Medgenics Reports Fourth Quarter and Full Year 2015 Results and Advancement of NFC-1 Development Programs

Medgenics Inc
February 17, 2016 8:00 AM

PHILADELPHIA, PA--(Marketwired - Feb 17, 2016) - Medgenics, Inc. (NYSE MKT: MDGN)

- Enrollment Initiated in Groundbreaking Non-interventional Phenotype/Genotype Study of mGluR Mutations in ADHD
- IND Clearance Received for 22Q11.2 Deletion Syndrome

Medgenics, Inc. (NYSE MKT: MDGN) today reported financial results for the three and twelve months ended December 31, 2015, as well as several key business and clinical development program highlights.

"We have made tremendous progress over the past year in transitioning our strategy toward becoming a leading genomic medicine company," said Mike Cola, CEO of Medgenics, "and today we are excited to announce the successful achievement of two key milestones for our development programs with NFC-1: the initiation of enrollment into our groundbreaking phenotype/genotype study in mGluR positive ADHD, and the acceptance of our IND for the 22q11.2 Deletion Syndrome program. There is a high degree of enthusiasm amongst our investigator and advocacy communities to begin these programs, and today's news represents key next steps in our plan to bring a novel therapy to these underserved populations.

"Our stated goal at Medgenics is to unlock the potential of genomic medicine to identify and treat patients with life-altering conditions. During the course of 2015, we took a number of additional steps to advance that goal. Regarding the advances to our pipeline; we presented key data supporting the development of our lead CNS program (NFC-1), we renewed our existing relationship with the Center for Applied Genomics (CAG) at Children's Hospital of Philadelphia (CHOP) to continue our leading edge genomic research, and we advanced our gene therapy collaborations with key academic partners such as

Stanford and Harvard Universities. Additionally, from an organizational standpoint, we strengthened our clinical operations team and we successfully raised a cash to strengthen our balance sheet positioning us well to advance to the NFC-1 program into clinical development."

Dr. Garry Neil, Medgenics' Chief Scientific Officer stated, "Our priorities in 2016 are to successfully generate data from three key clinical studies with NFC-1 and to generate additional data on the CNS applications of our unique *ex vivo* gene therapy (TARGT). I am extremely proud of the work done by our clinical team to initiate these programs, and we remain focused on our development efforts related to NFC-1. We also look forward to the addition of future programs from the CHOP collaboration, as we continue to progress our pipeline of genetic discoveries."

Upcoming Anticipated Milestones

- **NFC-1 Program - mGluR mutation positive ADHD (mGluR+ ADHD):**
  - Complete enrollment of the non-interventional phenotype/genotype study (MDGN-NFC1-ADHD-001) of metabotropic glutamate receptors (mGluR) mutations in children and adolescents with Attention Deficit Hyperactivity Disorder (ADHD). Medgenics will enroll 1,000 ADHD patients across 25 sites nationally and genotype them to learn more about the prevalence of metabotropic glutamate receptor (mGluR) mutations in this targeted population of ADHD patients aged 6-17. During the consent process participants will be offered the opportunity to be contacted for future research studies.
  - Initiate a Phase 2/3 interventional study with NFC-1 in mGluR mutation positive ADHD in Q2. Initial top-line data from the study are expected in the second half of the year.
- **NFC-1 Program - 22q11.2 Deletion Syndrome:**
  - Initiate an exploratory study of psychiatric symptoms in children with 22q11.2 Deletion Syndrome. The study will explore symptoms from three major neuropsychiatric disorders: ADHD, Anxiety and Autism Spectrum Disorders (ASD). Initial open-label responder data from the trial is anticipated by mid-year 2016.

Recent Medgenics Highlights

- **Data presented from the GREAT study at the 62nd Annual Meeting of the American Academy of Child and Adolescent Psychiatry (AACAP) in October 2015.** The

objectives of the study were to evaluate the safety, tolerability, and pharmacokinetics of NFC-1 and to evaluate the effect of NFC-1 on ADHD during four weeks of continuous treatment following one week of placebo therapy in several validated ADHD scales in mGluR+ adolescents with ADHD symptoms. The treatment effect of NFC-1 appeared more robust over time and at higher doses. NFC-1 was well tolerated, with no treatment-related serious adverse events reported.

- **Licensed novel, potentially permanent gene therapy technology from Stanford University.** Medgenics completed a license for a promoter-less and potentially permanent gene therapy technology, GeneRide, to be used in conjunction with the TARGT technology to advance the company's capabilities in *ex vivo* gene therapy.

- **Strengthened balance sheet.** In October, Medgenics successfully completed a registered public offering, raising $46 million in gross proceeds. The proceeds will be used to fund critical clinical development studies in mGluR+ ADHD and 22Q Deletion Syndrome with our lead compound, NFC-1.

- **Advancement of TARGT$_{CNS}$ program.** The Company demonstrated the viability of its TARGT micro-organs in the cerebral spinal fluid, and look to pursue preclinical proof of concept data by H2 2016.

Additionally, Medgenics announces the appointment of Colleen Anderson as Vice President of Clinical Operations. Ms. Anderson has over 20 years' experience in the operational and scientific aspects of drug development, ensuring optimal delivery of late-stage studies across multiple therapeutic areas (psychiatry, neurology, musculoskeletal, hematology, and infections / anti-infective diseases). She is an established people manager with considerable experience building high-functioning teams. Ms. Anderson received her Bachelor's and Master's in Education degrees from Loyola University in Maryland and her MBA in Pharmaceutical Marketing from St. Joseph's University in Philadelphia.

In connection with the appointment of Ms. Anderson, the Compensation Committee of the Medgenics Board of Directors has granted her inducement awards consisting of stock options covering up to 100,000 shares of the Company's common stock, $0.0001 par value per share (Common Stock), at a per share exercise price of $3.64, representing the closing price of the Common Stock on the grant date, February 16, 2016. These options have a 10-year term, with one-third of the options vesting on the first anniversary of grant, one-third vesting on the

second anniversary, and the final third vesting on the third anniversary of the grant date, subject to Ms. Anderson's continuous service through each vesting date. The Compensation Committee of the Medgenics Board of Directors, which is comprised solely of independent directors, granted this award on February 16, 2016 pursuant to stand-alone award agreements outside of Medgenics' Stock Incentive Plan as inducements material to Ms. Anderson's acceptance of her appointment to the company in accordance with Section 711 of the NYSE MKT Company Guide.

Fourth Quarter Financial Results

The Company reported financial results for the three and twelve months ended December 31, 2015 and the filing with the U.S. Securities and Exchange Commission (SEC) of the Company's Annual Report on Form 10-K. The Form 10-K includes audited consolidated financial statements containing the information presented below, as well as additional information regarding the Company. The Form 10-K is available at www.sec.gov and at www.medgenics.com.

Cash and cash equivalents as of December 31, 2015 were $53.06 million, compared to $33.29 million as of December 31, 2014. The increase in cash was primarily the result of the October financing which raised net new proceeds of $42.88 million.

Gross research and development (R&D) expenses for the three months ended December 31, 2015 increased to $5.43 million from $4.11 million for the same period in 2014. This increase was primarily driven by increased spending on third party related costs used to advance our clinical activities related to the NFC-1 program and the CHOP collaboration. Net R&D expenses for the three months ended December 31, 2015 increased to $4.31 million from $3.77 million for the same period in 2014 due to the increase in gross research and development expenses as detailed above offset in part by participation by the OCS of $1.12 million in the fourth quarter of 2015 compared with $0.34 million for the comparative period.

General and administrative expenses for the three months ended December 31, 2015 were $2.12 million, decreasing from $2.42 million for the same period in 2014 primarily due to a decrease in professional fees.

For the quarter ended December 31, 2015 the Company reported a loss of $6.46 million or $0.20 per share, compared with a loss of $6.20 million or $0.30 per share for the comparative quarter in 2014.

Full Year 2015 Financial Results

Gross R&D expenses for year ended December 31, 2015 increased to $18.36 million from $10.49 million in 2014. This increase was was primarily driven by increased spending on third party related costs used to advance our clinical activities related to the NFC-1 program and the CHOP collaboration. Net R&D expenses for the year ended December 31, 2015 increased to $15.44 million from $8.25 million in 2014 due to the increase in gross research and development expenses as detailed above offset in part by participation by the OCS of $2.91 million in 2015 compared with $2.24 million in 2014.

Non-recurring R&D expenses, including acquisition, milestone, and reimbursed R&D costs of $8.17 million in 2015, resulted from the acquisition of NFC-1 in the third quarter. Included in the $8.17 million expense is $2.0 million in an upfront cash payment, $6.0 million in a corporate milestone payment, and $0.17 million in reimbursed R&D costs. The $6.0 million milestone payment was paid in October and consisted of a cash payment of $2.8 million and $3.2 million in a non-cash equity payment.

General and administrative expenses for the yearended December 31, 2015 were $12.95 million, increasing from $10.69 million in 2014 primarily due to increased stock-based compensation expenses related to options granted to directors, G&A personnel and consultants of $2.01 million.

Financial expenses for the year ended December 31, 2015 were $1.41 million, increasing from $0.07 million 2014. This increase was mainly due to the non-cash change in valuation of the warrant liability.

Financial income for the year ended December 31, 2015 was immaterial, decreasing from $0.59 million in 2014. This decrease was mainly due to the non-cash change in valuation of the warrant liability.

For the year ended December 31, 2015, the Company reported a loss of $37.99 million or $1.52 per share, compared with a loss of $18.43 million or $0.96 per share in 2014. The increase in net loss was largely due to increased spending to support corporate operations and expenses from acquiring pipeline assets including non-recurring R&D charges related to the acquisition of NFC-1 of $8.17 million. Included in the net loss of $37.99 million is $9.19 million of non-cash stock based compensation and non-cash warrant valuation expense of $1.37 million.

MEDGENICS, INC. AND ITS SUBSIDIARY

CONSOLIDATED BALANCE SHEETS
U.S dollars in thousands (except share and per share

data)

	December 31,	
	2014	2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 33,288	$ 53,064
Prepaid expenses and other current assets	315	747
Total current assets	33,603	53,811
LONG-TERM ASSETS:		
Restricted lease deposits	83	23
Severance pay fund	99	-
Property and equipment, net	495	424
Total long-term assets	677	447
Total assets	$ 34,280	$ 54,258
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,076	$ 1,322
Other accounts payable and accrued expenses	2,562	2,586
Total current liabilities	3,638	3,908
LONG-TERM LIABILITIES:		
Accrued severance pay	368	-
Liability in respect of warrants	612	-
Total long-term liabilities	980	-
Total liabilities	4,618	3,908
STOCKHOLDERS' EQUITY:		
Common stock-$0.0001 par value; 100,000,000 shares authorized; 32,869,217 shares issued and 32,860,717 shares outstanding at December 31, 2015; 24,851,075 shares issued and 24,818,075 shares outstanding at December 31, 2014	3	4
Additional paid-in capital	129,797	188,476
Accumulated deficit	(100,138)	(138,130)
Total stockholders' equity	29,662	50,350
Total liabilities and stockholders' equity	$ 34,280	$ 54,258

MEDGENICS, INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS
US Dollars in thousands (except share and per share data)

	Year ended December 31,		
	2013	**2014**	**2015**
Research and development expenses	$ 8,870	$ 10,490	$ 18,356
Less: Participation by the Office of the Chief Scientist	(1,573)	(2,237)	(2,912)
Research and development expenses, net	7,297	8,253	15,444
Non-recurring research and development expenses resulting from acquisition	-	-	8,170
General and administrative expenses	10,521	10,686	12,954
Operating loss	(17,818)	(18,939)	(36,568)
Financial expenses	(20)	(68)	(1,408)
Financial income	726	586	1
Loss before taxes on income	(17,112)	(18,421)	(37,975)
Taxes on income	17	12	17
Loss	$ (17,129)	$ (18,433)	$ (37,992)
Basic loss per share	$ (0.97)	$ (0.96)	$ (1.52)
Diluted loss per share	$ (1.06)	$ (1.00)	$ (1.55)
Weighted average number of common stock used in computing basic loss per share	17,629,436	19,246,611	25,015,130
Weighted average number of common stock used in computing diluted loss per share	17,683,510	19,294,259	25,077,777

Conference Call and Webcast

Medgenics will host a conference call and live audio webcast on Wednesday, February 17, 2016 at 8:30 a.m. ET to discuss fourth quarter and 2015 year end financial results.

In order to participate in the conference call, please dial (888) 337-8169 (domestic). The conference passcode is 3724050.

The live webcast can be accessed under "Events" in the Investors section of the Company's website at www.medgenics.com or you may use the link:

https://www.webcaster4.com/Webcast/Page/1395/13252

A replay of the call will be available after the end of the conference on February 17, 2016 through May 17, 2016. To access the replay, please dial (888) 203-1112 (domestic) or (719) 457-0820 (international) and reference the replay passcode 3724050.

The archived webcast will be available for 30 days in the Investor section of Medgenics' website at www.medgenics.com.

About the Noninterventional Phenotype/Genotype Study of mGluR Mutations in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD)

The primary objectives of the noninterventional phenotype/genotype study will be to contribute to the understanding of ADHD by assessing the frequency of rare, recurring copy number variants (CNVs) impacting specific metabotropic glutamate receptors (GRM) genes in a cohort of children 6-17 years of age with ADHD, as well as to estimate the prevalence of metabotropic glutamate receptor mutations of special interest within the population of children 6-17 years of age with ADHD. A secondary objective of the study will be to evaluate the phenotypic features of children 6-17 years of age with ADHD with and without CNV's impacting the mGluR network. During the consent process participants will be offered the opportunity to be contacted for future research studies. The study will look to enroll 1,000 patients across 25 centers in the U.S.

About Medgenics, Inc.

Medgenics is dedicated to unlocking the potential of genomic medicine to identify and treat patients with life-altering conditions. Its efforts, including its internal research and development and ongoing sponsored research and licensing agreements with a well-respected pediatric academic medical center, give Medgenics the ability to focus on the underlying genetic pathway of pediatric diseases with the goal of finding therapeutic solutions for subpopulations of both children and adults living with rare and other difficult-to-treat diseases. Medgenics is the developer of TARGT™ (Transduced Autologous Restorative Gene Therapy), a proprietary platform for the sustained production and delivery of therapeutic proteins, monoclonal antibodies and peptides in patients using *ex vivo* gene therapy and their own tissue for the treatment of rare and orphan diseases. For more information, visit the Company's website at www.medgenics.com.

Forward-looking Statements

This release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and as that term is

defined in the Private Securities Litigation Reform Act of 1995, which include all statements other than statements of historical fact, including (without limitation) those regarding the Company's financial position, its development and business strategy, its product candidates and the plans and objectives of management for future operations. The Company intends that such forward-looking statements be subject to the safe harbors created by such laws. Forward-looking statements are sometimes identified by their use of the terms and phrases such as "estimate," "project," "intend," "forecast," "anticipate," "plan," "planning, "expect," "believe," "will," "will likely," "should," "could," "would," "may" or the negative of such terms and other comparable terminology. All such forward-looking statements are based on current expectations and are subject to risks and uncertainties. Should any of these risks or uncertainties materialize, or should any of the Company's assumptions prove incorrect, actual results may differ materially from those included within these forward-looking statements. Accordingly, no undue reliance should be placed on these forward-looking statements, which speak only as of the date made. The Company expressly disclaims any obligation or undertaking to disseminate any updates or revisions to any forward-looking statements contained herein to reflect any change in the Company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based. As a result of these factors, the events described in the forward-looking statements contained in this release may not occur.

Contact:

CONTACT:

Medgenics
Brian Piper
240-899-5554
Email Contact

Westwicke Partners
Chris Brinzey
339-970-2843
Email Contact