

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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): January 10, 2022 (January 10, 2022)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction of incorporation)

000-19034
(Commission
File Number)

13-3444607
(I.R.S. Employer
Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York
(Address of principal executive offices)

10591-6707
(Zip Code)

Registrant's telephone number, including area code: (914) 847-7000

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 Instructions 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 \$0.001 per share	REGN	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 2.02. Results of Operations and Financial Condition.

On January 10, 2022, at the virtual 40th Annual J.P. Morgan Healthcare Conference, Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”), and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron, are providing a corporate update.

The presentation includes information regarding the Company’s preliminary (unaudited) U.S. net product sales of EYLEA[®] (afibercept) Injection of approximately \$5.79 billion for the full year 2021 (based on preliminary (unaudited) fourth quarter 2021 U.S. net product sales of EYLEA of approximately \$1.54 billion).

The presentation also includes information regarding the Company’s preliminary (unaudited) U.S. net product sales of REGEN-COV[®] (casirivimab and imdevimab) of approximately \$5.82 billion for the full year 2021 (based on preliminary (unaudited) fourth quarter 2021 U.S. net product sales of REGEN-COV of approximately \$2.29 billion).

Item 7.01. Regulation FD Disclosure.

The information set forth under Item 2.02 of this Current Report on Form 8-K is incorporated by reference herein. A copy of the presentation referenced in Item 2.02 is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in this Item 7.01.

The information included in Item 2.02 and the information included or incorporated in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

[99.1](#) [Presentation by Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron Pharmaceuticals, Inc., at the virtual 40th Annual J.P. Morgan Healthcare Conference.](#)

104 Cover Page Interactive Data File - the cover page XBRL tags are 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.

REGENERON PHARMACEUTICALS, INC.

/s/ Joseph J. LaRosa

Joseph J. LaRosa

Executive Vice President, General Counsel and Secretary

Date: January 10, 2022

JP Morgan Healthcare Conference 2022

January 2022

REGENERON[®]

This non-promotional presentation is intended for the investor audience and contains investigational data as well as forward-looking statements; actual results may vary materially

Note regarding forward-looking statements & non-GAAP financial measures

This presentation includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation EYLEA® (afibercept) injection, Dupixent® (dupilumab), Libtayo® (cemiplimab), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza™ (evinacumab), Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebgn), REGEN-COV® (casirivimab and imdevimab), fasinumab, garefotamab, pozelimab, odronextamab, itepekimab, REGN5458, REGN5713-5714-5715, REGN1908-1909, Regeneron's and its collaborators' other oncology programs (including its costimulatory bispecific portfolio), Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including without limitation those listed above; the likelihood and timing of achieving any of the anticipated milestones described in this presentation; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval, ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties on the commercial success of Regeneron's Products and Regeneron's Product Candidates; the availability and extent of reimbursement of Regeneron's Products from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payors and new policies and procedures adopted by such payors; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA, Dupixent, Praluent, and REGEN-COV), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition; and the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's agreement with Roche relating to the casirivimab and imdevimab antibody cocktail (known as REGEN-COV in the United States and Ronapreve™ in other countries) and its REGEN-COV supply agreement with the U.S. government, to be cancelled or terminated. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

This presentation uses total revenues excluding REGEN-COV, which is a financial measure that is not calculated in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). This and other non-GAAP financial measures are computed by excluding certain non-cash and other items from the related GAAP financial measure. Non-GAAP adjustments also include the income tax effect of reconciling items. The Company makes such adjustments for items the Company does not view as useful in evaluating its operating performance. For example, adjustments may be made for items that fluctuate from period to period based on factors that are not within the Company's control, such as the Company's stock price on the dates share-based grants are issued. Management uses non-GAAP measures for planning, budgeting, forecasting, assessing historical performance, and making financial and operational decisions, and also provides forecasts to investors on this basis. Additionally, non-GAAP measures provide investors with an enhanced understanding of the financial performance of the Company's core business operations. However, there are limitations in the use of non-GAAP financial measures as they exclude certain expenses that are recurring in nature. Furthermore, the Company's non-GAAP financial measures may not be comparable with non-GAAP information provided by other companies. Any non-GAAP financial measure presented by Regeneron should be considered supplemental to, and not a substitute for, measures of financial performance prepared in accordance with GAAP. A reconciliation of the non-GAAP financial measure used in this presentation is provided on slide 28.

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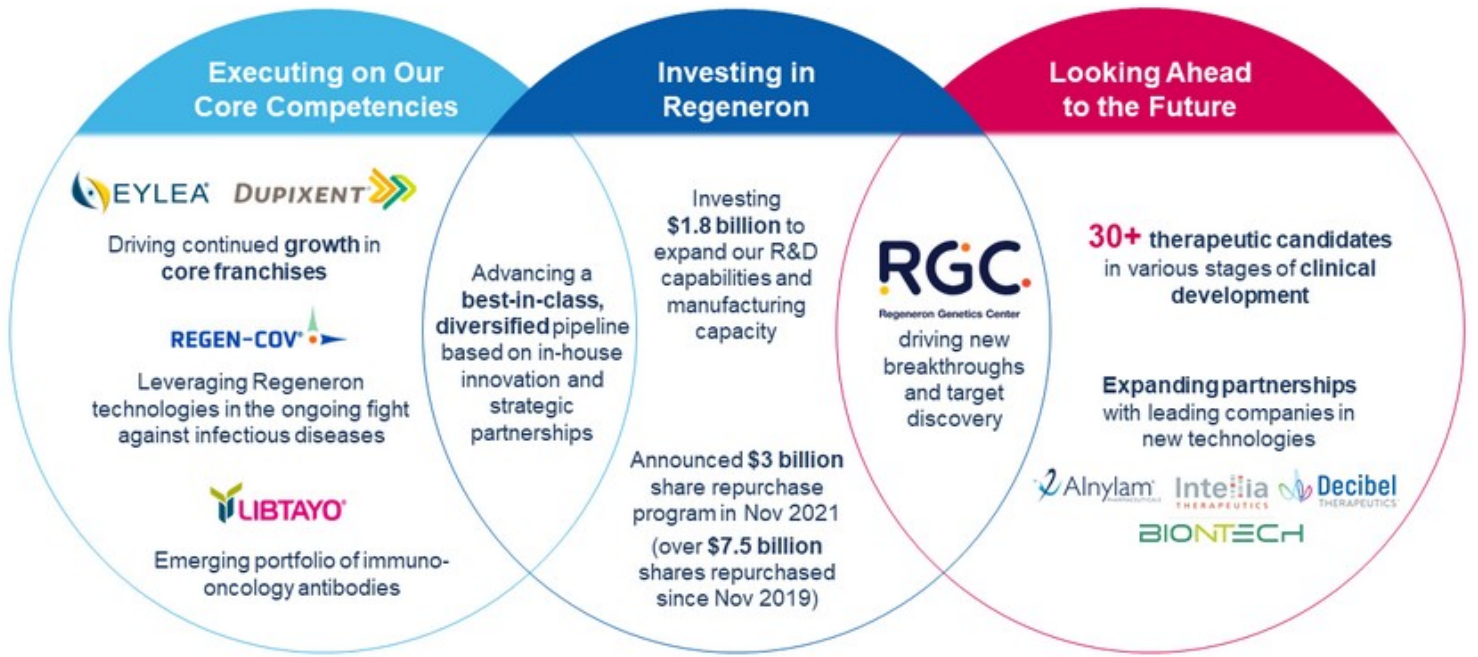
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Current Business Drivers



Leonard S. Schleifer MD, PhD
Co-Founder, President & Chief
Executive Officer

REGENERON



Delivering Results Across the Organization

3Q 2021 YTD
Total Revenues YoY*

+20%
Growth excluding REGEN-COV*

+83%
Growth including REGEN-COV*



Increasingly Diversified Growth Drivers

2021 R&D Pipeline Advancements



Positive Ph2 results for Aflibercept 8mg in wAMD



Positive Ph3 results in four potential new indications (CSU, PN, EoE, Pediatric AD)

Received approval in asthma for children ages 6 - 11



EUA expanded to include post-exposure prophylaxis, positive data in COVID-19 hospitalized patients



Positive Ph3 results when combined with chemotherapy in 1L NSCLC



Advancing CD3 & CD28 bispecifics platform



Emerging Genetics Medicines portfolio, established proof of concept for CRISPR-based therapy

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5 * Year-over-year growth, first nine months of 2021 vs. first nine months of 2020. See reconciliation of non-GAAP measure on slide 28

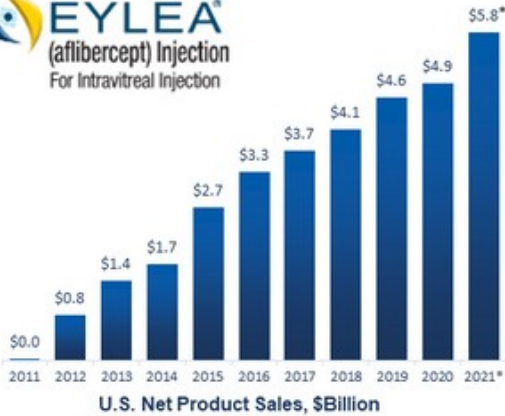
PN – Prurigo Nodularis; EoE – Eosinophilic Esophagitis AD – Atopic Dermatitis; CSU – Chronic Spontaneous Urticaria; NSCLC – Non-Small Cell Lung Cancer; wAMD – Wet Age-Related Macular Degeneration

This slide contains investigational products not yet approved by regulatory authorities

EYLEA®: 10 Years of Patient Impact

Extending leadership position based on efficacy and safety that has transformed millions of lives; 40+ million doses administered since launch

Developed using our proprietary Trap technology, development on aflibercept began in 2004 and became Regeneron's second FDA-approved treatment in November 2011 as **EYLEA**



The **#1** prescribed FDA approved anti-VEGF treatment for retinal disease

- 4Q2021 U.S. net product sales of **\$1.54Bn** (+15% YoY)*
- FY2021 U.S. net product sales of **\$5.79Bn** (+17% YoY)*

Impressive competitive durability

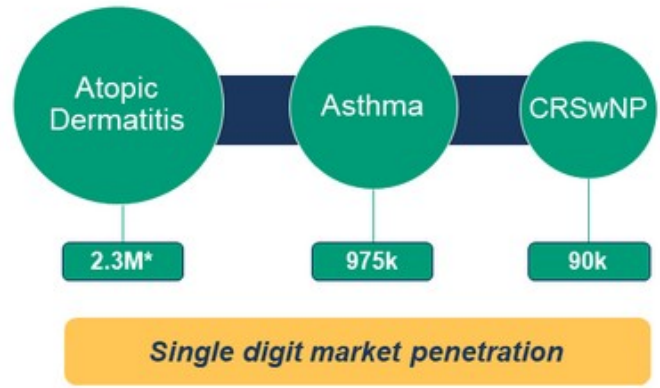
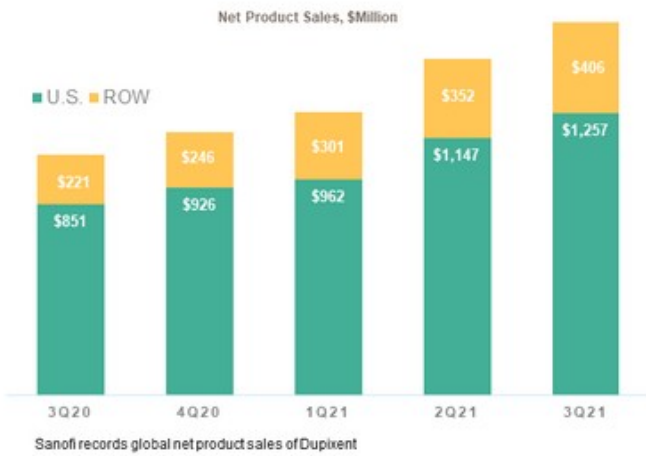
- **~75%** share of U.S. branded category
- Breadth of indications, effective treat-and-extend dosing, with established real-world safety

Continuing to drive **future growth**

- Diabetic eye disease continues to be a significant growth opportunity
- Ph3 readouts for Aflibercept 8mg expected **2H22**

Dupixent®: Strong Performance Across All Approved Indications With Significant Opportunity For Sustained Growth

Annualizing at ~\$6.6B run rate**



There remains a **substantial opportunity** for **more patients** to benefit as markets remain under penetrated

7 ** 3Q21 global net product sales multiplied by 4

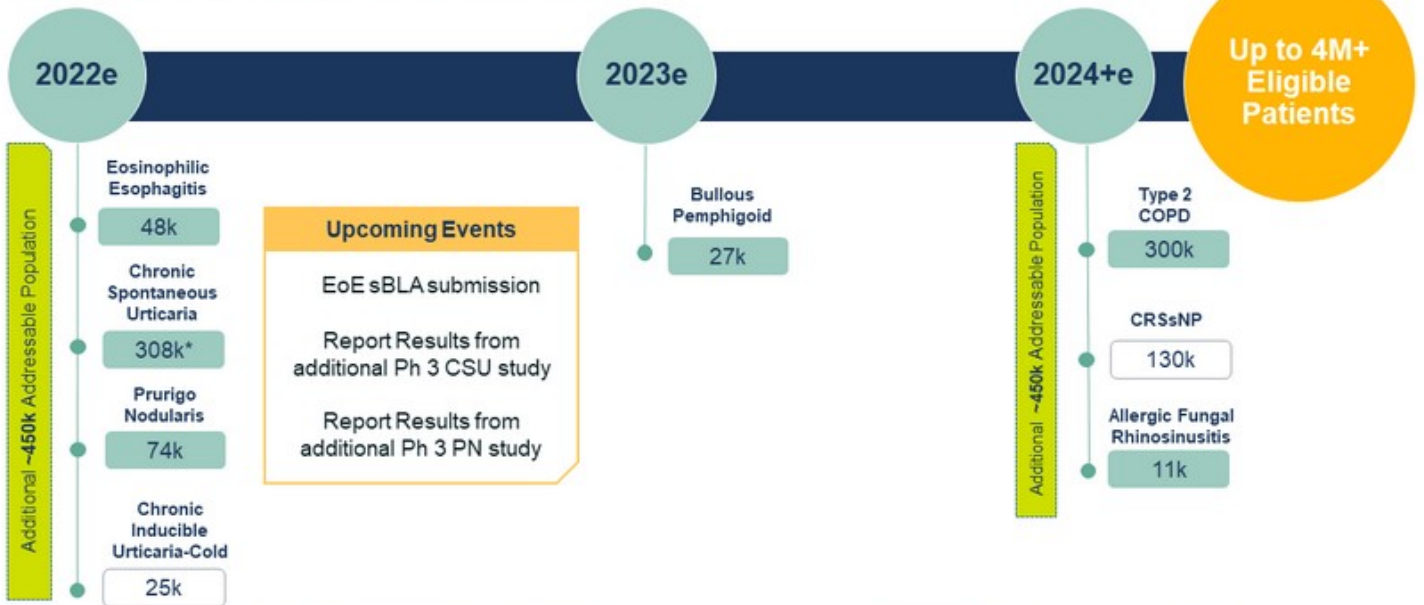
Figures represent U.S. Biologic-eligible target population; Source – Regeneron Internal Epidemiology Data

*Target population includes age groups that are not currently approved but in clinical development
CRSwNP – Chronic Rhinosinusitis with Nasal Polyposis



Dupixent®: Near- and Long-Term Opportunities to Drive Growth

Estimated regulatory submission timeline for new indications



8 Figures represent U.S. Biologic-eligible target population; dates represent expected first FDA submission
 Source – Regeneron Internal Epidemiology Data
 *Out of these eligible patients, the highest unmet need is in omalizumab non-responders (40-60% currently treated patients)
 COPD – Chronic Obstructive Pulmonary Disease; CRSsNP – Chronic Sinusitis without Nasal Polyposis

Potential indications with POC
 Other investigational uses

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Dupixent® & Itepekimab (anti IL-33) COPD Phase 3s Underway

Two-pronged approach against uncontrolled, moderate-to-severe COPD

Dupixent potential to address Type 2 COPD

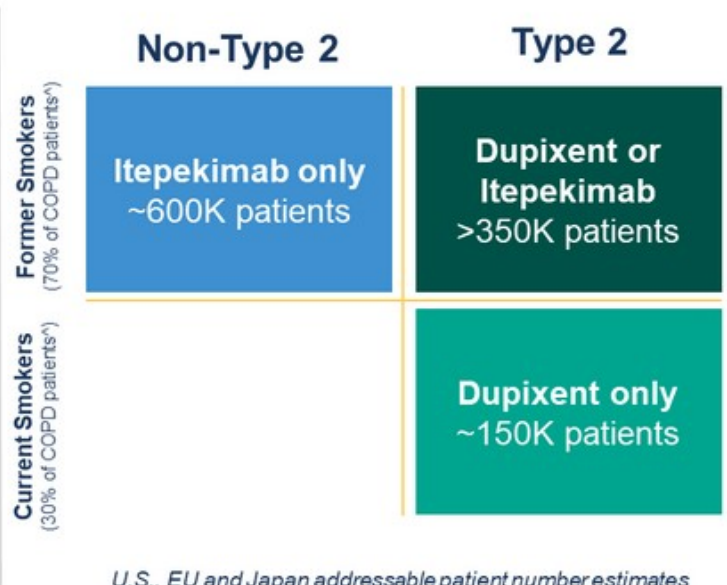
Achieved prespecified efficacy milestone in interim analysis of first Ph3 study

- Eosinophils $\geq 300/\mu\text{l}$
- Both former and current smokers
- Two Ph3 trials ongoing
- Pivotal data expected **2023**

Itepekimab potential also for non-Type 2 COPD

In a Ph2 study*, itepekimab demonstrated 42% exacerbation reduction vs. placebo in former smokers, regardless of Type 2 status, with no safety concerns

- No eosinophil restriction
- Focus on former smokers
- Two Ph3 trials ongoing
- Pivotal data expected **2024**



U.S., EU and Japan addressable patient number estimates

⁹ Dupixent and Itepekimab are developed in collaboration with Sanofi; COPD – Chronic Obstructive Pulmonary Disease
* Rabe et al. *Lancet Respir Med*. 2021
[^] US, EU and Japan epidemiology, patient populations exclude never smokers (Regeneron Internal Epidemiology Data)

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This slide contains investigational products not yet approved by regulatory authorities



Rapid Mobilization to Address COVID-19

Regulatory Status

- ✓ **EUA granted** for ambulatory treatment and in certain post-exposure prophylaxis settings
- ❑ **EUA under review** for pre-exposure prophylaxis and hospitalization
- ✓ **Approved** in the EU for treatment and prevention
- ❑ **Regulatory decision** on BLA submission for treatment and prophylaxis (PDUFA 4/13/22)
 - ❑ **FDA no longer plans** to convene an advisory committee to discuss our BLA

<u>4Q21:</u>	<u>2021:</u>
Delivered ~1.1M Doses*	Delivered ~2.8M Doses*
U.S. Net Product Sales \$2.29B**	U.S. Net Product Sales \$5.82B**

**Based on preliminary unaudited fiscal 2021 results

Regeneron is uniquely positioned to continue to address COVID-19 and other emerging Infectious Disease threats in the future

10 EUA: Emergency Use Authorization
BLA: Biologics License Application

*Roche supplied a portion of these doses to Regeneron to fulfill Regeneron's agreement with the U.S. government. Roche is primarily responsible for development and distribution outside the U.S.

REGEN-COV is an investigational medicine that is authorized by FDA under an EUA for certain uses. The development and manufacturing of REGEN-COV have been funded in part with federal funds from BARDA.

Strong Financial Position Enabling Critical Investments

Capital allocation priorities reflect business priorities

1. **Invest** in our best-in-class R&D capabilities

\$1.8B investment in Tarrytown R&D facilities
Continued investments in manufacturing capacity

2. **Pursue** and fund business development opportunities to enable and synergize our R&D capabilities and technologies

Productive collaborations with Alnylam and Intellia
Signed new agreement with Nykode in 4Q21

3. **Return** cash to shareholders through share repurchases

Over **\$7.5B** in share repurchases since November 2019
Announced **\$3B** share repurchase authorization in November 2021

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Upcoming Business Drivers



George D. Yancopoulos, MD, PhD
Co-Founder, President & Chief
Scientific Officer

Regeneron Technologies Power Our Pipeline: TRAPs, Antibodies and Bispecifics

- VELOCIGENE®
- VELOCIMOUSE®
- VELOCIMMUNE®
- VELOCIMAB®
- VelociT™
- VELOCIHUM®
- VELOCI-BI®

TARGET
DISCOVERY &
VALIDATION



CLINICAL
DEVELOPMENT

MEDICINES

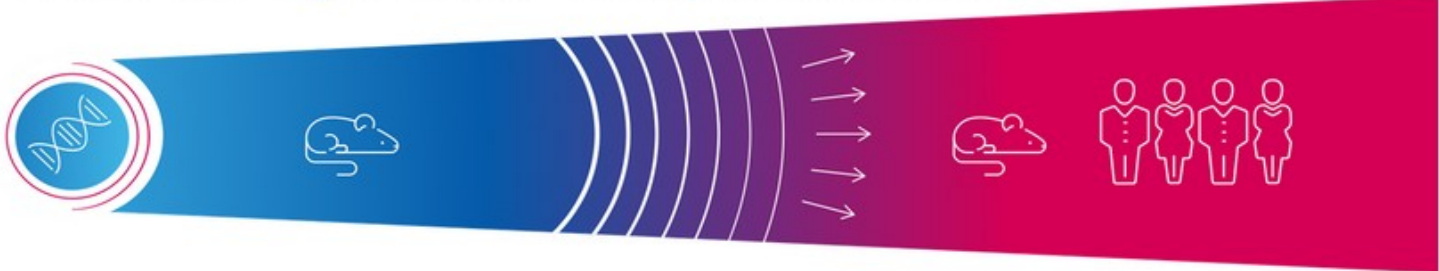


TURNKEY
THERAPEUTICS:
TRAPs & ANTIBODIES
(BISPECIFICS & COSTIMS)

MANUFACTURING

Regeneron technologies have delivered repeated breakthroughs by addressing limitations and bottlenecks in every step of the drug discovery

Synergistic Collaborations Supercharge Regeneron's Future Turnkey Genetics Therapeutics Platforms



Learnings from **mouse genetics**

VELOCIGENE[®]



Unlocking capabilities of **mouse and human genetics** through

VELOCIGENE[®]



RGC
Regeneron Genetics Center

Existing Turnkey Technologies
Biologicals



TRAPs



Antibodies & Bispecifics

Novel Turnkey Technologies
Gene Medicines



siRNA



Genome editing
(insertion/
knockout)



Gene Therapy

Alynham
PHARMACEUTICALS

Intellia
THERAPEUTICS

Decibel
THERAPEUTICS

REGEN-COV[®] : Addressing Treatment Need as well as the Long-Term Opportunity for COVID-19 Prevention

If SARS-CoV2 remains endemic, we anticipate an enduring need for the immunocompromised



Delta (B.1.617.2): Current REGEN-COV antibodies are active

Omicron (B.1.1.529): Multiple next generation monoclonal antibodies are active



Regulatory discussions are ongoing to establish clinical development plan

Next generation antibodies are expected to enter clinical development in the first quarter of 2022

Long-Term Potential Opportunity

Protecting the Immunocompromised



- In the U.S. alone, millions of immunocompromised people will not adequately respond to vaccination
- Monoclonal antibody treatments can be dosed prophylactically to prevent infection and severe COVID-19 disease

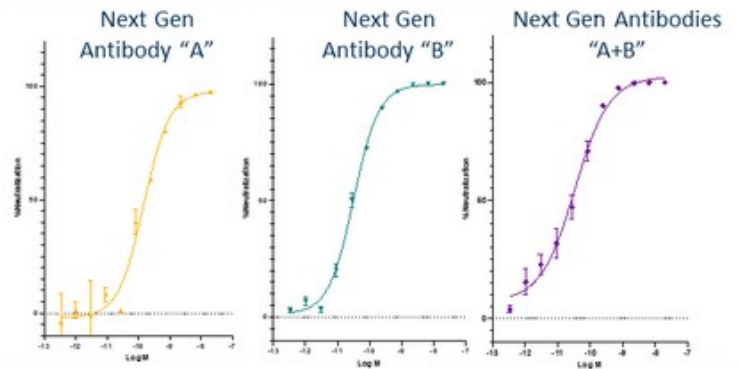
Regeneron Technologies Enable Rapid Response to Infectious Diseases

Next generation antibodies effectively neutralize the SARS-CoV2 Omicron variant as well as other variants of concern

VELOCISUITE®

Regeneron technologies have created a library of thousands of mAbs

We have identified multiple 'next generation' mAbs that are effective against Omicron and Delta variants



Using *VelociSuite*® technologies, discovery and preclinical validation and clinical manufacturing has been compressed 3-6 MONTHS vs. years with a standard process

OUTBREAK

Isolation of fully human antibodies

Creation of and preclinical testing in genetically-humanized mice

Creation of manufacturing-ready cell lines (18 days vs. 6-9 months)

Manufacture of clinical-grade antibodies for human use

Continued Progress & Developments Across Oncology Pipeline

Regeneron positioned to enhance and extend treatment benefit across many cancer settings



Dermato-Oncology

- First-in-class leading treatment for advanced CSCC
- Approved in 2L+ advanced BCC
- LAG-3 combination – 1L melanoma data presented at ASCO '21
- BioNTech FixVax combination in post-PD-1 melanoma Ph2 underway

Non-Small Cell Lung Cancer

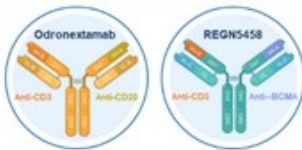
- Approved in 1L advanced NSCLC
- Submitted sBLA in 1L NSCLC in combination with chemotherapy

Solid tumor bispecifics



- **REGN4018 (MUC16xCD3)** – Dose escalation with Libtayo in ovarian cancer ongoing
- **REGN5668 (MUC16xCD28)** – Dose escalation with Libtayo in ovarian cancer ongoing; first patients dosed in combination with MUC16xCD3, well tolerated
- **REGN5678 (PSMAxCD28)** – Dose escalation with Libtayo in mCRPC ongoing
- **REGN4336 (PSMAxCD3)** – Now enrolling
- **REGN7075 (EGFRxCD28)** – Dose escalation with Libtayo in advanced cancers ongoing
- **REGN5093 (METxMET)** – Dose expansion in MET-altered NSCLC ongoing
- **REGN5093-M114 (METxMET ADC)** – Now enrolling

Heme-onc bispecifics



- **Odronextamab (CD20xCD3)** – Resumed enrollment in potentially pivotal Ph2 in R/R NHL
- **REGN5458 (BCMAxCD3)** – Ph1 data updated at ASH'21; potentially pivotal Ph2 in dose expansion
- Both will be entering combination studies with corresponding costim (CD28) bispecifics

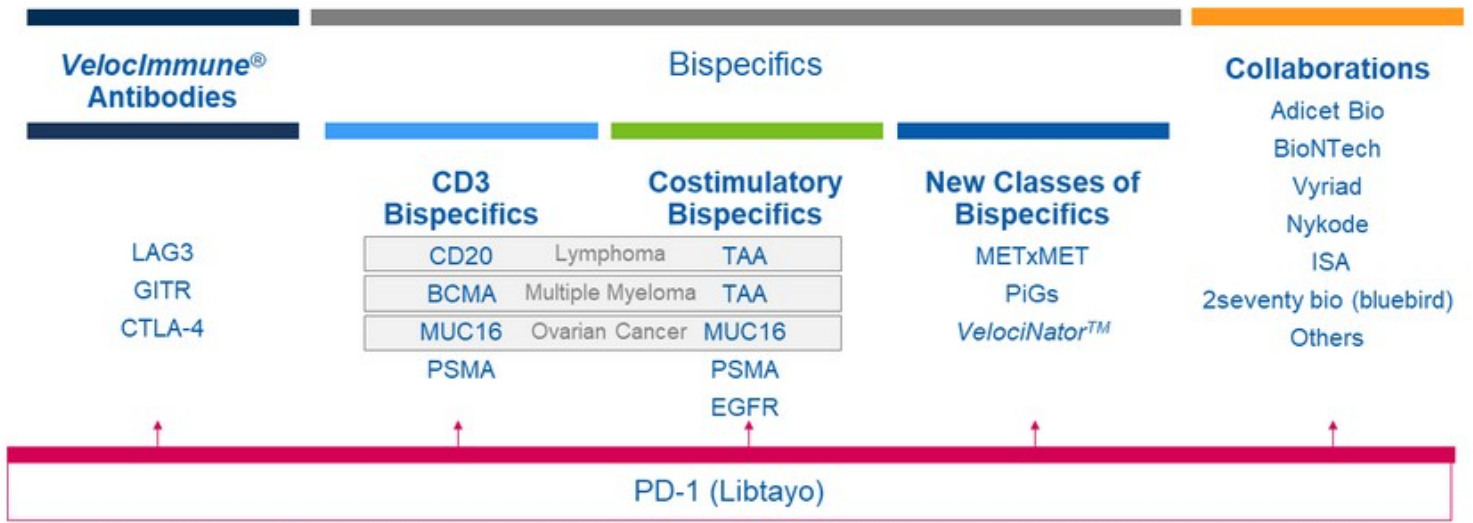
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CSCC – Cutaneous Squamous Cell Carcinoma; mCRPC – metastatic Castration-Resistant Prostate cancer;
BCC – Basal Cell Carcinoma; NHL – Non-Hodgkin's lymphoma
NSCLC – Non-Small Cell Lung Cancer;

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This slide contains investigational products not yet approved by regulatory authorities

Regeneron's Oncology Toolkit Provides Unique Combinatorial Flexibility



18 Libtayo is jointly developed with Sanofi. Several agents are studied in combination with Libtayo, in addition to the combinations highlighted by boxes.

Bispecifics for Heme-Onc Malignancies: Promising Results from Maturing CD3 Programs

Combinations with costimulatory bispecifics and other agents entering clinic soon



Odronextamab (CD20xCD3) Program Update

Summary – A single, off-the-shelf bispecific, effective in both indolent and aggressive lymphomas, including patients who failed CAR-Ts

- R/R FL: ORR=90% CR=70% (N=30)
- R/R DLBCL: CAR-T naïve ORR=55% CR=55% (N=11); post-CAR-T ORR=33% CR=21% (N=24)
- **Durable responses** (up to 3.5 years so far in FL)
- Acceptable safety profile

Progress to Date:

- Resumed enrollment in 2Q21, with positive recruitment trends since partial hold was lifted
- Over 450 patients dosed to date across program

Upcoming Milestones:

- Complete enrollment in potentially pivotal Ph2 in FL and DLBCL
- Initiate dosing with subcutaneous formulation
- Initiate OLYMPIA Ph3 program and additional combinations, including TAAxCD28 costim



REGN5458 (BCMAxCD3) ASH 2021 Update

Efficacy – Early, deep, and durable responses:

- 75% ORR, with 58% VGPR or better at higher doses (200-800 mg)
- 86% of responders with VGPR or better; 43% with CR or better
- Median DOR was not reached

Safety – Acceptable safety and tolerability:

- No Grade 3+ CRS; no grade 3+ ICANS
- CRS reported in 38% patients, vast majority of events were Gr1
- Maximum tolerated dose was not reached

Next Steps:

- Complete enrollment in the Ph2 part of the potentially pivotal study
- Report data from Ph2 study
- Start enrollment of Ph1 umbrella study of REGN5458 in combination with SOC
- Initiate additional combinations with TAAxCD28 costim

Bispecifics for Solid Malignancies: Potential to Extend Benefits of Checkpoint Inhibitors; Initial Data in 2022

Our footprint in oncology continues to expand

Lung, Advanced Cancers

REGN5093 (METxMET)

- Seeing early signs of clinical activity in **MET** exon14 skip mutation and **MET** protein overexpression patient populations
- Data anticipated in 2H22

REGN5093-M114 (METxMET ADC)

- Trial Enrolling

REGN7075 (EGFRxCD28)

- Dose escalation in combination with **LIBTAYO** ongoing

Ovarian Cancer

REGN4018 (MUC16xCD3)

- **Encouraging early signals** observed in a heterogeneous ovarian cancer population
- Data from dose-escalation monotherapy FIH study anticipated in 1H22
- Dose escalation with **LIBTAYO** ongoing

REGN5668 (MUC16xCD28)

- Evaluating combinations with **LIBTAYO** or with **MUC16xCD3**

Prostate Cancer

REGN5678 (PSMAxCD28)

- Dose escalation with **LIBTAYO** ongoing
- Initial data expected in 2022

REGN4336 (PSMAxCD3)

- Now enrolling
- Explored in monotherapy and in combination with **LIBTAYO**

Broad Oncology Pipeline Continues to Advance

ONGOING	LIBTAYO*		LIBTAYO*	Advanced Lung cancer (chemo combo); adjuvant CSCC
	REGN3767 (LAG-3)	+	LIBTAYO*	Advanced melanoma
	REGN6569 (GITR)	+	LIBTAYO*	Solid tumors
	REGN4018 (MUC16xCD3)	+	LIBTAYO*	2+ line Ovarian cancer
	REGN5668 (MUC16xCD28)	+	REGN4018 / LIBTAYO*	2+ line Ovarian cancer
	REGN5678 (PSMAxCD28)	+	LIBTAYO*	3+ line Prostate cancer
	PSMAxCD3	+	REGN5678/LIBTAYO*	Prostate cancer
	REGN7075 (EGFRxCD28)	+	LIBTAYO*	Solid tumors
	Odronextamab (CD20xCD3)			3+ line Lymphoma
	Odronextamab (CD20xCD3)	+/-	LIBTAYO*	3+ line Lymphoma
	REGN5458/9 (BCMAxCD3)			3+ line Multiple myeloma
	REGN5093 (METxMET)			Advanced MET altered Lung cancer
	REGN5093-M114 (METxMET ADC)			MET overexpressing advanced Cancer
UPCOMING	odronextamab (CD20xCD3)	+	B cell/CD28 costim	B-NHL
	odronextamab (CD20xCD3)	+	Standard of Care	B-NHL
	REGN5458/9 (BCMAxCD3)	+	Plasma cell/CD28 costim	Multiple myeloma
	REGN5458/9 (BCMAxCD3)	+	Standard of Care, Additional Combos	Multiple myeloma

Velocimmune® Antibodies

Anti-PD-1

CD3 BiSpecifics

Costim BiSpecifics

New BiSpecifics

Regeneron Genetics Medicines

Powerful resource linking human genetic variation to disease; empowering strategic partnerships to drive the future of medicine



World leading human sequencing

- >2M human exomes sequenced
- Linked to Electronic Health Records
- 100+ collaborations globally



Novel Genetics-based Drug Target Discovery

- RGC discovered >10 novel drug targets



Genetics-based Drug Development & Precision Medicine

- RGC database links drug targets with disease impact, enhancing probability of clinical trial success
- RGC database identifies patients most likely to benefit



Leveraging New Turnkey Therapeutic Approaches

- siRNA gene silencing
- Genome editing – Knockout/ Insertion
- Targeted viral-based gene delivery and expression

Regeneron is investing in and delivering technologies well beyond antibodies

- **3** genetics medicines programs in the clinic
- **3-5** additional potential targets to advance to IND-enabling studies in next 12 months
- **30+** additional programs in research and candidate selection phase
- **10+** novel genetic targets discovered

Several near-term opportunities emerging from Regeneron Genetics Medicines:

- Reported landmark TTR genome editing data in Jun'21; data update anticipated in 1Q22
- C5 combo program Ph3 initiations (Myasthenia Gravis and PNH)
- HSD17B13 siRNA healthy volunteer safety topline data read out in Nov'21
- APP siRNA Ph1 start for Alzheimer's
- DB-OTO gene therapy (hearing loss) Ph1/2 start in 2022

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REGENERON GENETICS MEDICINES

Building the Pipeline for the Future

Pre-IND

FACTOR 8 GENE INSERTION²
CRISPR/Cas9 + AAV Transgene Insertion

- Hemophilia A

PNPLA3¹
PNPLA3 siRNA

- Nonalcoholic Steatohepatitis

ALN-APP¹
APP siRNA

- Cerebral Amyloid Angiopathy, Alzheimer's Disease

DB-OTO³
OTOF AAV Dual Vector Gene Therapy

- OTOF Related Hearing Loss

FACTOR 9 GENE INSERTION²
CRISPR/Cas9 + AAV Transgene Insertion

- Hemophilia B

GAA GENE INSERTION²
CRISPR/Cas9 + AAV Transgene Insertion

- Pompe Disease

Clinical Development

POZELIMAB + CEMDISIRAN¹
C5 Antibody + C5 siRNA

- Myasthenia Gravis
- Paroxysmal Nocturnal Hemoglobinuria

CEMDISIRAN¹
C5 siRNA

- Immunoglobulin A Nephropathy

ALN-HSD¹
HSD17B13 siRNA

- Nonalcoholic Steatohepatitis

NTLA-2001²
CRISPR/Cas9

- Transthyretin Amyloidosis (ATTR)

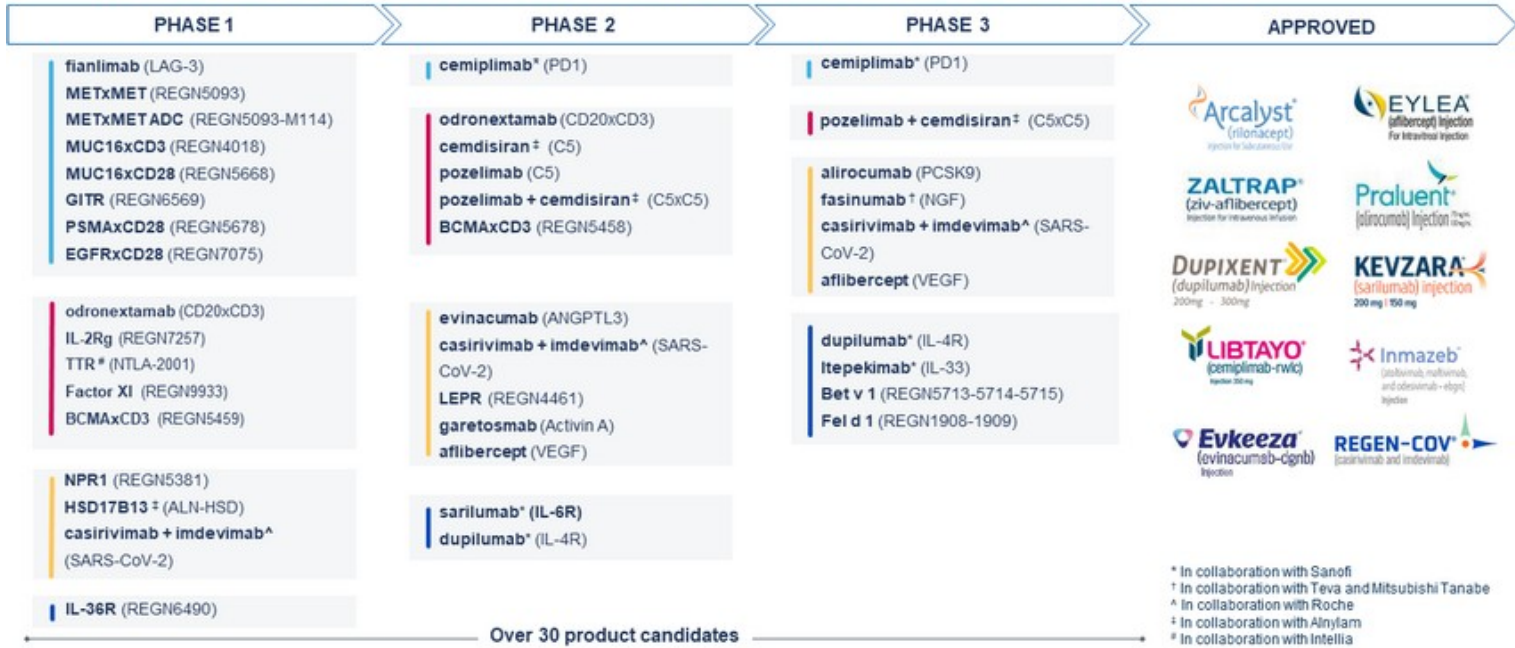
ADDITIONAL PROGRAMS
30+ Programs in Research and Candidate Selection

Collaborations with:
1. Alnylam Pharmaceuticals
2. Intella Therapeutics
3. Decibel Therapeutics

This graphic displays pipeline drug candidates currently undergoing clinical testing in a variety of diseases. The safety and efficacy of these drug candidates have not been fully evaluated by any regulatory authorities for the indications described in this section.

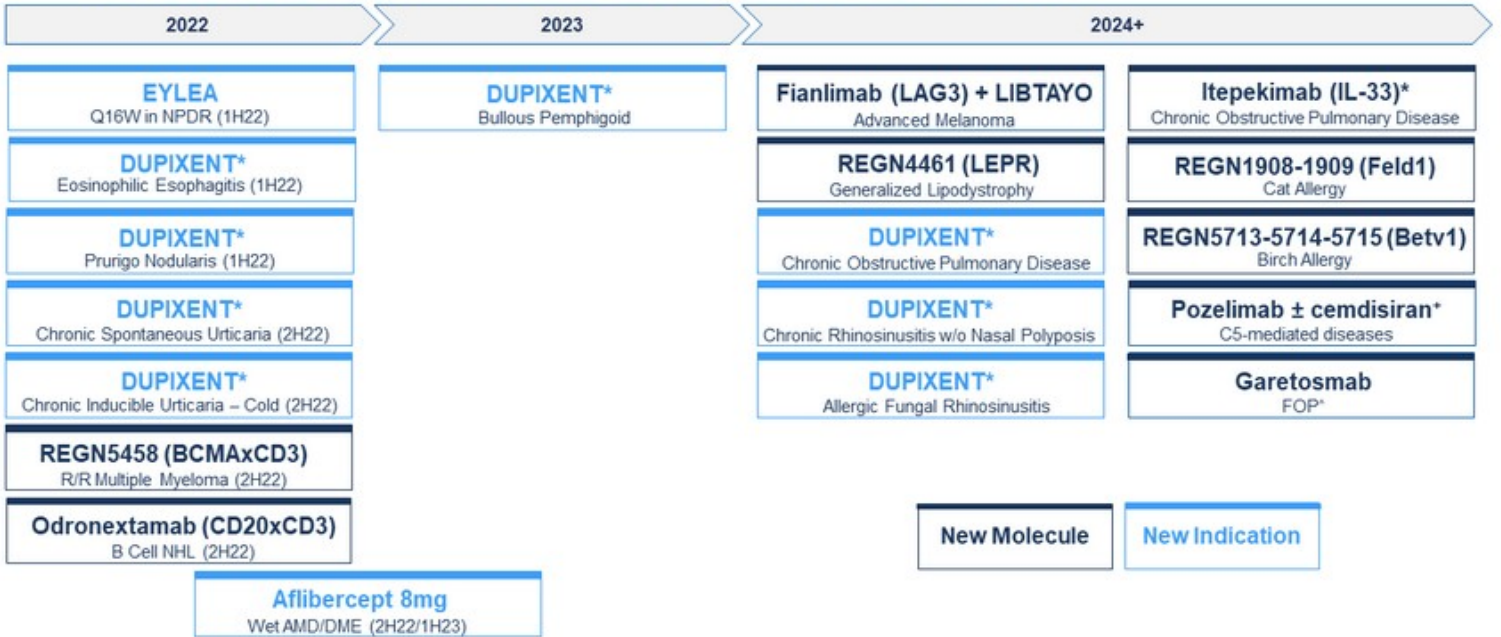
REGENERON

Regeneron-Discovered, Approved and Investigational Medicines Across a Wide and Diverse Set of Diseases



* In collaboration with Sanofi
[†] In collaboration with Teva and Mitsubishi Tanabe
[^] In collaboration with Roche
[‡] In collaboration with Alnylam
[§] In collaboration with Intellia

Multiple Potential FDA Submissions: 2022-2024+



Key Upcoming Milestones (Next 12 months)

EYLEA

- Ph3 data readout for Aflibercept 8mg formulation

Dupixent

- Complete regulatory submission for EoE
- Additional Phase 3 data readouts for CSU and PN
- Regulatory decision for AD in children (6 mo – 5 yrs)

REGEN-COV

- FDA decision on BLA for treatment and prophylaxis indications (PDUFA 4/13/22)
- BLA submission for hospitalized patients

Libtayo

- Regulatory decisions for 1L NSCLC chemotherapy combination

Solid Tumor Bispecifics

- Initial data for MUC16xCD3, PSMAxCD28 and METxMET

Odronextamab (CD20xCD3)

- Complete enrollment in potentially pivotal Phase 2 in NHL
- Initiate dosing with subcutaneous formulation
- Initiate OLYMPIA Ph3 program and additional combinations

REGN5458 (BCMAxCD3)

- Complete enrollment in potentially pivotal Phase 2 in multiple myeloma
- Ph2 data expected in multiple myeloma
- Initiate studies with subcutaneous formulation
- Initiate Phase 1 and Phase 3 studies exploring combinations with standard of care
- Initiate additional combination studies

Q&A



Leonard S. Schleifer MD, PhD
Co-Founder, President & Chief
Executive Officer



George D. Yancopoulos, MD, PhD
Co-Founder, President & Chief
Scientific Officer



Marion McCourt
EVP, Head of Commercial



Robert Landry
EVP, Chief Financial Officer

Reconciliation of Non-GAAP Measure

REGENERON PHARMACEUTICALS, INC.
RECONCILIATION OF TOTAL REVENUE (Unaudited)
(In millions)

	Nine Months Ended September 30,	
	2021	2020
Total Revenues	\$ 11,120.0	\$ 6,074.2
Less: REGEN-COV net product sales in the U.S.	3,530.1	40.2
Less: Global gross profit true-up payment owed from Roche in connection with sales of casirivimab and imdevimab	361.8	—
	<u>\$ 7,228.1</u>	<u>\$ 6,034.0</u>