



# Investor Presentation

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NASDAQ: SLP

Q1 FY24 Update





With the exception of historical information, the matters discussed in this presentation are forward-looking statements that involve a number of risks and uncertainties. Words like “believe,” “expect” and “anticipate” mean that these are our best estimates as of this writing, but that there can be no assurances that expected or anticipated results or events will actually take place, so our actual future results could differ significantly from those statements. Factors that could cause or contribute to such differences include, but are not limited to: our ability to maintain our competitive advantages, acceptance of new software and improved versions of our existing software by our customers, the general economics of the pharmaceutical industry, our ability to finance growth, our ability to continue to attract and retain highly qualified technical staff, our ability to successfully integrate the recently acquired Immunetrics business with our own, as well as expenses we may incur in connection therewith, and a sustainable market. Further information on our risk factors is contained in our quarterly and annual reports and filed with the U.S. Securities and Exchange Commission.

## **To create value for customers**

by accelerating development timelines and reducing the cost of drug development R&D through innovative science-based software and consulting solutions that optimize treatment options and improve patient lives.





## Leading Provider of Software and Consulting Services in the Biosimulation Market

AI-powered technology solutions optimize the outcomes of drug discovery, development, research, and regulatory submissions processes. Our software-based technology both models and simulates how drugs and diseases behave in humans and in other species.

**25+**  
YEARS

OVER 25 YEARS IN BUSINESS AND CONTINUING THE COMMITMENT TO IMPROVE PUBLIC HEALTH THROUGH INNOVATIVE SOLUTIONS

**300+**  
CLIENTS

OUR CLIENTS TRUST OUR EXPERT CONSULTING THAT SUPPORTS DRUG RECOVERY, CLINICAL DEVELOPMENT RESEARCH AND REGULATORY SUBMISSIONS

**18+**  
SOFTWARE  
SOLUTIONS

WE PROVIDE VALIDATED AI AND MACHINE LEARNING, MODELING AND SIMULATION SOFTWARE FOR NOVICE AND EXPERT USERS ALIKE



# Investment Highlights





**Biosimulation is software-based technology that models and simulates how drugs and diseases behave in the human body**

Biosimulation combines core principles in biology, chemistry and pharmacology with proprietary mathematical algorithms to predict how biology and drugs interact with one another.

-  Models can start in vitro (without animal or human testing) but are developed through the development cycle incorporating animal and human test results along the way.
-  Model uses include lead optimization, dose regimens, clinical trial protocol development, clinical trial simulation, bioequivalence evaluation, toxicity assessment and many more.



Our core mission – accelerating the development and delivery of better, safer, and more effective drugs

## CHALLENGES

– The median cost of developing a new drug averages \$1.5 to \$2 billion and the timeline can range from 10-15 years.

– On average only 11% of all drug candidates are approved

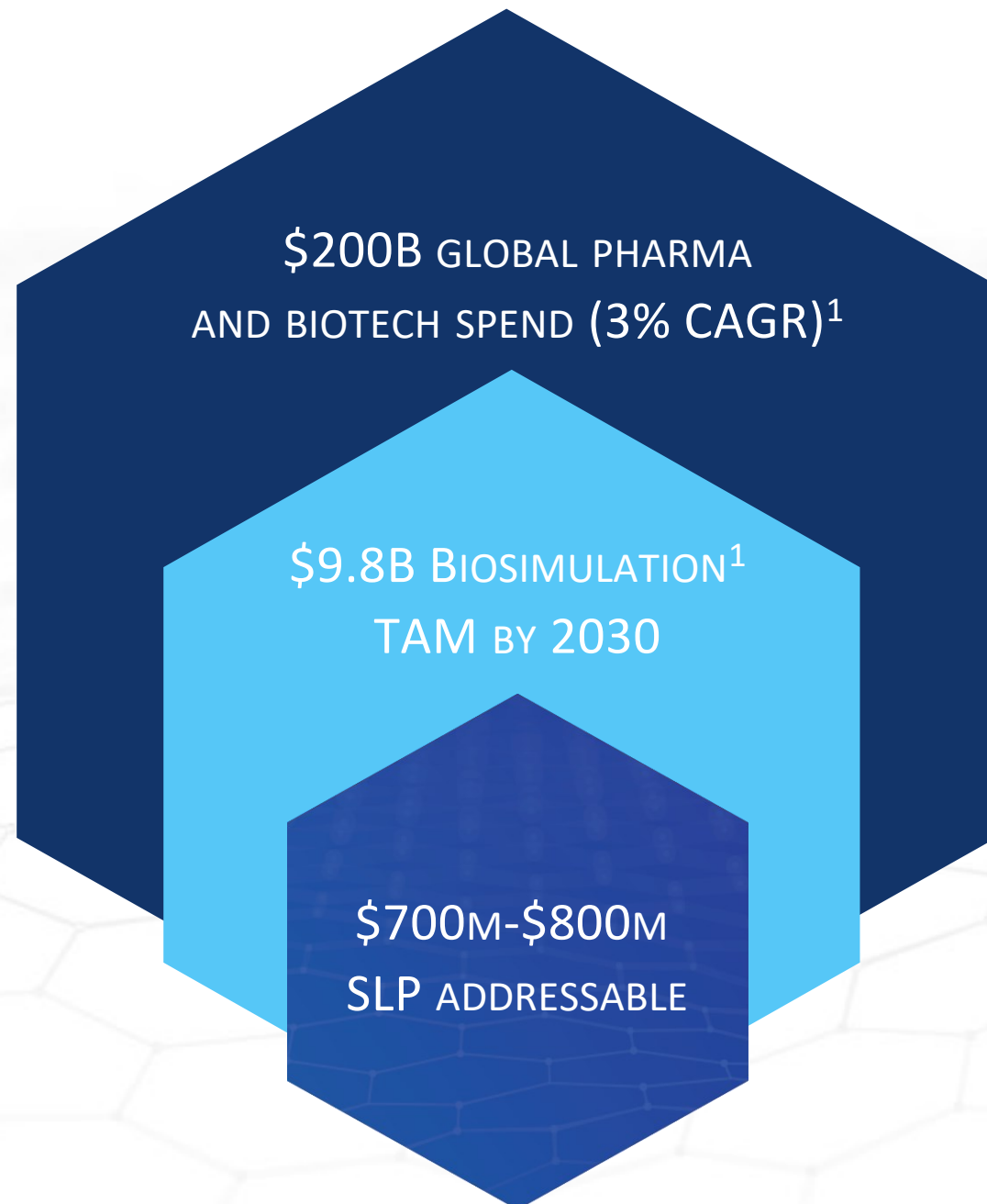
## SIMULATIONS PLUS SOLUTIONS

+ Simulations Plus offers AI-powered technology solutions to help optimize the outcomes of the drug discovery, development, research and regulatory approval processes to bring drugs to market faster

+ Simulations Plus solutions can help increase the number of candidates approved by streamlining the drug development process, creating efficiencies that lead to drug efficacy and safety, higher regulatory approval, improved commercial success and much more



Spending for biosimulation products continues to increase given need to bring drugs to market faster



Biosimulation market valued at \$2.8B in 2022 and is expected to expand at a 16.9% CAGR from 2022 - 2030<sup>1</sup>



Strategy to grow addressable market within the Biosimulation TAM through both internal R&D investment and strategic acquisitions

- Biosimulation TAM growing 4-5x faster than global pharma and biotech spend
- SLP is growing faster than the Biosimulation TAM



Highly fragmented and underpenetrated market with only a few larger players

- The global biosimulation market is segmented based on product, application, delivery model, and end users.

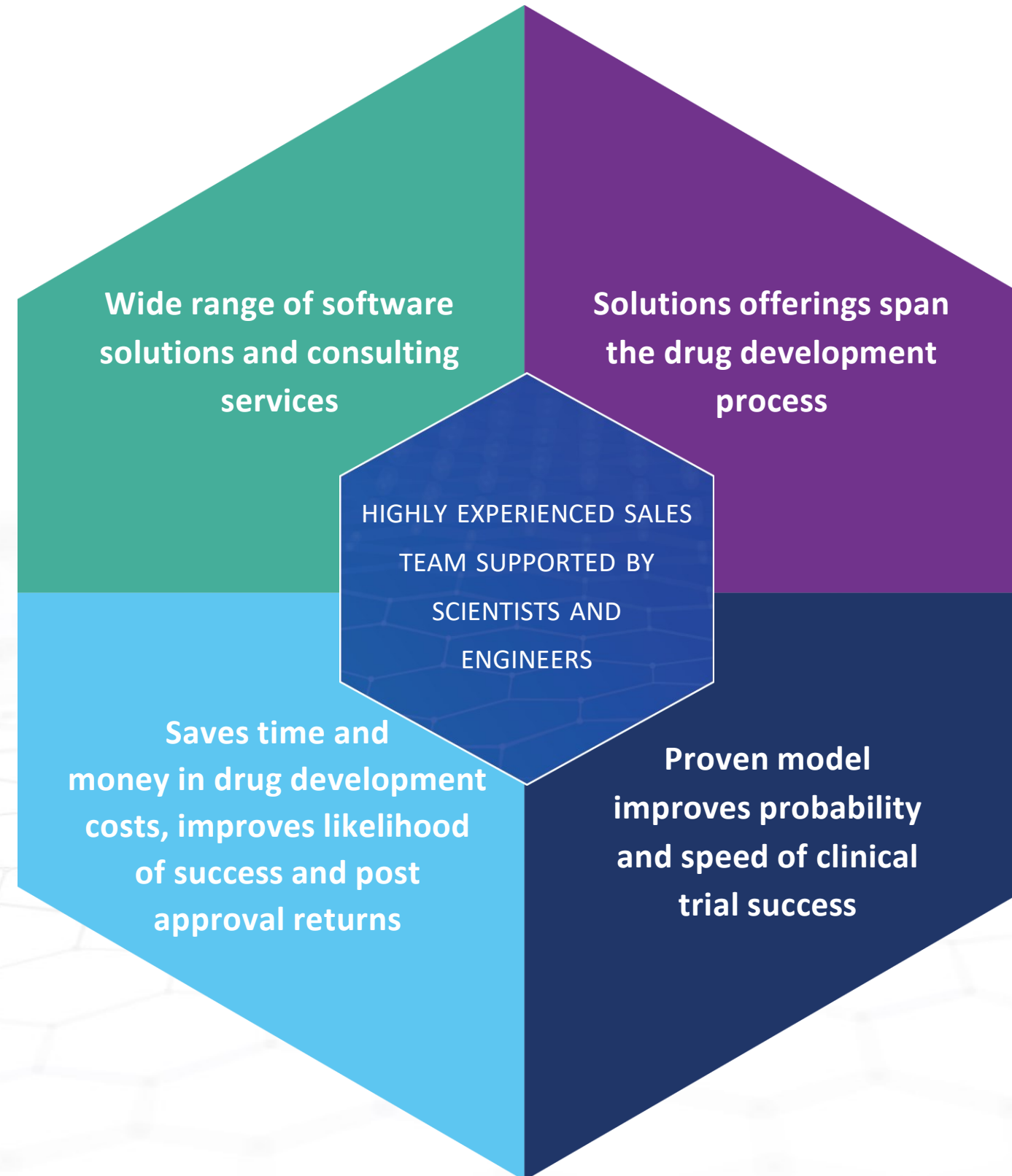


# Compelling Customer Value Proposition



- GastroPlus®
- ADMET Predictor®
- MonolixSuite™ (includes Monolix, Pkanalix, Simulix)
- QSP/T Models (including DILISYM, RENASYM, IPFSYM, etc.)

- Provides operational efficiencies and leads to accurate / timely decision making and regulatory reporting



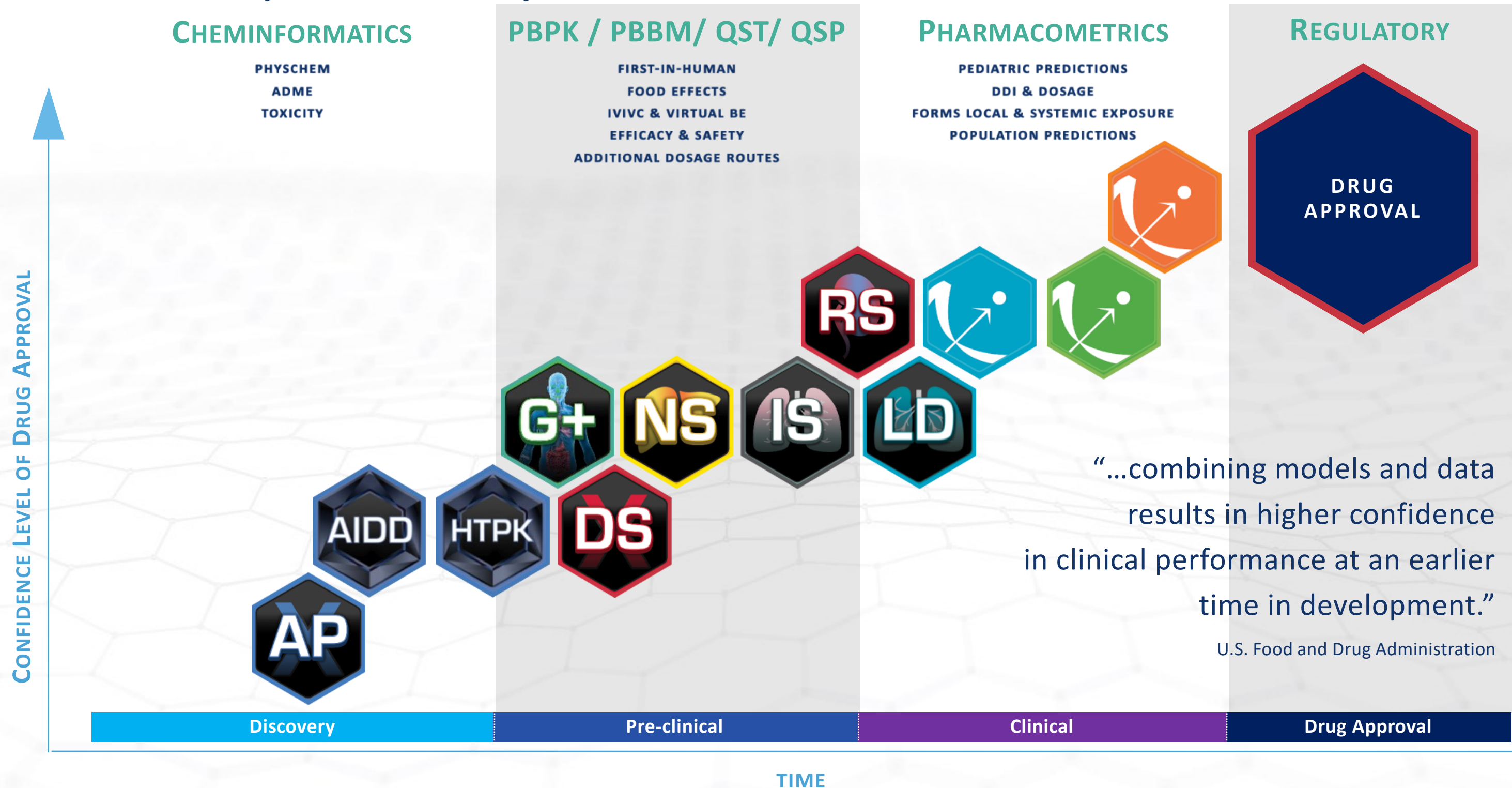
- Early drug discovery to preclinical
- Clinical data analysis
- Submission to regulatory agencies supporting product approval

- Only ~7% of proposed new drug compounds pass Phase I trials
- Only 53% of drugs that get to Phase III trials make it to market
- 70% of drugs fail in Phase II or Phase III due to safety and efficacy issues

# End-to-End Solutions Across the Development Life Cycle



Decrease development uncertainty, cost and time





# Strong Competitive Position



+

LEADING POSITION IN LARGE, GROWING, FRAGMENTED AND UNDERPENETRATED MARKET

+

LARGE, GROWING AND DIVERSE CUSTOMER BASE

+

MOST COMPREHENSIVE AND WIDELY RECOGNIZED TOOLS IN THE INDUSTRY

+

300+ CUSTOMERS

+

ACCUMULATED PUBLIC AND PRIVATE DATA THAT INFORMS OUR ALGORITHMS AND MODELS

## Delivering Double-Digit Revenue Growth / Industry Leading Margins

	FY18	FY19	FY20	FY21	FY22	FY23	6 Yr CAGR
<b>REVENUE</b> \$ in millions	\$29.7	\$34.0	\$41.6	\$46.4	\$53.9	\$59.6	<b>14.9%</b>
	FY18	FY19	FY20	FY21	FY22	FY23	6 Yr Avg
<b>GROSS MARGIN %</b>	73.1%	73.4%	74.4%	77.2%	79.9%	80.0%	<b>76.4%</b>
<b>EBITDA MARGIN %</b>	43.3%	39.1%	34.4%	31.2%	33.3%	19.2%	<b>33.4%</b>

- + Double digit revenue growth
- + Strong recurring revenue supported by a 90%+ Software Fee Renewal Rate
- + High gross/EBITDA margins to drive strong operating leverage
- + High-margin, recurring revenue over the life of the client relationship
- + Product mix skews toward higher margin software sales
- + \$113.9 million in cash and short-term investments<sup>1</sup> to fund growth

<sup>1</sup>As of Q1'24 quarter end



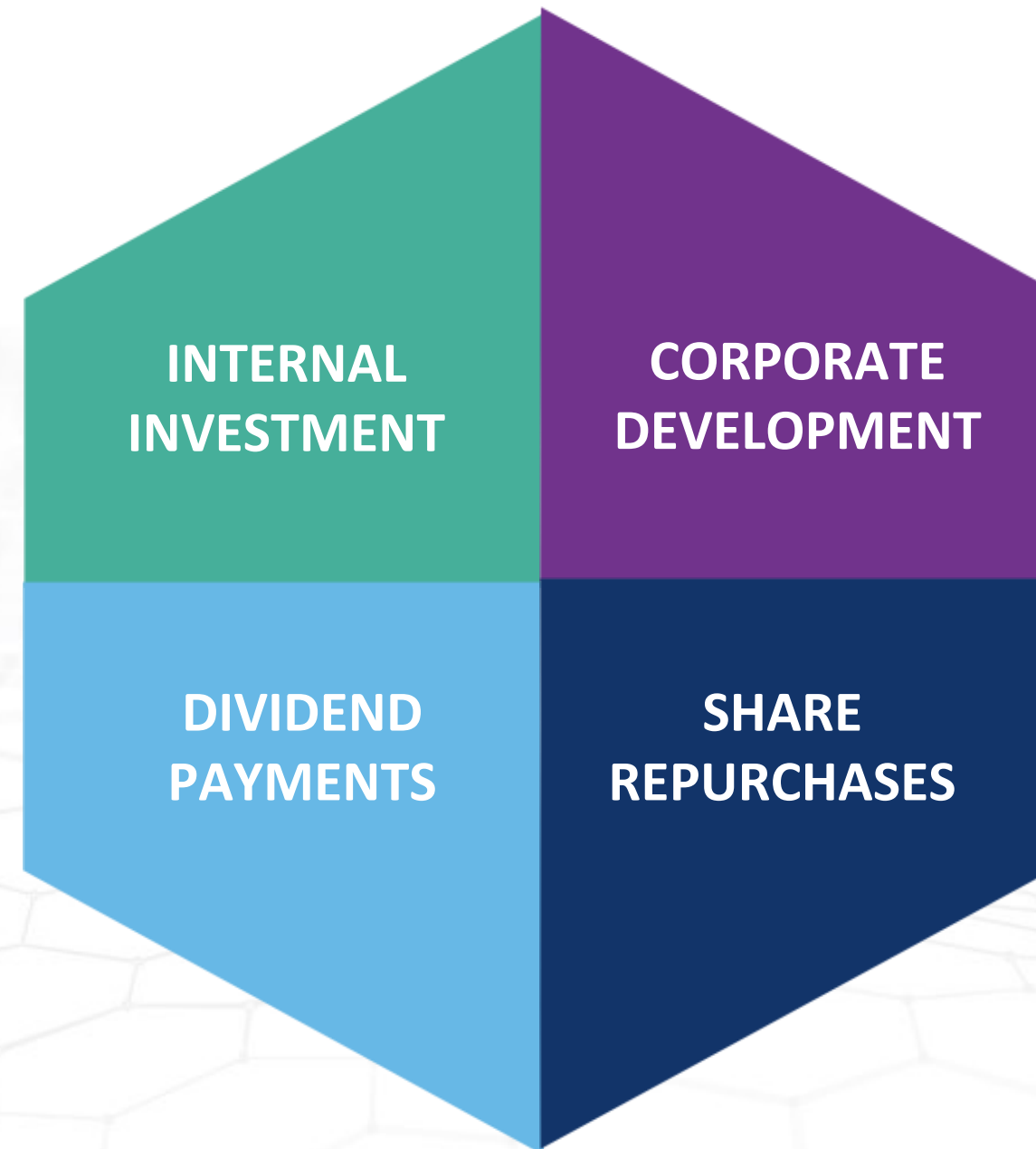


## Integration and consolidation efficiencies

- Quantitative Systems Pharmacology (QSP) is the discipline of building mathematical models to mechanistically stimulate the dynamics of diseases and treatments. These models incorporate public and proprietary data from in vitro, pre-clinical and clinical studies, and predict clinical outcomes across patient populations and treatment strategies
- Immunetrics has increased the range of therapeutic areas addressed by our QSP software and services offerings by more than 50%
- Ideal fit as the business leverages our existing infrastructure by expanding its therapeutic resources into largely underserved areas, including immunology and oncology
- Immunetrics chose Simulations Plus for its well-respected reputation
- Integration is going very well

- Employee Engagement and Development
- Product Development
- ERP Processes and Technology

- \$0.06 per share paid quarterly in FY'23



- Acquisitions (Immunetrics Q4'23)
- Earlier Stage Investments
- Strategic Partnerships and Alliances

- \$50M share repurchase program
- \$20M accelerated share repurchase (ASR) completed Q3'23

**We are committed to investing in our employees, products, and providing value to our shareholders**



## Strategic investments in early-stage companies to drive innovation and collaboration



### Key investment objectives:

- **Enhance Innovation and Adoption of Emerging Technologies:** Explore software and services innovation and seek deeper visibility into evolving technologies, including artificial intelligence-driven drug design (AIDD) and development.
- **Grow M&A Pipeline:** Seed investments and partnerships in early-stage companies are expected to broaden the opportunity pipeline and total addressable market (TAM).
- **Expand Revenue Opportunities:** Broaden portfolio offerings through software technology and scientific service partnerships and explore new partner revenue models.
- **Drive Shareholder Returns:** Optimize the combination of organic growth, operating leverage, and strategic M&A to deliver long-term sustainable returns to our stakeholders.

# Seasoned Management Team and Scientific Leadership



Highly experienced management team with deep life science industry expertise,  
track record of growth and strong returns



**Shawn O'Connor**  
*Chief Executive Officer*



**Will Frederick**  
*Chief Financial Officer*  
*Chief Operating Officer*



**Dan Szot**  
*Chief Revenue Officer*



**Sandra Suarez-Sharp, Ph.D.**  
*President*  
Regulatory Strategies



**Brett Howell, Ph.D.**  
*President*  
Quantitative Systems  
Pharmacology Solutions (QSP)



**Jill Fiedler-Kelly, M.S., FISoP**  
*President*  
Clinical Pharmacology &  
Pharmacometrics Services  
Solutions (CPP)



**John DiBella, M.S**  
*President*  
Physiologically Based  
Pharmacokinetic (PBPK)  
Solutions, Cheminformatics  
Solutions



**Jonathan Chauvin, Ph.D.**  
*President*  
Clinical Pharmacology &  
Pharmacometrics Software  
Solutions (CPP)



## CONTINUED LEADERSHIP POSITION IN BIOSIMULATION MARKET

### Delivering on our commitment to scientific leadership

- Internal R&D investment
- Expanding industry and regulatory partnerships
- Model-Informed Drug Development (MIDD+) – 3rd annual SLP sponsored conference

### Enhancing our client facing capabilities

- Appointed new CRO to lead sales effort
- Reorganized operations to put clients first
- Focus on supporting accelerated growth in distributor network

### Challenges being addressed

- Software renewal timing changes completed
- Small biotech churn
- General market dynamics: inflation, recession & forex

### Focus on capital allocation

- ASR program has been completed
- Immunetrics acquisition completed in Q4

**STRONG START TO FISCAL 2024**







# Secular Trends Driving Sustained Long-Term Growth



## Drivers include:

Biosimulation taking greater percentage of drug development spend annually

Scarcity of blockbuster drug opportunities drive industry focus to smaller market targets requiring increased development efficiency

Increased scrutiny and rising cost of animal studies and human clinical

Increased adoption of Modeling & Simulation by regulatory agencies and decision making based on Modeling & Simulation input

Increasing use cases for application of Modeling & Simulation methods to impact decision making



**The Drug Discovery and Development Industry can be broken down into several subindustries, including:**

**1. TARGET DISCOVERY AND VALIDATION**

**2. LEAD COMPOUND IDENTIFICATION AND OPTIMIZATION**

**3. PRE-CLINICAL DEVELOPMENT**

**4. CLINICAL TRIALS**

**5. REGULATORY REVIEW & APPROVAL**

**6. COMMERCIALIZATION**

**7. POST-APPROVAL SURVEILLANCE AND LIFE CYCLE MANAGEMENT**

Each of these subindustries represents a different stage of the drug development process and involves different tasks, such as identifying targets for drug development, synthesizing and testing compounds, conducting clinical trials, and seeking regulatory approval for marketing and sales. The subindustries within drug discovery and development are highly interdependent, with progress in one stage often impacting the progress in other stages.





## ENVIRONMENT

Reduced footprint of US-based facilities by 35% from 19,300 sf to 12,400 sf.

Established a process to gather GHG emissions data points and set targets for expected SEC disclosure requirements.

Implemented LearnUpon LMS and Adobe e-signature to reduce in-person training travel and printed materials with virtual on-demand programs using digital materials.

## SOCIAL

Updated company privacy policy and processes in the PDP Program to reflect changes to global personal data protection laws.

Developed and published Human Rights Policy to support our commitment to human rights.

Expanded University+ program to 307 free software licenses across 51 countries to further education in our industry and support the next generation of scientists.

## HUMAN CAPITAL

Established a paid parental leave program to support working parents.

Implemented employee engagement & recognition software to further promote and foster a culture of appreciation and inclusion.

Conducted employee engagement survey to ensure culture alignment and success of internal programs and benefits.

## GOVERNANCE

Engaged a third-party consulting firm to carry out a board evaluation process and joined NACD to support ongoing director education.

Implemented pay vs. performance analysis for SEC disclosure of company financial performance measure used to determine executive compensation.

Updated Code of Conduct policy to reflect that we and our business partners meet the standards of business governance, environmental sustainability, and human rights.





## Biosimulation Technology Leader Leveraging AI and Machine Learning

SLP software licensed to major pharma (19 of 20 largest)

**GastroPlus** - mechanistically based simulation software package that simulates intravenous, oral, oral cavity, ocular, inhalation, dermal, subcutaneous, and intramuscular absorption, biopharmaceutics, pharmacokinetics, and pharmacodynamics in humans and animals.

**ADMET Predictor** - the flagship machine learning platform for ADMET modeling with extended capabilities for data analysis, metabolism prediction, and AI-driven drug design.

**DILIsym is Quantitative Systems Toxicology (QST)** - software designed to be used during drug development to provide an indication of the potential drug-induced liver injury (DILI) hazard posed by individual molecules and/or to provide deeper insight into the mechanisms responsible for observed DILI responses at various stages of the development process.

**MonolixSuite** - built for model-informed drug development computing, MonolixSuite (including Monolix, Simulix, Pkanalix) is a fast, easy-to-use, and powerful suite of applications for pharmacometrics analysis, modeling, and simulation. Intuitive, effective offering the most advanced calculation capabilities.

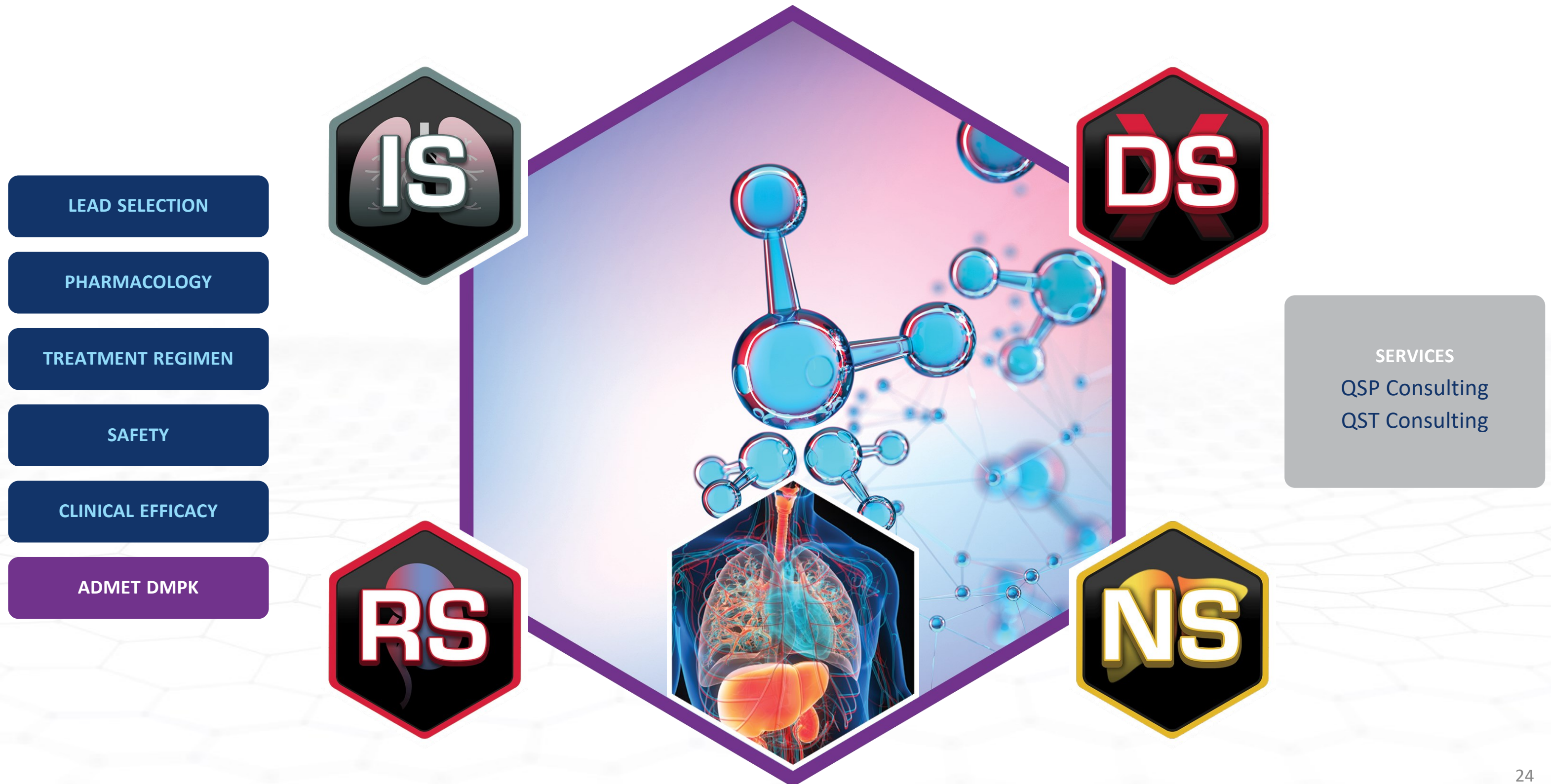
### QSP/T Models

- **ILDsym** - model of interstitial lung disease (ILD) associated with systemic sclerosis (SSc).
- **RENAsym** is quantitative systems toxicology (QST) software for predicting and understand drug-induced kidney injury.











LEAD SELECTION

PHARMACOLOGY

TREATMENT REGIMEN

SAFETY

CLINICAL EFFICACY

ADMET DMPK



## SERVICES

Pharmacometrics  
Clinical Pharmacology  
Clinical Regulatory  
Consulting





Provides customers with specialized knowledge and expertise

Delivers complementary capabilities to software application solutions

- Drives greater demand for its software solutions
- Provides stable, steady revenue streams

Helps clients minimize or eliminate questions posed by regulatory reviews while decreasing cost and time to develop detailed reports

Drives operational efficiencies for customers leading to timelier and more streamlined decision-making and regulatory reporting

Covers Pharmacometrics, PBPK, QSP/T and Regulatory Strategies disciplines

Offers specialized therapeutic, modeling and regulatory knowledge

Brings specialized knowledge and expertise as part of its consulting services, helping extend customers' internal capabilities in the biosimulation modeling and the simulation space

Average contract size of approximately ~\$200k

- Pharmacokinetic and Pharmacodynamic (PKPD) projects in the \$100K - \$300K range
- Quantitative Systems Technology (QST) and Quantitative Systems Pharmacology (QSP) platform contracts can be in the \$300K - \$700K range
- Customer contracts are sizable and provide steady revenue streams

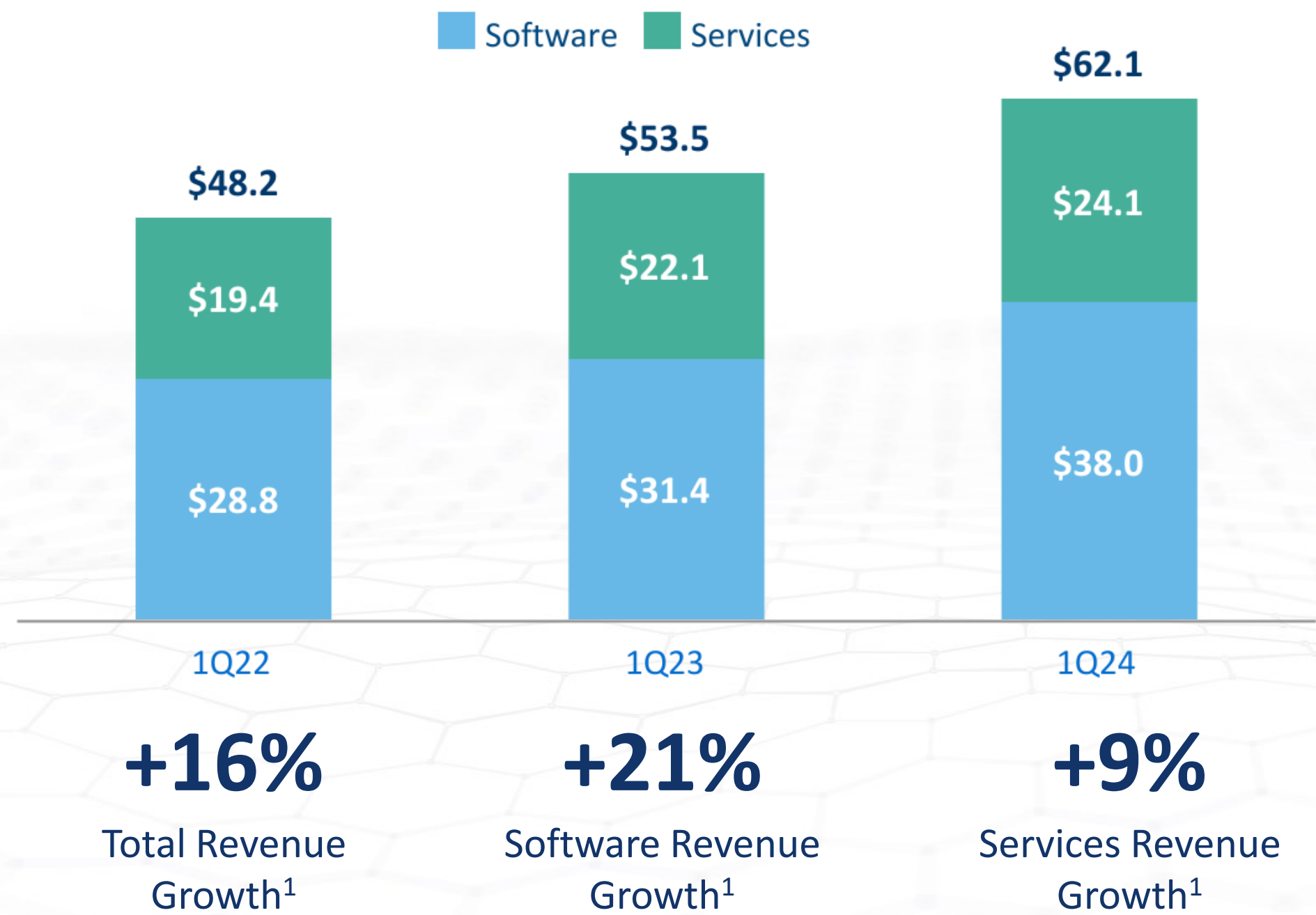


# Financial Results

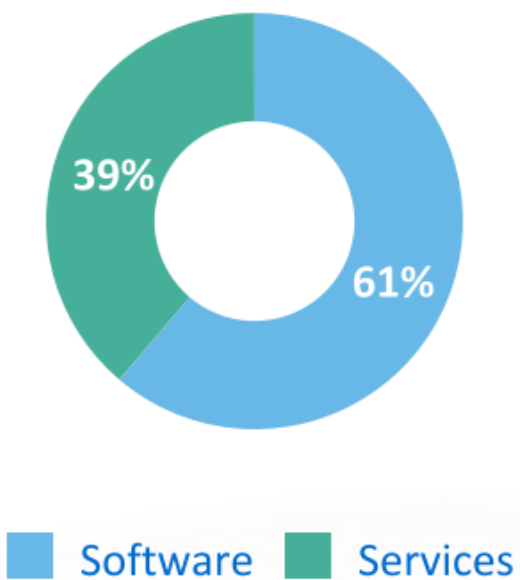
# Revenue - Trailing Twelve Months (TTM)



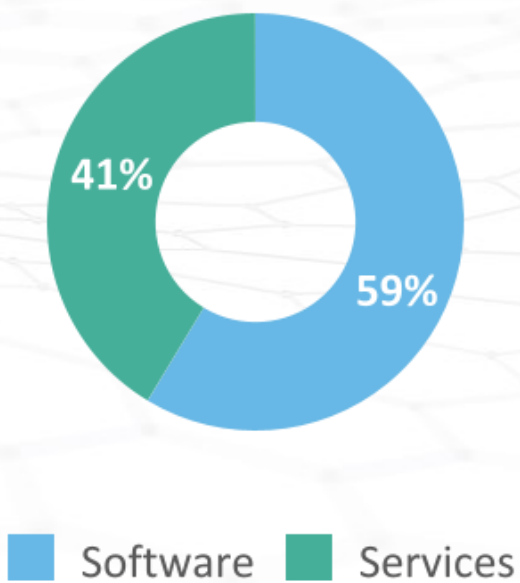
(in millions)



1Q24 Revenue Mix



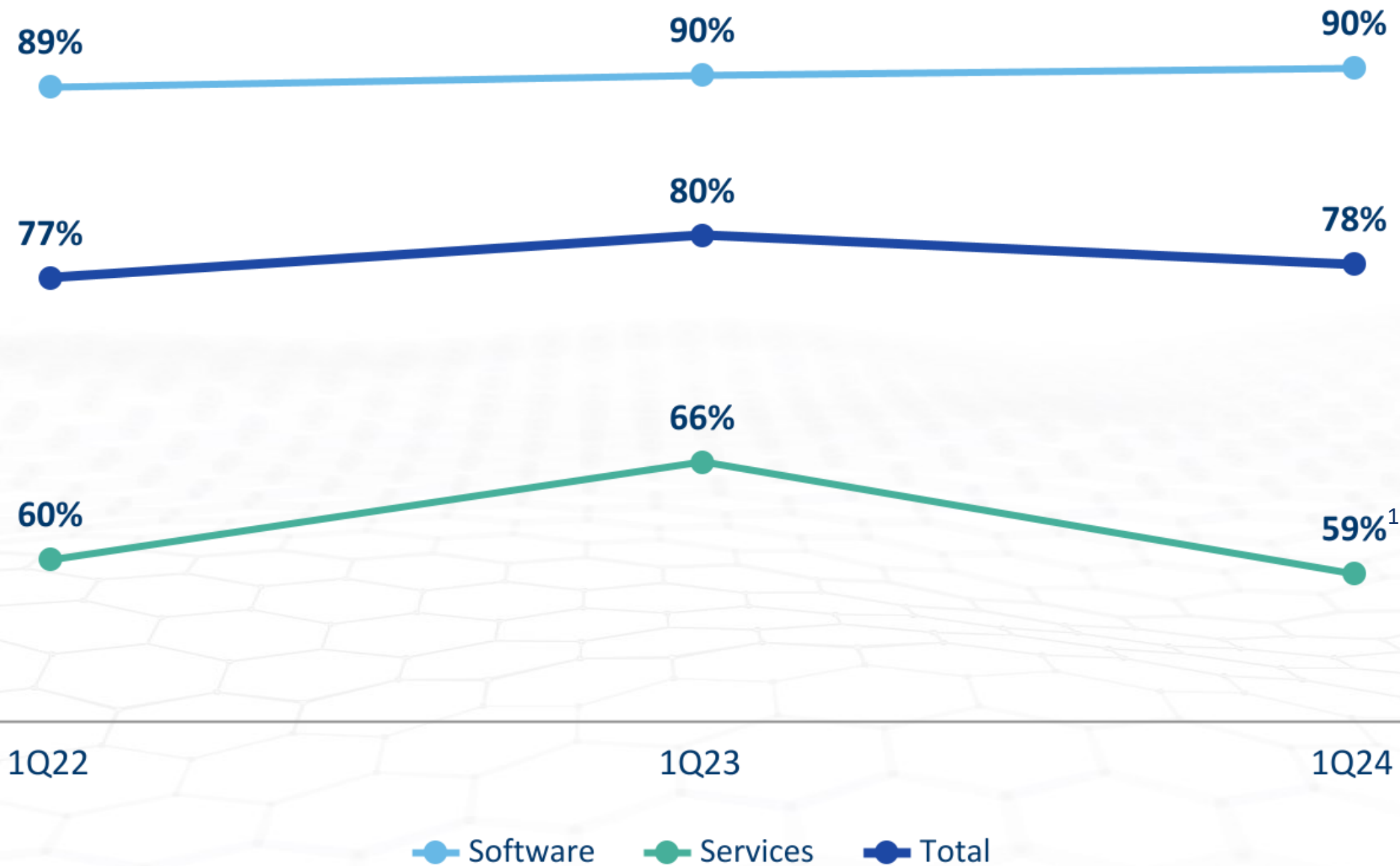
1Q23 Revenue Mix



<sup>1</sup> TTM 1Q'24 vs. TTM 1Q'23



# Gross Margin Trends – TTM

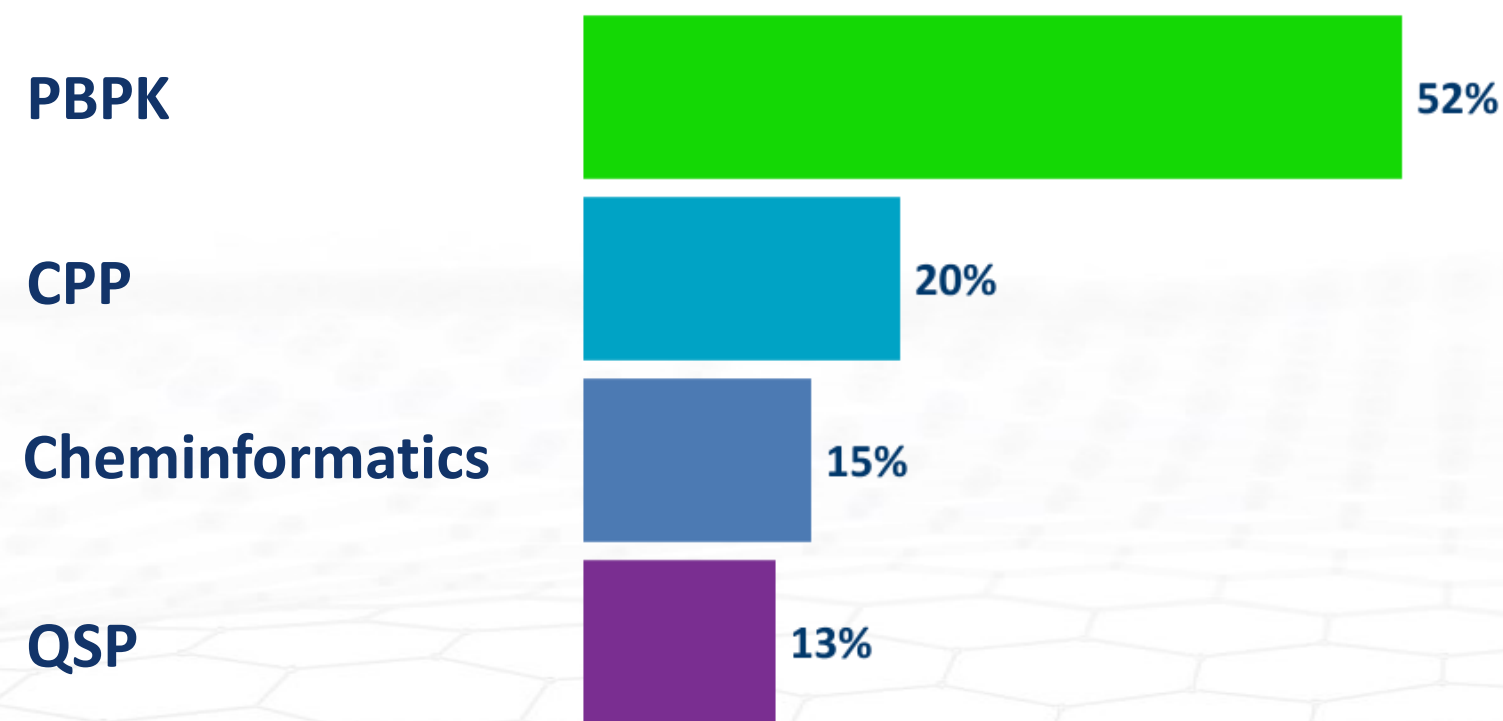


<sup>1</sup> Decrease in gross margin was partially due to a shift in reporting effective 1Q'24, where certain cost items are reflected in cost of revenues for services that were previously in SG&A expense.

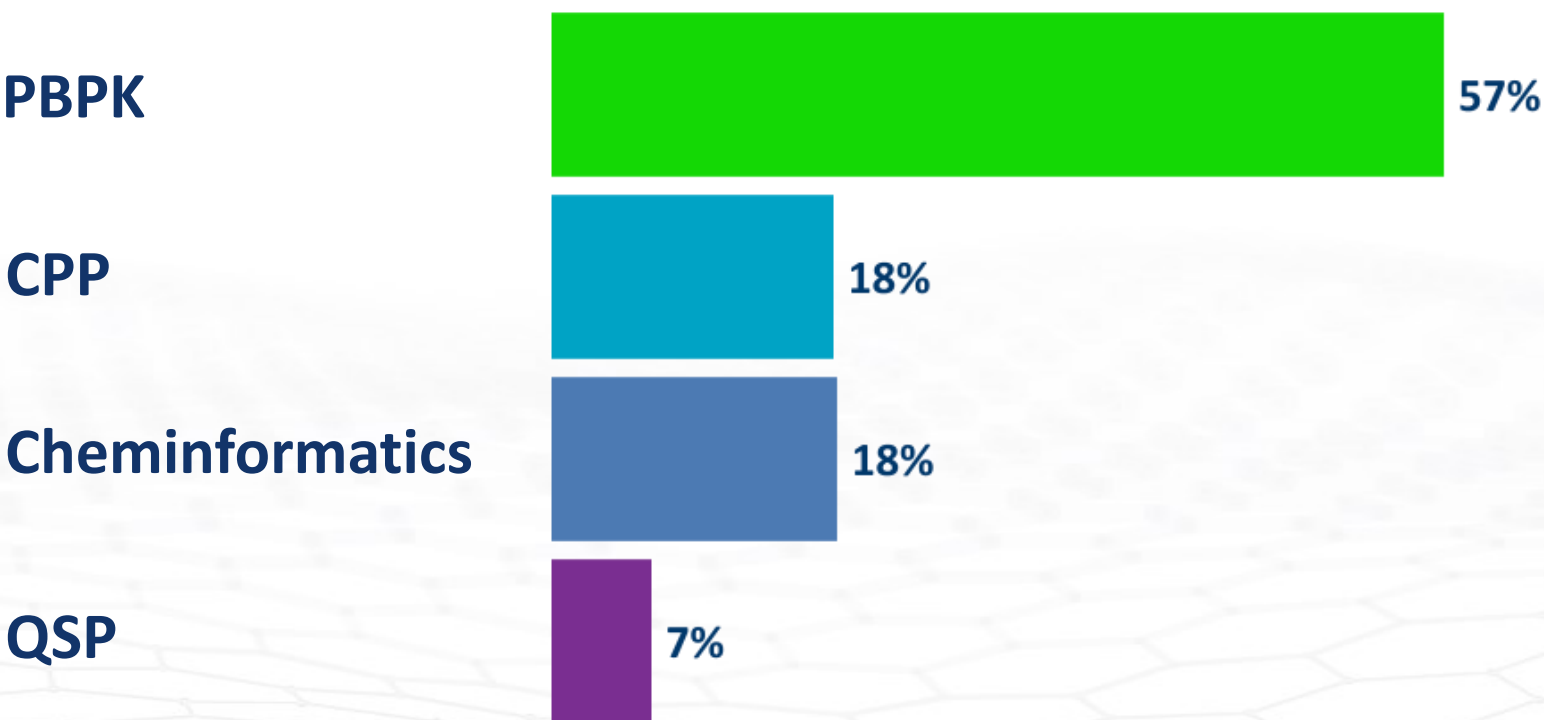
# Software Revenue by Business Unit



1Q24



TTM

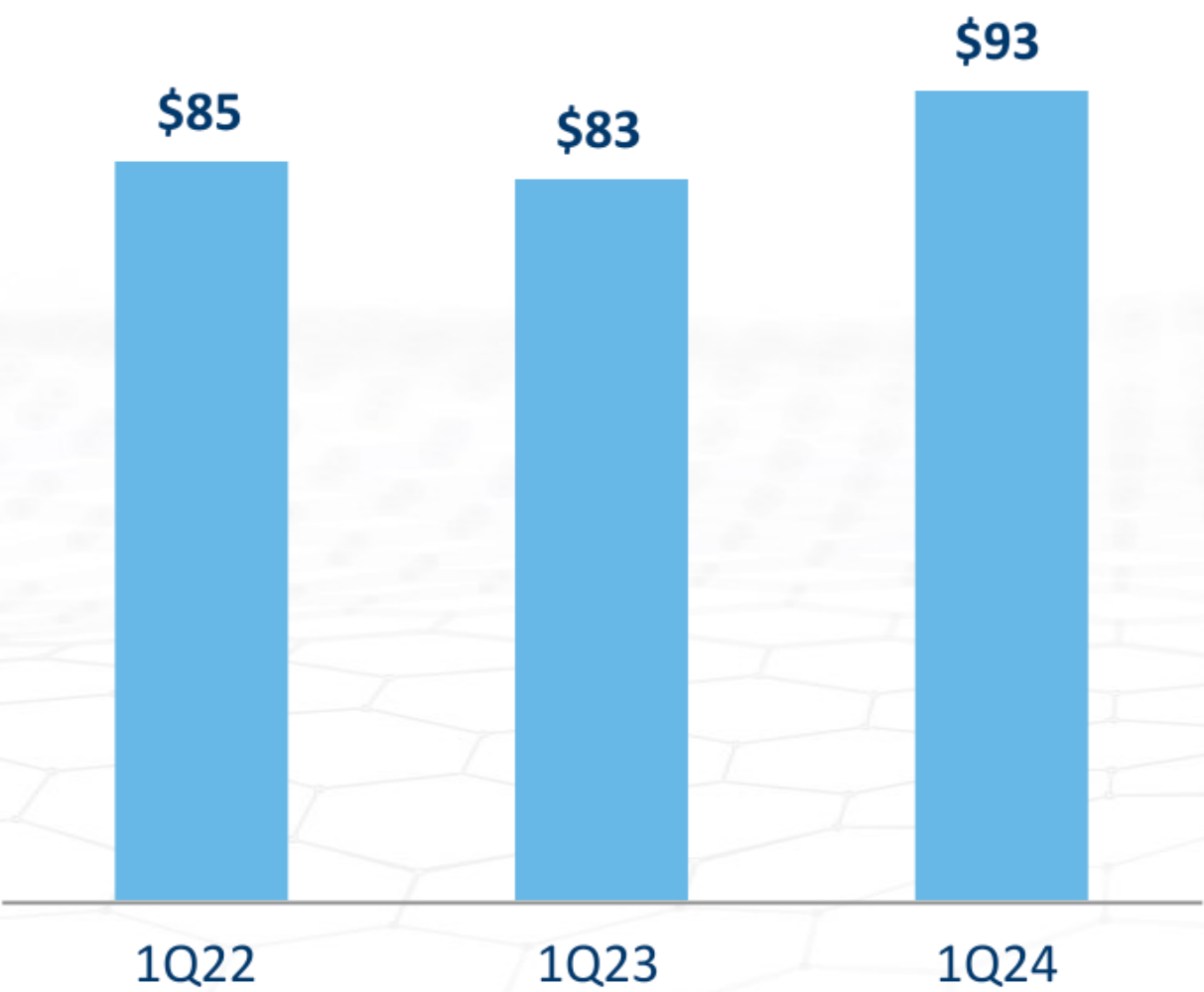


Software Business Unit as % of Software Revenue

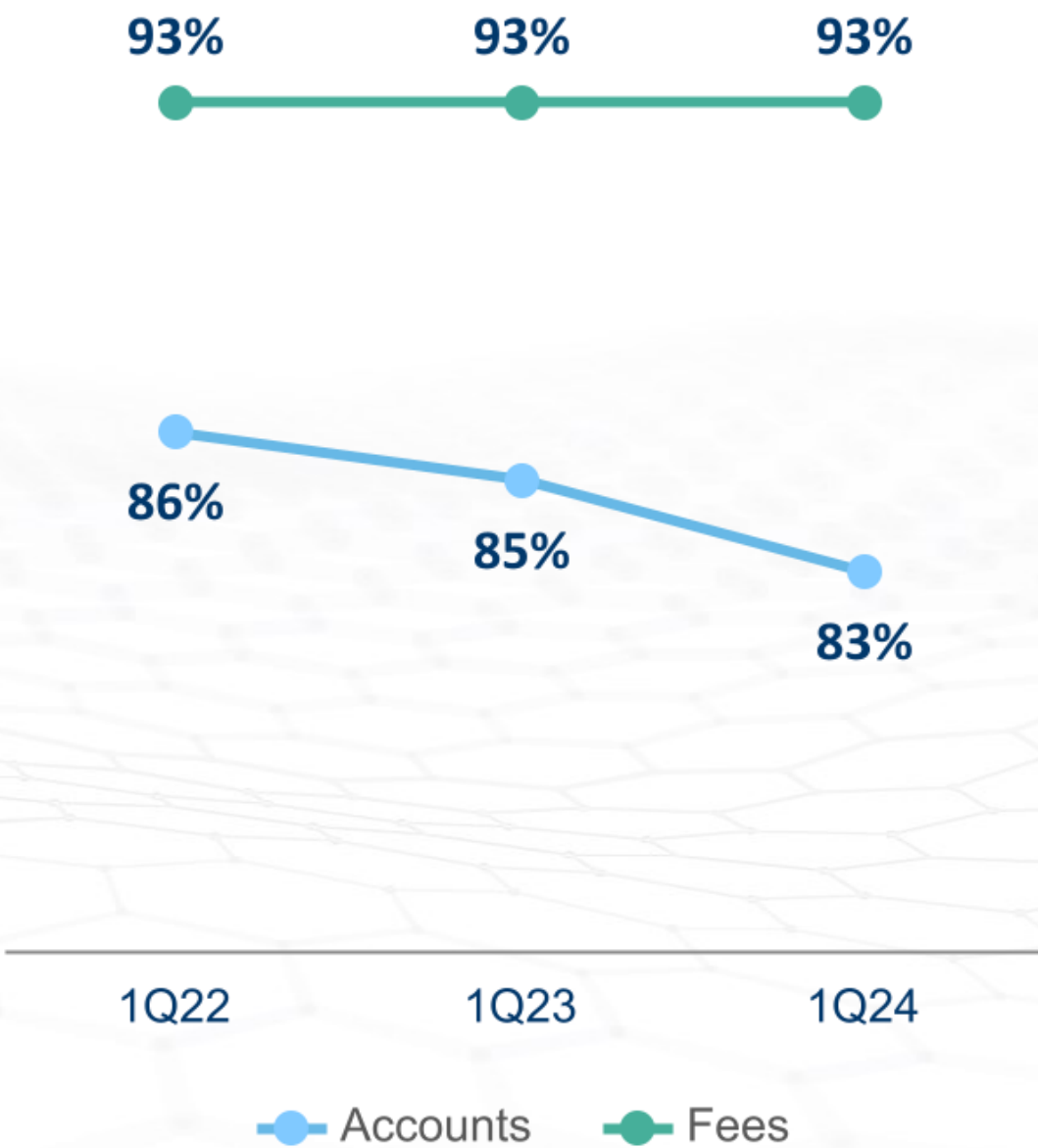


## Commercial Customers

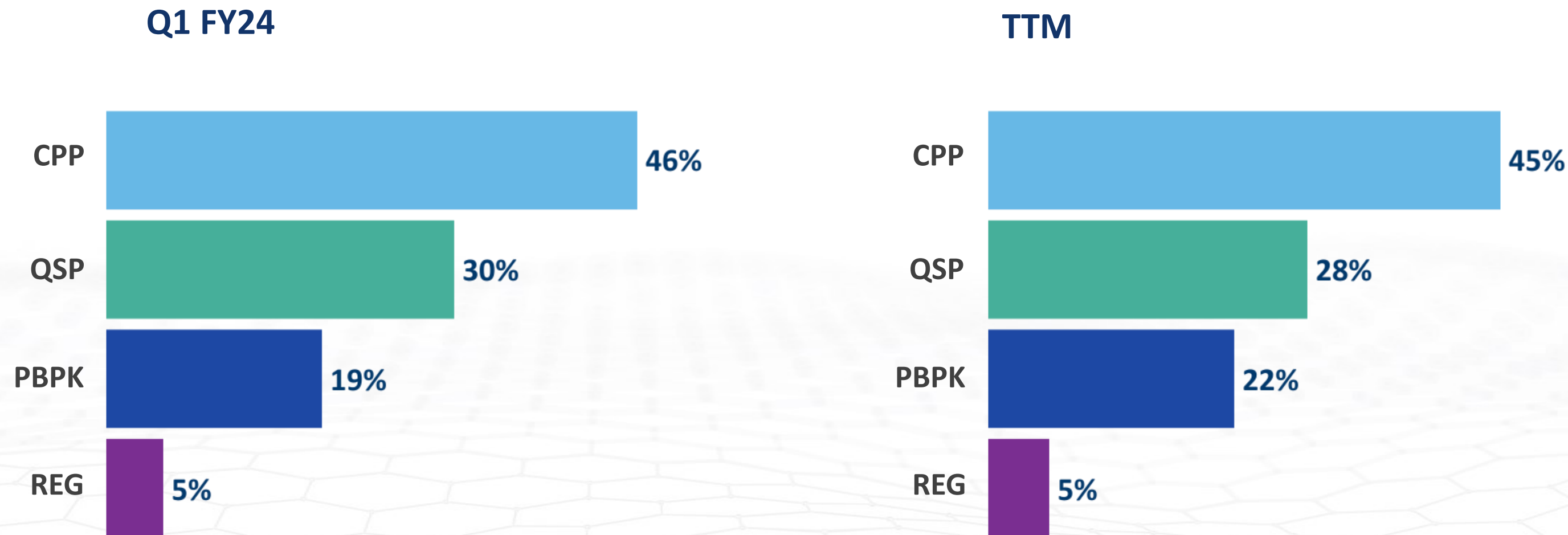
Avg. Revenue per Customer  
(in thousands)



Renewal Rates



# Services Revenue by Business Unit

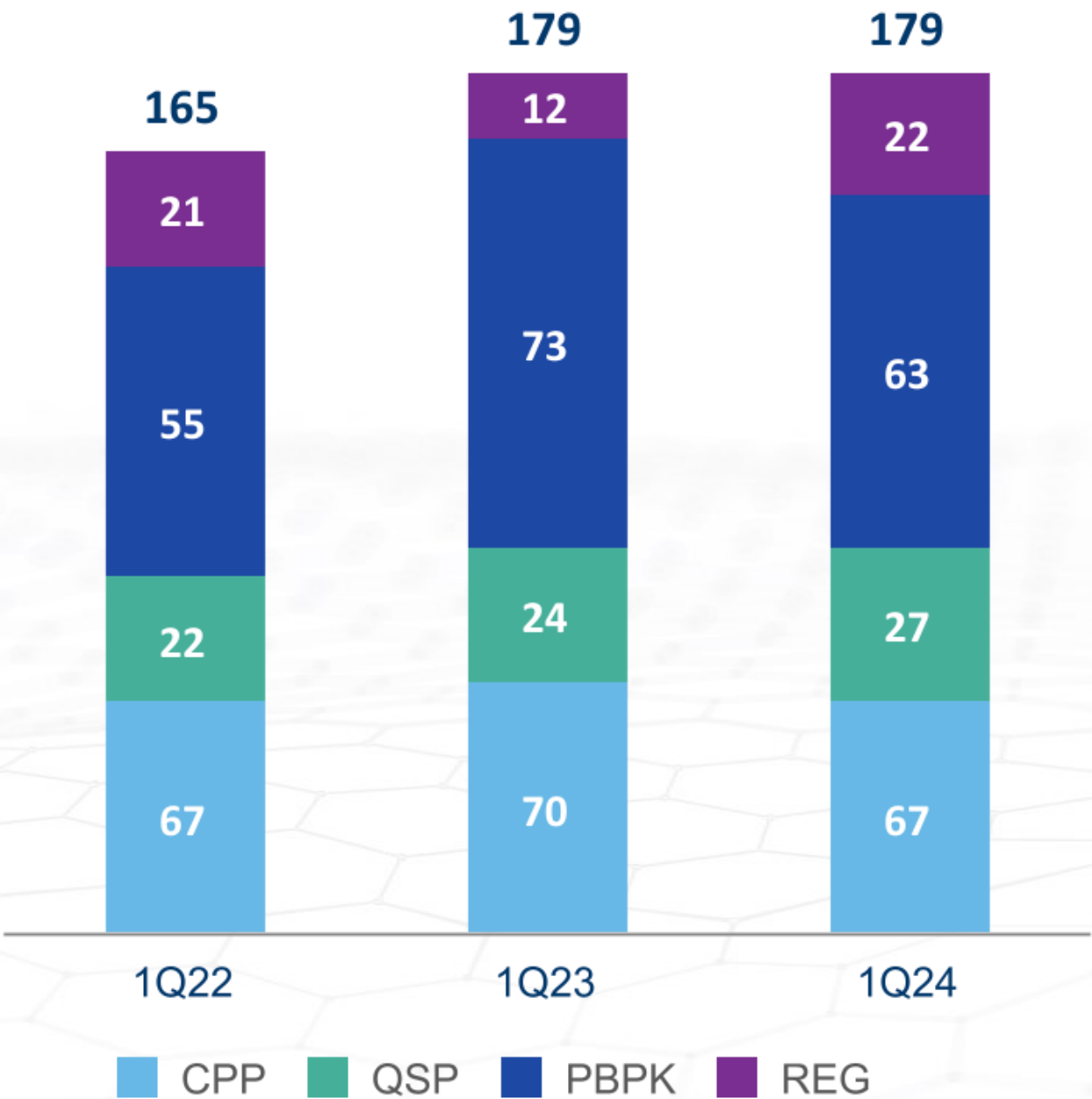


Services Business Unit as % of Services Revenue

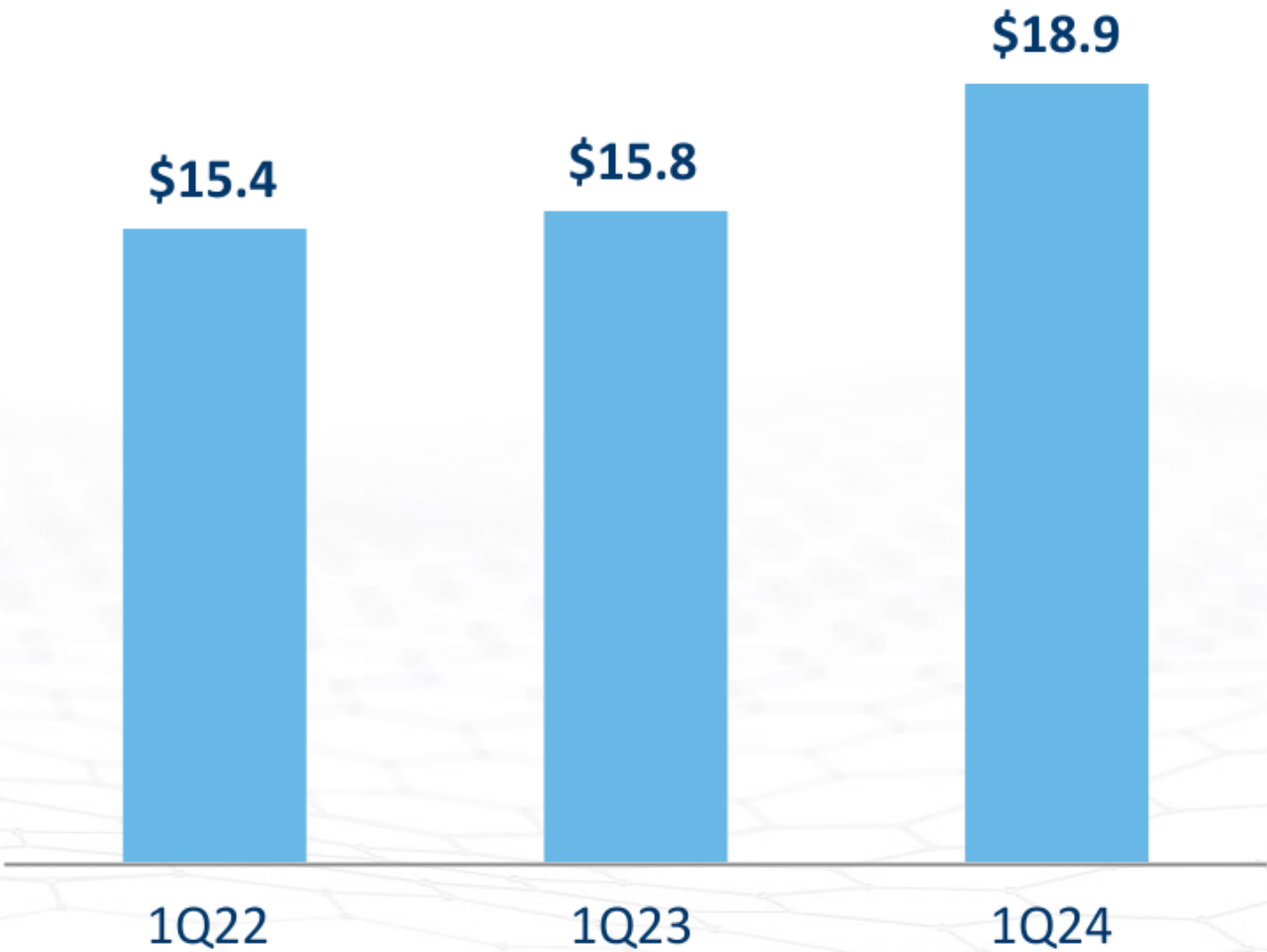




Total Projects



Backlog  
(in millions)



# Income Statement Summary - Q1 FY24



(in millions, except Diluted EPS)

	1Q24	% of Rev	1Q23	% of Rev
Revenue	\$14.5	100%	\$12.0	100%
Revenue growth	21%		(4)%	
Gross profit	9.8	68%	9.3	78%
R&D	1.2	8%	1.2	10%
S&M	2.0	14%	1.5	12%
G&A	5.7	39%	5.8	48%
Total operating exp.	8.9	61%	8.4	70%
Income from operations	1.0	7%	0.9	7%
Income before income taxes	2.4	17%	1.6	14%
Income taxes	(0.5)	3%	(0.4)	3%
Effective tax rate	19%		23%	
Net income	\$1.9	13%	\$1.2	10%
Diluted earnings per share	\$0.10		\$0.06	
Adjusted EBITDA	\$3.4	23%	\$3.0	25%



# Balance Sheet Summary



(in millions)

	November 30, 2023	August 31, 2023
Cash and short-term investments	\$113.9	\$115.5
Total current assets	129.7	130.4
<b>Total assets</b>	<b>\$185.8</b>	<b>\$186.1</b>
Current liabilities	8.6	12.0
Long-term liabilities	4.8	4.1
Total liabilities	13.4	16.1
Shareholders' equity	172.3	170.0
<b>Total liabilities and shareholders' equity</b>	<b>\$185.8</b>	<b>\$186.1</b>

	<u>Guidance</u>
<b>Total Revenue</b>	<b>\$66M to \$69M</b>
<b>Total Revenue Growth</b>	<b>10% to 15%</b>
<b>Software Revenue Mix</b>	<b>55% to 60%</b>
<b>Services Revenue Mix</b>	<b>40% to 45%</b>
<b>Diluted EPS</b>	<b>\$0.66 to \$0.68</b>





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