

Creating Breakthroughs

What Will Define Successful Biotech
Companies of the Future?

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In this report, we explore 3 questions

What is the state of the biotech industry?

How will the next generation of the biotech industry be different?

What should be on biotech CEO agendas?



What is the state of the

biotech industry today?

The last 20 years marked rapid development of the biotech industry

500+ therapies commercialized
by originator or via partners¹

~\$1.1T+ total value from
acquisitions²

~\$1.4T total shareholder
value generated³

Biotech defined by S&P Global Market Intelligence biotech industry classification with market cap below \$85B as of November 2022

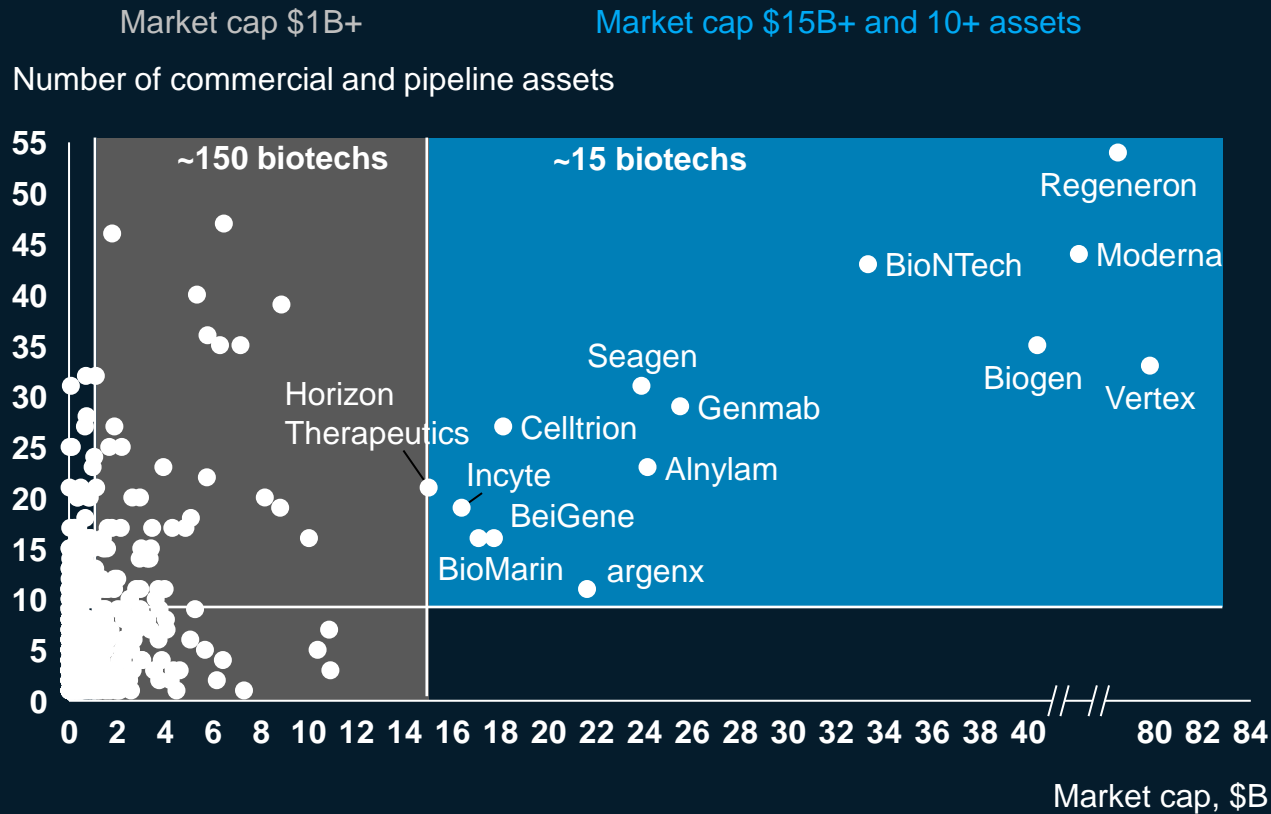
1. Therapies marketed between January 2002 – December 2021; duplicates removed for therapies launched through partnerships or in multiple regions

2. Biotech acquisition by another company from January 2002 – December 2021; deal transaction value is inflation-adjusted to 2022 value

3. Difference in total market cap from January 2002 – December 2021 for publicly traded biotech companies as defined above; excludes acquisitions

Biotechs have created significant value both for patients and the market

Top 1000 biotechs¹ by market cap and number of assets²



Biotechs also achieved success via M&A

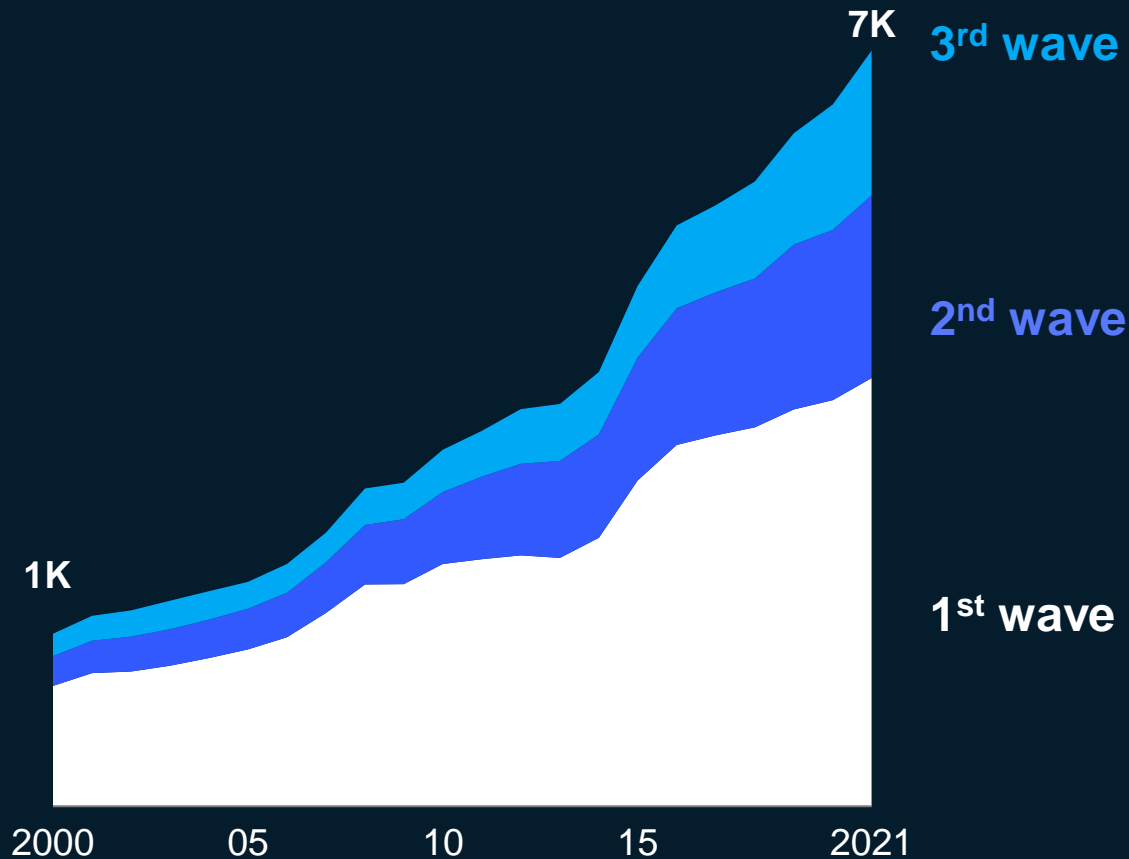
In the past 20 years³:

- 5+ deals over \$25B (value⁴)
 - Genentech & Roche (\$137B)
 - Celgene & BMS (\$108B)
 - Alexion & AstraZeneca (\$47B)
- 15+ deals between \$10B-25B
- 100+ deals between \$1B-10B

1. Biotech defined by S&P Global Market Intelligence biotech industry classification with market cap below \$85B; top 1,000 ranked by market cap as of Nov. 2022
 2. Assets defined as total preclinical, clinical, and marketed assets from EvaluatePharma
 3. Biotechs acquired by another company from January 2002-December 2021 in 2022 USD millions
 4. Target enterprise value shown: derived from transaction price, percent ownership, and outstanding debt; deal transaction value is inflation-adjusted to 2022 value
 Source: S&P Global Market Intelligence as of November 2022; EvaluatePharma November 2022, Evaluate Ltd.

Biotechs are leading new waves of innovation

Global biopharma pipeline composition,
Number of candidates in development¹ (K)



3rd wave
 CAR T-cell therapy
 Stem cell therapy
 Gene therapy
 RNA-based therapeutics

~**50** CGTs expected to launch by 2025
 Kite / Gilead and AveXis / Novartis led the industry into the era of CGT

2nd wave
 Peptides
 Monoclonal antibodies
 Recombinant proteins

~**100** mAb drugs on market today
 Biotechs such as Genmab and Regeneron built their portfolios on mAbs

1st wave
 Small molecules
 Nonrecombinant vaccines
 Natural extracts

>**1500** small molecules on market today

1. Phase I to Phase III for innovative drugs only, excluding reformulations and biosimilars; snapshot as of June each year with missing phases not approximated; phase based on most progressed indication

China is making its mark on the global biotech stage

~\$90B market cap¹

40% p.a. growth in clinical trial applications
in China for innovative molecules²

24 out-licensing deals for innovative drugs
to multinational PharmaCos in 2022 YTD

1. Sum of market cap as of November 2022; biotech defined by S&P Global Market Intelligence biotech industry classification with market cap below \$85B and headquarters in China as of November 2022; excluded distributors and generics players

2. From 2016-2021; innovative assets include both chemical drugs and biologics whose global status is Phase I–III or pre-registration

While biotechs have experienced success, **the industry faces some headwinds**

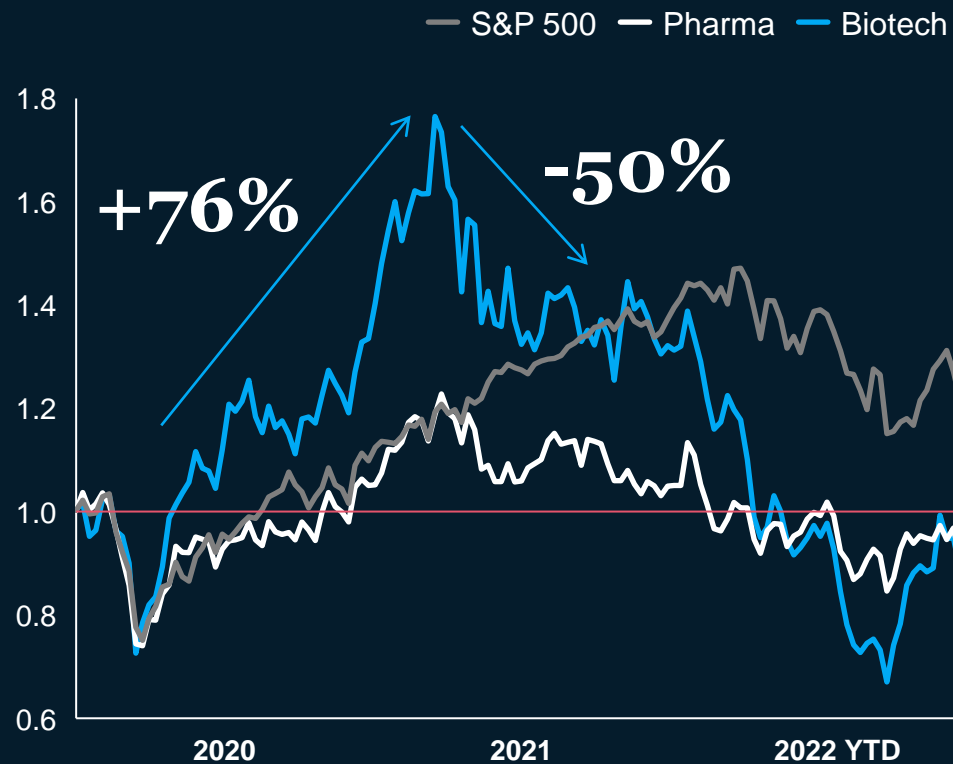
Tighter capital markets in the near term

Inefficient resource allocation at industry level, as many companies pursue the same targets and technologies

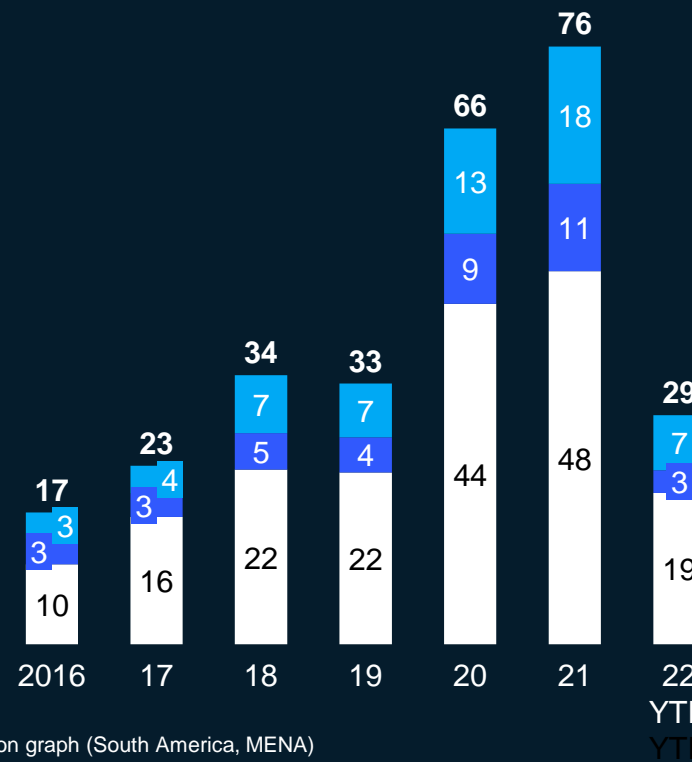
Persisting challenges for global access to innovative therapies

Biotech stock performance has declined since Q1 2021, overall funding remains in line with 2019

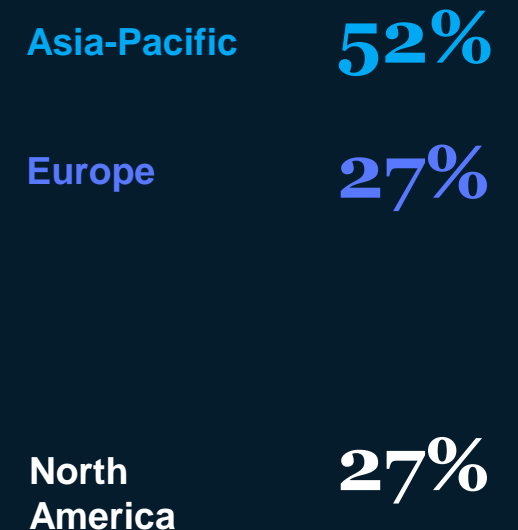
Stock performance, Normalized to Jan 1, 2020



Total biotech VC¹ and IPO funds by geography, \$B



CAGR (2016-21), Percent

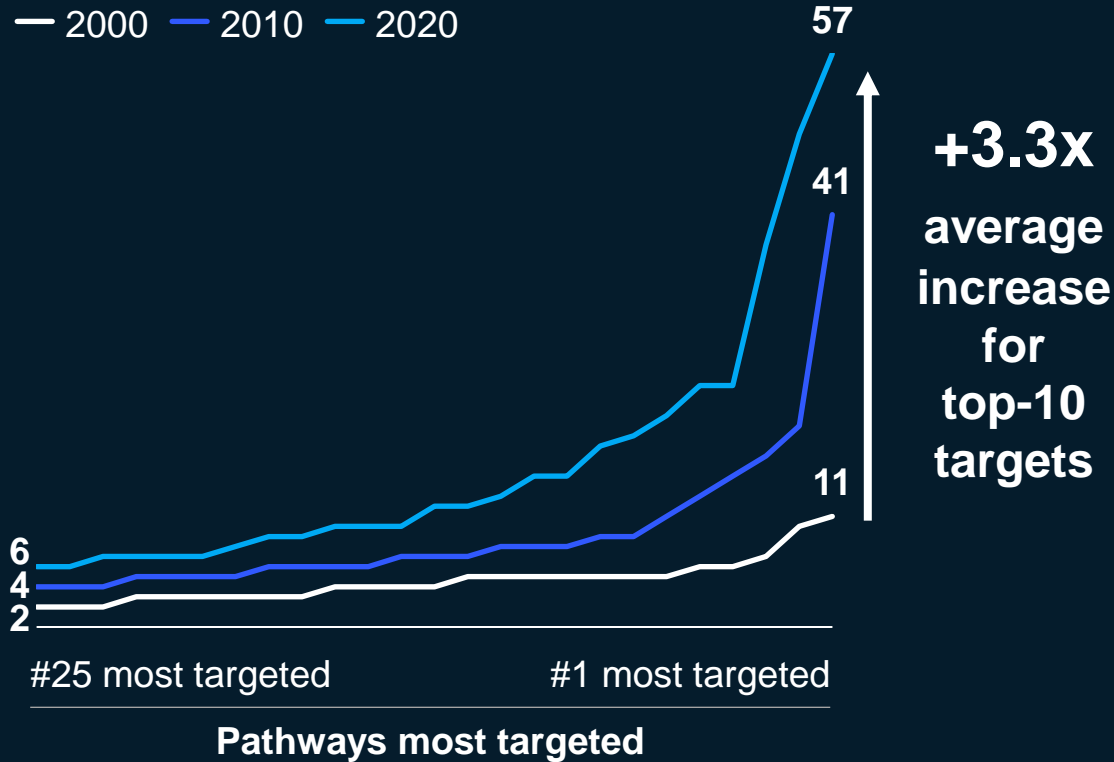


1.VC funding received by biotechs across all funding stages; regions with VC funding totaled <1% were not shown on graph (South America, MENA)

Source: S&P Global Market Intelligence as of November 2022; BCIQ as of November 2022, BioCentury Inc.

Herding in biopharma pipeline occurs at global and regional levels

Global pipeline assets¹ per target, Number of assets



Asia-Pacific

~6.6x

North America

~2.1x

Europe

~0.8x

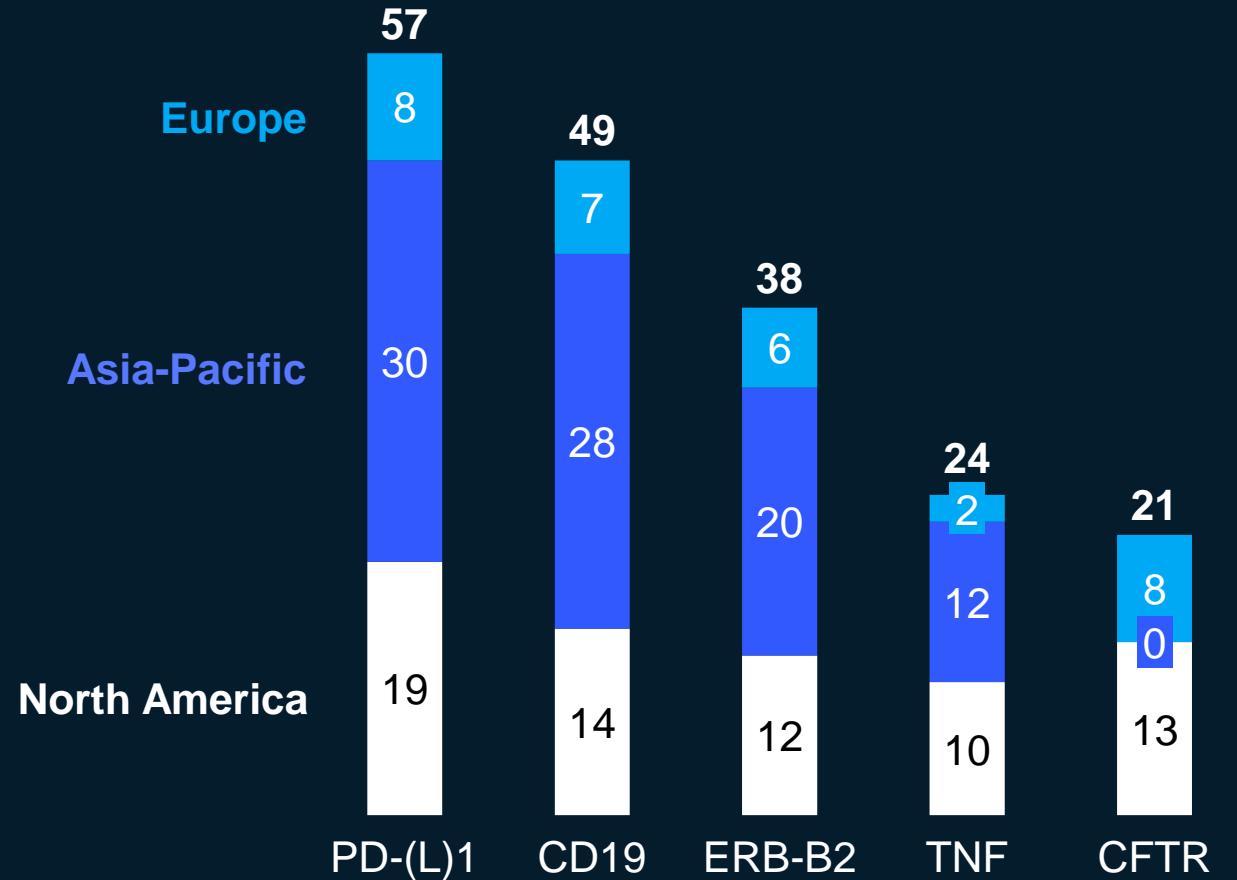
Average increase
in number of
assets per target
for the top 10
targets by region²

1. Analysis includes >250 companies in APAC, >150 companies in Europe, >250 companies in North America

2. Geographic region assigned based on originator's headquarters location

The top 5 most active targets each have **20+** assets in development globally

Pipeline assets¹ in the top 5 most active targets by region²,
Number of assets

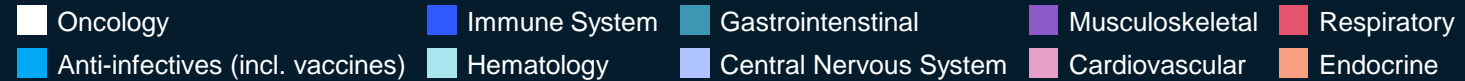


1. Includes only Phase I-III, excludes preclinical; analysis includes >250 companies in APAC, >150 companies in Europe, >250 companies in North America; one company can have multiple assets in development for the same target

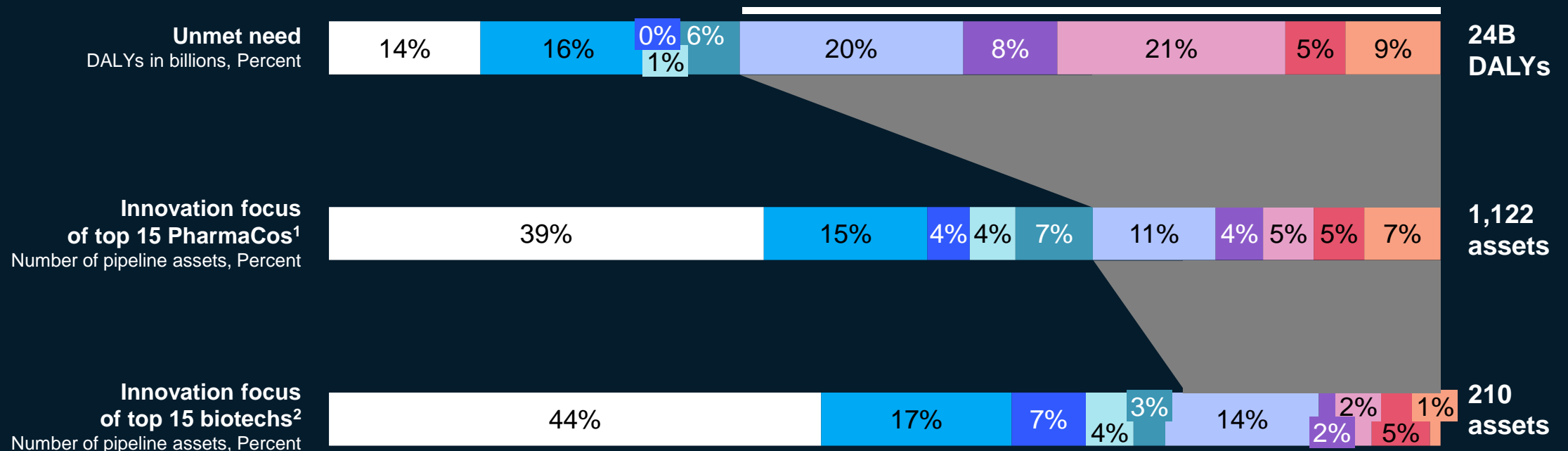
2. Geographic region assigned based on originator's headquarters location

Herding in therapeutic areas results in inefficient capital allocation versus unmet need

Not exhaustive of all TAs



Unmet need greater than innovation focus



1. Top 15 PharmaCos ranked by November 2022 market cap and classified as pharmaceutical companies by S&P Global Market Intelligence

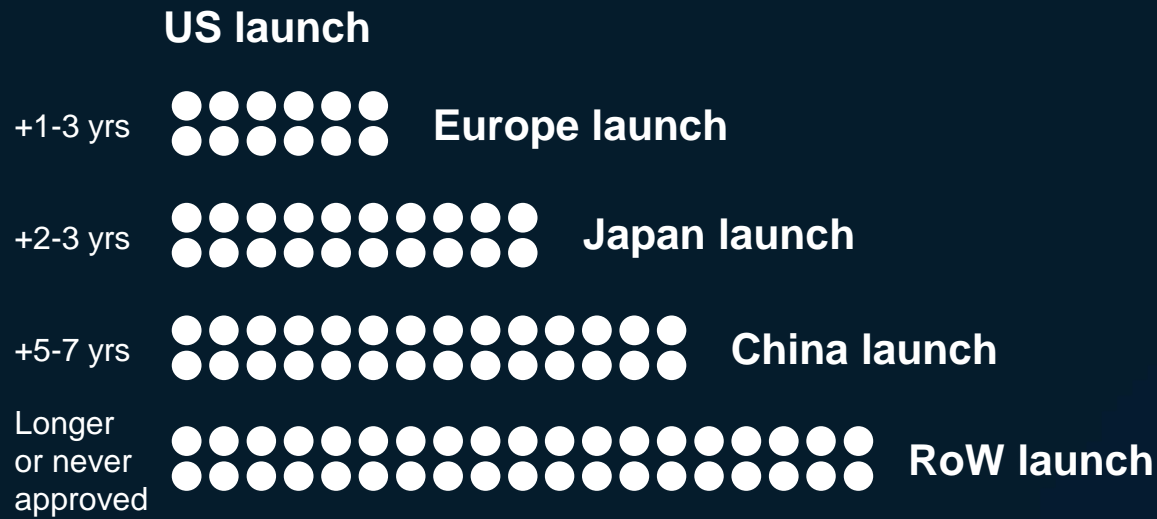
2. Top 15 biotechs defined by November 2022 market cap and classified as biotech companies by S&P Global Market Intelligence with a market cap less than \$85B

Sources: McKinsey & Co. [Helix: Rewiring the DNA for the next wave of impact in biopharma](#); EvaluatePharma November 2022, Evaluate Ltd.; IHME database as of October 2022; S&P Global Market Intelligence as of November 2022

Historically, delays have limited global access to innovative therapies...

... while progress has been made globally, challenges remain

Example: Oncology¹



- + Companies are prioritizing more rapid globalization
- + Regulators, particularly in Asia, are integrating into global regulatory standards
- Biotechs may lack the scale needed for globalization
- IP and how innovation is valued vary by geography

~1-2 M lost lives
worldwide due to delayed patient access

1. Estimated based on two oncology drug launches

Even with these headwinds,
there is still significant
innovation and investment
in the biotech industry



~

1

**biotech founded
per day over the
past decade¹**

1. Only includes publicly announced biotechs

Source: BCIQ as of November 2022, BioCentury Inc.



How will the **next generation**
of the biotech industry

be different?



Will the **next generation of biotech...**

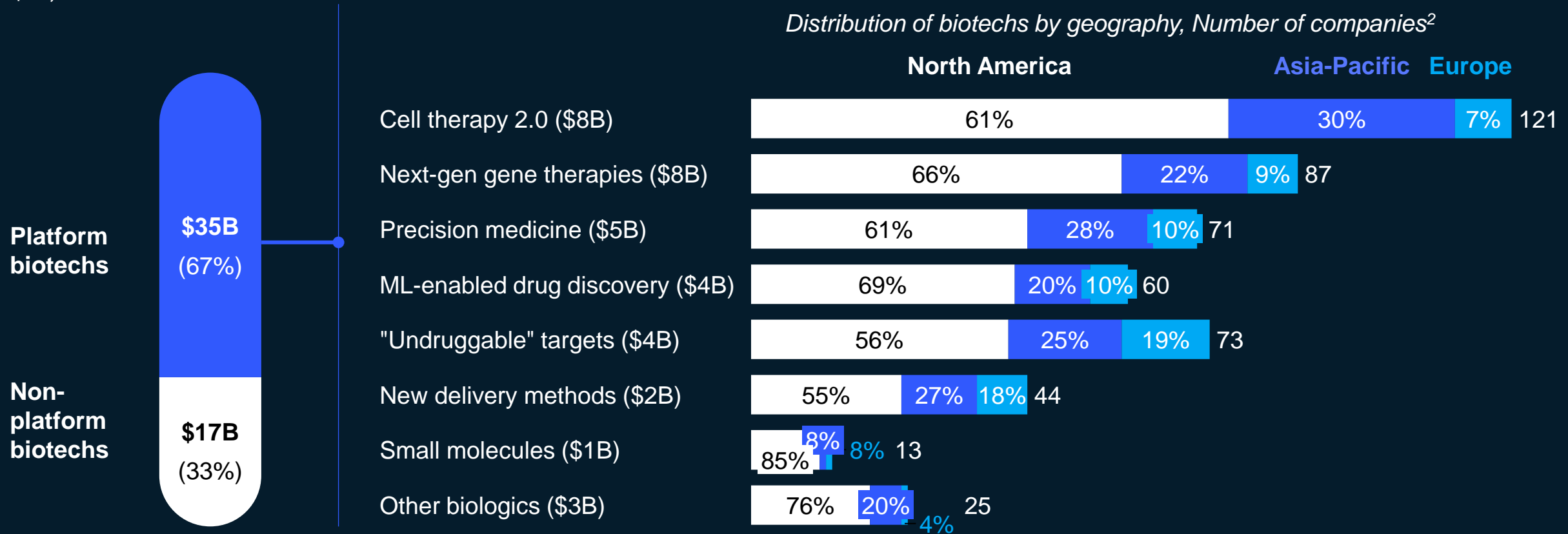
...be defined as an era
of platform players?

...lead with AI, advanced
analytics, and in silico methods?

...approach globalization
differently to maximize patient
impact and value creation?

Among all VC-funded biotechs, >65% of funds in past 3 years went to companies with platform technologies

Capital raised by biotech companies¹ by technologies (2019-21), \$B, Percent

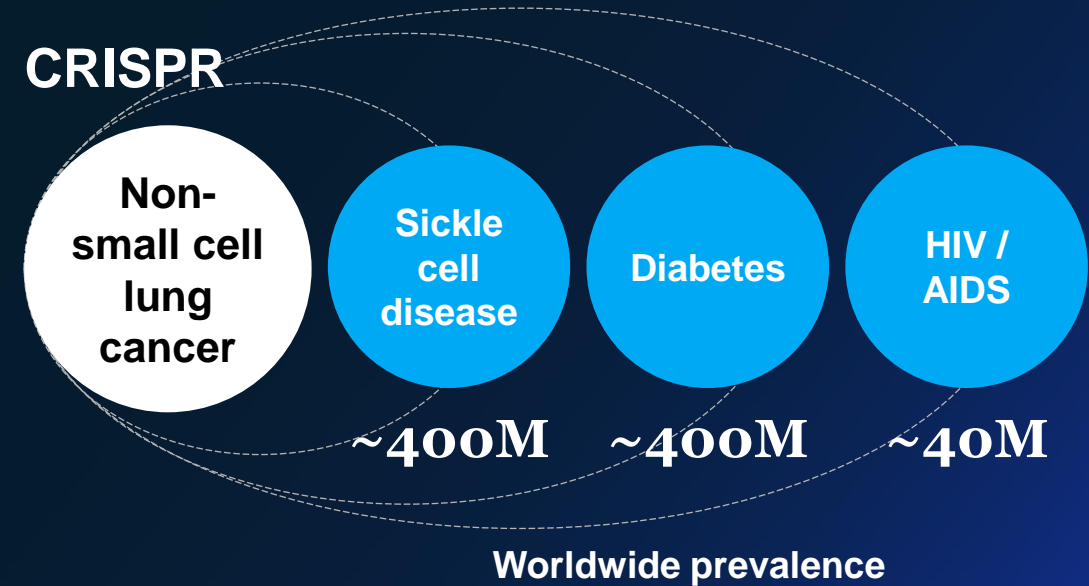
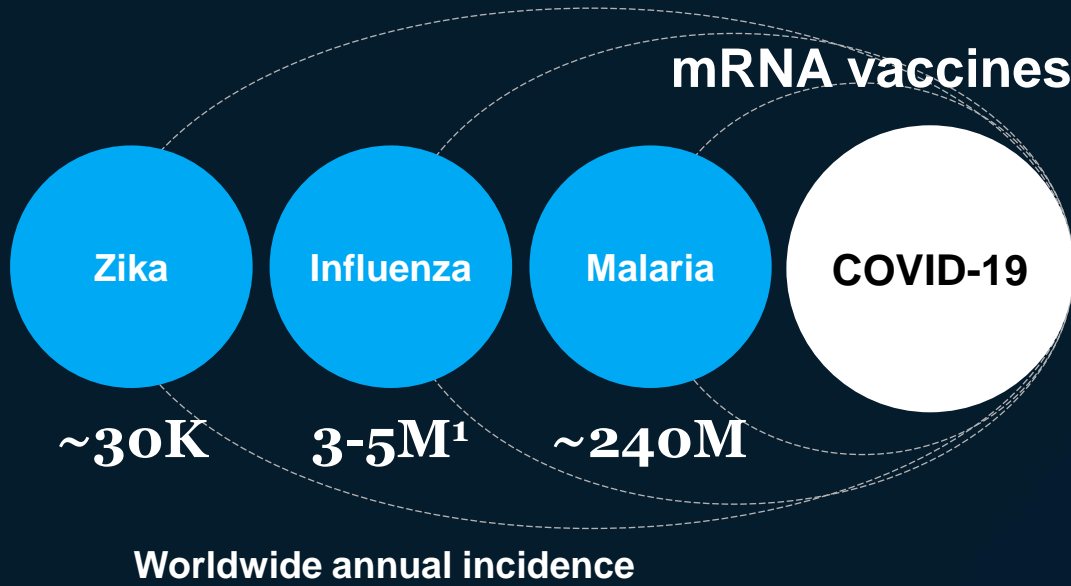


1. Includes privately held companies with deal size >\$10M from seed to series C from 2019-2021; excludes contract and research services, industrial biotechnology and food / agriculture

2. Regions with less than 2% representation (Africa / Middle East) were excluded from chart

Platform technologies offer potential to address high disease burden and increase health equity

● Initial approved indication ● Additional indications in pipeline



Examples of regions with highest disease burden

South America SE Asian countries Sub-Saharan countries

Sub-Saharan countries East & South Asia African region

1. Annual incidence of severe influenza cases

Source: WHO and PAHO as of October 2022

Early signals suggest platforms may deliver on their promise

Compared to non-platform biotechs, platforms¹ have...

~2.8X larger pipelines with similar pipeline maturity²

~3.0X more out-licensing deals over last 10 years³

“

We are starting to see the promise of platforms advancing in usually undruggable targets and very difficult-to-treat diseases with existing mAbs

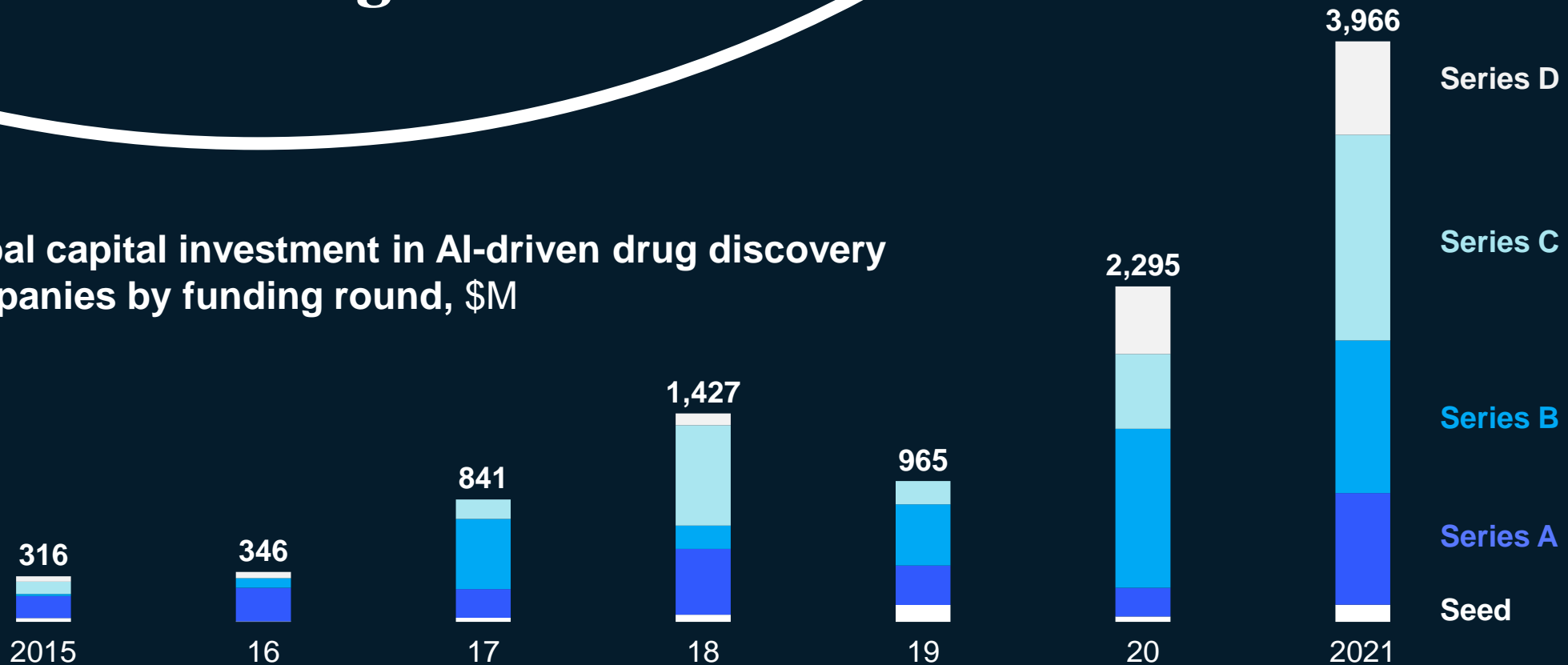
– Asian biotech CEO

”

1. Comparing top 20 platform vs. non-platform biotechs (based on 2021 revenues) with a lead asset in Phase III
2. Includes preclinical and clinical assets
3. Based on asset out-licensing deals since 2012 for the same top 20 platform and non-platform biotechs

AI-driven drug discovery companies are building momentum with increased private funding

Global capital investment in AI-driven drug discovery companies by funding round, \$M

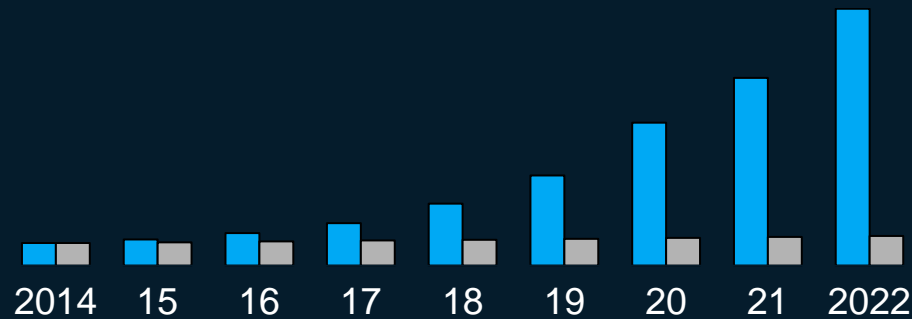


PharmaCos have been scaling their own AI capabilities

Job positions in top 30 PharmaCos¹,
Normalized number of FTEs by role²

AI, ML,
Analytics

Other³



CAGR (2014-22),
Percent

35.5%

3.5%

Companies are also establishing AI capabilities with sizeable partnerships:

- Sanofi partners with Insilico Medicine, worth up to \$1.2B
- Amgen partners with Generate Biomedicines, worth up to \$1.9B

“

In ten years when there is enough data, AI will be a commoditized tool across the industry to assist drug development, similar to how we shifted from using single-channel pipettes to multi-channel pipettes

– Asian biotech CEO

”

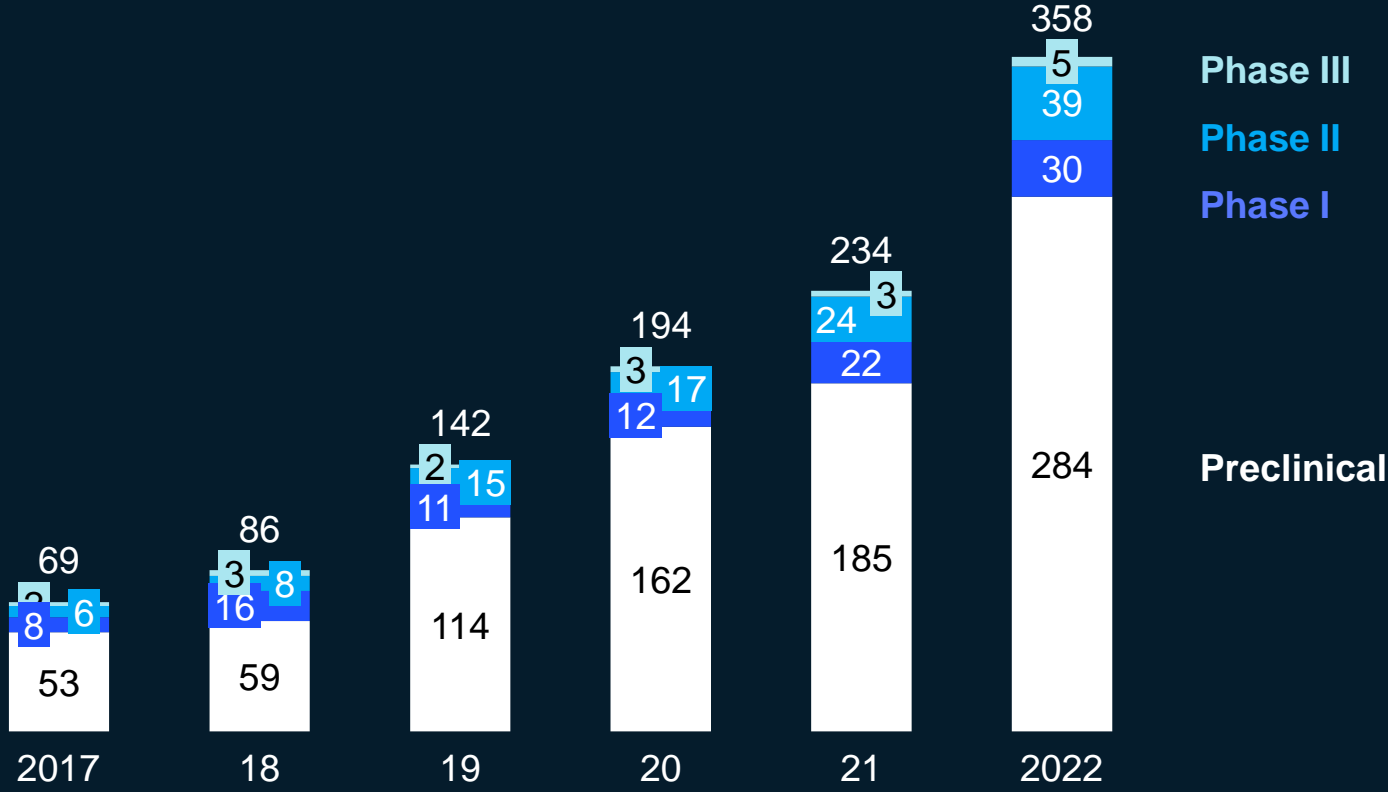
1. Top-30 PharmaCos by market cap as of October 2022

2. FTEs are normalized to 2014 FTEs

3. Other job positions include all job positions at top 30 PharmaCos that are not AI, ML, analytics (e.g., sales, management, bench scientists)

AI-driven drug discovery biotechs are advancing their own assets as well

Pipeline assets by AI-driven drug discovery companies¹,
Number of assets



AI-driven pipeline is in early stages of development with only

~12%

of assets in Phase II or Phase III

1. Products in pipeline includes assets from preclinical to Phase III products owned by AI-driven drug discovery companies
Source: Pharmaprojects | Informa, 2022

AI offers potential to reshape the biotech industry

Early signals that AI companies increase development efficiency

Biopharma target to validated lead
~24-36 months

Leading AI companies
~10-20 months

40-60%

Reduction in time

Benchmark for industry costs through preclinical studies¹

~\$25-50M

40-80%

Preclinical costs in leading AI biotechs

~\$5-15M

Reduction in cost

PTRS with traditional methods

~8-15%

~2X

PTRS with AI-enabled drug discovery

Potentially ~20-40%

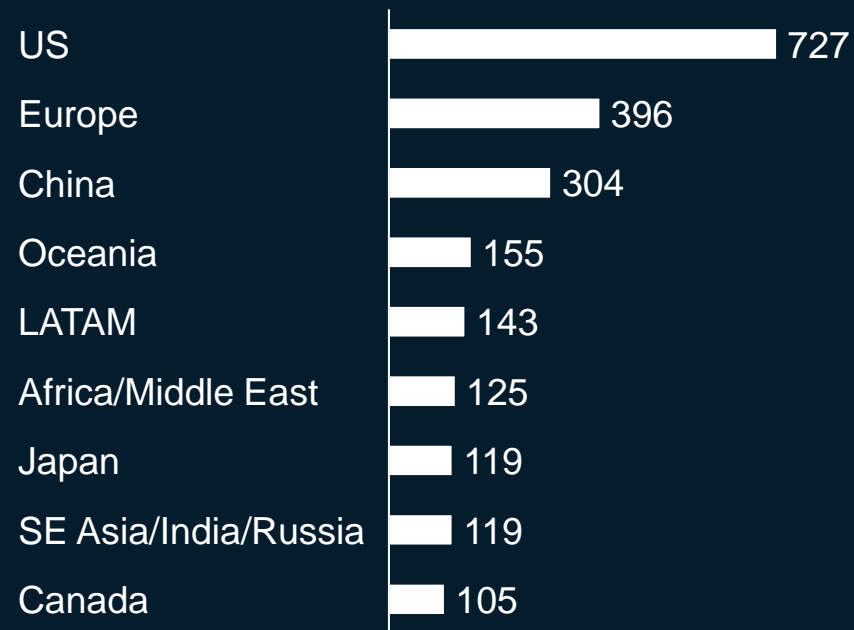
Potential promise for improvement in PTRS from preclinical to launch, still to be proven

1. All costs from post-target identification through preclinical for a single candidate, not accounting for risk adjustment

Source: Pharmaprojects | Informa, 2022; EvaluatePharma November 2022, Evaluate Ltd.; Paul *et al.* (2010) *Nat Rev Drug Discov.*; company press releases

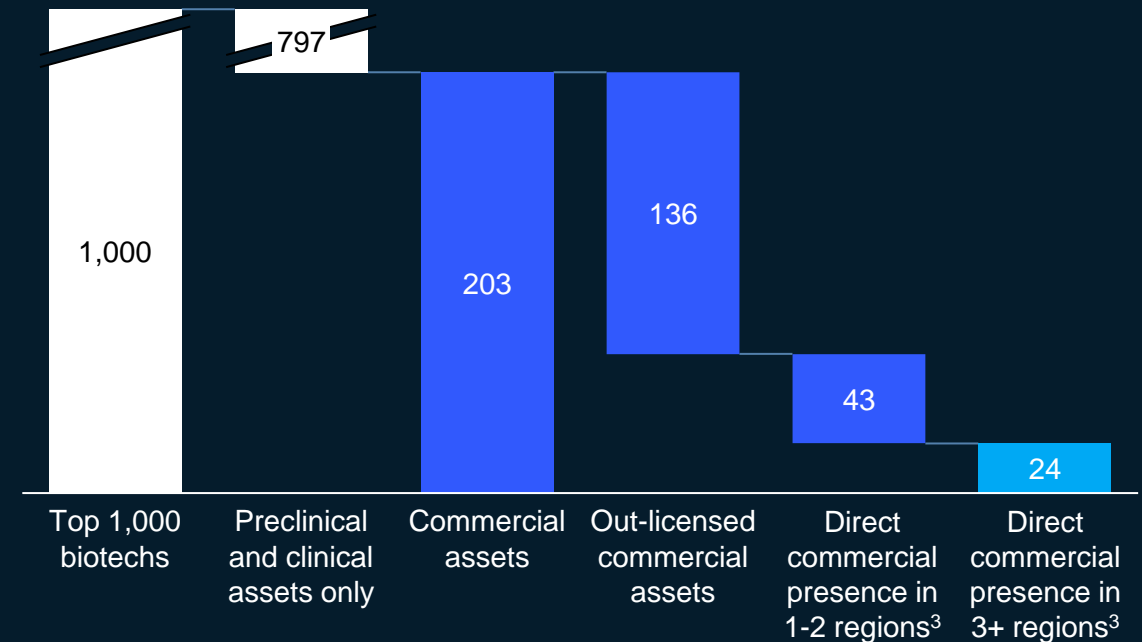
Historically, biotechs have built global clinical footprints...

**Clinical trial site locations for top 50 biotechs¹,
Number of ongoing clinical trials (2020 – present)**



...but few have developed true global commercial presence

**Top biotechs² by lead asset status,
Number of companies**



1. Number of ongoing clinical trials sponsored by the top 50 biotechs (ranked by 2021 revenues) from clinicaltrials.gov since 2020; ongoing trial defined as “active”, “available”, “enrolling”, “recruiting” or “completed”

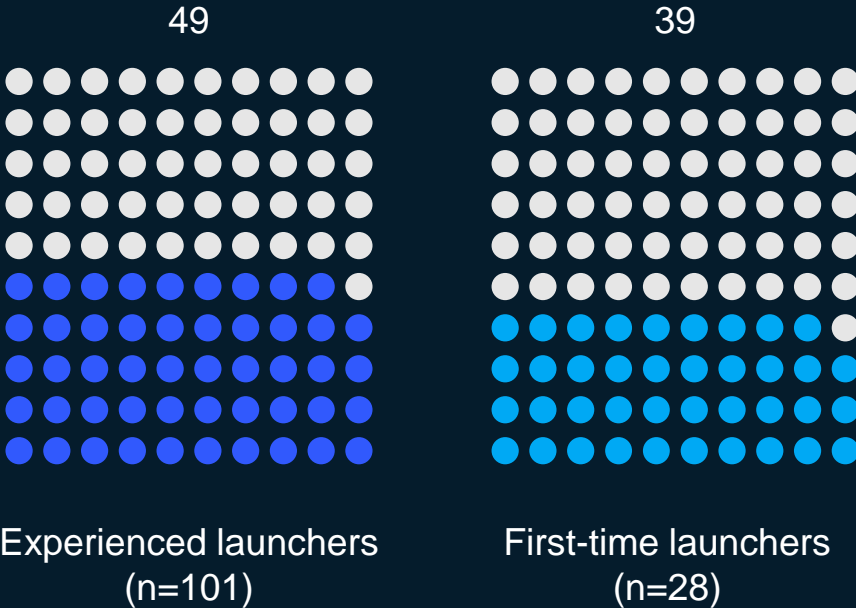
2. Top 1,000 biotech companies ranked by 2021 10K-reported revenues; includes all 156 companies listed on S&P XBI index as of October 2022

3. Regions include North America, Europe, Asia, Southeast Asia / Australia, Latin America, Middle East / Africa

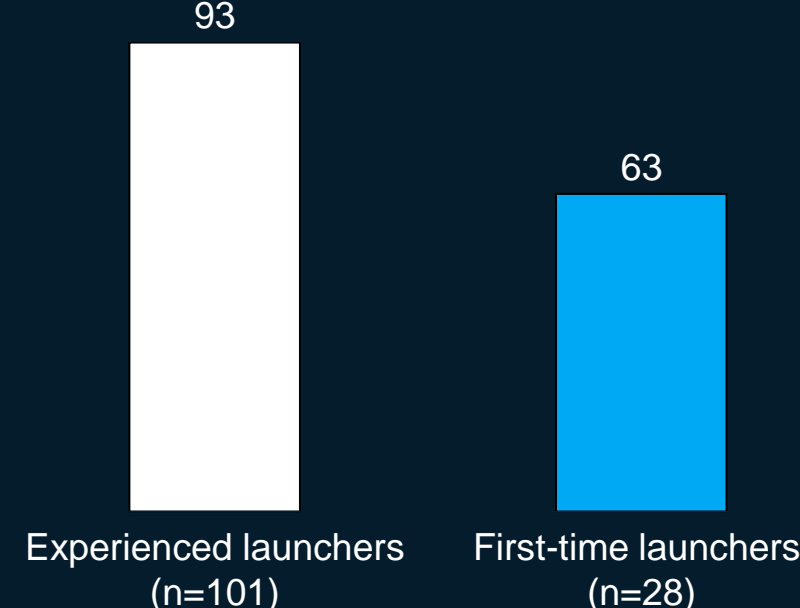
Source: clinicaltrials.gov as of November 2022; EvaluatePharma November 2022, Evaluate Ltd.; company 10Ks and investor presentations

Biotech companies face challenges when launching

Successful launches that exceed analysts pre-launch forecasts¹,
Percent of launches



Median achievement of expected forecasts²,
Percent of forecasted revenue achieved

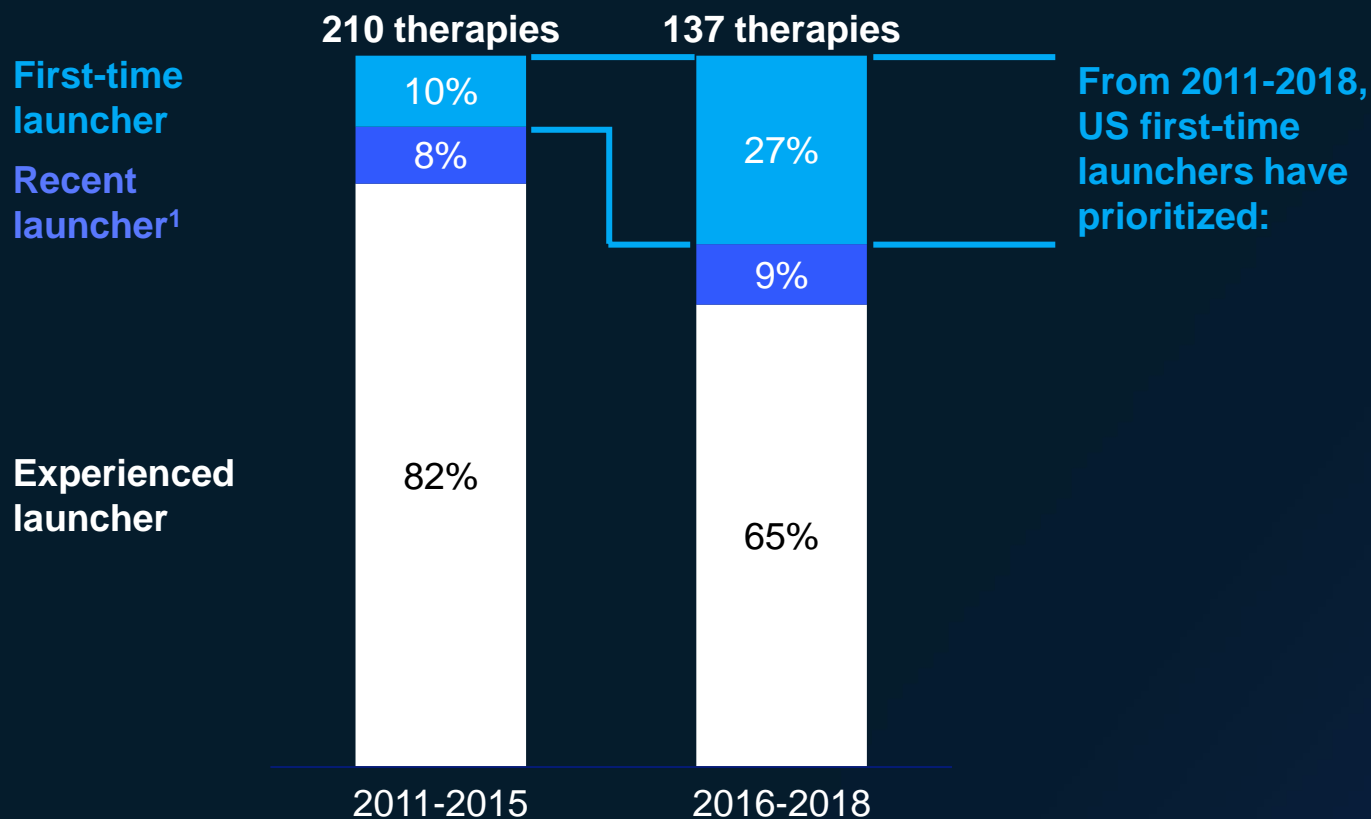


Almost all
first-time launchers
are biotechs

1. Based on all launches from 2014 to 2017; "successful" launchers had sales revenue for the first 3 years of launch that exceeded the final EvaluatePharma consensus forecast prior to launch
2. Based on all launches from 2014 to 2017; median deviation between actual sales and 3-year EvaluatePharma forecast made during launch year

NMEs from first-time launchers are increasing and often addressing new targets

NMEs launch per year in the US by company type, Percent



1. Companies that launched their first product after 2001
 2. Anti-infectives include antibiotics, antivirals, and vaccines
 3. 58 therapies in total between 2011 and 2018 by first-time launchers
 4. Defined as the first MoA launched in the US regardless of indications by FDA CDER and CBER

Biotechs are starting to form more peer-to-peer partnerships to expand globally

Non-exhaustive

Biotech-to-big Pharma partnership model

Biotech

Ultragenyx (US)
Legend Biotech (China)
Prothena (Europe)

Big Pharma

Daiichi Sankyo (Japan)
Janssen (US)
Bristol Myers Squibb (US)

Emerging biotech-to-biotech model

RemeGen (China)

Product development, commercialization in China

Seagen (US)

Worldwide commercialization outside China

CRISPR Therapeutics (US)

Preclinical and clinical development assist

Vertex (US)

Global development lead, manufacturing, and commercialization

argenx (Europe)

Product development

Zai Lab (China)

Development and commercialization in Greater China

Biotech

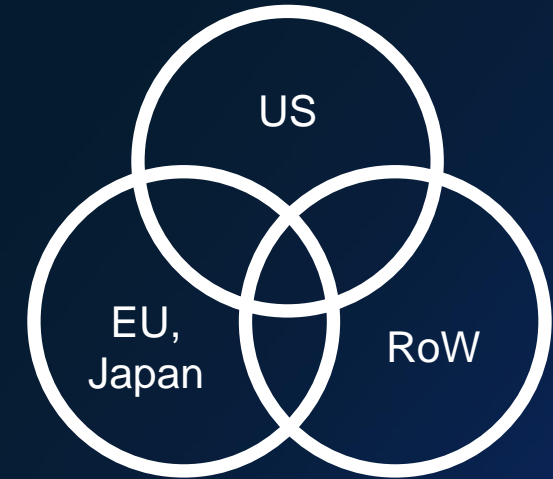
Biotech

More biotechs are pursuing simultaneous global expansion models

Historically, most companies pursued a sequential route in global expansion



Recent trends show simultaneous expansion accelerates global access



Recent examples of simultaneous expansion paths

- | | |
|--------------------------|--|
| BeiGene | Multi-regional clinical trials (within 2 years) and manufacturing facilities (within 6 years) of company inception |
| BioNTech, Moderna | In-house manufacturing facilities in US and Europe with plans to expand capabilities in Africa, Asia, and Australia |
| Seagen | Simultaneous strategic partnerships in different regions (Asia, Europe, and US) to commercialize globally at the same time |

The promise of the next generation of the biotech industry lies in its **ability to accelerate innovation**

Platforms offer the potential to scale innovation in unprecedented ways

AI could transform drug discovery and development, and will become an integral part of the industry

The upcoming generation of biotech companies may scale up and diffuse innovation globally more quickly



What should be on biotech

CEO agendas?

Five factors increasing in complexity

Always top of mind:

Innovation / pipeline

Access to capital

Talent

1

Regulatory

2

Pricing, re-
imbursement

3

Supply chain
risk

4

Industry-
shared assets

5

Patient
engagement

1. Despite progress, biotechs still face challenges navigating regulatory pathways

Biotechs often lack deep regulatory expertise...

“ It was so difficult to hire an internal regulatory expert to guide the company, we often had to resort to external regulatory consultants

Lack of internal expertise sometimes led to hiccups in the process when interacting with regulators

– US biotech CEO

”

...and the regulatory bar is rising for new modalities, requiring more data and engagement with regulators

>30%

of leading gene therapies¹ reported clinical holds² requiring additional safety data

Fully enrolled

confirmatory trials can still be required in accelerated approval pathways

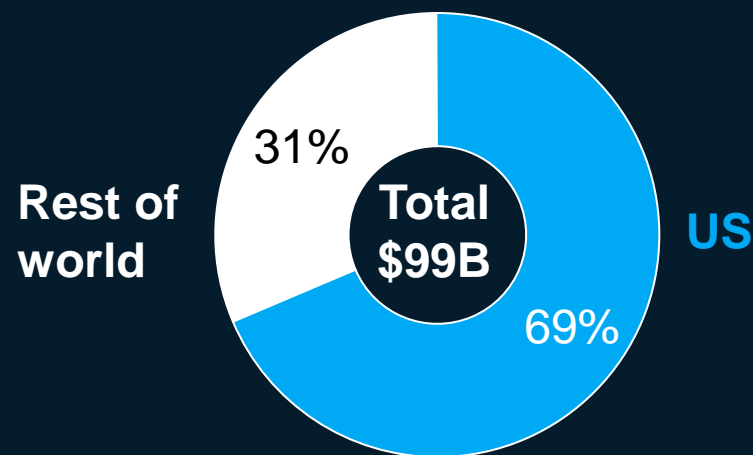
1. Includes Phase III and marketed gene therapies

2. Accounts for publicly reported clinical holds

Source: FDA PDUFA 2021; EvaluatePharma November 2022, Evaluate Ltd.; executive interviews as of November 2022; company press releases

2. Biotechs face increasing pricing pressure in the US with the introduction of the Inflation Reduction Act (IRA)

2021 revenue for top 15 biotechs with global breakdown reported¹



Changes

2023

Medicare inflationary rebates



Limits level of drug price increases year over year

2026

Medicare drug price negotiation



Impacts blockbuster drugs with likely spillover effects on entire TAs

2027+

Continuous increase in drugs subject to negotiation



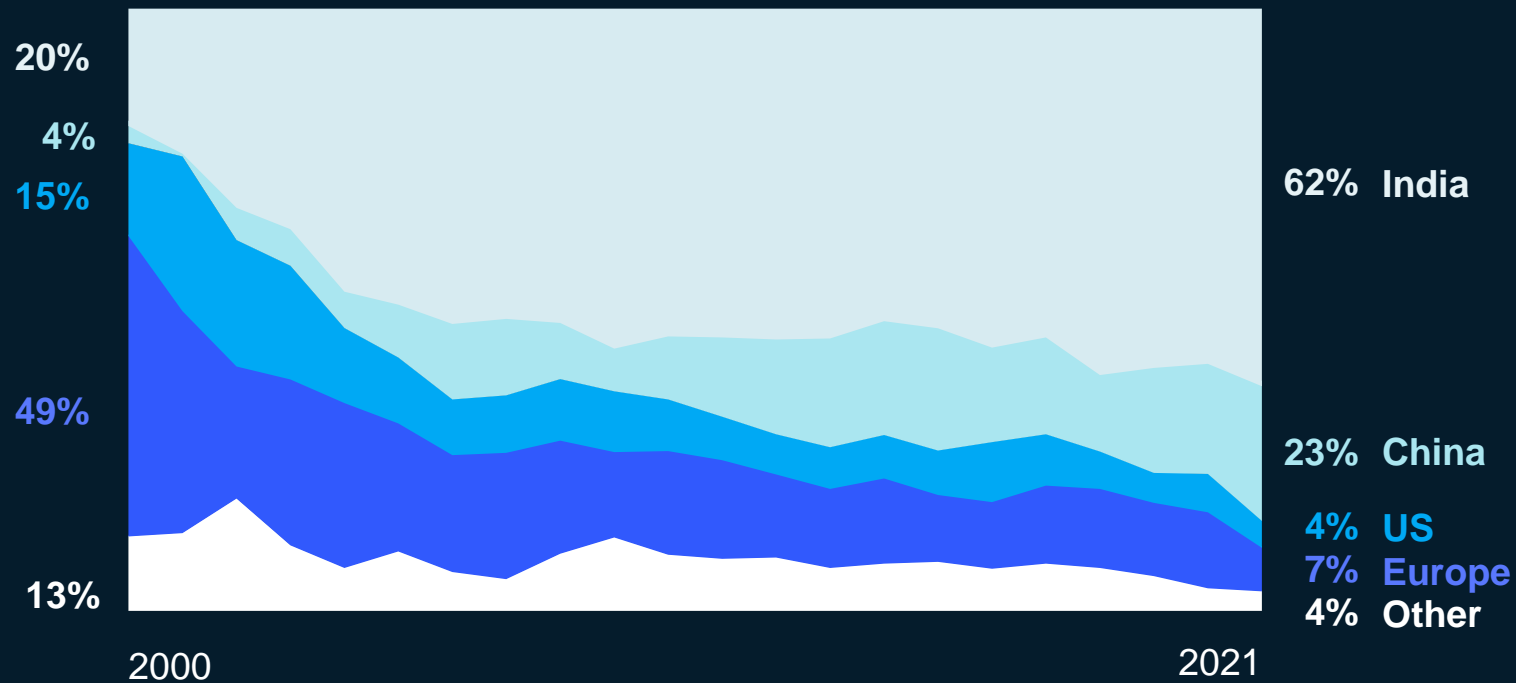
Increases pricing pressure across the industry

1. Biotechs ranked by 2021 global revenue; includes top 15 biotechs that reported revenues by region in their 2021 SEC filings

Source: US Federal Law; expert interviews as of October 2022; company 10Ks

3. Small molecule raw materials are geographically concentrated, with similar trends for new modalities

Active API drug by country of manufacturing, Percent of drug volume



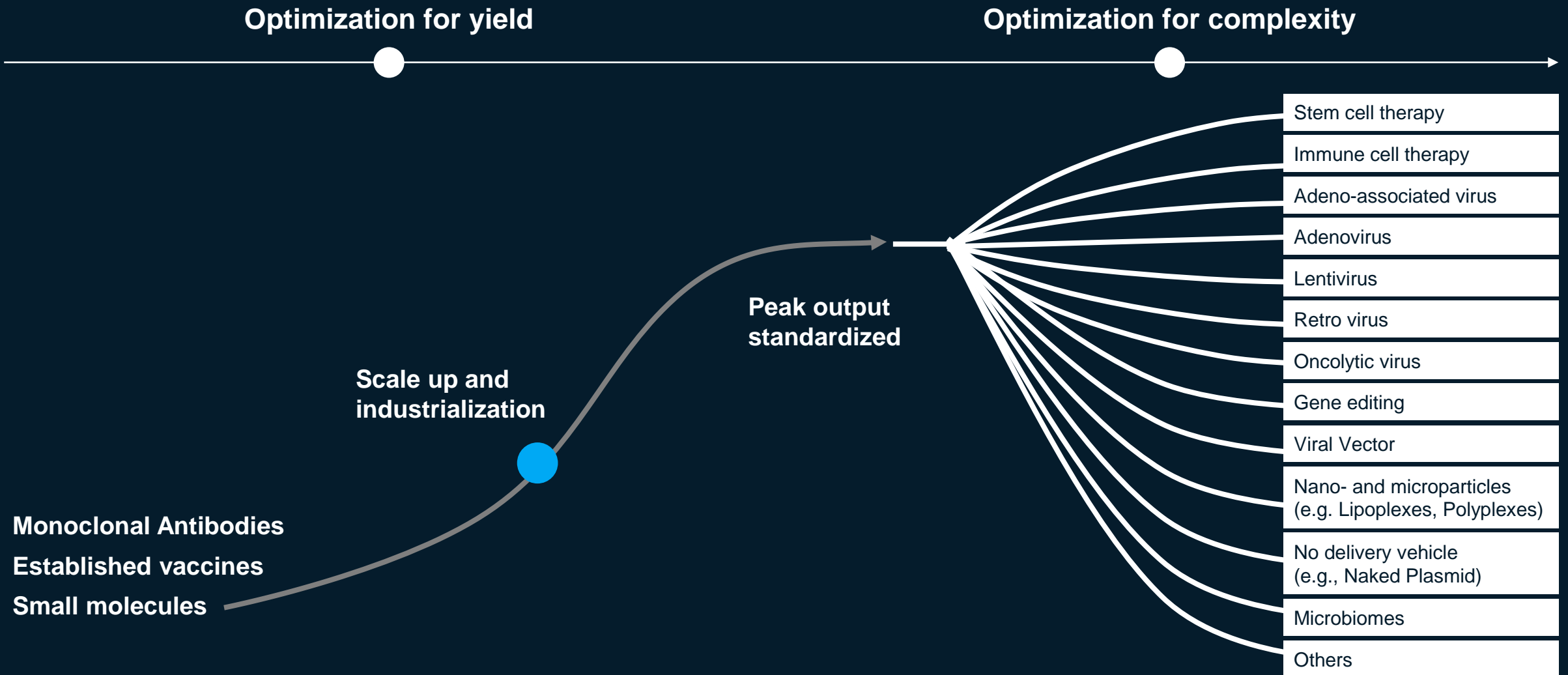
“

Almost all of our nucleotides were sourced from a single geography, which made our supply chain potentially vulnerable

– US Biotech CEO

”

3. Proliferation of new modalities is shifting the challenge from optimization of yield to optimization of complexity



This increased complexity raises the bar for the capital required and overall risk profile

With less fungible capacity, dedicated lines require early upfront investments and a higher risk tolerance

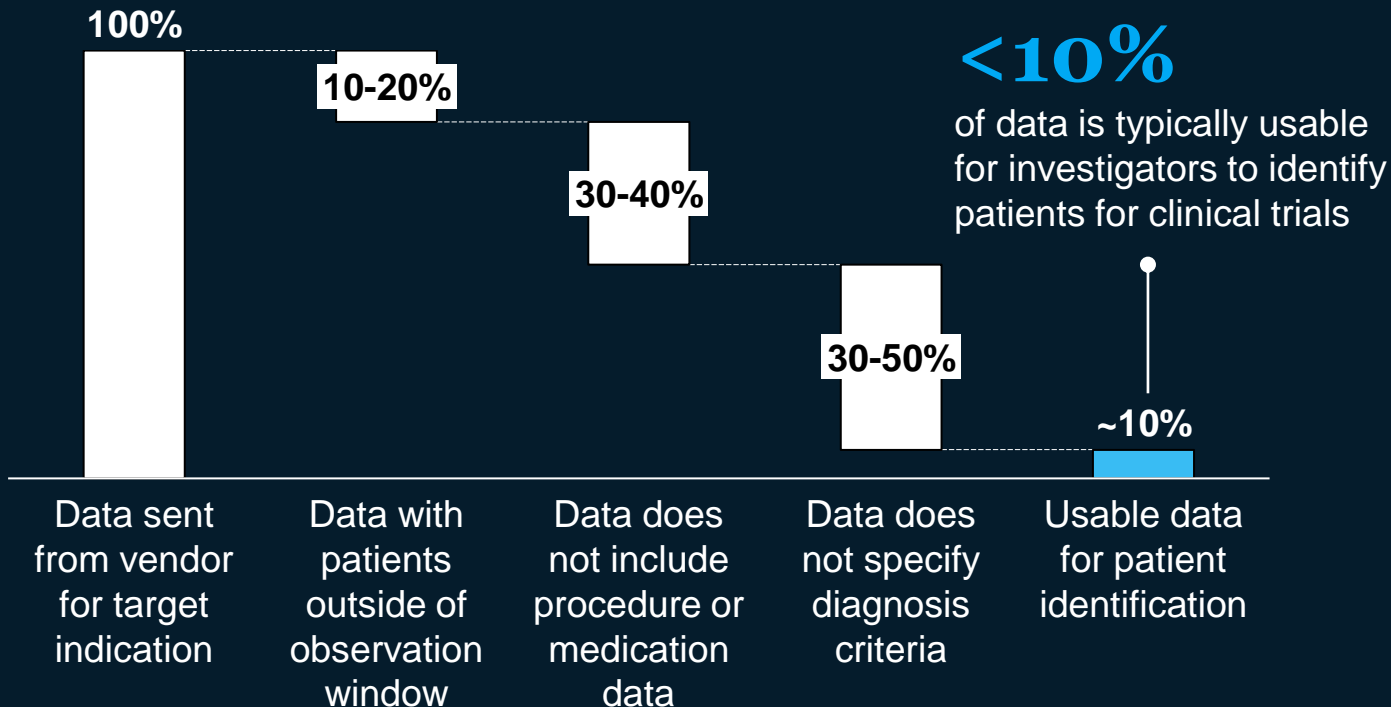
Companies across the value chain are responding to this challenge in various ways:

- Investing in parts of the supply chain
- Building end-to-end supply networks
- Early partnerships with CDMOs

4. Biotechs face challenges with the current data infrastructure

Existing data sets are incomplete, missing segments of patient data

EMR data for target patient identification, Percent of data
Specific disease area, representative example



“

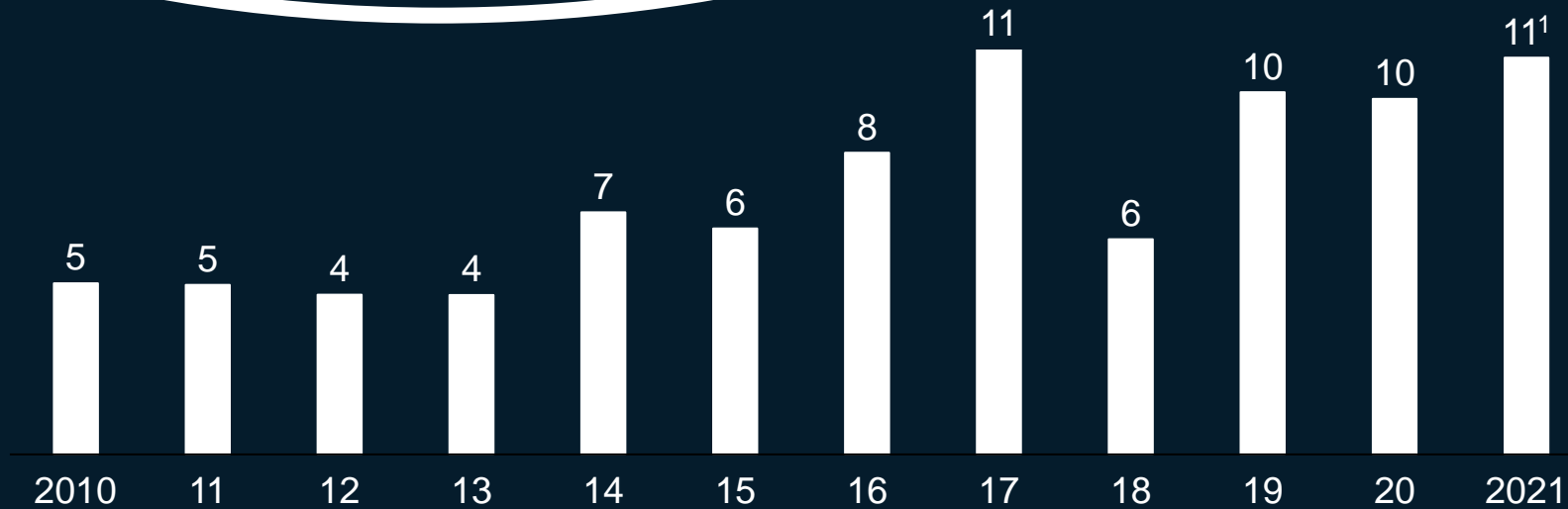
It is not feasible for individual biotechs to invest the time and capital into collecting data to create AI capabilities

– US biotech CEO

”

5. Number of patients in clinical trials has continuously increased over the past 10 years

~2X
increase



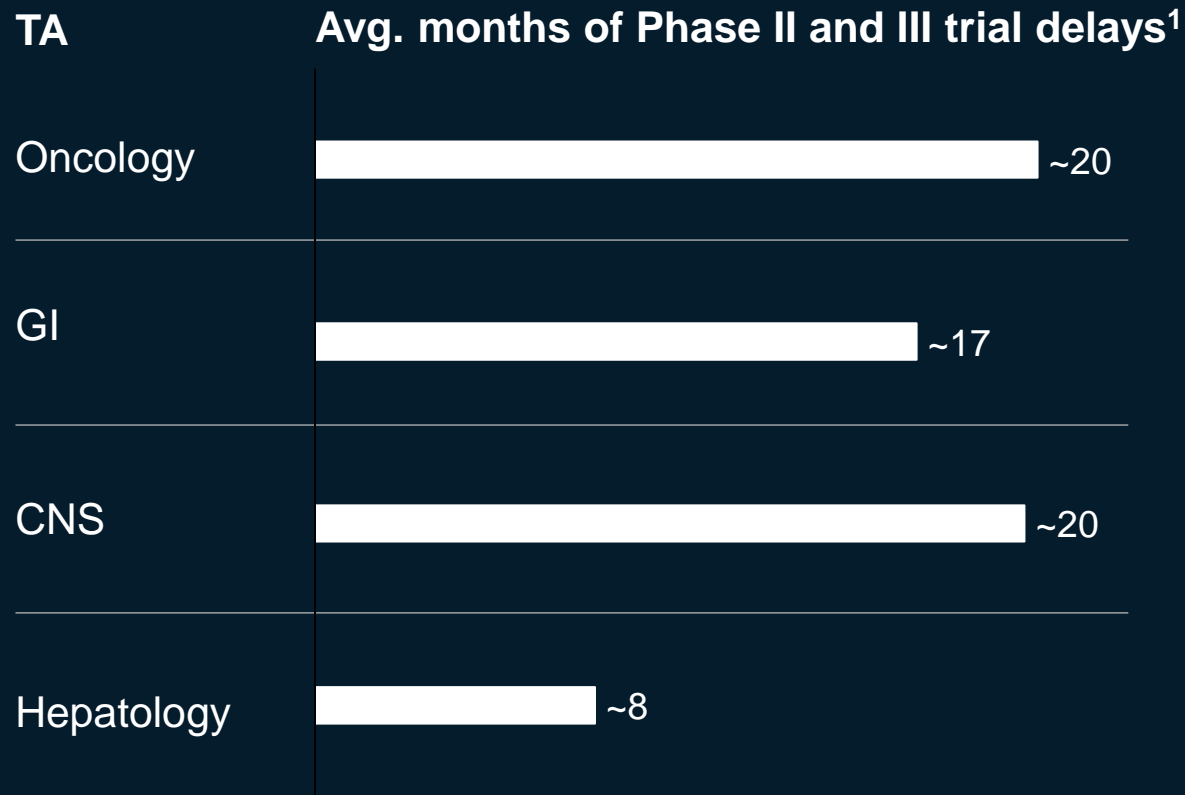
Patients enrolled in clinical trials by start year, Number of patients (M)

Regionally², patients from **Asia-Pacific³, Europe, and Africa** had the greatest growth with ~9% CAGR⁴ while North America remained relatively flat

Other than COVID-19, **oncology trials** have seen the greatest increase with ~8% CAGR⁴

1. 2 trials from 2021 were removed (~24M patients total); one for hirudotherapy (NCT05438901) and the other one for depression/suicide prevention (NCT04946955)
2. Regional patient enrollment was estimated based on the proportion of trial sites in each region; 9% of total trials did not report geographical locations; Middle East (<1% of patients), Central America (<1% of patients) and South America (<2% of patients) were excluded in the regional analysis
3. Includes Asia and Pacifica region (Australia)
4. CAGR calculated for 2010-2021

5. Patient enrollment remains one of the biggest bottlenecks to innovation



“

There are some indications that are becoming very challenging to recruit patients that fit your inclusion criteria. The inability to recruit adequate patients has definitely been one of the biggest reasons for our trial delays.

– US biotech CEO

”

1. Calculated based on expected trial anticipated primary completion date and actual primary completion date of 15-20 Phase II and Phase III trials per TA with completion date between 2018-2020 (~70 trials in total included in the analysis)

5. Patients have mixed feelings about participating in clinical trials



Source: McKinsey & Co. survey of clinical trial participants on their emotional state before, during, and after clinical trial (n=101); excludes Phase I trial participants

~1.1K

patients enroll
in clinical trials
each hour

Looking ahead, how can the industry raise the bar to deliver on the promise of innovation?

- Make it easier for patients to participate in trials
- Expand trial networks to reach more patients globally
- Broaden the aperture of innovation to address remaining disease burdens

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Or email us at biotech@mckinsey.com



For more materials on the biopharma industry:

- [The Helix report: is biopharma wired for future success?](#)
- [Vision 2028: How China could impact the global biopharma industry](#)
- [AI in biopharma research: A time to focus and scale](#)
- [A biotech survival kit for a challenging public-market environment](#)
- [Innovation sourcing in biopharma: Four practices to maximize success](#)
- [First-time launchers in the pharmaceutical industry](#)



