

## Celek Pharmaceuticals, LLC

Graham Allaway, Ph.D.

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### Management:

CEO: *Graham Allaway, Ph.D.*

CBO: *Gary Robinson, Ph.D.*

Industry: *biopharmaceuticals*

Number of Employees: 2

Bank: *Chevy Chase Bank*

Financial Advisors: *Bethesda  
Financial Group; Romano & Mitchell*

Law Firm: *Edwards Angell Palmer  
& Dodge*

Amount of Financing Sought: *\$7M*

Current Investors:

*Personal Funds*

Use of Funds: *Completion of CEL-  
031 proof-of-concept Phase II study*

**Business Description:** Celek is developing targeted drugs to treat bladder diseases. CEL-031 is a Phase II clinical-stage product in development for the treatment of non-muscle invasive bladder cancer (NMIBC). CEL-021 is an innovative treatment for interstitial cystitis/painful bladder syndrome (IC/PBS).

**Company Background:** Celek was founded in 2009 by Drs. Graham Allaway and Gary Robinson. The Company has exclusive rights to the lead compounds in its pipeline.

### Management:

**Graham Allaway, Ph.D., President and CEO.** Dr. Allaway was founding CEO of Panacos Pharmaceuticals (MD) and he played a key role in building that company from a private venture-backed start-up to a public company. Prior to Panacos, Dr. Allaway was CEO of Manchester Biotech (UK) and he previously headed therapeutics R&D at Progenics Pharmaceuticals (NY).

**Gary Robinson, Ph.D., Chief Business Officer.** Dr. Robinson was Senior Director of Business Development at Panacos Pharmaceuticals (MD), where he directed partnering, contracting, intellectual property and pre-launch marketing activities. Prior to Panacos, Dr. Robinson held business and corporate development positions at IGEN (MD), a biomedical diagnostics company.

**Products/Services:** CEL-031 is a potent anticancer drug that has the potential to be the first targeted treatment for non-muscle invasive bladder cancer (NMIBC). Tumor recurrence and progression are common in this disease despite currently available treatments, and there is a strong demand for more effective therapies with fewer side-effects. CEL-031 is well-suited for the treatment of NMIBC since its molecular target is overexpressed in bladder tumor cells and the compound has an attractive clinical safety profile, having been tested in more than 250 people in Phase I and Phase II trials. Celek plans to initiate a proof-of-concept Phase II clinical study of CEL-031 in NMIBC within 18 months.

Celek is developing CEL-021 as an innovative treatment for interstitial cystitis/painful bladder syndrome (IC/PBS). Current therapies for IC/PBS are only marginally effective. CEL-021 specifically inhibits the activity of Antiproliferative Factor (APF), a peptide found selectively in the urine of IC/PBS patients that is believed to play a key role in the etiology of this disease.

**Technologies/Special Know-how:** Celek has obtained exclusive rights to a portfolio of oncology assets from OSI Pharmaceuticals, including CEL-031 (formerly OSI-461). The IND for the compound is open and several hundred kilograms of cGMP drug substance are available. Celek also has rights to patents relating to APF and its analogs, including CEL-021, from the University of Maryland School of Medicine, Baltimore (UMB).

**Markets:** Bladder cancer is the 5<sup>th</sup> most common cancer in the U.S., with 71,000 new diagnoses and 14,000 deaths in 2008 and an overall prevalence of 600,000 patients. 70% of cases are diagnosed at the NMIBC stage. The need for lifelong frequent monitoring and treatment makes the cost per patient of bladder cancer the highest of all malignancies. Celek estimates that peak annual sales revenues of CEL-031 would be in the range of \$400-800M.

There are estimated to be ~1M people suffering from IC/PBS in the U.S. alone, 90% of whom are women. Celek estimates that peak annual sales revenues of CEL-021 could exceed \$500M.

**Distribution Channels:** Celek intends to take its products through Phase II proof-of-concept studies in patients and then seek partners or acquirers who have late-stage development and commercialization capabilities.

**Competition:** Current intravesical treatments for NMIBC include the immunogen BCG and the cytotoxic chemotherapeutics mitomycin C and valrubicin. Two drugs are in clinical development for NMIBC: Eoquin (Spectrum Pharmaceuticals), a pro-drug of MMC, and Urocidin (Bioniche), a variant of BCG. Unlike CEL-031, none of these drugs specifically targets tumor cells.

Current IC/PBS treatments are relatively ineffective, e.g. Elmiron (Ortho-McNeil-Janssen). Drugs in development, including tanezumab (Pfizer) and URG-101 (Urigen), generally attempt to treat the pain associated with the condition but not the underlying causes.

### Financial Projections (Unaudited):

	2008	2009	2010	2011	2012
Revenue:	NA	0	50	50	300
EBIT:					
(dollars in thousands)	NA	(153)	(1,034)	(2,761)	(2,876)

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**Business Description:** Biomedica Management Corporation is a privately-held research and development company headquartered at the UMBC TechCenter in Baltimore, MD. The company was formed in 1999 under an innovative business model that explores and develops therapeutic agents in collaboration with academic scientists in three critical biotechnology areas: wound healing (ClotFoam) with civilian and military applications, sepsis (Glyco 23), and inflammation (Neutrolide), These new agents address serious unmet medical needs.

**Company Background:** The Company product development has been funded by the Defense Advanced Research Projects Agency (DARPA), The National Heart, Blood, and Lung Institute (NHLBI) of the National Institutes of Health (NIH); the National Institute of General Medical Sciences,(NIGMS) NIH; The National Institute of Allergy and Infectious Diseases,(NIAID) NIH; The National Institute Digestive Disease and Kidney, (NIDDK) NIH; the U.S. Army Medical Research Command; the Maryland Technology Development Corporation (TEDCO ), Johnson & Johnson, the State University of New York Downstate, and the University of Maryland.

**Management:** Our team is made of business managers and worldwide recognized researcher with expertise in the fields of fibrinogen chemistry and trauma surgery. The team includes Warren Pearlson, former Pfizer executive with solid expertise in program development and commercialization, and Dr. Stella Manne, former Director of Technology Transfer and Research Administration at New York Medical College; Dr. Leonid Medved, a pioneer in fibrin chemistry, and Dr. Grant Bochicchio from University of Maryland Trauma Center. The team is led by George Falus, a biophysicist, former Director of the Interamerican College of Physicians and Surgeons

**Products/LEADING PRODUCT**

ClotFoam® is a proprietary state-of-the-art 2<sup>nd</sup> generation fibrin sealant for use in non-compressible severe hemorrhage. The sealant has important applications in trauma, laparoscopic and cosmetic surgery, and wound healing. Supported by NIH and Department of Defense grants, Biomedica is developing highly promissory technologies to address unmet needs in two coveted markets: 1) Glyco 23 to control sepsis, and 2) Neutrolide to extend organ life and improve graft in transplantation.

**Technologies/Special Know-how:** Biomedica holds provisional patents applications #61/133,051; 61/132,998;61/132999; 61/133,000 and non-provisional patent application #12/419734 and 12/487057 which protects the substance of matter, the form of application, and the manufacturing process. All patents are assigned to Biomedica.

**Market:** Over 4.3 million procedures compatible with the use of ClotFoan at an average cost of \$400 each, are conducted in the US every year. Thus, the potential market value for new surgical sealants is estimated at \$ 1.7 billion, without including over-the-counter hemostatic adhesive bandages or liposuction procedures.

**Distribution Channels:** The company will pursue a royalty revenue model with pharmaceutical or device partners. The company envisions the manufacturing and distribution of a critical component of the technology (fibrin monomer).

**Competition:** The wound healing market is dominated by Johnson & Johnson and Baxter, with a market share of 70%. None of this companies has develop an hemostatic sealant to be used in trauma and minimally invasive surgery.

**Five-Year Financial Projection**

	2010	2011	2012	2013	2014	
<b>Revenue from Grants (\$'000)</b>	1,580	1000	1000			
<b>Licensee Sales (\$'000)</b>	--	---	---	100,000	250,000	40
<b>Licensee Down payment (\$'000)</b>			2000			
<b>Royalties (10%)(\$'000)</b>				10,000	25,000	40
<b>EBIDTA (\$'000)</b>	(1000)	(3000)	300	7000	23,000	35

Proceeds include grants, investments, milestone payments, and royalties from licensing calculated as 11% of sales

# Remedium Technologies, Inc.

387 Technology Dr., College Park, MD 20742

www.remEDIUMtechnologies.com



**Company Overview:** Remedium Technologies is wound care company which has developed a proprietary novel hemorrhage controlling platform technology called “Nano-Velcro.” Specifically, their products utilize a biocompatible, anti-microbial biopolymer modified with novel nano-“hooks” which are able to orchestrate the **rapid self-assembly of a clot-like seal** upon contact with blood. Unlike any competing technology, this mechanism of clot formation is **reversible on-demand**.

**Problem Addressed:** Each year 21 million patients experience uncontrolled hemorrhage (e.g. car accidents, gunshot wounds, shrapnel, etc.), resulting in 5 million deaths. Readily available materials which can be applied during the “Golden Hour” (i.e. the first 60 minutes after injury) are the key to saving lives. While many products are offered to serve this need, all unfortunately have one of two critical drawbacks. That is, they either (1) stick to the injury too weakly (i.e. low efficacy), or (2) stick so strongly that they are impossible to remove without re-bleeds or serious tissue damage. **On-demand hemostat removability is a critical unmet need** for trauma surgeons. Hemostats which stick too strongly make the necessary tasks of injury identification and wound debridement immensely difficult.

**Solution:** The bonding ability of each nano-“hook” is individually very weak. By functionalizing the biopolymer backbone with many nano-hooks, the biopolymer is transformed into a **Velcro<sup>®</sup> analogue for hemostatic applications**. That is, much like the micro-sized hooks of Velcro, a large number of nano-hooks is able to form a correspondingly large number of weak bonds with blood and soft tissue cells. The **summation** of these weak bonds results in a **strong adhesion** which is **easily removable on-demand** without harm to the patient. Our first product, the **Remedium Bandage**, employs Nano-Velcro to provide excellent first aid, and subsequently streamline the job of the trauma surgeon.

**Intellectual Property:** Remedium Technologies has the exclusive license to 3 utility patent applications from the University of Maryland, College Park which covers the technology described here. UMCP performed an FTO analysis which indicated no infringements.

**Competitive Advantage:** Remedium’s Nano-Velcro hemostatic technology offers a superior combination of clinically relevant qualities which no other product offers. Below is a chart comparing Nano-Velcro with the key competitors offering military-directed *low-cost solutions* in this space. Of these competing technologies, only Nano-Velcro has the efficacy to expand into civilian surgeries, a high-opportunity area dominated by high-cost products.

Company	Remedium Technologies	Z-Medica	Z-Medica	Traumacure	Hemcon	Marine Polymer Technologies
Technology	Nano-Velcro Modified Chitosan	Zeolite powder	Zeolite gauze	Mineral powder	Chitosan Bandage	Chitin Bandage
High Efficacy	✓	✓	✓	✓		
Safe	✓				✓	✓
Easily Removable	✓		✓		✓	✓
Antimicrobial	✓				✓	

**Target Market:** Our initial customer focus is Department of Defense, which has the biggest need for advanced hemostatic technologies and, as such, is willing to tolerate the risks associated with new hemostats. Success of our technology in the military setting will allow us to establish benchmark clients in the following civilian markets: (1) Shock/Trauma centers, (2) EMS (First Responders), (3) Surgical Centers, (4) State and Local Law Enforcement.

**Market Size:** The global wound care market is \$25B. Within the US, acute wound care management is \$4.7B in 2010 and is forecasted to grow to \$6.5B in 2015 due to larger populations, more surgeries, and new technologies. Within that \$4.7B market is as **\$1.2 B** market for hemostatic products sales; this segment is estimated to reach \$1.8B in 2015.

**Finances and Strategy:** We expect to capture 0.2%, 0.4%, and 1% of the hemostatic products segment during the 1<sup>st</sup> 3 years of revenue generation (2011-2013), respectively, via direct military sales (~\$50M segment) and product licensing into the civilian surgical sealant space (~\$800M segment). Launch of 2 follow-up products (1) sprayable foam and (2) flowable tissue sealant will increase market share to 5% by 2016.

## Management:

Dr. Matthew Dowling, *CEO*

Dr. Tosin Ogunsola, *COO*

Peter Thomas, *CTO*

**Industry:** Wound Care/Hemostatics

**Founded:** 2007, Delaware C-Corp

## Business Contacts:

### Primary

Matthew Dowling, PhD

Chief Executive Officer

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### Secondary

John Shin

Director, VentureAccelerator

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## Law Firms:

Cohen & Grigsby (Corporate)

Whiteford, Taylor & Preston (IP)

## Financial Information:

Pre-Revenue, Pre-Venture Capital

Current Support :

\$125K TEDCO Funding

\$104K MILPS Funding

Seeking :

\$2M equity

## Use of Funds:

Product Development (\$1.5M)

IP Portfolio Development (\$0.3M)

Regulatory Advising (\$0.2M)

Applied Sciences, LLC  
 Wayne E. Moore, Ph. D.  
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# Very Early Melanoma Detection

Fax: 410-740-2115

Email: [w\\_e\\_moore@comcast.net](mailto:w_e_moore@comcast.net)

**Management:**

CEO – Wayne E. Moore  
 EVP Marketing – TBA\*  
 CSO – Wayne E. Moore  
 CTO – TBA\*

\*Names must be withheld.

**Industry:** Medical Devices

**Number of Employees:** 1

**Bank:** Sandy Spring Bank

**Auditor:** Clifton Gunderson, LLP

**Law Firms:** Terry, Antonelli and Stout,  
 The Dobe Law Group, Richard  
 Scheibstein, LLC, and William S.  
 Ramsey, Esq.

**Amount of Financing Sought:**

\$355K – Angel Start-Equity  
 Total 3-year \$5.2MM – Equity

**Current Investors:** None

**Use of Funds:** Product Development,  
 Device Materials, Facilities and  
 Operations, Clinical Trials, Professional  
 Services, Administration, Marketing.

**Business Description:** NanoFluor, LLC, dba **Applied Sciences**, is a Maryland LLC created in 2002 to license, develop and commercialize technology. It has an option to license a patent application for a melanoma detection method studied at a prominent eastern medical university and discussed in this summary.

**Company Background:** Nanofluor, LLC was created by Dr. Wayne Moore as a licensing company while he was CEO of Microcosm, Inc. Moore founded Microcosm in 1994. Microcosm operated until 2009 developing custom imaging systems for DoD. While developing over 30 unique imaging devices, Microcosm received several SBIRs for biological imaging systems and detection devices. **Applied Sciences** was registered in 2010.

**Management:** Dr. Moore is presently the sole member of **Applied Sciences**. In the past 20 years he has led three successful optical engineering and technology start-up companies. He has a broad scientific background in development of imaging devices in addition to his many years of business leadership and entrepreneurial experience. Key senior executives are being enrolled now.

**Products/Services:** Melanoma kills one American every hour. Showcased here is non-invasive thermal imaging system that measures the heat generated by melanoma lesions. This invention has shown its ability to identify and differentiate very early-stage melanoma (Clark Level 0-1) from healthy pigmented tissue.

Without this device doctors are not able to accurately diagnose melanoma. 15% of

the deadly lesions are missed. This device solves that problem with what appears to be low development risk and no risk to the patient. The device should clear FDA as a 510-K, depending on claims made by the Company.

**Technologies/Special Know-how:** The device relies on the comparison of heat generated by a cancerous lesion (mole) to the heat generated by healthy surrounding tissue. A conventional, hand-held thermal camera is used. Software analyzes the images and creates quantitative measures that identify the melanoma and its state of development. There is no comparable device available.

**Market:** In the U.S. there are about 80,000 medical doctors of whom about 10,000 are dermatologists. High-volume dermatology clinics are the primary target. Primary care physicians also will use the device for skin cancer screening as part of every routine physical exam. The incidence of melanoma is rapidly increasing 5 to 7% per year, and the patients themselves are important drivers of this market. We will sell the device as a point-of-care scanner with a small charge for each scan. Doctor and Company will share the revenue from the usage fee. This model promises recurring revenue reaching \$1B/year within 5 years of sales.

**Distribution Channels:** The device will be sold directly with an internal and external sales force. We may partner with other companies who have established access to the market. That is also one possible exit strategy.

**Competition:** Two public companies are working toward competitive devices. Publicly traded “Melafind” uses a spectral imaging technology to detect melanoma. FDA has delayed approval. It should be available within a year. T-Ray Inc. of Canada claims to be developing a TeraHertz technology with entry date unknown. We believe we can show that the device offered here is superior in cost and performance to either known potential competitor. The fact that others are able to attract public investors adds credibility to the market size we foresee.

**Financial Projections (Un-audited):**

We assume funding begins in 2011. Development will take 2.5 to 3 years. Negative EBIT (red) is the *cumulative* investment required. The company breaks even in the first year of sales. Revenues accelerate rapidly due to the recurring revenue generated as the number of devices in use increases each year, approaching \$50 MM in the second year with only 385 devices in service. Each device easily generates over \$30K per month. By Year-5 of sales, not shown below, recurring revenue can exceed \$1B/year.

	2011	2012	2013	2014	2015
<b>Revenue:</b>	0	0	0	\$19,347	\$105,726
<b>EBIT: (\$ in Thousands)</b>	(\$773)	(\$2,607)	(\$5,220)	\$884	\$48,200

## Cognapse, LLC

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Web Address: [www.cognapse.com](http://www.cognapse.com) (under development)

### Management:

**President:** E. Harrison Stone, Jr., Esq.

**Chief Commercialization Officer:**

Jonathan Cabral

**Chief Science Officer/Founder:** Majid

Fotuhi, MD, PhD

**Industry:** Nutraceuticals for the Brain

**Number of Employees:** 3

**Bank:** Wachovia

**Auditor:** Watkins, Meegan

**Law Firm:** Holland & Knight

**Amount of Financing Sought:**

\$2M Equity

**Current Investors:** N/A

**Use of Funds:** Commercialization of Remviva – Manufacturing, Sales, Marketing

**Business Description:** Cognapse believes it can become the market leader for nutraceuticals of the brain with its lead product Remviva. It will compete in the \$400M brain nutraceuticals market (10-15% CAGR), a segment of the overall \$3.5B brain health market inclusive of Rx products. Remviva is the first and only product to not only be formulated by a neurologist, but also to have compelling long-term published (Journal of Alzheimer's & Dementia, 2008) clinical data demonstrating the maintenance of cognitive function for those at risk for Alzheimer's.

**Company Background:** Cognapse, LLC is a Baltimore based healthcare start-up focused on nutraceuticals for the brain.

### Management:

- **Majid Fotuhi, MD, PhD, (Mfotuhi@cognapse.com)** Neurologist, Trained at Harvard Medical School, and Johns Hopkins University Medical School. He is widely published and considered a Key Opinion Leader in the field of Alzheimer's and other diseases of the brain as it ages.
- **Harrison Stone, Esq., (hstone@cognapse.com)** brings extensive start-up experience and leadership, with a focus on fundraising, operations and organizational effectiveness.
- **Jonathan Cabral, MBA, (Jcabral@cognapse.com)** has 20 years of executive experience in the healthcare sector, specializing in start-ups and launching game changing technologies.

**Products/Services:** Remviva is a once-a-day softgel pill formulated by a patented, proprietary combination of Vitamin C, E, Curcumin, Omega-3(DHA) and Bioperine. Remviva is the only formulation based on a published multi-year clinical study involving several thousand patients

**Technologies/Special Know-how:** Remviva is patent protected under "Dosage regimen and medicament for guarding memory and brain health and for preventing or reducing risk of onset of dementia by administration of specific vitamins and supplements". The priority Filing Date is January 28, 2008 and the patent is still in the preliminary phase. Hunton & Williams LLP serves as patent counsel.

**Market:** The target market is Baby Boomers (79MM in U.S., Born 1948-1964) and the elderly in the United States who suffer from diseases and disorders of the brain, or who are at risk of developing an issue predicated upon genetic predisposition. Specifically, those individuals in this demographic who are proactive in managing their health issues already and either have a brain health issue or are at risk for one. Women are more proactive than men and there is a strong correlation with education (more) and income levels (higher). This is a highly targeted, highly segmented direct-to-consumer model. REMVIVA pills will sell for \$39.99 (COGS \$9.99) for a one month supply and wholesale for \$19.99.

**Distribution Channels:** At launch, Cognapse will focus on retail sales generated by a multi-media marketing campaign that generates sales through our website and calls to our customer service team. Once established, Cognapse plans to wholesale product to the larger retail pharmacy chains.

**Competition:** Memory Essentials, Mind Power, Focus Factor, Cognitive, Cognizin. Existing competitors lack the supportive clinical data and the support of highly respected, well known neurologist.

### Financial Projections (Unaudited):

Remviva	2010	2011	2012	2013	2014	2015	2106	2107
Total Revenue	\$50,000	\$4,200,000	\$11,600,000	\$19,600,000	\$30,200,000	\$42,400,000	\$56,200,000	\$71,600,000
EBITDA	-\$111,850	\$737,600	\$3,784,800	\$6,308,800	\$9,965,600	\$14,627,200	\$19,293,600	\$24,964,800
EBITDA %	-936.40%	23.02%	42.76%	42.19%	43.25%	45.21%	44.99%	45.70%