



# *SimulationsPlus*

SCIENCE + SOFTWARE = SUCCESS

Credit Suisse 29th  
Annual Virtual  
Healthcare Conference

November 2020

Nasdaq: SLP

# 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.

# 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>1</sup>
- Ten-year track record of consistent revenue and profitability growth
  - Recent revenue CAGR of 20%+

# Enabling Drug Discovery and Development

MedChem Designer

ADMET Predictor

GastroPlus

DDDPlus

MembranePlus

Discovery

Preclinical  
Development

Clinical Studies

Regulatory  
Approval

Monolix

DILIsym

RENAsym

NAFLDsym

Consulting Services

# Our Value Proposition

**It costs ~\$1.4B and 10+ years to bring a drug to market<sup>2,3</sup>**

- Simulations Plus technologies allow customers to model and predict results of chemical and biological tests required in the drug R&D process
- Computational AI models help scientists streamline and improve their processes
  - Machine learning and ability to utilize ever-growing data sets improves models over time
- More rapidly find “drug-like” hits and leads and optimize them
- Better inform 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
- Improve success rates at multiple points in the process
- Technologies have helped bring 40 drugs to market and informed many more development programs

# Physiologically Based PK Software 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

# Population PK/PD Modeling

## Monolix Suite

Population PK/PD 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

# Quantitative Systems Pharmacology/Toxicology Modeling

## 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)



# Consulting Services

- Leveraging scientific skillsets of 70+ Ph.D. experts combined with software products to support model-based drug development
- Focused on lead selection, pharmacology, ADMET and DMPK, dose regimen, efficacy and safety
- Specific offerings include:
  - Population PK/PD 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

# Accelerating Regulatory Interactions: Janssen Case Study

## 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

# Strategic Use of Modeling and Simulation: Case Study

## **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

# Strong Drivers of Revenue Growth

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

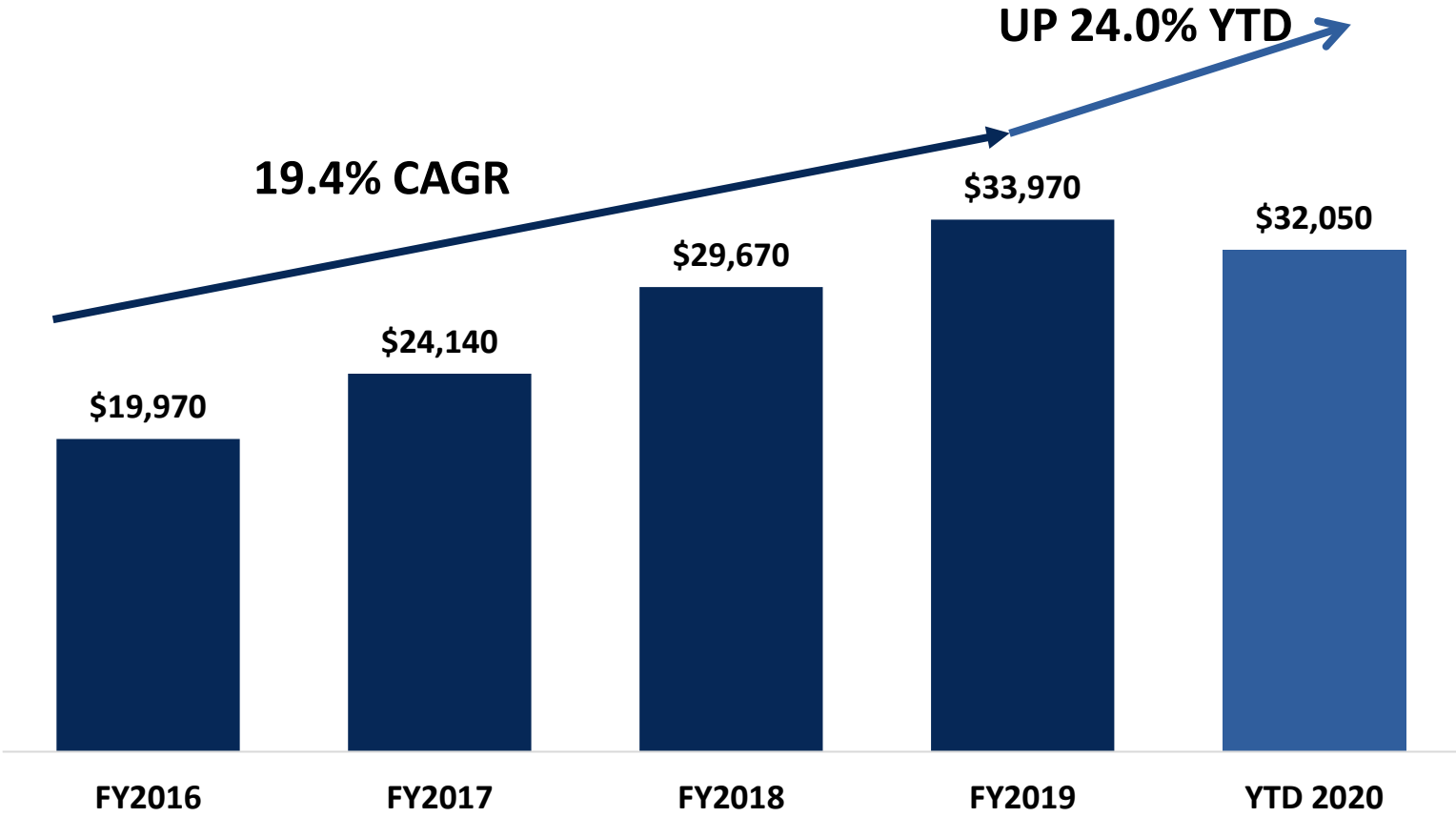
Steadily increasing industry R&D spend

Synergistic acquisitions

20%+  
Revenue CAGR

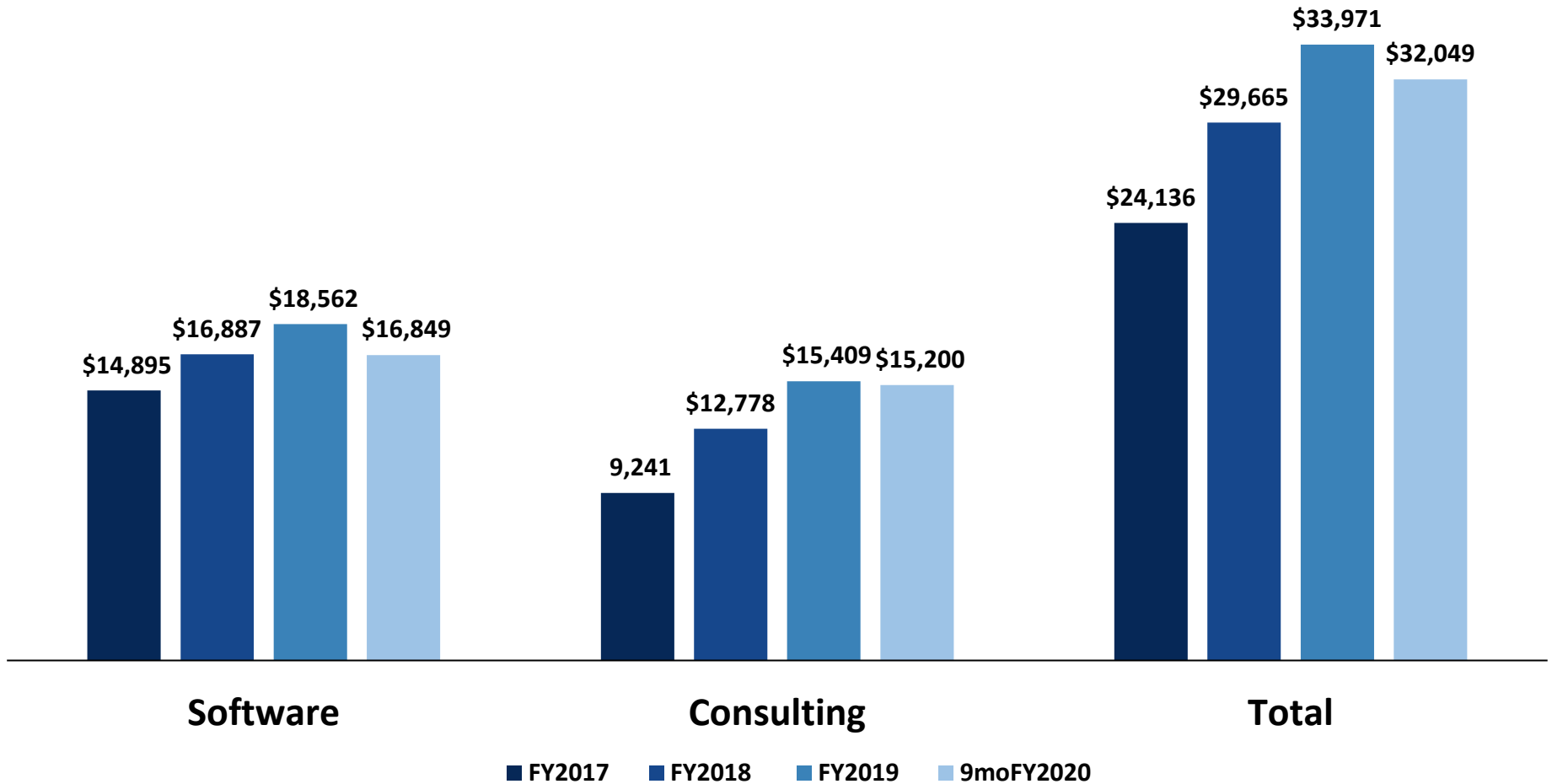
```
graph LR; A[Increasing acceptance of modeling and simulation by FDA and drug industry] --> G((20%+ Revenue CAGR)); B[High customer satisfaction with ~95% software contract renewal rate (by fees)] --> G; C[Recently improved and expanded sales infrastructure] --> G; D[Increasing opportunities for product and service cross-selling] --> G; E[Steadily increasing industry R&D spend] --> G; F[Synergistic acquisitions] --> G;
```

# Strong Revenue Performance



Numbers in thousands

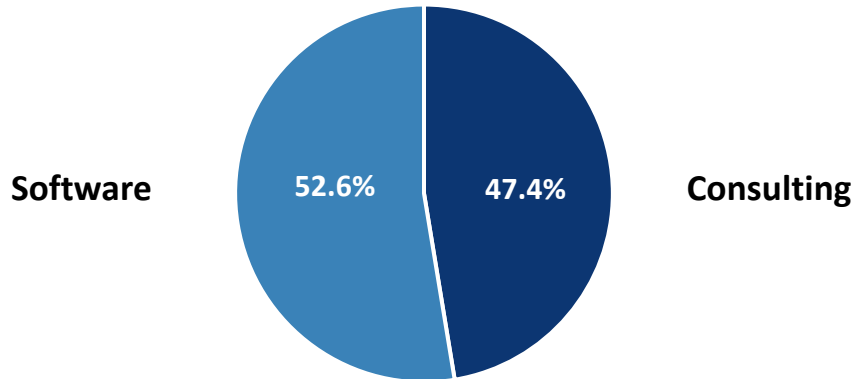
# Revenue by Product Category



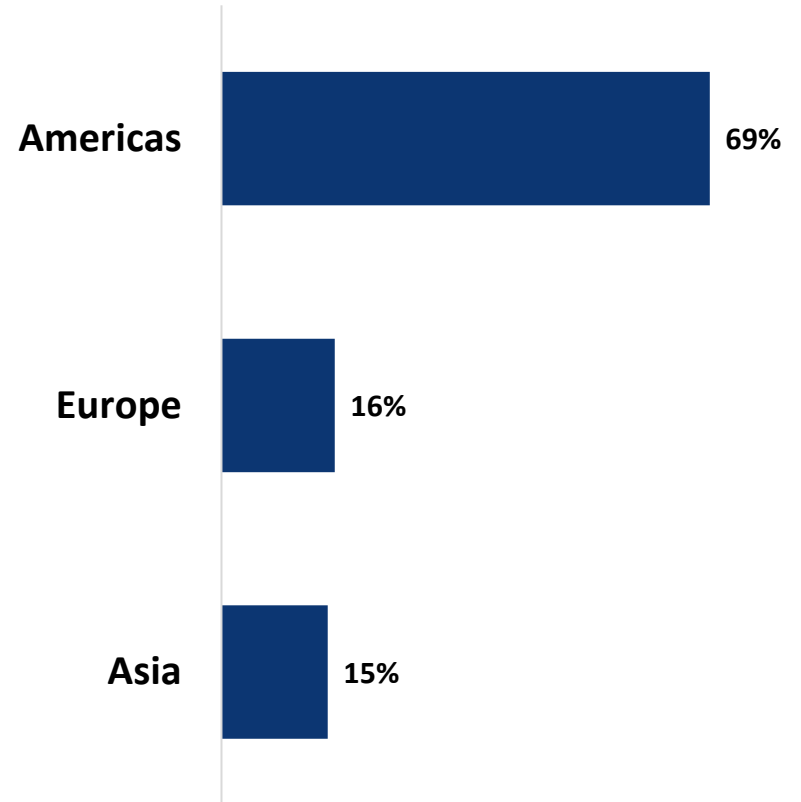
Numbers in thousands

# Revenue Breakdown – 9 Months FY2020

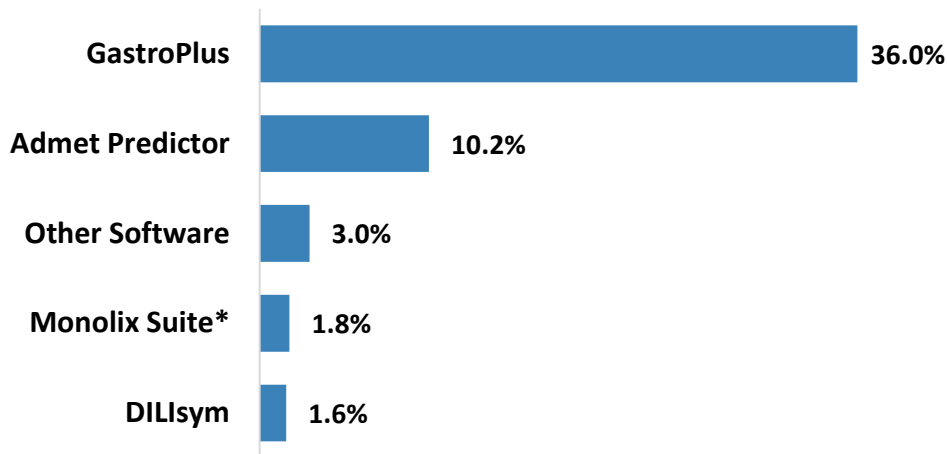
## Product



## Region



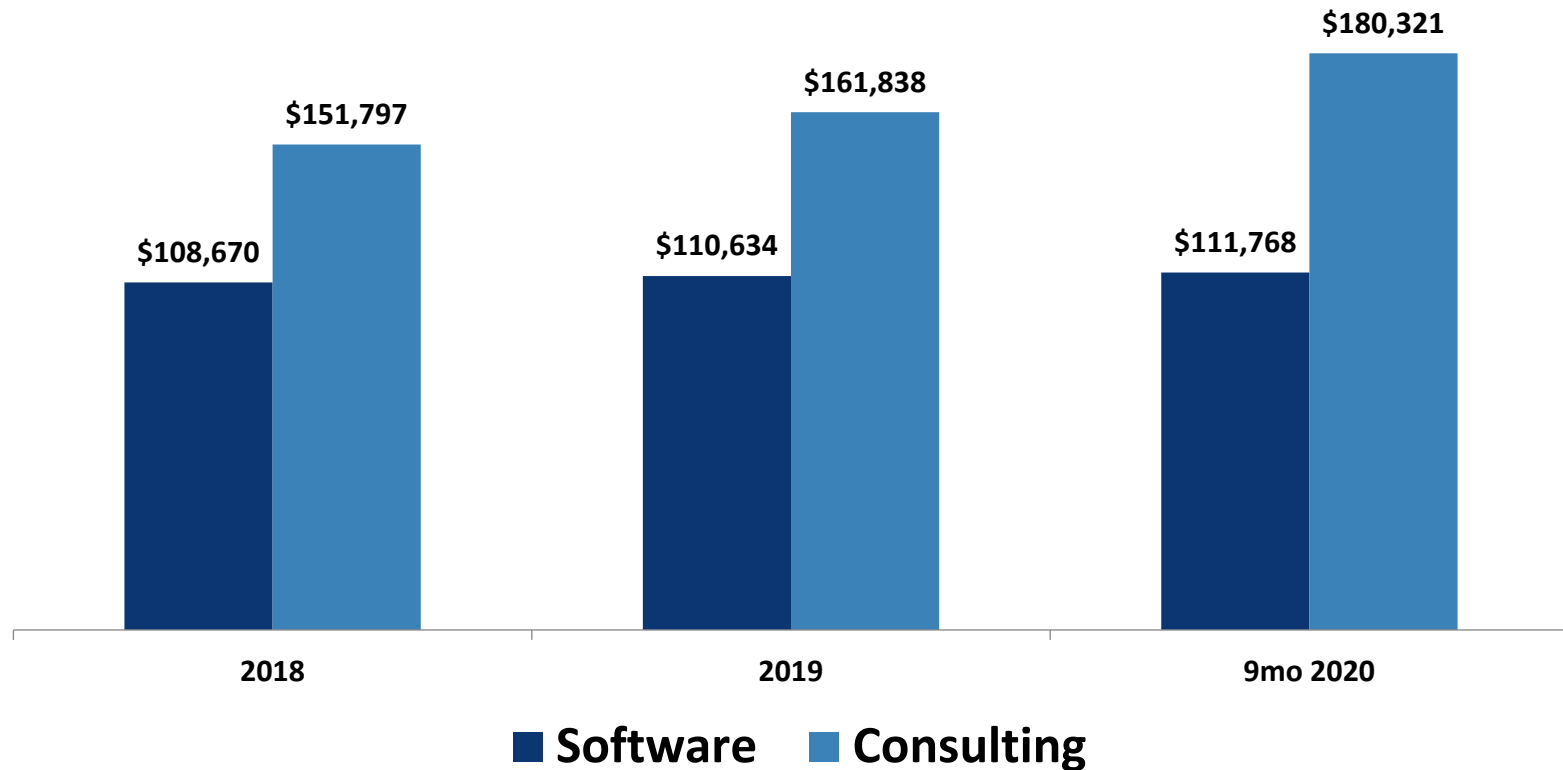
## Software Products % of Total Revenues



\* Includes two months of revenue recorded post acquisition

# Increasing Average Revenue per Customer

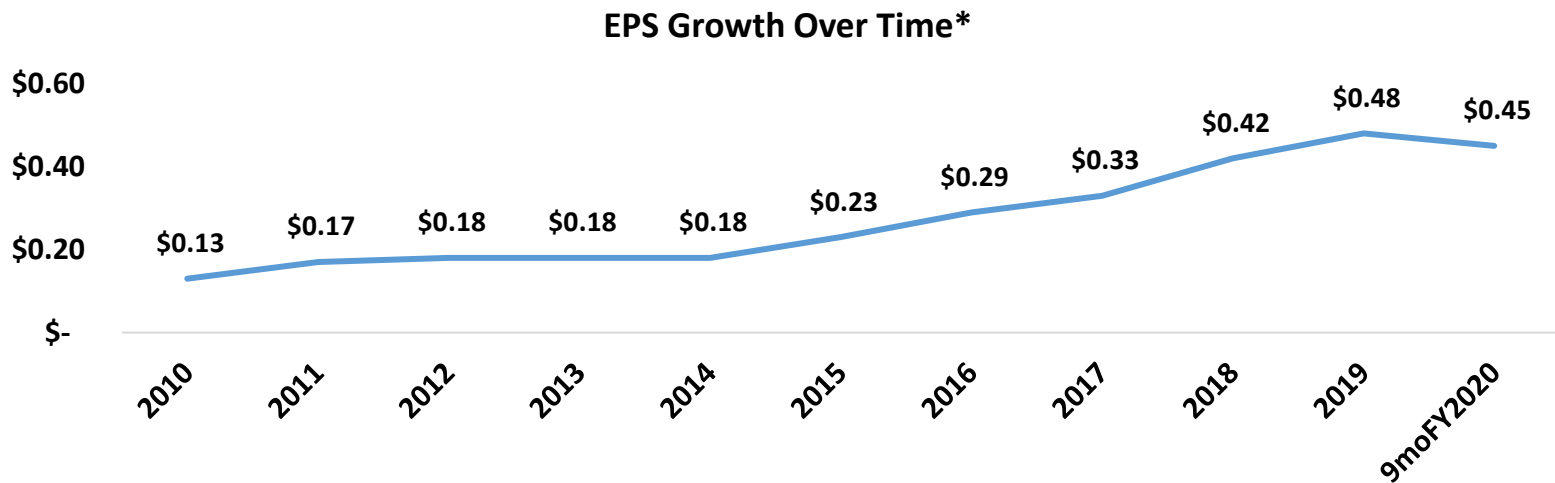
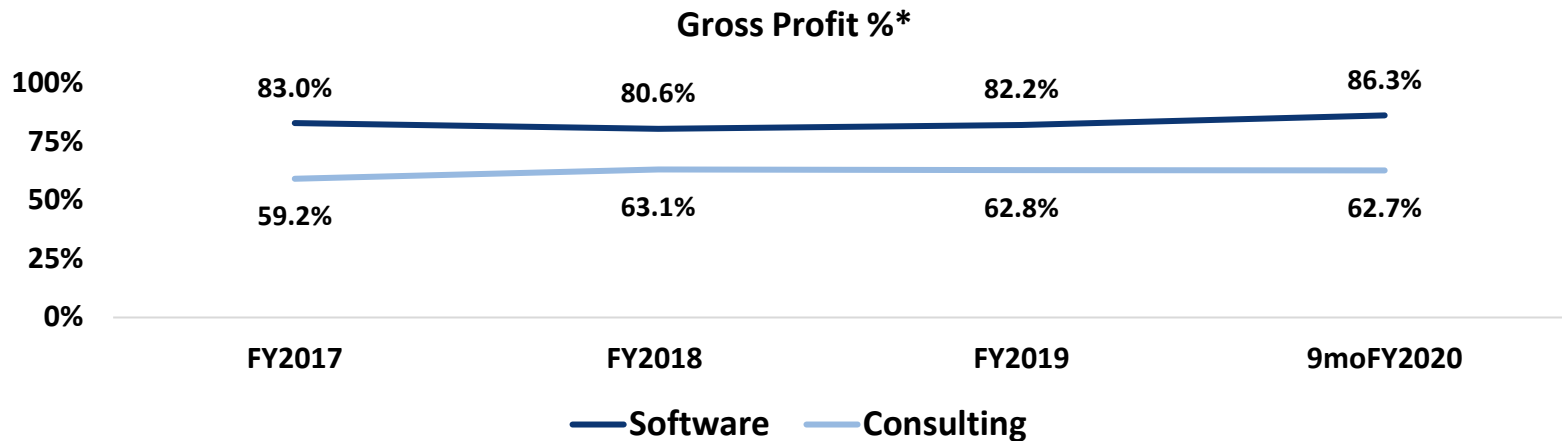
## Revenue Per Customer\*



\* Software revenue per customer excludes academic and non-profit customers



# Attractive Margins Deliver Steady EPS Growth



\* Pro forma non-GAAP numbers

# 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

# Income Statement Summary

	9 Months Ended	
	May 31, 2020	May 31, 2019
<b>Income Statement</b>		
Revenues	\$ 32,049,003	\$ 25,944,545
Cost of revenues	7,974,702	6,734,890
Gross margin	24,074,301	19,209,655
<b>Operating expenses</b>		
Selling, general, and administrative	12,646,512	8,613,788
Research and development	2,026,684	1,896,926
Total operating expenses	14,673,197	10,510,714
<b>Income from operations</b>	9,401,104	8,698,941
<b>Other income (expense)</b>		
Interest income	27,814	20,296
Interest expense	0	(109,078)
Change in value of contingent consideration	(81,000)	0
(Loss) income on currency exchange	1,283	(40,467)
Total other income (expense)	(51,902)	(129,249)
<b>Income before provision for income taxes</b>	9,349,202	8,569,692
Provision for income taxes	(2,205,276)	(2,045,590)
<b>Net Income</b>	<b>\$ 7,143,925</b>	<b>\$ 6,524,102</b>

# 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>1</sup>
- Ten-year track record of consistent revenue and profitability growth
  - Recent revenue CAGR of 20%+