

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) June 18, 2020

REPRO MED SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

New York
(State or other jurisdiction
of incorporation)

0-12305
(Commission
File Number)

13-3044880
(IRS Employer
Identification No.)

24 Carpenter Road, Chester, New York
(Address of principal executive offices)

10918
(Zip Code)

Registrant's telephone number, including area code (845) 469-2042

not applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
common stock, \$0.01 par value	KRMD	Nasdaq Capital Market

Item 8.01 Other Information.

Repro Med Systems, Inc. dba KORU Medical Systems (the “Company”) has made investor presentations using the investor presentation attached as Exhibit 99.1 hereto, which is incorporated herein by reference.

The investor presentation includes “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the investor presentation are “forward-looking” rather than historical. The information contained in the presentation is summary information that is intended to be considered in the context of the Company’s Securities and Exchange Commission filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in the investor presentation, although it may do so from time to time as its management believes is warranted.

The investor presentation contains Adjusted EBITDA as a non-GAAP financial measure. The Company defines Adjusted EBITDA as earnings (net income) before interest, income taxes, depreciation and amortization, reorganization charges, and litigation, manufacturing initiative and stock option expenses. Prior to January 1, 2020, discontinued product expense and manufacturing initiative expense was not included in the Company’s definition of Adjusted EBITDA. The Company believes that Adjusted EBITDA is used by investors and other users of its financial statements as a supplemental financial measure that, when viewed with the Company’s GAAP results and the accompanying reconciliation, the Company believes provides additional information that is useful to gain an understanding of the factors and trends affecting the Company’s business. The Company also believes the disclosure of Adjusted EBITDA helps investors meaningfully evaluate and compare the Company’s cash flow generating capacity from quarter to quarter and year to year. Adjusted EBITDA is used by the Company’s management as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations. Because management uses Adjusted EBITDA for such purposes, the Company uses Adjusted EBITDA as a significant criterion for determining the amount of annual cash incentive compensation paid to its executive officers and employees.

Non-GAAP measures should not be considered a substitute for GAAP-basis measures and results. The Company’s non-GAAP measures may not be comparable to non-GAAP measures of other companies. Slide 13 of the investor presentation provides a comparison of Adjusted EBITDA presented to the most closely analogous measure determined in accordance with GAAP.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Investor Presentation dated June 2020</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REPRO MED SYSTEMS, INC.
(Registrant)

Date: June 18, 2020

By: /s/ Karen Fisher
Karen Fisher
Chief Financial Officer



Investor Presentation

June 2020

NASDAQ: KRMD

DISCLAIMER / NON-GAAP MEASURES



This presentation contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward looking statements can be identified by words such as "expects", "plans", "goals", "future", and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding our long-term growth potential and sustainability, our strategic growth initiatives and long-term financial goals, issues expected with U.S. plasma supply, expected increase in IG supply, and the potential impact of COVID-19 in the market. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: impact of COVID-19; introduction of competitive products; availability of insurance reimbursement; changes in U.S. Food and Drug Administration regulations; changes to health care policies; success of our research and development efforts; our ability to raise capital if or when needed; acceptance of and demand for new and existing products; expanded market acceptance of the FREEDOM Syringe Infusion System; our ability to obtain required governmental approvals; success in enforcing and obtaining patents; continued performance by principal suppliers; continued customer preference to work through distributors; continued service of key personnel and attracting and maintaining new personnel; the costs, duration and ultimate outcome of litigation; and general economic and business conditions. Any forward-looking statement made by us is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Non-GAAP Adjusted EBITDA

Q1 2020 Adjusted EBITDA excludes from net income: tax expense, depreciation and amortization, interest income, net, operating expenses associated with the Company's organizational changes prior to March 31, 2019, discounted product expense, litigation costs, manufacturing initiative expenses, and stock option expense.

Non-GAAP Measures

This presentation includes non-GAAP financial measures that are not in accordance with, nor an alternate to, generally accepted accounting principles and may be different from non-GAAP measures used by other companies. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. Non-GAAP financial measures should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. They are limited in value because they exclude charges that have a material effect on our reported results and, therefore, should not be relied upon as the sole financial measures to evaluate our financial results. The non-GAAP financial measures are meant to supplement, and to be viewed in conjunction with, GAAP financial results. A reconciliation of our non-GAAP measures is included in this presentation.

NASDAQ: KRMD

New Life, New Beginnings -2-

KORU Medical Systems manufactures and sells the Freedom Integrated Infusion System that allows chronically-ill patients to self-administer *subcutaneous infusion therapy* in their homes



Supporting the Migration to At-Home Healthcare



Driving Down Healthcare Costs by Eliminating the Need for a Caregiver



Delivering Improved Patient Outcomes and Quality of Life



Strong Financial Performance; 20%+ Revenue Growth (Demonstrated + Targeted)

SCIg with Freedom Infusion Systems: Your Peace of Mind During Uncertain Times

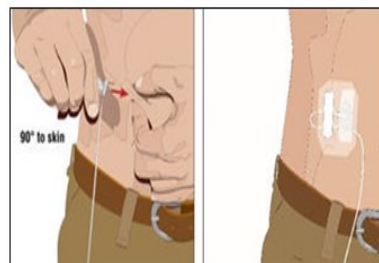


Dawn has gained "12 extra days" every month by receiving immunoglobulin G subcutaneously (SCIg) instead of intravenously (IVIg)

- 1. Decreased Exposure:** Patient can administer infusions in the comfort of their home, eliminating the need to go to the hospital or infusion suite
- 2. Time & Flexibility:** Therapy fits into the patient's schedule so they can live life and regain time spent commuting to and from appointments
- 3. Ease of Use:** The Freedom Infusion System requires no batteries or electricity, assuring self-sufficiency and patient independence
- 4. Improved Outcomes:** SCIg therapy using the Freedom Infusion System enables improved patient outcomes and quality of life when compared to IVIg

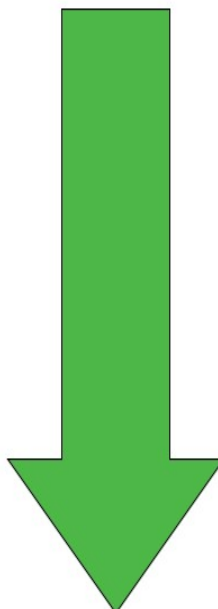
Subcutaneous Infusion

A small needle is inserted into the tissue between the skin and muscle, rather than a vein, and connected to an infusion pump. Medication is absorbed slowly and steadily by the body.



DIAGNOSES OF PRIMARY IMMUNODEFICIENCIES (PI) IMPROVE LIVES AND LOWERS COSTS

- A study by The Jeffrey Modell Foundation (2017) examined the economic burden of chronic immunodeficiency diseases
- Retrospective analysis of 1,388 patients undiagnosed with PI for at least 5 years
- Increased incidence of pneumonia, sinusitis, bronchitis, and otitis
- Higher rate of hospitalization, outpatient visits and outpatient drug utilization



Payor economics more favorable after diagnosis

\$85,782

**Decline in
Annual Treatment Costs
Per Patient
After Diagnosis of PI**

(before Ig treatment)

Chronic Patients Necessitate Treatment

Source: www.aimc.com/journals/supplement/2019/examining-the-application-immunoglobulin/managing-cost-of-care-and-healthcare-utilization-in-patients-using-immunoglobulin-agents

MARKET OVERVIEW

PLASMA SUPPLY IS RAMPING AS DEMAND RISES FOR Ig AND SCIg THERAPY

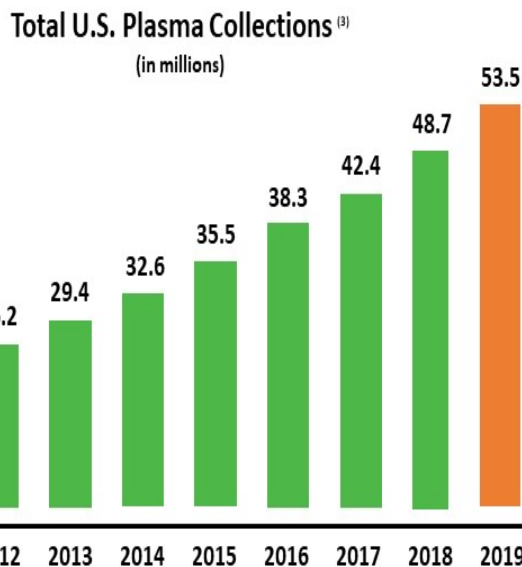


Total Available Market

Global Home Infusion Therapy Market
+7% CAGR to \$41.6 B by 2027 ⁽²⁾

(1) Fortune Business Insights.
www.fortunebusinessinsights.com/press-release/immunoglobulins-market-9134
(2) Grand View Research, February 2020
(3) https://www.ptaglobal.org/images/Data/Plasma_Collection/Total_Yearly_Collections_2008-2019.pdf

NASDAQ: KRMD



GRIFOLS

Plans to reach 370 approved plasma collection centers by 2024 globally

Form 20-F for FY ended 12/31/19

CSL

20 new U.S. plasma collection centers opened in 1H FY 2020

Press release, 2/12/20

Takeda

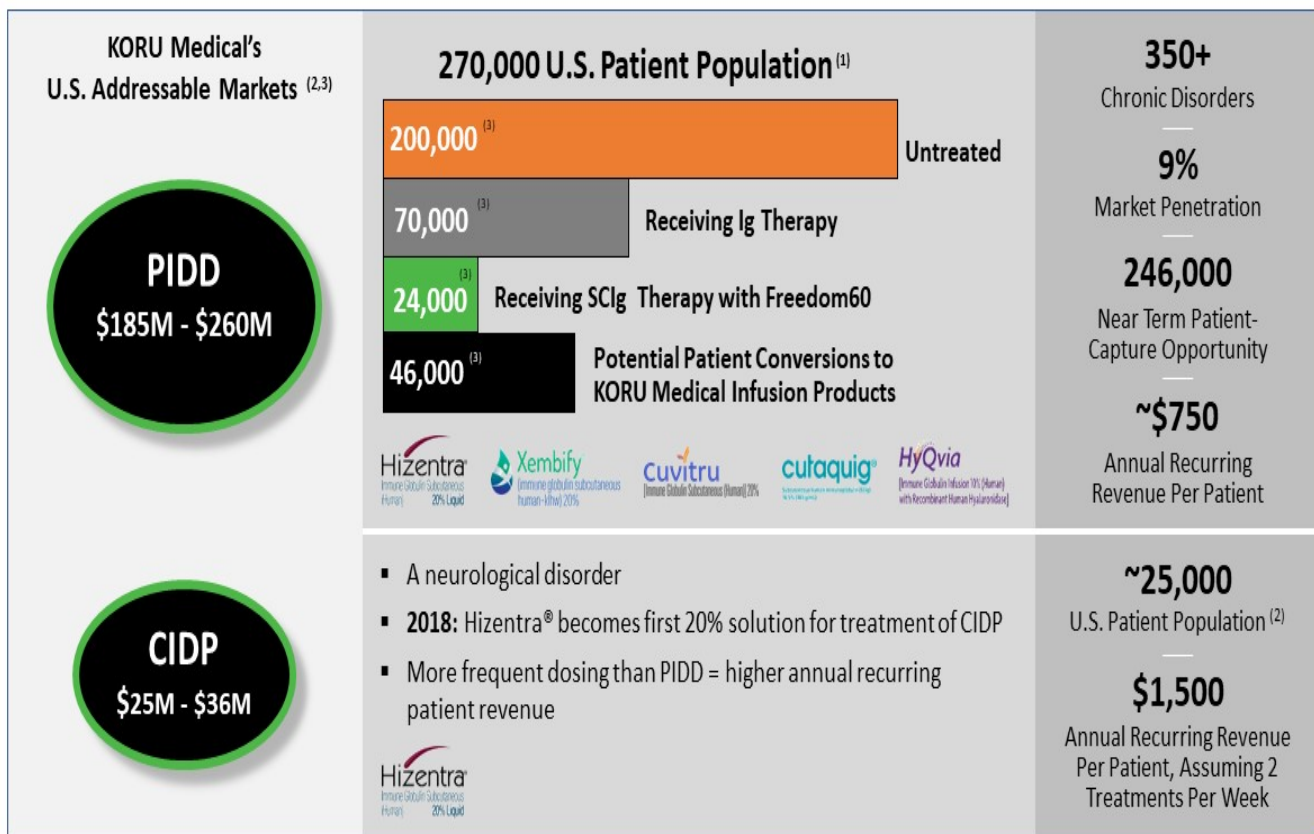
Intends to increase plasma supply and manufacturing capacity by >65% over the next five years

Fourth quarter earnings slides, 5/13/20

New Life, New Beginnings -6-

~\$300M CURRENT U.S. ADDRESSABLE MARKET

EXCLUDES OTHER DISEASE STATES AND SECONDARY IMMUNE DEFICIENCY DISEASES
INTERNATIONAL MARKET OPPORTUNITY ~2x – 3x U.S. ADDRESSABLE MARKET ⁽³⁾



NASDAQ: KRMD ⁽¹⁾ PIDD patient population from <https://www.myjesource.com/what-is-pi>
⁽²⁾ CIDP patient population (2018) from <https://www.aimc.com/journals/supplement/2018/examining-therapies-cidp/chronic-inflammatory-demyelinating-polyneuropathy-considerations-for-diagnosis-management-and-optimization-health> ⁽³⁾ KORU Medical estimate

FREEDOM INFUSION SYSTEMS

WIDELY ADOPTED SCIg DELIVERY SYSTEM



Easy-to-use,
easy-to train



Maintenance-free



No batteries or
electricity required



Highly accurate at
any fill volume



Low residual volume =
minimal drug waste

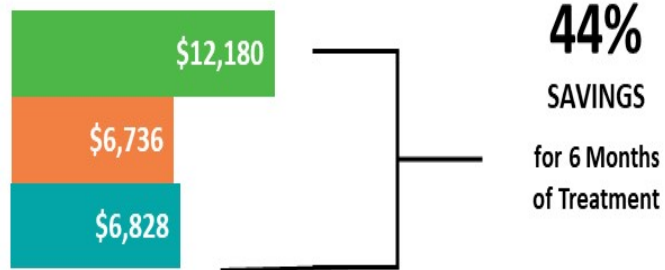


Dynamic Equilibrium
maintains safe pressure
of 13.5 psi throughout
infusion



Monthly Cost of Immune Deficiency Drugs for Privately Insured Individuals, 2018

Hospitals Physician Offices Patients' Home



"For certain administered specialty drugs, treatment at home can improve patients' physical and mental well-being and reduce disruption of work schedules and family responsibilities, all without increasing the likelihood of adverse drug events or side effects."

UNITEDHEALTH GROUP®

Reducing Specialty Drug Costs / September 2019

(1) UnitedHealth Group®: Reducing Specialty Drug Costs / September 2019.

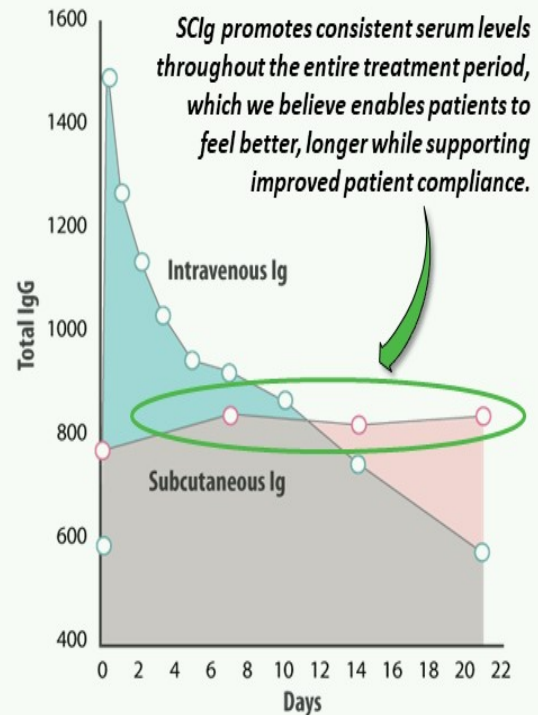
SCIg ENABLES IMPROVED PATIENT OUTCOMES AND QUALITY OF LIFE ⁽¹⁾



SCIg Offers Meaningful Benefits to Patients

- 1 Self-administer at home without the need for a nurse
- 2 Infuse under the skin, not through a vein
- 3 Freedom to go about daily activities with minimal interruption
- 4 Consistent serum levels...which we believe enables patients to feel better, longer

Subcutaneous and Intravenous Serum Ig Level



Team Sales Approach

KORU Medical leverages CSL Behring's large sales organization to educate and influence physicians, patients and SPs about the advantages of subcutaneous infusion with the Freedom60®



Source: www.hizentra.com



KORU Medical's Freedom60® is featured at www.hizentra.com and in a national advertising campaign for Hizentra® SCIg therapy

XEMBIFY® by Grifols: Launched December 2019

- New SCIg treatment introduced by Grifols
- Grifols is a leading producer of plasma medicines
- Validates therapeutic shift from IVIg to SCIg
- Grifols anticipates increasing global plasma donation centers
- Significant long-term growth potential for KORU



Source: www.sec.gov/Archives/edgar/data/1438569/000110465920043470/tm1919375d1-20f.htm.

KORU IMPROVES THE DELIVERY OF CARE

PHYSICIAN/PATIENTS/SPECIALTY PHARMACIES ARE PRODUCT DECISION MAKERS
KORU AND PHARMA ARE THE PRIMARY INFLUENCERS ON THESE DECISION MAKERS

Hospital /
Physician Visits



Immunologist
Diagnosis



Infusion Therapy
Prescribed



SP
Distributors




Self-Administer
At Home



Infusion Resupply
Direct to Patient



- 
- ✓ Chronic conditions in need of therapy
 - ✓ Expanding trend of physicians prescribing subcutaneous immunoglobulin
 - ✓ Proven solution
 - ✓ Increasing drug development for subcutaneous delivery
 - ✓ Freedom pump is the market-leading mechanical subcutaneous delivery solution
 - ✓ High margin, recurring revenue stream

NASDAQ: KRMD

New Life, New Beginnings -13-

NEW THERAPIES REPRESENT SIGNIFICANT MARKET EXPANSION POTENTIAL

SMALL- AND MID-LARGE VOLUME SCIg INJECTIONS / INFUSIONS

>100 Companies*

>10 Therapeutic Areas

>10 High Potential Future Candidates

Current Development Programs
Total Addressable Market = ~40M Patients



Secondary
Immunodeficiency



Hematology



Pulmonology



Nephrology



Rheumatic &
Autoimmune Diseases

KORU offers meaningful benefits to its pharma partners:
Expanded addressable markets, new therapeutic formulations, and patent runway extension

KORU'S POSITIONING

LEVERAGING OUR CORE STRENGTHS TODAY TO DRIVE GROWTH TOMORROW

- 

Significant Market Share and Growth Potential
- 

Differentiated Technology
- 

Strong Pharma Relationships
- 

Premium Customer Retention
- 

Unique Value Proposition That Benefits All Parties Across The Care Continuum

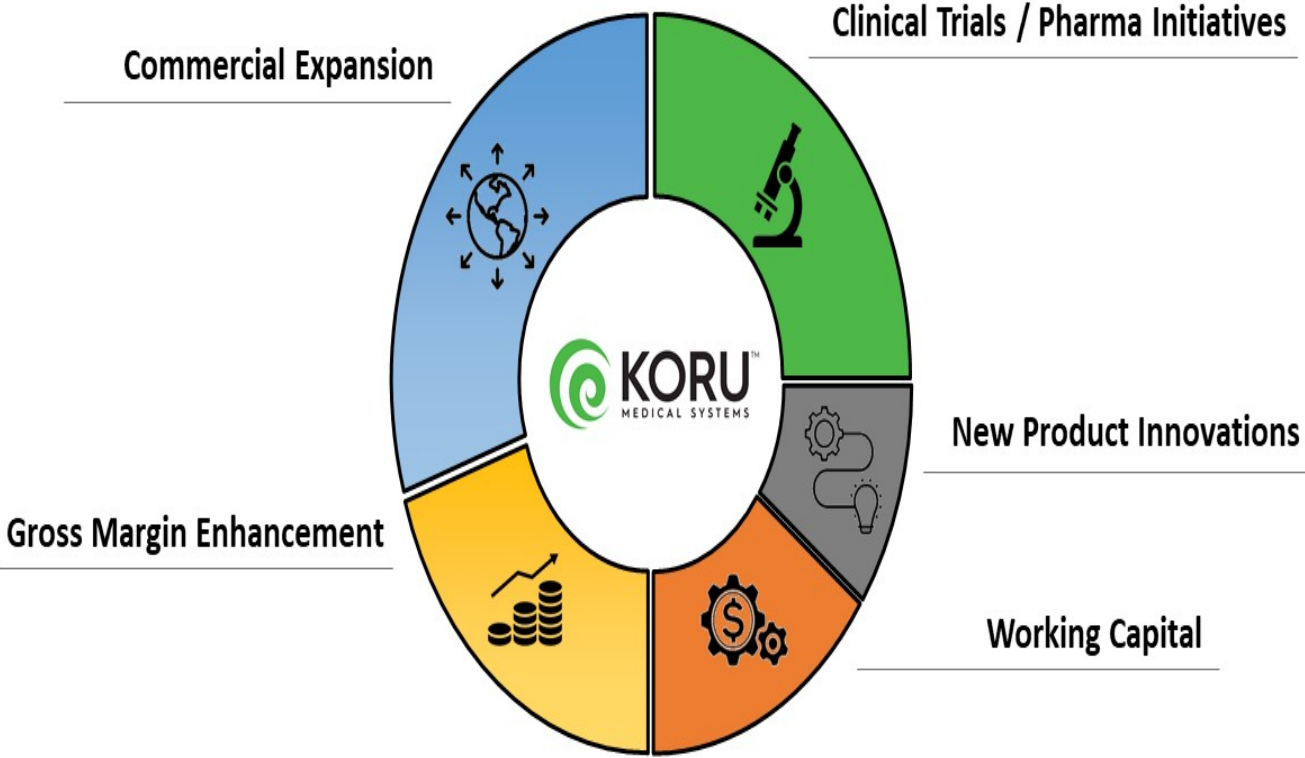


Growing Adoption and Opportunity in Current Space (Ig)	Expanded Indications for Existing Therapies (e.g. Secondary Immunodeficiency)
	
Expand Outside the United States	Support Drug Development for New Disease States
	

EXECUTING AGAINST OUR STRATEGIC GROWTH INITIATIVES

TO BECOME THE PREFERRED DRUG DELIVERY PARTNER FOR SPECIFIC INFUSION THERAPIES IN SELECT MARKETS



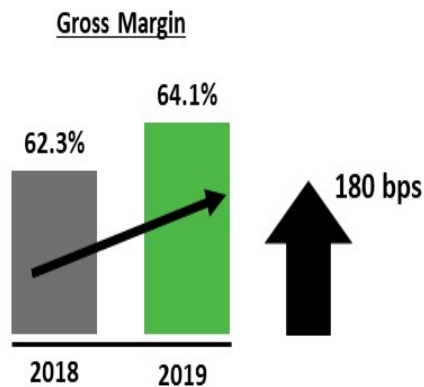
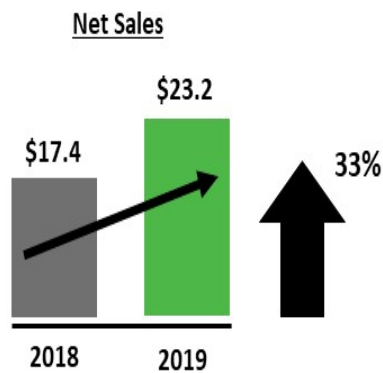


IMPROVED ANNUAL NET SALES AND GROSS MARGIN

(\$ in millions)

High Growth
24%
Revenue CAGR
(2016 - 2019)

**Improved
Gross Margin**



Long-Term Financial Goals

20%+
Annual Organic
Revenue Growth

70%+
Gross Margin
by End of 2022

Q1 2020 FINANCIAL SUMMARY

(\$ in millions)

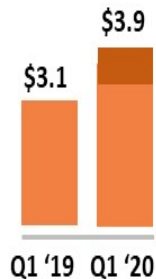
“We reported a strong Q1 2020 with net sales, net income, and Adjusted EBITDA rising from Q1 2019.”

- Don Pettigrew, President & CEO
KRMD Q1 2020 press release

NET SALES



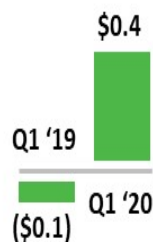
GROSS PROFIT*



GROSS MARGIN*



NET (LOSS) INCOME



ADJUSTED EBITDA**



* Q1 2020 gross profit and gross margin exclude a \$0.1 million discontinued product expense; including this expense, gross profit and gross margin were \$3.8 million and 60%, respectively.

** Adjusted EBITDA excludes from net income: tax expense, depreciation and amortization, interest income, net, operating expenses associated with the Company's organizational changes prior to March 31, 2019, discounted product expense, litigation costs, manufacturing initiative expenses, and stock option expense.

COVID-19

EXPERIENCED MINIMAL OPERATIONAL DISRUPTIONS
CONTINUING TO SUPPORT PATIENTS WITH CHRONIC MEDICAL CONDITIONS



The overwhelming majority of the patients we serve are treating **chronic**, life-long conditions



No material issues expected with **U.S. plasma supply** for this year *



IG remains tight, but with 15% U.S. unemployment, collection expected to soon **invert to increased supply** **



Crisis may result in greater awareness of the **benefits of home health** care and **acceleration** of SubQ therapy***

Our mission to provide our products to patients with chronic medical conditions is more important than ever
Longer-term, we believe that COVID-19 may accelerate the shift of drug infusion therapy to an at-home model and further advance the development of subcutaneous immunoglobulin drugs

* Based on pharma industry commentary and management research, both as of the date of this presentation.

** MST Marquee Equities Research, May 21, 2020.

*** Management belief

BALANCE SHEET AND CAPITAL STRUCTURE

(\$ in millions)



\$7.4

Cash & Cash Equivalents
at March 31, 2020

\$3.5

Line of Credit
effective April 14, 2020



\$2.5

Equipment Financing
Line of Credit
effective April 27, 2020



44.2

Diluted Shares Outstanding
at March 31, 2020

	March 31, 2020	December 31, 2019
Cash & Cash Equivalents	\$7.4	\$5.9
Current Assets	\$14.5	\$11.9
Total Assets	\$16.6	\$13.9
Total Liabilities	\$4.5	\$2.7
Shareholders' Equity	\$12.1	\$11.2

STRENGTHENED, SEASONED LEADERSHIP DRIVING GROWTH



Don Pettigrew
President & CEO

Joined 2018
24 years experience
Moog, Inc.
Baxter (Gambro)
Boston Scientific



Karen Fisher, CPA
CFO

Joined 2015
25 years experience
Armored Autogroup
Gilman Ciocia
New York Times
Thomson Financial



Manny Marques
COO

Joined 2015
23 years experience
Noble Biocare
Procera, LCC



Brian Schiller, Ph.D.
VP Medical Affairs

Joined 2019
20 years experience
Sanofi (Genzyme)
Avanir Pharm.
Amgen
Bristol Myers Squibb

EXPANDED AND STRENGTHENED BOARD OF DIRECTORS

ALL INDEPENDENT (Year Appointed / Committee)



R. John Fletcher (2019 / A NG)
Chairman

Fletcher Spaght, Inc.
Spectranetics Corp.
Boston Consulting Group



Joseph M. Manko, Jr. (2016 / C NG*)
Director

Horton Capital Management
BZ Fund Management
Deutsche Bank
Merrill Lynch
Skadden Arps



Daniel S. Goldberg (2018)
Director

electroCore
Synergy Disc Replacement
Milestone Medical
Xtant Medical Holdings
Sound Surgical Technologies



David W. Anderson (2016 / A*)
Director

Brain Temp, Inc.
Orteq Sports Medicine
Gentis, Inc.
Kensey Nash



Robert T. Allen, CPA (2018 / A NG)
Director

Coram/CVS Infusion Services
Titan Health Corporation
American Medical Response



James M. Beck (2018 / C*)
Director

Medical Specialties Distributors
American Hospital Supply/Baxter
AMSCO International



Kathy S. Frommer (2019 / A C)
Director

CRS Retail Systems
(Co-founder, CEO)
Acquired by Accel-KKR

Committees

A = Audit
C = Compensation
NG = Nomination & Governance
* = Committee Chair

NASDAQ: KRMD

New Life, New Beginnings -23-

Reconciliation of GAAP Net Income to Non-GAAP Adjusted EBITDA

	Three Months Ended		
	March 31,		
	2020		2019
GAAP Net Income / (Loss)	\$	449,428	\$ (85,390)
Tax Expense / (Benefit)		141,928	(22,099)
Depreciation/Amortization		87,224	83,651
Interest Income, Net		(19,030)	(17,480)
Reorganization Charges		--	354,926
Discontinued Product Expense		109,558	--
Litigation Expenses		99,158	492,515
Manufacturing Initiative Expenses		109,803	--
Stock Compensation Expense		<u>300,966</u>	<u>121,875</u>
Non-GAAP Adjusted EBITDA	\$	1,279,035	\$ 927,998

THANK YOU



NEW LIFE, NEW BEGINNINGS
