



Certara

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Chief Executive Officer

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CERTARA 

Disclaimer

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Non-GAAP Financial Information

This presentation contains “non-GAAP measures” that are financial measures that either exclude or include amounts that are not excluded or included in the most directly comparable measures calculated and presented in accordance with U.S. generally accepted accounting principles (“GAAP”). Specifically, we make use of the non-GAAP financial measures adjusted EBITDA, adjusted EBITDA margin, adjusted net income (loss), adjusted diluted earnings per share (“EPS”), and constant currency (“CC”) revenue, which are not recognized terms under GAAP and should not be considered as alternatives to net income (loss), GAAP EPS, or GAAP revenue as measures of financial performance or cash provided by operating activities as a measure of liquidity, or any other performance measure derived in accordance with GAAP. These non-GAAP measures have limitations as analytical tools and should not be considered in isolation, or as a substitute for our results as reported under GAAP. Because not all companies use identical calculations, the presentations of these measures may not be comparable to other similarly titled measures of other companies and can differ significantly from company to company.

Adjusted EBITDA represents net income (loss) excluding interest expense, provision (benefit) for income taxes, depreciation and amortization expense, intangible asset amortization, equity-based compensation expense, acquisition and integration expense and other items not indicative of our ongoing operating performance. Adjusted EBITDA margin represents adjusted EBITDA divided by revenue. Adjusted net income and adjusted diluted EPS exclude the effect of the same items noted above with respect to adjusted EBITDA from GAAP net income (loss) and GAAP EPS, respectively, as well as adjust the provision for income taxes for such charges. CC revenue excludes the effects of foreign currency exchange rate fluctuations by assuming constant foreign currency exchange rates used for translation. Current period revenue reported in currencies other than U.S. dollars are converted into U.S. dollars at the average exchange rates in effect for the comparable prior periods. You should refer to the appendix at the end of this document for a reconciliation of these non-GAAP measures in specific periods to their most directly comparable financial measures calculated and presented in accordance with GAAP for those periods.

Management uses various financial metrics, including total revenues, income from operations, net income, CC revenue and certain non-GAAP measures, including those discussed above, to measure and assess the performance of the Company’s business, to evaluate the effectiveness of its business strategies, to make budgeting decisions, to make certain compensation decisions, and to compare the Company’s performance against that of other peer companies using similar measures. In addition, management believes these metrics provide useful measures for period-to-period comparisons of the Company’s business, as they remove the effect of certain non-cash expenses and other items not indicative of its ongoing operating performance. Management believes that these metrics are helpful to investors, analysts, and other interested parties because they can assist in providing a more consistent and comparable overview of our operations across our historical periods. In addition, these measures are frequently used by analysts, investors, and other interested parties to evaluate and assess performance. In addition, our business has operations outside the United States that are conducted in local currencies. As a result, the comparability of the financial results reported in U.S. dollars is affected by changes in foreign currency exchange rates. We use CC revenue to evaluate the underlying performance of the business, and we believe it is helpful for investors to present operating results on a comparable basis period over period to evaluate its underlying performance. In evaluating adjusted EBITDA, adjusted net income (loss), adjusted diluted EPS, and CC revenue, you should be aware that in the future the Company may incur expenses similar to those eliminated in this presentation and this presentation should not be construed as an inference that future results will be unaffected by unusual items.

Drug development needs a new model

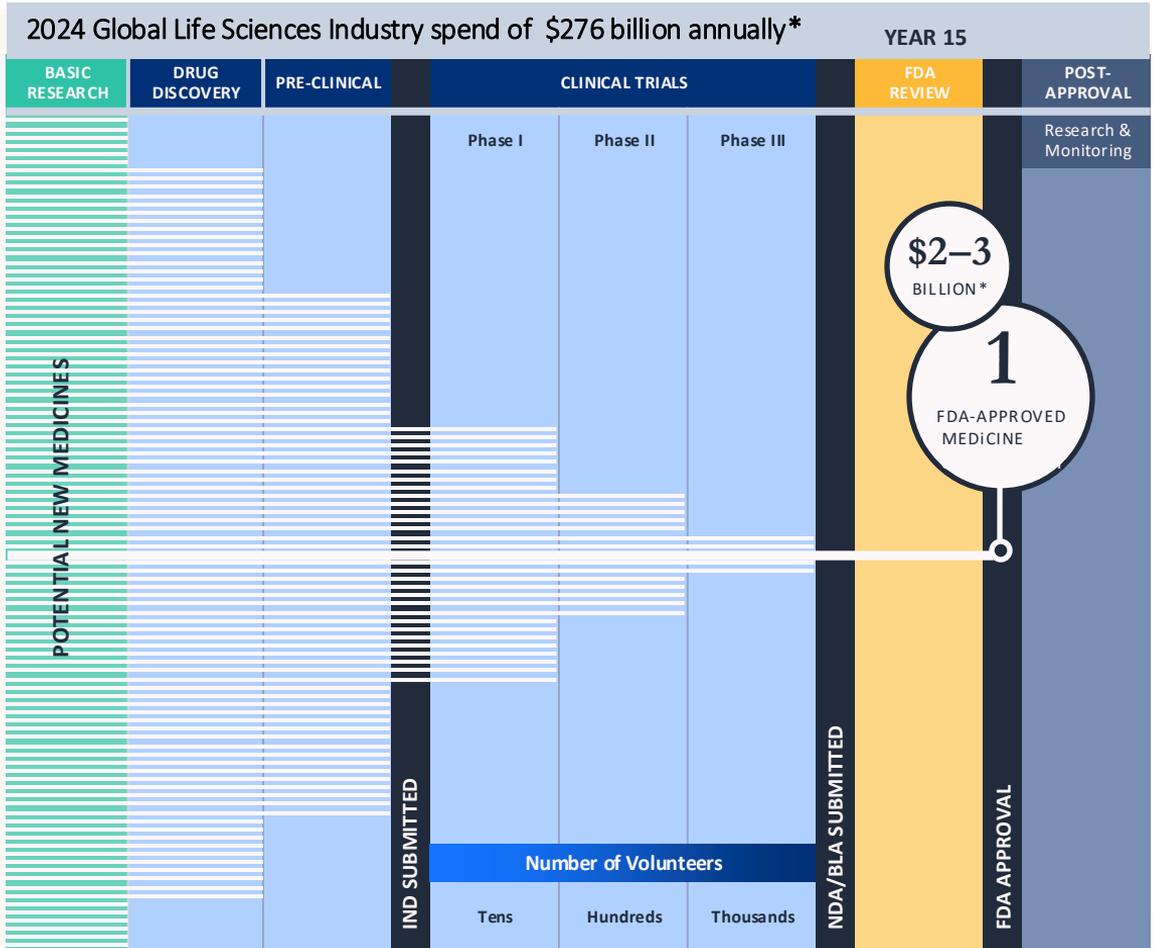
88% of new medicines that enter Clinical trials fail*

- 40–50% lack clinical efficacy
- 20–30% unmanageable toxicity
- 10–15% poor pharmacokinetic (PK) properties
- 10%+ fail due to lack of commercial viability*

*FTL Science 2022 <https://theconversation.com/90-of-drugs-fail-clinical-trials-heres-one-way-researchers-can-select-better-drug-candidates-174152>

<https://floscience.com/process-costs-drug-development/>

Comprehensive measurement of biopharmaceutical R&D investment



Driving Efficiency in Drug Development

≈ \$300
million*

Per drug, the potential savings from just a 3% increase in process efficiency

*Modeled using data from How 90% of clinical drug development fails and how to improve it <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9293739/> and management assumptions

Biosimulation: the use of modeling and simulation to predict how drugs behave in the human body.

Certara's AI enabled biosimulation platform:

- Save years of time
- Reduces costs
- Increases scientific understanding

2,400+

Customers across 70 countries;

30

Of the top 30 biopharma are customers

>90%

Of all novel drugs approved by the US FDA since 2014 supported by Certara solutions

Validated by

34K+

Scientific publications with scientists and technology

1550+

Global team members in 30 Countries



Mission: We use AI enabled biosimulation, data, and scientific expertise to **transform drug development** and accelerate new medicines to patients.

32%

Adj. EBITDA Margin in FY 2024

18%

Software growth FY 2024

>120 novel drugs
325 label claims
were approved by global regulators using Certara technology in lieu of clinical studies

Software adopted by

23

Global regulatory agencies

Certara's AI-enabled biosimulation platform uses biological systems models, technology and data to answer critical questions



DISCOVERY

- Target product profiles
- Best target
- Best candidate



PRECLINICAL

- Translate animal/NAM data to human dosing
- Toxicity and risk profiles
- Persevere with approach or pivot to another



EARLY CLINICAL

- Optimal safe and effective dose strategy
- Best clinical trial designs
- Responder populations



LATE CLINICAL

- Food and drug-drug interactions
- Impact on specific patient populations
- Data standardization for review and submission

Answering critical questions at every phase saving years of risk and cost

MIDD Saves ~10 months and \$5M per program

New publication from Pfizer highlights impact of MIDD on Drug Development Programs



- MIDD includes popPK, E-R modeling, PBPK, QSP, c-QT analysis
- 42 Pfizer Drug Development Programs were assessed
 - 11 Early Dev (FIH to POC)
 - 31 Late Dev (post-POC)
- Programs spanned 5 Therapeutic/Disease areas

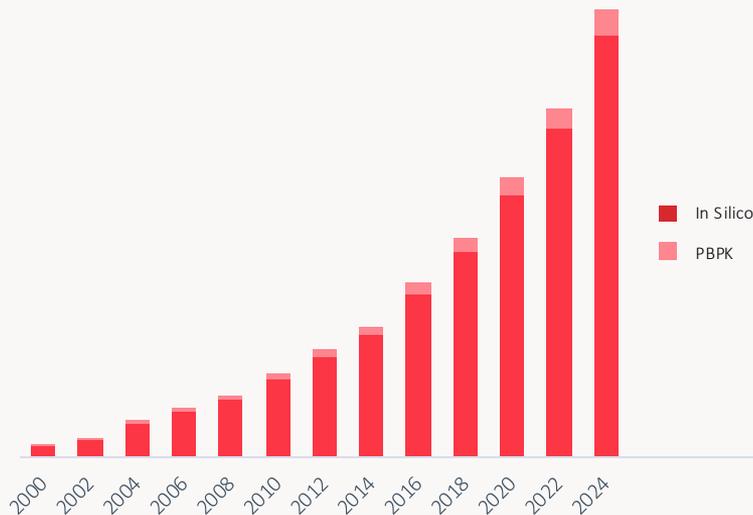
- Model-informed approaches facilitated decision making in EVERY development program with regard to:
 - Trial design
 - Dose and regimen selection
 - Extrapolation to special populations and reducing uncertainty.

“Some of the largest impacts of MIDD were related to “No-Go” decisions at the program level, which allow for reallocation of resources toward other programs with a higher probability of success.”

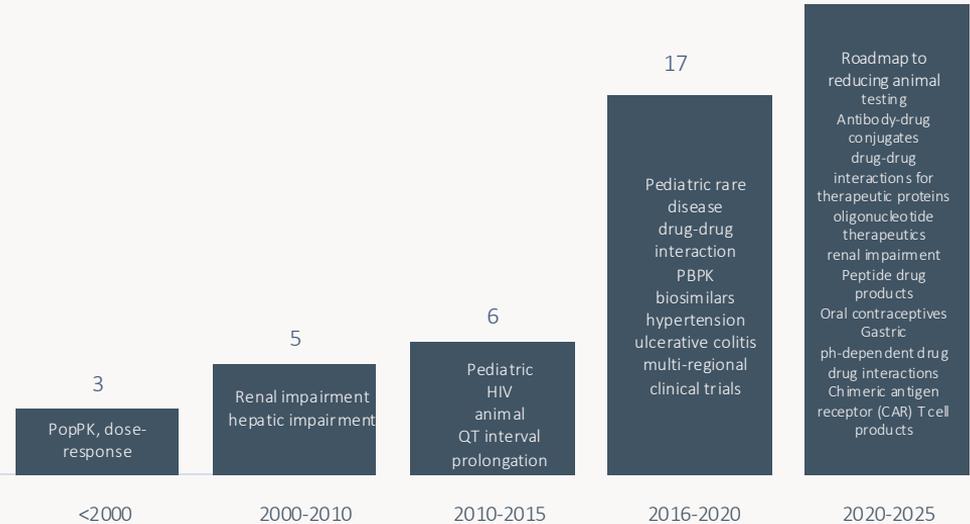
<https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.3636?af=R>

Industry and regulatory adoption of biosimulation is growing

Cumulative Scientific Publications on Biosimulation ¹



Cumulative Incorporation of Biosimulation in FDA Guidance ²
26



1. Science Direct search for publications by key search terms "in silico"

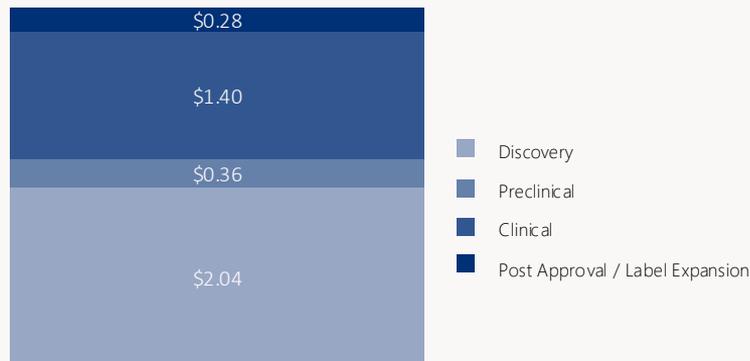
2. Model-Informed Drug Development: Current US Regulatory Practice and Future Considerations. Wang et al. Clinical Pharmacology and Therapeutics, April 2019"

In silico drug development addressable market

Market is large and growing as the use cases for biosimulation continue to expand

\$4.1 Billion in silico TAM; 1.5% of Total R&D Industry Spend

Biosimulation Total Available Market (in \$MM)



Value Creation By Development Phase

- Small percentage of success rate increase has large impact on the overall system (3%)¹
- Biosimulation solutions can capture 20%² of value created
- FDA approves an average of 64³ novel new medicines annually across drugs and biologics
- FDA approves an average of 120⁴ NDAs annually including new formulations that can benefit from biosimulation

Source: Company Research and Estimates

Footnotes:

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9293739/>
2. Management estimates using average ranges
3. FDA CDER and CBER Approvals
4. FDA NDA approvals
5. Biosimulation estimated value capture rate estimate for post approval label expansions is 1/5th that of novel medicines

April 10, 2025

FDA Plans to Phase out Animal Testing for Monoclonal Antibodies and Other Drugs with New Approach Methodologies (NAMs)

CERTARA[®]

Non-Animal Navigator[™]

Expert strategy and AI-enabled biosimulation to reduce, refine, or replace animal studies

*“Computational models can do as good a job or better, at predicting safety/toxicology” [of new medicines]” ...
“Those models should be replacing animal testing,”*

FDA Commissioner Marty Makary, interview with Megyn Kelly April 17th, 2025

DISCOVERY

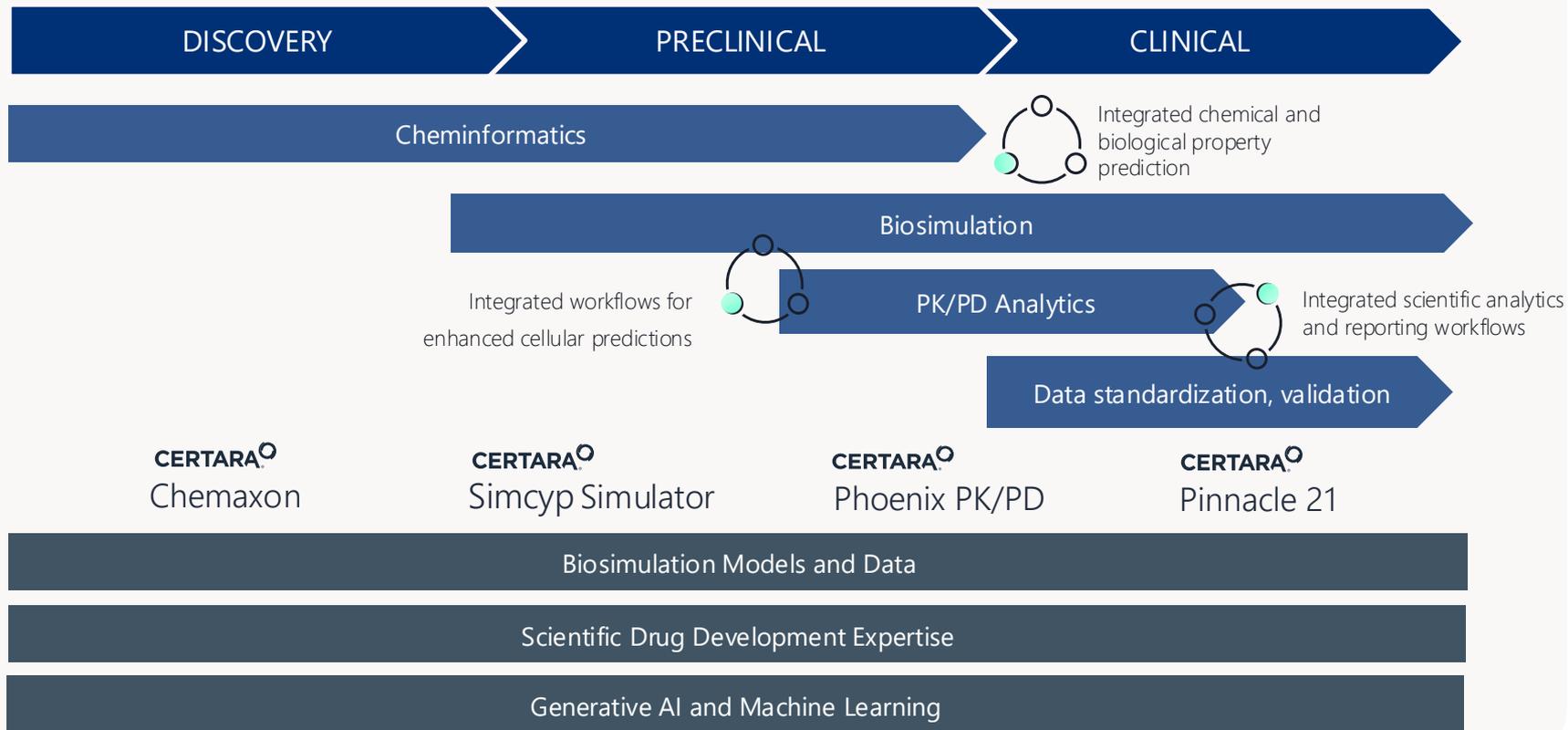
PRECLINICAL

EARLY CLINICAL

LATE CLINICAL

MARKET ACCESS & COMMERCIAL

Certara's Biosimulation Platform



Predict with Simcyp Simulator™

Model processes and systems to predict drug-human and human-drug effects

- Simulates virtual patient populations and trials
- Determines clinical endpoints and target populations
- Consults on Quantitative Systems Physiology

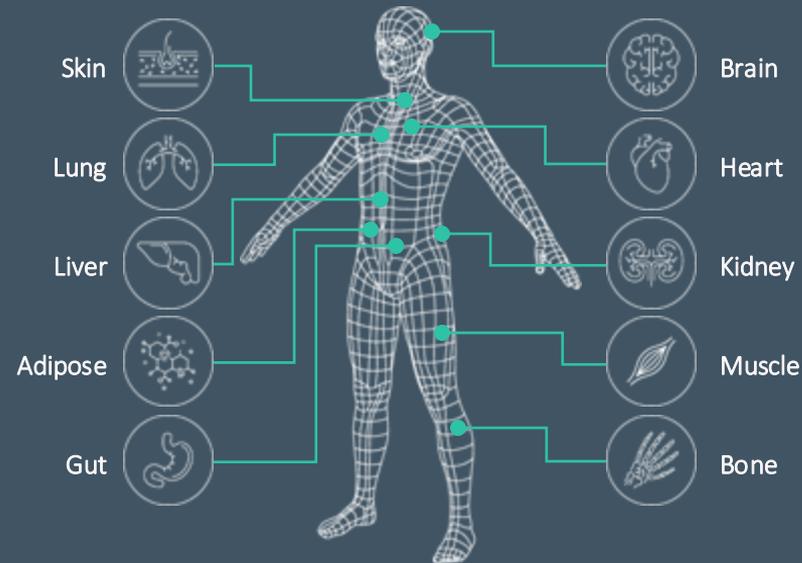
Label approvals of 120+ novel drugs **in lieu of clinical studies**, saving over 100s of millions \$

3-6 months

Saved per trial by using Simcyp.*

Simcyp Simulator models

CERTARA[®]
Simcyp™



25+ virtual patient populations are available to simulate disease impact.

DISCOVERY

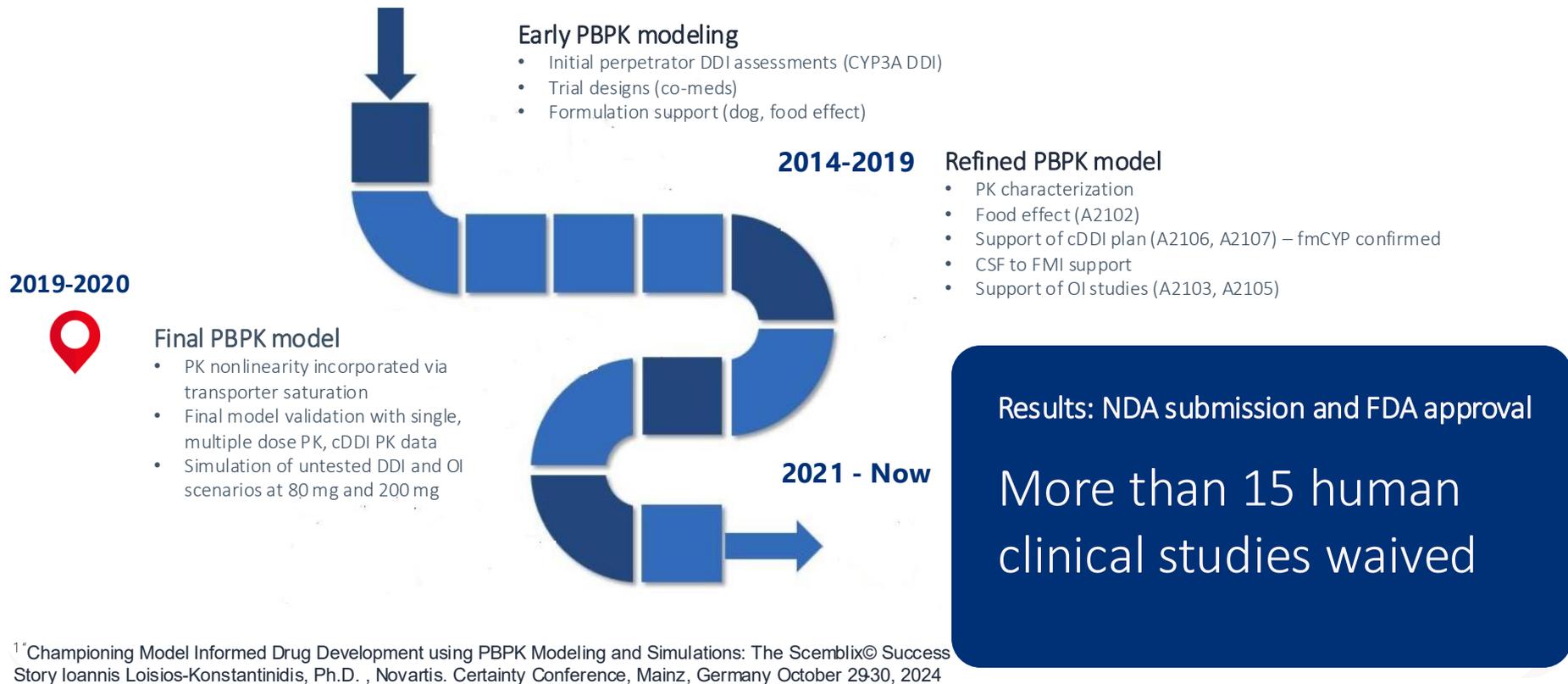
PRECINICAL

EARLY CLINICAL

LATE CLINICAL

MARKET ACCESS & COMMERCIAL

Case Study: Simcyp Simulator™ support for SCEMBLEX® (asciminib)¹



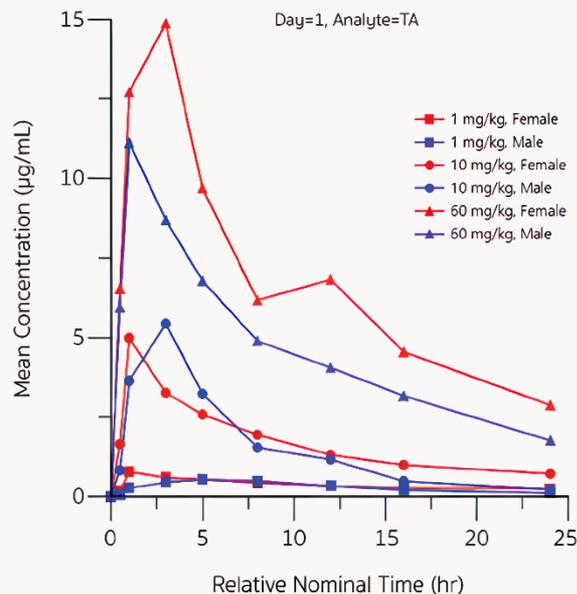
¹Championing Model Informed Drug Development using PBPK Modeling and Simulations: The Scemblix® Success Story Ioannis Loisos-Konstantinidis, Ph.D., Novartis. Certainty Conference, Mainz, Germany October 29-30, 2024

Phoenix™ PK/PD transforms data into decisions

Trusted by FDA, 10 international agencies, and over 70 of 100 top biopharma companies globally.

- Interprets PK/PD data to inform decisions
- Is the standard used by FDA for non compartmental analysis
- Widely used IVIVC module supports bioequivalence studies
- AI-enabled to select best model fit based on data

Industry gold standard for PK/PD and
NCA analysis



Pinnacle 21: Standardizing data for analysis and insight

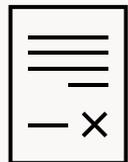
Data sources



Trial data



Trial standards

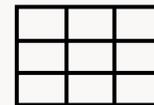


Data processes



Analysis-ready data

Compliant standard datasets, outputs for regulatory review

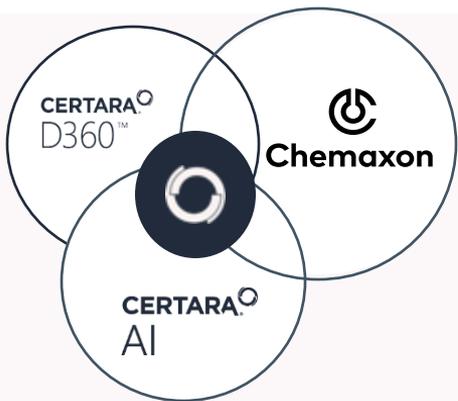


Define.XML



Data Reviewer's Guides

Outcomes: Faster cycle times to final clinical analyses: weeks vs. months



CERTARA[®] Discovery

RADNOR, PA., October 2, 2024
— **Certara, Inc.** (Nasdaq: CERT), a global leader in model-informed drug development, today announced it has completed the acquisition of **Chemaxon**.

Closing gaps in the
DMTA cycle

Leading compound
design, search and
prediction solutions

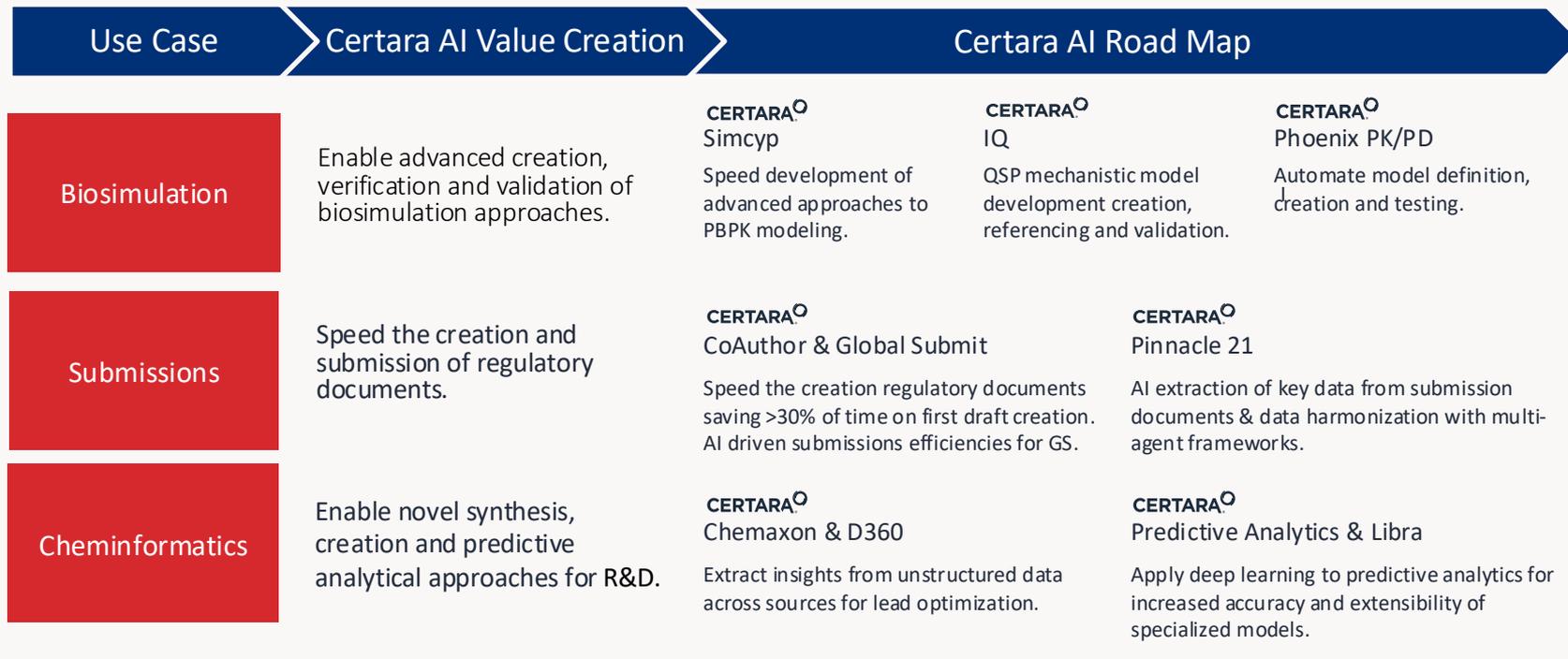
Integrating workflows
to speed
breakthroughs

New solutions to derisk drug
discovery

Application of secure, specialized AI technologies including LLMs and multi-agentic frameworks driven by life science use cases with ‘human in the loop’ oversight and extensive domain expertise provides highly differentiated Certara AI offerings



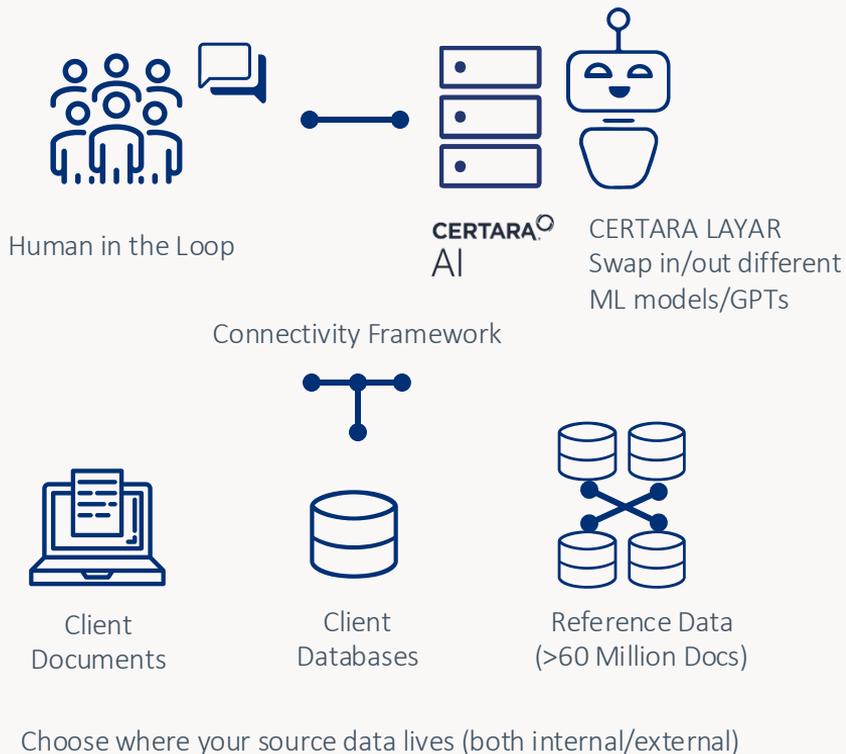
‘Human in the Loop’



CERTARA CLOUD & DATA FABRIC ARCHITECTURE

CERTARA[®] AI

Certara's secure, modular AI software infrastructure enables our platform to easily integrate with other tools and tackle a variety of use cases



- The Layar platform is secure and extensible – ML/DL/GPT models connect to data on an as-needed basis
- Layar can efficiently tackle a wide variety of use cases and slot into established workflows without significant retooling

DISCOVERY

PRECLINICAL

EARLY CLINICAL

LATE CLINICAL

MARKET ACCESS & COMMERCIAL

Successful M&A execution for growth

Integrated acquisitions have delivered strong returns since the IPO

The logo for PINNACLE 21, featuring the word "PINNACLE" in orange with a small triangle above the 'A', and "21" in a smaller font to the right.

Acquired in October 2021

Clinical data standardization software to standardize, validate, and harmonize data

Three new product introductions since acquisition expanding value and users.

The logo for applied biomath, featuring a green circular icon with a white molecular structure and the text "applied biomath" in green, with "REVOLUTIONIZING DRUG INVENTION" in smaller text below.

Acquired in December 2023

Scientific thought leadership - QSP team is the largest, most experienced in the industry

AI-enabled QSP will further accelerate growth

The logo for Chemaxon, featuring an orange circular icon with a white molecular structure and the word "Chemaxon" in orange.

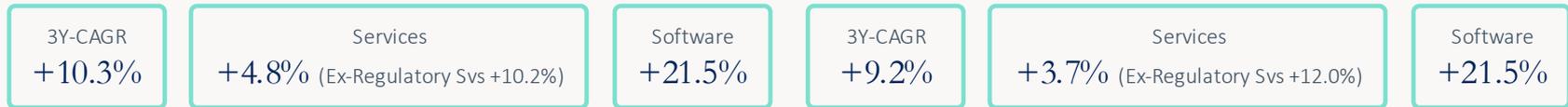
Acquired in October 2024

A discovery platform for chemical property and structure prediction.

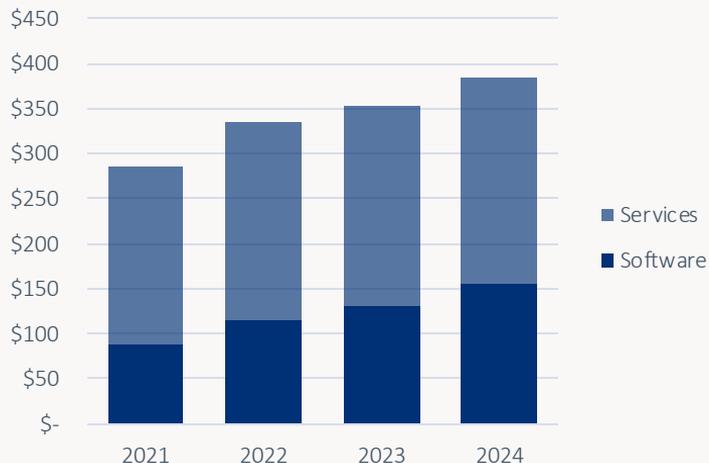
Strategic entry into the discovery biosimulation market at scale.

Financials

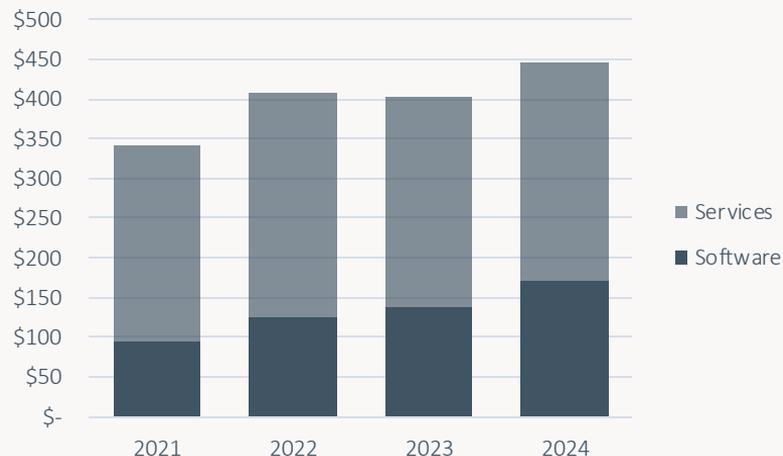
Certara's growth profile by software and services



Revenue (millions)



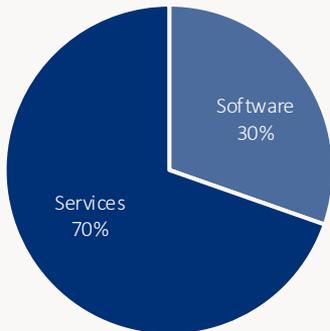
Bookings (millions)



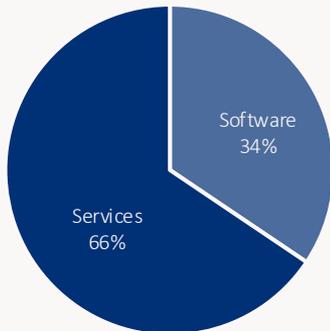
Certara's performance has been driven by strong software growth as customers accelerate the use of biosimulation.

Revenue mix shift to software

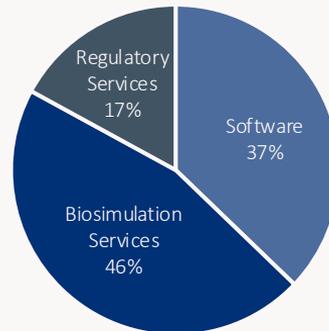
2021 Revenue
\$286M



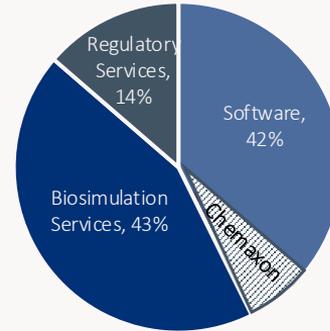
2022 Revenue
\$336M



2023 Revenue
\$354M



2024 Revenue
\$384M
(2024 Proforma-Revenue \$401M)*



*Pro forma revenues reflect Certara's FY24 Revenues had the acquisition of Chemaxon closed on January 1, 2024

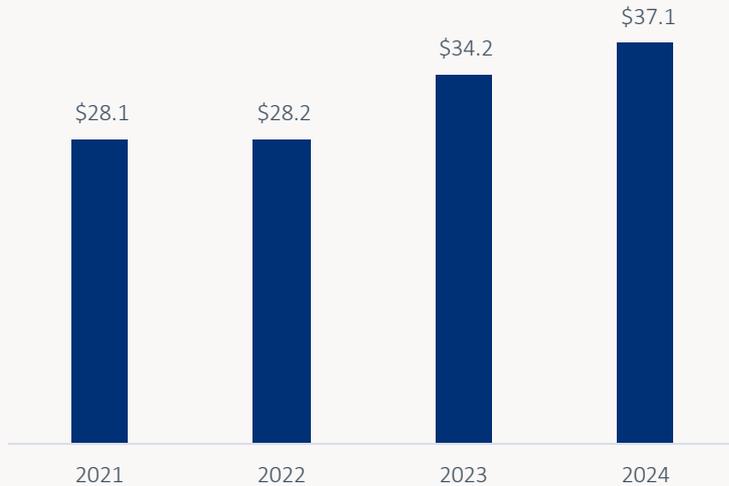
Regulatory Services Business Under Strategic Review
Revenue of \$54.7M 2024 and \$60.5M in 2023

Software Revenue Mix includes pro-forma 2024 Chemaxon Revenue of \$22.9M

With the addition of Chemaxon, Certara's revenue mix has seen a 1300 bp shift towards software since 2021

Investing in software business to drive sustainable growth

Research and Development Expense



Continued level of R&D investment during 2025 will support software innovation and growth



SUMMARY

- Leading the industry in biosimulation
- Investing in an AI-enabled integrated software platform embedded across all phases of drug development
- Saving years of time and risk

Transforming drug development
from molecule to market