



CS DIAGNOSTICS

**CS DIAGNOSTIC CORP f/k/a
FLASHZERO CORP**

SUPPLEMENTAL FILING

NOVEMBER 27, 2023



CS DIAGNOSTICS

Supplemental Filing Disclosure

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CS DIAGNOSTICS CORP COMPLETES ACQUISITION OF THE CS PROTECT-HYDROGEL

On September 4, 2023, CS Diagnostics Corp purchased 100% of the tangible product CS Protect-Hydrogel, its intellectual property, distribution rights and patents from the CS Diagnostics Group, headquartered in Germany. The CS Protect-Hydrogel is a hydrogel-based tissue spacer. It is used in radiation therapy to increase the distance between cancer cells and healthy tissue and thus protect healthy tissue from damage caused by high doses of radiation. Currently, hydrogel spacers are used exclusively in the treatment of prostate cancer. Here, the spacer pushes the rectum away from the prostate, thus reducing rectal damage from radiation therapy. The hydrogel spacer is injected once in liquid form through a thin needle into the space between cancer cells and healthy tissue and is broken down by the body after about six months. The CS Protect-Hydrogel is a "ready-to-use" product, which is sterile packed and can be applied directly. The hydrogel can be used in radiotherapy for **prostate, cervical, esophageal, bladder and breast cancer**.

On September 4, 2023, Tom Wrangmore, https://www.wrangmore.de/index_ger.html, a German public auditor and valuation firm, provided a certified valuation for the CS Diagnostics Hydrogel product. Mr. Wrangmore certified that: "The value of the CS Diagnostics Group's right to use CS Protect-Hydrogel is mainly dependent on the market penetration and the market share achieved as well as the achievable sales prices. In the most likely scenario of a market share of 50 % and sales prices of EUR/unit 1,100 (EUR (27)) and EUR/unit 1,900 (USA), the economic benefit as the net present value of future cash surpluses as of September 30, 2023, is EUR 961 million." See Exhibit A

On September 27, 2023, CS Diagnostics Corp, acquired 100% of the CS Protect-Hydrogel for a cost basis of Five Hundred Million USD in the form of 110,000,000 shares of CS Diagnostics Corp Common Stock. On November, 2023, CS Diagnostics Corp. filed its 3rd Quarter Report and Financial Statements with the consent of our PCAOB Auditors which represent the purchase of the CS Protect-Hydrogel. The issuer is requesting OTC Markets recognize the Issuer is no longer a shell and certainly not to be construed as a "Shell Risk". The issuer is now working with its partners to apply for approval of CS Protect Hydrogel with the relevant national regulatory authorities in Europe, North and South America.

Issuer Certification

Principal Executive Officer:

The issuer shall include certifications by the chief executive officer and chief financial officer of the issuer (or any other persons with different titles but having the same responsibilities).

The certifications shall follow the format below:

I, Thomas Fahrhoefer, certify that:

1. I have reviewed this Supplemental Filing Disclosure dated November 27, 2023 of CS Diagnostic Corp;
2. Based on my knowledge, this disclosure statement does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this disclosure statement; and
3. Based on my knowledge, the financial statements, and other financial information included or incorporated by reference in this disclosure statement, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this disclosure statement.

November 27, 2023

/s/ Thomas Fahrhoefer

Principal Financial Officer:

I, Thomas J Migotsch, certify that:

1. I have reviewed this Supplemental Filing Disclosure dated November 27, 2023 of CS Diagnostic Corp;
2. Based on my knowledge, this disclosure statement does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this disclosure statement; and
3. Based on my knowledge, the financial statements, and other financial information included or incorporated by reference in this disclosure statement, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this disclosure statement.

November 27, 2023

/s/ Thomas J Migotsch



Tom Wrankmore

Wirtschaftsprüfer

Tom Wrankmore, Ahornstraße 10, 06246 Bad Lauchstädt

CS Diagnostics Pharma GmbH
Mr. Thomas Fahrhöfer
Müller-zu-Bruck-Straße 12
83052 Bruckmühl

Date
2023-9-4

Dear Mr. Fahrhöfer,

You have asked me to evaluate the process for the production of CS Protect-Hydrogel on the basis of the future economic benefits to be achieved for the CS Diagnostics Group as of September 30, 2023. I would like to comment on this as follows:

Description and identification of the intangible asset

The CS Protect-Hydrogel is a hydrogel-based tissue spacer. It is used in radiation therapy to increase the distance between cancer cells and healthy tissue and thus protect healthy tissue from damage caused by high doses of radiation.

Currently, hydrogel spacers are used exclusively in the treatment of prostate cancer. Here, the spacer pushes the rectum away from the prostate, thus reducing rectal damage from radiation therapy.

The hydrogel spacer is injected once in liquid form through a thin needle into the space between cancer cells and healthy tissue and is broken down by the body after about six months.

The CS Protect-Hydrogel is a "ready-to-use" product, which is sterile packed and can be applied directly. The hydrogel can be used in radiotherapy for prostate, cervical, esophageal, bladder and breast cancer.

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The CS Hydrogel was developed by CS Diagnostics Pharma GmbH and CS Interpharm LLC, both companies of the CS Diagnostics Group, in cooperation with the Rheinisch-Westfälische Technische Hochschule Aachen and the DWI - Leibniz-Institut für Interaktive Materialien e.V. The patent application was filed with the German Patent and Trademark Office in 2023. The applicant for the patent is the DWI - Leibniz Institute for Interactive Materials e.V., which has granted CS Diagnostics Pharma GmbH an exclusive right to use the invention.

Competitive environment

Competitor products

In terms of tissue spacers, hydrogel-based as well as hyaluronic acid-based spacers are used in cancer treatment. However, hyaluronic acid spacers are niche products with a small market share.

In the case of hydrogel spacers, a competitor product from Boston Scientific Corporation is currently available on the market. The competitor product SpaceOAR Hydrogel System was developed in 2010 by Augmentix, Inc. The shares in Augmentix, Inc. were fully acquired by Boston Scientific Corporation in 2018 for a fixed purchase price of USD 500 million plus a variable purchase price component of USD 100 million upon achievement of certain sales targets. The competitor product has been further developed, is currently marketed under the SpaceOAR Vue Hydrogel trademark, and is approved exclusively for use in prostate radiation. The product marketed by Boston Scientific Corporation consists of three components that are mixed in a predetermined sequence and drawn into a syringe by a trained and skilled person.

The molecule of the CS Protect-Hydrogel differs significantly from the molecule of the competitor product. According to research by the Rheinisch-Westfälische Technische Hochschule Aachen or the DWI - Leibniz Institute for Interactive Materials e.V. and the CS Diagnostics Group, patent infringements are not to be expected.

Unique selling proposition (USP)

The CS Protect-Hydrogel is a more advanced hydrogel both from the molecular structure, chemical physical properties and medical applications. Compared to the competitor product of Boston Scientific Corporation, CS Protect-Hydrogel has the following practical, hygienic, medical and economic advantages:

Practical advantages:

- easy application of the CS Protect-Hydrogel since it is a "ready-to-use" product
- avoidance of a further work step

Hygienic advantages:

- immediate application of the CS Protect-Hydrogel after removal from sterile packaging
- no risk of contamination due to preparation and assembly of the product
- exclusion of another hygienic risk area within the treatment room

Medical advantages:

- no risk of wrong mixture (especially wrong sequence) and therefore no potential patient's missed appointment
- extended application range - besides prostate cancer also for cervical, esophageal, bladder and breast cancer
- hypofractionation possible - significantly fewer treatment sessions per patient
- dose escalation possible - acceleration of radiation therapy

Economic advantages:

- lower personnel costs during treatment due to the elimination of assistance for mixing the hydrogel
- lower room utilization costs per patient as there is no longer a risk of patients having to be treated again due to incorrect mixtures (higher number of patients per treatment room)
- lower cleaning costs due to the ready-to-use principle
- fewer lawsuits and/or insurance claims due to incorrectly mixed hydrogels requiring the patient to be treated again
- lower purchase price for the clinics than for the competitor product

Market entry barriers

The CS Protect-Hydrogel is a medical device and requires registration or approval by the respective governmental authorities, in particular the Food and Drug Administration (FDA) in the USA or the Federal Institute for Drugs and Medical Devices (BfArM) after CE testing and certification in Germany. Registration or approval is preceded by a testing procedure. The CS Diagnostics Group anticipates a period of 6 to 12 months for approval in the U.S. and 6 to 8 months for the testing procedure and registration of the CS Protect-Hydrogel in Germany.

Since a competitor product is already available on the market and is used worldwide for prostate irradiation, CS Protect-Hydrogel does not need to be re-explained or advertised for use in prostate irradiation. Extensive information and advertising is required for the treatment of other types of cancer.

The CS Protect-Hydrogel is a further developed substitute product for the competing product of Boston Scientific Corporation on the market. Due to the easier handling, the lower medical risks and cost risks, and the expanded scope of application, the CS Diagnostics Group expects that the respective purchasing departments of clinics (including specialty clinics) and hospitals will quickly adopt and list the CS Protect-Hydrogel in their portfolios.

Valuation of future economic benefits

Total market and market share

Hydrogel spacers are used in radiotherapy for prostate, esophageal, bladder, breast and cervical cancer. The use of hydrogel spacers is contraindicated in approximately 10 % of irradiated patients. For the major markets in the USA and the European Union, the potential use is as follows:

	new cases per year		thereof irradiation in %	thereof contra- indicated patients	application potential hydrogel patients
European Union¹⁾					209,897
Prostate Cancer	335,514	25.0	83,879	8,388	75,491
Breast Cancer	355,457	40.0	142,183	14,218	127,965
Bladder Cancer	157,484	3.0	4,725	473	4,252
Cervical cancer	30,447	5.0	1,522	152	1,370
Esophageal Cancer	30,327	3.0	910	91	819
USA²⁾					175,503
Prostate Cancer	288,300	25.0	72,075	7,208	64,867
Breast Cancer	297,790	40.0	119,116	11,912	107,204
Bladder Cancer	82,290	3.0	2,469	247	2,222
Cervical cancer	13,960	5.0	698	70	628
Esophageal Cancer	21,560	3.0	647	65	582
Total					385,400

¹⁾ Data source: International Agency for Research on Cancer (Data basis: 2020); <https://gco.iarc.fr/>

²⁾ Data source: American Cancer Society (Data basis: 2023); <https://www.cancer.org/>

With one application per patient, the annual sales potential of hydrogel spacers in the European Union and the USA is 385,400 units.

In addition to the CS Protect-Hydrogel, one competitor product is used worldwide. The CS Diagnostics Group believes that a market share of approximately 50 % can be achieved for the CS Protect- Hydrogel in the medium term due to its simpler handling, lower medical risks and cost risks, and expanded scope of application.

Prices and recoverable amounts

The competitor product of CS Protect-Hydrogel is currently offered for sale to clinics and hospitals at market prices ranging from EUR 1,100 to EUR 1,900, with prices of around USD 2,000 in the USA and between EUR 1,100 and EUR 1,800 in the European Union.

The CS Diagnostics Group will position the CS Protect-Hydrogel as a "ready-to-use" product below these prices. The Group is expected to call selling prices between EUR 1,100 to EUR 1,300 per unit in the European Union and USD 2,000 (i.e. approx. EUR 1,900) per unit in the USA.

With an expected market share of around 50 %, annual revenues of EUR 282 million to EUR 303 million would thus be achievable.

Future economic benefits

The future economic benefits from the CS Protect-Hydrogel for the CS Diagnostics Group results from the proceeds from the sale less the manufacturing costs of the hydrogel and the variable distribution costs.

In preliminary discussions of the CS Diagnostics Group with potential manufacturers of the hydrogel, manufacturing prices between EUR/unit 150 (European Union) to 180 (USA) have been promised. As variable distribution costs, the CS Diagnostics Group expects 25% of sales revenues.

The CS Diagnostics Group assumes a product life cycle of approximately 10 years from market launch. Market launch is expected after approval or registration of the product in 2025. A compound annual growth rate (CAGR) of 4.9 % p.a. is assumed for the overall market.

Overall, this results in the following assumptions for assessing the economic benefits of the CS hydrogel:

		EU (27)	USA
Selling price	EUR/unit	1,100	1,900
Production price	EUR/unit	150	180
Distribution costs	%	25.0	25.0
Compound annual growth rate (CAGR)	% p.a.	4.9	4.9

According to the planning of the CS Diagnostics Group, the target values for the market share of approx. 50 % will be achieved as follows:

	Target value Share of total market (in %)				
year	Prostate Cancer	Breast Cancer	Bladder Cancer	Cervical cancer	Esophageal Cancer
2025	10	5	5	5	5
2026	20	10	10	10	10
2027	30	20	20	20	20
2028	40	30	30	30	30
2029	50	40	40	40	40
2030	50	50	50	50	50
2031	50	50	50	50	50
2032	50	50	50	50	50
2033	50	50	50	50	50
2034	50	50	50	50	50

Taking these assumptions into account, the following future cash flows and their present values as of September 30, 2023 (risk- and maturity-equivalent interest rate of 10 % p.a.) result from the CS Protect-Hydrogel:

year	Profit margin /			
	Sales mio. EUR	Expenses mio. EUR	Cashflow mio. EUR	Net present value mio. EUR
2025	42	15	27	23
2026	89	32	57	44
2027	162	58	103	72
2028	241	87	154	98
2029	328	119	210	121
2030	394	143	252	132
2031	414	150	264	126
2032	434	157	277	120
2033	455	165	291	115
2034	478	173	305	109
Totals	3,038	1,099	1,939	961

The sum of the present values and thus the future economic benefit over the expected product life cycle is therefore **EUR 961 million**.

Sensitivity analysis

The future economic benefit of the CS Protect-Hydrogel is mainly dependent on market penetration and the achievement of market share as well as the achievable selling prices per unit. Changes in these assumptions result in the following present values of the future cash flows from CS Protect-Hydrogel for the sales markets of the European Union and the USA:

		market share					
		(%):	20	30	40	50	60
selling price (per unit):							
EU (27)							
950		126	189	252	315	378	
1,000		134	201	268	336	403	
1,050		143	214	285	357	428	
1,100		151	227	302	378	453	
1,150		159	239	319	399	478	
USA							
1,750		212	318	424	530	637	
1,800		219	329	438	548	658	
1,850		226	339	452	566	679	
1,900		233	350	466	583	700	
1,950		240	360	481	601	721	
Totals							
950/1,750		338	507	676	845	1,014	
1,000/1,800		353	530	707	884	1,060	
1,050/1,850		369	553	738	922	1,107	
1,100/1,900		384	576	769	961	1,153	
1,150/1,950		400	600	799	999	1,199	

Valuation of the intangible asset

The value of the CS Diagnostics Group's right to use CS Protect-Hydrogel is mainly dependent on the market penetration and the market share achieved as well as the achievable sales prices. In the most likely scenario of a market share of 50 % and sales prices of EUR/unit 1,100 (EUR (27)) and EUR/unit 1,900 (USA), the economic benefit as the net present value of future cash surpluses as of September 30, 2023 is **EUR 961 million**.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Tom Wrankmore'.

Tom Wrankmore

Wirtschaftsprüfer

[certified public auditor]