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): **December 13, 2021**

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 December 13, 2021, Innoviva, Inc. (the "Company") made available on its website a 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: December 13, 2021

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

Exhibit 99.1

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 ("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®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA® 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, 2020 filed with the Securities and Exchange Commission ("SEC") on February 25, 2021, ("2020 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 combines sustainable royalty cashflows with a long-term capital deployment strategy to drive innovation and maximize shareholder value

Robust, valuable royalty portfolio

Significant royalties from a durable and growing portfolio of blockbuster respiratory products

+

Thoughtful, accretive capital deployment

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

=

Long-term shareholder value creation

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

Over $300M net income to Innoviva shareholders generated in the last twelve months[1]

1 – As of September 30, 2021

Royalty portfolio

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

	Key royalty terms	2020 global net sales ($B)	2020 Innoviva royalties[1] ($M)	5-year projected royalties[1,2] ($B)
RELVAR®/ BREO® ELLIPTA® Asthma / COPD	15% on first $3B in annual sales; 5% on sales over $3B 100% economics	1.5	222	1.1
ANORO® ELLIPTA® COPD	Tiered 6.5-10.0% 100% economics	0.7	46	0.25
TRELEGY® ELLIPTA® Asthma / COPD	Tiered 6.5-10.0% 15% economics[1]	1.1	73	0.9
Totals		**$3.3B**	**$341M**	**~$2.2B**

1 – Trelegy royalties are assigned to Theravance Respiratory Company LLC, a subsidiary of Innoviva, where Theravance Biopharma holds 85% economic interest; 100% royalty economics shown
2 – Projections per analyst consensus on GSK forecast website accessed Nov 26, 2021; GBP converted to USD using Nov 26 exchange rate of $1.33; 2021-2025E royalties shown

Royalty portfolio

Our royalty product portfolio has demonstrated resilience and growth; we remain excited about its long-term potential while we build out the next generation of high impact products

Sizeable and differentiated	• Differentiated respiratory therapies portfolio with over $3B annual sales • Consensus projections imply royalties of **$2B+ over the next 5 years**[1]
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 growing	• Broad portfolio covers **all major respiratory drug classes** in easy-to-use single daily dose form • Portfolio contains products across the life cycle, including relatively **mature standard of care therapies** (Breo / Relvar, Anoro) and **fast-growing innovative products** (Trelegy) • Products approved and launching in **multiple geographies and indications**, reducing single-market risk

1 – Projections per analyst consensus on GSK forecast website accessed Nov 26, 2021; GBP converted to USD using Nov 26 exchange rate of $1.33; 100% Trelegy royalties included; 2021-2025E

Innoviva actively deploys 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**

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

Over the past twelve months we strategically repurchased GSK's equity stake for ~$400M and deployed $300M+ into high-potential assets – with $500M+ equity and investments currently on the balance sheet

Note: $507M equity and long-term investments assets on balance sheet as of September 30, 2021

Capital deployment

Strategic transactions detail: we approach deals in a thoughtful and disciplined manner

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**

Strategic investment execution

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 (across strategy, finance, development, commercial, governance, and other areas) as a key value creation driver

Strategic investment case study: infectious disease

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 specific bacterial diseases, along with viral and fungal diseases

Infectious disease 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

ENTASIS THERAPEUTICS

$68M cost basis
$166M fair value[1]
~60% ownership

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

- Novel potential carbapenem-resistant Acinetobacter treatment SUL-DUR has significant commercial promise following favorable efficacy and safety in pivotal trial
- Ongoing Phase 3 trial for gonorrhea antibiotic
- "Rational design" platform used to develop earlier stage antibiotics less susceptible to resistance

ARMATA PHARMACEUTICALS

$45M cost basis
$89M fair value[1]
~60% 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
- Broad development program with lead therapy focused on respiratory Pseudomonas aeruginosa infections in cystic fibrosis patients, an area of high unmet need

1 – Investment fair value as of September 30, 2021

Capital deployment

Innoviva is the sole manager of all Trelegy royalties via TRC, seeking to maximize long-term equity holder value

Additional detail in the appendix

An Innoviva subsidiary, **Theravance Respiratory Company LLC (TRC), receives all Trelegy royalties** from GSK

- $109M LTM[1] with approximately $900M projected over 5 years based on consensus estimates

Innoviva as Manager of TRC has a broad mandate and responsibility to maximize the value of TRC both by **active management of the Trelegy royalties** and via **strategic investments**

- Ultimately, 15% economics accrue to Innoviva (and 85% to Theravance Biopharma)
- Theravance Biopharma unsuccessfully challenged our ability to make investments in arbitration

Additional active strategic investing anticipated seeking significant value creation (with uncertainty removed due to the successful resolution of the Theravance Biopharma arbitration) in light of strong current opportunity set, benefiting from our long-term orientation

1 – Ending 3Q2021; Projections per analyst consensus on GSK forecast website accessed Nov 26, 2021; GBP converted to USD using Nov 26 exchange rate of $1.33; projections shown for 2021-2025E

Value creation

Innoviva's management and board have world-class expertise in healthcare and single-minded focus on value creation – brought to bear for the benefit of shareholders

The 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, Chief Accounting Officer	Experienced finance professional with over 20 years in accounting and strategic operations
Board of directors	**George Bickerstaff, Chairperson**	Managing Director at M.M. Dillon & Co.; former CFO of Novartis Pharma AG and IMS Health; director of CareDx
	Deborah L. Birx, M.D.	Physician-scientist and healthcare leader; former response coordinator of The White House Coronavirus Task Force
	Mark DiPaolo, Esq.	Senior Partner and General Counsel at Sarissa Capital; former senior member of Icahn Capital's investment team
	Jules Haimovitz	Founder, executive, and director of multiple companies across industries; former director of Ariad Pharma and ImClone
	Odysseas Kostas, M.D.	Partner and Senior Managing Director at Sarissa Capital; former biopharma analyst at Evercore ISI and practicing physician
	Sarah J. Schlesinger, M.D.	Professor at Rockefeller University with governance and clinical / science expertise; former director of The Medicines Company and Ariad Pharma

Why Innoviva

1. Strongly cashflow-generative, diversified and durable core royalty business
2. Deep and proven healthcare expertise – across governance, strategy, R&D, commercial, finance, and operations – brought to bear across everything we do
3. Thoughtful, robust approach to capital deployment with long-term horizon
4. Strong track record of growth and unrelenting value creation focus
5. Efficient and flexible platform enabling meaningful, sustainable value generation

Q1 – Q3 2021 highlights

- $295M revenues[1]
- $265M net cash provided by operating activities
- $2.96 basic net income per share[2]
- Strategically repurchased GSK's 32% equity stake for $392M
- Deployed $~50M in healthcare assets
- Added healthcare / infectious disease leader Deborah L. Birx to the Board

1 – Revenues include 100% Trelegy contribution
2 – $2.63 diluted net income per share; attributable to Innoviva stockholders

Appendix

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

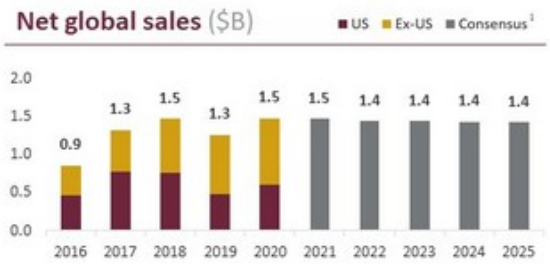
RELVAR® / BREO® ELLIPTA®

(fluticasone furoate 100 mcg and vilanterol 25 mcg inhalation powder)

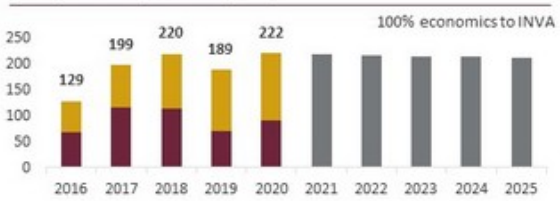
Indications (US)

- 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 US
- Relvar / Breo delivers superior, lasting proactive asthma control, with simple once-daily dosing in an easy-to-use device
- Historical resilience in a competitive, volatile environment supported by positive demographic trends

1 – Projections per analyst consensus on GSK forecast website accessed Nov 26, 2021; GBP converted to USD using Nov 26 exchange rate of $1.33

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

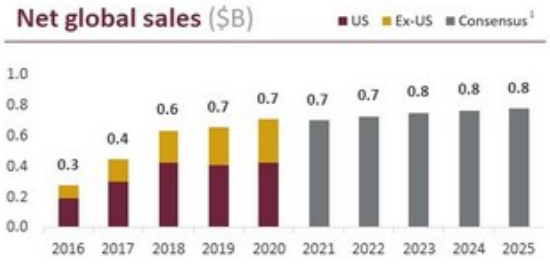
ANORO® ELLIPTA®

(umeclidinium 62.5 mcg and vilanterol 25 mcg inhalation powder)

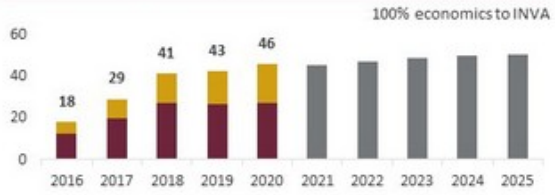
Indications (US)

- Long-term, once-daily, maintenance treatment of airflow obstruction 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 US
- Anoro delivers superior lung function improvement vs common initial maintenance therapy options[2]
- Class leader in the US due to clear differentiation
- Long-term prospects supported by positive demographics

1 – Projections per analyst consensus on GSK forecast website accessed Nov 26, 2021; GBP converted to USD using Nov 26 exchange rate of $1.33
2 – Superior improvement in lung function has been demonstrated in clinical trials of Anoro vs. Tiotropium (LAMA) and Spiolto (LAMA/LABA)

Royalty portfolio

Trelegy detail: First 3-in-1 inhaled corticosteroid / long-acting beta-agonist / long-acting muscarinic antagonist for COPD and asthma

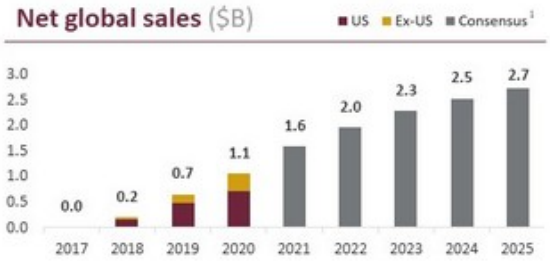
TRELEGY® ELLIPTA®

(fluticasone furoate 100 mcg, umeclidinium 62.5 mcg and vilanterol 25 mcg inhalation powder)

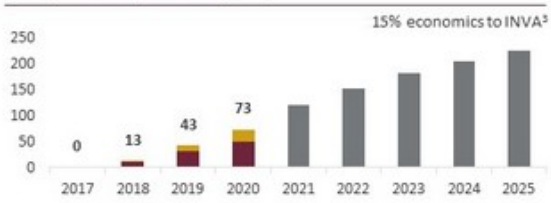
Indications (US)

- Long-term, once-daily, maintenance treatment of patients with COPD, including chronic bronchitis and/or emphysema
- Once-daily treatment of asthma in patients aged 18 years and older

Net global sales ($B)



Implied royalties ($M)



- Launched in 2017 as first-in-class ICS / LABA / LAMA single inhaler product in the US
- Trelegy demonstrated superior efficacy in clinical trials for COPD vs double combination drug classes[2]
- Strong growth driven by demographic tailwinds, increasing class adoption, and share increase across geographies

1 – Projections per analyst consensus on GSK forecast website accessed Nov 26, 2021; GBP converted to USD using Nov 26 exchange rate of $1.33
2 – FULFIL trial vs. Symbicort (ICS/LABA). IMPACT study vs. ICS/LABA and LAMA/LABA
3 – Trelegy royalties are assigned to Theravance Respiratory Company LLC, a subsidiary of Innoviva, where Theravance Biopharma holds 85% economic interest; 100% royalty economics shown

Royalty portfolio

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
RELVAR®/ BREO® ELLIPTA®	Vilanterol drug substance[1]	2025	ELLIPTA device[4]	2030
ANORO® ELLIPTA®	Specified LABA/LAMA combination for treatment of COPD and asthma[2,3]	2030	Process for aggregating particles of umeclidinium and/or vilanterol and/or fluticasone furoate[5]	2033
TRELEGY® ELLIPTA®	Specified LABA/LAMA combination for treatment of COPD and asthma[2,3]	2030	Process for aggregating particles of umeclidinium and/or vilanterol and/or fluticasone furoate[5]	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 frequently longer dated than in the US

1 – US patent 7439393. Original expiration 9/11/2022, granted additional exclusivity to May 2025 through 35 USC §156
2 – US patents 9750726 and 11090294
3 – Umeclidinium (contained in Anoro and Trelegy) is covered by US drug substance patent 7488827; original expiration 4/27/2025, granted extension to Dec 2027 through 35 USC §156
4 – US patent 8746242
5 – US patent 9763965

TRC additional information

Arbitration background

- While TRC actively manages its royalty-producing relationship with GSK, under the LLC Agreement TRC is permitted to "engage in any lawful business"; additionally, Innoviva was granted broad "decision-making authority as to the LLC"
- There have been two separate arbitrations brought by Theravance Biopharma against Innoviva and TRC over the last two years challenging the scope of Innoviva's authority as Manager of TRC to deploy capital rather than simply distribute royalty income
- The arbitrator ruled in favor of Innoviva and TRC in both arbitrations. The arbitrator has confirmed that the LLC Agreement broadly empowers the LLC to engage in any lawful business and that Innoviva has the "discretion" and "freedom" under the LLC Agreement to determine how to use the LLC's cash, including in investments unrelated to Trelegy. The arbitrator did not enjoin TRC from making additional investments
- Each of the arbitrator's decisions is publicly available

Example investments

INCARDA Therapeutics, Inc.

InCarda focuses on cardiovascular diseases; its lead drug is in late stage development for large, attractive PAF[1] market

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

1 – Paroxysmal atrial fibrillation
2 – Immuno-oncology