# **IPO ANALYSIS**

Research on upcoming IPOs for selected candidate companies.

Gossamer Bio

Cirius Therapeutics

Brainsway

February 2019

VentureDeal

### Gossamer Bio Files Proposed Terms For \$230 Million IPO

#### **Quick Take**

Gossamer Bio (GOSS) intends to raise \$230 million in an IPO of its common stock, according to an S-1/A registration statement.

The firm is advancing a pipeline of treatment candidates for inflammatory, immunological and oncology-related diseases.

### **Company & Technology**

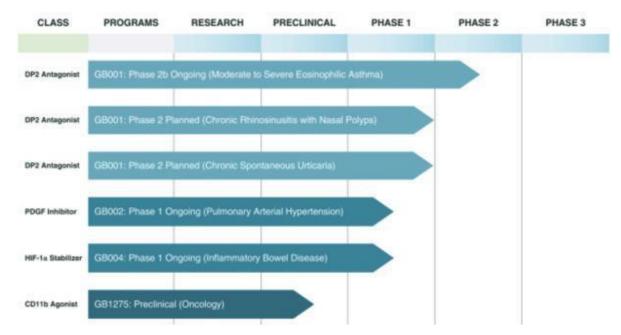
San Diego, California-based Gossamer Bio was founded in 2015 and commenced operations in 2017 to discover, develop, and manufacture therapeutics for various immunological, inflammatory and oncological diseases.

Management is headed by Co-Founder, Director, and CEO <u>Sheila Gujrathi</u>, who was previously Director at Ambrx.

The company's lead drug candidate GB001 is an 'oral antagonist of prostaglandin D2 receptor 2 in development for the treatment of moderate-to-severe eosinophilic asthma and other allergic conditions.'

Gossamer Bio has initiated Phase 2b clinical trial in October 2018 for GB001 for the treatment of moderate to severe eosinophilic asthma.

The company believes that GB001 can also prove to be a viable treatment for Chronic Rhinosinusitis With Nasal Polyps and Chronic Spontaneous Urticaria, with proof-of-concept Phase 2 clinical trials planned for 2019.



Source: S-1/A statement

Investors in Gossamer Bio included ARCH Venture Partners, Abu Dhabi Investment Authority, Invus, Omega Funds, The Baupost Group, Hillhouse Capital Group, and Polaris Partners. Source: <a href="Crunchbase"><u>Crunchbase</u></a>

### **Market & Competition**

According to a <u>2016 market research report</u> by Grand View Research, the global asthma therapeutics market is projected to reach \$25.6 billion by 2024.

The main factors driving market growth are the growing prevalence of asthma and the adoption of new medical technologies.

According to another <u>market research report</u> by Persistence Market Research, the North American region is projected to account for the largest share of the Eosinophilic Asthma Therapeutics market.

The Latin America and Asia-Pacific regions are projected to grow at the fastest rate between 2017 and 2027.

Major competitors that provide or are developing Eosinophilic Asthma therapeutics include:

- Regeneron Pharmaceuticals (REGN)
- Johnson & Johnson (JNJ)
- Novartis (NVS)
- Roche (OTCQX:RHHBY)
- Pfizer (PFE)
- Chiesi Farmaceutici S.p.A.
- Merck & Co. (MRK)
- Sunshine Lake Pharma
- Sanofi (SNY)

Source: Sentieo, S-1/A

#### **Financial Performance**

GOSS's recent financial results are typical of a development stage biopharma in that they feature no revenues and significant R&D and G&A expenses associated with pursuing regulatory approval for its pipeline of treatment candidates.

The company's financial results for the past two and \(^3\)4 years (Audited PCAOB for full years):

	Year Ended December 31,			Nine Months Ended September 30,				
	<u> </u>	2016		2017	\$8.5	2017		2018
			(in the	neands exeent	chare as	(una d per share data	ndited)	
Consolidated Statements of Operations Data:			Cin two	usanus, except	snare at	na per suare mara		
Operating expenses:								
Research and development	S	200	S	891	S	216	S	29,411
In process research and development		-		5,500		-		49,659
General and administrative		83		262	_	105		30,116
Total operating expenses	100	83	8	6,653	92	321		109,186
Loss from operations		(83)		(6,653)		(321)		(109,186)
Other income (expense):								
Interest income				-		-		1,022
Interest expense				(118)		-		(8)
Other Income		-		72.0	-			(3)
Total other income (expense)				(118)	-	_		1,011
Net loss	S	(83)	S	(6,771)	S	(321)	S	(108,175)
Net loss per share, basic and diluted(1)	S	(0.00)	S	(0.16)	S	(0.01)	S	(3.92)

Source: S-1/A

As of September 30, 2018, the company had \$256.4 million in cash and marketable securities and \$15.6 million in total liabilities. (Unaudited, interim)

#### **IPO Details**

GOSS intends to raise \$230.0 million in gross proceeds from an IPO of its common stock, not including customary underwriter options.

Per the firm's latest filing, it plans to use the net proceeds from the IPO as follows:

- approximately \$70.0 million to fund the research and development of GB001
- approximately \$40.0 million to fund the research and development of GB002
- approximately \$35.0 million to fund the research and development of GB004
- approximately \$40.0 million to fund research and development of our other development programs; and
- the remainder for working capital and general corporate purposes.

Management's presentation of the company roadshow isn't currently available.

Listed underwriters of the IPO are BofA Merrill Lynch, SVB Leerink, Barclays, and Evercore ISI.

### Commentary

Gossamer is braving a moribund IPO market so far in 2019.

However, management is pushing off the expected pricing date at least 20 days from the latest filing in order to follow the Rule 473[b] that requires at least 20 days time to elapse in the event the SEC is unable to review the filing due to its shutdown.

Management also stated that if the SEC reopens for S-1 review before the end of the 20-day time period, it will 'reevaluate the use' of the 20-day rule.

The trial status for its lead candidate, GB001, is somewhat mixed. In one Phase 2 trial, the results showed 'statistically significant improvement in time-to-first asthma exacerbation compared to placebo.'

But, in another Phase 2 trial, GB001 did not meet its primary endpoint, although management believes it can improve the study design and do a better job at patient selection.

The market opportunity for its lead candidate is large, however, it features several large and well-funded pharma firms developing or providing treatments.

Gossamer has no disclosed commercial collaborations, which increases the risk associated with its programs.

BofA Merrill Lynch is the lead left underwriter for the IPO. IPOs led by the firm over the last 12-month period have generated an average return of 7.2% since their IPO. This is a mid-tier performance for all major underwriters during the period.

As to valuation, management is asking investors to purchase IPO stock at an enterprise value of approximately \$710 million.

With only one candidate in Phase 2 trials and one of those trials having failed, the company is still in a very early and high-risk stage.

Additionally, the IPO appears quite pricey, especially in relation to the larger biopharma IPO group's performance over the past six months.

**Expected IPO Pricing Date:** February 13, 2019.

## Cirius Therapeutics Files For \$86 Million U.S. IPO

### **Quick Take**

Cirius Therapeutics (<u>CSTX</u>) intends to raise gross proceeds of \$86.25 million from a U.S. IPO, according to an <u>S-1 registration statement</u>.

The firm provides is developing small-molecule treatments for nonalcoholic steatohepatitis [NASH] with fibrosis.

CSTX has seen promising results in Phase 2b trials for its drug candidate.

When we learn more details about management's assumptions on the IPO's pricing and valuation, I'll provide an update.

### **Company & Technology**

San Diego, California-based Cirius Therapeutics was founded in 2015 to develop small molecule pharmaceuticals for the treatment of NASH while addressing the commonly associated negative side effects observed with other types of thiazolidinediones [TZDs].

Management is headed by CEO <u>Robert Baltera</u>, who has been with the firm since 2017 and previously co-founded Hawkeye Therapeutics.

NASH is most often caused by overnutrition. An excess amount of pyruvate (energy source for cells) gets transported into the mitochondria of cells at a fast rate through the mitochondrial pyruvate carrier [MPC] leading to the alteration of multiple downstream pathways, including transcription factors. The effects of these alterations include increased fat storage, insulin resistance, inflammation, cell damage, decreased fat oxidation, and fibrosis.

The company's lead drug candidate is MSDC-0602K, a 'second generation TZD' designed to selectively bind to the MPC and adjust the entry of pyruvate into the cell's mitochondria. Cirius believes that by intervening upstream, its lead drug candidate can treat the core pathologies of both NASH and Type 2 Diabetes.

The firm is currently conducting a Phase 2b clinical trial of MSDC-0602K at 62.5mg, 125mg, and 250mg once daily. In Oct. 2018, the company performed an 'interim analysis of the first 328 subjects reaching their six-month follow-up visit.'

Patients in the 125mg dose group had statistically significant placebo-corrected reductions in ALT and AST - markers for liver health. Moreover, more than 50% of subjects in the two higher dose groups with elevated baseline ALT or AST had improved to normal range. Similar rates of emergent adverse events were observed across placebo and all MSDC-0602K dose cohorts.

Investors in Cirius Therapeutics include Novo Holdings, Frazier Healthcare Partners, Hopen Life Science Ventures, Renaissance Venture Capital Fund, and Adams Stream Partners. Source: <a href="Crunchbase">Crunchbase</a>

### **Market & Competition**

According to a 2018 market research report by Allied Market Research, the global NASH market was valued at \$1.18 billion in 2017 and is projected to reach \$21.48 billion by 2025, growing at a CAGR of 58.4% between 2021 and 2025.

The main factors driving market growth are increased demand for more effective NASH therapeutics with fewer side-effects, the growing prevalence of NASH, and the expected launch of pipeline drugs.

The Asia-Pacific region will grow at the highest CAGR of 62.6% during the forecast period.

Major competitors that provide or are developing treatments include:

- Tobira Therapeutics (ANG)
- Cadila Healthcare (CADILAHC.NS)
- Conatus Pharmaceuticals (CNAT)
- Galmed Pharmaceuticals (GLMD)
- Gemphire Therapeutics (GEMP)
- Genfit (OTCPK:GNFTF)
- Gilead Sciences (GILD)
- Intercept Pharmaceuticals (ICPT)

The company believes that by targeting intervening upstream, its lead drug candidate can treat the core pathologies of both NASH and Type 2 Diabetes.

### **Financial Status**

CSTX' recent financial results are typical of a clinical-stage biopharma in that they feature no revenues and significant R&D and G&A expenses associated with its trial efforts.

Below are the company's financial results for the past two and ¾ years (Audited PCAOB for full years):

	Years Enc	Years Ended December 31,		Nine Months Ended September 30,	
	2016	2017	2017	2018	
		(in thousands, except sh	are/unit and per share/unit	data)	
Statement of Operations Data:					
Operating expenses:					
Research and development	S 4,227	S 16,351	S 10,623	S 14,146	
General and administrative	501	1,946	1,339	2,209	
Total operating expenses	4,728	18,297	11,962	16,355	
Loss from operations	(4,728)	(18,297)	(11,962)	(16,355	
Other income (expense):					
Interest income	40	225	162	110	
Interest expense	_	_	_	(6)	
Change in fair value of warrant liability				(5:	
Total other income (expense)	40	225	162	(4	
Net loss and comprehensive loss	(4,688)	(18,072)	(11,800)	(16,359	
Cumulative preferred return on preferred units	(863)	(303)	(303)		
Net loss attributable to common stock/units(1)	S (5,551)	S (18,375)	S (12,103)	S (16,359	
Net loss per share/unit, basic and diluted(1)	S (0.30)	S (1.00)	S (0.66)	S (0.8	

Source: Company registration statement

As of September 30, 2018, the company had \$22.3 million in cash and \$4.1 million in total liabilities. (Unaudited, interim)

### **IPO Details**

CSTX intends to raise \$86.25 million in gross proceeds from an IPO of its common stock, not including customary underwriter options.

Per the firm's latest filing, it plans to use the net proceeds from the IPO as follows:

for costs associated with the clinical development of MSDC-0602K;

for costs associated with manufacturing of MSDC-0602K; and

the remaining proceeds to fund working capital and other general corporate purposes, including the additional costs associated with being a public company.

Management's presentation of the company roadshow is not available yet.

Listed underwriters of the IPO are Citigroup, Credit Suisse, Needham & Company, and Wedbush PacGrow.

### Commentary

CSTX is seeking to fund additional trials for its only drug candidate, MSDC-0602K.

In Phase 2b trials, based on an interim readout of the data, it has delivered enticing results for this hard-to-treat condition.

The market opportunity for NASH treatments is expected to grow at a very high rate, but there is significant competition from publicly held firms as well as private biopharmas who are developing treatment options.

Management has disclosed no commercial collaborations, whether out of choice or outside of its control, so this presents a higher risk profile as the firm has to 'go-it-alone.'

Still, I prefer its focus on one treatment area vs. pursuing a wide range of conditions as some biopharma IPO candidates have done.

Citigroup is the lead left underwriter for the IPO. IPOs led by the firm over the last 12-month period have generated an average return of a negative (13.4%) since their IPO. This is a lower-tier performance for all major underwriters during the period.

When we learn more details about the IPO's proposed pricing and valuation, I'll provide an update.

**Expected IPO Pricing Date:** To be announced.

### Brainsway Aims To Raise \$30 Million In U.S. IPO

### **Quick Take**

Brainsway (<u>BWAY</u>) intends to raise gross proceeds of \$30 million from a U.S. IPO, according to an <u>F-1 registration statement</u>.

The medical device company develops and markets non-invasive neuromodulation products.

BWAY is expanding the conditions for its treatment device as it seeks U.S. investment. Its stock is listed on the Tel Aviv Stock Exchange with a current market cap of ILS357 million (\$96.8 million).

When we learn more details about pricing and valuation from management, I'll provide an update.

### **Company & Technology**

Jerusalem, Israel-based Brainsway was founded in 2003 to develop and sell non-invasive neuromodulation products that use its proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) technology for the treatment of major depressive disorder [MDD] and obsessive-compulsive disorder [OCD].

Management is headed by President and CEO <u>Yaacov Michlin</u>, who has been with the firm since 2017 and was previously President and CEO at Yissum - Hebrew University Technology Transfer.

Brainsway has developed the Deep TMS technology modulates the physiological activity of the brain by using magnetic pulses to stimulate neurons. The company believes its technology has the potential to be 'safe and effective for the treatment of a wide range of psychiatric, neurological and addiction disorders beyond MDD and OCD.'

The Deep TMS technology includes an H-Coil that is 'designed to transmit electric current flows at varying rates, creating an electromagnetic field that serves to depolarize cortical neurons and activate neural networks in certain areas of the brain in accordance with the operating frequency, with the effect of treating the disorder associated with that area of the brain.'

The company's first commercial Deep TMS product received FDA clearance in 2013 for the treatment of MDD in adults who failed to achieve improvement from antidepressants in the current episode.

Brainsway is currently holding multicenter clinical trials to get FDA clearance of Deep TMS for smoking cessation and post-traumatic stress disorder [PTSD] and is planning other trials for opioid addiction, fatigue in multiple sclerosis [MS], and post-stroke rehabilitation.

Below is the current status of the company's condition treatment pipeline:

Indication	Exploration	Clinical Trials	FDA Clearance	Commercial Launch
MDD				
OCD				
Smoking Cessation				
PTSD				
Opioid Abuse				
Post-Stroke				
MS				

Source: F-1 statement

The firm is currently developing a 'next generation multichannel stimulator allowing for simultaneous modulation of different areas of the brain with independent stimulation parameters, thus potentially enabling more flexible and effective treatment of various brain disorders.'

Investors in the company included Phoenix Insurance Company, IBI Investment House and Yelin Lapidot Investment House. Source: <a href="Crunchbase">Crunchbase</a>

### **Customer Acquisition**

In the US, which accounts for 89% of the Brainsway's revenue, the company acquires customers through its wholly-owned subsidiary Brainsway USA as a direct marketing and sales channel. The company currently has existing sales, marketing, and support infrastructure.

Sales and marketing expenses as a percentage of revenue have been uneven in recent periods, per the table below:

### Selling & Marketing Expenses vs. Revenue

Period	Percentage	
To O3 2018	51.6%	

2017	56.8%
2016	44.9%

Sources: Company registration statement, IPO Edge

### **Market & Competition**

According to a 2018 market research report by Market Research Engine, the global neuromodulation market is projected to surpass \$11 billion by 2022, growing at a CAGR of 11% between 2018 and 2022.

The main factors driving market growth are a growing incidence of neurological disorders, increasing geriatric population and a rising awareness regarding the safety and effectiveness of neuromodulation devices.

Major direct competitors that provide or are developing TMS treatments include:

- Neuronetics (<u>STIM</u>)
- Magventure
- Magstim
- MAG & More
- Cloud TMS
- Nexstim

### **Financial Status**

BWAY's recent financial results show strong growth in topline revenue, gross profit, and gross margin. Negative EBITDA has been reduced but cash flow used in operations has increased.

Below are the company's financial results for the past two and ¾ years (Audited PCAOB for full years):

### **Total Revenue**

Period	<b>Total Revenue</b>	% Variance vs. Prior
To Q3 2018	\$ 11,265,000	49.3%
2017	\$ 11,145,000	-3.3%
2016	\$ 11,524,000	
Gross Profit (Loss)		
Period	<b>Gross Profit (Loss)</b>	% Variance vs. Prior
To Q3 2018	\$ 9,141,000	56.0%
2017	\$ 8,550,000	-6.0%

2016	\$ 9,097,000
2010	7 7,077,00

### **Gross Margin**

Period	Gross Margin

To Q3 2018 81.1% 2017 76.7% 2016 78.9%

### **EBITDA**

Period	EBITDA
To Q3 2018	\$ (3,362,000)
2017	\$ (6,611,000)
2016	\$ (2,069,000)

### **Cash Flow From Operations**

Period	<b>Cash Flow From Operations</b>
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To Q3 2018	\$ (2,769,000)
2017	\$ (3,467,000)
2016	\$ (2,402,000)

Source: Company registration statement

As of September 30, 2018, the company had \$9.5 million in cash and \$14.4 million in total liabilities. (Unaudited, interim)

### **IPO Details**

BWAY intends to raise \$30.0 million in gross proceeds from an IPO of ADSs representing its common stock, not including customary underwriter options.

The firm is currently listed on the Tel Aviv Stock Exchange as "BRIN".

Per the firm's latest filing, it plans to use the net proceeds from the IPO as follows:

for sales and marketing

for our clinical trial of Deep TMS for opioid addiction; ... for our clinical trial of Deep TMS for fatigue in MS; and... for our clinical trial of Deep TMS for post-stroke rehabilitation;

to repay the outstanding balance of our borrowings under our credit facility, which bears interest equal to quarterly LIBOR + 6%, and is repayable in eight equal quarterly installments commencing April 2019 and ending January 2021; and

the remainder for working capital and general corporate purposes.

Management's presentation of the company roadshow isn't available yet.

The sole listed underwriter of the IPO is Cantor.

### Commentary

Brainsway seeks to broaden its investor base from its current listing in Israel to the U.S. as it also seeks to broaden the conditions that its neuromodulation system can potentially treat.

It also seeks to continue R&D work to create a next-generation device that can selectively target various areas of the brain with differing stimulation currents.

The market opportunity for neurostimulation devices is growing reasonably quickly, but the industry has many 'me too' products, so the firm faces competition, even if much of it is noise.

Additionally, it faces pharmaceutical-based competition, as medications for various brain disorders continues to be developed.

Management has succeeded in generating impressive topline revenue growth through Q3 2018, but that was after a result in 2017 that showed negative growth vs. 2016. So, topline growth has been uneven.

Cantor is the sole underwriter for the IPO. IPOs led by the firm over the last 12-month period have generated an average return of 5.4% since their IPO. This is a middle-tier performance for all major underwriters during the period.

Brainsway represents an interesting IPO candidate, as the firm has promising prospects. However, the upside is really in an expanded set of approved treatment indications and physician sales cycles can be long, especially for new products.

Valuation of the IPO will be critical. On the TASE, "BRIN" has a current market capitalization of \$357 million. I look forward to learning management's assumptions for its IPO in the U.S.

**Expected IPO Pricing Date:** To be announced.