

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) November 17, 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))

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	The Nasdaq Stock Market

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.

ITEM 7.01 REGULATION FD DISCLOSURE.

On November 17, 2010, Repro Med Systems, Inc. dba KORU Medical Systems (the "Company") posted an investor presentation to its website at <https://www.korumedical.com/investors/news-events>. A copy of the investor presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed subject to the requirements of amended Item 10 of Regulation S-K, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Repro Med Systems, Inc. Investor Presentation dated November 17, 2020

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: November 17, 2020

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



Investor Presentation

November 2020

NASDAQ: KRMD

FORWARD-LOOKING STATEMENTS / NON-GAAP MEASURES



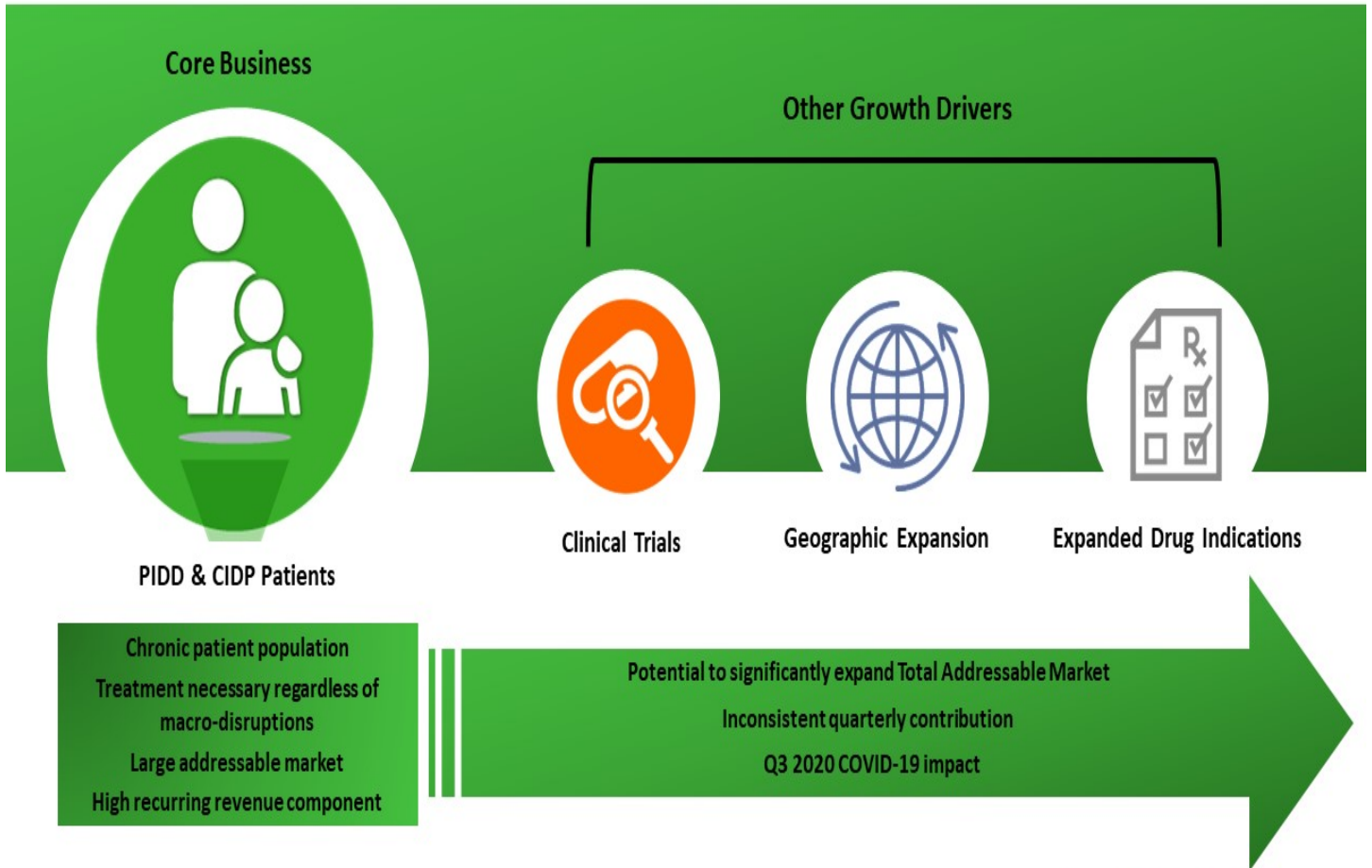
This presentation contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "expect," "plan," "goals," "believe," "intend," "see," "could," "should," 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; 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

Adjusted EBITDA excludes from net income / (loss): income tax expense, depreciation and amortization, interest income, net, reorganization charges, discontinued product expense, litigation expenses including stock-based settlement expense, manufacturing initiative expenses, and stock option expense

Non-GAAP Measures

This presentation includes the non-GAAP financial measure of "Adjusted EBITDA," that is 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, this non-GAAP measure is 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 measure is meant to supplement, and to be viewed in conjunction with, GAAP financial results. A reconciliation of our non-GAAP measure is included in this presentation.



NASDAQ: KRMD



Representative YTD 2020 Revenue Profile

NASDAQ: KRMD



Core Business / U.S. PIDD + CIDP Patients

- Chronic disease state
- Large addressable markets
- High recurring revenue component; minimal patient churn
- Growth aligned with that of Ig market



Clinical Trials

- Potential to significantly expand Total Addressable Market
- Approvals add to Core Business
- Utilize “off-the-shelf” product; customize where necessary
- Creates new and strengthens existing pharmaceutical relationships
- Position us to participate in new clinical trials



International Sales

- A developing revenue stream
- Potential to significantly expand Total Addressable Market

KORU MEDICAL SYSTEMS

PUTTING THE PATIENT FIRST WITH EASY-TO-USE HOME INFUSION SOLUTIONS



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



Pursuing Multiple Growth Pathways



Clinical Trial Activity



Benefitting from Secular Growth Trends



Lowering Costs; Delivering Improved Outcomes



Strong Core Business

NASDAQ: KRMD

New Life, New Beginnings -5-

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 / Recurring Revenue Component**
-  **Value Proposition 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
	

OUR CORE BUSINESS OPPORTUNITY

UNDERPENETRATED MARKETS = COMPELLING GROWTH OPPORTUNITY

EXCLUDES OTHER DISEASE STATES AND SECONDARY IMMUNE DEFICIENCY DISEASES



Primary Immunodeficiency Disease

400+ immune diseases

\$750

Annual Recurring Revenue
Per PIDD Patient

\$375 M

Total U.S.
Addressable Market



500,000

Undiagnosed U.S.
PIDD Population

5%

Total U.S. Market
Penetration (KRMD)

Market leader
High patient retention

6,000,000

Estimated Global PIDD Patient
Population; High Potential for
Additional Diagnosis

Chronic Inflammatory Demyelinating Polyneuropathy

Expanded Indication

\$1,500

Annual Recurring Revenue Per Patient
(Assumes 2 treatments per week)

\$37.5 M

Total U.S. Addressable
Market



25,000

U.S. CIDP Population

US PIDD patient population data from <http://www.csbeking.com/patient/finding-your-disease/immunodeficiency-and-autoimmune-disease>

Global PIDD patient population data: <https://www.businesswire.com/news/home/20200913005293/en/European-Medicines-Agency-Approves-Label-Update-for-HYQVIA-Human-Normal-Immunoglobulin-3D-and-Recombinant-Human-Hyaluronidase-Expanding-its-Use-to-a-Broader-Group-of-Patients-with-Secondary-Immunodeficiencies>

CIDP patient population (2018) from <https://www.ajmc.com/journals/supplement/2018/evaluating-therapies-cidp/chronic-inflammatory-demyelinating-polyneuropathy-considerations-for-diagnosis-management-and-population-health>.
Other figures are KORU Medical estimates.

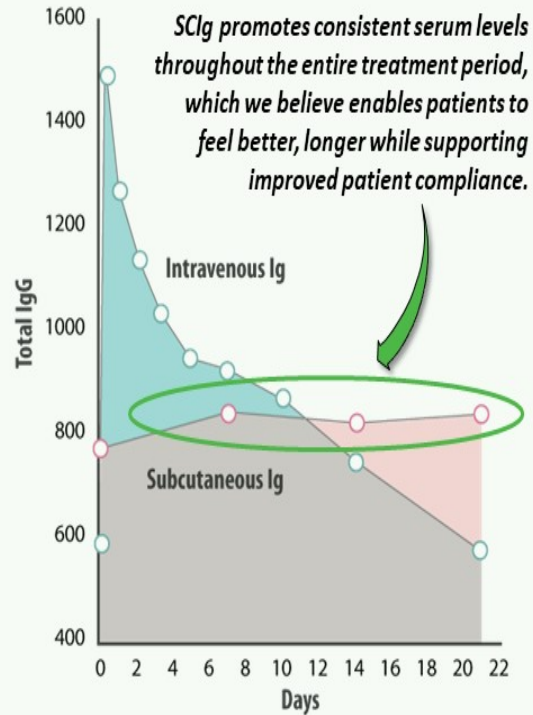
NASDAQ: KRMD

New Life, New Beginnings -7-

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

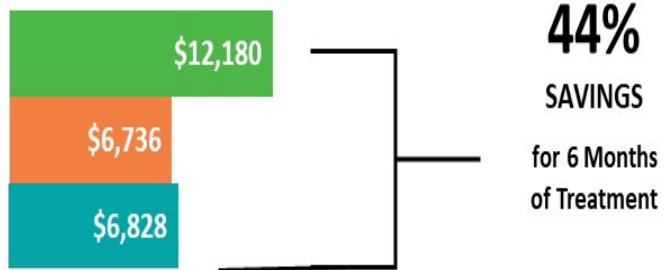
Subcutaneous and Intravenous Serum Ig Level





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.

CORE BUSINESS: GROWING NUMBER OF SClg DRUGS



CSL Behring

First 20% SClg therapy cleared to treat PIDD

Cleared to treat CIDP (2018)

Collaborative approach - KORU + Pharma companies



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

Source: www.hizentra.com



NASDAQ: KRMD

New Life, New Beginnings -10-

Therapeutic Focus



Hematology



Nephrology



Neurology



Respiratory



Oncology



Acute Care
Instrumentation



Immunology / Inflammation



Primary + Secondary
Immunodeficiency

Total Addressable Patient Market Potential +100 M Worldwide**

NASDAQ: KRMD

*October 2020. Some of these agents and applications are investigational and have not been evaluated or approved by the US Food and Drug Administration (FDA) or any other regulatory agency worldwide for the uses under investigation. There is no guarantee any of the agents or applications will demonstrate clinical/commercial success.

**Based on management analysis

New Life, New Beginnings -11-

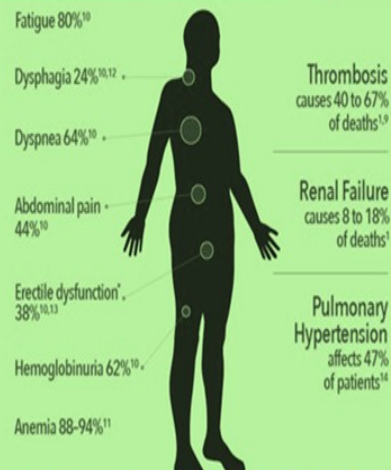
CLINICAL TRIAL INITIATIVES:
COMPLETED PHASE III HEMATOLOGY CLINICAL TRIAL USING FREEDOM SYSTEM



Paroxysmal Nocturnal Hemoglobinuria (PNH)
15,000 Patients Worldwide Afflicted with PNH



SIGNS AND SYMPTOMS OF PNH



Source: <https://twitter.com/alexionpharma/status/1082966719524732928?lang=da>

This new PNH drug is advancing towards its planned 2021 U.S. / global launch

KRMD believes that its Freedom System will be used in several additional upcoming clinical trials focused on expanding indications and disease states for this same drug.

FOCUSED ON GROWTH
IN CURRENT MARKETS

ONGOING EXPANSION INITIATIVES
APPLICATIONS + APPROVALS



Nordic Countries



United Kingdom



Germany



France

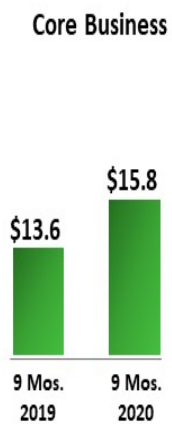
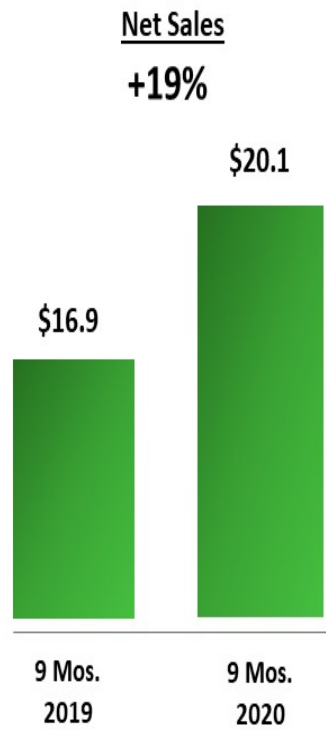


Canada



Japan

2020 NINE MONTH NET SALES (\$ in MM\$)



BALANCE SHEET AND CAPITAL STRUCTURE



\$32.4 M
Cash & Cash Equivalents
September 30, 2020



48.0 M
Diluted Shares Outstanding
September 30, 2020



\$10 M
Share Repurchase
Plan Authorized

(\$ in millions)	September 30, 2020	December 31, 2019
Cash & Cash Equivalents	\$ 32.4	\$ 5.9
Current Assets	\$ 42.6	\$ 11.9
Total Assets	\$ 45.4	\$ 13.9
Total Liabilities	\$ 5.5	\$ 2.7
Shareholders' Equity	\$ 39.9	\$ 11.2

INVESTMENT CONCLUSIONS



Leading Product
Market Share



Expandable Patient Base in
Core Addressable Markets



Exploring Multiple
Growth Pathways



Clinical Trial
Participation



Supporting Migration
to At-Home Care



Well Capitalized



YTD 2020
Adjusted EBITDA \$3.9 M
Cash Flow Positive

RECONCILIATION OF GAAP NET INCOME TO NON-GAAP ADJUSTED EBITDA



	Nine Months Ended			
	September 30,			
		2020		2019
GAAP Net Income/(Loss)	\$	(377,435)	\$	644,606
Income Tax Expense		316,200		189,265
Depreciation and Amortization		297,801		252,594
Interest Income, Net		(23,690)		(59,091)
Reorganization Charges		—		354,926
Discontinued Product Expense		71,318		—
Litigation*		2,446,747		2,481,471
Manufacturing Initiative Expenses		194,804		120,386
Stock Option Expense		<u>1,011,140</u>		<u>640,775</u>
Non-GAAP Adjusted EBITDA**	\$	3,936,885	\$	4,624,932

*For the nine months ended September 30, 2020, litigation consisted of a \$2.2 million non-cash, stock-based settlement expense.

**Adjusted EBITDA excludes from net income / (loss): income tax expense, depreciation and amortization, interest income, net, reorganization charges, discontinued product expense, litigation expenses including stock-based settlement expense, manufacturing initiative expenses, and stock option expense.

THANK YOU



NEW LIFE, NEW BEGINNINGS
