



# *SimulationsPlus*

SCIENCE + SOFTWARE = SUCCESS

(NASDAQ:SLP)

Needham 23<sup>rd</sup> Annual Virtual  
Growth Conference  
January 14, 2021

# Safe Harbor Statement

With the exception of historical information, the matters discussed in this presentation are forward-looking statements that involve a number of risks and uncertainties. The actual results of the Company could differ significantly from those statements. Factors that could cause or contribute to such differences include, but are not limited to: continuing demand for the Company's products, competitive factors, the Company's ability to finance future growth, the Company's ability to produce and market new products in a timely fashion, the Company's ability to continue to attract and retain skilled personnel, and the Company's ability to sustain or improve current levels of productivity. Further information on the Company's risk factors is contained in the Company's quarterly and annual reports and filed with the Securities and Exchange Commission.

# Company Overview

- ❑ **Industry-leading** provider of modeling and simulation solutions used by major pharmaceutical, biotech, chemical, consumer goods companies and regulatory agencies worldwide
- ❑ **Innovative software and services** to improve drug development from discovery to regulatory approval with supportive guidance from the FDA and ability to **lower cost** and time to market with a **higher likelihood of success**
- ❑ Solutions bridge **machine learning** and include pharmacokinetic-pharmacodynamic (**PKPD**), quantitative systems pharmacology & toxicology (**QSP/QST**), and physiologically based pharmacokinetic (**PBPK**) modeling
- ❑ 10+ year track record of **consistent revenue and profitability** growth and successful M&A strategy

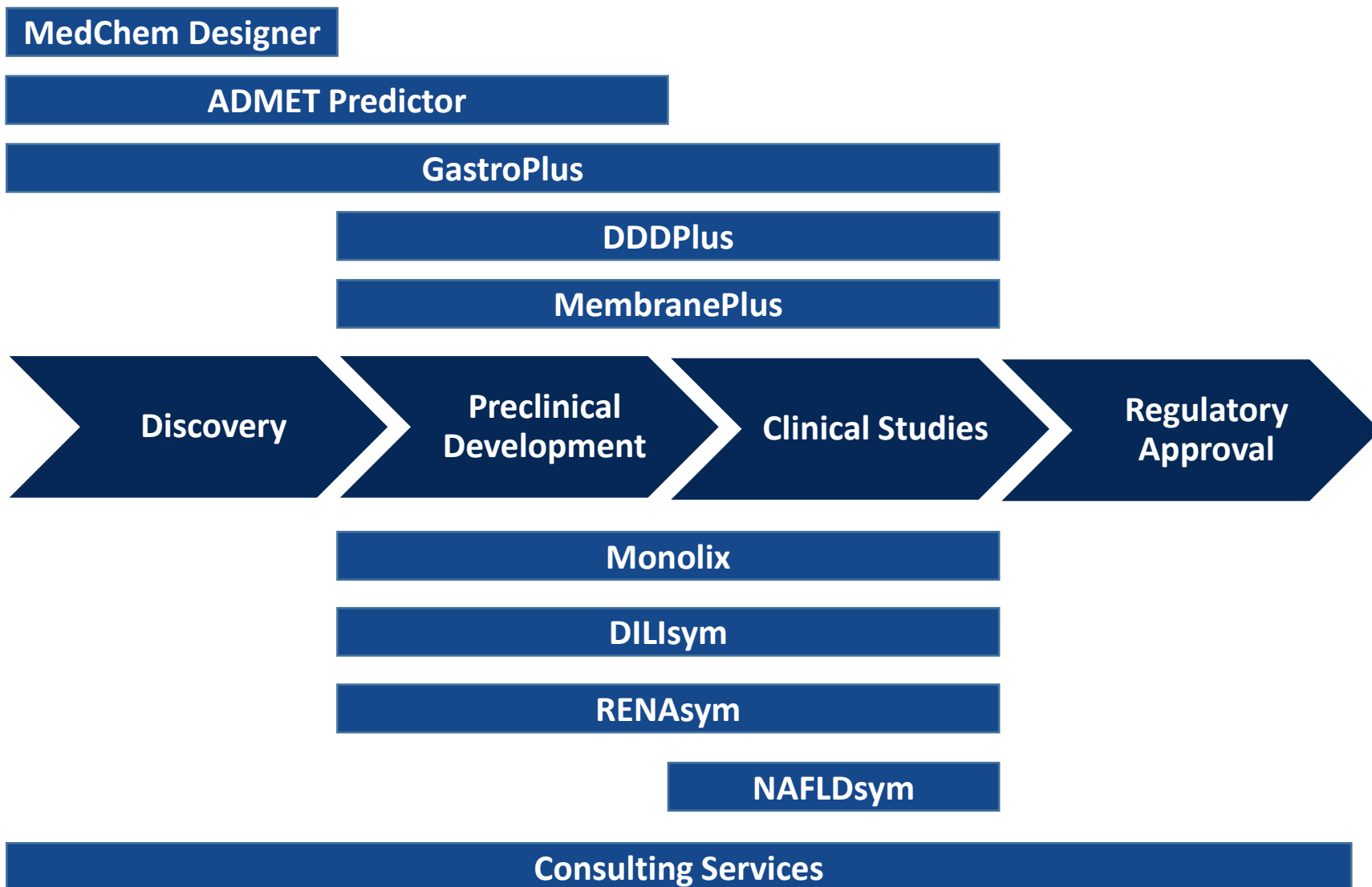
# Our Value Proposition

## **Avg. cost of \$1.4B and 10+ years to bring a drug to market <sup>1,2</sup>**

- Our solutions allow customers to model and predict results of chemical and biological tests required in the R&D process to improve success rates at multiple points in the process:
  - Computational AI models help scientists streamline and improve their processes
  - Machine learning improves the models with ever-growing data sets
  - Better informed clinical trial design and analyze clinical results
  - Identify potential safety liabilities earlier, avoiding costly clinical failures
  - Optimize efficacy and minimize toxicity by efficiently identifying dosing regimens

**We've helped bring 40+ drugs to market and informed multiple development programs**

# We Improve Drug Discovery and Development



# PKPD Software Solutions

## Monolix Suite

Population PKPD Model to support dose regimen, risk exposure, clinical trial protocol design and analysis, drug label specifications and regulatory submission

### Datxplore

Exploration and visualization of data

### PKanalix

Non-compartmental and compartmental analysis

### Mlxplore

Exploration and visualization of complex models

### Monolix

Non-linear mixed effects (NME) modeling engine

### Simulx

Clinical trial pharmacometrics simulations

## KIWI

Cloud-based data management application

# QSP/QST Software Solutions

## DILIsym

Determine potential drug-induced liver injury hazard posed by individual drug candidates to support clinical trial optimization

## RENAsym

Assess the potential for drug-induced kidney injury of drug candidates to support clinical trial optimization and clinical trial decision making

## NAFLDsym

NASH model to predict efficacy for treatment modalities to support clinical trial optimization and clinical trial decision making

## Additional QSP models

IPFsym (Idiopathic pulmonary fibrosis)  
RADAsym (Acute radiation exposure)

# PBPK Software Solutions and AI Data Mining

## GastroPlus

Simulating IV, oral, oral cavity, ocular, inhalation, skin and IM absorption, PBPK, PBBM, PD modeling and drug-drug interactions

## ADMET Predictor

QSAR modeling enabling rapid prediction of 140+ ADMET properties  
Used for lead generation and optimization

## DDDPlus

Mechanistic simulation engine for the in vitro dissolution predictions to accelerate and optimize drug formulation

## MembranePlus

Predict how fast a drug candidate will pass across the important physiological membrane barriers (GI, BBB)

## MedChem Designer

Chemical sketching tool with ADMET property predictions in connection with ADMET Predictor



# Services Solutions

- 70+ scientific PhD experts provide insightful solutions to improve the productivity of science-based drug development
- Focusing on lead selection, pharmacology, ADMET and DMPK, dose regimen, efficacy and safety
- Capabilities include:
  - Population PKPD data assembly, modeling, simulation, analysis and regulatory submission
  - PBPK modeling and simulation
  - Liver and kidney safety modeling and analysis
  - QSP/QST modeling support and analysis
  - AI drug candidate prioritization
  - Global regulatory strategies
  - Regulatory and scientific writing

# Janssen Case Study: Accelerating Regulatory Interactions

## Virtual crossover trials to establish drug product specification after manufacturing changes

- Janssen changed the manufacturing process to improve efficiencies with scale-up techniques post approval
- FDA requested clinical study to confirm bioequivalence
- Built and validated the baseline model in GastroPlus® using existing clinical data from previously approved lots
- Assessed impact of formulation changes; defined drug product specifications
- Performed virtual trial simulations in different populations to confirm bioequivalence
- FDA accepted the GastroPlus® modeling results, clinical study request was waived

Virtual Bioequivalence Study Simulations

API Lot	PE/NPE	Dose (mg)	AUC <sub>∞</sub> (ng.h/mL) (N=250)		C <sub>max</sub> (ng/mL) (N=250)	
			GM	GMR (90% CI)	GM	GMR (90% CI)
Lot 5	PE	50	4180	113.3	551	139.3
Lot 1	NPE	50	3688	(110.7, 116.1)	395	(136.0, 142.7)
Lot 5	PE	100	8242	103.0	551	106.4
Lot 3	NPE	100	8001	(100.9, 105.1)	395	(104.3, 108.6)
Lot 5	PE	300	24998	102.2	3118	100.0
Lot 2	NPE	300	24460	(99.8, 104.6)	3117	(97.7, 102.4)
Lot 5	PE	100	8242	98.2	1068	95.1
Lot 4	NPE	100	8395	(96.2, 100.2)	1123	(93.2, 97.0)
Lot 5	PE	300	24998	101.9	3118	98.3
Lot 4	NPE	300	24525	(99.8, 104.1)	3171	(96.3, 100.4)

API: active pharmaceutical ingredient; AUC<sub>∞</sub>: area under the plasma concentration-time curve from time 0 to infinite time; CI: confidence interval; C<sub>max</sub>: maximum observed plasma concentration; GM: geometric mean; GMR: geometric mean ratio; NPE: non-particle-engineered; PE: particle-engineered

# Client Case Study: Strategic Use of Modeling & Simulation

## **In Silico Methods Improve the Probability of Phase 3 Success**

- Client with novel antibody for prophylactic use in competitive migraine market had Phase 3 development plan with predicted probability of success of <15%
- Iteratively developed model throughout Phase 1 & Phase 2
- Implemented model-based clinical trial simulation strategy to improve Phase 3 design
- Phase 3 trials demonstrated safety and efficacy in preventing migraine
- Months of development time and millions of dollars saved by avoiding failed Phase 3 trials, also reduced time to approval and market
- Reduced unnecessary burden on patients by evaluating multiple alternatives in silico before running trials

# Revenue Growth Drivers

Increasing acceptance of modeling and simulation by FDA and drug industry

High customer satisfaction with ~95% software contract renewal rate (by fees)

Recently improved and expanded sales infrastructure

Increasing opportunities for product and service cross-selling

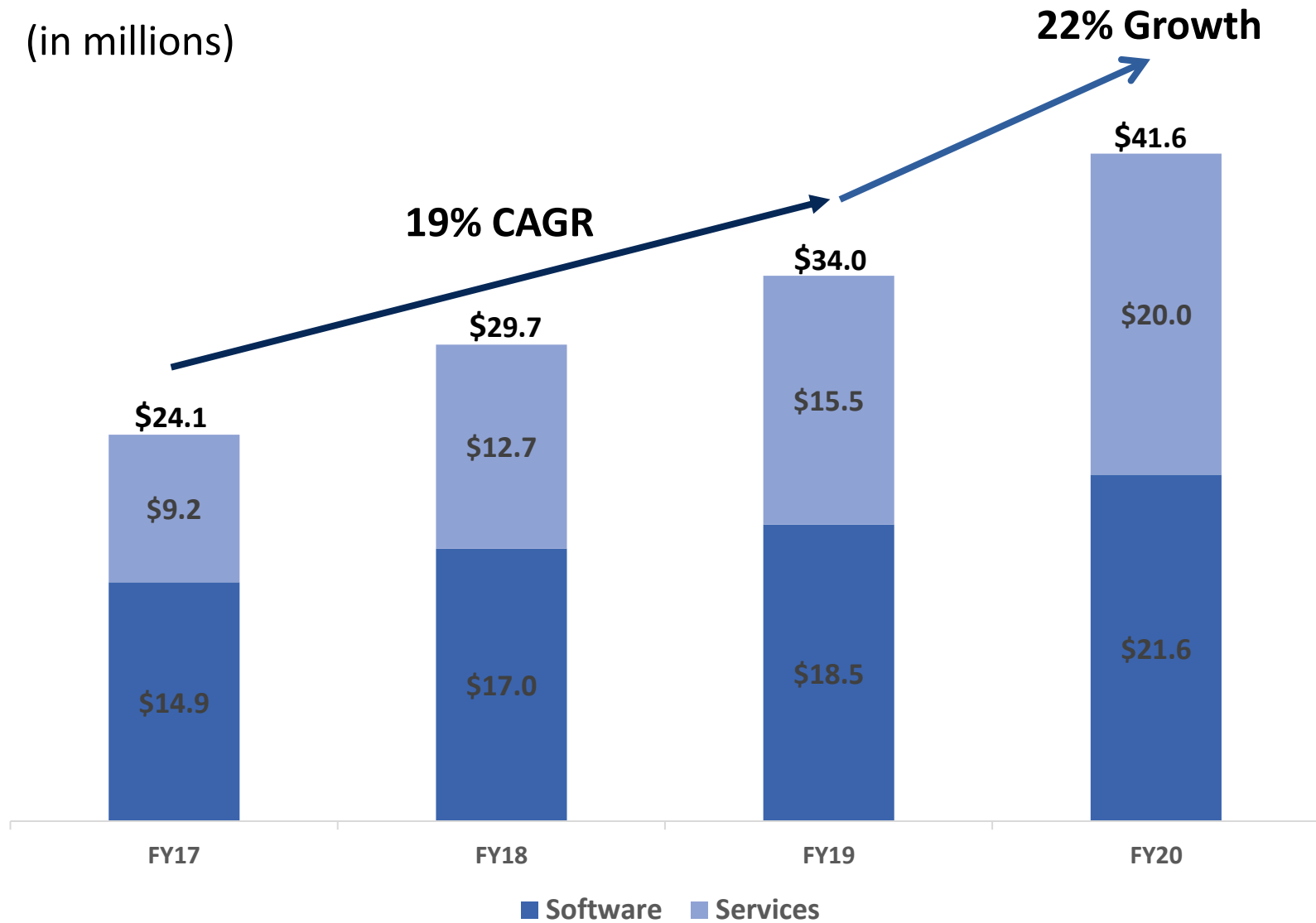
Steadily increasing industry R&D spend

Synergistic acquisitions

**19%+**  
Revenue CAGR

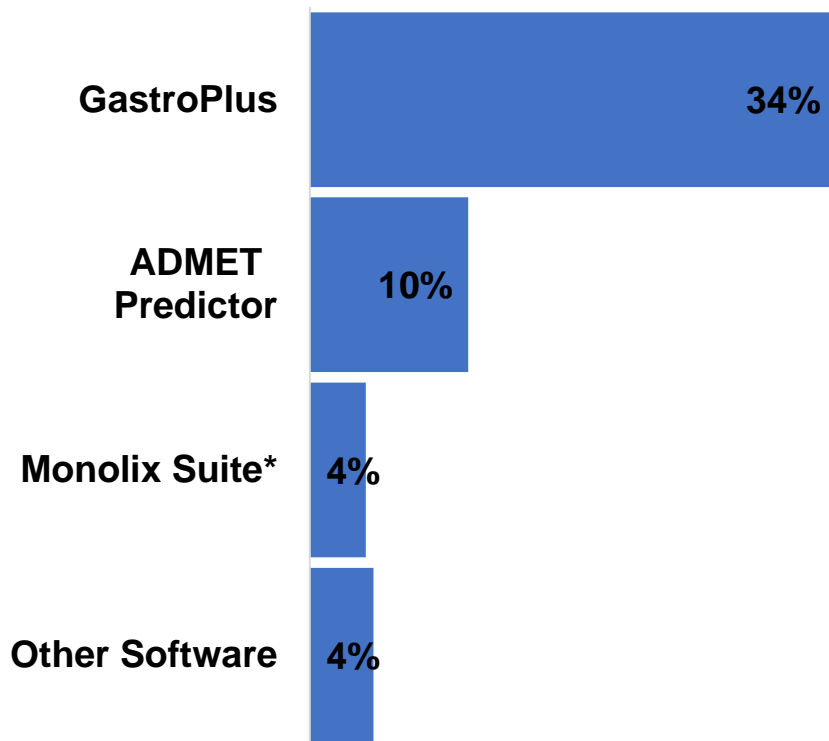
# Consistent Year-over-Year Revenue Performance

(in millions)

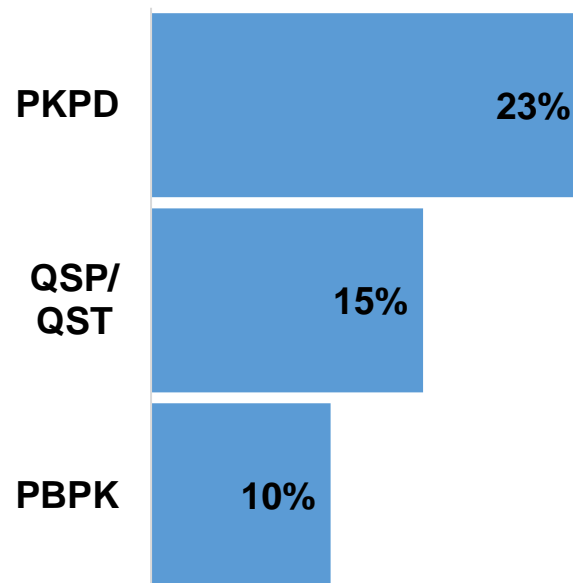


# FY20 Software and Services Mix

## Software Products % of Total Revenues



## Services Offerings % of Total Revenues



# Strategic Opportunities for Expansion and Growth

- Expand product offerings through opportunistic acquisitions
  - Fill gaps in the current product offerings
  - Focus on immediately or near-term accretive opportunities
  - Fragmented industry amenable to consolidation
- Further expand global sales reach
  - Increase sales effort to drive new customer growth in U.S., Europe and Asia
  - Expand client base in the small and mid-sized biotechnology space
  - Focus on cross-selling efforts to increase average revenue per customer
- Increase R&D investment to enhance existing models and develop new tools to broaden product offerings

# Q1 FY21 Performance & FY21 Full Year Outlook

- Total Revenue Growth

- Q1 performance: 14% y/y growth
- Full-year target range: 15-20% y/y organic growth plus 3-5% from Lixoft

- Software Revenue Growth

- Q1 performance: 35% y/y growth
- Full-year target range: 20-25% y/y growth

- Services Revenue Growth

- Q1 performance: 6% y/y decline
- Full-year target range: 25-30% y/y growth

- Q1 Profitability

- Gross margin was 77%, up from 72%
- Net income increased 21% y/y to \$2.5 million
- Diluted earnings per share increased 9% y/y to \$0.12

- M&A Efforts

- Continuing to explore opportunities and acquisitions would be incremental to revenue growth targets above



# Investment Highlights

- Provider of innovative modeling and simulation software and consulting services focused on pharmaceutical and biotechnology companies
  - Solutions from early discovery through regulatory approval
- Pure play in the in silico drug discovery space
- Growing acceptance of technology by regulators and industry with supportive guidance issued by the FDA
- Products have the potential to reduce drug development costs and time while improving success rates
- Steady growth in pharmaceutical industry R&D expenditures provides expanding target market
  - ~\$170B in 2020 growing around 3% per year<sup>3</sup>
- Ten-year track record of consistent revenue and profitability growth
  - Recent revenue CAGR of 20%+

# Financial Summary and Selected Financial Information

	<b>Nasdaq</b>	<b>SLP</b>
<b>Q1 Cash and short-term investments</b>		<b>\$119M</b>
<b>Q1 Borrowed Debt Outstanding</b>		<b>\$0</b>
<b>Market Capitalization (a/o 1/5/21)</b>		<b>\$1.5B</b>
<b>Q1 Fully Diluted Shares Out</b>		<b>20.8M</b>
<b>30-Day Average Daily Trading Volume (a/o 1/5/21)</b>		<b>~198K</b>

# Thank you!

<https://www.simulations-plus.com>

# References

1. *J Health Econ.* 2016 May;47:20-33.
2. Brochure: [“Biopharmaceutical Research & Development: The Process Behind New Medicines”](#). PhRMA.
3. EvaluatePharma® World Preview 2017, Outlook to 2022, 10th Edition, June 2017, p. 19.