin II)

XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use

XERAVA® (eravacycline) for injection

Zoliflodacin

Strategic healthcare assets

Diversified portfolio of promising healthcare assets with high growth potential currently valued at over $450M[2]

ISP fund

ARMATA PHARMACEUTICALS

ImaginAb

GATE NEUROSCIENCES

INCARDA Therapeutics, Inc.

NANOLIVE Looking inside life

Over $230M net income generated in last twelve months (LTM)

1. Net product sales includes metrics prior to La Jolla acquisition by Innoviva
2. As of 3/31/2023, ISP Fund valued at $318M, Armata ownership valued at $88M, and other assets valued at $50M per the Company 10Q

Note: LTM in this presentation refers to twelve months ending March 31, 2023.

Royalty Assets

Our royalty assets, composed of widely used respiratory therapies commercialized by GSK, have produced durable, resilient revenues that are de-risked via geographic and drug class diversification

Product	LTM global net sales	5-year consensus projected sales[1]	Royalty rate	5-year projected royalty to Innoviva[1]
 **RELVAR® / BREO® ELLIPTA®** First once-daily inhaled corticosteroid / long-acting beta-agonist for asthma and chronic obstructive pulmonary disease	**$1.4B**	**$6.6B**	**15%[2]**	**~$1B**
 **ANORO® ELLIPTA®** Best-in-class long-acting beta-agonist /long-acting muscarinic antagonist for COPD	**$0.6B**	**$2.9B**	**6.5%[3]**	**~$0.2B**
			Total	**~$1.2B**

1. Projections per analyst consensus on GSK forecast website accessed May 10, 2023; GBP converted to USD using May 10 exchange rate of $1.26; implied 2023-2027E royalties shown
2. 15% on first $3B in annual sales; 5% on sales over $3B
3. Tiered 6.5-10.0%

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Royalty Assets

Relvar/Breo and Anoro are protected by an IP estate with meaningful remaining exclusivity

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

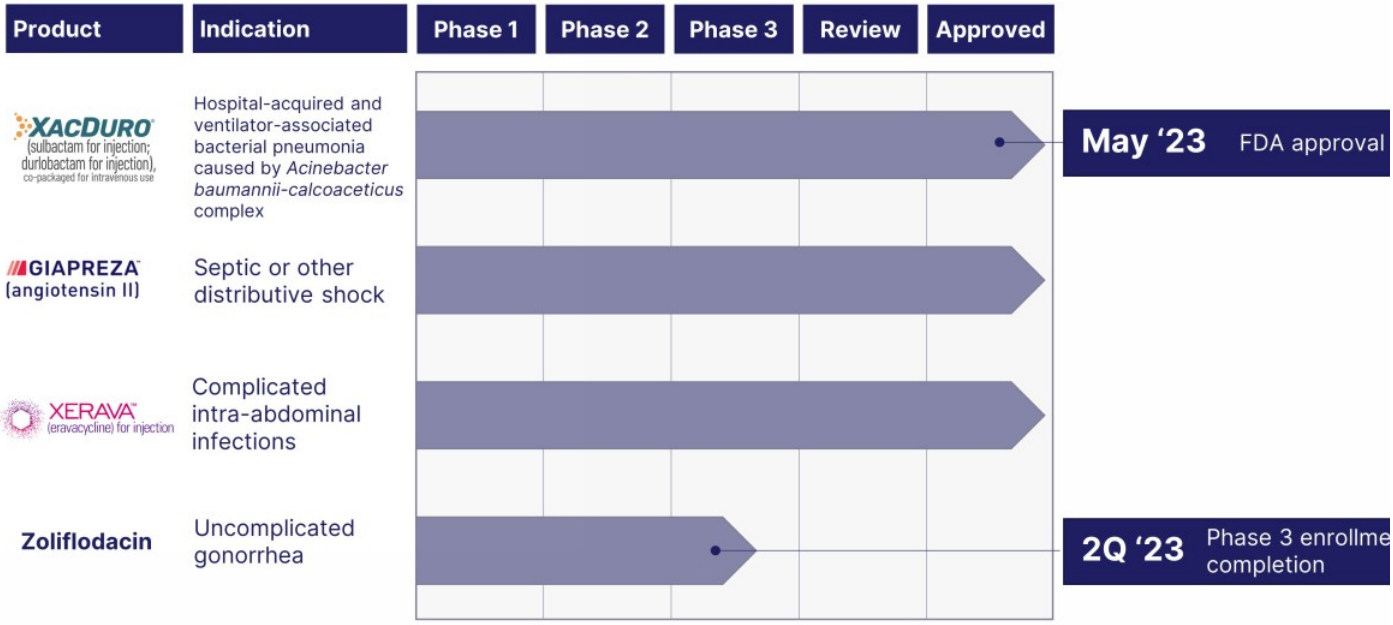
For each of the portfolio products, the secondary patent expiration date would be the later date for purposes of royalties

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

Innoviva Specialty Therapeutics Assets

Our recent acquisitions of Entasis Therapeutics and La Jolla Pharmaceutical Company formed a robust, growing commercial business supported by an attractive late-stage pipeline



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Innoviva Specialty Therapeutics Assets

XACDURO is an important therapy to address serious infections for which there is a significant unmet need

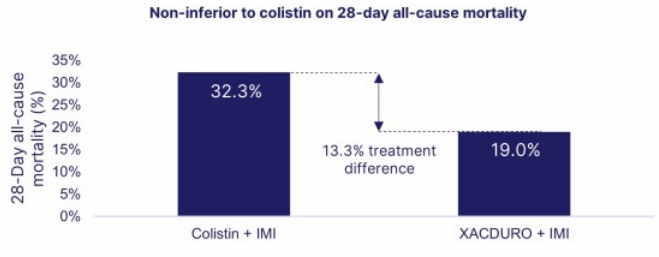
About XACDURO

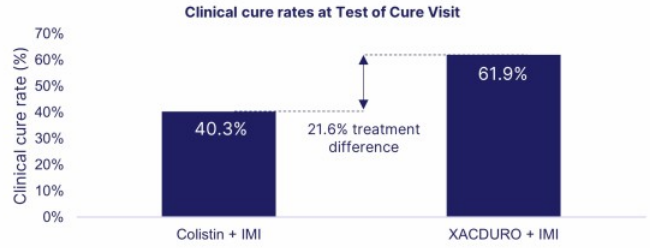
XACDURO is the **first pathogen-targeted therapy approved** for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus* complex

Drug resistant *Acinetobacter* has been identified by the CDC as an **urgent global public health threat with over 300K annual deaths**[1] associated with carbapenem-resistant infections worldwide

XACDURO demonstrated statistical **non-inferiority to colistin** on 28-day all-cause mortality in patients with carbapenem-resistant *Acinetobacter* infections. Clinical cure rates in the CRABC m-MITT population at the Test of Cure (TOC) Visit were **61.9% for XACDURO versus 40.3% for colistin**

Results from pivotal ATTACK trial[2]





1. Antimicrobial Resistance Collaborators *Lancet* 2022; 399: 629–55
2. Kaye et al. *Lancet Infect Dis.* 2023 May 11:S1473-3099(23)00184-6

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Innoviva Specialty Therapeutics Assets

GIAPREZA's mechanism of action enables rapid and effective vasoconstriction for critically ill patients

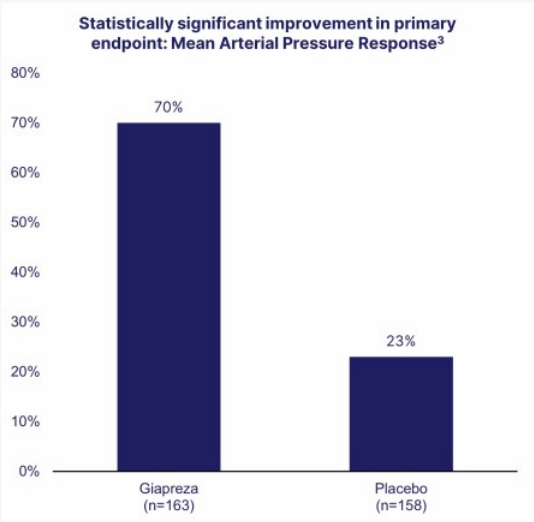
About GIAPREZA

GIAPREZA is a **vasoconstrictor** approved to increase blood pressure in adults with septic or other distributive shock

More than 150K shock patients each year fail 1st and 2nd line vasopressor therapies and need a rapid-acting option with a unique mechanism of action[1]

GIAPREZA mimics the body's **endogenous angiotensin II peptide** which is central to the renin-angiotensin-aldosterone system that naturally regulates blood pressure

Results from pivotal ATHOS-3 trial[2]



1. Estimate based on: 35.4% 28-day mortality rate from Russell et al, New England Journal of Medicine 2008; 358:877-87; 48.5% 28-day mortality rate from De Backer et al, New England Journal of Medicine 2010; 362:779-789; and 54.6% non-responder rate from Sacha et al, Annals of Intensive Care 2018; 8:35; 2; N Engl J Med 2017;377:419-430; 3. MAP of 75 mm Hg or higher or an increase in MAP from baseline of at least 10 mm Hg at Hour 3 without an increase in the dose of background vasopressors

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Innoviva Specialty Therapeutics Assets

XERAVA is a broad spectrum, potent antibiotic that addresses ESBL and other resistance related to overreliance on carbapenems and beta lactams

About XERAVA

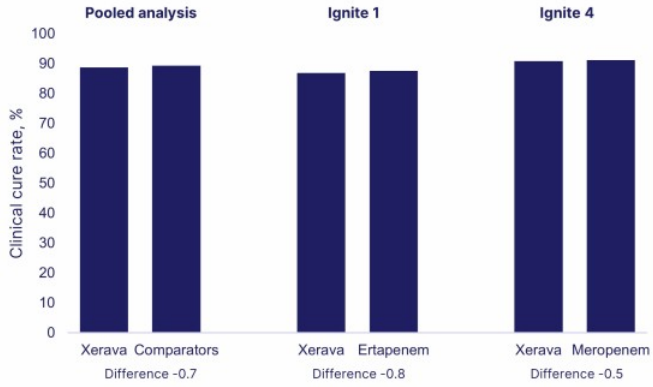
XERAVA is a tetracycline-class antibiotic indicated for the treatment of **complicated intra-abdominal infections (cIAI)** caused by susceptible microorganisms

XERAVA is **2 to 4 times more potent than tigecycline in vitro** against gram-positive and gram-negative bacteria[2]

Proven to be as non-inferior to two leading carbapenems in cIAI patients and a critical alternative to combat **growing ESBL-related resistance**[1]

Results from pivotal Phase 3 trials[1]

Clinical response in micro-ITT population at the TOC visits showed non-inferiority to ertapenem and meropenem



Concurrent bacteremia was present in 32 patients in the XERAVA group and 31 patients in the pooled micro-ITT population; the rates of clinical response were 87.5% for XERAVA and 77.0% for comparators

1. JAMA Surg, 2017;152(3):224-232, Clin Infect Dis. 2019;69(6):921-929
2. Zhanel GG, Cheung D, Adam H, et al. Review of eravacycline, a novel fluorocycline antibacterial agent. Drugs. 2016;76(5):567-588.

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Innoviva Specialty Therapeutics Assets

Therapeutic assets are a key value driver providing excellent growth potential and significant embedded operating leverage

Critical care and infectious disease are important areas due to high unmet medical need and scarce capital access

- The pressing need for novel therapeutics is becoming a **serious global threat**, especially for drug resistant infections
- Historical underinvestment exacerbated development and commercial challenges, creating **opportunity to acquire de-risked assets at attractive valuations**

The combination of Entasis and La Jolla uniquely positions us for success in this sector

- Our advantage is driven by **long-term vision and expertise** combined with Entasis' **innovation** capabilities and La Jolla's historically targeted, robust **commercial platform**
- Asset differentiation and benefits of scale expected to drive value creation

Goals for the business focus on growth and expansion while ensuring profitability

- **3+ differentiated products** on the market by end of year with strong growth profile
- Robust commercial platform for hospital specialty therapeutics
- Innoviva seen as **a leader** in critical care and infectious disease space

Strategic Healthcare Assets

Our robust portfolio of strategic healthcare assets in areas of high unmet medical need with significant long term value creation potential

		Value as of 3/31/2023[1]
Innovative anti-infectives R&D	• **Armata has R&D and manufacturing capabilities** along with a platform in bacteriophages, a new therapeutic modality	**$88M**
Minority investments in high growth areas	• Strategic equity investments in **high-potential healthcare companies** with significant promise	**$50M**
ISP Fund providing further exposure to healthcare	• $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	**$318M**

1. Innoviva 1Q2023 10-Q

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Innoviva has actively deployed capital to maximize shareholder value

We thoughtfully approach capital deployment with a strong value focus

1. Includes $300M placed with ISP fund, approximately $125M deployed into Armata, and over $50M deployed into investments into InCarda, ImaginAb, Nanolive and Gate Neurosciences.

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Innoviva has robust financials with multiple sources of value

$250M	**$55M[1]**	**$233M**
Anoro & Breo Royalty Revenue (LTM)	Net Product Sales and License Revenue (LTM)	Net Income attributable to Innoviva stockholders (LTM)
$144M	**$456M**	**$454M**
Cash and Cash Equivalents (as of March 31, 2023)	Equity and Long-term Investments (as of March 31, 2023)	Debt (as of March 31, 2023)

1. Includes revenues prior to Innoviva's acquisition of La Jolla Pharmaceutical
Note: Numbers shown for the twelve months ending March 31, 2023, unless otherwise noted

INNOVIVA

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
Management Team	**Pavel Raifeld, Chief Executive Officer**	Experienced finance and life sciences professional; formerly with Sarissa Capital, Credit Suisse, McKinsey and BCG
	Marianne Zhen, CPA, Chief Accounting Officer	Experienced finance professional with over 20 years in accounting and strategic operations
Board of Directors	**Mark DiPaolo, Esq., Chairperson**	Senior Partner and General Counsel at Sarissa Capital; former senior member Icahn Capital's investment team
	Deborah L. Birx, M.D.	Physician-scientist and healthcare leader; former response coordinator of The White House Coronavirus Task Force
	Jules Haimovitz	Founder, executive, and director of multiple companies in life sciences and entertainment; former director of Ariad Pharma
	Odysseas Kostas, M.D.	Partner and Senior Managing Director at Sarissa Capital; former life sciences analyst at Evercore ISI and physician
	Sarah J. Schlesinger, M.D.	Professor at Rockefeller University with governance and clinical / medical expertise; former director of MDCO and Ariad Pharma
	Sapna Srivastava, Ph.D.	Senior biopharma executive; former CFO at Abide and Intellia; senior biotech analyst at GS and MS; experienced director

INNOVIVA

INNOVIVA

Thank you

Investor contact: Innoviva@argotpartners.com

Media contact: InnovivaMedia@grcomms.com

Appendix

INNOVIVA

Royalty assets

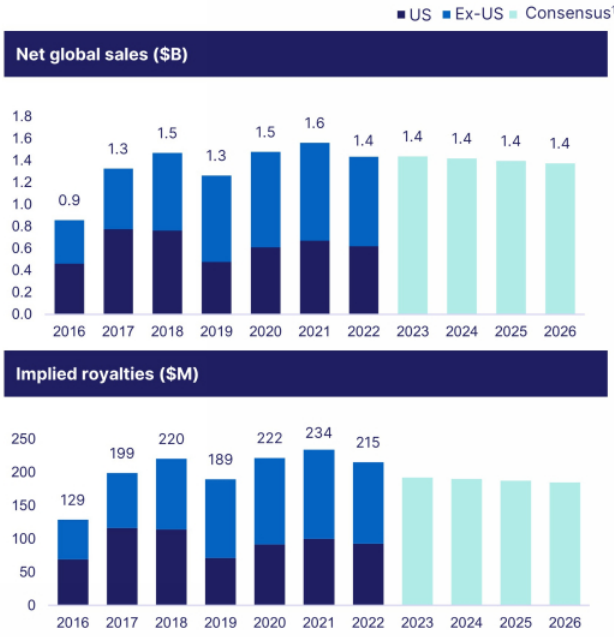
Relvar / Breo detail: First once-daily inhaled corticosteroid / long-acting beta-agonist for asthma and chronic obstructive pulmonary disease

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



- Launched in 2013 as first and only once-daily ICS / LABA in the US
- 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 May 10, 2023; GBP converted to USD using May 10 exchange rate of $1.26; 2023-2027E royalties shown

INNOVIVA

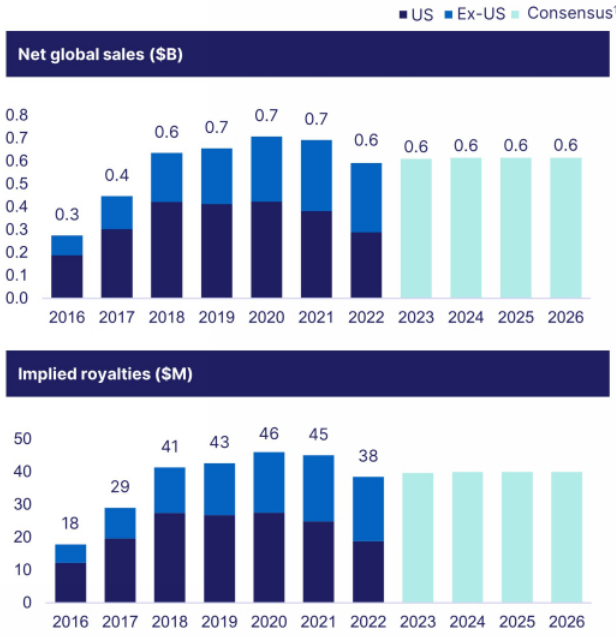
Anoro detail: Best-in-class long-acting beta-agonist / long-acting muscarinic antagonist for COPD

ANORO® ELLIPTA®

(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



- Launched in 2014 as first-in-class LABA / LAMA single inhaler product in the US
- ANORO delivers superior lung function improvement vs common initial maintenance therapy options[2]
- Class leader in the US due to clear differentiation
- 2022 net sales decline due to idiosyncratic pricing pressures in the US

1. Projections per analyst consensus on GSK forecast website accessed May 10, 2023; GBP converted to USD using May 10 exchange rate of $1.26; 2023-2027E royalties shown
2. Superior improvement in lung function has been demonstrated in clinical trials of ANORO vs. Tiotropium (LAMA) and Spiolto (LAMA/LABA)

Innoviva Specialty Therapeutics Assets

Zoliflodacin is a novel, promising drug candidate in an area of unmet medical need

About Zoliflodacin

Zoliflodacin is a novel orally administered antibiotic developed for the treatment of uncomplicated gonorrhea

Gonorrhea is one of the **most commonly diagnosed sexually transmitted infections** in the U.S. and globally

We believe there is a growing unmet need for a **single-dose oral** antibiotic that will reliably treat patient with gonorrhea, including multidrug-resistant strains which are emerging globally

Clinical development of zoliflodacin is sponsored by our nonprofit collaborator, the **Global Antibiotic Research and Development Partnership**, responsible for Phase 3 clinical trial conduct and clinical development expenses

The Phase 3 trial is designed to demonstrate **non-inferiority to ceftriaxone**, the current standard of care for gonorrhea treatment

Compelling results from Phase 2 trial

The NEW ENGLAND JOURNAL of MEDICINE

N ENGL J MED 379;19 NEJM.ORG NOVEMBER 8, 2018

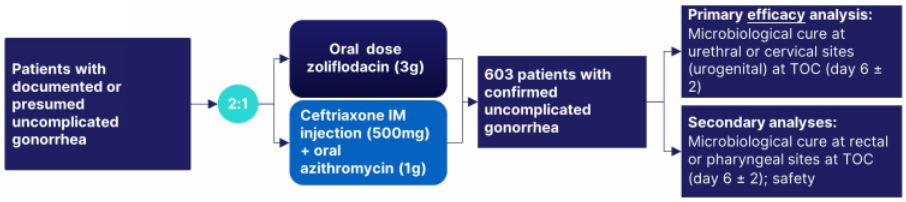
Microbiological Efficacy[1]

Anatomic Site	Zoliflodacin (3 g)	Ceftriaxone
Urogenital	47/47 (100%)	21/21 (100%)
Pharyngeal	7/9 (78%)	4/4 (100%)
Rectal	6/6 (100%)	3/3 (100%)

[1]Represents results for the per-protocol population.

- Trial results showed urogenital **efficacy in 47 out of 47 patients**
- Zoliflodacin was generally well tolerated at clinically effective doses

Phase 3 trial expected to complete in 2023



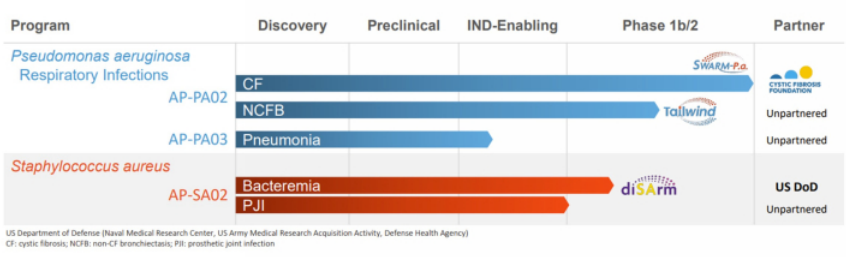
INNOVIVA

Strategic Healthcare Assets

Armata is an innovator in anti-infectives addressing significant unmet medical need

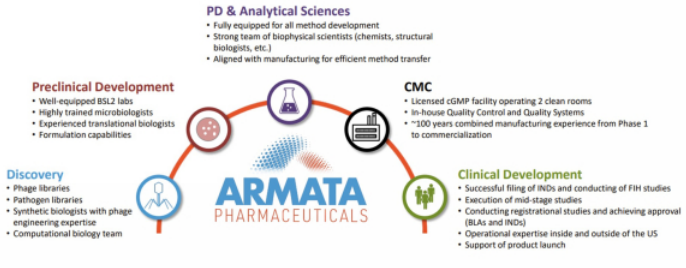
Armata is a clinical-stage biotechnology company focused on the development of precisely targeted bacteriophage therapeutics for the treatment of antibiotic-resistant and difficult-to-treat bacterial infections

Diverse bacteriophage pipeline with multiple "shots on goal"



US Department of Defense (Naval Medical Research Center, US Army Medical Research Acquisition Activity, Defense Health Agency)
CF: cystic fibrosis; NCFB: non-CF bronchiectasis; PJI: prosthetic joint infection

Broad, robust capabilities



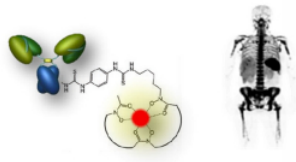
INNOVIVA

Strategic Healthcare Assets

Additional minority portfolio investments

ImaginAb

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



GATE NEUROSCIENCES

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

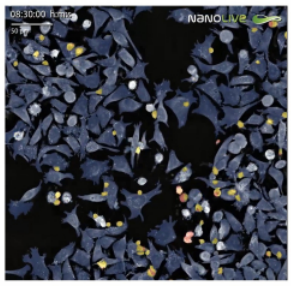
Program	Mechanism	Disease Area	Preclinical	Ph1	Ph2a	Ph2	Ph3
Zolpidem	NMDAR Modulator	Major Depressive Disorder (MDD) + other psychiatric disorders					
Apimostinel	NMDAR Modulator	Acute Severe MDD + other acute depression subsets					
GATE-252	NMDAR Modulator	Neurocognitive Disorders					
GATE-102	mGluR2/3 Antagonist	Central Sleep Disorders					
GATE-301	IGFBP2 Mimetic	Neurocognitive Disorders					

*Next Phase 2 study to be initiated in 2022.

NANOLIVE

Looking inside life

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 Therapeutics, Inc.

InCarda focuses on cardiovascular diseases; its lead drug is in late-stage development for PAF[1]

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